The Efficacy of Reflexology in the Management of Chronic Low Back Pain

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Abstract

Background: The use of complementary medicine (CM) for the management of chronic low back pain (CLBP) continues to rise. However questions regarding the efficacy of many CM therapies for CLBP remain unresolved. This study was designed to evaluate the effectiveness of one such therapy, reflexology, in this domain.

Design: Pragmatic RCT. N=243 participants were randomised to one of three groups: reflexology, relaxation, or non-intervention (usual care by GP).

Method: At recruitment all participants were interviewed with regard to the previous treatment they had experienced. In addition, all participants completed a questionnaire booklet before and after the treatment phase, and at six months follow up. This measured their general health status, pain, functioning, coping strategies, mood and satisfaction with social support. Finally, post treatment qualitativie interviews were conducted with a sub-sample of 22 participants from the reflexology and relaxation groups. These interviews were designed to elicit details of participants' experience of treatment and its outcome.

Results: Repeated measures ANOVA found no significant differences between the groups pre and post treatment on the primary outcome measures of pain ($F_{(4, 310)} = 1.152$, $p = .332$) and functioning ($F_{(4, 318)} = 2.039$, $p = .132$). There was a main effect of pain reduction, irrespective of group ($F_{(2, 310)} = 8.185$, $p = .0005$). However, trends in the data illustrated that pain reduction was greatest for participants in the reflexology group. Analysis of the post treatment interview data, using an interpretative phenomenological approach, revealed six predominant themes. These were: therapist/therapeutic relationship; role of self; effects; explanatory models; environmental factors and future use. The majority of participants reported treatment led to reduction in pain, increased relaxation and an enhanced ability to cope.

Conclusion: The quantitative data suggested that reflexology was not effective for managing CLBP. Thus it cannot be recommended as an effective treatment for the management of CLBP, nor can its widespread use or funding within the NHS be sanctioned. In addition, the incongruence between quantitative and qualitative results raises important questions for the design of research studies into the efficacy of CM

therapies. Should the patient's view of efficacy be negated because 'objective' measures showed no effect? or the appropriateness of the scientific parameters questioned because they are in conflict with patient's notion of efficacy? Whatever the verdict it is apparent studies which consider treatment outcome need to define that outcome in terms that have currency for providers and consumers alike.

Introduction

Organisation of the Thesis

This thesis is concerned with reporting the development, implementation, results and conclusions of a pragmatic randomised controlled trial designed to evaluate the efficacy of reflexology for the management of chronic low back pain. These aspects of the study are organised into the following chapters:

Chapter One: Presents a review of literature relevant to the study. It begins by looking at pain and models of pain, before going on to discuss CLBP from a biopsychosocial perspective. Next, evidence for the effectiveness of orthodox and complementary treatments is reviewed, along with reasons for the increased use of complementary therapies. Following this, the therapy under scrutiny, reflexology, is described and the pertinent literature critically analysed. In addition, due to the potential role of the relaxation response in reflexology, relaxation as a treatment for CLBP is also discussed. Finally the main points of the review are summarised to provide a rationale for the current investigation.

Chapter Two: Methodological considerations are outlined in this chapter. It begins with an exploration of the research base in complementary therapy. An evaluation of the utility of the RCT within this domain is provided. This is followed by a brief outline of the strengths and weaknesses of quantitative and qualitative methods which provides justification for the use of each type of data collection within the current study.

Chapter Three: This chapter provides details of the method and procedures used throughout the study. It is split into two sections. The first concerns the whole study, and includes information on sample size, recruitment and the instruments used throughout. The second, provides further details of the recruitment procedure, interview process and analytical techniques utilised with a sub-sample of participants in the post treatment interview.

Chapter Four: Results from each aspect of the study are contained within chapter four. It is divided into three sections, which reflect the different methods used to collect data throughout the study, i.e. questionnaires, interview one and interview two. The first section concerns the main quantitative results. A brief overview of the analyses conducted on Time 1,2,3 & 4 questionnaire data is followed by a description of the sample. The results of the analyses are then comprehensively outlined. Section two provides results of the thematic analysis conducted on the data gathered at recruitment, via interview one. Participants are divided into two groups: non-users and previous users of CM, and their experience and knowledge of CM described. The third section contains details of the qualitative analysis carried out on interview two data collected from a sub-sample of participants after the treatment phase. The themes which emerged from the analysis are presented, along with examples of each.

Chapter Five: The discussion chapter. This chapter is divided into four sections, the first three of which mirror the results chapter. Section one is concerned with the primary aim of the project, i.e. assessment of the effectiveness of reflexology in the management of chronic low back pain, via the questionnaire results. Section two refers to the results of interview one and discusses these in relation to previous research on CM use. The third section provides conclusions from the results of interview two concerning the participants' perceptions of the therapy they received. The final section contains a comparative analysis of the quantitative and qualitative results. In addition the strengths and limitations of the methods adopted are described, implications for the practise of CM considered, and recommendations for the direction of future research outlined.

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Chapter One

Introduction and Review of the Literature

1.0 Introduction

This thesis is concerned with the evaluation of reflexology for the management of chronic low back pain (CLBP). Accordingly the literature review, which provides the background and rationale for the study, covers a number of disparate, but substantial, areas of research endeavour. First, pain and CLBP specifically, are considered, and a number of psychosocial factors which have been associated with differential adaptation to CLBP are reviewed. A brief evaluation of some of the orthodox treatment options available for CLBP sufferers follows. Before going on to consider the use of complementary therapies (CM) in the context of CLBP, the increase in popularity and use of such therapies is examined. Next, the CM therapy under scrutiny, reflexology, is described and the relevant research literature critically analysed. In addition, due to the potential role of the relaxation response in reflexology, relaxation as a treatment for CLBP is discussed. Finally, the main points of the literature review are summarised to provide a rationale for the current investigation.

1.1 Pain

> 'Illness is the most heeded of doctors: to kindness and wisdom we make promises only: pain we obey'
>
> Marcel Proust (1871-1922)

The very nature of pain leads a sufferer into an environment full of choices, conflicts and paradoxes. It is the accepted view that pain gives us a warning of damage, prevents us from doing further damage and is therefore a useful mechanism to prevent serious impairment or even death (Melzack and Wall, 1984) This provides a satisfactory description for the experience of acute pain (i.e. pain of recent onset) as it is usually associated with trauma and so does act as a warning preventing further damage by making the sufferer protect the affected area. After a short time the pain reduces and the affected area can be reused with care, followed by complete use once the pain disappears. This may be seen as the normal event as acute pains are common everyday occurrences and our responses to them are second nature.

Chronic pains however do not fit this scheme. Many are not associated with any discernible damage, or occur in areas of previous trauma after healing has taken place. It is inevitable that the sufferer should react in the manner suggested by 'normal' acute pains, however this time the pain doesn't resolve in the normal way. In some instances this may be explained. For example, the pathological situation which caused the acute pain could continue unabated, as in malignant disease or osteoarthritis. This leads to a situation where either the level of pain is consistent or where the pain gets progressively worse. Alternatively, pain may not resolve in the acute phase because of breakdowns in the normal functioning of the pain systems. Nerve damage or sensitisation at one or more levels of the pain pathways can predispose the sufferer to pathologic pain conditions such as the complex regional pain syndromes (Alexander & Black, 1992). However, for some individuals, pain persists despite the lack of any underlying, definable pathology, and in these instances, many psychosocial factors have been implicated in the maintenance of the condition (e.g. Turk et al., 1983, Fordyce et al., 1985, Waddell, et al., 1993).

Thus, whatever the cause of the chronic pain, the sufferer encounters a dichotomy of experience. In one sense, the pain represents a signal for them to rest and protect the affected spot, however the longevity of chronic pain means that rest and protection has to be offset by the need to continue with the activities of everyday living.

Before going on to examine the implications of this for the management of chronic pain, some of the theories which have attempted to explain the experience of pain will be considered.

1.2 Theories and Models of Pain

Early theories regarded pain as a passive response to painful stimuli, e.g. Descartes described a direct 'pain pathway' from the source of pain, such as a burnt finger, to an area of the brain which detected and responded to the painful stimulation. In this respect pain was thought to vary as a function of the quality and intensity of the sensory stimulus, while cognitive and affective factors were only considered as secondary 'reactions' to the pain. Stimulus-response models led to the assumption that pain could be alleviated or reduced by removal of the pain stimulus, or by action upon the 'pain pathways' to block nerve impulses to the brain. These models have been criticised by more recent theorists e.g. Melzack & Wall (1965, 1984) as being both mechanistic and reductionist. However to a great extent they still influence many forms of treatment, such as the use of analgesics to block the pathways or surgical interventions to sever them, often utilised by conventional Western biomedicine to treat pain.

Briefly, Melzack & Wall's (1965, 1984) Gate Control Theory of Pain (GCT) accepted that pain could still be understood in terms of a stimulus-response pathway, but proposed that the pathway was complex, and mediated by a number of processes, which interacted at the 'gate' suggested to exist at spinal cord level. These processes included information from the peripheral nerve fibres at the site of pain, and also information from the brain, via descending fibres, related to the psychological state of the individual, which potentially reflected their behavioural state, emotional state, and previous experiences in terms of dealing with pain. Thus GCT represented a three process model of pain, comprising sensory-physiological; motivational-affective; and cognitive-evaluative processes, in which psychological components had the potential to exert a powerful influence and thereby increase or decrease the individual's perception of pain. Hence, within this process the individual was not viewed as a passive responder to painful stimuli, but rather as active in interpreting and appraising such stimuli.

GCT represented a shift away from the Cartesian model of pain, as mind and body were seen to interact in the active perception and experience of pain. However, it was still dependent upon an organic basis for pain, as it was this input from a site of physical injury or trauma, which the sufferer appraised. Nevertheless, in refuting simplistic models, and recognising psychological variables, GCT offered a plausible solution to account for differential reports of pain levels among individuals with the same degree of tissue damage. It also acted as a catalyst for much of the research which has been conducted since.

In recent decades, pain research focused on the expansion of a comprehensive understanding of pain from a biopsychosocial perspective. This led to the development of more complex and multidimensional models, such as those proposed by Fordyce (1976, 1988), Turk, et al. (1983), Letham et al. (1983), and Waddell (1987, Waddell, et al., 1993) which provide a framework for the study of chronic pain.

Fordyce (1976) first highlighted how operant learning could influence pain behaviour. He noted how traditional medical treatment concentrated on the subjective experience of pain, to the exclusion of pain behaviour. His work led to the development of the prototypic pain clinic, where the primary objective was to treat 'excess disability and expressions of suffering' (Fordyce et al., 1985, p115) via the use of behavioural methods. Although in direct contrast to 'medical' interventions, Fordyce noted that the type of treatment he provided could also result in effects such as modification of nociception, but that these were regarded as secondary gains, as functional restoration was the goal.

Contemporaneously Turk et al. (1983) developed a cognitive behavioural model in which the attitudes, emotions and beliefs of patients regarding their pain, and perception of control over it were paramount. Individuals' maladaptive beliefs and perceptions of poor self-efficacy are suggested to contribute directly to the experience of pain. Thus the primary aim of treatment based upon this model is to increase adaptive beliefs, to encourage appropriate behaviour in order to cope effectively with pain and pain related distress, as well as to promote increased functioning (Bradley, 1996).

These two models have informed the treatment of pain generally, and chronic pain in particular, via the use of cognitive and behavioural principles. However Gatchel & Turk (1999) noted that while such treatments are successful, the distinction between behavioural and cognitive behavioural is not always clear. In addition, many interventions use aspects of both (Gatchel & Turk, 1996). Bradley (1996) argues that this should not present difficulties as the models have theoretical commonalties, in that they each recognise the interaction between individual factors and environmental agents as influential in the patient's perception and presentation of pain.

Other models which have developed these themes have looked at specific cognitive and behavioural factors in the context of chronic pain. Letham et al. (1983), Philips (1987) and Linton, et al. (1985) considered avoidance behaviour, its antecedents, and factors which maintain it. Letham et al. (1983) proposed a theoretical model of exaggerated pain perception which recognised the potential role of fear and anxiety specifically in the context of low back pain. The primary focus of the model, fear, is represented by a continuum. At one end are 'confronters' while at the other are 'avoiders'. The model suggests that confronters are adaptive copers who exhibit a strong rehabilitative drive, and confront their back pain, while avoiders are those who present with exaggerated pain perception. Avoiders fear activity which they expect will result in pain, which in turn reinforces sustained, inappropriate reduction of such activity, and leads to avoidance of adaptive behaviours. A further consequence may be loss of physical fitness as well as a lack of opportunity to reverse the trend of avoidance, by disconfirming the fear of increased pain associated with activity. Thus the model also implicates the psychosocial context within which these behaviours occur, which is influential in determining whether an individual displays more adaptive or avoidant behaviour. There is evidence to suggest that this model has utility in providing an explanation for some of the psychological dysfunction present in a number of chronic pain conditions (Rose, et al., 1992).

Finally, Waddell (1987, 1996) posits a biopsychosocial model of illness which he suggests encapsulates the multidimensional character of CLBP, and can account for the increased disability associated with the condition in Western industrialised countries. Firstly, Waddell notes that, while levels of back pain remained fairly stable in the latter half of the last century in the UK, the disability associated with back pain increased at a greater rate. He suggests that this is because of the legislative framework in this country, which provides remuneration for sickness and disability as a right. Thus his model incorporates the notion of a 'sick role' (Parsons, 1951) within which pain, psychological distress, cognitive factors and illness behaviour interact.

The model relates specifically to low back pain which begins in the majority of cases with a physical problem. It is suggested that the primary psychological disturbance associated with the condition is distress, which is exemplified by inappropriate illness behaviour. Importantly the wider social environment is recognised, as an agent which either directly or indirectly reinforces the disability associated with low back pain, e.g. via the State, the family, the NHS. Although mainly descriptive, the model does provide a useful clinical and theoretical heuristic for subjective disability in CLBP, and highlights the need to treat patients and their illness, rather than simply the physical pathology.

This brief overview above does not constitute a comprehensive critique of all theories or models of pain. However, it does serve to provide the reader with a flavour of some that are pertinent in the context of CLBP. It also illustrates how our knowledge of pain and the experience of pain from the perspective of the individual within society has advanced. It is perhaps inevitable that the development of pain theories and models has paralleled the development of models used to explain health and illness in mainstream medicine. There has been a shift away from the dominant paradigm of biomedicine, towards more holistic models incorporating the dynamic interplay between biopsychosocial aspects. It is suggested that this multidimensional approach is particularly appropriate to the study of CLBP, where the pain may be initiated by biological factors, psychological factors influence the perception and experience of it, and socio-economic factors can have a mediatory role in the response of an individual to it (Waddell, 1998).

Some of these psychosocial factors will be considered in greater depth in section 1.4. First however, CLBP is discussed.

1.3 Back Pain

Low back pain is common, indeed it is recognised as one of the most common and costly health problems of contemporary society (Linton, 1994, Rosen, 1994, van Tulder, et al., 1995). Both orthodox and complementary practitioners have traditionally regarded it as a mechanical problem of the spine (Croft, et al., 1997). However, as stated previously, a substantial body of literature now exists which demonstrates that low back pain cannot simply be regarded solely as a physical problem, rather it needs to be viewed as one which encompasses psychological and social aspects too (e.g. Waddell, 1987; Turk & Melzack, 1992). Thus back pain is a subjective experience.

The objective assessment of back pain is therefore difficult. It is a symptom, which sufferers report may vary from minor aches to severe and debilitating pain. There is no external standard by which its presence can be validated, the symptom being what the person reports (Papageorgiou, et al., 1995). Indeed, studies of the spine have shown that individuals with an apparently healthy spine may experience back pain, while others with demonstrable abnormalities remain symptom free (e.g. Boos et al., 1995). Therefore, assessment of the condition and its severity are necessarily derived from the self-report of individual sufferers.

1.3.1 Definition

Acute pain is generally perceived to be adaptive (Melzack & Wall, 1984, Grzesiak, 1990) and is described as pain which resolves within six weeks. Chronic pain on the other hand is usually defined as pain which has persisted for three months or longer. It has often ceased to serve any function for the sufferer in terms of it being indicative of any underlying damage (Black, 1990), and may be dissociated from the original pain problem. Accordingly acute and chronic pain represent qualitatively different subjective experiences in terms of duration and thus their impact on the sufferer.

It has been suggested, that the acute/chronic dichotomy may not be appropriate to describe the nature of back pain, which is often recurrent, and so may not satisfy the criteria for chronicity (Von Korff et al., 1990; Spitzer, et al., 1987). An acute episode of back pain may resolve quickly only to recur or to leave some persisting symptoms which fluctuate in intensity, and are not consistently present to the same degree for 12 weeks or more (Deyo, 1993). Nevertheless, the majority of clinicians and researchers accept that pain of less than 6 weeks is acute, pain that lasts longer than 6 weeks but less than 12 weeks is termed sub acute, while chronic pain is that which persists beyond 12 weeks (Frank, 1993; & Croft, et al., 1997).

The current study is concerned with 'simple backache' or 'mechanical back pain' (Rosen, 1994), also known as non-specific low back pain, of a chronic nature, i.e. reported by the patient as exceeding 12 weeks duration. Non-specific low back pain is described as that which is localised in the lumbar spine or referred to the leg or foot, where other specific causes of the pain had been excluded (Frank, 1993, Rosen, 1994).

1.3.2 Prevalence

Low back pain is one of the commonest symptoms presented in primary care. Indeed during any year, 7% of the adult population will present with this problem, while around one in ten adults throughout the course of a year will experience prolonged interference with daily activities due to back pain (Croft, et al., 1997). Estimates of its prevalence have been derived from a number of epidemiological and social surveys. The most recent figures for the UK suggest that the approximate one month prevalence (i.e. the proportion of people in the general population who experienced back pain at some time during one month) of low back pain is between 35 and 37% (Papageorgiou, et al., 1995; Walsh, et al., 1992; Mason, 1994; & OPCS, 1997). While the annual prevalence is estimated to be around 38%, with lifetime prevalence reported at 60-80% (Papageorgiou, et al., 1995; Walsh, et al., 1992, Borenstein & Weisel, 1989).

Figures for CLBP are more difficult to determine, and are dependent upon the definition employed. Mason (1994) found that 30% of the population reported back pain of prolonged duration during the last month. However others have noted much lower rates. Rigge (1990) suggests the figure is 11%, over half of whom state that back pain restricted their ability to work and lead a normal life. Croft et al. (1997) argue the annual prevalence of CLBP is around 6% of the population. Furthermore, it is often reported that around 90% of low back will resolve within a month (Waddell, 1987, Coste et al., 1994). However in a recent study of patients who consulted their GP with an acute back pain problem, Croft et al. (1998) found that while 90% did cease to consult their GP for back pain, only 25% reported they had fully recovered at one year follow up. This led them to conclude that although many people stop consulting their GP, they continue to experience symptoms. This suggests that the population survey figures of Mason (1994) may provide a more valid estimation of prevalence than figures derived from patients who attend primary care services.

1.3.3 Economic costs of CLBP

In general practice, back pain is the third most commonly reported symptom, after headache and tiredness, thus it is associated with substantial health care costs. The most recent report from the Clinical Standards Advisory Group on back pain (Rosen, 1994) noted that in 1993 the annual cost to a GP practice in the UK with a list of 10,000 patients was estimated at £88,000 annually, while the cost to the NHS for the same period was in the region of £480 million. These figures are small in comparison with the costs to industry and the exchequer in terms of sickness and disability benefits. During 1993, there were estimated to be around 52 million days lost from work, leading to indirect costs of £3.8 billion, and the equivalent of 106 million days benefit paid, at a cost of £1.4 billion (Rosen, 1994).

The figures above relate to all back pain. Costs pertaining to CLBP in particular are not available, however they have been inferred, albeit in very broad terms. Mason (1994) suggests that CLBP sufferers account for more than 90% of the social costs associated with incapacity due to back pain, and 80% of health care usage for back pain. This is within the range of 75-90% of societal costs proposed by van Tulder et al. (1995). It is apparent therefore, that back pain represents a huge burden on resources. However, many back pain problems are self-limiting and the majority of costs associated with the condition can be attributed to back pain of a chronic nature.

1.4 Psychosocial factors and CLBP

Costs to the individual sufferer are less easy to quantify, but have been shown to be multiple and may be experienced along physical, psychological and social dimensions (e.g. Waddell & Turk, 1992, Klapow et al., 1995). However, not everyone with low back pain of a chronic nature becomes disabled by it, some people appear to continue functioning quite well in spite of the pain. Myriad psychosocial factors have been shown to be associated with this differential adaptation to CLBP (Pearce & Erskine, 1993). These include coping style (Jensen et al., 1991), anxiety (McCracken & Grost, 1993), depression (Sullivan et al 1992) & the level of social support (Jamison & Virts 1990). In addition, many authors argue that psychosocial variables are more predictive of therapeutic success than factors such as medical findings (Rosenstiel & Keefe, 1983; Spinhoven et al.,1989; Harkapaa et al.,1991; Frymoyer, 1992; Klapow et al., 1993; Hazard et al., 1994; Burton et al., 1995; & Hildebrandt et al,, 1997).

The current investigation adopts a biopsychosocial perspective and is concerned with evaluating the effectiveness of reflexology for CLBP. In recognition of the potential mediatory role of psychosocial factors in relation to treatment outcome, a number of them will also be measured and monitored throughout the duration of the study. Thus factors which are relevant to the current investigation, i.e. coping style, depression and social support, are now considered.

1.4.1 Coping

Many of the variables shown to influence pain and disability in relation to chronic pain can be viewed within the construct of coping, and it this construct which has perhaps received the greatest attention in the research literature. Pain is a stressor, which when appraised leads to the use of cognitive and/or behavioural mechanisms to manage or reduce it. In these terms, coping with chronic pain may be defined as the thoughts and actions in which individuals engage in their efforts to manage pain on a daily basis (Estlander, 1989, Katz et al 1996). Such thoughts and actions are identified as coping strategies, and it is apparent that these may be multiple and complex, as well as dependent upon the individual and their personal situation.

Jensen et al. (1991) presented a review of the literature on coping with chronic pain and noted that differences in the coping styles and strategies employed by chronic pain sufferers have been found to explain some of the variation in functioning and response to treatment apparent in this group. A wide variety of coping strategies have been identified. Broadly, their differential classifications have included: problem/emotion focused (Lazarus and Folkman, 1984); avoidant/non-avoidant (Suls and Fletcher, 1985); cognitive/behavioural (Rosenstiel and Keefe, 1983; Fernandez, 1986); active/passive (Brown and Nicassio, 1987) and illness focused/wellness focused (Jensen et al., 1995). Furthermore within each of these classifications there may be further subcategories. The number of terms which have been used to operationally define broadly similar strategies, has led to a number of criticisms. Not least is the criticism that they substantially limit comparison between studies, and may lead to confusion on the part of the practitioners and researchers alike (Katz et al., 1996).

In addition, a large number of instruments have been developed to measure the plethora of strategies identified, and this has also impeded interpretation across studies. Many of the available tools contain subscales which differentiate between specific categories of coping strategies. For example the Coping Strategies Questionnaire (CSQ)(Rosenstiel & Keefe, 1983) measures the extent to which individuals use 6 cognitive and 1 behavioural coping strategy to cope when the pain is bad. The cognitive strategies include: praying and hoping; catastrophising; diverting attention; reinterpreting the pain sensation; ignoring the pain; and coping self-statements. It is suggested that the use of composite scales (in this example, 'cognitive') as opposed to individual subscales may be inappropriate, as they fail to enable researchers to discern which particular strategies are related to functioning (Jensen et al., 1992, Dozios et al., 1996). However Jensen et al. (1991) also suggest that this needs to be balanced with other considerations, such as study size. Where the sample is small, the use of a composite score may increase the power of statistical tests, and reduce Type I error by limiting the number of such tests. Research which has considered the role of coping in relation to chronic pain has therefore employed a continuum of coping, from that which identifies individual strategies to that which measures broad categories of coping.

Brown and Nicassio (1987) argue that whatever their type, coping strategies may be classified as either active or passive, based upon their relationship to levels of pain severity and psychosocial functioning. Active strategies may be defined as efforts by the patient to function despite the pain, while passive strategies reflect a tendency to relinquish control and depend upon others. In this way, active coping strategies are generally perceived to be adaptive and associated with increased psychological and physical function. The use of passive strategies on the other hand is related to increased distress, lower functioning and a poorer outcome.

Brown & Nicassio (1987) developed the Vanderbilt Management Pain Inventory (VMPI), a pain specific self-report questionnaire with two scales: active and passive, each of which contain cognitive and behavioural strategies. Using the VPMI in longitudinal, correlational research and controlling for pain, they found that coping at initial assessment was related to physical functioning and adjustment six months later. Specifically it was noted that whilst passive coping strategies were related to increased pain severity, depression and higher functional impairment, active coping demonstrated the opposite relationship with these variables. These findings were confirmed in a subsequent study by Brown et al. (1989) and have been supported by other researchers, e.g. Jensen et al. (1991b) and Snow Turek et al. (1996).

The utility of the cognitive/behavioural distinction has been questioned by Keefe et al. (1992). who suggest that all coping strategies are cognitive. Thus 'behavioural strategies' are more suitably viewed as the outcome of a cognitive strategy. In this respect taking medication, which is considered by some to be a behavioural strategy, is seen as the outcome of a cognitive attempt to cope with the pain.

In research which utilised the CSQ, Keefe et al. (1990) studied patients over a six month period, and reported that patients scoring high on the catastrophising subscales of the CSQ also had higher pain ratings, and higher physical and psychological disability levels. These results have been confirmed by Geisser et al. (1994) using the CSQ with 152 chronic pain patients. Catastrophising and praying/hoping were related to poorer adjustment as measured by the West Haven-Yale Multidimensional Pain Inventory (WHYMPI, Kerns, et al., 1985), and the ability to control and decrease pain was related to better adjustment.

These studies highlight another issue within the coping literature, i.e. the debate surrounding the construct of catastrophising. Sullivan & D'Eon (1990) defined catastrophising as a cognitive process characterised by negative expectations about future outcomes and lack of confidence. In the CSQ it is exemplified by statements such as 'It is terrible and I feel as it is never going to get any better'. Although it has been consistently linked with poor adjustment to chronic pain and higher levels of psychological distress (e.g. Robinson et al., 1997, Keefe et al. 1990), some have questioned whether it can be described as a coping strategy. Jensen et al. (1991) suggest that it is more suitably viewed as an appraisal. Katz (1996) argued that labelling catastrophising as a coping strategy is incongruent, as it cannot be considered as an intentional effort to manage a stressor.

Furthermore, Sullivan and D'Eon (1990) have argued that catastrophising mainly reflects depression, and should not therefore be considered as a coping strategy. Catastrophising has been found to be associated with increased psychological distress (Geisser, et al., 1994a; Geisser et al., 1994b; Robinson et al., 1997). This association between catastrophising and depression in patients with chronic pain has led others to question whether the two are indeed separate constructs (Jensen et al., 1991). However, it is apparent that while the two are related, cognitive theories of depression view negative cognition (catastrophising) as distinct from depression (Beck, 1976).

The studies mentioned highlight the important role of coping in the context of an individual's response to CLBP and/or treatment aimed at its management. Additionally there is evidence to suggest that particular types of coping strategies may be more effective than others in terms of increasing physical and psychological functioning in patients with chronic pain. However this needs to be viewed within the complex and dynamic psychosocial world of the individual sufferer. What is effective for reducing pain or increasing function for an individual on one occasion, may not be on another, or for a different individual. Nevertheless, it is apparent that some assessment of coping style and measurement of its effect is essential in any intervention study concerned with CLBP. As Turk (1996) stated '...if one accepts that pain is a complex subjective phenomenon that is uniquely experienced by each individual, then knowledge about ...appraisals and coping repertoires becomes critical for accurately evaluating treatment' (p148).

1.4.2 Social Support

Social support has also been hypothesised to have a mediatory effect upon coping style, physical and psychological functioning in CLBP. Research in this area has focused upon two main themes. The first is that social support may have a positive effect, and act as a 'buffer' against the stress of chronic pain (Cohen & Wills, 1985). Thus high levels of social support would be associated with greater adjustment to chronic pain and improved functioning. The second is that some types of social support may have a negative effect and function to maintain pain behaviours (i.e., overt demonstrations of pain) via operant conditioning (Fordyce, 1976). In this respect high levels of social support may be related to decreased adjustment and lower levels of functioning.

This second view has been confirmed by Romano et al. (1992) and others. Gil et al. (1987) observed levels of pain behaviour in 51 patients with chronic pain and compared them to the patients' reports of satisfaction with social support and the availability of people for support. They found that individuals reporting high satisfaction with social support also displayed high levels of pain behaviour and decreased functioning. In contrast to level of satisfaction, there were no significant differences in pain behaviour whether the availability of people for support was high or low. This suggested that it is not the actual level, but the individuals' perceptions of the social support which is effective in mediating pain behaviour and functioning. Furthermore these results offer no support for the 'buffering' hypotheses, but rather endorse the notion that pain behaviours may be operantly reinforced.

In contrast, Jamison & Virts (1990) asked 521 chronic pain patients to rate the degree to which their family was supportive or non-supportive. Comparison between the two groups demonstrated that patients who reported having a non-supportive family (n=275) tended to show more pain behaviours and emotional distress and to have more pain sites compared to those who came from supporting families (n=233). A follow up study of 181 randomly selected patients from both groups found that those from supportive families (n=81) reported less interference and greater activity levels than those from non-supportive families. These results suggest that some types of support may indeed be positive and act as a 'buffer' against chronic pain.

The complexity of the relationship between social support and chronic pain cannot be overemphasised. Indeed, it is argued that it is not the perceived level of social support per se, but rather the nature of that social support which determines pain behaviour and functioning levels. Solicitous (i.e. sympathetic) responses have generally been considered in a negative light, and found to be associated with an increase in pain behaviours and reported interference. This has to be balanced with the possibility of their potential positive effects, in 'buffering' the CLBP sufferer from the stress of chronic pain and improve adjustment and functioning.

1.4.3 Depression

Depression is frequently observed in patients with chronic pain, and major depressive disorder in patients with CLBP is estimated to be around three or four times greater than in the general population (Sullivan et al., 1992). However prevalence rates vary across studies, dependent upon the population and measurement tool used. Romano & Turner (1985) report levels of between 10% and 100% in patients with chronic pain, whereas Banks & Kerns (1996) estimate it to be between 30% and 54%. For CLBP specifically, Gatchel et al. (1994) found that prevalence of depression was between 57-61%. These differences may be partially explained by the overlapping symptomatology, which both depression and chronic pains share.

The diagnostic criteria for depression (DSM-IV, 1994) includes reference to several somatic symptoms, which may also be attributable to chronic pain, e.g. sleep disturbance. Therefore patients might score highly on somatic items in self report questionnaires because of their chronic pain condition rather than their mood state (Geisser et al, 1997; Williams & Richardson, 1993). This has led to suggestions that cut off scores be raised when generic instruments are used with a chronic pain population in order to reduce the instances of potential 'false positives' (Bishop et al., 1994).

As previously stated, correlational research has demonstrated a relationship between particular coping strategies, physical functioning and depression (e.g. Jensen et al., 1991; Brown et al., 1989). However there is disagreement concerning whether depression occurs before, simultaneously, or as a result of chronic pain, which further highlights the uncertainty surrounding the intricacies of the relationship between the two conditions.

An additional consideration is, that chronic pain sufferers who restrict their activity in order to manage their chronic pain, subsequently also limit the level of social reinforcement they get from participating in enjoyable activities, which may lead to increased mood disturbance (Pearce & Erskine, 1993). However the 'buffering hypothesis' of social support has been postulated to insulate individuals from affect disorders, which may arise due to low levels of instrumental activity. In a study with 105 chronic pain patients Goldberg et al. (1993) found an association between low levels of instrumental activity and high levels of depression. Furthermore it was noted that high levels of perceived support moderated the relationship between the two, which suggests that perceived social support serves as a buffer against the effects of low levels of activity on depression, and further highlights the importance of considering contextual issues when assessing levels of depression in relation to coping and functioning within this group.

1.4.5 Summary

There has been a wealth of research conducted on a range of psychosocial factors in the context of chronic pain and CLBP in particular. It is apparent from the above brief review of some of this research that a number of variables have been found to be related to differential levels of pain, physical functioning and outcome to treatment. Similarly it can be seen that the experience of CLBP is not solely a response to the pain per se, but rather an individual's response to their perception of it, which in turn may be influenced by other psychological and social factors as highlighted above. Moreover, it is evident that a dynamic relationship exists between many of these factors, and some may be interdependent (Klapow et al., 1995). Accordingly, it is suggested that these variables need to be considered concurrently when evaluating any therapeutic outcome in the context of CLBP.

1.5 Therapeutic Modalities for CLBP

A wide range of conservative (i.e. non surgical) orthodox and complementary (CM) therapies are available for low back pain (van Tulder, 1997a, 1997b). GPs are the most sought after source of professional help for back pain, however around 80% of people with low back pain also report using a wide range of self care methods (Croft et al., 1997). These may include: advice from family, friends, the media, self help literature or the pharmacist as well as the use of CM therapies. Before going on to consider which treatments are effective for low back pain it may first be useful to define what is meant by orthodox and CM therapies.

Within the literature on health care generally, there exists debate surrounding the terms used to define treatments not perceived to be part of mainstream medicine. A variety of labels have been used to operationally define such treatments, including: alternative; complementary; fringe; non-conventional; unorthodox; holistic and natural medicine (Vincent & Farnham, 1996). However, there has recently been a shift towards consensus, with the term complementary and alternative medicine (CAM) used predominantly. In this way treatments outside the dominant Western biomedical medical system are seen as either alternative or complementary to it. For the purposes this study, the term complementary medicine (CM) was preferred, as within the domain of CLBP, such treatments are not generally viewed as an alternative to conventional treatment, but rather an adjunct to it. Thus the BMA (1993) definition of CM as 'those forms of treatment which are not used by the conventional health care professions, and the skills of which are not taught as part of the undergraduate curriculum of conventional medical and paramedical health care courses' is adopted. Orthodox medicine (OM) is used to describe the dominant biomedical system.

Many orthodox and CM treatments available for back pain are utilised regardless of the duration of pain, although those aimed at acute problems are not necessarily appropriate for low back pain of a chronic nature (Croft et al., 1997). In addition, evidence for the effectiveness of some therapies is ambiguous, and no treatment has been universally accepted (Hoffman et al., 1994; Lanes et al., 1995; van Tulder et al., 1997) or shown beyond doubt to be effective (Evans & Richards, 1996). Moreover, there is considerable scientific evidence that a number of the methods of treatment routinely used for low back pain are ineffective (e.g. Spitzer et al., 1987, AHCPR, 1994). Evidence for particular treatments is briefly outlined in sections 1.5.1 and 1.5.3 below.

In recent years there has been an increase in the practice of evidence based health care. Extensive guidelines for the management of low back pain based on scientific evidence have been developed (Rosen 1994; AHCPR, 1994; RCGP, 1996, et al.) supported by a series of excellent systematic reviews conducted by the Cochrane back group (van Tulder et al., 1997) and a number of other reviewers (Spitzer et al., 1987; Frank, 1993; AHCPR, 1994; Koes et al., 1994; Koes et al., 1996; Evans & Richards, 1996 & Croft et al., 1997).

Briefly, current advice for the management of non-specific back pain in primary care argues for the adoption of conservative treatment. Maintenance of normal activity is encouraged, while rest and inactivity is discouraged. The use of simple analgesia or NSAIDS (non-specific anti inflammatory drugs) for symptomatic relief is indicated when necessary, and physical therapy is suggested if symptoms persist. In addition reassessment, of a biopsychosocial nature, is encouraged at six weeks for those with persistent symptoms. Figure 1.1 is taken from the CSAG guidelines (Rosen, 1994) and provides an example of an algorithm developed for the management of back pain in primary care.

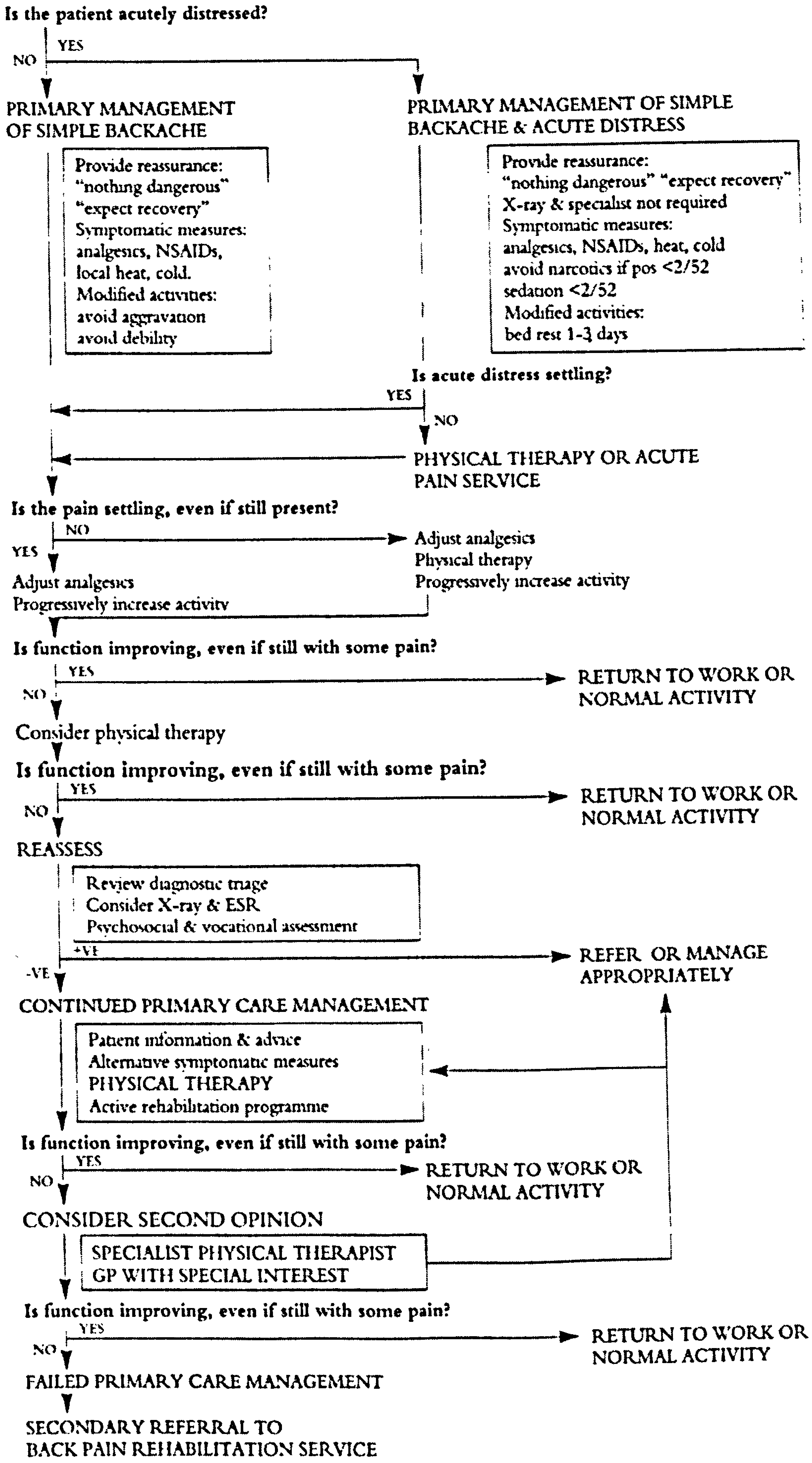
MISSING

PAGES

NOT

AVAILABLE

Figure 1.1: Primary Care Management of Simple Backache


PRIMARY CARE MANAGEMENT OF SIMPLE BACKACHE

Prior to the development of such guidelines, it was suggested that inappropriate advice and treatment was responsible for much of the disability associated with CLBP (Waddell, 1987). Indeed, the general standard of NHS care for the condition was criticised as '...ineffective, potentially harmful and a waste of NHS resources' (Rosen, 1994). To date there is no evidence to support the notion that the production of treatment guidelines has done anything to remedy this situation. Indeed Van Tulder et al. (1997b) in a retrospective, descriptive study conducted in the Netherlands on the management of low back pain in primary care, found that despite recent guidelines on active management, advice to rest was still given to one in five or six patients. Furthermore they noted that management of the condition in primary care lacked consistency, suggesting that guidelines were not routinely adhered to. While the problem of compliance with guidelines is not within the remit of the current investigation, it does serve to highlight the difficulty of changing the routine of established practices within health care systems, and may be relevant to the integration of CM therapies in this domain. However, before going on to consider evidence for CM treatments, evidence for OM therapies is briefly outlined.

1.5.1 Evidence for the effectiveness of OM treatment for CLBP

Detailed reviews of evidence for the back pain treatments available, particularly OM therapies, can be found in the guidelines and associated publications listed above. In addition Waddell (1998) provides a useful summary. In brief they suggest that there is clear evidence from systematic reviews to demonstrate the efficacy of behavioural treatment (van Tulder et al., 1997). In their review, a very broad definition of behavioural treatment was adopted. It included cognitive behavioural, cognitive, operant and respondent treatment. Respondent treatment aims to modify the physiological response system directly, e.g. by reducing muscle tension.

In addition, back schools have been shown to be effective (Koes, et al., 1994,). Based on the Swedish model (Zachrisson-Forsell, 1980) these include education, instruction on lifting technique and discussion of mechanical strain in the context of posture. Those delivered in occupational settings were found to be the most effective.

Multidisciplinary treatments also have some evidence for their utility in the management of CLBP (van Tulder et al., 1997). These programmes generally incorporate cognitive and/or behavioural treatment as well as education, exercise and relaxation and vary in duration from one week to a month. Outcome associated with such programmes includes improved physical and psychosocial functioning. However it should be noted that within such comprehensive programmes, it is difficult to tease out whether the whole package of treatment is required, or if it is only particular aspects which are responsible for the improved outcome.

Treatments with moderate evidence for efficacy include exercise treatment and NSAIDS (van Tulder, 1997). Exercise therapy may be instrumental in encouraging CLBP sufferers to increase their normal daily activity and an increase in fitness generally may improve their level of physical function (Evans & Richards, 1996) rather than have any direct effect upon the pain. In contrast, NSAIDS have been shown to provide symptomatic relief, and to be more effective than placebo. However, this needs to be viewed within the context of the potential side effects associated with this category of drugs (Henry et al., 1996, Gabriel, 1997).

Evidence is either equivocal, or limited to the extent that no decision regarding effectiveness can be provided at the present time for the following treatments: TENS (Deyo et al., 1990), analgesics, lumbar supports, muscle relaxants, antidepressants, advice to stay active, epidural steroid injections, 'trigger point' injections, physical therapy and manipulation (van Tulder et al. 1997). Additionally the Cochrane systematic review reports that there is some research evidence to support the notion that traction, facet joint injections, electro myographic biofeedback are ineffective.

It is apparent therefore, that many orthodox treatments have not been shown to be effective for CLBP. However it should also be noted that the conclusions reached by the Cochrane Back Group and other systematic reviewers are based on a sometimes small number of studies which are of high quality. They do not include many other, less rigorous studies, or those which are unpublished, which could result in a bias towards studies which have significant findings (Easterbrook et al., 1991). While it is recognised that studies of low quality cannot be said to demonstrate efficacy due to methodological limitations, it is suggested that in combination they may provide a growing body of evidence to support the notion that some treatments are plausible, and it is perhaps this which is responsible for their continued use. Certainly, failure to demonstrate that a therapy is effective does not mean that it is ineffective. Indeed all authors conclude from their reviews that there is a need for more, better quality, methodologically sound studies of many therapies. Perhaps then it is right, that conclusions from such reviews are more suitably viewed as preliminary, rather than fixed, to be modified as and when further rigorous evidence becomes available, as is the case with the Cochrane Collaboration.

This last point is even more pertinent in the domain of CM therapies for back pain. Despite many of them having a long history, research designed to demonstrate the efficacy of some CM is not well developed, with few rigorous studies available (BMA, 1993). Thus such treatments may be even less likely to be included in systematic reviews. This is not the case for all CM therapies; some of the most popular ones used for back pain, such as acupuncture, chiropractic, and osteopathy have undergone rigorous scrutiny (e.g. Richardson & Vincent, 1986; van Tulder et al., 1997; Meade et al., 1990, 1995; Lehmann et al., 1986; MacDonald & Bell, 1990). Thus they have been considered within many of the published guidelines, though it is difficult to find unequivocal evidence for their utility. Yet despite the relatively slight evidence to support them, the CSAG report (Rosen, 1994) does recommend the use of CM therapies for managing acute back pain as part of a multidisciplinary approach (Peters et al., 1995).

Prior to considering the available evidence on CM therapies for CLBP, the increased use of this type of treatment generally will be examined. As previously stated, it is apparent that many commonly prescribed OM treatments have not been shown to be effective. Therefore it is perhaps understandable that, as Hoffman et al. (1994) note, how both clinicians and patients alike express dissatisfaction with the outcome of conventional medical treatment for the condition. This factor could, in part, be responsible for the avid and serial use of OM health care resources displayed by some patients in the relentless, often futile search for relief from their pain (Pither, 1989). Indeed it may be fair to say that CLBP represents a 'difficult area' for the medical profession. When this is considered alongside the fact that one of the primary reasons suggested for patients increased use of CM therapies, is dissatisfaction with the inability of OM to relieve their symptoms (Vincent & Furnham, 1996), it is perhaps inevitable that a substantial minority of CLBP sufferers have been attracted to a variety of CM therapies.

1.5.2 Increased use of CM

The last two decades have witnessed increased interest in, and use of, CM in the UK (Fulder & Munro, 1985; BMA, 1986; Which?, 1986; Thomas et al., 1991; Sharma, 1992; BMA, 1993; Fisher & Ward, 1994; Which?, 1995). Similar trends are reported in other

Western cultures for example the US (Eisenberg et al., 1993) and Canada (Maclennan et al., 1996). It is suggested that growth of this type of treatment is consumer led (Dickinson, 1996). Indeed much of the provision of CM therapy is within the private sector, and it is estimated that individuals who access this type of treatment collectively spend around £1.6 billion per annum in so doing (White & Ernst, 2000).

The number and type of people utilising CM is difficult to assess and some studies have reported different rates of use. There may be a number of factors responsible for this. Firstly, the time period of the study must be considered, growth in the number of CM practitioners and training courses is evidence enough of the increased use of this type of treatment. Thus earlier studies may underestimate current rates of use. Secondly, the study population needs to be considered. Some authors have suggested that CM varies within different socio-economic, demographic and/or geographic locations (e.g. White et al., 1997). Thus results of localised studies may not be applicable nationally. Finally, the definition of CM utilised by researchers is important, as this may lead to over or under reporting of use. A large US study (Eisenberg et al, 1993) was criticised as potentially overestimating the use of CM because of the definition of CM employed.

Eisenberg and colleagues defined CM employed as '...interventions not taught widely in US medical schools, or generally available in US hospitals' (p246). This also included vitamin, mineral and food supplements along with other things such as exercise which are not generally viewed as CM therapies. Their telephone survey of 1539 adults in the US found that 34% had used CM in the previous year. Of these, one third had actually consulted a CM practitioner. Using these figures Eisenberg et al. calculated that more visits were made to CM therapists than to all US primary care physicians. In addition, they reported that expenditure on CM was comparable to that spent on all hospitalisations in the US, though of course this needs to be viewed with caution in light of their over inclusive definition of CM.

In the UK, a number of surveys have been conducted. Two of the most frequently cited are Fulder & Munro (1985) and Thomas et al. (1991). Fulder & Munro conducted a postal survey of CM practitioners from demographically diverse areas of the country. They included all CM therapists, with the exception of psychological therapists, practitioners who did not view their work as primarily therapeutic and those whose role comprised mainly teaching, such as yoga instructors. Fulder & Munro then extrapolated these results to the whole population and concluded that CM consultations averaged 19500 per 100

000 people, which is around 6.5% of GP consultations. Of these acupuncture, chiropractic and osteopathy were the most popular with around 2 million visits per year.

Subsequently, Thomas et al. (1991) surveyed CM practitioners (N=1575) who were registered with the professional associations of the following therapies: acupuncture, chiropractic, homeopathy, osteopathy, naturopathy and medical herbalism. As previous studies, Thomas et al extrapolated from their results that, even when using this relatively narrow sample of CM practitioners, for every 55 GP consultations, one CM consultation occurs. Thus there are around four million consultations with CM practitioners per year.

More recently a survey for Which? (1995) found that around 1 in 4 (31%) of people in the UK were using some form of CM. This represented an increase in use from the 1 in 7 people who reported using CM in a previous survey (Which?, 1986). Similar rates are reported within the literature on pain, albeit using a relatively small survey. The CSAG (2000), as part of their most recent report on services for patients with pain, asked 245 patients attending pain clinics whether they had used CM therapy. Of these 1 in 3 (34%) reported that they had used some form of CM for their pain. Importantly the Which? surveys utilised the same criteria and operational definition of CM on each occasion, so perhaps provide the most conclusive evidence for growth in the use of this type of therapy.

In addition, Which? (1995) noted that, in parallel with conventional GP care, users of CM were predominantly women. This supported the findings of previous studies by Fulder & Munro (1985), Thomas et al. (1991) and Sharma (1992) which similarly found women were more frequent users of CM than men. Furthermore, although CM is used by all social groups, classes I & II predominate (Fulder & Munro, 1985; Sermeus, 1987; Thomas et al., 1991; Paramore, 1997), and CM users are likely to have more education and greater disposable income than non-users (Sharma, 1992). It is likely that there is a relationship between class, education and income. Thus it is apparent that in a country where the majority of OM is free at the point of delivery and the bulk of CM is provided privately, access to CM is greater for these groups and this may account for their over representation in user surveys.

Along with research which has established levels of CM use, patients' consulting patterns have been simultaneously considered. It is apparent that the majority of visits to CM practitioners are for chronic rather than life threatening conditions, with musculoskeletal problems being the primary presenting condition (Kronenfeld & Wasner, 1982; Which? 1995; Verhoef & Sutherland, 1995; Paramore, 1997; Paterson, 1997), accounting for more than 78% of consultations (Thomas et al., 1991). As back pain has been found to be responsible for around half the cases of incapacity due to musculoskeletal problems (Rosen, 1994), one may infer that many patients attending CM therapists are back pain sufferers.

As previously noted, one of the reasons put forward for the increased use of CM is dissatisfaction with OM, which may be particularly pertinent in the context of CLBP, a notoriously difficult condition to manage in primary care. However, a number of other potential factors have been suggested (Furnham, 1994). These include the zeitgeist favouring the holistic nature of CM, fear of OM and its potential side effects, flight from science, morbid self interest, the philosophy of CM, belief in the effectiveness of CM for particular conditions, and the development of a consumerist attitude to health. A number of these are obviously related, for example the holistic nature of CM may be inextricably linked to the philosophy of particular therapies, which in turn may influence beliefs about their efficacy. Furthermore, of the aforementioned reasons, it is apparent that two are most commonly reported by users of CM, i.e. dissatisfaction with OM and an attraction to CM (Moore, et al., 1985).

Furnham and colleagues have conducted a number of studies (Furnham & Smith, 1988; Furnham & Bhagrath, 1993; Furnham & Fovey, 1994; Furnham et al., 1995 and Furnham & Kirkaldy, 1996) which compared the beliefs and behaviours of patients attending CM with those of patients attending OM practitioners. The results of this series of studies indicated that although CM users were more critical and sceptical about the efficacy of OM, they were also more loyal to their practitioner, believed treatment should concentrate on the whole person and that their general health could be improved by CM treatment they were undertaking. Thus Furnham suggests that individuals increasingly seek CM less because of their disenchantment with OM, and more because of their beliefs about the effectiveness of CM.

A further study (Vincent and Furnham, 1996) presented patients from three CM practices (acupuncture, osteopathy, and homeopathy) with 20 reasons why they may have opted for the treatment they were engaged in. Analysis of the results revealed five factors. The primary factor was labelled a 'pull' factor and included items which operationalised CM as more natural, relaxing, and that the patient could take an active part in it. The second factor was a 'push' factor and concerned the inability of OM to relieve their symptoms. Two of the remaining factors were also considered 'push' factors. These related to the side effects of OM and poor communication between OM practitioners and patients. Finally the fifth factor was fairly non specific and contained items on the easy availability of CM. Thus Vincent & Furnham (1996) argue that patients may be 'pushed' and/or 'pulled' into using CM.

Finnigan (1991) also argued that there are two types of people who utilise CM therapies. Those who turn to CM because of belief in the treatment and those who attend as a last resort, but do not embrace the underlying philosophy of CM. In a small study with patients attending an NHS CM centre (N=38), he found that 45% were there because of a failure of OM to improve their condition satisfactorily and 21% believed in the philosophy of CM. Interestingly 18% reported that they were there at the suggestion of their doctor. This last point raises a question for the literature on CM use. The majority of users are self funding (White & Ernst, 2000) and their reasons for consulting a CM practitioner, may or may not be, qualitatively different than those users who were referred for treatment at no direct personal financial cost. However none of the studies conducted to date differentiate between funded and self financing patients.

A further point that should be raised within this discussion on the use of CM, is that many patients are not exclusively users of CM. Rather they frequently consult OM and CM practitioners simultaneously. Thomas et al's (1991) study found that 64% of CM patients in their sample (n=2473) reported receiving treatment from an OM practitioner prior to beginning CM. Of these, 25% continued to use both types of treatment. In addition Furnham (1996) notes that it is increasingly clear that it is rare for patients of CM to abandon OM. He suggests that patients' choices are pragmatic. They consider a range of therapeutic options, dependent upon their condition, before deciding which type of treatment to use.

Growth in the use of CM by patients is also reflected to some degree by an increase in the interest of some OM practitioners towards CM. In 1997, White et al. conducted a questionnaire survey of 461 primary care physicians in Devon and Cornwall. Of these, n=74 personally practised some form of CM, the most common being homeopathy (5.9%) and acupuncture (4.3%). In addition, n=115 had referred patients to CM practitioners in the previous week and n=253 had recommended and/or endorsed CM treatment. Thus, 68% of the sample had been involved in CM during the previous week. While the authors acknowledge that the response rate was low, they point out that the figure is similar to the 63% found by Paterson (1997).

However, White et al. also note that surveys of GPs in other regions of the UK demonstrate different rates of involvement with CM: 37% in Avon (Warton & Lewith, 1986); 16% in Oxford (Anderson and Anderson, 1987) and 15% in Dorset (Franklin, 1992). The disparity may be due to the variety of survey methods used by different authors, the date of the study, socio-economic and demographic differences in the geographical regions surveyed or within responders. Whatever the explanation it is apparent that the most recent studies, Paterson (1997) and White et al. (1997) suggest relatively high rates of interest in CM by OM practitioners, which may to some extent be driven by their patients demand for information and knowledge in this area.

Similarly, two British Medical Association (BMA) publications exemplify the changed attitude of many OM practitioners towards CM. In their 1986 report on 'Alternative therapies' the BMA initially described CM as a 'passing fad'. However during the 1990s as even more people began to consult CM practitioners, the BMA had to respond to the increasing demand for information from doctors and patients alike, and so published a revision of their initial stance 'Complementary Medicine: New Approaches to Good Practice' (BMA, 1993). This report revealed a healthy scepticism and an eagerness to examine evidence for the efficacy and safety of CM.

It can be seen therefore that both the medical profession and patients, have increased their interest in, and use of CM, in recent decades. There may be a variety of reasons for this, though it is suggested that the primary ones are: patients' dissatisfaction with OM to relieve their symptoms, or a belief that specific CM therapies are particularly effective for certain conditions. Furthermore it is apparent that CM is utilised primarily for chronic conditions, with musculoskeletal problems, particularly back pain, being the most prevalent.

Contemporaneously to the growth in popularity of CM has been an increased demand for this type of provision to be made more widely available, particularly within the NHS. However, for provision to increase within the dominant culture of evidence based health care which exists within the NHS, good evidence of efficacy is required. While there has certainly been a plethora of research (Sharma, 1992), not all of it has been of a significantly rigorous nature to inform potential purchasers of the clinical effectiveness of many CM therapies.

Nevertheless a number of CM therapies widely used in the management of back pain have been subject to scrutiny. These are very briefly described within the following section, which considers the evidence available for the effectiveness of CM therapies for CLBP.

1.5.3 Evidence on the effectiveness of CM treatment for CLBP

Chiropractic, acupuncture and osteopathy are the three main CM therapies used for back pain and have consequently received much attention in the research literature. Other types of therapy are utilised, however little research has been conducted in this domain. Indeed there is a paucity of good quality evidence to support their claims for efficacy, with most the subject of either case series or observational studies. They include: spa therapy (Constant, et al., 1998), Snoezelen (Schofield et al., 1998), massage (Vickers, 1996), mind body intervention (Berman & Singh, 1997), biofeedback training (Donaldson et al., 1994) and spiritual healing (Brown, 1995). In addition, reflexology is frequently used, and as this treatment represents the focus of the current study, it is examined in greater depth in section 1.7. First however, the evidence base for chiropractic, osteopathy and acupuncture is briefly considered.

Two of the most commonly utilised CM therapies for back pain are osteopathy and chiropractic. However, a difficulty which arises when looking for evidence on these therapies is that they are often both considered under the same umbrella, i.e. manipulative therapies (Croft et al., 1997). Such an approach was adopted by van Tulder and colleagues as well as the CSAG (Rosen, 1994), where physical therapy was used to describe manipulation given by osteopaths, chiropractors and physiotherapists. This mechanistic definition of the treatment may fail to take into account the idiosyncrasies of individual treatment systems. A similar criticism may also be extended towards acupuncture, which is not only practiced by traditional acupuncturists, but by other therapists too, e.g. physiotherapists.

Nevertheless, there is some evidence available for particular types of manipulation. In their review, Shekelle et al. (1992) noted that a particularly controversial trial of chiropractic treatment (Meade et al., 1990) had been the catalyst for their reappraisal of the literature. The Meade et al. study, a pragmatic RCT, compared people with back pain referred to either chiropractors or standard hospital outpatient physiotherapy services, and found positive results for chiropractice, which were sustained at follow up (Meade, et al. 1995). The review by Shekelle and colleagues considered studies which looked at either acute, chronic or combined populations. They concluded that the data were neither sufficient to refute, or support, claims for efficacy in CLBP, whereas patients with an acute problem may derive some benefit from chiropractic.

Other reviewers have reached similar conclusions with regard to manipulation generally, and comment that the quality of studies available restricts the conclusions that can be drawn. Koes et al. (1991) suggest that results are promising but ambivalent for CLBP, as do Van Tulder et al. (1997). All recommend that more rigorous RCTs are needed to inform further evaluation.

This is also the case with acupuncture treatment. Many studies have looked at the therapeutic use of acupuncture for a variety of pain symptoms and syndromes, and a number of meta analyses and reviews have been conducted (Bhatt-Sanders, 1985; Richardson & Vincent, 1986; Filshie & Morrsion, 1988; Patel et al., 1989; Ter Reit, 1990; Ernst & White, 1998). Overall the results of these are inconclusive. Acupuncture seems to provide some benefit, though whether this is due to the acupuncture, therapist or placebo effect, is unclear. As before, the main reason for this inconsistency is often cited as methodological flaws, which prevent firm conclusions being made (Vincent & Furnham, 1997).

In the specific domain of low back pain, van Tulder et al. (1999) reviewed 11 randomised controlled trials. They suggest that while there have been some positive studies, overall the evidence demonstrates that acupuncture is not any more effective than placebo, waiting list controls or conservative treatment. Similarly, Ernst & White (1998) found 12 randomised controlled studies which they subjected to meta-analysis. Two of the trials had a very positive outcome for acupuncture (Gunn et al., 1980; Coan et al., 1980). In contrast to van Tulder and colleagues they concluded that acupuncture is more effective than control interventions for back pain, with an odds ratio of 2·3, and that the effect is not only statistically significant but also clinically relevant. Differential methods of selecting trials and combining data may be responsible for the disparity between these two reviews.

Thus it is apparent that, as is the case with OM treatments, there is little evidence to support the notion that the majority of CM therapies highlighted above are effective for the management of CLBP. Furthermore many CM treatments have not been subject to the type of scientific testing, i.e. RCT, which is considered necessary to demonstrate efficacy in this domain, thus at this time it is not possible to comment upon their effectiveness.

The therapy which is the focus of the current study, reflexology, falls into this latter category. It is widely used by CLBP sufferers, and while there are many case studies and much anecdotal evidence to suggest that reflexology can be effective in the treatment of CLBP (e.g. Tiran, 1996; Booth, 1994; Evans, 1990) there is little empirical evidence to support this (Ernst & Koder, 1997). However a small number of RCTs have been conducted which have considered the utility of reflexology for a number of other chronic conditions, and these are outlined within section 1.7 which provides a brief description of reflexology followed by a comprehensive review of the available literature. First however, it has been suggested that the perceived benefits of reflexology may in fact be due to the relaxation response (Ernst & Koder, 1997). Therefore studies which have examined the utility of relaxation for chronic pain generally and CLBP in particular, will now be examined.

1.6 Relaxation

Relaxation is frequently provided as a component of many multidisciplinary pain management programmes (Linton, 1994; Jessop & Gallegos, 1994). Despite this widespread use, few studies have investigated relaxation as a treatment for chronic pain. However, it has been used as a comparison condition in trials of other treatments in this domain, and these data in combination have provided some indication of its effectiveness. Nevertheless, the precise role of relaxation in the management of chronic pain remains unclear (McCaffrey et al., 1994).

Relaxation therapy has been described as '...a systematic approach to teaching people to gain awareness of their physiological responses and achieve both a cognitive and physiological sense of tranquillity...' (Arena & Blanchard, 1996, p180). Similarly Benson (1977) described the relaxation response as opposite to the flight/fight response identified by Cannon (1932). The flight/fight response is exhibited when a person prepares to deal with real or imagined danger. It comprises a series of physiological changes to the body's state of equilibrium, such as increase in blood pressure and heart rate. Conversely the relaxation response is represented by changes in the same systems in the opposite direction.

A variety of different relaxation therapies are available, though there are commonalities between them and the aim of all is to induce a relaxed state in the individual. Progressive muscle relaxation (PMR) is the most commonly utilised (Arena & Blanchard, 1996). PMR is based on the procedures of Edmund Jacobson developed in the 1920s (Jacobson, 1977). It was first developed to combat stress, and is based on the idea that muscle tension or relaxation influences the state of the entire person. It involves an individual tensing and then relaxing successive groups of muscles, focusing attention on the differential experiences of each state (Ryman, 1994). In this way an individual learned to identify the presence of muscle tension and then reduce it by applying the technique. Jacobson's original method involved learning to relax over 200 different muscle groups, and therefore took a great deal of practice to master. Since then more simplified versions have been devised, and these variants of Jacobsonian PMR are widely used procedures in the context of chronic pain (Arena & Blanchard, 1996).

Intuitively, if one accepts that pain may be caused or exacerbated by muscle tension (Turner, 1982), then it is apparent that a reduction in muscle tension, via relaxation therapy, may mitigate pain (Melzack & Wall, 1999). Indeed Linton (1994) described relaxation as breaking the vicious cycle of pain leading to chronic tension, which itself produced more pain, and in turn caused further tension. In the context of CLBP, theories which concern the relationship between muscle tension and the pain can divided into two main types: biomechanical theory and stress causality theory (Arena & Blanchard, 1996). Biomechanical theory posits that the muscles of the lower back are inordinately lower than would normally be expected. Or that there is a left-right asymmetry in the lower back, which is thought to be the result of mechanical or physical pathology. Whereas stress causality theory assumes that back pain is the result of ineffective stress coping skills which causes increased activity in these muscles. There is little evidence to support these theories, however the use of relaxation therapies to correct this abnormal muscle tension is common (Arena & Blanchard, 1996).

In addition to suggestions that relaxation could be effective for the management of chronic pain by reducing tension, a number of other potential mechanisms of action have also been identified. Craig (1994) argued that relaxation may reduce anxiety and increase coping ability rather than affect pain per se. On the other hand, Seers (1993) suggested that it may work as a simple distraction technique and help people dissociate from the pain. In cancer care, Vasterling et al. (1993) found no significant differences in post chemotherapy nausea between one group taught relaxation and another taught distraction. This supports the notion that some of the effects of relaxation are non-specific and may be due to distraction alone. In addition there may be other non-specific factors, such as the interpersonal interaction between the therapist and patient, environmental factors, expectations of the patient etc. which influence treatment outcome. As previously stated these are present in many types of therapeutic encounter, and are not peculiar to relaxation and reflexology, however they are seldom considered in research which attempts to evaluate outcome to treatment for chronic pain.

Studies which have examined the utility of relaxation therapy for chronic pain generally and CLBP in particular will now be briefly reviewed.

1.6.1 Evidence for the effectiveness of relaxation

The most recent and comprehensive review of relaxation treatment for chronic pain was carried out by Carroll & Seers (1998) and is summarised in the HTA systematic review of outpatient services for chronic pain control (McQuay et al., 1997). Studies which considered relaxation in combination with other treatments were excluded, and a total of 9 RCTs were included. The number of participants from all studies was 414, of whom n=196 received relaxation, with the largest treatment group being n=30. PMR was the most common type of relaxation evaluated, and the primary outcome measure was pain measured by the McGill pain questionnaire. However, Carroll & Seers stated that meta analysis was not possible because of inadequate reporting of data from the original studies, therefore a narrative systematic review was presented.

Of the 9 studies reviewed, 3 reported a significant difference in favour of relaxation (Shaw & Erlich, 1987; Dulski & Newman, 1989; Sloman et al., 1994). Two of these were in cancer pain and the other in chronic pain. In addition 2 of the 9 studies found significantly better improvements in the control group as opposed to the relaxation group (Gunther et al., 1994; Okeson et al., 1983). The remainder did not report any significant differences between treatments (Gaffam & Johnson, 1987; Funch & Gale, 1984; Seers, 1993; Donaldson, et al., 1994), although there were some within group differences pre and post treatment. However, in the absence of differences between relaxation and control groups, no comment on efficacy could be made. Therefore Carroll & Seers concluded that there was insufficient evidence to support the effectiveness of relaxation for chronic pain.

In addition, Carroll & Seers highlighted a number of problems with the studies they had reviewed, which were mainly of a methodological nature. A study by Seers (1993) was the only one of those included in the review to report pre hoc power calculations. This had ensured an adequate sample size was recruited and allowed enough power to detect any differences between the treatment groups. Small sample sizes and the problems associated with them were an issue for the remainder of the studies reviewed. In addition, some authors did not comprehensively describe the method of relaxation used. Carroll & Seers therefore suggested that more well designed and executed studies are required to examine the effect of relaxation on chronic pain.

The one study in Carroll & Seers review which concerned CLBP (Donaldson, et al., 1994) did not find a positive effect for relaxation. Other studies which were not included have also considered relaxation or relaxation in combination with another treatment in the context of CLBP. Of course, it must be recognised that methodological quality was the reason that most were excluded. Indeed Arena & Blanchard (1996) report that they had planned a critique of relaxation therapy for CLBP. However, this was not completed, as after an exhaustive review, they deemed the literature too methodologically flawed, and argued that this would prevent any meaningful conclusions being drawn. Nevertheless, it may be useful to very briefly describe the studies which have been conducted in order to highlight and discuss some of their methodological weaknesses.

Biederman et al. (1987) conducted a RCT study (N=24) in which three groups of CLBP sufferers were given relaxation plus one of three types of biofeedback (n=8 per group) and found no significant differences between groups. In contrast, Stuckley, et al., (1986) compared relaxation (n=8), relaxation plus EMG biofeedback (n=8) and no treatment (n=8) using a RCT design, and reported that relaxation was effective for reducing CLBP. Similarly, Strong et al. (1989) compared two types of relaxation for patients with CLBP, applied relaxation and applied relaxation plus biofeedback. They found that both groups demonstrated similar improvements on the McGill pain questionnaire, which they argued suggested relaxation may have some utility for the management of CLBP.

Linton & Gotesham (1984) considered 3 groups: relaxation, relaxation plus operant conditioning and a waiting list control group in a small study with N=15 CLBP sufferers.

Although they found both treatment groups improved significantly more than the control group, they were not significantly different than each other. Therefore they argued no conclusions regarding the efficacy of relaxation could be drawn. In a further study Linton et al. (1985) compared cognitive behavioural therapy (CBT) and relaxation (n=8) with routine care (n=10) and a waiting list control group (n=10). Those in the relaxation and CBT group improved significantly more than the other two groups. However as relaxation was delivered in conjunction with CBT, it is not possible to determine whether relaxation, CBT, or both were the effective components of treatment.

Nicholas et al. (1991) compared 6 groups using a RCT design. These were: cognitive therapy (n=10); cognitive therapy and relaxation (n=8); behaviour therapy (n=10); behaviour therapy and relaxation (n=10); attention control (n=10) and no attention (n=11). Their findings suggest that the addition of relaxation to either cognitive or behavioural therapy made no difference to treatment outcome.

Jensen (1982) randomised N=36 participants with CLBP to one of three groups: relaxation; relaxation plus CBT, and a waiting list control group. Participants in both the relaxation and the relaxation plus CBT groups improved significantly more than the control group on measures of pain, depression and functioning. Thus, Jensen concluded that both relaxation and relaxation plus CBT were effective. However as there were no differences between the treatment groups, an alternative explanation may be that relaxation was effective, but the addition of CBT did not lead to any further improvement.

In a relatively large study, Turner & Jensen (1993) randomised N=102 CLBP patients to one of four groups: relaxation; cognitive therapy; relaxation and cognitive therapy; or waiting list control. They found that a significant reduction in pain intensity from pre to post intervention for all treatment groups, with the exception of the waiting list controls, and this continued at follow up, 12 months later. As there were no significant differences between the treatment groups, relaxation and/or cognitive therapy may be effective for CLBP.

A problem which is evident in all the aforementioned studies of relaxation for CLBP, with the exception of Turner & Jensen (1993) is that of the small sample size. For one study, this was as few a 5 participants per group (Linton & Gotesham, 1984). It is recognised that in order to determine what constitutes an adequate sample size, a number of factors need to be taken into consideration, including the size of the difference one is hoping to detect. However, none of the above studies presented *a priori* power calculations or described the difference between pre and post intervention measures, or between groups which would constitute a significant change. In addition any differences that were reported post hoc, were statistically, but may not have been clinically, significant. Failure to detect a significant difference between treatment groups in some studies may therefore mean that relaxation is not effective. Alternatively relaxation may be effective, but the small sample used and associated lack of power resulted in a Type II error.

Furthermore, a number of studies found effects that were not specifically due to one particular therapy. This was either because relaxation was delivered in conjunction with another treatment, or because, although treatment groups improved significantly more than the control group, they did not significantly differ from one another. Therefore as the effects were not specifically due to any therapy but occurred for all, it is possible that 'non-specific' effects of treatment were the catalysts for change, e.g. interaction with the therapist.

In addition to the above factors, lack of detail concerning the relaxation intervention was a problem. As Carroll & Seers (1998) pointed out in their review, this limited the extent to which comparisons between studies could be made, as even researchers who reported which type of relaxation they provided, may have delivered it differently, for example: one to one; in a group situation or via a tape recording.

It is apparent from the above brief review of relaxation CLBP that poorly designed studies can severely restrict the extent to which meaningful conclusions can be made. Indeed, as Carroll & Seers (1998) suggested in the context of chronic pain, more methodologically sound research is needed before the use of relaxation can be either supported or refuted. However, as Bandolier (2000) note, while evidence for the pain relieving effects of relaxation is underwhelming, the therapy may still make people feel better. They go on to state '...we do not deny that it may have a benefit, we merely say it does not relieve pain'(p53). Therefore it is argued that, as CLBP is increasingly accepted to be a biopsychosocial condition, it may also be appropriate to consider outcomes other than pain reduction in future research developed to evaluate the effectiveness of relaxation in this domain.

The previous sections presented a brief evaluation of both OM and CM treatments which are available for the management of CLBP. Furthermore, relaxation was discussed in greater detail, as relaxation has been postulated to account for some of the apparent benefits of reflexology, the therapy under scrutiny in the present study. However, the literature on reflexology per se has not yet been considered. Thus, the following sections provide a description of the therapy, followed by a review and critique of the available research literature.

1.7 Reflexology

In recent years reflexology has undergone a huge growth in popularity (e.g. FIM, 1999). Ernst & Koder (1997) in a review of research into reflexology note that it is '...fast becoming one of the most prevalent treatments within complementary medicine' (p52), with prevalence rates varying dependent upon the population questioned from 0.7% to 15% (MacLennan et al., 1996; Danish Institute of Clinical Epidemiology, 1994, respectively). Kristof et al (1998) in a survey of CM users, found that reflexology was utilised by more than half of all respondents and it is reported to be the most frequently used CM in Denmark (Launso, 1995). In 1994 there were around twenty five thousand certified practitioners world-wide (Strohecker, 1994).

Reflexology is a non-invasive CM which involves the application of pressure by the hands of the therapist to one part of the body, usually the feet, to produce effects in other parts of the body. Practitioners of reflexology claim to be able to treat a variety of conditions, generally of a chronic nature, particularly pain. Kitai, et al.(1998) reporting on patterns of use of CM in a sample of 480 primary care patients in Israel, found 90 who had used CM previously, the majority of whom had utilised reflexology for musculoskeletal pain. Indeed evidence suggests that pain in the musculoskeletal system is one of the most common conditions reflexologists encounter in their everyday practice (Launso, 1995). As back pain has been found to be responsible for around half the cases of incapacity due to musculoskeletal problems in the UK (Rosen, 1994), one may infer that many patients attending reflexology practitioners are back pain sufferers. This notion is supported by Ernst & Koders' overview of reflexology (1997) which cited a recent UK survey of 53 reflexologists who reported the condition they treat most frequently was back pain. Similarly Coxon (1998) reporting on her own practice stated back pain was the most common complaint she encountered.

The following sections will briefly describe what reflexology is, then go on to consider the history of reflexology and present an outline and critique of modern reflexology and its current research base. Finally the utility of reflexology in the context of chronic low back pain will be considered.

1.7.1 What is Reflexology?

Unlike massage, which involves a generalised kneading or rubbing motion, reflexology is a specific pressure technique concerned with precise reflex points on the feet (or sometimes the hands). Generally the thumb and forefinger are used to apply 'firm but gentle compression' (Booth, 1994). It is based on the idea that the reflex points represent energy zones, and that these correspond with all other parts of the body. The aim of the treatment is to restore homeostasis, by removing blockages in the energy zones, thus allowing the body to heal itself. Indeed treatment seems to be based on energy principles of the type which inform some forms of Oriental medicine (Chi) and the zones are akin to meridians of acupuncture. Ingham (1934, 1984) however considered that small crystalline deposits of uric acid and calcium on the nerve endings in the feet resulted from malfunction of any organ or part of the body. The pressure used by the reflexologist leads to a breakdown of these deposits which speeds up their elimination.

To date there are no reported side effects to treatment, though a variety of transient reactions, often called the 'healing crisis' are possible. The healing crisis is thought to be related to the body cleansing itself of the previously dormant accumulated waste products and toxins mobilised by the reflexology treatment (Sahai, 1993). It may be differentially exemplified as flu like symptoms, increased urination, flatulence, diarrhoea, or skin rashes, which usually only last for a couple of days. They are then reported to be followed by a feeling of increased energy and well-being. In addition some contraindications to treatment have been reported, though these vary depending upon the text consulted. They include: circulatory disorders of the lower limb; the first trimester of pregnancy; renal calculi; patients with a pacemaker; and damage or injury to the feet (Booth, 1994, Sahai, 1993). Furthermore, some therapists recommend that reflexology is not given to patients who have recently had surgery, at least until the wound has healed as the improved circulation which the treatment is said to induce may increase the danger of bleeding.

Before going on to consider theories which attempt to explain the mechanisms of action in more detail it may be useful to look at the history of this therapy.

1.7.2 History

The precise origins of reflexology are obscure, though its recent development is more fully documented. It is suggested that reflexology is based upon techniques used by ancient civilisations. Ancient Chinese writings described the use of hand and foot pressure for the treatment of pain and other conditions over 5000 years ago (Goodwin, 1988). This was followed around 2500 years ago with the development of acupressure and acupuncture. Briefly, both acupressure and acupuncture are designed to stimulate specific points on the surface of the body known as meridians, which are energy pathways or channels that link the organs of the body. Acupressure is stimulation by the hand to these points, while acupuncture relies on the use of needles inserted into the skin at points on the meridians. It is thought by some that modern day reflexology may be based on similar principles (Dougans and Ellis, 1992).

An Egyptian wall painting discovered at the tomb of Ankhm'ahor at Saqqara in 1897, and dating from around 2250 BC, is also thought to provide further evidence for the ancient roots of the therapy as it is said to depict a form of reflexology therapy taking place. While it is apparent from the figures in the painting that massage or manipulation of the foot, hand or shoulder is occurring in the scene, it is not possible to determine whether the purpose of this is therapeutic. In addition, a number of American Indian tribes are also reported to have used treatments like this for centuries, to relieve pain and treat disease (Marquardt, 1984). However it is unclear whether such techniques were ever used in Western traditional folk medicine.

It was in the late 19th and early 20th century that Dr William Fitzgerald 'rediscovered' reflexology in the West (Griffiths, 1996). During his work as an ear nose and throat surgeon he observed that application of pressure to certain parts of the feet or hands led to patients experiencing limited anaesthesia. He argued pressure on an area that corresponded to the painful area could reduce pain in the affected area, while if the pressure was firm enough it could produce an anaesthesic effect. This technique allowed him to perform some minor operations without recourse to cocaine or local analgesics, and without the patient experiencing any pain. In 1917 he and his colleague, Dr Edwin Bowers published 'Reflex Zone Therapy' which outlined their thesis. Essentially this postulated that the body was divided up into ten longitudinal energy zones, five on each side of the body (see figure 1.2), which terminated in the hands and feet.

Figure 1.2 Reflexology energy zones on body and feet

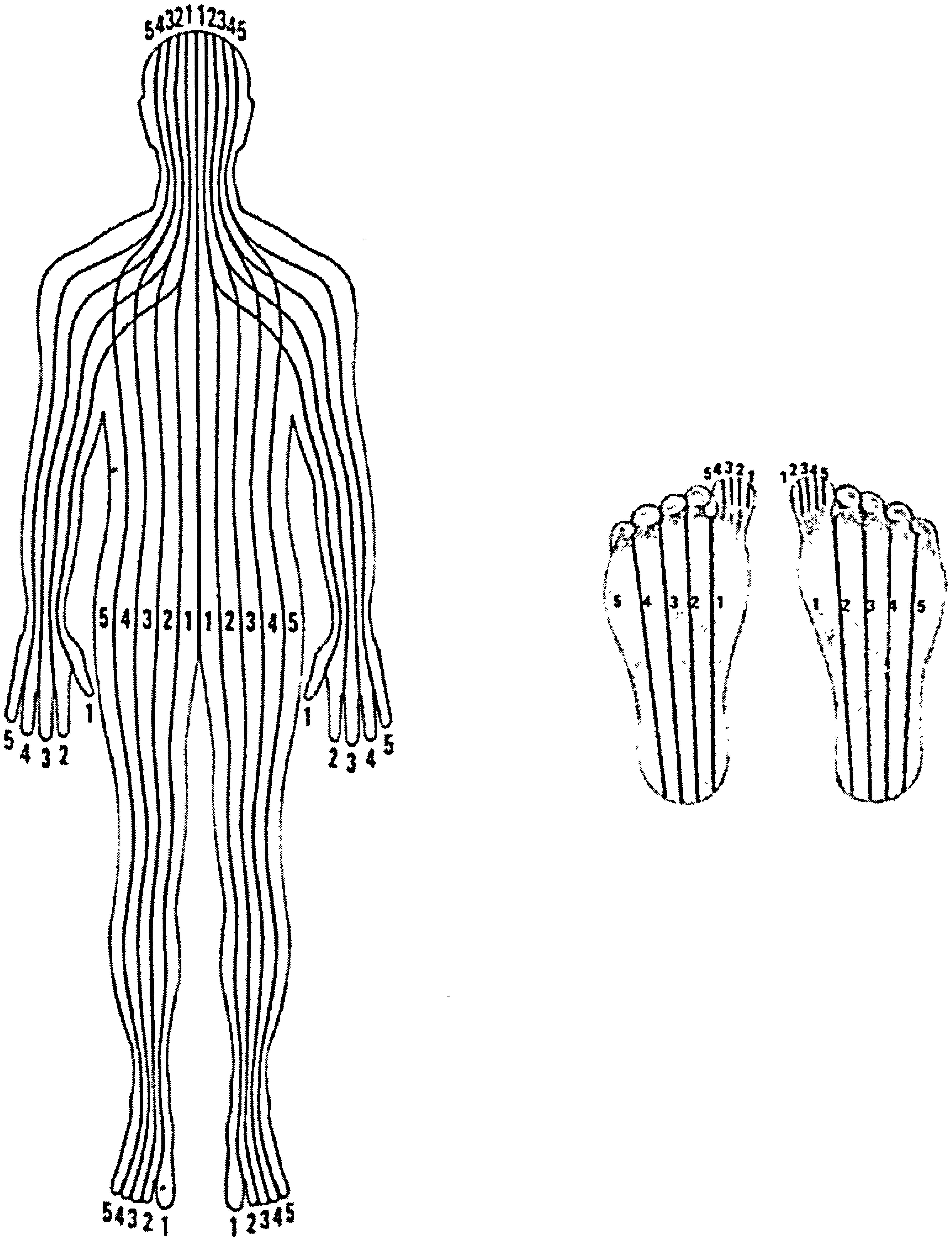
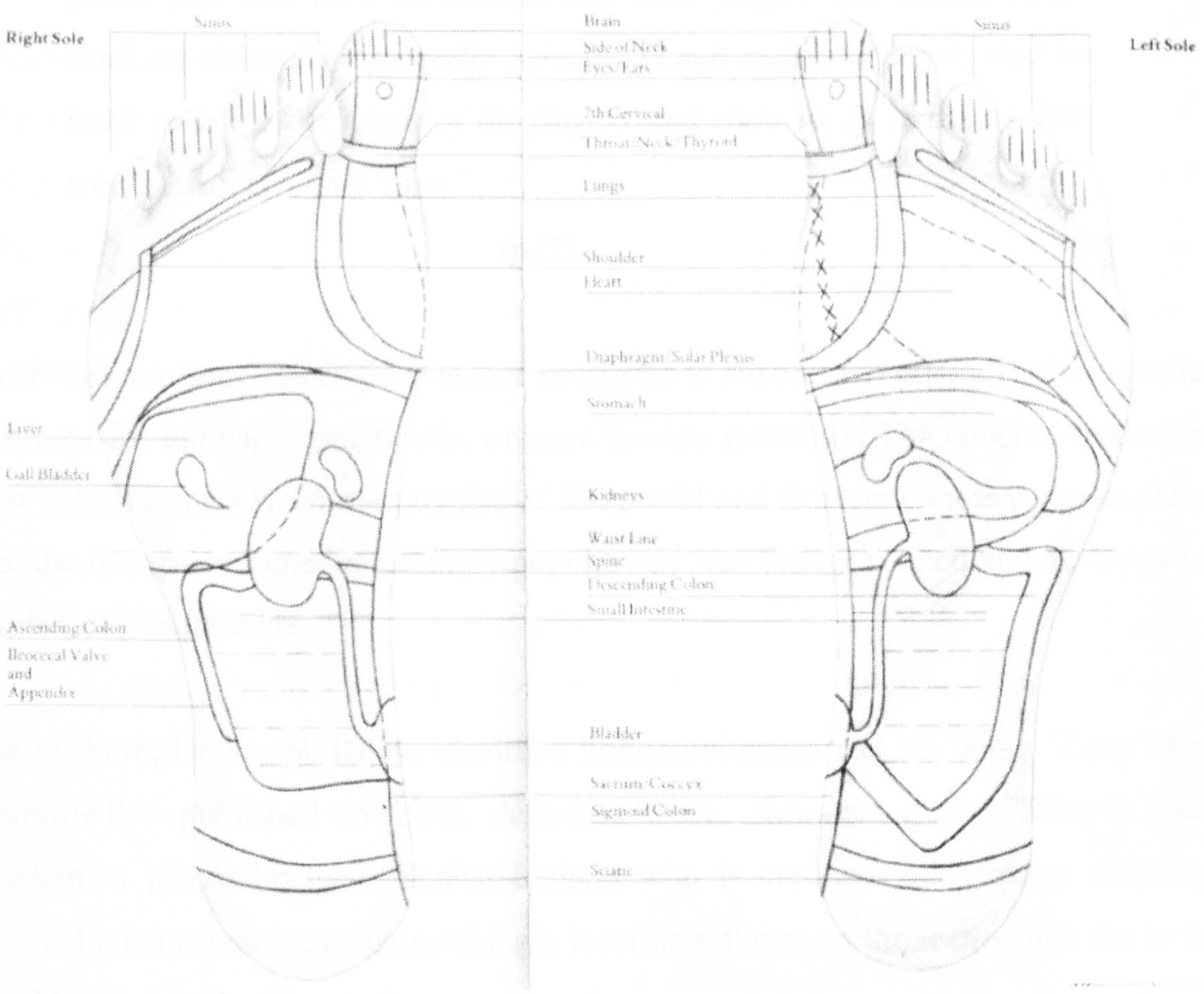


Figure 1.3 Areas of the body which correspond to zones on feet



They demonstrated the relationship between areas in the same zone, and showed how the application of pressure at a particular point of the zone could alleviate tension or pain elsewhere within that zone. This led to the ‘mapping out’ of the zones on the feet (an example of which is illustrated in figure 1.3) and hands and the connections between them, which Fitzgerald claimed demonstrated the utility of the therapy for a variety of painful conditions. These included: toothache; neck and thyroid problems; insomnia; headache; hysteria; uterine problems; back pain and others. Based upon his observations Fitzgerald argued that the pain relief or anaesthesia were not merely transient states brought about by a ‘nerve block’ but that when the pain was relieved, the condition which produced the pain was most often relieved too. It should be noted however that Fitzgerald did not only apply this pressure with the hands, but often used other implements, such as pegs, combs, clamps and elastic bands. For example, Crane (1997) states in her practitioner’s guide to reflexology:

> *'Fitzgerald often spoke of curing lumbago with a comb; his instructions were to press the teeth into the palmar surface of the thumb first and then the second and third fingers and occasionally work on the webs, especially between thumb and first finger, and to work even the very tops of the fingers and right up to wrists as this would help the entire zone.'*
>
> *(p17)*

However there is no scientific evidence presented to support the efficacy of this particular treatment for lumbago specifically, or zone therapy generally. The conclusion that zones exist is based entirely on the premise of Fitzgerald and Bowers own experience. Despite this, the therapy became increasingly popular and was further refined and developed by a number of practitioners.

One of these, Dr Joseph Riley, identified horizontal zones and his book: 'Zone Therapy Simplified', published in 1920, describes these. However it was Riley's research assistant, a physiotherapist, Eunice Ingham who is credited with further refining the theory. Ingham spent years painstakingly locating reflexes on the feet, which she believed should be specific targets for treatment because of their sensitivity. From these she compiled charts which illustrated the zones and their effects on the rest of the body in relation to the feet. Ingham discovered that by varying the amount of pressure applied to reflex points on the feet she could achieve therapeutic effects as well as pain reduction. (Sahai, 1993). Her own method of 'compression massage' was outlined in a book published in 1934: Stories the Feet Can Tell. It is this technique upon which most contemporary reflexology is based. More recently (1966) Doreen Bayley, a nurse who was trained in reflexology by Ingham in the US, returned to Britain and began to promote the therapy in Europe (Botting, 1997). Since this time reflexology has grown in popularity and a number of different schools have evolved.

1.7.3 Different Schools

There are a variety of schools of reflexology throughout the world. Standards, training and qualifications also vary widely between them, which can be confusing for potential consumers. This is further hampered by the fact that there is more than one professional body in the UK, for example The Association of Reflexologists is not affiliated to any one school, whereas the British Reflexology Association is the official teaching body of the Bayley school.

Graham (1999, p227), Botting (1997, p124), and Griffiths (1996, p13) list the following different schools of reflexology: Traditional Ingham Method (Ingham, 1934, 1984); Metamorphic Technique (St Pierre & Boater, 1982); Vacuflex Reflexology (Dougans & Ellis, 1992); Reflex Zone Therapy (Goodwin, 1992); Multidimensional Reflexology (Ashkenazi, 1993); Rwo Shr Method (Adamson, 1994) and Morrell Reflexology (Griffiths, 1996).

Many of these differ in their methods of treatment and the precise location of some of the reflexes. However common to them all is the notion that the feet represent a microcosm of the entire body, and that by applying pressure to particular 'reflex' points on the feet, symptoms experienced elsewhere in the body can be relieved. The number of different schools does not appear to present a problem to practitioners of the therapy. Issel notes in her foreword to Doogans & Ellis' (1992) book on a new approach to reflexology using the Chinese Meridian theory, that there is no correct theory of how reflexology works. She suggests that whatever specific methods reflexologists use, or the theory which informs them, they all agree

> *'1. that the body is reflected on the feet through a system of reflexes, and*
> *2. the objective of the reflexologist is to stimulate these reflexes'*
>
> *(p vii)*

Some argue that consumers are accepting of this situation, for example Coxon (1998) reflected on her ten years experience in a community reflexology practice, and noted that patients do not require to understand the 'nature of reflexology' (p15) and 'that a 'scientific explanation' has never been requested (p16). This is in direct contrast to others who report that patients are interested in knowing how reflexology works (e.g. Dryden, et al., 1999; Cromwell et al., 1999). However it should be noted that all the above schools with the exception of 'Vacuflex' use the hands to conduct specialist massage of the feet, thus the physical experience of having the therapy must be broadly similar whatever the philosophical or theoretical inclination of the therapist. This may not be the case for the non-specific effects the treatment may have, as the cognitive, affective and/or spiritual experience of the therapy may be qualitatively different. Therefore therapy from different schools may result in different effects, and this highlights the need for practitioners and researchers to be explicit about the type of reflexology they provide or are scrutinising. Such information would allow stakeholders and consumers to make informed choices regarding potential NHS provision and the clinical effectiveness of particular types of treatment.

Implicit in the argument about differential mechanisms of effect is the notion that reflexology *does* work. However this remains open to question, and before going on to consider this in more detail a number of 'models' which have been put forward to explain how reflexology might work will now be explored.

1.7.4 Possible Mechanisms of Action

> *'There is plenty of empirical evidence that reflex therapy works and that by pressing points on the soles of the feet specific parts of the body are affected. I know from personal experience that this is so... But just how and why reflexology works is not so clear'*
>
> Goodwin (1992, p70)

The above quotation highlights the still current situation concerning the lack of consensus about the mechanism of effect in reflexology. There has been much speculation, but the majority of this has been of a descriptive rather than explanatory nature with little scientific evidence to support many of the claims about a relationship between 'reflex' points and the rest of the body.

Booth (1994) offers an example to illustrate that there is some foundation to the idea of a such a relationship. He describes angina pectoris, where the first sign of oxygen deprivation to the heart muscles is experienced as tingling or pain in the left arm, to demonstrate how structures on the surface of the body which are apparently unrelated, may have some connection because they developed in close proximity in the embryo. However while this confirms correlation between two structures, it does not provide evidence that the relationship is reciprocal, i.e. that manipulation to the surface can affect internal organs therapeutically.

As previously noted reflexology is not a new therapy, but has been around in some form for many years. Dougans states 'I believe that reflexology originally developed in conjunction with acupuncture. The reason for massaging the foot was primarily to stimulate the six main meridians that run through the feet. During the course of history, the relationship between these two practices was somehow lost and forgotten' (Dougans & Ellis, 1992, p45). Others have also suggested that many of the 'reflex points' on the feet correspond to points used in acupressure (e.g. Vickers, 1996) and this is apparent from studying the charts of the feet presented in most texts (e.g. Crane, 1997). Therefore it follows that the mechanisms of action in both of these therapies may share some common elements. Both are concerned with restoring balance to the 'energy' or 'life force' within the body, though the precise nature of this energy is open to debate. However just as there is no evidence for the concept of energy zones within reflexology, there is similarly no scientific evidence to support the existence of meridians in acupressure. Like reflexology there are some studies which establish a correlational relationship between the therapy and positive effects, but no research demonstrates or proves what the causal mechanism may be.

The fuzzy relationship between reflexology and traditional acupressure points is further complicated when one explores another hypothesis put forward that reflex points are nerve receptors, and stimulation of these pathways accounts for the mechanism of action. Many meridians follow the line of a nerve, which would indicate that neural pathways could be involved. In the context of reflexology and the treatment of pain, this hypothesis may have some currency. Stimulus-response models of pain posit that pain can be alleviated or reduced by removal of the pain stimulus, or by action upon the 'pain pathways' to block nerve impulses to the brain. These models influence many forms of medical treatment, such as the use of analgesics to block the pathways or surgical interventions to sever them. It is possible that pressure on the nerve endings in the feet could have a similar, though perhaps less potent effect. Reflex zone therapy as practised by Fitzgerald, whereby pressure was applied to various parts of the body and resulted in transient anaesthesia, may be more comprehensively explained by this mechanism. However it is difficult to understand how the mechanism could account for the lasting effects practitioners claim for the treatment.

Another suggestion for how reflexology might work also relates to the nervous system. It concerns the idea that pressure on the reflex points may trigger the release of naturally occurring painkilling substances, or opiods such as Beta-enodrphin. (Szmelskyj, 1998). There are no published studies which explore this in the context of reflexology, although in a paper which reviewed whether CM stimulate the body's natural painkilling medications (Szmelskyj, 1998) concluded that there is insufficient evidence to support the notion that acupuncture, chiropractic and osteopathy induce endogenous opiate analgesia. While the practice of acupuncture/acupressure and reflexology remain distinct, hypotheses concerning their mechanisms of effect are linked. Therefore it is unlikely that reflexology would have a significant impact on the production of these naturally occurring opiods.

Similarly, other proposals for the effective component of reflexology treatment combine the 'neural' and 'energy' hypotheses (e.g. Lynn, 1993, Goodwin, 1992). These argue that manipulation of the feet reduces the amount of lactic acid in the tissues while releasing tiny calcium crystals accumulated in the nerve endings of the feet. Or that the therapy has a detoxifying effect whereby manipulation dissolves crystals of uric acid that settle in the feet, allowing them to be eliminated. In both instances, removal of these 'blockages' that hold back the free flow of energy results in a return to homeostasis, and well-being. There is no evidence to support this.

Finally Frankel (1997) suggests what he terms a 'psychological theory' of reflexology which is linked to the notion that 'reflexology exherts some of its effects rather like meditation' (p80). That is, it focuses the mind to the transition between being awake and asleep, evoking a deep relaxation which is restful for both conscious and unconscious mind. However he fails to expand upon how this could influence pain perception or lead to improved wellbeing. This is not the first time that psychological mechanisms have been postulated to account for the apparent efficacy of reflexology. Fitzgerald gave four reasons for how reflexology worked (Crane, 1997). Three are broadly related to the hypotheses concerning energy zones and neural pathways considered above, while the other states that reflexology works: 'Through the soothing influence of animal magnetism' It is possible that this alludes to the nature of the relationship between the two people, i.e. the therapist and the patient. There is a wealth of literature concerning the positive effect of the therapeutic relationship (e.g. Corey, 1996) and this could occur in the context of the reflexology session (Troudsell, 1996; Mackereth, 1999). Thus the '...quality and quantity of the personal contact between the patient and therapist...' may be responsible for some of the therapeutic effect (Botting, 1997, p125).

It is apparent that throughout the history and development of reflexology numerous explanations for its effect have been postulated. However there is little or no direct scientific evidence to support any of these, and they remain conjecture at this present time. As a uniform theory of reflexology does not exist, this has led some to argue that the apparent benefits of reflexology are more suitably explained by the relaxation response (Graham, 1999; Ernst & Koder, 1997). Certainly the treatment is designed to induce a relaxed state in the patient, which in turn could lead to e.g. a reduction in pain, stress, or a greater feeling of wellbeing. However the effects of this induced state would be a secondary consequence of the treatment mediated by the relaxation response. In this instance one would have to argue whether the use of specific relaxation techniques would more appropriately and efficiently produce the same results.

As a result of the incomplete explanations for how the treatment works, reflexologists have suggested that the question of primary importance is not 'how does reflexology work? but 'does it?' (Sahai, 1993, p723). The following section now consider this question in the context of the available literature on reflexology.

1.7.5 Evidence for efficacy

Vickers (1996) notes that despite wide scale practice and claims of efficacy for a variety of conditions, reflexology remains an under researched therapy. The reasons for this are unclear, but may be a reflection of the lack of research expertise on the part of practitioners themselves (FIM, 1997) or due to the lack of funding opportunities for research into CM generally, compared with orthodox medicine (OM). However there is much anecdotal evidence that reflexology is effective for some conditions (e.g. Barron, 1990; Crowther, 1991) and some scientific research has been reported, although not all of this is of a sufficiently rigorous nature to inform potential purchasers of its effectiveness. Two recent reviews (Botting, 1997; & Ernst & Koder, ibid.) support this, and criticise many of the studies that have been carried out as being methodologically flawed. Indeed Ernst & Koder concluded that 'reflexology is popular yet based on unproven ideas that fly in the face of science. Most crucially, there is no clinical evidence for its effectiveness beyond a (potentially powerful) placebo effect' (p56). Graham (1999) has suggested that the few research reports available appear to be positive. However she counters this by suggesting that this may be explained by a relaxation effect, and states that 'there is a need for more carefully controlled research' (p226).

To date there have been eight randomised controlled trials looking at the efficacy of reflexology for a variety of chronic conditions. However none of these have considered its effectiveness in the context of chronic low back pain (CLBP). This is surprising when one considers that CLBP is the most common condition reflexologists report treating. In addition to these there are numerous published case studies/cohort series, and a couple of studies looking at the physiological effects of the treatment. While these are low in terms of a hierarchy of evidence, in conjunction with the other research they do contribute to the conclusion that there may be some effect from the treatment and helped to identify areas for further investigation.

1.7.6 Review of available literature on reflexology

Siev-Ner et al. (1997) compared the effects of reflexology to non-specific massage to the calf area for multiple sclerosis (MS) using a RCT design. They identified four measurable outcomes: paraesthesiae; urinary symptoms; muscle strength; and muscle spasticity and found that reflexology could relieve some of these. 71 MS patients started the study but only 53 completed all the treatment sessions, representing a 25% drop out rate. Those in the reflexology group demonstrated significantly increased improvement in urinary and spasticity symptoms compared to those in the massage group, which indicates that reflexology was effective to some extent for particular symptoms of MS. The non-randomised controlled trial conducted by Joyce & Richardson (1997) also supports this. They compared reflexology with no extra intervention in a volunteer sample of MS sufferers who recorded their rating of 19 symptoms (major/minor/not applicable) during treatment and at follow up, 3 months later. Those in the reflexology group reported a 45% improvement in symptoms compared to 13% in the control group during the treatment phase though this benefit was not sustained at follow up. While the Siev-Ner et al. (1997) trial is considered to be methodologically sound, Joyce & Richardsons' study has been subject to some criticism (Mackereth et al., 2000), including in particular the inclusion/exclusion criteria for the study and the non randomisation of participants to the reflexology group. In addition it is suggested that the study could have been improved by the use of more appropriate, less subjective, outcome measures of the type commonly utilised in the evaluation of medical interventions with this patient group.

Similarly, in a very small study (n=9), Thomas (1973) compared daily foot reflexology, no intervention, and ½ hour daily reassurance, all for 8 days in patients with anxiety. He found that patients in the reflexology group reported feeling less anxious, than those in the other two groups. Despite the positive results, the lack of objective outcomes and the extremely small sample size mean that this type of study needs to be repeated with a much larger sample using validated measures of anxiety.

A particularly rigorous design was used by Olesen & Flocco (1994) who evaluated the efficacy of reflexology for 32 women suffering from pre-menstrual syndrome (PMS). Participants were randomised in two groups: reflexology or placebo treatment (overly light or very rough massage on points not appropriate for PMS). Women kept diaries and recorded their somatic and psychological symptoms on each day of the week prior to menstruation. At baseline the mean symptom score was similar for both groups. At the end of treatment Olsen and Flocco report that women in the reflexology group demonstrated a 45% decrease in both somatic and psychological symptoms compared with only 20% of those in the placebo group ($p<.001$) and that this was maintained at follow up. As those in the placebo group thought they were getting reflexology, this demonstrates that the results were not simply the result of the placebo effect.

The authors of the above study speculated that the experience of profound relaxation reported by the women in the reflexology group may have induced the type of psychophysiological response to stress which Goodale et al.(1990) proposed relaxation produced, and that it is this reduction in stress which helped alleviate the symptoms of PMS. However Vickers (1996) pointed out that as those in the reflexology group also received manual pressure at the site of some classical Chinese acupuncture points, this may have influenced the outcome. Ernst & Koder (1997) argued that it is possible that the therapist in this study may have been unconsciously biased, which could have resulted in the reflexology group being exposed to non-specific positive effects such as expectation or empathy.

Lafeuente, et al. (1990) looked specifically at the use of reflexology for headache relief. They randomised 32 headache sufferers to receive either sham reflexology and Flunarizin™ or reflexology and a placebo. Participants were required to keep a diary to record the frequency, severity and duration of headaches they experienced. Reflexology treatments were given 12-30 times over a 2-3 month period. Lafeuente et al. reported that those in the reflexology and placebo group improved more than those in the sham reflexology and Flunarizin™ group, though this result was not statistically significant. Despite the relatively small sample size and variation in age as well as the type of headache suffered, it was concluded that reflexology was at least as effective as Flunarixin™ and may be a particularly appropriate alternative for patients with contraindications to pharmacological treatment.

Vickers (1996) and Ernst & Koder (1997) each reviewed the RCT conducted by Eichelberger (1993) to determine whether reflexology could reduce the need for post-operative medication. Both criticise the lack of experimental and statistical detail provided in the study report. 60 women catheterised after gynaecological surgery were randomised to 2 groups: reflexology versus no intervention. Eichelberger (1993) reports that only 10% of those in the reflexology group required medication after removal of catheter compared to 40% in the non-intervention group. Ernst & Koder (1997) argued that the design did not control for the non-specific effects of reflexology, therefore the results cannot be taken to conclusively demonstrate that reflexology was effective, as factors such as 'attention given' and 'expectations raised' in that group may have been responsible.

Peterson et al. (1992) examined reflexology for the treatment of bronchial asthma using a RCT. Thirty patients were randomised to 10 weekly reflexology treatments or non-specific counselling. Diary and symptom scores were identified as outcome measures, along with medication and objective measures of pulmonary function at baseline, 3, and 6 months later. There were no significant differences between groups at the end of the trial. From this we may conclude either that reflexology is ineffective or more specifically that reflexology is ineffective for bronchial asthma. Vickers (1996) noted that there was only one practitioner delivering the treatment, thus it is possible that the therapist, not the therapy, was ineffective in this instance. In addition Johannessen (1997) pointed out that while the researchers' report of the study was negative for reflexology, the report of the reflexologist who delivered the treatment (Fosholt, 1992) was not. Fosholt evaluated the treatment using the diaries that patients had completed regarding their experience of the therapy, and concluded that it was effective.

It is accepted that the therapist's evaluation of her own practice, even with the use of patient diaries may be subject to bias. However this incongruence between results in the same trial presents an interesting dilemma for anyone looking at the evidence for efficacy. Peterson et al (1992) based their conclusions on objective outcome parameters. This leads to the question of whether the patients' views of efficacy be negated because 'science' showed no effect or should the appropriateness of those scientific paramenters be questioned because they are in conflict with the notion of efficacy that patients have? Whatever the conclusion it is apparent that in the context of studies that consider the outcome of particular treatments, that outcome needs to be defined in terms that have currency for both providers and consumers alike.

Another study which reported negative results on objective parameters is that of Engwquist & Vibe-Hansen (1977). They compared the effects of reflexology to the pituitary and adrenal zones with light reflexology to the shoulder zone for surgical stress, using changes in plasma cortisol levels as an outcome, and found no difference between the groups. However the sample used was small (n=16), and the reflexology was only given for 10 minutes prior to surgery. As reflexologists generally report treatment durations of between 30 and 60 minutes per session, it may be that 10 minutes was not long enough to induce any effect.

Ernst & Koder (1997) reviewed the English abstract of a study by Wang (1993) but noted that the limited information available in the abstract prohibited a comprehensive evaluation of the study. Patients with Type II Diabetes Mellitus (n=32) all continued with their standard care and were randomised to receive either daily reflexology for 30 days or no additional care. Wang reported that blood glucose levels of those in the reflexology group returned to normal, whereas those of the control group did not. This suggests that reflexology had some effect for this condition, though without the full details of the study we must also accept that there may have been other factors which could have resulted in the normalisation of blood glucose levels, e.g. changes in diet, or exercise.

In addition to the above trials a number of other studies have also been reported, generally in nursing journals and practitioner handbooks. These will be briefly considered in the following section.

1.7.7 Case series/studies

There are many case studies which indicate the potential beneficial effects of reflexology for a number of conditions. These include: relieving symptoms of cystic fibrosis (Wynn, 1988); improvements in patients with MS (Ashkenazi, 1993); palliative care (Shaw, 1987; Burke & Sickora, 1992); ante and post natal care (Evans, 1990, Tiran, 1996); infant colic (Wilson, 1995); healing through touch (Smith, 1990) and pain relief (Lockett, 1992; Griffiths, 1996).

It is apparent that the therapists' evaluations of their own practice presented in the context of a single case study or series, may be subject to bias, as invariably they are not representative of their whole case load. Vickers (1995) pointed out that the case histories published are probably the most interesting the therapist has, and there may be other less successful histories or even instances where the client has discontinued with treatment which are not reported. However they do suggest that there is some foundation to the notion that reflexology is effective for some conditions. A few therapists have attempted to evaluate their own practice more formally, by asking patients for their perceptions of the treatment's effect.

Trousdall (1996) reported that reflexology may appear to be work because it meets emotional needs. She evaluated the effect of offering reflexology to 15 women who were attending a drop in group at a mental health centre. Each received 30 minute reflexology treatments once a week for eight weeks. Open ended semi-structured interviews used before treatment began and at end of course, were designed to find out participants' feelings about the effects of treatment. Also at the end of this process, three focus groups helped to validate the data. Trousdall states that many of the women reported physical improvements, including alleviation of back pain, PMS, normalisation of blood pressure, and increase in energy levels. However the lack of a control group makes it difficult to accept that these self reported improvements were solely due to the reflexology. Furthermore the analytic techniques utilised with the qualitative data were not described in any detail. Nevertheless the patients' perceptions of the treatment are interesting, as they do not only pertain to the physical aspects of the therapy, but also include issues such as 'being heard and taken seriously' (p10).

Coxon (1998), in a questionnaire survey of her patients, found that all reported experiencing relief from their symptoms, primarily back pain, after treatment. Ten of those surveyed also said they experienced relief from symptoms other than those for which they had originally consulted. Of course the results of this survey may be subject to all the criticisms of the above study. However it would appear that from the patients' perspective there was some degree of satisfaction with the treatment which was a result of its apparent efficacy in relieving their symptoms.

As evidence data from this type of research are less robust than that from controlled studies. However while the results do not provide good evidence that reflexology is effective, they do highlight aspects of the treatment which patients perceive to be beneficial and point to the need for more rigorous research in this area. Furthermore, in conjunction with the positive results of some RCTs they appear to suggest that reflexology treatment has some effect, albeit non-specific. Indeed when considering the results of some studies it is apparent that the reduction in anxiety, the deep relaxation which the therapy induces and the therapeutic relationship may be responsible for certain of the positive outcomes experienced by patients. Each of these are greatly influenced by interindividual and interpersonal psychological factors, which would suggest that the psychological theory of reflexology has the most currency.

However, it needs to be recognised that these 'peripheral' factors are not unique to reflexology but are implicit within other types of holistic therapies. Thus it is suggested any study concerned with the evaluation of reflexology would have to adopt a methodology which took this into account. In addition it is argued that the role of relaxation in outcome to reflexology treatment would need to be similarly considered. Certainly this review of the literature on reflexology has suggested that the relaxation response may be an active component of the treatment, and as such would warrant further investigation.

1.8 Summary and rationale

The proceeding review of the literature concerning back pain and CM therapies has highlighted a number of areas of interest. It is evident that back pain of a chronic nature is a common and distressing problem, which is most suitably viewed within a biopsychosocial perspective. In addition, although there are a variety of OM treatments available for the management of the condition, few have been shown beyond doubt to be effective. Contemporaneously there has been a rise in the use of CM therapies, with back pain being one of the most common consulting conditions. Thus it is suggested that an increasing number of sufferers are seeking alternative solutions in the form of CM to manage the condition, usually at considerable financial cost. However, there remains a lack of evidence to support the use of many CM treatments for CLBP. Indeed, while a plethora of research has been conducted, not all of this has been of a sufficiently rigorous nature to inform potential purchasers of the clinical effectiveness of many therapies. This has led to calls for more and better quality research from a range of sources, including: CM practitioners themselves; their patients; the BMA; and GPs faced with increasing demands for information regarding the safety and efficacy of particular modes of CM.

Nevertheless, a number of the therapies most commonly utilised for CLBP, i.e. acupuncture, osteopathy and chiropractic have, and continue to be, subject to controlled trials. However, a rapidly expanding CM therapy which is frequently used by CLBP sufferers, reflexology, has not been subject to rigorous research in this domain, despite claims from both reflexologists and their patients that it works. Intuitively the use of 'holistic' therapies would appear to be relevant to the management of CLBP within a biopsychosocial paradigm. However this has not been tested. Thus the aim of the current investigation was to address the distinct lack of research in this area and present the first controlled trial of reflexology in the context of CLBP. Furthermore, in order to explore the notion that relaxation experienced during treatment is the mechanism of action in reflexology, relaxation therapy was used as a comparison condition in the current study.

While the literature review and this brief summary provided justification for the timeliness of conducting a study to evaluate the effectiveness of reflexology, they did not expand upon some of the methodological weaknesses identified in previous research. In order to provide a rationale for the methodology adopted in the current study, these issues were explored in greater depth. Therefore the following chapter 'methodological considerations' considers some of these issues and provides a comprehensive explanation for the study design.

Chapter Two

Methodological Considerations

2.0 Introduction

The previous chapter identified and evaluated the current evidence base of reflexology, and highlighted the timeliness of carrying out a study to assess its efficacy in the context of CLBP. In addition a number of methodological issues related to research on both OM and CM treatments for CLBP were described. This chapter briefly considers the utility of the randomised controlled trial (RCT) in CM. Following this, quantitative and qualitative methods are outlined and the rationale for the design of the current study provided, along with details of the variables to be measured.

2.1 Utility of the RCT for Evaluation of CM

It is apparent that despite the increased popularity of CM, it has not been wholly accepted by OM, and it is suggested that this is primarily because of the lack of evidence for the effectiveness of many CM therapies (e.g. BMA, 1993). Moreover it is argued that it is the perceived lack of RCTs in CM which poses the greatest barrier. However, as Vincent & Furnham (1996) state 'CM practitioners are often concerned that subjecting their therapy to the scrutiny of a randomised controlled trial will distort the purpose of what they are doing and disguise or negate the efficacy of their therapy' (p157). These concerns are not confined to CM, many other therapies or those which require an individual approach, for example, psychotherapy, are subject to the same problems. Nevertheless, if a therapy claims to be able to treat specific conditions, there should be evidence available to support those claims. Therefore some form of evaluation is required.

As with any form of research enquiry, the method adopted must be appropriate for the question to be answered, and not driven by the therapy under scrutiny (CM or OM) or its philosophical foundations. If the question concerns the evaluation of an intervention, then a methodology which allows one to attribute any effect on the patient to the intervention specifically, is required. The preferred means, indeed the 'gold standard' way to establish cause of an effect is via the RCT, whereby the treatment under scrutiny is assessed against a control treatment, placebo, or standard care.

The primary strength of the RCT is that it reduces bias. More specifically, the random allocation of participants to alternative treatments ensures that the groups being compared differ only by chance. However, the RCT has been subject to criticism in recent years (e.g. Vincent & Furnham, 1996; Launso, 1995). Problems identified include issues such as: feasibility of blinding; artificial standardisation of treatment; over stringent inclusion criteria resulting in non-representativeness of trial participants; ethical dilemmas associated with placebo treatments; participation affecting behaviour and therefore outcome; failure to take into account individual variation in response to treatment and over emphasis on group effects. Each of these are applicable to both OM and CM. However, some are of greater relevance in the context of CM, because of the individualised, patient centred, flexible approach to treatment which such therapies adopt.

It is argued that blinding of treatment is not possible for many CM therapies, particularly those which include manipulation or massage, including reflexology. Certainly it would present a challenge in reflexology. Indeed it may be seen as impractical in pragmatic terms as an experienced therapist would be able to determine what treatment s/he was giving. Furthermore one could argue that the therapist is integral to the treatment, thus therapeutic effectiveness ought to be judged from assessment of the whole encounter, and not restricted to the physical aspects of the therapy alone (Anthony, 1993).

In addition, it is argued that the inability to blind participants to the treatment they receive presents a significant methodological problem. The principal reason for blinding is to control for psychological components of the placebo effect, i.e. to ensure that treatment does not only work because participants expect it to (Von Korff et al., 1998).

However CM therapists would argue that treatment is designed to benefit both body and mind. Evidence exists to support the notion of an interactive relationship between the brain and the immune system (e.g. Kiecolt-Glaser & Glaser et al., 1986). Therefore, if participants were not aware of the treatment they received, the full potential for self-healing would not be harnessed.

A related issue, is the standardisation of therapy, which it is argued may remove some elements of treatment that are integral to it (Vincent & Richardson, 1986). As Vincent & Furnham (1999) state 'In the interest of standardisation few trials have allowed therapists to work as they would in practice and this might be detrimental to the treatment's efficacy' (p175). In addition standardisation may also place potentially unmanageable demands on therapists as well as remove autonomy from practitioners, who generally tailor treatment to the current needs of the individual patient. Furthermore, the evaluation of a standardised treatment would be so far removed from what happens in day to day practice, that the results of such an endeavour would have little clinical application in the 'real world.' Vincent & Richardson (1986) argue that trials could be more flexible on the content of treatment, while at the same time still ensuring some level of standardisation, such as number and length of treatment sessions.

Moreover, the identification of an appropriate control condition is difficult for many hands on therapies. The use of placebos in the form of 'sham' treatments is probably unethical (e.g. Kleijnen & de Craen, 1996). Although Resch & Ernst (1996) suggest in some circumstances it would be ethically acceptable, i.e. where no gold standard treatment exists. However, Vickers (1996) posits that there is no need for placebo or standardised treatments and points out that it is a misconception that all RCTs in OM are double blinded, and placebo controlled. Thus, when the arguments concerning blinding and standardisation are considered, it is apparent that a methodological design which enables practitioners to provide individualised treatments, in real world settings, based on their clinical experience, is required. The use of a pragmatic RCT would fulfil these requirements.

A number of authors in recent years have discussed the evolving nature of the classical RCT, and evaluated the consequences of this for CM (Vickers, 1996; Thomas & Fitter, 1997; Fitter & Thomas, 1997; Gatchel & Maddrey, 1998; Vincent & Furnham, 1999).

However, as long ago as 1967, in a landmark paper, Schwartz & Lellouch, defined the difference between explanatory and pragmatic RCTs in OM. Explanatory trials are the gold standard RCT whose aim is to provide evidence to explain mechanisms of action. Such trials evaluate treatment by comparing two (or more) treatments which are alike with the exception of the 'active ingredient' in one of them. On the other hand, pragmatic trials evaluate treatment *in vivo,* frequently by comparing the existing standard treatment with a novel one.

The largest advantage of the pragmatic RCT is that it enables interventions to be compared in a realistic setting, thus conclusions from such studies, if accepted, can be adopted directly into practice (Roland & Torgerson, 1998). Furthermore, it allows treatments to be provided as they would in practice. Indeed, as Schwartz & Lellouch state 'It is characteristic of the pragmatic approach that treatments are flexibly defined and 'absorb' into themselves the contexts in which they are administered' (p 638). Thus the use of a pragmatic RCT negates the need for patient and practitioner blinding as each is aware of the treatment given.

In addition this method has been used previously in the context of CM therapy with CLBP patients. Meade et al. (1990) compared chiropractic with a hospital based physiotherapy service. In their rationale for the use of a pragmatic RCT instead of a fastidious trial Meade and colleagues argued that the question of most interest to doctors, therapists and patients is whether the treatment is effective in day to day practice, not whether it is effective when delivered in a specific way under highly controlled conditions. Thus while it is recognised that the use of a pragmatic trial involves the loss of some control over extraneous variables, the resultant ecological validity of the results can compensate for this. Indeed the value of research on real life, clinical populations in real world settings, with the attendant methodological difficulties, is becoming increasingly accepted (Knottnerus & Dinant, 1997).

Having determined that a pragmatic RCT represents an appropriate method with which to determine the efficacy of reflexology, a number of other questions need to be addressed. These include: how would effectiveness be measured? who would be recruited? who would be excluded? what treatment could be used for comparison? and what should be the duration of follow-up evaluations? The sections that follow consider these issues.

2.2 Outcome Measures

Chapter one highlighted how CLBP is best viewed as a multidimensional problem that can potentially effect all aspects of an individual's life. In addition, a number of psychosocial variables found to be related to treatment outcome were identified. It was argued that intuitively, the use of a holistic therapy, such as reflexology, would appear to be relevant to the management of CLBP. Thus it is suggested that variables which reflect the multidimensional nature of both the condition and the therapy be utilised to evaluate effectiveness. Furthermore, as Waddell & Turk (1992) stated that 'It is important to acknowledge that for chronic low back pain...a number of psychological and behavioural factors also need to be considered as there is no simple one-to-one association among physical pathology, pain, and disability' (p31). This indicated the interdependence of factors associated with the CLBP experience, and thus provided a rationale for their simultaneous measurement.

The current study was concerned primarily with the evaluation of a relatively novel therapy, reflexology. Hence it was considered that the application of commonly used, previously validated, measures designed to reflect the complexity of CLBP were necessary. An advantage of this was that the results would be more easily accessible to health care professionals, in a currency which was familiar to them. In addition, this would also facilitate comparison with other studies which have used the same measures to evaluate therapeutic interventions for CLBP. In health care evaluation, traditional measures of efficacy include indices of morbidity and mortality. However, these are not relevant to a condition such as CLBP which is not life threatening. In the field of CM therapy, Resch & Ernst (1996) stated 'If the intervention is aimed at alleviating symptoms rather than claiming to interfere causally with the underlying disease, a 'symptomatic variable' seems justified as the main outcome measurement (e.g. pain, quality of life, well-being)' (p26). Similarly, with regard to CLBP, few interventions would claim to be able to cure the condition, however most would argue that they can help to alleviate the symptoms.

For the majority of clinical researchers, the use of a single outcome measure does not provide a high enough level of precision, thus a set of core instruments is most frequently used. In the field of pain management there have been recent moves towards developing a consensus on measurement tools which are broad enough to encompass all the domains necessary, yet brief enough to ensure patient compliance with completion (Deyo et al., 1998; Turk et al., 1983). Measures to reflect the psychosocial factors associated with adaption to CLBP identified in chapter one would need to include instruments to assess: quality of life, pain, functioning, mood, coping, and social support.

The measurement of quality of life, or subjective health status has now become an accepted part of health care evaluation and health services research (Jenkinson, 1994), and a number of instruments are available to assess this domain. One of the most frequently used in primary care research is the SF36 (Ware & Sherbourne, 1992) which is generally perceived to be the most up to date generic measure of health status (Barrett, 1997). The SF36 provides a measure of patients health related quality of life along eight dimensions, including bodily pain. A number of studies have been carried out to validate the SF36, and these have provided normative population data, as well as norms for low back pain patients from primary care (Brazier et al., 1992, Jenkinson et al., 1993; and Ruta et al., 1994). In addition, the SF36 has been shown to be responsive to change (e.g. Katz et al., 1992; Garratt et al., 1994; Fitter & MacPherson, 1995; Vickers, 1996).

In the context of clinical trials in CLBP, use of the SF36 has been recommended (Bronfort & Bouter, 1999). Similarly for studying quality of life, McGourty (1993) suggests the SF36 may be applied to CM therapies. Indeed it has been utilised in a number of studies as a measure of outcome (e.g. Brown, 1995; Gough & Frost, 1996; McKinnon et al., 1996). However, despite its widespread use, the SF36 may not be suitable for use with patients over the age of 65 (Brazier et al., 1992). In addition, a number of authors have argued that whilst the SF36 is increasingly the instrument of choice in health care evaluation and research, it is generic, and as such should be used alongside disease specific measures (Ruta et al., 1994).

More specifically, the SF36 Pain dimension has been used as a primary outcome to treatment for chronic pain, including CLBP (e.g. Fitter & MacPherson et al., 1995; MacPherson et al., 1999; Gough & Frost, 1996; McKinnon et al., 1996; Rogers et al., 2000), and this is proposed in the current study. Indeed it is argued that in order to evaluate the effectiveness of treatment for CLBP the assessment of pain is essential. However, it is recognised that this may be difficult. Pain, is by nature, a subjective experience, therefore it is not possible to measure objectively. Nevertheless a variety of assessment methods have been devised to reflect different aspects of the pain experience (Turk & Melzack, 1992, Jensen & Karoly, 1992). These include observational ratings, as well as a number of self-report questionnaires, which range from a small number of items contained within larger health status measures such as the SF36, to large, pain specific questionnaires such as the McGill Pain Questionnaire (MPQ, Melzack, 1975). Furthermore, short visual analogue or numerical rating scales are frequently used (Jensen et al., 1992).

In addition to the pain per se, a primary question is the effect that pain has on day to day activity, as it is this interference with normal functioning which has been posited to account for the high levels of physical and psychological disability which may result from CLBP (e.g. Waddell, 1997). The SF36 contains dimensions which relate to physical and social activity, but the questions address limitations in relation to general health as opposed to back pain specifically. Thus as Ruta et al. (1994) suggested, the use of a back pain specific measure of functioning is required.

Two of the most frequently used measures of function in the field of back pain are the Roland & Morris Disability Questionnaire (Roland & Morris, 1983) and the Oswestry Disability Questionnaire (ODQ)(Fairbank et al., 1980). Both of which were recommended by Deyo et al. (1998) for the evaluation of CLBP interventions. However, the Roland Morris contains 24 items compared to 10 items on the ODQ. Therefore, in order to reduce the burden on participants, use of the ODQ is proposed. Fisher and Johnston (1997) report that the ODQ has good face validity among patients asked to complete it. In addition they recommend its use as '...a relevant measure of disability with evidence of validity, reliability and sensitivity to change for both clinical and research purposes' (p79). Furthermore, the ODQ was used by Meade et al (1990) in trial comparing efficacy of standard hospital physiotherapy care with chiropractic treatment for low back pain, where it was shown to be sensitive to change.

As previously stated, a selection of instruments were required, to evaluate outcome to a complex condition such as CLBP. However, it was recognised that one or two of these would need to be selected as the primary outcome variables, in order to determine the size of sample required for the study. Data from studies which had evaluated CM therapies for back pain were available to indicate clinically significant levels of change on the ODQ and SF36 Pain dimension. Thus for the purposes of the current study Pain as measured by the SF36 and Functioning measured by the ODQ were selected as the primary outcome measures. In addition, a number of the other psychosocial variables identified in chapter one to potentially influence outcome to treatment were also assessed.

Coping

First it must be stressed that the assessment of coping in the context of chronic pain can be problematic (Boothby et al., 1999, Richardson & Poole, 2001). As with any chronic condition, the very nature of its chronicity means that it is often associated with many secondary difficulties, such as changes in socio-economic status. Therefore it is often difficult to isolate what a chronic pain sufferer is doing to cope with their pain away from their methods of coping with the associated problems arising from having the pain. Job loss, financial insecurity and dysfunctional relationships are all common difficulties that chronic pain sufferers have to cope with (Gatchel and Turk 1999).

Nevertheless a range of self report instruments designed to measure a large variety of different coping styles has been developed. Chapter one briefly considered some of these. However, the use of the Coping Strategies Questionnaire (CSQ) (Rosenstiel & Keefe, 1983) was proposed for the present study. The CSQ was specifically designed to measure coping with pain, and is the most frequently utilised instrument in this domain (Jensen et al., 1992; Maes et al., 1996).

Depression

Chapter one outlined the issues surrounding the measurement of depression in the context of chronic pain, and these apply equally to CLBP. As with previous variables, a large number of instruments are available to measure this construct. However, with the exception of the Modified Zung Depression Scale (Main & Waddell, 1992) none are specific to CLBP. Nevertheless, the Beck Depression Inventory (BDI IA) is one of the most widely used instruments to detect and assess depression in a range of populations, including chronic pain patients (Mikail et al., 1993; Callahan et al., 1991). In recent years, the BDI has undergone some redevelopment and the latest version of the instrument, the BDI II is available. A number of somatic items have been removed from the instrument, and this may have implications for the measurement of depression in CLBP, as it could reduce the likelihood of criterion contamination. Thus the use of the BDI II was proposed for the present study.

Furthermore Beck et al.(1996b) state that '...transition from the usage of the BDI IA to that of the BDI-II should introduce no meaningful interpretative problems' (p596). In addition, to facilitate researchers and clinicians who wish to compare BDI IA and BDI II scores they provide equivalence tables for raw scores on either instrument. Therefore, although the utility of the BDI II has not been established with this population, the long history of the BDI IA, and the potential to compare scores across instruments, will ensure that comparisons with other study samples can be made.

2.3 Additional design considerations

Along with the selection of appropriate instruments to measure outcome, a number of the other methodological problems apparent in previous research were addressed. These are outlined in the following section, which presents the rationale for more specific aspects of the study design.

Comparative treatment

As previously stated, placebo is not an ethically viable option for a control condition. Therefore comparison with standard care was proposed. In addition, it has been suggested that the apparent effects of reflexology are solely due to the relaxation response which the treatment is thought to induce (Ernst & Koder, 1997). Hence, in order to control for this, relaxation was also introduced into the design for comparative purposes. Furthermore, this enabled the time and attention of the therapist to be controlled for.

It was recognised that in the context of CLBP, standard care can vary and may include a variety of treatments, including over the counter or prescribed medication, manipulation, and physiotherapy among others. Frank (1993) provides a table of the therapeutic options in CLBP. In addition, treatment guidelines are outlined in the CSAG report (Rosen, 1994). It was apparent therefore that it would not be possible to explicitly define 'standard care' for CLBP. Thus it was proposed that 'usual care' i.e. that which the patient usually received, would be recorded by the patient, and this information used in subsequent analyses.

Sample size

Altman (1980) suggests that sample size calculations are mandatory in the context of RCTs for ethical as well as statistical reasons. Similarly, Prescott et al. (1999) argue that studies with a sample too small to detect a difference may be scientifically useless and therefore unethical. In addition, too large a sample would be equally unethical as it would represent a waste of participants, practitioners and researchers time etc. One of the main criticisms of previous research on reflexology, and other CM treatments, concerned the inadequacy of the sample size. The present study aimed to address this issue. Once the primary outcome variables were selected, the size of effect considered to be indicative of a clinically significant change was determined by referring to the results of previous studies. This enabled the size of sample necessary to detect such an effect to be calculated. These figures can be found in the following chapter which describes the methodological procedures adopted.

Randomisation

Central to the RCT design is the concept of randomisation, as it ensures that differences in outcome are not due to differences in groups at the start of the trial, thereby reducing potential systematic bias. Indeed, Schultz et al., (1995) suggested that failure to properly randomise has been shown to lead to significant over estimation of the effect of a therapy under investigation. A variety of randomisation methods are available (see Pocock, 1983). However, as previously stated, in the present study, treatment was not to be blinded, therfore it was not necessary to blind participants to their allocated group. Nevertheless, three key factors were identified which the author considered may impact upon outcome. These were: age and chronicity of pain (e.g. Valat et al., 1997, Cherkin, 1996) and employment status (e.g. Hildebrandt et al., 1997). Therefore a minimisation technique was proposed for the present study (Taves, 1974) to ensure that these factors were balanced throughout the groups.

Inclusion/exclusion criteria

The use of inclusion or exclusion criteria in RCT designs can either enhance or reduce the generalisability of the results (Begg, 1988). Wide inclusion criteria, with few exclusions may increase the chance of achieving the required number of patients, and ensure that results will be applicable to a similarly wide population. Whereas, the advantage of restricting criteria is that of obtaining an homogeneous group, therefore reducing between participant variation (Turk et al., 1993). Of course the condition under scrutiny will influence the decision regarding inclusion/exclusion, and may lead to the selection of a very specific group, for example research with monozygotic twins. In the case of CLBP this decision is more difficult because of the unspecific aetiology and the lack of an external standard to validate its presence, the symptom being what the patient reports (Papageorgiou et al., 1995). Thus the present study adopted a symptom based definition of CLBP, and anticipated that the randomisation process would equally distribute prognostic factors between the groups and so minimise any bias that could occur because of differences at baseline.

However, a number of exclusion criteria were proposed. Firstly, anyone with a contraindication to reflexology treatment was excluded. The obvious reason for this was that any participant may be randomised to receive reflexology. No contraindications to relaxation were identified. In addition, patients with any other major medical disorder were excluded. This was a pragmatic decision, and aimed to restrict the number of confounding variables

Evidence for the impact of litigation on outcome is equivocal, although some studies have shown that it can be detrimental (Blake & Garrett, 1997; Valat et al., 1997; Vaccaro et al., 1997). Anecdotal evidence from clinicians is that those who are in the process of litigation are less likely to demonstrate an improvement after treatment (whatever that treatment is) because they currently have a 'vested interest' in remaining as they are in pain or disabled. This is supported by a small study (n=20) conducted by Blake and Garrett (1997) who found that those patients who were pursuing compensation claims related to their back pain (n=11) did not achieve the same improvements as the other patients, which led them to conclude that '..the presence of ongoing litigation makes people less amenable to restoration of function' (p125). Thus in the present study all those in the process of litigation concerning their back pain were to be excluded.

Participant Treatment Preferences

One of the functions of RCT methodology is to ensure that individual characteristics are dispersed throughout the groups. However it is apparent that the question of patient preferences and the confounding effect they may have on outcome is one that is seldom considered (Torgerson et al., 1998). McPherson et al. (1997) argued that patient preferences and pre-conceived ideas about treatment have the potential to influence response to that treatment via psychological mechanisms, and that this may be wrongly attributed entirely as treatment effects. This has important repercussions for the interpretation of RCT data. Outcome for those participants who obtain their preferred treatment may be enhanced, irrespective of the effect of the treatment. Whereas those who do not receive their desired treatment could experience disappointment, which may have a negative effect on outcome. However, it is suggested that if participants' preferences were elicited prior to randomisation, the potential effects of this problem could be considered in the outcome analyses, and therefore inform interpretation of the results.

The preceding sections have provided the rationale for the use of a pragmatic RCT to evaluate the efficacy of reflexology, and considered a number of related issues. However, a limitation of the RCT design is that it focuses on group rather than individual responses to treatment. Furthermore, while such a design could address the question of outcome to treatment, it is not able to provide information on the therapeutic process or outcome from the perspective of the participant. Thus the use of an additional method of data collection was proposed.

2.4 Qualitative dimension to the study

Estimates of effectiveness in terms of the primary quantitative outcome measures have been defined. It is accepted that this is only one definition of efficacy. However, the individual participant's view of an effective intervention may have little to do with the author's definition, and more to do with the process and quality of the treatment experience. In today's climate consumers of health care are increasingly prepared to fund their own treatments, as with many complementary therapies. Therefore research that fails to take into account the meaning of a positive outcome for all parties involved will have little utility for the everyday lives of the healthcare consumers, who either directly or indirectly fund research.

Furthermore, whilst the primary aim of the current study is to evaluate whether and to what extent reflexology is effective for the management of CLBP, it is recognised that there is a paucity of research within the therapy per se. Thus, should the treatment appear to be effective, it may be useful to try to ascertain why this was, in order to inform further research.

Mixed methods

The utility of quantitative methods within the RCT has been demonstrated (e.g. Pocock, 1983). However, for some aspects of outcome research, over enthusiastic reliance on such a mechanistic, reductionist approach may result in data that has limited ecological validity. The use of both qualitative and quantitative methods in the same study can provide a vehicle with which to address some of the issues previously raised. Multiple means of data collection and analysis within the same study can represent a test of convergent validity, but this is not the only advantage to be gained by combining methods. Such studies allow the researcher to incorporate individuals' views making them active participants in the research process. The investigator is able to consider both process and outcome as well as contextual issues, thus increasing the applicability of research findings and leading to a more complete picture of the phenomenon under scrutiny.

The use of multiple methods in the same study is not a new phenomenon. Campbell & Fiske (1959) first used the term triangulation to describe the use of multiple methods of data collection within the same study. More recently it has been proposed as a means for merging qualitative and quantitative methodologies (Duffy, 1987). The basic premise in methodological triangulation is that inherent weaknesses in each method are compensated for by the strengths of the other (Morse, 1991). There is little interaction between methods during the data collection phase, however findings may complement one another at the end of the study. Therefore the aim/purpose is to obtain different but complementary data on the same topic (in this case outcome) rather than to replicate the results. Myers & Hasse (1989) present guidelines for integration of quantitative and qualitative approaches.

The epistemological questions surrounding the philosophical foundations of each method, have received much attention, particularly in the nursing literature (e.g. Duffy, 1987) and these will not be reiterated here. The author's stance is a pragmatic one, that is, selection of the most appropriate means of data collection and analysis will be driven by the specific aims of the research being conducted, whatever the theoretical foundations of the researcher. Nevertheless, it must be accepted that the use of more than one method within the same study can present some practical problems. Not least increased demands on the investigator, particularly in terms of the expertise necessary to employ particular methods and to analyse the data derived from them, as well as how to combine findings from each during the process of interpretation (Poole et al., 1999).

2.5 Summary

Chapter one identified some of the inadequacies of previous studies which have attempted to evaluate reflexology and/or treatment for CLBP. The present study attempts to address many of these, including adequate sample size, recognised outcome measures, and follow up procedures. Hoffman et al. (1994) state 'when investigators both provide the treatment and evaluate the outcome, their knowledge, beliefs or self interest may influence the intensity and result of the search for particular outcomes' (p2069S). A particular strength of the present study, is that this is not the case, the author is not a reflexologist or CM therapist of any type, but rather considers herself to be objective in the research process.

Furthermore, it is argued that the design selected, a pragmatic RCT, represents the best method of evaluating the efficacy of reflexology in the management of CLBP within a primary care setting. It retains many of the advantages of the classical RCT, but will also allow the consideration of contextual factors, and enable practitioner autonomy regarding the treatment process to be maintained. Furthermore, the addition of a qualitative aspect to the study will ensure that the process of treatment is considered as well as the outcome, and that participant views of the treatment are taken into account.

The following chapter presents full details of the methods used throughout the duration of the study.

Chapter Three

Method

3.0 Introduction

This chapter contains details of the methodology adopted in the current study. Information on recruitment, sample size and treatment is presented first. This is followed by a description of the instruments and procedures used throughout the study. Finally, a comprehensive outline of the recruitment procedure, interview process and analytical techniques utilised in interview two is provided. However, to begin, the aim of the study is reiterated.

3.1 Study aim

The main aim of the current investigation was to present the first controlled trial of reflexology in the context of CLBP, in order to evaluate its efficacy in this domain. Specifically, via the use of valid and reliable outcome measures, selected to represent the complex nature of CLBP, this study aimed to determine the effect that a course of reflexology had upon perceived health status and functioning levels.

In addition, via interviews conducted with a sub-sample of participants after the treatment phase, the study aimed to explore outcome from the perspective of the CLBP sufferer, as well as gain insight into the process of treatment.

3.2 Method

3.2.1 Recruitment of Practices

In the first instance GPs from an area on the outskirts of Liverpool were approached. Subsequently, in order to achieve the rate of recruitment necessary to complete the project within the proposed time scale, GPs in the North Cheshire area were also invited to participate. GPs were contacted and asked if they would like to participate in the project. The researcher met with a GP and/or administrator from each interested practice and outlined the aims of the research to them. This meeting also provided an opportunity to discuss the consequences of participation for GPs and surgery staff, in terms of the potential increased workload it may incur, such as, the time taken to identify patients who satisfied the inclusion/exclusion criteria and to book rooms for interviews/treatment. A total of 12 practices agreed to participate in the study.

3.2.2 Design

Pragmatic randomised controlled trial, utilising both quantitative and qualitative methods, in which participants were randomised to one of three groups: reflexology; relaxation; or maintain usual care. Figure 3.1 overleaf provides an overview of participants progress throughout the trial, along with brief details of the data collected at each time point.

3.2.3 Ethical approval

Approval was sought and granted from the following Ethics committees: JMU, North Cheshire, and St Helens and Knowsley Ethics Committees.

3.2.4 Sample size

Sample size calculations were computed to determine the size of sample necessary to detect a clinically significant change in the two primary outcome measures: functioning as measured by the Oswestry Low Back Pain Disability Questionnaire (ODQ)(Fairbank et al., 1986) and the Bodily Pain dimension of the SF36 (Ware & Sherbourne, 1992). Figures to represent clinically significant differences were derived from previous research, in particular for the ODQ: Fisher & Johnson (1996) and for the SF36: Fitter & MacPherson (1995). Thus based on these studies, in order to have a 95% chance of detecting a mean difference between groups of 11.9 points on the ODQ, at a 5% level of significance, n = 41 patients were needed in each group. However, to detect a mean score change of 19.3 on the SF36 Bodily Pain dimension, at the 5% level of significance, n = 59 were required. Drop out was estimated at 25%, which increased the numbers in each group to n = 80. Thus a total of approximately 240 patients with CLBP who met the inclusion/exclusion criteria were required.

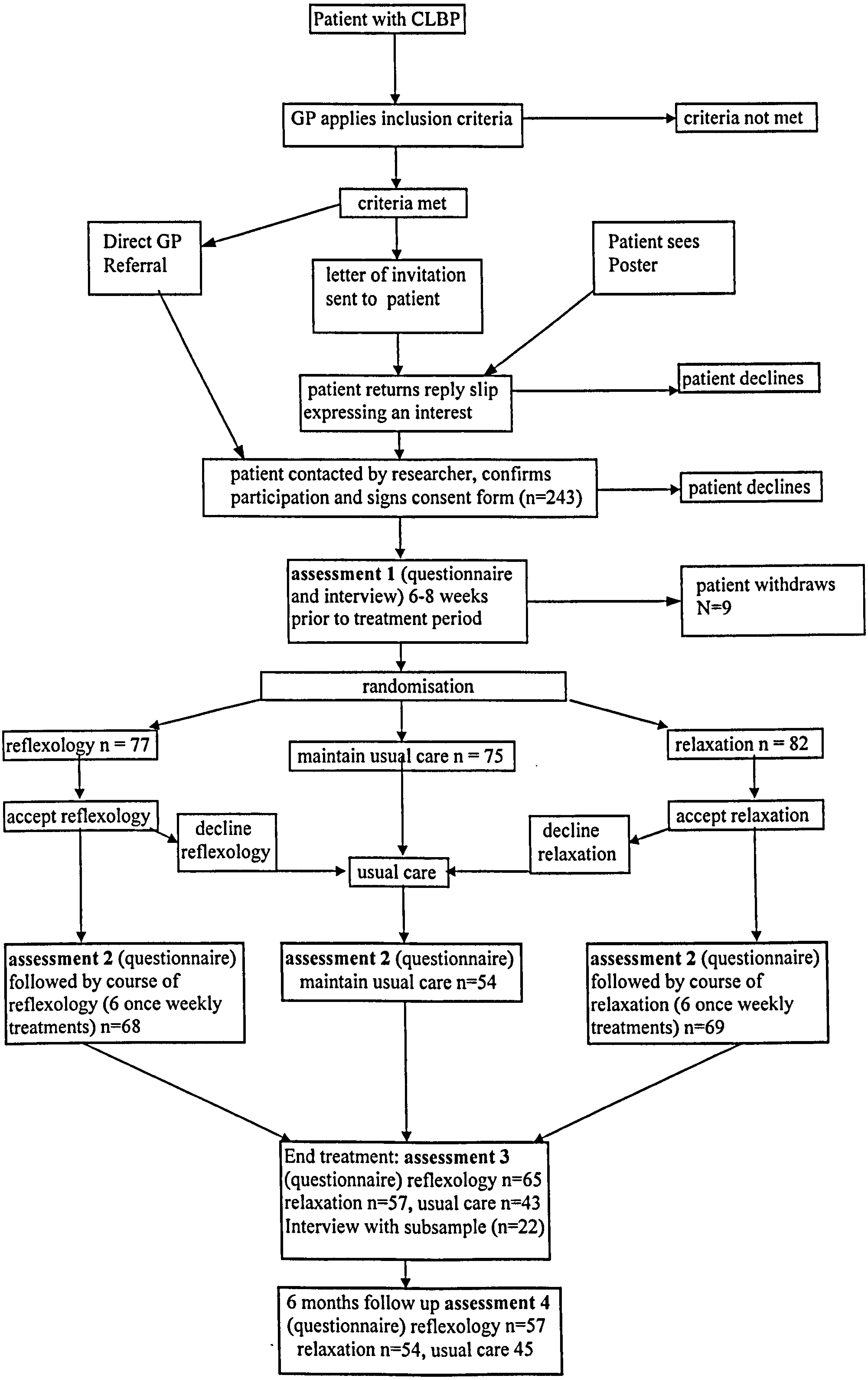


Figure 3.1 Patient recruitment and follow up procedures

3.2.5 Recruitment procedures

Participants were recruited from 12 primary care sources in the Merseyside and North Cheshire areas. Initially GP's utilised a standard referral form (see appendix 1) for patients presenting at surgery with CLBP who expressed an interest in the study, and satisfied the inclusion/exclusion criteria. Preliminary discussions with GP's had indicated that recruitment during a normal consultation with patients would be the most appropriate method. However, the slow rate of response to this method necessitated the setting up of additional means of recruitment. Thus two further methods were developed in consultation with GPs and practice administrators. A letter of invitation together with an information sheet and reply slip (see appendices 2 & 3) which could be sent to patients suffering from CLBP was utilised by those GPs who had IT facilities which enabled them to identify such patients. At a small number (n=3) of practices, with computing systems that were not developed enough to run sophisticated searches, individual GPs generated lists of patients with CLBP who fit the inclusion/exclusion criteria and the invitation letter was sent to them. In addition, posters were displayed in some surgeries for patients and staff to observe. Interested patients were invited to ask staff for further information about the study and given the invitation letter. Recruitment was staggered over a 17 month period to facilitate patient flow throughout, and to manage the workload for the therapists.

3.3 Participants

N=243 participants with CLBP were recruited using the following inclusion/exclusion criteria

3.3.1 Inclusion criteria

Patients from primary care sources between the ages of 18 and 65 years with chronic benign low back pain (i.e. back pain of >3months duration).

3.3.2 Exclusion criteria

Patients were excluded for the following reasons:

- Pregnancy
- Significant co-existing major medical illness
- Significant co-existing psychiatric disorder based on DSM IV criteria
- Contraindication to reflexology including: recent surgery and circulatory disorders of the lower limb.
- Those in the process of litigation related to their back pain.

3.4 Treatment

3.4.1 Therapists

All five therapists who provided treatment throughout the study had previous extensive experience of working within NHS settings. At the time of the study, each was also working within the primary care sector in a private capacity and/or at their own private practice. All reflexologists were members of the British Association of Reflexologists, and trained in the Morrell technique. All relaxation therapists had expertise in the use of progressive muscle relaxation.

During the developmental stages of the study, therapists were consulted concerning the number of treatment sessions that would required for patients with CLBP to demonstrate some improvement. The financial implications of this were also considered. The consensus among therapists was that approximately six sessions would be needed. Calculation of treatment cost for the size of sample required, revealed that this was within the financial limitations of the project budget, and therefore six treatment sessions were offered to participants randomised to receive reflexology or relaxation.

3.4.2 Reflexology

Treatments were provided by reflexologists trained in use of Morrell technique. No standardised protocol was provided, other than to treat the participant for their back pain. Reflexology comprised a course of six treatments of approximately 1 hour duration, over a period of 6-8 weeks, provided on an individual basis.

3.4.3 Relaxation

Relaxation also comprised six one hour sessions at weekly intervals for six weeks, provided by therapists trained in progressive muscle relaxation techniques for pain management. The majority of these sessions were provided on an individual basis, while others were conducted in small groups (maximum 4 participants). This was dependent upon room availability as well as the number of participants who were randomised to relaxation at each surgery.

3.4.4 Maintain Usual Care

The remaining group received no intervention, but continued with the care they were already getting from their GP or secondary care. As previously noted it is recognised that usual care may constitute a variety of treatments, including over the counter or prescribed medication, manipulation, among others. (A table of the therapeutic options in CLBP is provided by Frank, 1993). No attempt was made to regulate the treatment participants received. However for the purposes of this study, the care received was recorded and monitored throughout the trial period by the participant using a self report form.

3.4.5 Venues

The majority of treatments were provided in a vacant room at GPs' surgeries. In the Kirkby area, a local clinic run by all GPs' in that district was utilised. This type of provision concurred with the pragmatic nature of the trial as venues were those that would be used for treatment provided in primary care. In addition, it was anticipated that these locations had the added advantage of proximity for participants, and negated the need for them to travel to the University for treatment

3.5 Apparatus

3.5.1 Questionnaire

At four time points within the study, participants completed a self report questionnaire (see appendix 4). Each questionnaire contained a selection of instruments designed to measure the identified outcome variables, plus a number of other factors which have been shown to have a mediatiory effect upon functioning in CLBP. In addition, questionnaire 1 included a request for demographic information (appendix 4), while questionnaires 2, 3 & 4 asked participants for details of visits to health professionals or any treatment they had used for their back pain since last completing the questionnaire (appendix 4). The questionnaire contained the following instruments:

Patients perceived health status: 'SF-36' (Ware & Sherbourne, 1992)

A generic self report measure designed to provide an assessment of individuals health related quality of life, and is frequently used in research to evaluate health care interventions. It comprises 36 items which measure eight variables: physical functioning (10 items); social functioning (2 items); role limitations due to physical problems (4 items); role limitations due to emotional problems (3 items); mental health (5 items); energy and vitality (4 items); pain (2 items) and general perception of health (5 items). In addition to this there is one more item which questions changes in health over the previous 12 months. Responses to items are coded, summed and transformed into a scale from 0 to 100 for each dimension, where 0 = worst possible health status and 100 is equivalent to best possible health status. The SF36 demonstrates good face validity and reliability with Chronbachs alphas ranging from 0.73 (social functioning) to 0.96 (physical role limitations).

Oswestry Low Back Pain Disability Questionnaire (ODQ) (Fairbank et al., 1980; MRC modification, Meade et al., 1986)

A self report measure originally developed to assess levels of functioning in low back pain sufferers undergoing rehabilitation, it has been widely used in research and to monitor treatment success. The ODQ comprises 10 sections, each containing six statements designed to assess limitations on the following activities of daily living: lifting, personal care, walking, social life, standing, sitting, sex life, sleeping and travelling. In addition pain intensity is also measured. Each statement is scored on a scale of 0 (no disability) to 5 (greatest disability), with the total score expressed as a percentage. Higher percentages indicate higher impairment, and thus reduced functioning.

Beck Depression Inventory II (BDI) (Beck et al., 1997)

Comprising 21 items, a self report measure designed for use in the general population to measure the presence and severity of depressive symptoms during the past two weeks. As previously stated this is a relatively new instrument and no data is currently available concerning its use with the current population. However Beck et al. (1997) provide a conversion table in the manual, thus comparisons with the BDI IA should be possible. Nevertheless, internal consistency is reported to be high, with Cronbachs alphas of .092 for outpatients, and 0.93 from a student sample. Items are scored on a 4 point scale ranging from 0-3. Higher scores indicate the presence of more depressive symptoms. For the purposes of the current study, the cut off scores provided by Beck et al. were utilised.

Coping Strategies Questionnaire (CSQ) (Rosenstiel & Keefe, 1983)

This instrument assesses the use of pain coping strategies in response to pain. It comprises 44 items, with seven subscales, each containing six statements, designed to measure six cognitive coping strategies (diverting attention; catastrophising; reinterpreting the pain sensation; ignoring sensations; praying or hoping; and coping self-statements) and one behavioural strategy (increasing activity level). Participants use a seven point Likert scale to indicate the extent to which they utilise each strategy, ranging from 0 (never use) to 6 (always use). In addition, two remaining items ask participants to evaluate their ability to control and reduce the pain using the strategies identified. Reliabilities for each of the subscales range from 0.71 to 0.85.

Short form social support questionnaire (SSQ6) (Sarason, et al., 1987)

A generic measure designed to assess the number of social supports an individual perceives they can rely on in addition to their level of satisfaction with that support. It comprises 6 statements, e.g. who accepts you totally, including both your worst and best points? After which participants are asked to list anything from 0-9 people and their relationship to them. In addition, for each of the 6 statements, participants are required to rate their satisfaction with their support on a scale of 1-6 where 6 is very satisfied and 1 is ver dissatisfied. Internal reliabilities are high, 0.90 for the number of supports, and 0.93 for satisfaction with those supports

Pain Drawing (Margolis, et al., 1986)

Patients are requested to indicate the location of their usual pain on the drawing, which displays front and back views, and presents a face valid, 'user friendly' means for identification of pain site.

Pain intensity

Two visual analogue scales were used to measure current pain intensity and average pain intensity over the last week. Both were designed to assess subjective experience of pain on a scale ranging from 0-100mm, representing 'no pain' and 'worst possible pain' respectively

Demographic information sheet (Questionnaire 1 only)

Requested details of age, gender, educational level, and employment status, along with details of current/past employment and duration of back pain.

Current treatment sheet (Questionnaires 2, 3 & 4 only)

Information concerning participants current medication/treatment usage, along with details of any visits to health professionals (both OM and CM) since last completing the questionnaire was requested.

3.5.2 Interview 1

Conducted with all participants at Time 1, this semi-structured interview was designed to ascertain participants current treatment regimes and previous treatment histories for both complementary and orthodox medicine. In addition participants' perceptions of the effectiveness of the therapies experienced were sought, as well as their views about CM generally and reflexology in particular. Furthermore, participants preferences for the treatments available in the study were sought, and recorded. A copy of the schedule can be found in appendix 5.

3.5.3 Interview 2

This was a semi-structured interactive interview conducted with a randomly selected subgroup of patients (n = 22) from the reflexology and relaxation groups at the end of the treatment period. The aim of the interview was to elicit participants' views on their experience of the process of treatment and any effects, both positive and negative in relation to psychological and physical functioning. Full details of the methodology adopted for this part of the study can be found towards the end of the current chapter in section 3.7 and a copy of the interview schedule is provided in appendix 6.

3.5.4 Treatment record sheets

These were designed to be completed at each reflexology and relaxation session by the therapist and participant. Participants were required to complete two VAS pain intensity scales for current pain and average pain over the last week (see above) as well as provide information on any other treatment they had continued to receive. Therapists recorded details of the treatment given and their perception of how participants responded to it (see appendix 7).

3.6 Procedure (See also figure 3.1 for an overview of the methodological procedures)

Upon receipt of the referral form from the GP, or reply slip to the letter of invitation or poster, the author contacted the patient and arranged an interview with them at their GP's surgery. This telephone contact also provided an opportunity for the author to ensure that patients conformed with the inclusion/exclusion criteria. At the interview, the study and what participation would entail was explained to patients in more detail, and an opportunity for them to ask questions was provided. Informed, written consent was obtained from patients willing to participate.

3.6.1 Assessment 1

After informed consent was obtained, interview one was conducted and time was provided for participants to complete questionnaire one. The interview and questionnaire were counterbalanced to minimise potential order effects.

3.6.2 Randomisation and Minimisation

After completion of interview one and the first questionnaire, participants' details were recorded for use in the randomisation procedure which was conducted at the university. Participants were randomised, using a minimisation technique, to one of three groups: reflexology, relaxation and maintain usual care, using only trial numbers for identification. Minimisation, a form of stratified randomisation, was incorporated into the procedure to ensure that the following factors were equally represented in each group: work status (benefit or non benefit); age; and chronicity of pain. None of the aforementioned factors were weighted. Minimisation was conducted using the procedure outlined by Pocock (1984), which is described below.

First a simple randomisation table was prepared using random numbers. This was used to determine the treatment group of the first participant. The characteristics of subsequent participants on each level of the three factors (age>50; age<50; chronicity >5; chronicity <5; benefit-yes and benefit-no) were used to determine treatment group. In this way participants were always assigned to the group with the smallest number of participants with similar characteristics. In instances were more than one treatment group had equal numbers of such participants, the simple randomisation table was used to assign treatment. The following example illustrates the procedure. E.g N=115 participants were already assigned to treatment groups. The figures below show the number of participants on each level of the three factors: age, benefit, and chronicity of pain. If the next patient who came along was 48 years old, on benefit and had had back pain for 3 years. The number of patients in each group with the same characteristics would be summed. In this instance the totals would be:

A $29 + 18 + 24 = 71$ **B** $30 + 17 + 25 = 72$ **C** $32 + 19 + 27 = 78$

		Number on each treatment			Next participant
		A	B	C	
Age	<50 years	29	30	32	←
	>50 years	10	6	8	
On benefit	Yes	18	17	19	←
	No	21	23	19	
Chronicity of pain	<5 years	24	25	27	←
	>5 years	15	11	13	

Therefore treatment A would be assigned as that is the group with the smallest number of patients with those characteristics.

Once randomisation with minimisation was completed, the results were recorded and participants were identified by their trial number. All participants were informed by letter of the results and the group to which they had been randomised.

Following this, the author liased with practice administrators, therapists, and participants to arrange appointments for the reflexology and relaxation treatments which commenced approximately six weeks after recruitment and assessment one.

3.6.3 Assessment 2

Questionnaire 2 was posted to all participants approximately six weeks after completion of questionnaire one. Also included was a freepost envelope, along with a request to complete and return the questionnaire to the University as soon as possible. In addition, participants in the reflexology and relaxation groups were sent appointments to commence treatment. Approximately two weeks later, a reminder, including another copy of questionnaire 2, was sent to those participants who had failed to return the questionnaire.

3.6.4 Assessment 3

Assessment 3 took place after the treatment phase, i.e. approximately 12-14 weeks after the start of treatment. Questionnaire 3 was sent to all participants by post, along with a freepost envelope. As before, participants were requested to complete and return the questionnaire as soon as possible. Similarly, those participants who failed to return the questionnaire after 2 weeks were sent a reminder by post.

In addition, this is when interview two was conducted with a sub-sample of 22 participants from the reflexology and relaxation groups (see section 3.7 for a more detailed explanation of this).

3.6.5 Assessment 4

Questionnaire 4 was sent to all participants by post approximately six months after the end of the treatment phase. As before, this included a freepost envelope. Also a reminder along with another copy of the questionnaire was sent two weeks later, to those participants who had failed to return the questionnaire.

3.6.6 Data management

All questionnaires were scored according to the standard protocol. This information, along with the other data collected was coded by trial number and stored on computer for use in further analysis, details of which can be found in the quantitative results section 4.1.2.

Qualitative data was transcribed and transferred to WINMAXPRO, a computer based package designed to aid the analysis and management of textual data. Details of the analysis undertaken can be found in the following sections which contain further information on the methodology adopted specifically for interview two.

3.7 Interview Two

This section contains further details of the rationale and procedures adopted for interview two, which was conducted with a sub-sample of participants after the treatment phase of the study.

3.7.1 Rationale

It is generally accepted that RCTs represent the 'Gold Standard' research design for determining the effects of particular treatments or interventions. The pragmatic RCT has addressed the question of whether and to what extent reflexology and relaxation are efficacious for managing CLBP. However, as chapter two highlighted, it is also recognised that this approach has some limitations. Not least, the emphasis on the treatment outcome, as opposed to treatment process and the concentration on group rather than individual response to treatment. This interview was designed to address these issues, and look at the process of treatment from an individual perspective via participants own views of the treatment and its effects.

The quantitative aspects of the study addressed the issue of outcome in terms of statistical and clinically significant differences on the self report questionnaire. It is possible that there were changes experienced at an individual level, which the questionnaire did not address or was not sensitive enough to detect. Analysis of the interview data provided another perspective on efficacy and enabled the process of treatment or the active components of the therapy to be described. In addition an indication of the incidence of any unpleasant or adverse effects to treatment was obtained.

Thus this aspect of the study was concerned with exploring the participants' own experiences, as opposed to their experience within the confines of the dimensions addressed by the questionnaire. To facilitate this it aimed to adopt a phenomenological, 'insiders' perspective (Conrad, 1987). However it was recognised that to obtain this perspective, interpretation and analysis of the participants' accounts by the researcher was necessary. Therefore the methodological procedure described as Interpretative Phenomenological Analysis (IPA, Smith 1995) was employed. This particular qualitative approach recognises the researcher as analyst and leads to results which can be described as a '...co-construction between participant and analyst, in that it emerges from the analyst's engagement with the data in the form of the participant's account' (Osborn & Smith, 1998, p67)

3.7.2 Method

3.7.3 Participants

The participants comprised 22 patients from primary care sources with CLBP who were taking part in the main study. As part of the main study, n=10 of the participants had attended six, 60 minute, sessions of relaxation therapy at their GPs surgery over a two month period. The remaining n=12 participants had attended six, 60 minute, reflexology sessions, which were also provided at their GPs surgery over a two month period. Treatments were given to each of the participants by one of four therapists from the six who provided all the treatments in the main study.

3.7.4 Interview schedule

A semi-structured interview schedule was developed which outlined areas of interest to be discussed during the interview, and provided enough flexibility for the interviewee to introduce aspects of the treatment experience which had importance for them (see appendix 6). The schedule lists a number of broad open questions pertaining to different aspects of the treatment, followed by a series of 'prompts' These were designed to be used where necessary, to encourage participants to talk in greater detail about the various topics and not simply reply with yes or no answers. It is important to note that the schedule was not viewed as prescriptive. The interviews were designed to take place within the context of a dialogue between two people, thus questions were addressed in no particular order, but at appropriate points within that dialogue.

3.7.5 Selection of participants

Participants from the reflexology and relaxation groups were included in the selection process. This was completed by another member of the research team who did not have any contact with the participants or therapists. Indeed selection was completed with individuals identified by trial number only and using their scores on the ODQ and BDI II at recruitment (Time 1).

In order to ensure a diverse sample, participants were categorised as either low, medium or high functioning based upon their ODQ and BDI II scores. Throughout the study as participants completed their course of treatment a number were selected as potential interviewees, who were representative of each category. The number selected was dependent upon the number completing treatment around the same time. It also included 'reserves' who were only contacted in the event of one of the other participants refusing to be interviewed for a second time.

The author contacted participants selected for interview by telephone. The aims of the study were reiterated and participants were asked whether they were prepared to be interviewed for a second time. All but one of those participants first identified agreed. In the case of the participant who declined to be interviewed again, the 'reserve' was contacted, and agreed to take part. Thus interview appointments with arranged with 22 participants throughout the duration of the project.

Interviews with 20 of the participants took place in their own homes. The other two were conducted at The University in a quiet room arranged especially for the purpose, as this venue was more convenient for those particular participants.

All interviews began with the anonymity of the participants being assured and confidentiality guaranteed. The aims of the study were reiterated, and in particular it was emphasised that the purpose of the interview was not to 'check up' on the therapist but to gain access to the participants' perceptions of the treatment. Interviewees were asked whether they objected to the interview being tape recorded, as this would negate the need for the author to make copious notes throughout. All participants agreed to allow recording of the interview. The interview proceeded with the author asking a general question regarding the participant's experience of the treatment. The interview continued with the author referring to the schedule only to maintain continuity or to refer to aspects of the treatment that had not been mentioned.

At the end of the interview participants were asked whether there was anything else they would like to add, then thanked for their time and their interest in the project.

The taped interviews were transcribed verbatim by the author. However in two instances the quality of the recording did not permit this. In these cases the interviewer's notes, and memory of the interview were also used. These accounts were then sent to the interviewees for verification, both of whom agreed with their content.

Electronic versions of the transcripts were stored on WINMAXPRO, a computerised qualitative data management package for use in further analysis. In the first instance transcripts from participants in the reflexology and relaxation groups were considered separately. Analysis followed the IPA procedure described by Smith (1995, 1999) detailed below.

3.7.6 Analysis

For each group:

1. The first interview text was read a number of times in order to ensure a 'sense' of the account as a whole was acquired, and potential themes were noted. It is important to note that this process was also informed by the author's remembered experience of the interview itself, as well as the process of transcription.
2. This text was then re-read and the emergent themes identified and labelled.
3. Themes were then looked at in more detail and refined. Interrelationships between the themes were considered and some themes were clustered together to form superordinate themes, which resulted in a preliminary table of themes (see appendix 8)
4. The whole process was then repeated with the remaining texts, instances of already identified themes were recorded and any new emergent themes were noted. Previous texts were reviewed again to check for occurrences of the new themes.
5. After completion of the above procedures it was apparent that the majority of the preliminary themes identified were common to each group, thus both groups were combined for the final stage of the analytic procedure.
6. Step three was repeated and finally a table of six master themes which had emerged from the transcripts of the whole group was constructed (see appendix 8).

In addition to the above steps a number of procedures, designed to increase the validity and reliability of the analysis, were carried out.

The first transcript was looked at independently by the author's supervisor. After this, both discussed the transcript and emergent themes. Agreement was reached regarding the theme categories, before analysis proceeded to subsequent transcripts. At all stages of the study the author's supervisor acted as a check on the analytic account. As Osborn & Smith (1998) highlight, this process was designed to ensure that the developing analysis was systematic, and the results supported by the data. It was not intended to produce a satisfactory inter-rater reliability score to support one 'true' or irrefutable reading of the data. Indeed the process aimed to assess the validity of the work and ensure that the account presented was sound and supported by the data.

Furthermore four of the 22 participants were randomly selected and sent a summary of their individual interview analysis (for an example of this see appendix 8). These were accompanied by a cover sheet which asked them to review the summary (see appendix 8) and provide feedback where appropriate. All four participants agreed entirely with their summary, demonstrating high testimonial validity for the analyses conducted and the accounts presented.

Chapter Four

Results

4.0 Introduction

This chapter contains the results of all aspects of the study. It is divided into three sections which reflect the different methods used to collect data throughout the study, i.e. questionnaires, interview one and interview two.

The first section concerns the main quantitative results. A brief overview of the analysis conducted on Time 1, 2, 3 & 4 questionnaire data, is followed by a description of the sample and a brief evaluation of the extent to which they are representative of CLBP sufferers. The quantitative results are then comprehensively outlined.

Section two refers to the results of the thematic analysis conducted on the data gathered at recruitment, via interview one. Participants are divided into two groups: non-users and previous users of CM, and their experience and knowledge of CM described.

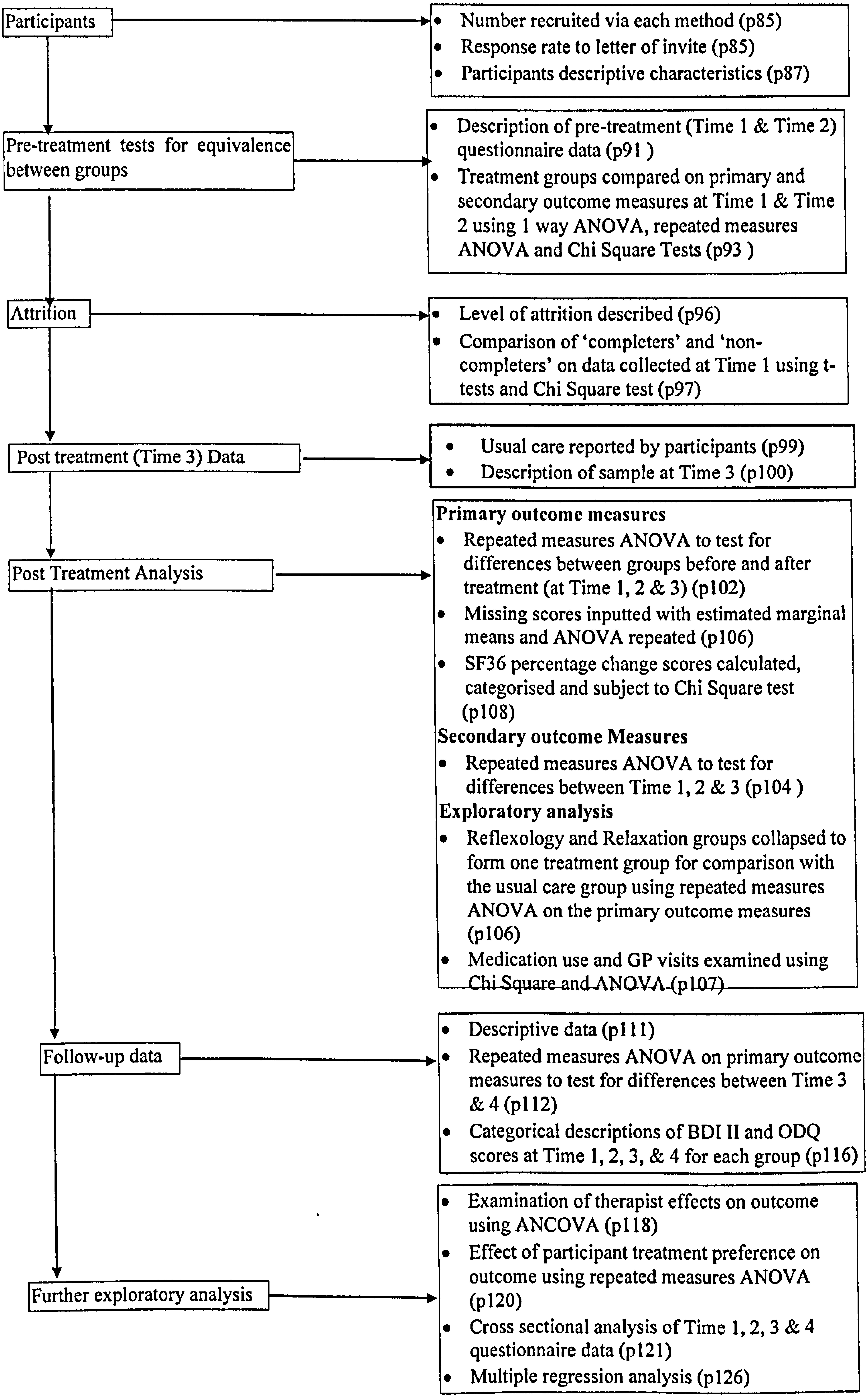
The final section, three, contains details of the qualitative analysis carried out on interview two data collected from a sub-sample of participants after the treatment phase. The themes which emerged from the analysis are presented, along with examples of each.

4.1 Quantitative results

4.1.2 Analysis

Figure 4.1 overleaf briefly summarises the analysis conducted on the quantitative data collected at Time 1 (recruitment), Time 2 (prior to the treatment phase), Time 3 (post treatment) and Time 4 (6 months follow up). More specific details of the analyses carried out are contained within the relevant results sections.

Figure 4.1: Analysis completed on quantitative data



Participants
- Number recruited via each method (p85)
- Response rate to letter of invite (p85)
- Participants descriptive characteristics (p87)

Pre-treatment tests for equivalence between groups
- Description of pre-treatment (Time 1 & Time 2) questionnaire data (p91)
- Treatment groups compared on primary and secondary outcome measures at Time 1 & Time 2 using 1 way ANOVA, repeated measures ANOVA and Chi Square Tests (p93)

Attrition
- Level of attrition described (p96)
- Comparison of 'completers' and 'non-completers' on data collected at Time 1 using t-tests and Chi Square test (p97)

Post treatment (Time 3) Data
- Usual care reported by participants (p99)
- Description of sample at Time 3 (p100)

Post Treatment Analysis

Primary outcome measures
- Repeated measures ANOVA to test for differences between groups before and after treatment (at Time 1, 2 & 3) (p102)
- Missing scores inputted with estimated marginal means and ANOVA repeated (p106)
- SF36 percentage change scores calculated, categorised and subject to Chi Square test (p108)

Secondary outcome Measures
- Repeated measures ANOVA to test for differences between Time 1, 2 & 3 (p104)

Exploratory analysis
- Reflexology and Relaxation groups collapsed to form one treatment group for comparison with the usual care group using repeated measures ANOVA on the primary outcome measures (p106)
- Medication use and GP visits examined using Chi Square and ANOVA (p107)

Follow-up data
- Descriptive data (p111)
- Repeated measures ANOVA on primary outcome measures to test for differences between Time 3 & 4 (p112)
- Categorical descriptions of BDI II and ODQ scores at Time 1, 2, 3, & 4 for each group (p116)

Further exploratory analysis
- Examination of therapist effects on outcome using ANCOVA (p118)
- Effect of participant treatment preference on outcome using repeated measures ANOVA (p120)
- Cross sectional analysis of Time 1, 2, 3 & 4 questionnaire data (p121)
- Multiple regression analysis (p126)

4.1.3 Response rate

A total of 243 participants were recruited from 12 practices in the Merseyside and Cheshire areas, via the following methods: GP invitation letters (12 practices); poster (2 practices) and direct referral (1 practice). The majority of participants (n = 191) were recruited via a letter of invitation from their GP, with remainder responding to the poster (n = 49) or directly referred by their GP (n = 3). This illustrates that the most effective means of recruitment was the letter of invitation and highlights the inefficacy of the direct referral method.

As the letter of invitation was not the only means of recruitment to the study, it was not possible to determine a 'true' response rate. The number of patients who read the poster and were not interested in it, or who were told by their GP about the study and did not want to take part is not known. However response rate to the letters of invitation was calculated, and this provides some indication of the level of interest in the project displayed by CLBP patients from primary care sources.

A total of 650 letters were sent by 12 practices to patients with CLBP who met the inclusion/exclusion criteria. The number of replies received was 278, giving a total response rate of 42.8%. Of these 44 indicated that they were not interested in hearing any more about the study. A further 20 of the remainder were excluded after initial contact with the researcher revealed that they did not meet the inclusion/exclusion criteria (14 were aged over 65 years, 4 were in the process of litigation concerning their CLBP, and 2 had other serious medical conditions).

Therefore, appointments with 214 interested patients were arranged. Sixteen patients did not attend their appointment and of those that did, an additional 7 did not want to participate after hearing more about the study. The remaining 191 agreed to participate and written consent was obtained. Thus 29.4% of those who received letters of invitation were recruited into the study.

4.1.4 Participants

A total of 243 patients with CLBP consented to participate in the study. They were subject to randomisation with minimisation on three factors: age, chronicity of pain, and whether or not they were in receipt of sickness or invalidity benefit. This resulted in the following numbers per group: n=79 reflexology; n=85 relaxation and n=79 usual care.

Of these n=9 (n=2 reflexology, n=3 relaxation and n=4 usual care) actively withdrew during the baseline phase (between Time 1 and Time 2). All but one withdrew when the results of the randomisation became known, however the remaining participant explained that the development of a serious health problem was the reason for withdrawal. Thus the descriptive baseline data (Time 1) which follows is calculated on a sample of N= 234 (n=77 reflexology, n=82 relaxation and n=75 usual care)

4.1.5 Description of the sample

Tables 4.1 to 4.2 below summarise the demographic and occupational status of the sample at baseline and provide a comparative description of each group. Information on chronicity of pain, use of CM treatment and treatment preference are also included.

Table 4.1: Baseline descriptive characteristics of the total sample and a breakdown of each group

	Total sample (N = 234)		Reflexology (n = 77)		Relaxation (n = 82)		Usual Care (n = 75)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Age (Range 19-65years)	46.68	10.93	47.19	10.50	45.60	11.96	47.35	10.23
Chronicity of pain (Range 3-504 months)	121.39	108.29	120.59	114.54252	128.38	104.47	114.67	106.68
	N	%	n	%	n	%	n	%
Gender								
Male	95	40.6	29	12.4	29	12.4	37	15.8
Female	139	59.4	48	16.8	53	22.6	38	20.5
Age when finished full time education								
Up to 16	175	74.8	54	23.1	64	27.4	57	24.4
Post 16 to 18	31	13.2	11	4.7	11	4.7	9	3.8
Post 18	28	12	12	5.1	7	3	9	3.8
Qualifications								
None	94	40.2	32	13.7	30	12.8	32	13.7
Olevel/GCSE/NVQ	52	22.2	18	7.7	19	8.1	15	6.4
Alevel/GNVQ/Access	62	26.5	17	7.3	25	10.7	20	8.5
Degree	20	8.5	7	3	7	3	6	2.6
Postgraduate training	6	2.6	3	1.3	1	0.4	2	0.9

Table 4.2: Baseline descriptive characteristics of the total sample and a breakdown of each group (Continued)

			Whole sample		Reflexology		Relaxation		Usual Care	
			N	%	n	%	n	%	n	%
Unemployed			27	11.5	10	4.3	7	3	10	4.3
Retired			30	12.8	9	3.8	11	4.7	10	4.3
Off sick due to pain			29	12.4	12	5.1	9	3.8	8	3.4
Student			2	0.9	0	0	2	0.9	0	0
Homemaker			21	9	6	2.6	7	3	8	3.4
Employed			125	53.4	40	17.1	46	19.7	39	16.7
Social Class		**% in General Population**								
I	Professional	3.7	5	2.1	4	1.7	0	0	1	0.4
II	Managerial/Teacher	20.9	45	19.2	13	5.6	19	8.1	13	5.6
IIIm	Skilled Manual	21.9	29	12.4	12	5.1	8	3.4	9	3.8
IIInm	Clerical/minor supervisory	24.3	81	34.6	23	9.8	32	13.7	26	11.1
IV	Semi Skilled Manual	18.0	39	16.7	11	4.7	13	5.6	15	6.4
V	Unskilled Manual	6.4	35	15	14	6	10	4.3	11	4.7
Used CM			119	50.9	34	14.5	45	19.2	40	17.1
Not used CM			115	49.1	43	18.4	37	15.8	35	15
Treatment preference										
Reflexology			128	54.7	41	17.5	44	18.8	43	18.4
Relaxation			17	7.3	5	2.1	7	3	5	2.1
Reflexology or Relaxation			38	16.2	13	5.6	13	5.6	12	5.1
No preference			51	21.8	18	7.7	18	7.7	15	6.4

Previous treatment history

At interview 1, participants reported a variety of previous treatments they had sought and/or had been prescribed in an attempt to gain relief from their CLBP problem, with the most common being physiotherapy and prescribed medication. As table 4.2 highlighted, 50.9% of the sample had previously used some form of CM, and these are detailed in table 4.3 below, along with the other forms of therapy used. It is important to note that many participants had tried more than one treatment, and thus an individual may contribute to several points on the table.

Table 4.3: Previous treatment modalities participants reported using for CLBP at interview 1.

Treatment	N° Used	% Used
	n	%
Prescribed medication	196	83.7
Physiotherapy	176	75.2
Over the counter medication	135	57.7
Osteopathy	46	19.7
Aromatherapy massage	45	19.2
Acupuncture from CM therapist	30	12.8
Injection into back (various)	25	10.7
Chiropractic	24	10.2
Acupuncture from physiotherapist	24	10.2
TENS	12	5.1
Pain Management Programme	7	2.9
Homeopathic remedies	5	2.1
Sports therapy	4	1.7
Reiki	4	1.7
Herbalism	4	1.7
Hypnotherapy	4	1.7
Alexander technique	2	0.8
Faith healer	1	0.4
Bowman technique	1	0.4

4.1.6 Representativeness of the sample

Comparison of the current sample with previous research populations of CLBP sufferers indicates that they appear to be fairly typical in most respects. Duration of pain is congruent with that of some prior studies (e.g. Turner et al., 2000, Pfingsten et al., 1997, Van Tulder et al., 1997, Estlander, 1989), though it is recognised to be greater than that of others (e.g. Hoffman, et al., 1994; Bronfort et al., 1996; Cherkin et al., 1996). However the inclusion/exclusion criteria employed by some researchers may be responsible for this to a certain extent. Nevertheless these figures do illustrate that back pain for a substantial minority of patients is a lifelong chronic condition.

The mean age of the sample is congruent with previous studies (e.g. Hartigan et al., 2000; Turner et al., 2000; Von Korff et al., 1998; Pfingsten et al., 1997; Van Tulder et al., 1997; Bronfort et al., 1996; Ruta et al., 1994). There are slightly more females than males. Women are reported to be more likely than men to consult with low back pain (e.g. Croft et al., 1998; Mckinnon et al., 1997). In addition, women are more frequent users of both orthodox and complementary medicine than men (e.g. Thomas, 1991; Sharma, 1992). Furthermore when the slightly higher prevalence rate of back pain for women (Waddell, 1998) is taken into consideration, it is apparent that the trends in this data are to be expected.

Comparison of the current sample with previous research which has considered the socio-economic status of CM users, would seem inappropriate as not all are currently users of CM. Indeed the process of randomisation may result in some remaining non-users (i.e. participants in the usual care group). However it is useful to note the differences, as participants' characteristics may be relevant in terms of outcome. A number of researchers (e.g. Thomas et al., 1991; Sermeus, 1987) have found that although CM is used by all socio-economic groups, classes I and II predominate. This may be explained in financial terms as these classes generally represent higher paid occupations, with higher education level, and greater disposable income to fund CM.

The current sample has a greater proportion of classes III-V than one would expect to find in the population generally, and users of CM in particular. However this may be due to the sample population, i.e. CLBP sufferers. Although the link between socio-economic status and back pain is a complex one, Walsh et al. (1992) provide evidence which suggests that back pain is more prevalent in men from social classes IV & V due to the types of occupation these classes represent. In addition Papageorgiou et al. (1998) reported that women, especially those from classes IV & V were more likely to consult their GP about back pain. Either of these reasons could explain the over representation of these classes in the current sample.

4.1.7 Pre-treatment tests for equivalence between groups

To ascertain whether there were any significant differences between the groups on the questionnaire variables (SF36, CSQ, BDI II, ODQ, SSSQ6, VAS for pain, age, chronicity of pain, and number of GP visits in the last 12 months) before the treatment phase commenced (i.e. at Time 1 and Time 2), a series of one way ANOVA or Kruskall Wallis tests were computed. Unless otherwise stated 0.05 was adopted as the significance level for all analyses.

In addition the following categorical variables were examined for significant differences between groups using the Chi-Square test: gender; social class; vocational status; SF36 Change in Health Status, and previous use of complementary therapies. However social class I comprised only 5 participants, thus these were combined with social class II for the purposes of this test. Additionally the vocational status category: student, contained only 2 participants. As this category could not be meaningfully combined with any of the other categories it was removed from the analysis.

Tables 4.4 to 4.9 provide a summary of these results, and demonstrate that there were no differences between the groups on these variables at either Time 1 or Time 2. However, the differences between the relaxation group and the other two groups did approach significance on the SF36 Physical Functioning dimension (*p*=.051). No new treatments were implemented during this baseline phase (i.e. the time from recruitment until immediately before the treatment phase) thus this lack of differences is to be expected. The lack of differences at Time 1 indicate that randomisation with minimisation was effective in distributing variance on all measures throughout the treatment groups. Whilst at Time 2, the similarities between groups indicate that although participants were aware of the treatment group they had been randomised to, this did not appear to induce a significant 'expectancy effect' in the reflexology or relaxation group. Furthermore these results are encouraging in terms of the analysis of post treatment data, as each group was 'equal' in terms of their characteristics on all measures before the treatment phase began.

Assessment of the groups over time before the treatment phase began, i.e. between Time 1 & Time 2 was conducted within the repeated measures ANOVA used to evaluate the pre-post treatment data (see section 4.1.12). They illustrated that, the only significant difference to occur between Time 1 & Time 2 was on the current level of pain as measured by VAS1A scale (F = 5.628, df = 1, 151, *p* = .019) with the mean level of pain increasing from 39.61 (SD 26.07)mm at Time 1 to 45.06 (SD 26.29)mm at Time 2. The remainder of the questionnaire scales did not demonstrate any significant differences between Time 1 & 2. Therefore any differences between groups found at Time 3 on these measures may be more confidently attributed to the treatment.

Table 4.4: Comparison of group mean scores for each scale on the questionnaire at **Time 1 (Baseline)**

Scale	N	Reflexology		Relaxation		Usual Care			
SF36 Subscales*		Mean	SD	Mean	SD	Mean	SD	F	p
Physical functioning	234	49.61	29.56	56.67	29.10	45.41	27.86	3.009	0.051
Social functioning	234	58.44	30.45	61.92	30.44	58.22	29.67	0.378	0.686
Role limitations (physical)	229	36.36	43.96	36.07	42.13	29.11	39.76	0.712	0.492
Role limitations (emotional)	231	61.90	43.50	57.50	46.23	58.11	45.52	0.217	0.805
Pain	234	38.38	22.91	43.77	23.25	37.48	20.32	1.861	0.158
Mental Health	234	59.68	21.65	61.27	21.59	60.16	18.44	0.123	0.884
Energy/vitality	231	41.97	21.36	41.11	22.26	39.73	23.19	0.193	0.824
General health perception	230	54.29	22.57	52.07	24.71	54.96	23.05	0.325	0.723
CSQ Subscales									
Diverting attention	225	1.24	1.24	1.48	1.40	1.47	1.33	0.820	0.442
Reinterpreting pain sensation	223	0.87	1.18	0.80	1.00	0.90	1.14	0.145	0.865
Catastrophising	223	1.59	1.37	1.56	1.37	1.71	1.40	0.253	0.777
Ignoring sensations	223	2.22	1.48	2.01	1.35	2.02	1.30	0.514	0.599
Praying/hoping	224	1.58	1.41	1.77	1.34	1.84	1.48	0.654	0.521
Increased behavioural activity	224	2.12	1.37	1.99	1.33	1.85	1.12	0.835	0.435
Coping self statements	224	3.25	1.43	3.17	1.50	3.36	1.37	0.338	0.714
Ability to control pain	223	3.04	1.43	3.15	1.32	2.92	1.22	0.595	0.553
Ability to decrease pain	223	2.63	1.40	2.83	1.18	2.61	1.21	0.706	0.495
Oswestry Disability Questionnaire	234	32.95	8.17	33.16	19.83	36.61	17.70	0.932	0.395
Beck Depression Inventory II	231	12.87	8.84	13.52	11.45	14.35	9.77	0.394	0.675
Mean number of social supports	226	2.64	1.78	2.86	2.03	2.53	1.77	0.591	0.555
Mean satisfaction with social support	211	5.17	1.00	5.15	1.22	5.25	0.83	0.185	0.831
VAS1 Current pain intensity	234	41.78	28.63	36.48	23.82	39.14	28.87	0.763	0.467
VAS2 Seven day mean pain intensity	234	51.71	26.94	47.14	26.05	52.41	24.62	0.953	0.387
Chronicity of CLBP (months)	234	20.59	114.54	28.38	104.47	114.67	106.68	0.305	0.737
GP consultations in last 12 months	234	3.48	4.23	3.65	4.84	3.72	5.27	0.046	0.955

Table 4.5: Comparison of group mean scores for each scale on the questionnaire at **Time 2 (pre-treatment)**

Scale	**N**	**Reflexology**		**Relaxation**		**Usual Care**			
SF36 Subscales*		Mean	SD	Mean	SD	Mean	SD	F	p
Physical functioning	189	50.22	28.25	56.89	27.76	47.55	29.56	1.796	0.168
Social functioning	190	64.73	29.15	68.14	29.49	60.17	30.54	1.075	0.343
Role limitations (physical)	188	31.43	40.44	40.44	44.06	32.55	38.79	0.944	0.391
Role limitations (emotional)	188	60.70	44.92	53.92	46.08	57.23	44.51	0.379	0.685
Pain	190	42.32	23.77	44.77	25.35	41.93	24.33	0.254	0.776
Mental Health	191	60.87	23.23	61.16	21.31	64.53	20.12	0.504	0.605
Energy/vitality	191	46.30	20.84	45.29	23.98	41.23	23.57	0.805	0.448
General health perception	189	52.25	22.32	52.22	24.56	53.90	21.53	0.100	0.905
CSQ Subscales									
Diverting attention	187	1.38	1.18	1.68	1.45	1.49	1.20	0.910	0.404
Reinterpreting pain sensation	184	0.84	1.10	1.01	1.19	1.03	1.20	0.465	0.629
Catastrophising	187	1.56	1.20	1.29	1.24	1.18	1.20	1.532	0.219
Ignoring sensations	185	1.98	1.43	2.17	1.48	2.21	1.53	0.447	0.640
Praying/hoping	188	1.62	1.21	1.60	1.25	1.28	1.22	1.343	0.164
Increased behavioural activity	187	1.96	1.06	2.05	1.23	1.93	1.12	0.187	0.829
Coping self statements	185	2.98	1.25	3.24	1.42	3.32	1.48	1.036	0.357
Ability to control pain	184	3.11	1.49	3.26	1.35	2.87	1.44	1.102	0.334
Ability to decrease pain	184	2.51	1.39	2.92	1.11	2.46	1.49	5.116 *	0.077*
Oswestry Disability Questionnaire	192	33.26	18.43	32.67	20.56	34.02	19.14	0.073	0.929
Beck Depression Inventory II	190	12.03	8.65	13.51	10.88	12.89	9.01	0.407	0.666
Mean number of social supports	172	2.56	1.71	2.49	1.99	2.50	1.46	0.028	0.973
Mean satisfaction with social support	160	5.04	1.21	5.14	1.35	5.34	0.67	0.879	0.417
VAS1 Current pain intensity	191	44.48	24.82	40.75	28.59	40.60	26.73	0.432	0.650
VAS2 Seven day mean pain intensity	190	49.96	23.94	45.40	29.61	48.40	27.66	0.490	0.613

*CSQ Ability to decrease pain: difference between groups not significant ($X^2 = 5.116$, df = 2, $p = .077$)

Table 4.6: Comparative number of males and females in each treatment group.

	Male	Female	Total
Reflexology	29	48	77
Relaxation	29	53	82
Usual Care	37	38	75
Total	95	139	234

Chi Square test revealed there was no relationship between gender and group ($X^2 = 3.579$, df = 2, $p = .167$).

Table 4.7: Comparative number of participants from social classes II - V in each treatment group.

	Reflexology	Relaxation	Usual Care	Total
II	17	19	14	50
IIInm	12	8	9	29
IIIm	23	32	26	81
IV	11	13	15	39
V	14	10	11	35
Total	77	82	75	234

Chi Square test revealed there was no relationship between social class and treatment group ($X^2 = 9.109$, df = 10, $p = .530$)

Table 4.8: Comparative number of participants from each treatment group and their vocational status.

	Reflexology	Relaxation	Usual Care	Total
Unemployed	10	7	10	27
Retired	9	11	10	30
Off sick due to pain	12	9	8	29
Homemaker	6	7	8	21
Employed	40	46	39	125
Total	77	80	75	232

Chi Square test revealed there was no relationship between treatment group and vocational status ($X^2 = 2.566$, df = 10, $p = .959$)

Table 4.9: Number of participants who had used/not used CM previously in each treatment group.

	Used CM	Not used CM	Total
Reflexology	34	43	77
Relaxation	45	37	82
Usual Care	40	35	77
Total	119	115	234

Chi Square test revealed there was no relationship between treatment group and those who had/had not used CM ($X^2 = 2.098$, df = 2, $p = .350$)

4.1.8 Attrition

In common with other longitudinal studies, attrition occurred in the present study, though rates varied dependent upon group. Fifteen participants who had been randomised to a treatment group did not attend any sessions at all, while others attended some but not all. Table 4.10 details how many session participants in each group attended. It demonstrates that participants in the reflexology group were more likely to attend, and also more likely to comply with attending all treatment sessions.

Table 4.10: Number of treatment sessions attended by participants in the reflexology and relaxation groups

	Number of sessions attended							
Group	0	1	2	3	4	5	6	Total
Reflexology	5	0	5	3	1	5	58	77
Relaxation	14	6	3	4	9	9	37	82

In addition, a large number of participants in the Usual Care group did not return questionnaires at either Time 2, Time 3 or Time 4. Table 4.11 provides a summary of questionnaire return rates for the whole sample and each group throughout the study.

This represented the following 'drop out' rates at Time 3:

Reflexology 16% Relaxation 30% Usual care 43%

Table 4.11: Total and group numbers of participants who returned questionnaires at each stage of the study.

	Number of questionnaires returned			
Group	**Time 1**	**Time 2**	**Time 3**	**Time 4**
Reflexology	77	68	65	57
Relaxation	82	69	57	54
Usual Care	75	54	43	45
Total	234	191	165	156

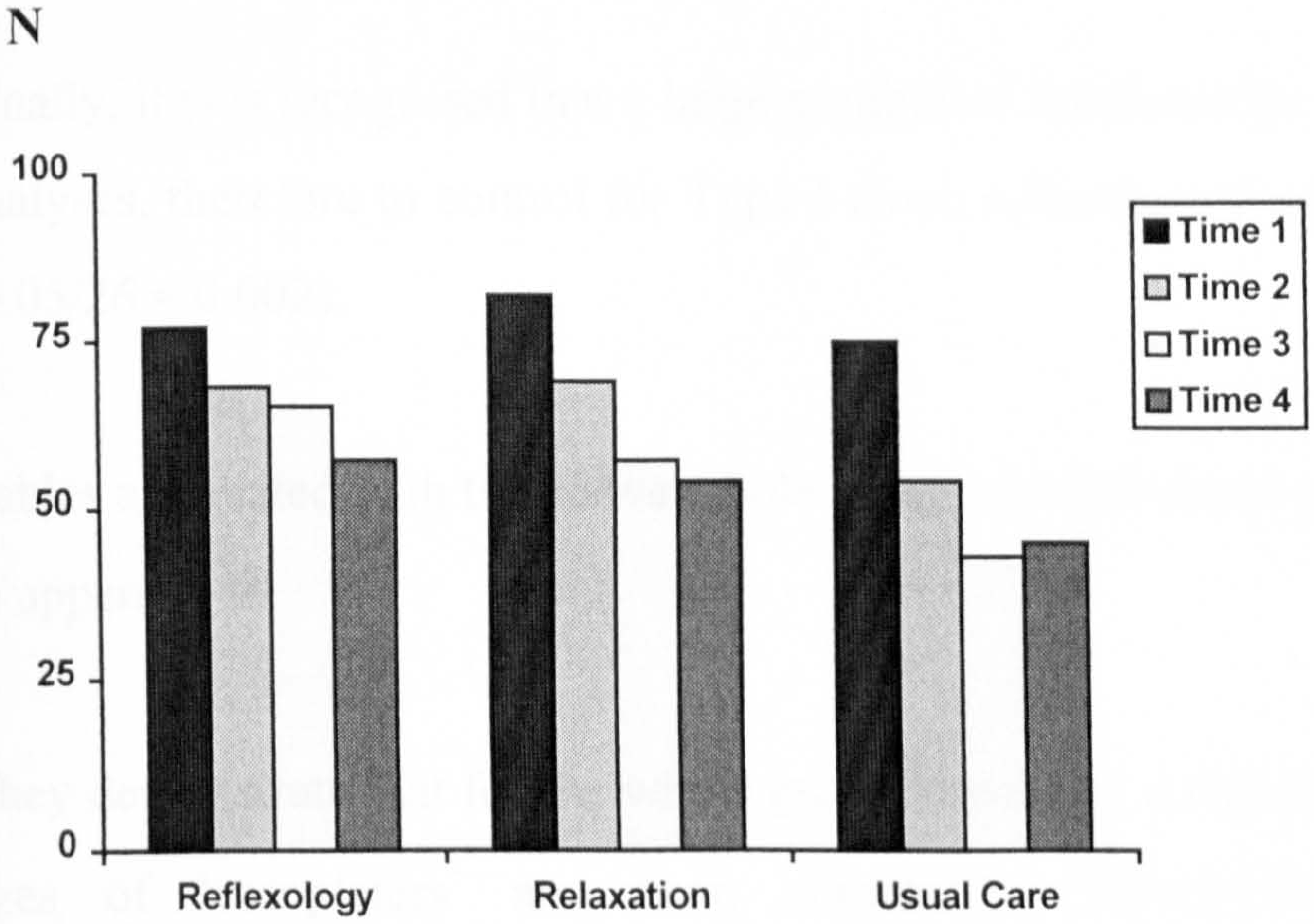


Figure 4.2: Number of questionnaires returned at Time 1, 2, 3 & 4

4.1.9 Comparison between 'completers' and 'non-completers'

Thus to ascertain whether those who returned Time 1, 2 & 3 questionnaires were significantly different on any of the questionnaire or demographic variables at Time 1 than those who did not, the whole sample were re-categorised into two groups: those with scores on the two main outcome measures (i.e. SF36 Pain and ODQ) at Times 1, 2 & 3 and those without (n=165 & n=69, respectively).

A series of t-tests were conducted on the questionnaire variables (SF36, BDI II, ODQ, CSQ, SSSQ6, VAS for pain) age and chronicity of pain. Similarly a number of Chi Square tests were computed to determine whether there were any differences between completers and non completers on any of the categorical variables at Time 1 (gender, previous use of CM, treatment preference, social class, vocational status and qualifications).. In addition the aforementioned tests were was also carried out on each treatment group separately, for the same comparative purposes, i.e. to determine whether those who complied with completion of the questionnaires were representative of the individual treatment groups. However Chi Square tests were not conducted for individual groups on the following variables: social class, vocational status and qualifications, because the low numbers meant that some categories on these variables contained no participants, while others were represented by less than 5 participants.

Finally, it was recognised that a large number of relationships were to be examined in the analyses, therefore to control for Type I error, a Bonferroni adjustment was implemented $(0.05/26 = 0.002)$.

Tables associated with the above whole group and individual group analyses can be found in appendix 9.

They demonstrate that for the whole group, there was a significant difference in the mean ages of 'completers' and 'non completers' (48.64±10.31yrs & 41.94±11.01yrs respectively). For the whole group, those who had used CM previously were more likely to comply with completion of the questionnaires at Times 1, 2, & 3. Consideration of the sub-group analyses however, demonstrated that this was only the case for those in the relaxation group ($X^2 = 12.83$, df = 1, $p = .0005$), where those who had not used CM were less likely to comply. The relationship between compliance and previous use of CM was not significant in the reflexology group ($X^2 = .295$, df = 1 , $p = .587$) or the usual care group ($X^2 = 5.652$, df = 1, $p = .017$). The only other significant difference between completers and non completers occurred within the reflexology group, where compliant participants were less likely than non completers to cope with their pain by ignoring it (CSQ Ignoring sensations $t = -3.372$, $p = .001$). However this difference did not occur in the whole group. All other comparisons between those who complied with completion of the questionnaires at Time 1, 2 & 3 were not significant.

4.1.10 Usual care reported during treatment phase

All participants were asked to provide details of their care during the treatment phase of the study (i.e. between Time 2 and Time 3). N = 165 participants supplied these details (n = 43 usual care, n = 57 relaxation and n = 65 reflexology). Table 4.12 below presents this information. Please note that percentages add up to more than 100 because some participants reported more than one treatment or visit to a health practitioner. In addition the percentages given in the table are representative of the whole group (N=165).

Table 4.12: Usual care reported by all participants during the treatment phase

Treatment	**Reflexology n = 65**		**Relaxation n = 57**		**Usual Care n = 43**	
	n	**%**	**n**	**%**	**N**	**%**
None	31	18.8	21	12.7	13	7.9
Prescribed medication	28	17	30	18.2	24	14.6
Over the counter medication	12	7.3	9	5.5	8	4.8
Osteopathy	1	0.6	1	0.6	-	-
Acupuncture	-	-	2	1.2	2	1.2
Physiotherapy	-	-	1	0.6	5	3
Aromatherapy massage	-	-	1	0.6	2	1.2
TENS	-	-	2	1.2	1	0.6
Sports therapy massage	-	-	1	0.6	-	-
Chiropractic	-	-	1	0.6	-	-
Reiki	-	-	1	0.6	-	-
Herbal remedies	-	-	-	-	3	1.8
PMP	-	-	-	-	1	0.6

It is apparent that prescribed medication and over the counter medications were similarly utilised by participants from all groups. However, participants in the relaxation and usual care groups were more likely than those in the reflexology group, to report accessing other types of treatment, many of which were CM therapies. While the number of instances is small for each treatment, when considered in proportion to the number of participants in those groups (10 for 57 relaxation participants and 15 for 43 usual care participants), they represent a substantial proportion of all treatment utilised. These instances are perhaps also responsible for the lower number of participants in these groups who reported that they had not used any other treatment, compared to the reflexology group. This may indicate that reflexology participants were satisfied with the treatment and this negated the need for consulting other practitioners.

4.1.11 Post treatment (Time 3) Descriptive Data

Table 4.13 presents means and standard deviation values for the questionnaire data collected at Time 3 (post treatment) for each group. Means and standard deviation values for Time 1 & Time 2 are contained within tables 4.4 and 4.5.

Table 4.13: Group Mean and standard deviation scores for all questionnaire scales at Time 3 (Post-treatment)

Scale		Reflexology		Relaxation		Usual Care	
SF36 Subscales*	Total N	Mean	SD	Mean	SD	Mean	SD
Physical functioning	163	53.85	27.82	57.09	30.24	45.23	28.91
Social functioning	164	65.28	29.60	69.40	28.11	59.17	29.47
Role limitations (physical)	162	45.00	42.67	42.27	43.80	23.21	37.20
Role limitations (emotional)	161	59.38	46.18	66.06	43.74	53.97	43.53
Pain	163	50.00	25.74	47.22	26.32	41.80	25.60
Mental Health	163	66.56	20.55	65.79	17.95	63.63	20.47
Energy/vitality	163	47.66	19.98	47.95	22.38	39.19	21.71
General health perception	162	54.42	23.27	55.46	24.04	48.62	23.57
CSQ Subscales							
Diverting attention	153	1.49	1.39	2.03	1.31	1.51	1.18
Reinterpreting pain sensation	153	0.93	1.16	1.39	1.39	1.01	1.23
Catastrophising	153	1.45	1.43	1.51	1.25	1.59	1.28
Ignoring sensations	153	1.92	1.36	2.44	1.34	2.39	1.50
Praying/hoping	154	1.68	1.60	1.79	1.32	1.53	1.30
Increased behavioural activity	153	2.11	1.17	2.50	1.31	1.84	0.98
Coping self statements	153	3.10	1.33	3.41	1.17	3.39	1.32
Ability to control pain	160	3.03	1.24	3.04	1.19	2.76	1.51
Ability to decrease pain	160	2.95	1.12	2.82	1.15	2.40	1.47
Oswestry Disability Questionnaire	165	29.83	19.61	33.40	22.28	36.74	19.91
Beck Depression Inventory II	166	10.98	10.15	12.93	11.69	14.37	10.51
Mean number of social supports	144	2.72	1.79	2.32	1.57	2.59	1.60
Mean satisfaction with social support	144	5.05	1.21	2.06	1.21	5.37	0.80
VAS1 Current pain intensity	165	34.90	25.88	37.91	26.98	48.90	29.28
VAS2 Seven day mean pain intensity	165	41.03	26.68	44.05	31.50	53.14	27.73

4.1.12 Pre-Post treatment evaluation

Analyses computed to determine whether and to what extent reflexology and relaxation are effective for the management of CLBP were conducted on the complete sets of Time 1, 2, & 3 data that were available at Time 3. Participants who did not attend or failed to complete treatment are included in the analysis where Time 3 data were available.

Repeated measures ANOVA were used to evaluate the two primary outcome variables: Function as measured by the Oswestry Disability Questionnaire (ODQ) and Pain measured by the SF36 Pain dimension at Time 1, 2 & 3. In addition the secondary questionnaire outcome measures (remaining SF36 dimensions, BDI II, CSQ, SSSQ6 and VAS for pain) were subject to the same type of analysis.

Primary outcome variables

Tables 4.14 and 4.15 below provide a summary of results for the ODQ and SF36 Pain. There was no effect of function, and there was no significant effect of treatment group on function over time as measured by the ODQ. Similarly, it is apparent that although there was a significant main effect of pain reduction over time, the group by pain over time interaction was not significant. Therefore treatment did not have a significant effect on pain or pain related disability.

Table 4.14: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Functioning as measured by the ODQ (Oswestry Disability Questionnaire).

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	997.56	2	498.78	.495	.611
Error 1	160352.98	159	1008.51		
		Within subjects			
Function (ODQ)	184.16	1.885	97.70	2.039	.135
Function(ODQ)* Treatment Group	263.94	3.77	70.01	1.461	.217
Error 2	14358.50	299.69	47.91		

Note: Greenhouse-Geisser corrected test results are reported.
Total N=162 entered into analysis. Means/SDs for Time 1, 2 & 3 can be found in tables 4.4, 4.5 & 4.13 respectively.

Table 4.15: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = pain as measured by the SF36 Pain scale.

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	1170.38	2	585.19	.472	.625
Error 1	192110.86	155	1239.43		
		Within subjects			
Pain	3559.93	1.915	1859.08	8.185	.0005
Pain*Treatment Group	1002.21	3.830	261.69	1.152	.332
Error 2	67413.69	269.81	227.13		

Note: Greenhouse-Geisser corrected test results are reported.
Total N=158 entered into analysis. Means/SDs for Time 1, 2 & 3 can be found in tables 4.4, 4.5 & 4.13 respectively.

Secondary outcome variables

Tables associated with the analyses on the secondary outcome variables (all SF36 dimensions with exception of SF36 Pain, BDI II, CSQ, SSSQ6 and VAS for pain) can be found in appendix 10. In addition, means/SDs for Time 1, 2 & 3 can be found in tables 4.4, 4.5 & 4.13 respectively.

The repeated measures ANOVA conducted on the secondary outcome variables revealed a number of main effects and one interaction. The interaction occurred between the SF36 General Health Perception dimension measured over time and treatment group ($F_{(4,304)} = 2.648$, $p = .034$), and is displayed in figure 4.3 below. It is apparent that although the interaction is statistically significant the percentage change in scores is relatively small, and is not evidence of clinically significant changes in SF36 General Health Perception scores.

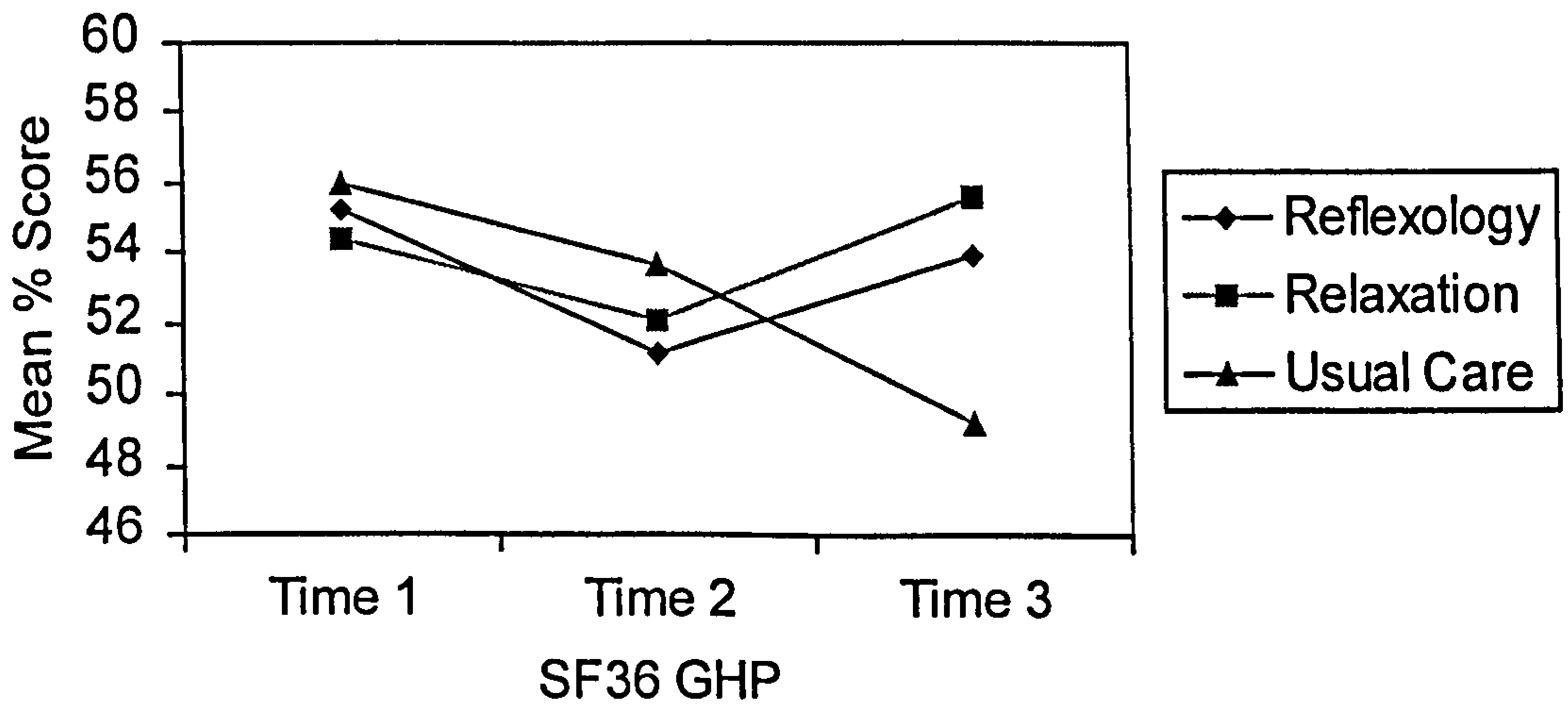


Figure 4.3: Interaction between treatment group and scores on the SF36 General Health Perception dimension

The majority of main effects that occurred concerned other SF36 variables. The Mental Health dimension ($F_{(2,310)} = 7.130, p = .001$), along with Social Functioning ($F_{(1.88,293.49)} = 3.616$, $p = .031$), Physical functioning ($F_{(2, 306)} = 4.815$, $p = .009$), and Physical Role limitations ($F_{(1.91, 284)} = 3.159$, $p = .046$), all increased significantly between Time 1 & Time 3 regardless of treatment group. This indicates that participants general health status along these dimensions improved throughout this period. However this was not the case for the SF36 Emotional role limitations ($F_{(2,300)} = 1707, p = .183$), or SF36 Energy and Vitality ($F_{(2, 308)} = 1.882, p = .154$), which did not differ significantly throughout the duration of the study.

Pain assessed by the primary outcome measure, SF36 Pain dimension, reduced over time and this was also the case with pain as measured by the visual analogue scales. Participants seven day mean pain intensity (VAS2) reduced ($F_{(2, 306)} = 3.155, p = .044$), while current pain intensity, increased between Time 1 & Time 2 but decreased during the treatment phase ($F_{(2, 302)} = 4.438, p = .013$) for all participants.

There was a significant increase in the use of reinterpreting the pain sensation as a coping strategy throughout the study by all treatment groups ($F_{(1.86,\ 258.04)} = 4.378, p = .016$). However there were no significant differences in the use of any other coping strategies measured by the CSQ, or in participants reported ability to decrease or control their pain using the strategies they had identified on this instrument.

The number of social supports participants identified, and their satisfaction with those supports did not change significantly between Time 1, 2 & 3 ($F_{(1.66, 207.04)} = 2.488, p = .096$ and $F_{(2, 216)} = .221, p = .802$ respectively). This suggests that these factors remain fairly stable over time.

Finally, there were no significant differences in the intensity or number of symptoms of depression reported by participants from all groups at each assessment ($F_{(1.71, 265.53)} = .642$, $p = .504$). However, this needs to be viewed within the context of the relatively low mean scores on the BDI II for all groups throughout the trial, which may have produced a 'floor effect' whereby participants had little scope to demonstrate improvement from an already low score.

4.1.13 Exploratory Analysis

Pre-Post treatment analysis (missing data imputed)

The previous analyses were computed using complete sets of Time 1, 2 & 3 data. However it is generally accepted that, where possible, all participants should be included in the analysis, particularly when evaluating treatment outcome (Pocock, 1984). Therefore the primary outcome variables: SF36 Pain and ODQ at Times 1, 2, & 3 were analysed using the missing value procedure in SPSS version 10. Briefly, this procedure describes patterns of missing data and uses EM (expectation-maximisation) to estimate means, covariances and correlations. Missing values are then replaced by imputed values and saved into a new data file for use in further analysis. Using this data, repeated measures ANOVA were recalculated for the two primary outcome measures, and the results are shown in appendix 11.

Results are congruent with those described previously, conducted on available data only (section 4.1.12). There was a significant main effect of pain reduction over time ($F_{(2, 462)} = 12.912, p = .0005$). The group by pain over time interaction was not significant ($F_{(4, 462)} = 1.555, p = .185$). In addition both function (ODQ) over time and the group by function over time interaction were not significant ($F_{(1.92, 443.97)} = 1.665, p = .192$ and $F_{(3.84, 443.97)} = 1.475, p = .209$, respectively).

Pre-post comparison of Treatment versus Usual Care

There were no differences between the Reflexology, Relaxation and Usual Care groups on the main outcome variables. Therefore in order to evaluate the extent to which treatment in addition to usual care had an effect on SF36 Pain and ODQ scores, the reflexology and relaxation groups were collapsed to form one 'treatment' group for comparison with the usual care group. As before repeated measures ANOVA was utilised. The tables associated with this analysis can be found in appendix 12. Results are congruent with those described previously. There was a significant effect of pain reduction over time ($F_{(1.91,298.09)} = 5.347, p = .005$). The treatment group by pain interaction was not significant (F

$_{(1.91, 298.09)}$ = 5.347, p = .448). In addition both function (ODQ) over time and the group by function interaction were not significant ($F_{(1.880, 300.76)}$ = .937, p = .388 and $F_{(1.880, 300.76)}$ = 1.309, p = .272).

GP Visits

Chi-Square test was used to evaluate whether treatment groups differed in their GP consulting behaviour during the baseline period (i.e. between Time 1 & 2) and the treatment phase (i.e. between Time 2 & 3). Tables associated with this analysis can be found in appendix 13. There were no differences in consultation behaviour between the groups during the baseline period (X^2 = 2.458, df = 2, p = .293). However during the treatment phase, participants in the reflexology group were less likely to consult their GP than participants in either the usual care or relaxation groups (X^2 = 9.209, df = 2, p = .010).

In addition, one way analyses of variance were computed to determine whether participants from each group who consulted their GP during the baseline or treatment phases, differed in the number of consultations they made. Details of these results can be found in appendix 13. They demonstrate that there were no significant differences in the number of visits made to GPs during either baseline ($F_{(2, 180)}$ = 1.589, p = .207) or treatment ($F_{(2, 150)}$ = 2.905, p = .058) phases.

Change in Medication

Details of the amount and type of medication participants were taking was requested at Times 1, 2, & 3 via the questionnaire. The reporting of this information was variable. Some participants did not provide any details, while others listed the type of medication but did not indicate the dose. In addition, a number of participants failed to provide the information on all 4 questionnaires. However, using the data available (n = 149) an attempt was made to determine the extent to which participants reported levels of medication use changed over time, dependent upon the treatment group they were in.

Participants self reported medication and dosage levels were recorded at Time 1, 2 & 3. The difference between pre-treatment levels (Times 1 & 2) and post-treatment levels (Time 3) were categorised into 'more' 'less' 'same (on medication)' and 'same (not on medication)' i.e. reported 'no medication' throughout. Figure 4.4 below presents details for each group. In addition Chi Square was computed, and the results indicated that there was no association between treatment group and change in medication ($X^2 = 4.919$, df = 6, $p = .554$).

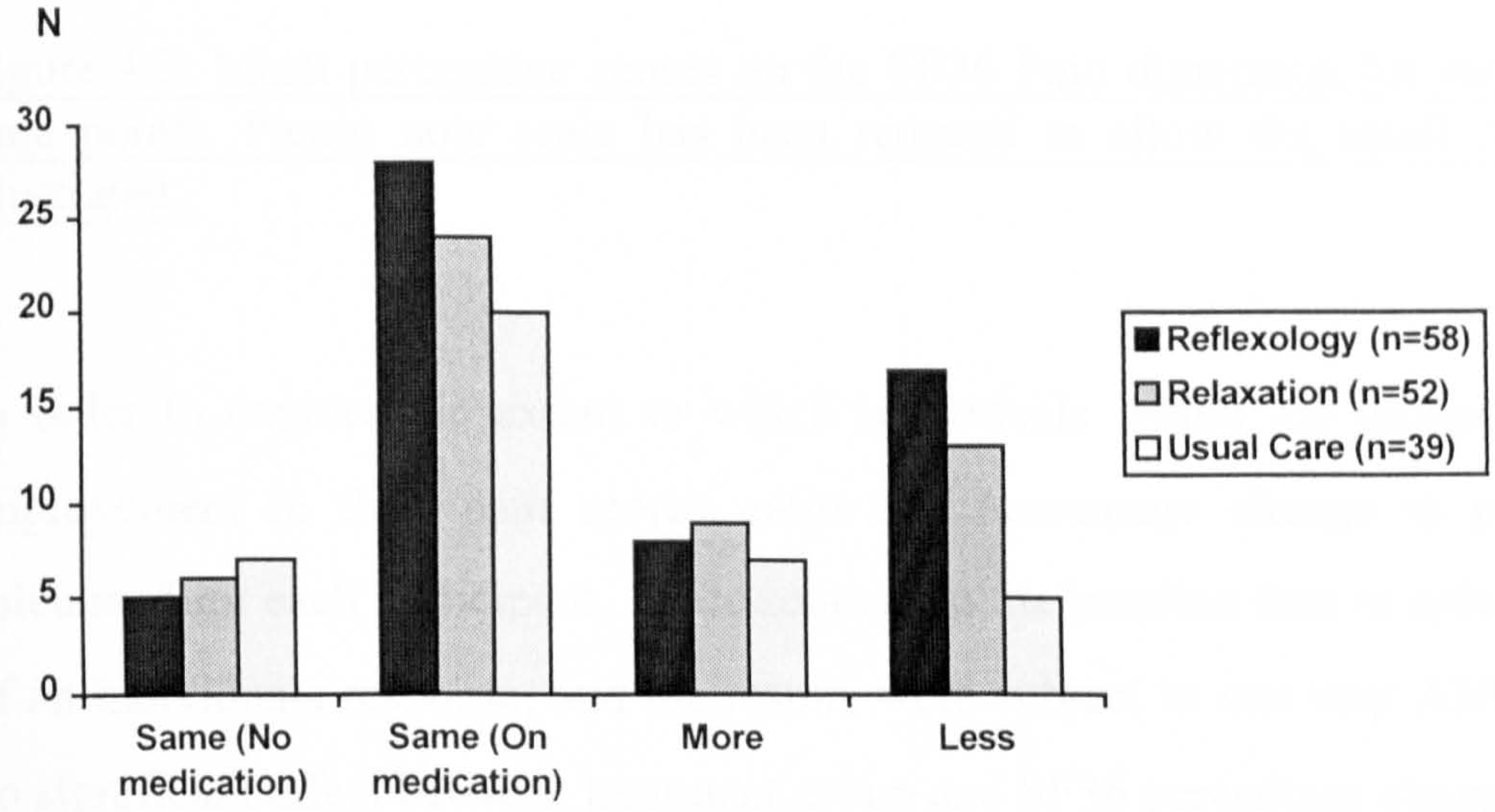


Figure 4.4: Number of participants in each group and their post treatment (Time 3) change in medication.

Pre-post treatment analysis of categorical pain data

The pre-post treatment analysis noted there were no significant differences between groups on the two primary outcome measures (ODQ and SF36 Pain dimension). However consideration of figure 4.5 below demonstrates that the greatest improvement in the SF36 Pain mean score occurred in the reflexology group (from 38.38% at Time 1 to 50% at Time 3).

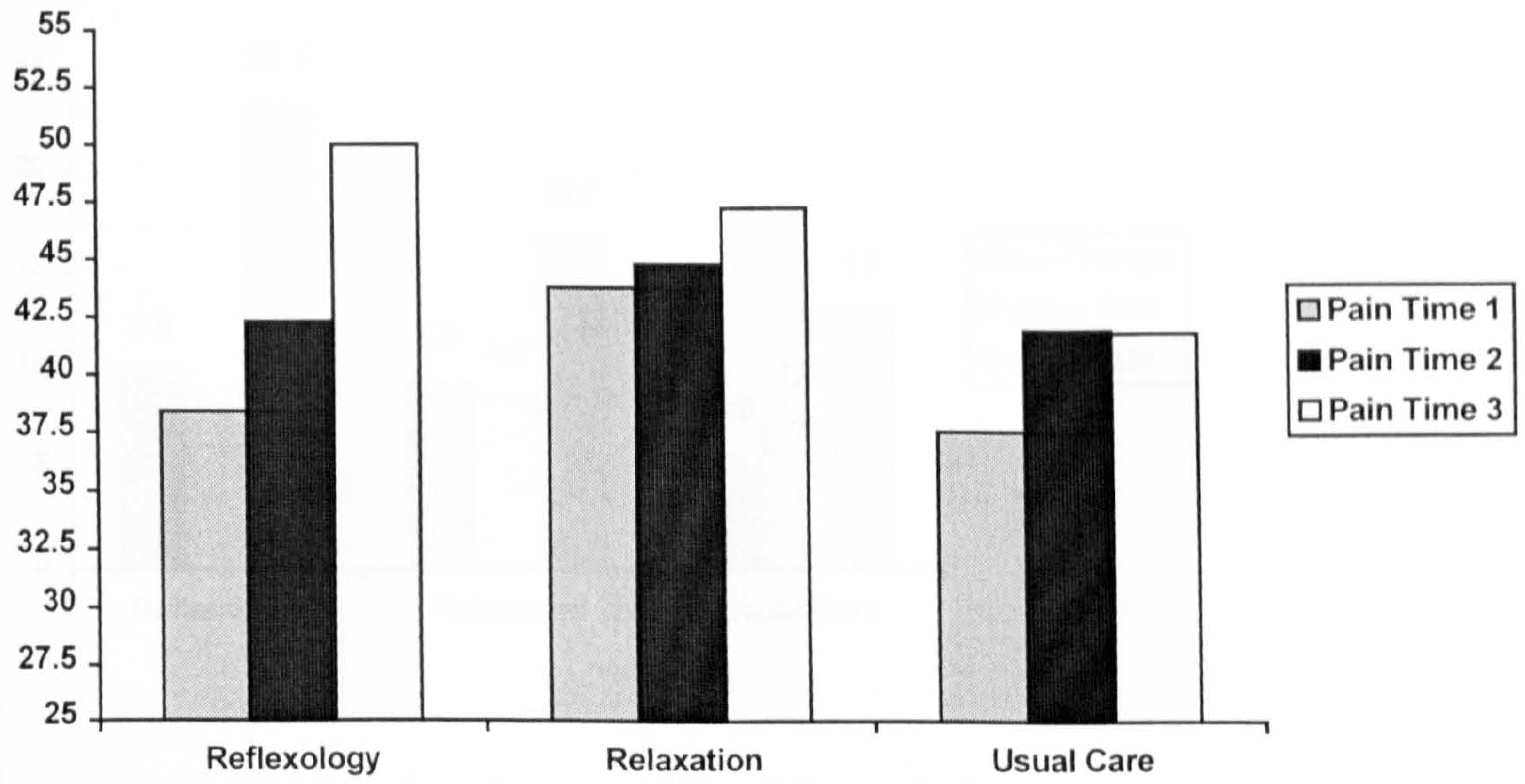


Figure 4.5: Mean percentage scores on the SF36 Pain dimension for each group at all 3 time points. Please note scale has been reduced to allow the small differences to be illustrated.

In order to explore the extent to which individuals within the groups experienced an improvement in their pain scores, ratio and percentage change in pain scores were calculated for each participant. These scores use the baseline data to assess the magnitude of an individuals response, and the results were subject to one way ANOVA. There was no significant effect between treatment group and SF36 percentage change in pain ($F_{(2,151)} = 1.550$, $p = .216$). The table associated with this analysis can be found in appendix 14.

Percentage change scores were categorised into 'no change' 'less pain' and 'more pain' and figure 4.6 below presents details for each group. Figures above the bars represent the percentage in terms of the total sample (N= 162). In addition Chi Square was computed, and the results indicated that there was no association between treatment group and change in pain ($X^2 = 3.295$, df = 4, $p = .510$).

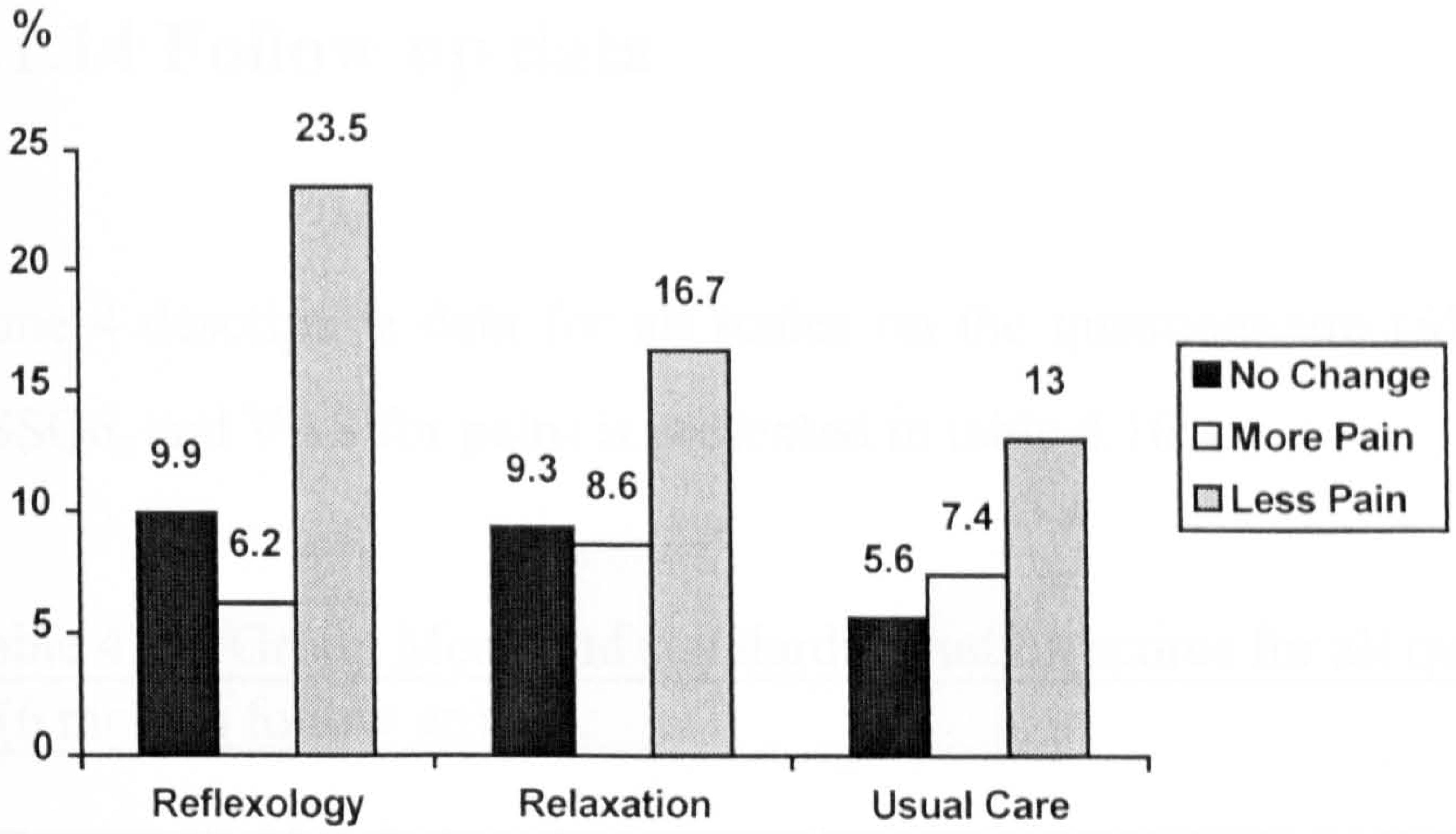


Figure 4.6: Change in pain category at Time 3 for each group

4.1.14 Follow up data

Time 4 descriptive data for all scales on the questionnaire (SF36, CSQ, ODQ, BDI II, SSSQ6, and VAS for pain) is presented in table 4.16.

Table 4.16: Group Mean and standard deviation scores for all questionnaire scales at Time 4 (6 months follow up)

Scale	**Total N**	**Reflexology**		**Relaxation**		**Usual Care**	
SF36 Subscales*		**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Physical functioning	155	57.14	30.24	57.31	31.80	52.22	29.48
Social functioning	155	68.08	31.79	66.66	31.57	61.48	30.76
Role limitations (physical)	154	48.21	46.43	53.24	45.05	37.78	42.51
Role limitations (emotional)	155	54.97	46.50	62.96	43.76	62.02	43.99
Pain	153	50.68	27.14	48.77	25.85	44.44	28.45
Mental Health	154	66.07	22.31	64.37	20.69	67.73	18.48
Energy/vitality	155	48.15	23.22	44.81	21.30	43.33	21.77
General health perception	155	57.55	24.69	52.41	22.77	55.02	24.14
CSQ Subscales							
Diverting attention	147	1.43	1.43	1.83	1.38	1.43	1.07
Reinterpreting pain sensation	148	0.99	1.27	1.37	1.37	0.85	0.99
Catastrophising	147	1.52	1.57	1.30	1.25	1.33	1.21
Ignoring sensations	147	1.91	1.52	2.64	1.51	2.35	1.47
Praying/hoping	148	1.53	1.51	1.75	1.39	1.36	1.16
Increased behavioural activity	147	2.05	1.33	2.13	1.25	1.87	1.03
Coping self statements	151	2.98	1.38	3.46	1.28	3.14	1.38
Ability to control pain	151	3.09	1.44	3.34	1.09	3.11	1.35
Ability to decrease pain	151	2.64	1.41	2.98	1.05	2.74	1.36
Oswestry Disability Questionnaire	155	29.04	20.15	31.28	21.05	32.91	17.61
Beck Depression Inventory II	155	11.56	10.87	12.63	10.93	12.84	9.17
Mean number of social supports	145	2.56	1.84	2.52	2.07	2.44	1.59
Mean satisfaction with social support	145	5.15	1.12	4.90	1.46	5.40	0.97
VAS1 Current pain intensity	155	39.84	29.22	41.26	28.47	42.73	28.45
VAS2 Seven day mean pain intensity	155	42.16	28.20	49.34	30.62	47.22	26.42

Follow up evaluation

Repeated measures ANOVA were used to assess the extent to which participants differed on the primary and secondary outcome variables between Time 1 (recruitment), Time 2 (pre-treatment), Time 3 (post treatment) and Time 4 (6 months follow up). These analyses were conducted using complete sets of data available at Time 4. As table 4.11 highlighted, there was further dropout between Time 3 and Time 4 in the reflexology and relaxation groups. This can account for the differential profile apparent when the results of the repeated measures ANOVAS conducted on Time 1, 2, & 3 data are compared with those carried out on Time 1, 2, 3 & 4 data.

Primary outcome variables

Tables 4.18 and 4.19 below provide a summary of results for the ODQ and SF36 Pain. There was a main effect of pain reduction over the four assessment points. However the group by pain over time interaction was not significant. Similarly there was a significant main effect of increased functioning, but the group by function over time interaction was not significant. This indicates, as the post treatment analysis did, that treatment did not have a significant effect on pain or pain related disability. However, as figures 4.7 and 4.8 show, there were slight trends towards greater pain reduction and increased functioning for those in the reflexology group compared to the other two conditions, though this was not statistically significant. In addition, it is important to note that although the main effects for the whole group are statistically significant, they are not indicative of a clinically significant differences. As stated in the sample size calculation (section 3.2.4) this would be indicated by a mean change in scores of 19.3 on the SF36 Pain dimension, and 11.9 points on the ODQ scale.

Table 4.18: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Functioning as measured by the ODQ (Oswestry Disability Questionnaire).

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	2109.249	2	1054.625	.764	.468
Error 1	189027.356	137	1379.762		
		Within subjects			
Function (ODQ)	814.070	2.664	305.165	5.319	.002
Function(ODQ)* Treatment Group	198.257	5.327	37.214	.648	.673
Error 2	20969.002	364.928	57.461		

Note: Total N=158 entered into analysis. Means/SDs for Time 1, 2, 3 & 4 can be found in tables 4.4, 4.5, 4.13 & 4.16 respectively.

Table 4.19: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = pain as measured by the SF36 Pain scale.

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	1749.196	2	874.598	.505	.604
Error 1	230135.336	133	1730.341		
		Within subjects			
Pain	6032.481	2.661	2266.659	9.172	.0005
Pain*Treatment Group	1078.751	5.323	202.666	.820	.542
Error 2	87474.262	353.966	247.126		

Note: Greenhouse Geisser corrected results reported. Total N=136 entered into analysis. Means/SDs for Time 1, 2, 3 & 4 can be found in tables 4.4, 4.5, 4.13 & 4.16 respectively.

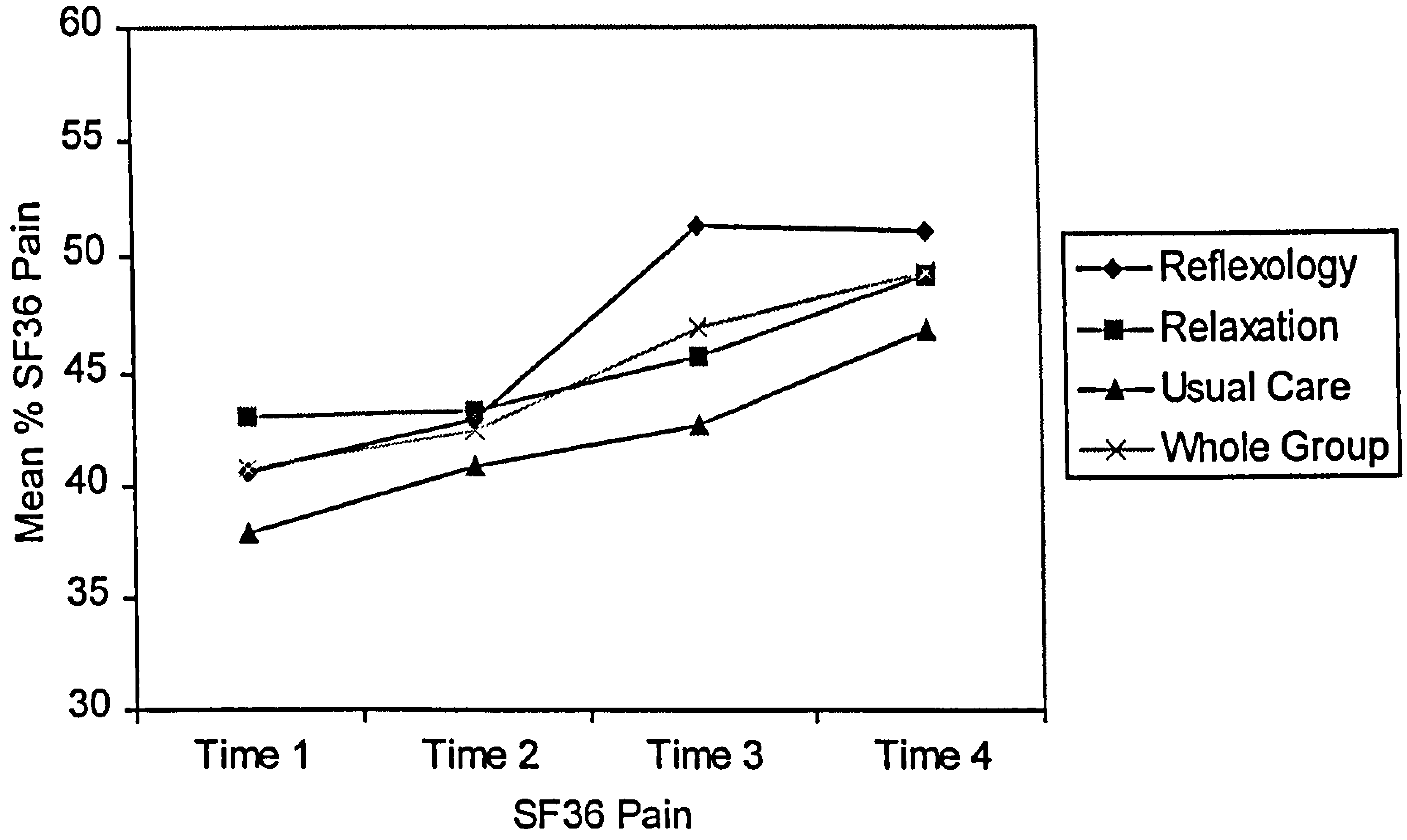


Figure 4.7: Mean SF36 Pain scores for each group at Times 1, 2, 3 & 4

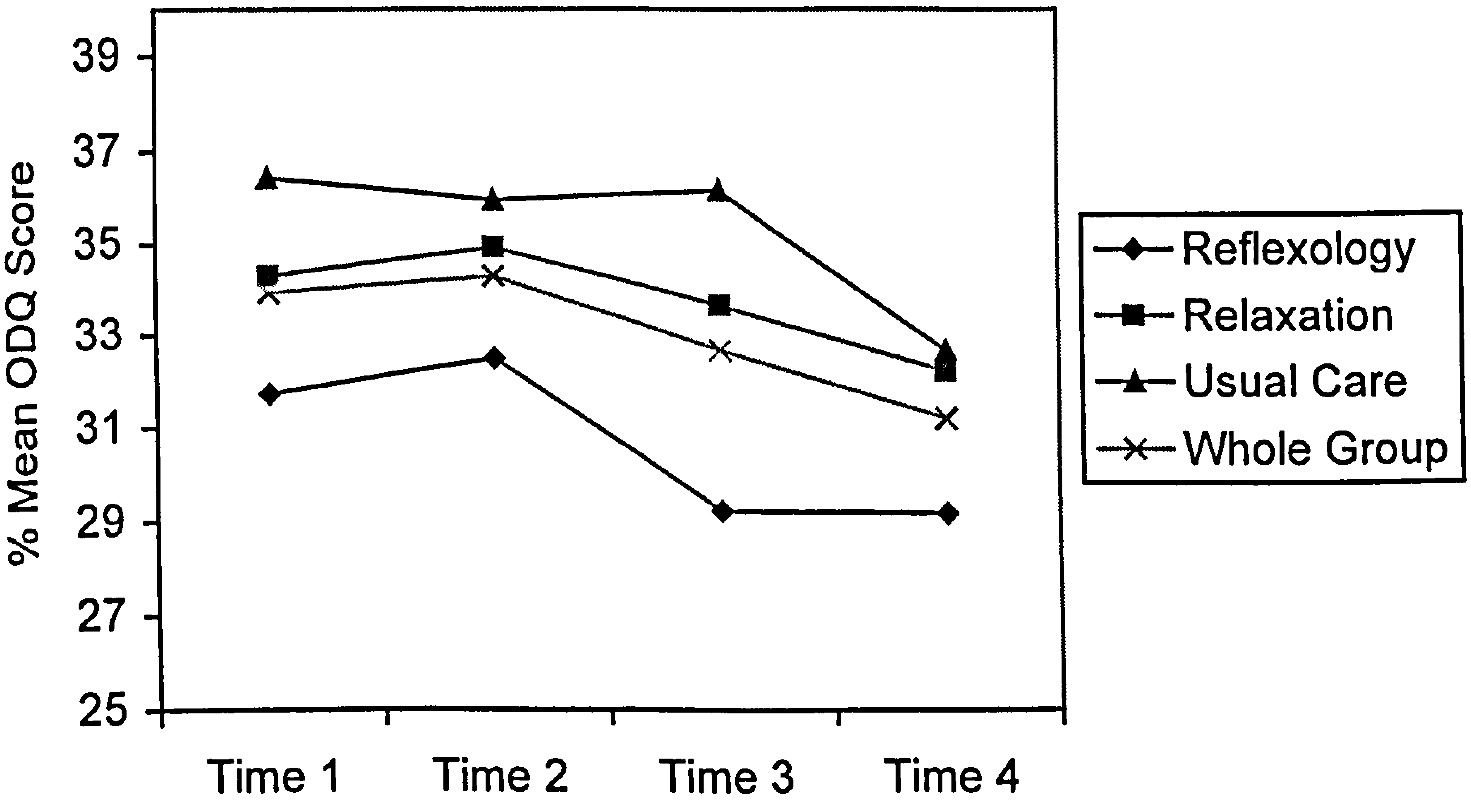


Figure 4.8: Mean ODQ scores for each group at Times 1, 2, 3 & 4

Secondary Outcome Variables

All tables associated with these analyses are contained within appendix 15. In addition, Means/SDs for Time 1, 2, 3 & 4 can be found in tables 4.4, 4.5, 4.13 & 4.16 respectively.

The repeated measures ANOVA conducted on the secondary outcome variables revealed a number of main effects. However there were no interactions between treatment group and any of the secondary outcome variables.

Four of the SF36 dimensions demonstrated main effects. There was an increase in participants General Health Perception throughout the duration of the trial ($F_{(2.58,\ 340.65)} = 3.871, p = .013$), along with improvements in SF36 Physical Functioning ($F_{(2.75,\ 359.98)} = 4.654, p = .004$), SF36 Role Limitations due to physical problems ($F_{(2.89,\ 373.72)} = 6.911, p = .0005$), and SF36 Mental Health ($F_{(2.92,\ 385.30)} = 5.800, p = .001$). There were no significant differences between scores on the remaining SF 36 dimensions.

The use of catastrophising as a coping strategy, measured by the CSQ, reduced significantly for the whole group between recruitment (Time 1) and follow up (Time 4) ($F_{(2.79,\ 338.015)} = 3.177, p = .027$). However the decrease in the use of catastrophising was not associated with a significant increase in the use of any of the other coping strategies measured by the CSQ. In addition it was not accompanied by any change in participants reported ability to control or decrease their pain, using strategies they had identified on the CSQ.

Average pain intensity over the last week, measured by a visual analogue scale also reduced significantly throughout the trial ($F_{(3,\ 393)} = 2.720, p = .044$). However current pain intensity, measured by a visual analogue scale was not significantly different over the duration of the trial ($F_{(3,393)} = 2.192, p = .088$).

Finally there were no significant changes in the intensity and number of symptoms of depression, measured by the BDI II, reported by participants throughout the study. Nor were there any significant effects concerning the number of social supports identified by participants or their perception of satisfaction with that support.

SF36 Change in Health evaluation

The SF36 Change in Health dimension asked participants how they would rate their health in general now compared to one year ago. Figure 4.9 below provides details for the whole group and demonstrates the percentage of participants in each category at Time 1, 2, 3 & 4.

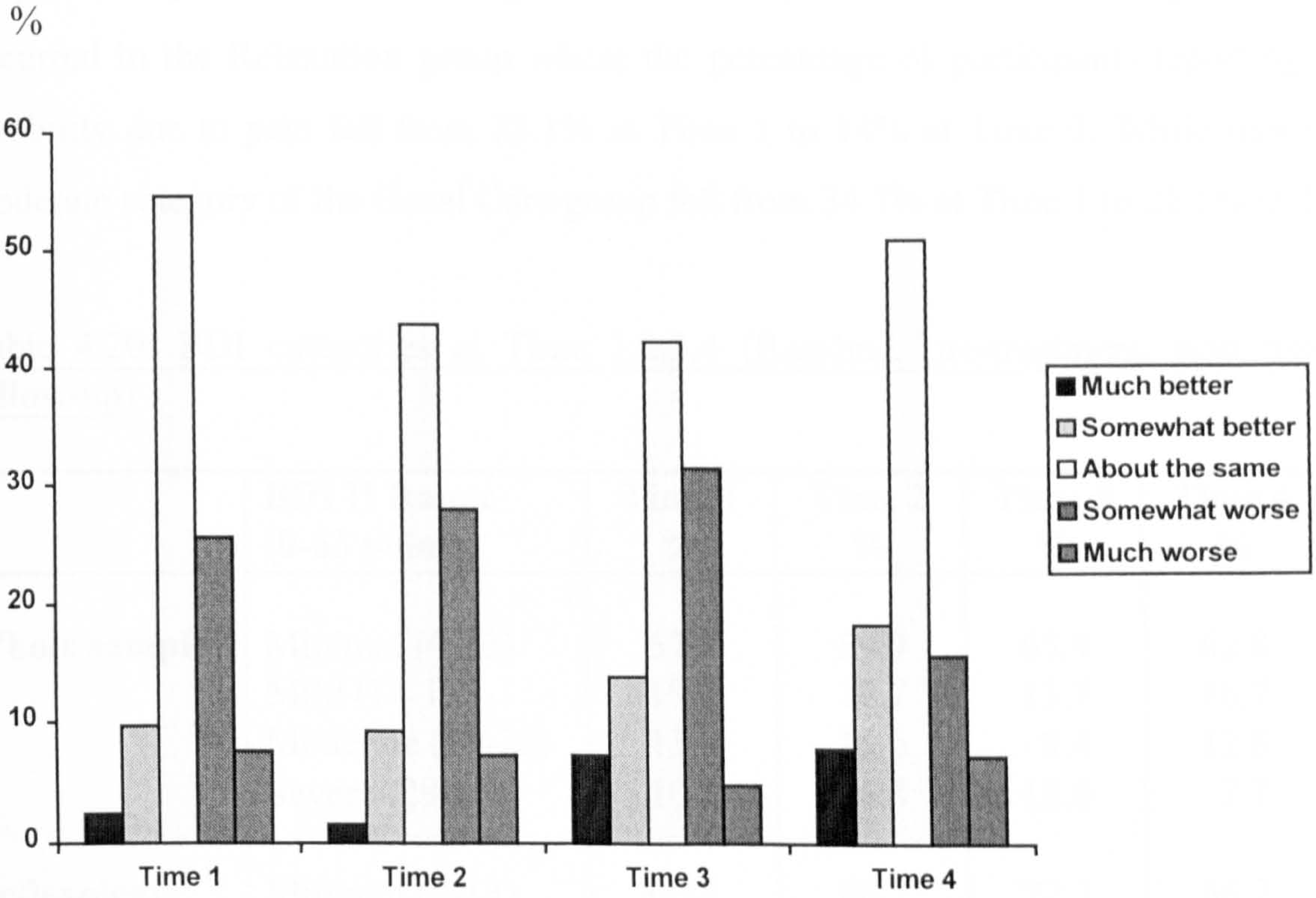


Figure 4.9: Percentage of the whole group in each category of the SF36 Change in Health dimension at Times 1, 2, 3 & 4

Categorical changes in depression and functioning

Time 1, 2, 3 & 4 means and standard deviation values for the BDI II and the ODQ are contained within tables 4.4, 4.5, 4.13 and 4.16. However in practice, categories are frequently utilised to describe patients on these measures. Tables 4.20 and 4.21 provide this information. They demonstrate that at Time 1, more than half of the sample (57.1%) were classified as minimally depressed with approximately one third (30.8%) reporting that they were minimally disabled by their pain.

The reflexology group experienced the greatest changes in BDI II scores over time, with those reporting moderately severe depression falling from 17.5% at Time 1 to 3.7% at Time 3. In addition the minimal category increased from 60.8% at Time 1 to 72.3% at Time 3. Furthermore the percentage of participants in the Usual Care group who reported mild depressive symptoms reduced from 28% at Time 1 to 15.9% at Time 3.

Changes in scores on the ODQ were less marked with the whole sample remaining proportionally similar in all categories at Time 1, 2 & 3. However the greatest change occurred in the Relaxation group where the percentage of participants reporting severe disability due to pain fell from 23.1% at Time 1 to 14% at Time 3. While those in the moderate category of the Usual Care group fell from 34.7% at Time 1 to 22.1% at Time 3.

Table 4.20: BDI categories at Time 1,2,3,4 (Baseline, pre-treatment, post treatment, follow-up)

	BDI II Range (0-63 points)	**Time 1 %**	**Time 2 %**	**Time 3 %**	**Time 4 %**
Whole sample	Minimal (0-13)	57.1	59.9	65.9	62.8
	Mild (14-19)	19.1	17.7	13.7	16.7
	Moderate (20-28)	13.0	15.6	8.4	12.8
	Severe (29-63)	10.8	6.8	12.0	7.7
Reflexology	Minimal (0-13)	60.8	66.7	72.3	66.7
	Mild (14-19)	14.9	15.9	13.2	17.5
	Moderate (20-28)	17.5	11.6	3.7	8.8
	Severe (29-63)	6.8	5.8	10.8	7.0
Relaxation	Minimal (0-13)	62.2	53.6	65.5	66.7
	Mild (14-19)	14.6	11.6	12.1	7.4
	Moderate (20-28)	9.8	18.8	10.3	14.8
	Severe (29-63)	13.4	8.7	12.1	11.1
Usual Care	Minimal (0-13)	48	59.3	56.8	53.3
	Mild (14-19)	28	18.5	15.9	26.7
	Moderate (20-28)	12	16.6	18.2	15.6
	Severe (29-63)	12	5.6	9.1	4.4

Table 4.21: ODQ categories at Time 1,2,3,4 (Baseline, pre-treatment, post treatment, follow-up)

	ODQ Range (0-100%)	Time 1 %	Time 2 %	Time 3 %	Time 4 %
Whole sample	Minimal (0-20)	30.8	34.5	34.9	39.7
	Moderate (21-40)	33.3	26.8	31.4	28.2
	Severe (41-60)	26.5	26.8	21.7	23.1
	Crippled (61-80)	9.0	10.9	11.4	8.4
	Exaggerating symptoms (80+)	0.4	1.0	0.6	0.6
Reflexology	Minimal (0-20)	31.2	34.8	38.5	45.6
	Moderate (21-40)	35	29.0	32.3	21.1
	Severe (41-60)	24.7	23.2	20.0	26.3
	Crippled (61-80)	9.1	11.6	9.2	7.0
	Exaggerating symptoms (80+)	0	1.4	0	0
Relaxation	Minimal (0-20)	36.6	38.6	33.3	40.7
	Moderate (21-40)	30.5	22.8	36.9	29.7
	Severe (41-60)	23.1	28.6	14.0	14.8
	Crippled (61-80)	8.6	8.6	14.0	12.9
	Exaggerating symptoms (80+)	1.2	1.4	1.8	1.9
Usual Care	Minimal (0-20)	24	29.1	38.1	31.1
	Moderate (21-40)	34.7	29.1	22.1	35.6
	Severe (41-60)	32	29.1	34.1	28.9
	Crippled (61-80)	9.3	7.0	11.4	4.4
	Exaggerating symptoms (80+)	0	0	0	0

4.1.15 Further Exploratory Analysis

Therapist effects

There was no effect of treatment on outcome. However, it was considered possible that some therapists may have been more effective than others. Thus, covariate analysis was employed in order to explore whether and to what extent individual therapists were effective. Both reflexology and relaxation treatment groups were considered together, as the therapists rather than the therapy were under scrutiny. Pre-treatment pain (SF36 Pain at Time 2) was the covariate, post treatment pain (SF36 Pain at Time 3) the dependent variable, and therapist the between subjects factor. Tables 4.22 and 4.23 below contain the results of this analysis. After controlling for pre-treatment level of pain, no significant differences in post-treatment levels of pain were found for participants treated by each therapist. Therefore it is apparent that no individual therapist was significantly more effective than the other therapists.

Table 4.22: Mean pre and post treatment SF36 Pain scores for participants treated by each therapist

Therapist	Mean (SD) SF36 Pain Pre-Treatment	Mean (SD) SF36 Pain Post-Treatment
1	34.95 (22.69)	46.81 (26.71)
2	44.93 (27.72)	40.52 (29.11)
3	56.57 (22.72)	60.49 (22.94)
4	51.85 (23.26)	58.02 (19.07)
5	43.16 (22.29)	44.44 (24.46)

Recall higher scores = less pain

Table 4.23: ANCOVA: Comparison of therapist and post-treatment pain, after controlling for pre-treatment pain.

Source	SS	Df	MS	F	Sig
		Between subjects			
Pre-treatment pain	18863.636	1	18863.636	39.218	.0005
Therapist	2090.243	4	522.561	1.086	.367
Error	52428.011	109	480.991		

Note: Total N=162 entered into analysis, for Means/SDs, see above table 4.22

Effects of group preference

Finally, it was apparent from the descriptive data in table 4.2 that many participants were not randomised to the group they had expressed a preference for at the Time 1 assessment. In order to explore the extent to which this may have had an effect on outcome, participants were re-categorised into two groups: those who got their preferred group and those who did not. Appendix 16 provides a table which demonstrates how participants were categorised.

Repeated measures ANOVA was used to evaluate whether there was a difference in outcome on the S36 Pain dimension, between those who got their preferred treatment and those who did not. The results of this test are shown in table 4.24 below. There was a main effect of pain reduction over time, but there was no interaction between pain and preference. Thus, whether participants group preference was satisfied or not, had no significant effect on outcome, as measured by the SF36 Pain dimension.

Table 4.24: Repeated measures ANOVA. Comparison of treatment preference and time variables. Dependent variable = SF36 Pain.

Source	SS	Df	MS	F	Sig
		Between subjects			
Preference	188.654	1	188.654	.152	.697
Error 1	193092.588	156	1237.773		
		Within subjects			
SF36 Pain	3933.464	1.918	2050.975	9.114	.0005
SF36 Pain* Preference	1089.270	1.918	567.964	2.524	.082
Error 2	67326.628	299.185	225.034		

Note: Greenhouse Geisser corrected results reported. Total N=158 entered into the analysis

Cross sectional analysis

Cross sectional analysis was completed to accomplish two main objectives. Firstly, as pain had been shown to reduce over time regardless of treatment group, multiple linear regression analysis was proposed as a means of exploring the relationship between pain at Time 3 and a number of variables measured taken at Time 1. This would enable the author to identify which, if any, psychosocial variables were predictive of outcome. Therefore Time 1 and Time 3 data were analysed to assess the levels of collinearity between the variables for use in multiple regression analysis.

Secondly, previous chapters have discussed the considerable literature which exists that describes the nature of the correlational relationship between pain and a number of other psychosocial factors. Preliminary analysis of Time 1 data (Poole et al., 2000) revealed the current sample demonstrate similar characteristics with regard to the association between these variables. In order to examine whether these relationships were maintained over time, in the context of mean reduction in pain throughout the whole sample, further correlational analysis was conducted on Time 2 data. This, in conjunction with the analysis completed above provided details of the relationships between the variables at Time 1, 2 & 3. Furthermore, as before, in order to reduce the likelihood of Type I error, $p = .0005$ was adopted as the significance level.

Tables 4.25 to 4.28 provide a summary of these results. A large number of significant associations are apparent, and consideration of all four tables indicates that these associations remain consistently significant at all four time points. Of particular note are the relationships between the Oswestry Disability Questionnaire (ODQ), the Beck Depression Inventory (BDI), the Catastrophising scale of the CSQ, pain and the subscales of the SF36. Functioning (ODQ) is positively correlated with depression, pain intensity, and the use of catastrophising as a coping mechanism and negatively correlated with all SF36 scales.

Table 4.25: Correlations (Pearsons *r*) between questionnaire scales at **Time 1** (N 229-234)

Scale	1	2	3	4	5	6	7	8	9	10	11
1 BDI II											
2 ODQ	.600*										
CSQ											
3 Catastrophising	.452*	.451									
4 Increased activity	.157	.139	.315*								
5 Praying Hoping	.200	.298*	.543*	.380*							
6 Ignoring sensations	-.111	-.130	-.101	.326*	-.020						
7 Diverting attention	.208	.222	.292*	.622*	.449*	.298*					
8 Coping self statements	-.122	-.080	.059	.438*	.145	.664*	.331*				
9 Reinterpreting pain sensation	.062	.020	.107	.351*	.169	.527*	.445*	.440*			
10 Control pain	-.246*	-.289*	-.297*	.097	-.032	.254*	.051	.240*	.097		
11 Decrease pain	-.135	-.217*	-.251*	.087	-.067	.094	.088	.079	.038	.519*	
SF36											
12 General Health Perception	-.542*	-.585*	-.353*	-.116	-.176	.164	-.189	.133	.016	.252*	.194
13 Pain	-.456*	-.746*	-.495*	-.104	-.288	.123	-.082	.039	.028	.299*	.250*
14 Physical functioning	-.475*	-.810*	-.394*	-.129	-.309*	.118	-.191	.072	-.022	.286*	.157
15 Energy/vitality	-.646*	-.591*	-.360*	-.135	-.197	.182	-.127	.090	-.013	.297*	.189
16 Social functioning	-.623*	-.721*	-.467*	-.111	-.311*	.211	-.198	.159	-.005	.344*	.207
17 Mental health		-.485*	-.411*	-.140	-.201	.172	-.138	.163	.017	.299*	.188
18 Role limitation (physical)	-.400*	-.567*	-.424*	-.146	-.255*	.108	-.172	.007	-.070	.168	.064
19 Role limitation (emotional)	-.540*	-.428*	-.252*	-.053	-.133	.208	-.087	.172	.072	.186	.019
20 VASA1	.364*	.551*	.291*	.164	.138	-.093	.095	-.066	-.012	-.191	-.236*
21 VASB1	.366*	.590*	.326*	.052	.226	-.130	.088	-.087	-.003	-.300*	-.226
22 Number of Social Supports	-.144	-.066	-.101	.058	-.069	.091	.003	.025	-.071	.062	.137
23 Satistfaction with Soc Supp	-.349*	-.224*	-.135	.161	.007	.098	.061	.192	-.010	.212*	.181

Scale	12	13	14	15	16	17	18	19	20	21	22
SF36											
12 General Health Perception											
13 Pain	.472*										
14 Physical functioning	.511*	.683*									
15 Energy/vitality	.556*	.493*	.530*								
16 Social functioning	.496*	.635*	.644*	.607*							
17 Mental health	.508*	.399*	.430*	.652*	.603*						
18 Role limitation (physical)	.387*	.611*	.571*	.345*	.552*	.269*					
19 Role limitation (emotional)	.316*	.340*	.416*	.437*	.599*	.316*	.373*				
20 VASA1	-.384*	-.581*	-.419*	-.388*	-.390*	-.299*	-.362*				
21 VASB1	-.345*	-.671*	-.516*	-.398*	-.512*	-.344*	-.429*				
22 Number of Social Supports	.155	.133	.013	.093	.095	.145	.078	.019	-.087	-.103	
23 Satisfaction with Soc Support	.273*	.124	.145	.178	.262*	.265*	.209*	.284*	.009	-.073	.208*

* correlation is significant at the 0.0005 level (2 tailed)

Table 4.23: Correlations (Pearsons *r*) between questionnaire scales at Time 2 (N181-191)

Scale	1	2	3	4	5	6	7	8	9	10	11
1 BDI II											
2 ODQ	.529*										
CSQ											
3 Catastrophising	.436*	.444*									
4 Increased activity	.047	.158	.212								
5 Praying Hoping	.130	.307*	.420*	.435*							
6 Ignoring sensations	-.224	-.318*	-.244	.233	.011						
7 Diverting attention											
8 Coping self statements	-.249	-.205	-.199	.347*	.123	.709*	.291*				
9 Reinterpreting pain sensation	-.013	.029	.024	.343*	.222	.583*		.516*			
10 Control pain	-.293*	-.392*	-.396*	.034	-.060	.348*	.178*	.139	.164		
11 Decrease pain	-.136	-.342*	-.356*	.141	-.065	.224	.143	.113	.080	.597*	
SF36											
12 General Health Perception	-.527*	-.639*	-.483*	-.136	-.224	.299*	-.063	.246	.087	.311*	.165
13 Pain	-.425*	-.733*	-.495*	-.177	-.295*	.293*	-.095	.157	.017	.416*	.356*
14 Physical functioning	-.430*	-.852*	-.433*	-.164	-.250	.275*	-.167	.171	-.017	.331*	.287*
15 Energy/vitality	-.625*	-.587*	-.387*	-.192	-.182	.245	-.161	.167	.061	.348*	.187
16 Social functioning	-.653*	-.727*	-.429*	-.156	-.215*	.263*	-.239	.234	.023	.330*	.261*
17 Mental health	-.725*	-.459*	-.405*	-.075	-.182	.253*	-.166	.238	.054	.283*	.179
18 Role limitation (physical)	-.342*	-.642*	-.448*	-.193	-.253	.159	-.179	.101	-.066	.295*	.245*
19 Role limitation (emotional)	-.610*	-.561*	-.380*	-.133	-.210	.189	-.187	.269*	-.040	.195*	.171
20 VASA1	.352*	14*	.407*	.146	.257*	-.089	.155	-.051	-.007	-.266*	-.313*
21 VASB1	.347*	.618*	.450*	.097	.240	-.143	.090	-.089	-.024	-.372*	-.391*
22 Number of Social Supports	-.232*	-.137	-.125	.023	-.005	.089	-.042	.116	-.031	.054	.057
23 Satisfaction with Soc Supp	-.304*	-.207*	-.026	.051	.116	.128	.024	.187	.019	.097	.097

Scale	12	13	14	15	16	17	18	19	20	21	22
SF36											
12 General Health Perception											
13 Pain	.597*										
14 Physical functioning	.587*	.661*									
15 Energy/vitality	.644*	.502*	.603*								
16 Social functioning	.531*	.596*	.696*	.698*							
17 Mental health	.454*	.400*	.426*	.620*	.602*						
18 Role limitation (physical)	.527*	.722*	.699*	.481*	.563*	.321*					
19 Role limitation (emotional)	.446*	.480*	.482*	.530*	.646*	.597*	.475*				
20 VASA1	-.482*	-.653*	-.527*	-.364*	-.484*	-.327*	-.487*	-.404*			
21 VASB1	-.496*	-.732*	-.559*	-.371*	-.495*	-.300*	-.542*	-.386*	.829*		
22 Number of Social Supports	.182	.133	.145	.226*	.201*	.237*	.127	.228*	-.206	-.103	
23 Satisfaction with Soc Support	.162	.139	.238*	.156	.226*	.282*	.207*	.309*	-.002	-.032	.282*

*correlation is significant at the 0.0005 level (2 tailed)

Table 4.27: Correlations (Pearsons *r*) between questionnaire scales at Time 3 (N 154-163)

Scale	1	2	3	4	5	6	7	8	9	10	11
1 BDI II											
2 ODQ	.631*										
CSQ											
3 Catastrophising	.597*	.580*									
4 Increased activity	.140	.181	.285*								
5 Praying Hoping	.149	.276	.432*	.528*							
6 Ignoring sensations	-.113	-.232	-.207	.152	-.026						
7 Diverting attention	.149	.247	.235	.720*	.503**	.323*					
8 Coping self statements	-.141	-.122	-.084	.344*	.218	.675*	.354*				
9 Reinterpreting pain sensation	.068	.046	.108	.427*	.235	.583*	.581*	.483*			
10 Control pain	-.220	-.399*	-.298*	-.073	-.172	.260	.023	.163	.037		
11 Decrease pain	-.262	-.406*	-.273*	-.032	-.032	.150	-.063	.117	-.022	.631*	
SF36											
12 General Health Perception	-.595*	-.714*	-.582*	-.056	-.116	.259	-.087	.151	.042	.240	.246*
13 Pain	-.461*	-.785*	-.518*	-.192	-.303*	.175	-.197	.019	-.026	.319*	.307*
14 Physical functioning	-.423*	-.781*	-.517*	-.140	-.322*	.309*	-.171	.183	-.008	.333*	.361*
15 Energy/vitality	-.658*	-.678*	-.472*	.011	-.170	.256	-.010	.211	-.017	.411*	.456*
16 Social functioning	-.607*	-.737*	-.527*	-.122	-.209	.204	-.188	.179	-.014	.435*	.436*
17 Mental health	-.693*	-.506*	-.540*	-.099	-.120	.152	-.117	.220	-.011	.304*	.346*
18 Role limitation (physical)	-.437*	-.670*	-.448*	-.104	-.176	.204	-.177	.101	-.052	.282*	.270
19 Role limitation (emotional)	-.581*	-.532*	-.462*	-.091	-.121	.100	-.109	.177	-.086	.310*	.340*
20 VASA1	.452*	.667*	.447*	.121	.200	-.137	.108	-.045	-.040	-.374*	-.336*
21 VASB1	.451*	.698*	.509*	.104	.216	-.174	.076	-.064	-.080	-.346*	-.316*
22 Number of Social Supports	-.248*	-.193	-.122	.071	-.009	.106	.023	.068	.047	.191	.181
23 Satisfaction with Soc Support	-.290*	-.137	-.169	.083	.172	.157	.130	.168	.049	.091	.145

Scale	12	13	14	15	16	17	18	19	20	21	22
SF36											
12 General Health Perception											
13 Pain	.663*										
14 Physical functioning	.560*	.675*									
15 Energy/vitality	.649*	.599*	.548*								
16 Social functioning	.607*	.679*	.619*	.690*							
17 Mental health	.466*	.453*	.318*	.665*	.647*						
18 Role limitation (physical)	.622*	.662*	.594*	.563*	.678*	.307*					
19 Role limitation (emotional)	.458*	.436*	.408*	.539*	.620*	.664*	.451*				
20 VASA1	-.586*	-.696*	-.536*	-.523*	-.550*	-.367*	-.500*	-.500*			
21 VASB1	-.599*	-.785*	-.602*	-.532*	-.607*	-.430*	-.568*	-.467*	.892*		
22 Number of Social Supports	.257*	.330*	.128	.246*	.214	.255*	.235*	.200	-.212	-.208	
23 Satisfaction with Soc Support	.213	.159	.135	.261*	.257*	.334*	.163	.242*	-.076	-.149	.322*

* correlation is significant at the 0.0005 level (2 tailed)

Table 4.28: Correlations (Pearsons *r)* between questionnaire scales at **Time 4** (N 147-156)

Scale	1	2	3	4	5	6	7	8	9	10	11
1 BDI II											
2 ODQ	.640*										
CSQ											
3 Catastrophising	.637*	.610*									
4 Increased activity	.018	.157	.337*								
5 Praying Hoping	.229*	.286*	.468*	.447*							
6 Ignoring sensations	-.164	-.224*	-.211	.223*	.002						
7 Diverting attention	.187	.316*	.364*	.722*	.485*	.259*					
8 Coping self statements	-.149	-.131	-.042	.411*	.215*	.774*	.336*				
9 Reinterpreting pain sensation	.053	.052	.120	.454*	.244*	.511*	.540*	.500*			
10 Control pain	-.298*	-.444*	-.373*	.079	-.115	.307*	-.002	.207	.110		
11 Decrease pain	-.255*	-.374*	-.406*	-.061*	-.166	.120	-.053	-.035	.036	.574*	
SF36											
12 General Health Perception	-.647	-.720*	-.577*	-.118	-.274*	.185	-.202	.129	.015	.392*	.306*
13 Pain	-.480*	-.766*	-.551*	-.082	-.253*	.217*	-.225*	.068	.080	.439*	.365*
14 Physical functioning	-.583*	-.890*	-.556*	-.115	-.281*	.256*	-.259*	.186	-.017	.384*	.295*
15 Energy/vitality	-.690*	-.719*	-.510*	-.009	-.166*	.224*	-.103	.193	.029	.392*	.349*
16 Social functioning	-.695*	-.793*	-.600*	-.080	-.299*	.214*	-.201*	.173	.010	.474*	.379*
17 Mental health	-.792*	-.620*	-.650*	-.001	-.240*	.196	-.129	.190	.038	.336*	.290*
18 Role limitation (physical)	-.489*	-.680*	-.517*	-.131	-.223*	.195	-.252*	.116	-.043	.421*	.291*
19 Role limitation (emotional)	-.648*	-.594	-.531*	-.061	-.287*	.153	-.171	.107	-.095	.381*	.245*
20 VASA1	.424*	.637*	.544*	.129	.275*	-.148	.259*	-.052	.070	-.354*	-.315*
21 VASB1	.482*	.684*	.548*	.100	.266*	-.111	.213	-.015	.030	-.334*	-.288*
22 Number of Social Supports	-.158	-.131	-.256*	.014	-.003	.078	-.056	.086	.076	.197	.037
23 Satisfaction with Soc Supp	-.209	.054	-.126	.169	.200	.043	.048	.178	.006	.118	.248*

Scale	12	13	14	15	16	17	18	19	20	21	22
SF36											
12 General Health Perception											
13 Pain	.685*										
14 Physical functioning	.665*	.744*									
15 Energy/vitality	.743*	.650*	.688*								
16 Social functioning	.729*	.705*	.750*	.759*							
17 Mental health	.676*	.522*	.576*	.753*	.726*						
18 Role limitation (physical)	.604*	.692*	.701*	.607*	.637*	.461*					
19 Role limitation (emotional)	.580*	.492*	.595*	.613*	.690*	.687*	.632*				
20 VASA1	-.508*	-.717*	-.590*	-.519*	-.580*	-.429*	-.577*	-.451*			
21 VASB1	-.559*	-.768*	-.627*	-.578*	-.650*	-.499*	-.577*	-.486*	.872*		
22 Number of Social Support	.138	.163	.058	.189	.184	.247*	.075	.224*	-.215*	-.198	
23 Satisfaction with Soc Supp	.243*	.017	.068	.190	.124	.355*	.065	.168	-.015	.017	.343*

* correlation is significant at the 0.0005 level (2 tailed)

Multiple linear regression

Multiple linear regression was conducted to explore the relationship between pain at Time 3 and a number of variables measured at Time 1. The correlational relationship between depression (BDI), catastrophising (CSQ), Pain (SF36P), disability (ODQ) in this sample has already been highlighted, and confirms previous research findings. In addition, it was hypothesised that satisfaction with social support and duration of pain may be related to outcome at Time 3, thus they too were included in the equation.

The initial analysis considered the effect of six predictor variables (SF36 Pain, ODQ, BDI, CSQ Catastrophising, SSSQ6 at Time 1, along with duration of pain) on Pain at Time 3. Using the stepwise method (*p* to enter <.050) two significant models emerged.

Model 1 ($F_{(1, 144)} = 122.58, p < .0005$). Adjusted R square = .495. Significant variables are shown below.

Predictor Variable	**Beta**	***p***
ODQ	-.707	.0005

BDI, CSQ Catastrophising, SSSQ, duration of pain and SF36 Pain at Time 1 were not significant predictors in this model.

Model 2 ($F_{(2, 143)} = 65.35$, $p < .0005$). Adjusted R square = .509. Significant variables are shown below.

Predictor Variable	**Beta**	***p***
ODQ	-.565	.0005
SF36 Pain at Time 1	.195	.0005

BDI & CSQ Catastrophising, SSSQ6 and duration of pain were not significant predictors in this model.

Note: N=128 were entered into the analyses. Details of the means/SDs for each of the variables can be found in tables 4.4 (Time 1) and 4.13 (Time 3).

It can be seen that functioning at Time 1 as measured by the ODQ explains around 50% of the variance in reported levels of pain at Time 3 (SF36 Pain). Furthermore while pain at Time 1 was entered into model 2, it is apparent that the amount of additional variance it explained was relatively insignificant (1.4%).

4.1.16 Summary of quantitative results

N=243 patients with CLBP consented to participate in the study. Nine withdrew before the treatment phase began, resulting in the following numbers per groups: reflexology (n=77), relaxation (n=82) and usual care (n=75).

The remaining 234 participants were 60% female with a mean age of 46.68 (SD10.93) years, and a mean duration of pain of 121.39 (SD108.29) months.

Analysis of the pre-treatment data did not reveal any significant differences between the groups at either Time 1 or Time 2. In addition, with the exception of VAS current pain intensity, there were no differences between Time 1 and Time 2 on any of the questionnaire variables. The mean level of current pain intensity increased from 36.91mm (SD26.01mm) at Time 1 to 45.06mm (SD26.29mm) at Time 2.

Pre-post treatment analysis of the primary outcome variables: Pain as measured by the SF36 and Functioning assessed by the ODQ revealed no effect of treatment group on functioning or pain. However, while there was no main effect of functioning over time, SF36 Pain did reduce throughout the duration of the study independently of treatment group. Furthermore it was noted that this reduction in pain was greatest in the reflexology group, though as stated this was not significantly greater than the reduction in the other two groups.

There was a number of main effects concerning some of the secondary outcome variables. These were SF36 Mental Health, SF36 Physical Functioning, SF36 Social Functioning, SF36 Role Limitations due to physical factors and pain measured by the visual analogue scales. In addition there was a significant interaction between SF36 General Health Perception and treatment group, with the usual care group reporting greater general health than the other two groups. However, while this was statistically significant, it represented only small changes in SF36 GHP scores, and was not considered indicative of a clinically significant differences between groups.

There was a significant increase in the use of reinterpreting the pain sensation as a coping strategy across all groups, but no significant increase or decrease in the use of any other coping strategy.

The remaining secondary outcome variables (BDI II, SSSQ6) did not vary significantly before and after the treatment phase. That is, there were no significant differences in the mean intensity or number of symptoms of depression reported by all patients at each time point. In addition, participants reported similar levels of satisfaction with social support and mean numbers of social supports throughout the study. Furthermore, the number of GP visits and reported levels of medication use did not differ between groups before or after the treatment phase.

The SF36 Change in Health dimension is descriptive, and revealed that less participants considered their health to be worse or somewhat worse than a month ago at Time 4 than did at Time 1.

The levels of attrition were high and varied dependent upon group. However comparison of the Time 1 data from those who completed the study and those who did not revealed two differences between them. Those who complied with completion of the questionnaires more likely to have used CM before and be older than those who did not.

Correlational analysis of the questionnaire data at each time point confirmed a number of previously reported relationships. In particular, high rates of depression were associated with increased pain, reduced function and the use of catastrophising as a coping strategy.

Finally, further exploratory analysis revealed that the best predictor of pain, as measured by the SF36, at Time 3 was the ODQ functioning score at Time 1.

A detailed examination of the implications of these results can be found in chapter five, section 5.1.

4.2 Interview One Results

4.2.1 Participant views of CM at recruitment

As previously stated, the semi-structured interview which took place at recruitment (Time 1) was designed to find out about participants previous and current treatment regimes, CM use, and whether they had a preference for a particular treatment group within the study (see appendix 5 for a copy of the schedule). Details of the types of treatment and preferences reported can be found in table 4.2. In addition the interview asked specific questions regarding participants reasons for using or not using CM therapies previously. Responses to these questions were considered using thematic analysis, and the results are presented in this section.

The analysis revealed a number of dominant themes that were dependent upon participants' previous experiences of CM. Thus the sample were categorised into two groups: 119 who had used CM previously (50.9%) and 115 who had not (49.1%).

4.2.2 Users of CM

4.2.3 Reasons for use

When those who had used some form of CM previously were asked why they had opted for a particular therapy, a variety of reasons were reported. These included recommendation by a friend or family member (47.9%), recommendation by their GP (21%), or because of information about CM in the media (9.2%). In addition, other reasons pertaining to conventional care were reported by some participants. 14.3% said they were dissatisfied with conventional care, 9.2% were willing to try anything, and 11.6% suggested that lack of conventional care had led them to seek alternatives. Furthermore 4.2% were attracted to CM because it did not involve taking medication.

The most dominant reasons were that CM had been recommended by someone else. These recommendations were based on personal or vicarious experience of the therapy itself, or of a professional nature. For 47.9% of participants, a family member, friend or colleague had recommended a particular treatment. This person had either had a positive outcome to the treatment itself or knew someone who had.

'...recommended by my mother in law at the time, who had been to see him'
'Chap I play golf with gave me the number of one in Southport and said he was good, he'd sorted him out when he had sciatica'

In addition, 21% of previous users indicated that it was their GP who had recommended or suggested treatment by a CM therapist for their back pain problem. In each of these instances, the therapy was osteopathy, chiropractic or acupuncture. As there is more research data on these treatments for pain than most other CM therapies, this is perhaps to be expected. However it is not possible to hypothesise about the reasons for GPs endorsing these particular therapies, and it has to be accepted that their recommendations may have a similar basis to those of friends, family and colleagues.

'I had acupuncture, My husband was in BUPA at that time and I had a health check, the doctor recommended acupuncture'

'The doctor suggested I give the osteopath a go, it's expensive but worthwhile'

A further 9.2% of participants said that their choice of therapy was based upon information they had acquired through media coverage of CM. Of these 4.2 % went on to select a CM therapist, at random, from the telephone directory.

'While I was waiting for physiotherapy appointment I read an article in Runners World and 'phoned the Association of Chiropractors who recommended a local practitioner'

'when I saw the doctor and he said it could be sciatica, I looked for one in the 'phone book (osteopath), the handiest one. He was very good, in fact I've recommended him to several people since and they've agreed'

Participants who expressed a reason for using CM therapy primarily cited a sense of dissatisfaction with the efficacy of conventional treatment for their pain problem as the main factor influencing their decision (14.3%). Indeed some spoke of becoming so desperate they were willing to try anything (9.2%).

'...rest and ibuprofen not working so tried chiropractor'

'I was getting desperate, so I went to see a local chap, one that everyone went to...it helped'

In addition, 4.2% referred to the fact that CM did not involve taking pills etc. These participants seemed to be attracted to the more 'natural' ways of healing associated with CM.

'There must be something better than taking chemicals all the time'

'I don't like taking tablets really, well I know what taking things can do for you... like my chest'

However 11.6% suggested that it was not the inefficacy of conventional treatment but rather the lack of it which led them to seek alternatives. They simply felt that their GP was not doing enough.

'I was getting nowhere with the doctor, so sought my own alternatives...'

'It's been that bad that I haven't been able to walk, and I just felt I wasn't getting anywhere at all with the doctor' (participant who went to osteopath)

Efficacy of CM

When asked how effective they found the CM therapy they had used, participants responded in one of three ways: ineffective (29.4%), effective (39.5%) or effective for a very short time after the treatments (30.2%).

'nope, that didn't work' (acupuncture)

'only worked as long as I kept it up. At first he said he would see me for eight sessions then I would probably be able to come once a month, but I found when I left a longer time between sessions the pain got just as bad again'

'The physio couldn't help much, my back was rigid, so she suggested a holistic therapies clinic... I saw someone who used Bowan technique... had two treatments in ten days and that was that, the pain was greatly reduced, I had a couple more, and nothing more for six months... It was very beneficial'

'Must admit it was 100% better, I was fine' (after acupuncture)

'See chiropractor on a sort of three month maintenance scheme now, keeps me pain free, well relatively compared to worst pain'

'Went to osteopath, it was more painful at first but then I got some benefit, nothing long term though'

4.2.4 Reasons for discontinued use of CM

Only 13.4% of participants were still using some form of CM therapy when interviewed. The remainder had ceased to use CM for a variety of reasons, these included cost; inefficacy; therapist discontinuing treatment or the negative effects of treatment.

Cost

The most frequently cited reason for discontinued use was cost. This was a factor for 35.3% of participants, who simply could not afford to continue self funding the treatment, despite some of them finding it to be helpful.

'it was great, she used oils and a heat lamp. It seemed all right at the time, very relaxing and the heat felt good... I couldn't afford to continue the treatments at £25 to £30 a time'

Inefficacy

Others did not want to continue paying for treatment that did not appear to be effective. Indeed, 13.4% of participants stopped seeing their CM therapist because the treatment did not work.

'I saw a chiropractor, spent £150 on treatment, I went four or five times but it wasn't getting better... so I stopped going'

Interestingly this is not as many as those who reported that the treatment was ineffective. This indicates that some participants continued with treatment despite the lack of effect it had on their CLBP. However as participants were asked specifically whether they found the treatment effective for their back pain, it may be that those who continued with treatment were experiencing other benefits from it, which were not expanded upon in the context of the interview.

In addition, 10.1% of participants reported that the therapy appeared to cease being effective, whereas initially it had seemed to help them, and this prompted them to discontinue treatment. In these instances some participants spoke about not wanting to waste money on treatment for little or no further benefit.

'the sessions were nice, relaxing but there was no long lasting change and I began to wonder whether it was worth the money. It was expensive, around £30 for half hour session'

'I was in that much pain, I'd have gone anywhere really. It worked at first then stopped... went about seven times, stopped going when it stopped working.

Furthermore seven participants revealed that, a significant improvement in their condition meant they no longer felt the need to attend CM. However it is not clear whether this improvement was due to the treatment itself, or a consequence of the natural variability of the condition.

Therapist discontinued treatment

The simple reason for some (5%) discontinuing with CM was that they had come to the end of a course of treatment provided on the NHS, and did not have the option to continue. Whilst four participants reported that the therapist they were consulting privately, discharged them saying that they could do nothing more to help. In two of these cases the participant found this to be an encouraging sign of honesty from the therapist, who they felt recognised the limits of their own abilities.

'I saw an osteopath about seven or eight times, but then he said he couldn't do much more for me so I stopped going'

Negative effects

Finally five participants explained that a negative experience of treatment, in terms of the discomfort it caused, had led them to discontinue CM therapy. Each of these instances concerned a manipulative therapy. However it must be remembered that these types of therapies were also the most commonly utilised by participants, and this may account for the high incidence of negative effects reported by the current sample.

'Went to osteopath, once. One of worse things I've ever done. He was lethal, gruesome... made my nerves jangle. I never went back'

'A client recommended an osteopath to me who did home visits, ... it killed me, two hours later I still couldn't move. I wouldn't go to that guy again'

It is argued that such experiences could deter an individual from accepting further CM treatment. However, reflexology and relaxation do not involve manipulation of the spine by the therapist, and it is perhaps this aspect of treatment that attracted those particular participants to the study.

4.2.5 Non users of CM

4.2.6 Reasons for non-use of CM

Participants (n=115) who had not previously used CM were asked whether there was any particular reason this. The majority of participants (45.2%) reported that they had no particular reason for not using it or that they simply had not considered it. This is interesting in the context of this study, and suggests that it was the invitation to take part and possibly receive some additional treatment for their back pain which attracted these participants, as opposed to any intrinsic desire to try a CM therapy.

Cost

For those who actively expressed an interest in using CM, financial factors were the main barrier for not pursuing it. This was the case for 29.6% of participants who could not afford to consult a therapist privately.

> *'cost, to put it bluntly. We're both on income support'*

> *'not that I don't want to, some friends have recommended I give it a go, but it's down to money. The cost really'*

Efficacy

For others financial issues were more complex and related to issues of efficacy. 7.8% of participants were more concerned that they may be wasting their money on 'unproven treatments.

'well to be honest I didn't like to pay for something that might not work'

'I 'phoned around a couple of places, but it was terribly expensive. The cheapest I found was £20 a session, then you think - is it worth paying all that money when you don't know whether it'll work'

The issue of efficacy per se, unrelated to cost, was also a factor in the decision not to use CM for some (9.6%).

'didn't know whether they worked or not'

'never been advised on it, or told they'd be any good for you or anything to be honest'

'Doesn't ring true to me, that they'd work, maybe the effects are psychological?'

Lack of knowledge

Related to this was a lack of knowledge or information about CM therapies. This was the reason 15.7% of participants had not utilised them. This lack of knowledge about therapies encompassed more than just information on efficacy. It included knowledge about what treatment entailed, as well as details of the therapists, their training and how to access them.

'haven't considered it because don't know anything about it really'

'well it's knowing how to use them isn't it? I wouldn't know where to start, there's nowhere really to get info about them. You hear about them, but nothing firm, other than word of mouth RXN*'*

'I probably would like to know more about them before I went down that road'

In addition 7.8% said that they had thought about CM and would have liked to try a particular treatment, but did not know how to access it locally.

'thought of it, but wouldn't know how you go about seeing these people'

'I don't know if they have things like acupuncture in Warrington'

While others (7.8%) demonstrated the fear and resultant inaction that lack of knowledge can lead to. These fears pertained to 'unscrupulous' practitioners; and the idea of consulting someone other than their GP about their back pain.

> *'I wanted to try acupuncture, but I didn't know where to go, and you have to be careful nowadays, you wouldn't want someone who didn't know what they were doing sticking needles into you.'*
>
> *'just haven't ventured to use it, you've got to know what you're doing, it has to be done right'*
>
> *'been frightened of making it worse or doing the wrong thing'*

Passive approach to health care

A number of participants displayed a 'passive' approach to their health care, demonstrating a predominant external locus of control with regard to their back pain problem. Suggesting that the reason they had not used CM is because no one had told them to. This was the case for 14.8%.

'never been asked to'

'...I've just had what doctor gave me'

'the doctor has never mentioned anything like that'

However the alternative hypothesis is that participants display great faith in conventional medicine to manage their back pain, so perceive little or no utility in CM, indeed eight people said that this was the case.

'just thought the doctor could get me right. I always just see the doctor if I'm not well'

'Dr X is very good, very understanding'

'...just went to the doctors, I suppose it's like blinkers where everything else is concerned, all I know is I go and see the doctor, the specialist... then it's OK'

Two participants said they would only use CM if their doctor recommended it. So similarly displaying faith in doctors ability to know what is right for them rather than taking control of their own health.

'Other than being recommended someone by the doctor, I'd be too scared to go to someone I didn't know'

'I wouldn't go to just anyone but if recommended by GP I would try it'

Advice from GP

In contrast, 3.5% of participants said their doctor was the reason they had not used CM. Indeed they had considered it and asked their GP's opinion, only to be told that for their particular problem, consulting a CM therapist would be a waste of time and/or money, and that they had to learn to live with their pain.

'Basically just listening to doctor, saying just learn to live with it, I'd be wasting my time and money'

'I 'phoned the doctor to ask him if it was all right to take it (a herbal remedy) *and he said with the tablets I was taking it would be like having a piddle in the middle of the Atlantic ocean, that is you'd probably not notice the difference, a waste of money, but it wouldn't do you any harm'*

4.2.7 Summary

As these results demonstrate approximately half of the participants had used CM before taking part in the current study. In addition, a large number of those who had not used CM expressed an interest in doing so. However for many the cost of treatment prevented this. Similarly, of those who consulted CM therapists, cost was cited as one of the main reasons for them ceasing to attend.

Another big issue which concerned participants was that of efficacy. There were reports of inefficacy from users of CM, and a number suggested that this was a reason for no longer attending treatment sessions. Similarly non-users were interested in knowing whether a particular therapy worked or not before trying it.

A factor which appeared to address the issue of effectiveness to some degree was a recommendation from a person that the participant trusted. In many instances participants recounted how someone they knew said that the treatment worked, or that the doctor had recommended it. The implication here being that the doctor would not advocate CM unless it was likely to be helpful. Similarly a small number of those who had not used CM, said that they would if the doctor recommended it. Furthermore it is suggested that this reliance on a health professional's opinion of what is or isn't effective, was implicit for those who displayed a passive approach to health care and said they had not used CM because they had never been asked to.

In contrast, there were some non-users of CM who admitted that their own lack of knowledge about the therapies available therapies, or where to access them, was the reason for not pursuing them.

Thus it is apparent that participants' decisions to either use or not use CM are influenced by many common factors. It is suggested that these may be similar to those used by individuals to make decisions about engaging in conventional health care treatments or other healthy behaviours. This notion will be further explored within the discussion chapter.

4.3 Interview Two Results

4.3.1 Participants

The characteristics of the sample as a whole are presented in table 4.29, along with comparative figures for each group. It is apparent that while the groups were broadly similar in most respects, a greater proportion of those in the relaxation group had used CM previously compared to those in the reflexology group.

Details of participants' scores on the two primary outcome variables utilised in the main study (SF36 Pain and ODQ) are presented in Table 4.30 along with scores of the whole sample for comparison. Statistical analysis was not performed, as the groups were not independent. However, consideration of this data revealed they were broadly similar, as the mean scores of the sub-sample were not greater that one standard deviation different than the whole sample. However it was noted that mean scores for the sub-sample were indicative of marginally more pain and lower functioning than the whole group. Statistical analysis on this data was not possible

Table 4.29: Characteristics of participants who were interviewed

	Reflexology (n = 12)	Relaxation (n = 10)	Whole Group (n = 22)
Age Mean (SD) years	51.41 (8.96)	50.60 (8.40)	51.01 (8.68)
Chronicity of back pain Mean (SD)months	152.73 (139.74)	166.10 (156.15)	159.42 (147.95)
Male	2	3	5
Female	10	7	17
Used CM previously	3	9	12
Not used CM Previously	9	1	10
Referral method to main study			
GP invite letter	10	7	17
Poster	1	3	4
GP direct referral	1	0	1
Treatment preference			
Reflexology	5	7	12
Relaxation	0	2	2
Reflexology or Relaxation	3	0	3
No Preference	4	1	5

Table 4.30: Sub-sample scores (mean/SD) on the primary outcome measures at Time 1, 2, & 3 along with comparative scores for the whole group.

Outcome		Whole group (N=234)		Interview 2 sub-sample n=22)	
		Mean	SD	Mean	SD
Time 1	SF36 Pain	39.98	22.32	34.34	20.26
	ODQ	34.20	18.62	40.86	16.40
Time 2	SF36 Pain	43.10	24.41	35.85	19.68
	ODQ	33.26	19.33	38.64	15.98
Time 3	SF36 Pain	46.91	25.95	40.91	21.52
	ODQ	32.87	20.47	37.50	21.84

4.3.2 Results

Participants were generally very positive about the treatment they had received and expressed satisfaction with it, even in the absence of any long lasting effects. Their views on the experience of treatment did not differ significantly dependent upon the type of therapy received. Thus this section presents the six major themes that emerged from analysis of all the interview data, i.e. from both reflexology and relaxation groups. The six themes were: therapist/therapeutic relationship; role of self; effects; explanatory models; environmental factors; and future use. Please note that participants' names coded to preserve their anonymity and guarantee confidentiality. Each has been given the prefix RFY (reflexology) or RXN (relaxation) to indicate the treatment they received, followed by their interview number (001-022).

In addition to the aforementioned themes, analysis of the interview data revealed that three of the ten participants in the relaxation group had expressed disappointment at not being randomised to the reflexology group. While it was apparent that this theme was not common to both groups, or one expressed by the majority of the relaxation group, it was considered pertinent within the context of the pragmatic RCT methodology adopted in the main study. Therefore these instances are reported at the end of the results section, after the six themes have been presented.

4.3.3 Therapist/therapeutic relationship

This was the most dominant theme throughout all the interviews. Indeed, participants referred to the therapist more than the actual physical experience of having the treatment when asked about the sessions. It was difficult to separate discourse regarding the therapist from that concerning the nature of the relationship between therapist and participant. The personal qualities of the therapist were generally described within the context of that relationship, so both aspects are contained within this theme. Participants all spoke of the therapists themselves in warm and affectionate terms.

'Yeah well she's really nice and bubbly and talk to anybody and I think that helps, she makes you feel relaxed and she's not abrupt or anything' (RFY013)

'... I really enjoyed the relaxation and I found C [therapist] very pleasant, she's lovely to talk to and we got on very well.' (RXN001)

Other participants were pleased to find that because of small numbers at some GP's surgeries, the relaxation therapy they received was given on an individual basis, and they felt that this further facilitated the development of the relationship between the therapist and themselves.

'And I was quite pleased it was one to one, it was more personal, and she is lovely she really is, she really relaxes me you know' (RXN004)

Participant RXN004 expanded this to describe how the interpersonal qualities of the therapist further enhanced this. In particular, RXN004 felt that the therapists own experience of back pain allowed her to demonstrate empathy and understanding, which enabled her to be more open and responsive to the treatment.

'I think she understands because she suffers as well, she's a sufferer isn't she? which made it easier for me to talk to her rather than someone who doesn't suffer because I think that unless someone suffers with their back and they know, they have no idea, absolutely no idea what you're talking about. I mean everyone can say, oh yeah bad back, but unless you've suffered badly I don't think you've got any idea what it's like'

Participants also made comparisons between the therapist and their experience with other practitioners, such as their GP. They spoke of feeling valued, treated as a person and being active in the process of treatment, as opposed to the passive recipients of prescriptive medicine. It was apparent for many, that these sort of factors were viewed as integral components of a more holistic style of therapy, and therefore not the sort of thing you would necessarily expect from OM treatments.

'It was all just part and parcel of it, I enjoyed the relaxation and I enjoyed talking to someone that understands, I mean you go to the doctor and he goes oh well take the tablets, the best he's done for me is that, he's not like X (the therapist) '(RXN005)

'But yes, I mean, it wasn't just come in, oh hello Mrs X, sit down, lets do it.. it was, we were quite chatty and it was quite enjoyable.' (RXN002)

These examples also illustrate how participants were comfortable with the egalitarian relationship the therapists offered. The following account provides an example of how participants found the equality within the relationship advantageous. They were empowered to talk more fully about their condition, and seek out or utilise information as they deemed appropriate. In this instance RFY014 recounts how the luxury of time facilitated these positive aspects of the therapeutic relationship which in her view are more important than the physical features of the reflexology treatment. This view was echoed by many, and demonstrates an implicit perception that the limited contact time of most appointments in primary care hinders the development of this type of relationship.

'Right well, erm I think first off I found it useful in that it was, not particularly the physical treatment, but it was useful to talk to someone who was knowledgeable but objective about things. Erm the doctor doesn't have the time and you wouldn't dream of talking to the doctor in such a relaxed situation anyway and I found that quite beneficial even though what she said might not have applied to me or I might not have found that I wanted to actually heed her advice I did like the idea of talking, I suppose it's a bit indulgent really' (RFY014)

A key feature of many accounts were descriptions of the therapists differential roles within the context of the treatment. Therapists were seen not only as providing procedural information about the practical and physical aspects of treatment, but also support and encouragement for the participant.

'...I found it very difficult on the first session to actually [relax]... I did say this to her and we had quite a laugh about it. And she said ...you can't just relax like that, you have to learn and be taught how to do it. It's a very difficult thing to do' (RXN006)

This is not only therapist as teacher, implicit is reassurance and a recognition that participant RXN006 won't perhaps get it right straight away. It may require practice, so it's OK to have doubts initially. Similarly, participant RFY012 highlighted how the therapist shared information about the process of treatment, which helped to make her experience a very positive one, and illustrates again the open and relaxed nature of the relationship offered by each of the therapists.

'And I felt better for going afterwards. I found her very, very good. I really did... for putting me at ease. Explaining everything she was doing and what she, and you know what she was trying to do... she just was very good, I was totally at ease with her and could talk to her about anything' (RFY012)

4.3.4 Environmental Factors

Another aspect of treatment that was dominant in the participants' accounts concerned situational or environmental factors. Treatments were provided in a consulting room at the participants own GPs surgery or local clinic, as would be the case if therapies such as these were integrated into primary care. At one surgery, a room specifically designed by and for CM therapists was utilised. Participants' views varied dependent upon the surgery they attended. In some instances the general level of activity within the surgery proved a distraction for participants receiving either reflexology or relaxation, and may have had an effect on the outcome of treatment.

'I think the thing was you're there and she's saying right ... she pulls the curtain round and she's massaging your feet what ever it is, and all's you can hear is bang, bang, doors banging and the next one is going in and the doctor saying 'oh hello how are you' you know and it's a bit you know, it's there, you can, can (hear it) and she's saying try and relax and shut your eyes and but you, you're focusing you know like on what's going on around you and outside' (RFY011)

'Yes, well it's just because of the place isn't it? you can't avoid that at the doctors can you really? it's always busy isn't it?' (RXN001)

The following excerpt highlights how after becoming more practised at the relaxation technique, things did improve for this participant and she was able to detach herself from the external distractions and fully attend to the therapy.

'...the second week I went a little bit wiser because I knew what was going to be involved but I still found it quite difficult just to lie there and do nothing, very, very difficult sort of to listen to her, listen to the music, empty your mind and all the time you've still got the sounds going on from up and down the corridor outside... so you've got that distraction, but you haven't got to think of the distraction, ...but it did go better' (RXN002)

In contrast, treatment at another surgery was provided at the weekend, and consequently these sorts of distractions did not occur.

'In fact as I say it was probably the most relaxing hour I had in a week and it was lovely and you thought and it was quiet because the doctors surgery really wasn't open as a surgery on a Saturday morning so there wasn't a lot of noise and bustle' (RXN003)

One participant, found it difficult to fit appointments around her work commitments and the therapist gave her the option to attend a holistic therapies clinic in the local village during the evenings instead. Thus she received four reflexology treatments at her GP's surgery, and the rest at the clinic, which gave her the opportunity to compare the two venues.

'The whole, erm what to say, the whole ambience was different in the clinic, it was cosy it was small and it was quite intimate. The doctors is the doctors and will always be the doctors even though the room we used is not my doctors room, so I had never been in that room until I saw H (the therapist), er it was still the doctors... but I didn't think of it in those terms... but certainly cause H said, do you like it here and I did, the clinic was much nicer, but I mean that's what they're building their business on isn't it? making you feel welcome and cosy and warm, yeah, but it was better' (RFY012)

It is apparent that the above participant was satisfied with receiving treatment at the doctors, despite the medical connotations. It was the therapist's question that prompted her to make comparisons between the two venues, and made her realise how much the atmosphere at the clinic affected her experience of the same treatment.

These accounts demonstrate that participants perceived certain environmental or situational factors to be desirable for the process of treatment to be optimised. This could have implications for the integration of therapies such as these into primary care settings.

4.3.5 Role of self

This theme encompassed the intrapersonal factors which contributed to participants' experiences of the treatment.

Expectations concerning the treatments were articulated by all participants. There were variations in the type of expectations described, some were positive, some negative and some said they were 'open minded' or neutral. Interestingly few participants spoke explicitly of the outcome they expected from the treatment, such as reduced pain, whereas all referred to the treatment itself.

'Well I knew it was going to be, they were going to do it through your feet, I knew that' (RFY015)

If expectations are derived from existing information, knowledge and experience, then the relatively non-specific expectations exhibited by many participants are perhaps to be anticipated and may be a consequence of the limited experience some participants had of CM.

'...I just went with an open mind, I sort of didn't go with any preconceptions about it, cause I didn't know anybody else who'd had it done so I just went and thought well I'll try it' (RFY013)

'I don't know what I was expecting, because I'd never done anything like that at all... if someone had just said to me erm, why don't you go and have some relaxation classes.. the only relaxation classes I've ever had is when I was pregnant and you go ... so other than that I'd had no, nothing at all, had no idea what it would involve, what it would entail, so I went with a very open mind.' (RXN006)

Participants who did have some notion of what the treatment would entail described feelings of apprehension before the first treatment. However in each case their positive experience of the treatment changed this.

'Yeah I was a bit surprised, cause I can't stand anybody touching me feet, and I was that was the only thing that was bothering me, everybody will tell you , you know erm, but it was fine' (RFY008)

Similarly participants who had negative beliefs about the treatment and its potential effects were still willing to engage in the therapy. Of course in this instance the therapy was provided free of charge, and thus participants had '*nothing to lose*' financially. In addition when one recalls the litany of previously tried and failed treatments that many participants reported in the main study, this may be viewed as normal behaviour for an individual looking for relief from the pain.

'... I mean, as I say it opened my eyes really because I thought oh it's a load of .. and I suppose everybody said the same thing, well I don't know really... it's something I tried, you know, well I had the opportunity of trying and taking part in' (RFY012)

Furthermore the fact that many participants had had their condition for some considerable time, may have added to their negative expectations of treatment outcome.

'Oh yes, yes I'm a very open minded person. I mean I heard about reflexology before, I basically know how it works you touch certain parts of your foot and, you know it relieves the pain like, but erm but I don't know whether it, whether my back pain I've had that long and got so used to, you know it's going to take a lot to shift it' (RFY019).

An exception to this was participant RFY016, for whom the treatment (reflexology) had no validity at all, and did not alter his belief that it would be ineffective.

'I've tried like but er, but she, she really believed like, oh I can feel stuff here and you know and I can, and that's your spine and that's your neck and all that and you know on me feet and she's saying well that's sore there and that's sore there and I can feel, and so you should have a bit of pain there and I thought well, it it's obviously there the pain, and I'm thinking, I'm thinking she obviously knows where my pain (is)...' (RFY016).

RFY016 did not experience any long lasting effects from the treatment, and it is apparent that he was not impressed by the actions of the therapist. He assumed she knew all about his back pain from 'his notes'. With the expression of such scepticism, one must question whether RFY016 was able to fully engage in the treatment, as well as the extent to which the therapist was able to work 'with' him. In contrast, this point was illustrated more positively by another participant, RFY020, who found his experience of the treatment beneficial, though difficult to articulate. He likened it to having reiki treatment from his wife, as the treatment would not be effective if the person was not 'open' to 'receiving' it.

'you have to want to have it... to sort of believe in it' (RFY020)

Participants spoke of being active in the process of treatment, although some recognised the difficulty of responding to internal thoughts and distractions which prevented them from fully engaging in the therapy initially.

'I think with me I'm too wound up in a mornings cause I'm thinking, with it being the nine 'o' clock one, I'm thinking I've got to get home and get this done and get that done, I think I would have fell asleep if it was in an afternoon when I knew I'd done everything and I could relax' (RFY011)

'...and I, at one point, I thought why am I lying here? I could be doing this, I've charged home from work, I could be doing that, right, you know?' (participant RXN002 thoughts on the first session)

However, as this further excerpt from the above participant's account demonstrates this became less of a problem as her relaxation skills developed. In it she refers to another client of the therapist. Other participants also felt they gained more from the treatments as they became more practised in the relaxation skills, were able to actively attend to the voice of the therapist, and therefore disengage themselves from attending to internal distractions outside the therapeutic alliance.

'This woman was convinced that she was hypnotising her, right. Well you're not, because you are aware of her voice, the sounds, you're aware of everything, but it just, it just doesn't bother you' (RXN002)

Commitment to the treatment was also demonstrated by all participants. Though this needs to be viewed within the context of the study, whereby only those who had attended some treatment sessions were included in the interview selection process. Many participants continued to attend sessions despite not gaining any long term relief from their CLBP. Indeed some continued to attend even when they experienced unpleasant effects which they attributed to the therapy.

'...and then as I say at the beginning the pain was really bad, that night and into the next day and they were saying at work, oh God you better not go again, you know I'm thinking no no, you've got to go and stick it out, cause really I was fascinated cause she'd never touched my back and I hadn't done anything over that period, over that 24 hours to make it worse, and I was fascinated that that could have an effect and it was as solid as that' (RFY014)

4.3.6 Effects

All participants referred to the outcome of treatment in terms of the effects they had experienced. Not all of these were positive, though unpleasant effects were more likely to be reported by those in the reflexology group. However, all except one found these unpleasant effects to be transient and outweighed by the more positive aspects of treatment. Participant RFY022 was the exception, but it is interesting to note that even she is enthusiastic about the reflexology treatment itself.

'the actual treatment is wonderful... but as regards me back, it didn't do anything... the first week I had it I had excruciating pain in me knee for the whole week... and that's about it, it's not made it any easier.' (RFY022)

Other unpleasant 'side effects' included headache and increased pain. Although it is apparent that participants were reassured by the therapist that these had been experienced by others in the past, so were not unusual.

'after the first session I had a terrible headache, I know that much... but after that, then again she explained that I may suffer with a bad headache so, but after that, after the next couple of treatments I did I felt better, I still do, perhaps that's what happens anyway'(RFY020)

'I mean my husband laughed when I was telling him, I said its not funny, it does work, I mean you've got to go through it yourself to, you know to I mean some people probably think oh you know it's all mmm, but it's not. I mean I thought at first, at first after the first time she did it I thought it feels worse you know when I came home. Then after the second

time it didn't feel so bad, then the third time I could feel, that it was getting improvement... I thought well while its there I'll go and have it done, you can't lose anything you know, but I didn't really think I suppose that it could have any effect, I don't know cause I'd never really heard of it before... but it has, it has helped' (RFY011)

RFY011 was one of only two participants who experienced sustained relief from their pain, both of whom received reflexology. For the majority, reduction in pain was of a transient nature. However participants' comments indicated that *any* reduction in pain, whatever the duration, was viewed as a very positive outcome to treatment.

*'... I'd said I'd try it and I'd say to anybody, you know to give it a go, because I think apart from anything, mm I think it relaxes you so that helps you, you know you're not as tense, so as I said, she asked me and I said to her, even if you only get a few hours free (*from the pain) *it's better than nothing, Yeah.' (RXN005)*

'Oh yeah, yes I'd carry on and I'd say to anybody have a go at it you know it might, it's like, like medication, you know the same medication doesn't suit everybody but if it means you don't have to take even one tablet, you know if it drops one or two off a week it's better than nothing' (RFY013)

'Relaxing' both physically and psychologically was how participants described the experience of reflexology and relaxation. It is perhaps this effect, or the distraction which relaxation provided, which led to the reduced perception of pain experienced by many throughout the duration of the treatment sessions, and for a short time afterwards.

'I found it great, erm it's not solved the problem with the pain but erm, I found it very relaxating, relaxing. And I felt better for it after going, and I felt better for the rest of the day and night' (RFY017)

'well I enjoyed the relaxation, it's not really erm mmm made a vast improvement to my back but I really enjoyed the relaxation and I think it did me good' (RXN001)

Participants also spoke about other consequences of the treatment which they perceived as highly positive. A major one of these was an feeling of improved affect and an increase in general psychological well-being.

'I can't say it helped the back pain all that much but it helped me to feel a lot better cause I was feeling down in the dumps because I'd been off work and it, and I think that was the start of what made me start feeling better in myself... it reduced the pain, and I think with feeling better in myself as well I was able to perhaps not dwell on the pain as much' (RFY017).

'I think I'm more aware of the after effects, one of the things is when you're in pain, you're very irritable, and as I say that irritability seems to have gone. Now whether that's the lack of pain or the fact the I now know I can control the pain better, this is, you know there is not that kind of desperation when I've got the pain anymore' (RXN007)

Furthermore these improvements were seen to have a 'knock on effect' upon the way in participants responded to their pain. For some, increased psychological well being appeared to be directly related to an increased ability to cope with their pain on a daily basis.

'Well I think if you're feeling better through this anyway, I think you could cope better anyway with any pain you've got, you know mentally... and I found that I was... but as I say I think you can overcome it better, if you're more relaxed and you're not tensed up'(RFY012)

'...but I enjoyed it and it did seem to work, apart from one occasion where it didn't sort of rid the pain on that one day, but the other occasions I seemed to be able to deal with the pain' (RXN003)

For participant RFY020 in particular, the perception of an increased ability to cope led to an increase in confidence and a reduction in the fear which accompanied some physical activities.

'I, since the end of the treatment, well before the end I felt like... I was coping better... like I said I tried to do a bit of wallpapering over the Christmas... and I failed miserably so I... but again it was, even just that, it was having that, just to go and move, you know rather than being scared to, to do anything' (RFY020)

Thus it can be seen that although a long term reduction in pain did not occur for most participants, many were very satisfied with other positive outcomes from the treatment, which may have indirectly had an effect on their experience of pain.

4.3.7 Explanatory Models

In conjunction with describing the effects of treatment, some participants hypothesised about the cause of the effect they had experienced. Others however were not interested in exploring this, but were content with the knowledge that it worked for them.
'it works, and that is what is important' (RFY019)

Psychological mechanisms were suggested by some participants. Iain questioned whether the treatment had worked or whether it was his 'mind' that triggered the effects. While others considered 'distraction' as an explanation.

'I think it makes me more relaxed, whether it's just in the mind or what I don't know, but whatever it is it's a good thing anyway' (RFY012)

'...and it does relieve, it does, because you're doing something and it's taking your mind off, isn't it?' (RXN005)

Some believed that reflexology and relaxation were like other types of treatment they had encountered. Simply that they worked for some people and not for others.

'I'm sure that some people would, you see I believe about these sorts of things that they, some people, they would benefit some people more than others, I think it's an individual thing' (RXN018)

Participant RFY021's beliefs about the treatment were totally incongruent with those of the therapist. Because of this he found it difficult to attribute any positive effects he experienced to the treatment, and instead searched for alternative explanations. Participants with more neutral beliefs about the treatment also adopted this pragmatic approach to explaining its effects, with the natural variability of the condition being a predominant theme amongst these.

'...well to be honest I really thought it was a bit like a er, a clairvoyant telling me things after she's just read your life history, you know what I mean? but she really believed like it was gonna work, you know she says you will feel better and she was very nice like, she was no problem at all, but I couldn't see any difference to be honest... I mean now and again after a session like I did feel a bit better... I mean you have good days and bad days, may the next day I'd be really bad, and then the next time I go I'd be not so bad... I don't know whether it was that or the tablets or this or what I don't know' (RFY021)

Participants who did not have any pain reduction, despite experiencing other positive effects from the treatment tried to explain this. They were not dismissive of the therapy, rather they regretted that it had not 'worked' for them, whereas it might for others. They perceived themselves, and in particular the nature of their pain, as the problem as opposed to the inefficacy of the treatment. Once again, in the context of the many failed treatments reported by participants at recruitment, this is perhaps to be expected.

'... my back pain, I've had it that long and got so used to... you know it's going to take a lot to shift it' (RFY019)

4.3.8 Future Use

Participants' accounts contained references to continued use of the therapies. It is suggested that an expressed intention to continue using either reflexology or relaxation could be indicative of participants satisfaction with treatment and its outcome. Though it is also recognised that the intention may not always lead to a behavioural expression of that intention.

Participants intentions regarding future use of the therapies were related to the effects they had attributed to the treatment, and the accessibility of the therapist.

'I, oh I intend to go back to her, 'cause she's at the village, so I said once a month I will go, just for feeling well being really' (RFY017)

'I mean I am considering going back. Because as we were talking on Friday, I wasn't aware that they were open in the evening and at weekends at the clinic in the village and that would suit me much better I mean obviously that wasn't available as part of the

scheme but erm you know I would 'cause if you're looking to relax then possibly that would be a better situation' (RFY012)

For others the decision to continue with treatment or not, was a financial one. Participant RFY019 would probably never have tried reflexology because of the cost, and reported feeling

'lucky and privileged to have had the opportunity to try it for free' (RFY019)

Despite the benefits she experienced and the fact that she would like to continue with treatment, the high cost prevents this. Similarly participant RXN010's intention was constrained by financial factors.

'I would use it again, certainly, if it was offered on the NHS... if I could afford it I would pay the it' (RXN010)

For participant RXN004 cost was considered in the context of the benefits she had experienced, and she expressed an intention to pay for future treatment if necessary.

*'She was excellent and they were so relaxing I thought they were wonderful... I yeah, telling all my friends about her I they're quite expensive though aren't they? about £20 an hour?...If I started with chronic pain again I would (*pay for it)... *mmm...I would seek it out if I was in a lot of pain again I'm sure I would' (RXN004)*

In contrast RFY021 would have liked more treatment for the relaxation effect were they to be offered without charge, but did not believe the therapy was worth paying for. He described how he had been invited to purchase further treatment on another occasion, after receiving acupuncture on the NHS.

*'No. I definitely wouldn't do that [*pay for more treatment*], I don't think that the benefit would be sufficient to justify an outlay of expenditure. Mmm I wouldn't pay for the acupuncture. I mean the acupuncturist said because they can only do so much on the NHS at a time, and she said to me that you probably need this several times a week really, continuously and she said there's no way that's available on the NHS but you could go privately and she was talking about something like £40, which would just be absolutely ridiculous' (RFY021)*

The above examples exemplify one of the problems with CM generally, i.e. treatment costs. These therapies are not available to all. Even when patients receive NHS treatment which they perceive to be effective, it is often of a limited duration, because of the demand for treatment and associated costs. Those with less disposable income are prevented from pursing further treatment because of the cost implications. Thus this type of treatment remains a luxury for all but the few who can afford to purchase it themselves.

4.3.9 Relaxation Group

This section presents the excerpts from the accounts of the three participants from the relaxation group who expressed regret at not being randomised to the reflexology group. It should be noted however that all three participants reported some positive effects from the relaxation treatment, though with the exception of participant RXN002, these were not long lasting.

'I mean I did not want to go for this relaxation and you know, I mean I think when I said, I saw you first of all I would like to have had the reflexology. Don't ask me why, I just fancied it, but I was very pleasantly surprised how much I enjoyed it (the relaxation) (RXN002)

'I, think the reflexology, it would be, it's more personal, because its hands on so I think that would be better' (RXN019)

'...there are so many different things out there, but I'm sure these relaxation, I don't know, I didn't try the reflexology, I would have liked to try that, but I'm sure the relaxation is useful in a lot of circumstances... but I'm a bit sceptical about it reducing chronic pain' (RXN018)

4.3.10 Summary

The preceding sections demonstrate that participants from both the reflexology and relaxation groups had similar views regarding the treatment they received, broadly categorised into six major themes: therapist/therapeutic relationship; environmental factors; role of self; effects; explanatory models; and future use. In addition a specific theme of 'regret' was expressed by 3 of the 10 participants from the relaxation group.

While it is accepted that this theme was not common to both groups, or dominant in the relaxation group, it was considered a relevant area for examination given the RCT methodology adopted in the main study.

A discussion of these results in the context of the extant literature is presented in chapter five, section 5.3.

Chapter Five

Discussion

5.0 Introduction

This chapter contains a discussion of the results from each aspect of the study. It comprises four main sections. The first is concerned with the quantitative results from the questionnaires and therefore the primary aim of the project, i.e. assessment of the effectiveness of reflexology in the management of CLBP. The second section refers to the results of interview one and discusses these in relation to previous research on CM use. Section three provides conclusions for the data generated by interview two concerning the participants' perceptions of the therapy they received. The last section, four, contains a comparative analysis of the qualitative and quantitative results. The extent to which they support one another is assessed, and the implications of this for the evaluation of CM therapies is examined. In addition, the strengths and limitations of the approach adopted in the current study are described. Finally, conclusions based on simultaneous consideration of the results from each aspect of the study are provided and recommendations for the direction of further research outlined.

5.1 Discussion of Quantitative Results

The main aim of the study was to evaluate whether and to what extent reflexology is effective in the management of CLBP. To reiterate, a sample of patients from primary care with CLBP were randomised to receive either reflexology, relaxation or maintain their usual care. Two primary outcome variables, and a number of secondary variables were selected to assess any differences between groups before and after treatment. The results of these analyses are contained within chapter four, and the reader is reminded that a summary is presented in section 4.1.16

5.1.1 Primary Outcome Variables

The pre-post treatment analyses on the primary outcome variables, SF36 Pain and Functioning as measured by the ODQ, did not reveal any significant differences between treatment groups. However, while there was no main effect of functioning, there was a significant main effect of pain reduction throughout the duration of the study, regardless of treatment group. Therefore the current study did not demonstrate that reflexology was significantly more effective than relaxation and/or usual care for the management of CLBP.

However, when the mean SF36 Pain scores for all three groups at each time point were considered (see figure 4.6), it was apparent that as a whole, the reflexology group experienced the greatest reduction in pain between Time 1 and Time 3, and contributed most to the main effect of a reduction for the whole sample. Similarly, when the percentage change in individual participant's SF36 Pain scores were calculated and categorised as more, less, or the same pain at Time 3 compared to Time 1, the largest proportion of those in the less pain category were in the reflexology group. While these findings demonstrate a favourable trend towards greater pain reduction for those who had reflexology, this was not significantly different than the changes in pain experienced in the other two groups, nor was it indicative of a clinically significant change (Lansky et al., 1992; Ruta et al., 1994, MacPherson et al., 1999).

Taken together these findings highlight one of the strengths of the pragmatic RCT design, and perhaps provide a partial explanation for previous anecdotal and case study evidence for the effectiveness of reflexology. For example, the reflexology group from the current study taken in isolation illustrate an alternative research design, i.e. one in which participants act as their own controls. They received no treatment in the baseline monitoring phase, then were reassessed after the treatment phase. These results showed a reduction in pain, and it is possible that this would have been attributed to the effects of reflexology treatment. However, the use of comparative groups, in this instance relaxation and usual care, demonstrated that the reduction in pain also occurred in the absence of such treatment, in people from the same population. Thus it is unlikely that reflexology alone was responsible for the change.

The ability of the SF36 Pain dimension to detect changes over time is encouraging, and lends further support to the notion that it is sensitive to change (Katz et al., 1992; Ware & Sherbourne, 1992, Garratt et al., 1994; Ruta et al., 1994; Rogers et al., 2000). Furthermore, to some extent it refutes the suggestion of McKenna et al (2000) that the SF36 is incapable of measuring change in health status over time. However it is appreciated that the magnitude of change detected was not absolute, but must also have included some marginal measurement error generated by the instrument itself. Nonetheless, results of the analysis on SF36 Pain dimension raise some questions about the current study.

Failure to detect a difference between treatment groups leads to a number of possible conclusions. First that there were no differences between groups and therefore all treatments were equally effective, or indeed equally ineffective, in which case spontaneous remission could account for the improvement. Further explanations include the possibility that the chosen questionnaire inventory might not have been sensitive enough to detect any changes which did occur. In addition, there may have been insufficient power in the design to detect a difference, that may have actually existed. In this regard other factors may be implicated, for example the level of attrition throughout the duration of the study.

Before going on to consider these explanations further it may first be useful to review the profile of the current sample on the SF36 and ODQ in comparison with norms, data on back pain patients and previous similar clinical study populations. Scores on all dimensions of the SF36 at each assessment (recruitment, pre-treatment, post-treatment and follow up) were lower than UK normative data (Jenkinson et al., 1996) but within the expected range for patients with back pain (Garratt et al., 1993). In addition, they were in accordance with other samples of back pain patients from primary care (e.g. Miller et al., 1999; Emanuel et al., 1996). Nevertheless, it should be noted that while the difference was not more than one standard deviation, the SF36 Physical Role Limitation scores were consistently higher in this sample than those reported by Garratt and colleagues, suggesting that they perceived themselves to be less impaired physically by their back pain.

Furthermore, it is interesting to note that all SF36 dimension scores remained within the expected range throughout the duration of the study, despite evidence of statistically different changes over time on SF36 Pain, Mental Health, Physical Functioning and Role Limitations due to Physical Problems. This highlights that although participants did improve on these variables, the magnitude of change was relatively small and not clinically significant. Mean scores remained within the normative range for patients with back pain, and were not characteristic of those of the general population.

No normative data exists for the ODQ as it is a condition specific instrument. However it is widely used as an outcome measure with this population. The mean ODQ scores of the current sample throughout the duration of the trial are in accordance with those reported in previous studies by Meade et al. (1990, 1995), Hartigan et al. (2000) and MacPherson et al. (1999). However they were consistently lower than those noted by Fairbank et al. (1980) who developed the instrument, suggesting that this sample perceived themselves to be less disabled by their pain initially, although, as before, the difference was not greater than one standard deviation. Therefore the current study population may be viewed as broadly typical of patients with back pain.

Sample size calculations, based on the two primary outcome measures (SF36 Pain and ODQ) were carried out prior to recruitment in the current study (see chapter three for details). These revealed that to detect a change on the ODQ n=41per group were required, while n=59 per group were necessary to detect a change on the SF36. This figure was inflated to n=80 to account for an estimated drop out rate of 25%. However as the results show, dropout was greater in some groups compared to others. At Time 3 the rates were: 16% reflexology, 30% relaxation and 43% usual care. Thus it is possible the reduced sample size and unequal groups that remained, may not have provided enough power for the analyses conducted to detect a difference between groups, if one existed.

However there were more than n=41 participants in each of the three groups immediately post treatment, therefore the sample was large enough to detect changes on the ODQ. Moreover, Ruta et al. (1994) suggest that samples of around 65 per group are necessary to enable a statistically significant difference of 20 points to be detected on all of the SF36 dimensions. They also point out that groups of around 30 allow similar differences to be detected on six of the dimensions, including SF36 Pain. The difference stated in the sample size calculations for this dimension is marginally smaller than this (19.3points). However as there were more than 30 participants in all of the groups in the current study, it is suggested that had a difference occurred the sample was large enough to detect it. Thus it is argued, the parsimonious explanation is that there were no significant differences between the three groups.

This may mean that all treatments were equivalent, which lends support to the notion that the non-specific factors were responsible for the reduction in pain rather than the treatment per se. The potential relationship between non-specific factors and treatment outcome is considered in section 5.3 of this chapter in relation to the data generated by interview two, and will be examined again in the final discussion section. Also, as stated previously, it is possible that the natural variability of the condition, or spontaneous remission, was responsible for the apparent effect of each treatment. This is in accordance with the definition of CLBP proposed by Croft et al. (1998) wherein it is viewed as a chronic condition interspersed with periods of relative freedom from pain. However, given that the majority of participants had long standing persistent low back pain of a chronic nature, this explanation appears less likely. Finally, regression to the mean represents an alternative phenomenon which should also be considered in any explanation of the reduced SF36 Pain scores apparent during the post treatment period of the study.

Attrition did occur, although as previously stated, the sample may still have been large enough to detect differences between groups on the primary outcome measures. The overall dropout rate was 34% at Time 4, and the prospective design which required patients to complete questionnaires on four occasions may have accounted for some of this. However there were differences in the level of dropout, and rates varied from 26%

reflexology, 34% relaxation and as high as 40% in the usual care group. This identified another question, which concerned the extent to which the remaining sample could be considered representative of the initial N=234. In particular, it was recognised that attrition could have introduced bias, in either direction, to the results. That is, those who did not complete all assessments and/or treatments may have done so because they improved, or because they felt worse. Of course, the data on those participants who failed to comply with completion of the questionnaires, was not available. Nonetheless, comparison of the presenting data from both 'completers' and 'non-completers' revealed that there was little variation in their demographic and psychosocial variables at recruitment.

However, two differences were apparent. The first concerned the mean ages of the two groups, each of which were between 41 and 49 years with similar standard deviations. If age had been a categorical variable, these means would have fallen into the same decade range, therefore this difference was not considered to be particularly meaningful in terms of outcome. The second concerned participants' previous use of CM, and this may have been relevant. Participants who complied with completion of the questionnaires were more likely to have used CM before than those who did not. It is suggested that participants who had some experience of CM were perhaps more accepting of the treatments offered, reflexology and relaxation, than those who had never visited a CM therapist before. It must be remembered that the current participants were primary care patients with CLBP who had been introduced to the study by their GP. Thus it is possible they may have been more likely to be looking for something which could help their CLBP, rather than seeking a CM therapy per se. Although some, as previous users of CM, may have been attracted to the fact that the study was researching a CM therapy. Such participants were perhaps more willing to comply with the assessment requirements in order to supply data which would help to either support or refute the efficacy of reflexology, dependent upon their previous experience of CM treatments.

In addition, the previously stated differential rates of attrition in each group supports the notion that participants were attracted to the study because of the opportunity to receive reflexology. Certainly participants in the reflexology group were more likely to attend all treatment sessions and comply with completion of the questionnaires, compared to those in the relaxation group. This may be indicative of what Kole-Snijders (1996) describes as 'treatment credibility' a pre-requisite for willingness to participate in treatment, and an important predictor of self reported pain, observed activity tolerance and pain behaviour at follow up. All participants were fully informed about the purpose of the study before they gave their consent, and each was aware that reflexology was the treatment under scrutiny. Thus it is possible that those who did not receive reflexology, excluded themselves because of this. Interestingly, attrition was less in the relaxation group than the usual care group and it is argued that the receipt of some type of additional treatment, albeit one with less face validity, may have been responsible.

Attrition, or loss to follow up is not a problem unique to the current study, indeed it is a common issue in RCTs generally (Prescott et al., 1999). Moreover, as Turk et al. (1993) stated 'pain treatment outcome studies are not immune to the problem of patient dropout' (p18). Van den Hoogen et al. (1997) in a study of pain and health status in primary care patients with back pain reported that 39% (167 of 430) were lost to follow up, a similar figure to that reported here. In addition, MacPherson et al., (1999) recorded 30% dropout in a pilot study (N=20) for a RCT to assess the utility of acupuncture for low back pain. Other studies have experienced much higher rates, e.g. 64% from referral to follow up (Rose et al., 1997), which therefore leads to questions about the sample who go on to complete. It is argued that completers may represent a 'highly selective, motivated group of individuals who possess strong rehabilitative drive' (Reilly, 1993, p254). Alternatively, if one assumes that non-completers stopped attending treatment because it was not effective, then completers may comprise the remainder for whom the therapy was effective. However, given the relative lack of differences between completers and non completers in the current study, and the lack of clinically significant changes after treatment, this is unlikely to have occurred here.

Richmond & Carmody (1999) suggest that the reason for treatment dropout may be qualitatively different dependent upon when it occurs. Attrition may happen at various stages of treatment, such as: not attending the initial interview; if allocated a treatment, failing to attend the first appointment; beginning treatment, only to drop out later; and simply not returning the questionnaire at follow up, or indeed at any time throughout the study, particularly for those in the usual care group. Importantly Richmond & Carmody report that dropout can be more of a problem when treatment is provided at no cost to the participant, as it was in the current study. Thereby suggesting that had participants invested financially in their treatment, they might have been more likely to continue with it. Of course, as previously stated, in the absence of any data from non-completers, it is not possible to positively determine the reasons why some participants dropped out of treatment. Thus it is suggested that in future studies, an attempt be made to access this type of information.

5.1.2 Secondary variables

The previous section demonstrated that participants scores on the SF36 were within the range expected for patients from primary care with back pain, at all data collection points (recruitment, pre-treatment, post-treatment and follow up). The SF36 dimensions Mental Health, Social Functioning, Physical Functioning and Role Limitations due to Physical Problems each demonstrated main effects. However it is argued that although these were statistically significant too, they were not indicative of clinically significant changes (Lansky et al., 1992; Ruta et al., 1994, MacPherson et al., 1999). In addition, as with the SF36 Pain scale, participants improved, but not to the extent that they were typical of the general population. Similarly the interaction which occurred between SF36 General Health Perception and treatment group was not of a sufficient magnitude to indicate significant clinical change. This perhaps demonstrates how with large samples, relatively insignificant treatment effects can sometimes be viewed incorrectly as clinically meaningful changes simply as a function of their statistical significance.

The main effect of a reduction in current pain intensity and seven day average pain intensity, as measured by the visual analogue scales (VAS), is congruent with that displayed by the SF36 Pain dimension. The chapter on methodological considerations highlighted some of the difficulties inherent in measuring a subjective experience such as pain. Nevertheless, VAS are frequently used and have been shown to be reliable (Jensen et al., 1986; Price et al., 1983). In addition it is accepted that participant responses to the questionnaire were dependent upon memory for pain, and it cannot be denied that there may have been inaccuracy in recalling pain (e.g. McGorry et al. 1999). However it is suggested that the use of the VAS and SF36 Pain dimension, which each measured pain in different ways, demonstrated consistency in participants responses at each assessment point throughout the study. In addition, the similarities between the two measures provided further concurrent verification for the validity of the SF36 measure with the current population.

The only other main effect to occur on the secondary outcome variables concerned the CSQ. Reinterpreting pain as a method of coping with it, increased significantly throughout the study. However it is argued, given the relatively small changes in the mean use of this strategy, that this was simply significant in a statistical sense. There were no apparent differences in the use of any other type of coping strategy employed throughout the study. In some respects this is perhaps to be expected as treatment was not directly aimed at promoting the use of any particular method of coping. However, implicit in relaxation therapy was the notion that PMR techniques provide a way of coping when the pain is bad, even if only via distraction, yet this was not reflected in scores on the distraction subscale of the CSQ.

Comparison of the mean CSQ scores of the current sample revealed they were within the expected range, though generally slightly lower than, the mean scores of the normative data for back pain patients presented by Rosenstiel & Keefe (1983), as well as those of previous research populations (e.g. Jensen et al., 1994). In addition the use of praying and hoping in this sample was considerably less. While it is recognised that there are two aspects to this coping strategy, it is possible that praying was interpreted in a spiritual sense and thus the reduced incidence of praying could be a reflection of the secularisation of wider society. Furthermore, the current sample were recruited from primary care sources, and over 50% described themselves as employed. It is argued this could have indicated that many were managing their CLBP effectively, suggesting they were perhaps better copers than research populations recruited from secondary care, and this was reflected in their marginally reduced use of each coping strategy.

Similarly, it was apparent from the pre-treatment data that the majority of participants were in the mild and moderate categories for depression. This may have been responsible for a type of 'floor effect' whereby participants were unable to demonstrate a reduction in symptoms, as they reported relatively few to begin with. The cut off points presented by Beck et al. (1997) in the BDI manual were used to categorise participants as either: minimal; mild; moderate; or severely depressed. They were designed for sensitivity rather than specificity, that is, they represented lower thresholds for detecting depression in order to reduce the probability of false negatives. Thus the use of these scores potentially inflated the prevalence of depressive symptomatology in the current sample, suggesting that an even greater percentage of them would have been in the minimal to mild categories had more stringent criteria been applied.

It is recognised that the BDI is not a diagnostic instrument. Nevertheless it does provide an indication of the number and severity of symptoms of depression experienced within the last two weeks, and is frequently utilised as a screening instrument with chronic pain patients (e.g. Turk et al., 1983; Mikail et al., 1993; Williams & Morley, 2000). As stated in chapter one, the assessment of depression in this patient group is difficult due to the overlapping symptomatology the two conditions share (Geisser et al., 1997; Williams & Richardson, 1993). This has implications for estimates of the prevalence of depression in patients with chronic pain, which Banks & Kerns (1996) suggested was around 30-50%. If one adopts a stringent cut off score of >19 to represent 'caseness' to reduce the number of potential false positives, then prevalence in the current sample fell from 23.8% at recruitment to 20.5% at follow-up. Lower than might perhaps be expected. In addition, it is interesting to note that those in the reflexology group experienced the greatest change (24.3% to 14.5%). While these are not significant differences, they do demonstrate that even though they were less depressed to begin with, some improvement was still evident.

However, assessment of prevalence needs to be viewed within the context of the instrument used to measure this construct, the BDI II (Beck et al., 1997). The BDI II was developed to update the BDI IA and reflects changes in the diagnostic criteria for depression (DSM IV, 1995). Whilst the BDI IA has an extensive history of use with chronic pain patients, at present, the BDI II lacks this. Moreover, in the redevelopment of the BDI a number of somatic items were dropped. Previous authors (e.g. Williams & Richardson, 1993) have argued that criterion contamination may be responsible for the inflation of chronic pain patients total scores on the BDI IA, thereby overestimating the prevalence of depression. It is suggested that this phenomenon may be less of a problem with the BDI II. In an exploratory study, Poole et al. (2000), transformed patients (N=165) raw scores on the BDI II to the BDI IA, using the conversion table presented in the manual (Beck et al. 1997). Results indicated that this procedure led to some changes in the number of patients in each category. Less were classified as having minimal depressive symptoms, while more had scores representative of mild and moderate symptoms. Thus it is tentatively suggested that the use of the BDI II, with its concomitant reduction in somatic items, may provide a more accurate indication of the profile of depressive symptomatology in this patient group. However it is recognised that further research comparing both instruments within the same population is required to confirm this notion.

5.1.3 Relationships between variables

In addition to considering the extent to which participants varied between treatment groups or over time on the main outcome variables, the relationships between variables were also explored. The number of variables measured in the present study was considerable. They were selected on the basis of their relevance to the experience of CLBP as well as their prior history in the evaluation of outcome to treatment for CLBP. As such the interrelationships between some of the variables were already known, and the present study was able to confirm a number of these.

There was a significant association between the functioning (ODQ), depression (BDI) and catastrophising (CSQ) at times 1, 2, 3 & 4. Which indicated that throughout the duration of the study an individual with reduced functioning was more likely to experience psychological distress and frequently use catastrophising as a coping strategy. In addition, this correlation indicated the opposite scenario, i.e. that someone with few symptoms of depression is likely to be less functionally impaired by their back pain, and also less likely to catastrophise about that pain as a means of coping. This confirms previous research findings (e.g. Turner et al., 2000; Hajustrapopolous et al., 1999; Vienneau et al., 1999; Sullivan et al., 1998; Robinson et al., 1997; Turk & Rudy, 1992; Rosenstiel & Keefe, 1983).

Furthermore the extent to which participants felt they could control their pain was also found to be important. Ability to control pain was associated with less depression, reduced pain, higher functioning and increased health status. In addition, such participants were also less likely to adopt catastrophising as a coping strategy. Belief that one can control the pain may reinforce the use of adaptive coping strategies in a reciprocal relationship, whereby success in coping with the pain will further reinforce belief in the ability to control pain. In this regard, Social Learning Theory (Bandura et al., 1977) may offer an explanation for the increased health status of those who believe the coping strategies they use are effective.

The relationship between the SF36 health status dimensions, depression, functioning, catastrophising, and the ability to control pain were maintained throughout the duration of the study. Interestingly, there were few associations between health status and any other type of coping strategy. Thus it would appear that the only coping style to consistently differentiate between positive and negative adaption to the pain was catastrophising. Increased use of catastrophising was linked with poorer outcome. Although it is recognised that evidence of an association between variables does not indicate a causal relationship, it is argued that as these associations were broadly similar over time, they were not due to spurious data, nor a statistical artefact. Thus it is suggested that they warrant further investigation.

In the meantime, the growing body of evidence concerning the links between high levels of catastrophising and increased pain severity, depression and dysfunction may have implications for cognitive behavioural interventions in the treatment of CLBP. These types of treatment have already been shown to be effective (van Tulder et al., 1997), and it is suggested that their efficacy may be further enhanced if more emphasis was placed upon reducing the use of catastrophising, as opposed to promoting the use of other coping strategies, such as increased activity or reinterpretation of the pain sensation, which the present study did not find to be associated with increased health status.

The first chapter of this thesis highlighted the debate concerning the nature of the relationship between catastrophising and depression (e.g. Sullivan & D'Eon, 1990 Jensen et al., 1991; Sullivan et al., 1995). However, a more recent theoretical paper by Sullivan et al. (2001) brings together much of the previous work in this area and presents a reasonable argument for a distinction between catastrophising and depression (see also comments by Turner & Aaron, 2001). Admittedly, it is still possible that the high correlations found between these constructs in the present study indicate an element of redundancy in the measures. However, given the findings of Sullivan and colleagues, this appears less likely.

The notion of redundancy between the instruments contained within the questionnaire booklet is one that has implications for clinical practice as well as future research. Once issues of appropriateness, validity and reliability have been answered, the demands placed on patients/participants must be a prime consideration when selecting outcome measures. Those utilised in the present study represented a considerable number of domains, and were selected on the basis of their previous use with this population, as well as their theoretical relevance. Nonetheless, it is recognised that completion of the questionnaire usually took participants at least 20 minutes. Therefore it may be pertinent to further evaluate whether any of the domains of measurement were replicated by different instruments in the questionnaire. If so, a case may be made for their exclusion in further studies.

All scales of the SF36 appeared to display logical relationships, with high positive correlations between them. As this instrument was designed to reflect general health status, high correspondence between the individual dimensions is perhaps to be expected. However, a degree of redundancy between the SF36 and other conceptually similar measures is indicated, particularly the Physical Functioning dimension and the ODQ. Correlations between these two scales ranged from -.781 to -.890 throughout the duration of the study. While it is based on the same number of questions, the SF36 Physical Functioning dimension covers less dimensions of activity and asks participants how much their 'health' restricts their daily activities, not their back pain. Thus it is argued in this instance, that while they are highly correlated and pertain to similar aspects of the pain experience, the ODQ provides a more detailed illustration of the extent to which activities are restricted by CLBP. This supports the suggestion of Garratt et al. (1994) that the SF36 is best combined with a disease specific measure.

The number of dimensions measured also has implications for the analyses conducted. With the exception of the SF36 and the CSQ, each of the scales in the current questionnaire are represented by total scores. However a total score cannot be computed for the SF36, as although related, each dimension is considered to be distinct. This leaves the CSQ. The present study used mean scores for each of the seven individual strategies of coping identified by the CSQ in the analyses conducted. The rationale for this was to increase the possibility of identifying which, if any, specific strategies were associated with improved outcome. Other researchers have not considered CSQ scale scores but rather factor analysed results and then interpreted composite factor scores, such as cognitive and behavioural coping strategies, in relation to outcome or adjustment (e.g. Rosenstiel & Keefe, 1983; Gross, 1986; Turner & Clancy, 1986; Dozios et al., 1996). It is noted that individual scales may be less reliable as they contain fewer items, and it is argued that the use of composite scores could enhance statistical power, interpretation, and help identify general coping mechanisms. However, it is suggested that this could also reduce the possibility of identifying the subtle differences in the effects of specific strategies. Certainly the use of composite scores, in the current study would have failed to identify the relationship between catastrophising and a number of other variables, which informed the regression analyses. Thus, the author concurs with the recommendations of others (e.g. Jensen et al., 1991) that individual as opposed to composite scores be used in analysis of coping data.

Before going on to discuss the results of the regression analyses, the relationship between social support and other variables will be considered. It was apparent that participants who were satisfied with the support available to them, reported less symptoms of depression. Furthermore they were also more likely to experience decreased functioning, although this was not related to the level of pain reported. That social support is linked with reduced function concurs with the findings of Romano et al. (1992) and others, (e.g. Gil et al., 1987), and suggests these results offer little support for the 'buffering' hypothesis (Cohen & Wills, 1985). Indeed they would appear to indicate that high levels of social support can serve to reinforce 'pain behaviour' which interferes with daily activities and in turn maintains low levels of functioning. However, the decreased level of depression in those who expressed high satisfaction with their social support, imply otherwise, and suggest that social support can act as a buffer against the psychological distress often associated with CLBP (Jamison & Virts, 1990). It is the author's opinion that both explanations are simultaneously plausible. Thus satisfaction with one's social support could have both a negative and positive effect upon different aspects of the CLBP experience.

It is accepted that these results are correlational, and as such no causal relationships can be inferred. Nevertheless, they do serve to highlight that the complexities of the relationship between social support and CLBP warrant further study. In particular it may be useful in terms of intervention, if the specific aspects of support which relate to improved psychological well-being or reinforcement of reduced function were identified. Whilst it is recognised that this may be difficult, due to variation between individuals, it is suggested that the results of such an endeavour could be used to promote aspects of support which have positive consequences for the patient. At the same time, those from whom patients receive support could be educated in order to reduce aspects which have the opposite effect.

5.1.4 Prediction of Outcome

The findings of the present study support the notion of a relationship between catastrophising and pain, however they do not support findings from other studies which have demonstrated catastrophising to be predictive of pain severity (e.g. Dozios et al., 1996). Indeed the only variables to be entered into the regression equation which predicted pain at Time 3 were functioning and pain at recruitment (ODQ and SF36 Pain respectively). Furthermore, it was apparent that the most significant predictor was functioning at Time 1 which accounted for 49.5% of the variance in pain at Time 3. Pain at recruitment added little to the model (1.4%). Thus those who were less disabled by their pain to begin with, i.e. those whose day to day activities were only marginally restricted by their back pain, however severe that pain was, were more likely to report less pain at the end of the treatment phase. This is in line with, and supports current recommendations for patients with back pain, i.e. to maintain normal levels of activity (Rosen, 1994). As these results demonstrate, those who manage to do this, subsequently report less pain.

The failure of the remaining psychosocial variables (BDI, CSQ Catastrophising, SSQ6, and duration of CLBP) to predict significant levels of variance in pain at Time 3 initially appear to suggest that, contrary to previous research findings, these factors had little effect upon pain in this sample. Nevertheless, these results need to be considered within the context of the statistical analyses performed. Examination of the residuals plots, condition indices and eigenvalues associated with the analyses revealed no outliers and confirmed that assumptions regarding homogeneity of variance and linearity were not violated (see appendix 17). Similarly comparison of the sample means with the expected norms for this patient group indicated scores within the expected ranges, and demonstrated that these results were unlikely to be due to spurious data. One explanation may be the lack of adequate variance in the dependent variable. Despite evidence of the SF36 Pain dimension's sensitivity to change (e.g. Rogers, 2000), scores on the instrument are represented on a 0-100 point scale, which is actually derived from a possible score of 0-11 for this dimension. As such there are only 0-11 scores possible on the 0-100 scale. This is relatively small when considered in relation to the more extensive variability of the scores for some of the predictor variables.

In addition the relative lack of differences between participants in each treatment group throughout the study may be implicated. As previously stated, it has to be accepted that while there was a statistically significant reduction in pain throughout the duration of the study, this was not indicative of a clinically significant change. Thus it is possible that a lack of variation in the dependent variable could have had an effect upon the outcome of the analyses. However, it is both intuitively attractive and supportive of the current knowledge base to accept that one's level of functioning is predictive of subsequent pain. Nonetheless, it does lead to the question of which psychosocial or physical variables are responsible for the remainder of the variance in the outcome measure. This question was not addressed in the present study. A large amount of exploratory analyses had already been conducted, and the choice of variables to be entered into the initial regression equation had been theoretically driven and informed by the correlational analyses. There was no rationale for entering additional variables, or conducting further analyses with new variables.

Along with the above variables, a number of other factors were also considered in the statistical analyses of the quantitative data, and the implications of these results will now be discussed.

5.1.5 Treatment Preferences

Participants' preference for a particular treatment at recruitment did not appear to have a significant effect on outcome. This is in contrast to the suggestion put forward by MacPherson et al. (1997) who argued that preferences have the potential to influence response to treatment via psychological mechanisms, and that this may be wrongly attributed entirely as treatment effects. The apparent absence of any treatment effects in the current study, led the author to hypothesise that for some participants, failure to receive their preferred treatment may have meant that psychological mechanisms worked in the opposite direction. However this was not found to be the case, and this supports the findings of others (e.g. Klaber Moffett et al., 1999; Williams et al., 1999).

As in the current study, Klaber Moffett et al. (1999) elicited participants' preferences for treatment in a RCT but did not act upon them. The potential size of sample required to take preferences into account precluded this. They were however controlled for in the subsequent analysis by Klaber Moffett and colleagues, who found preferences did not significantly effect outcome to the intervention (exercise for low back pain). In contrast, Williams et al. (1999) included patient preferences in their RCT to evaluate inpatient versus outpatient treatment for chronic pain. Williams and colleagues asked patients if they were willing to be randomised to inpatient, outpatient, or waiting list control. Those who refused, were accepted for their preferred treatment (inpatient or outpatient) and treated alongside the randomised patients. However, they too found that there were relatively few differences between randomised and non randomised patients with regard to outcome, although patients living further from the treatment centre were less likely to agree to randomisation (a function perhaps of the travelling which would be required if one was randomised to the outpatient group). These two studies, in combination with the findings of the current investigation suggest therefore that, in the evaluation of treatment for chronic pain conditions, participants' preferences have little effect on outcome.

In addition, while preferences were not influential, it is apparent that resentful demoralisation (Bradley, 1993) did not occur. None of the participants in either the relaxation or usual care group reported going out to seek reflexology treatment themselves. Nevertheless those in the usual care group did report more instances of seeking treatment from other types of CM therapist. However this needs to be viewed within the levels of attrition which occurred in that group, data was simply not available for some participants. Moreover, it must be accepted that failure to get one's preferred treatment may have been a reason why some participants dropped out of the study.

Of the usual care which was reported by all participants throughout the trial, those in the reflexology group accessed the least. Indeed they were significantly less likely to consult their GP during the treatment phase than participants in either of the other two groups. This suggests that consultation with the reflexologist represented a meaningful alternative to consultation with a doctor, and thus appeared to negate the need to seek additional care. Furthermore, it was apparent from the data available on medication use (N=149), that a greater number of those in the reflexology group reported using less medication after the treatment phase than those in the relaxation and usual care groups. Similarly they were also less likely to report using more medication. This lends additional support to the notion that reflexology treatment reduced the need for their usual care, and suggests that it also led to a reduction in medication use. However, it is stressed that the quality of the data on medication use may not have been reliable, and thus these conclusions ought to be viewed with caution.

Aside from the fact that this data was entirely self report, judgements concerning what constituted a reduction or increase in use were difficult. Type as well as amount of drug can change. For example, how does one determine the difference between eight codydramol per day or eight paracetamol and three ibuprofen? The WHO medication classification ladder (WHO, 1986) was used to place drugs into categories, e.g. NSAIDS, opioid analgesics. Participant reports of pre and post treatment doses, or changes in category of drug were then rated as less, more, or the same, by the author. These ratings were verified by a specialist pain nurse, and any disagreements discussed and resolved. It is recognised that these ratings were not precise. Nevertheless, given the quality of the data, and in the absence of any rubric for classifying changes in medication, this represented the best method available.

Furthermore, although not an *a priori* intention of the study, economic analysis of the cost of treatment was considered. As White & Ernst (2000) argued in their systematic review, there is an need for rigorous studies and high quality investigation into the cost/benefit of CM therapies. However, an obvious pre-requisite for this is proven effectiveness, which is not available in the current study. Thus as reflexology and relaxation were additional to usual care, it is apparent that they would increase costs rather than reduce them. Nevertheless, given that the reflexology group reported the greatest reduction in pain, and used the least amount of additional care, it was considered that reflexology may provide relief for some primary care patients at little or no extra cost. Unfortunately, the quality of the data obtained on visits to other therapists, prescribed and over the counter medication use and dose was variable, and rendered the proposed analysis unfeasible.

5.1.6 Therapist effects

The skills of individual therapists did not appear to have an effect on reported levels of pain at Time 3. The current study employed five therapists in order to address a criticism directed at previous research in reflexology (e.g. Eichelberger, 1993 and Petersen et al., 1992). Vickers (1996) argued that in some instances, failure to demonstrate an effect of treatment may have been due to the ineffectiveness of the therapist rather than the therapy. The use of more than one therapist was considered to have substantially reduced this potential problem. However, it has to be accepted, that, while unlikely, all therapists in the current study could have been ineffective. A further point is that these analyses were exploratory, the sample size calculations did not include consideration of therapist effects, thus there may not have been enough power in the analyses to detect a difference had one occurred.

The previous discussion on therapist effects leads on to a related point concerning the therapy provided. Treatment was not standardised, but rather reflexologists were instructed to treat participants' back pain. Apart from that instruction, therapists remained completely autonomous, thus treatment was individualised as it would be in practice, and not reduced to a specifically outlined mechanistic procedure. This was seen to be one of the biggest advantages of the pragmatic RCT design as it enhanced the clinical relevance and ecological validity of the study. Furthermore, as stated in the chapter on methodological considerations, it provided a solution to the problem of therapists' unwillingness to provide 'sham' treatment and the associated ethical problems (Fitter & Thomas, 1997). In addition, it is suggested that effectiveness of treatment in day to day practice is what is of most interest to doctors and therapists (Meade et al., 1990).

Moreover, during the initial planning of the study, after discussion with the therapists concerning the usual number of treatments required for patients with CLBP to improve, and consideration of the financial costs, it was decided to offer participants six treatment sessions. Whilst the mean score for each group demonstrated small reductions in pain after treatment, it is apparent that there were some individuals who improved more than others. This leads one to question whether six sessions were enough for some participants, and to ask whether further treatment could have led to similar gains for those who had not improved after the initial six. Certainly CM therapists would argue that they treat patients as individuals, thus each is different and may require a different duration or frequency of treatment. Similarly, within the psychotherapeutic literature, there is some evidence to suggest that more sessions result in more clients improving (e.g. Howard et al., 1986). Nevertheless, it is suggested that within the current market economy of the NHS, or indeed the financial constraints of the private user concerned about cost effectiveness, six sessions might be regarded as adequate time for some benefit to be demonstrated.

5.1.7 Summary

It is apparent that participants in the reflexology group experienced the greatest reduction in pain, the largest improvement in functioning, visited their GP or any other type of therapist less, and took less medication than those in the other two groups. However, with the exception of visits to their GP, none of these differences were significant. Therefore, while these results demonstrate a slight trend towards a more favourable outcome for those who had reflexology, they do not indicate that reflexology is clinically effective. Furthermore, the treatment preferences expressed by participants at recruitment did not appear to have an effect on outcome, nor did the individual therapist who conducted the treatment. Nevertheless, as stated in the introductory chapter of this thesis, in relation to other treatments (both OM and CM) for back pain, failure to demonstrate an effect does not mean that the therapy is ineffective. However, it must be stated, that in the absence of any differences between treatment groups, there is insufficient evidence to support the efficacy of reflexology for CLBP.

In addition, results add to the debate surrounding the use of relaxation treatment for CLBP. Relaxation is a common component of many pain management programmes (e.g. Linton, 1994) and is used frequently in the management of pain. However, while there have been some positive studies, a recent systematic review of relaxation treatment for chronic pain found that there was not enough evidence to support its effectiveness. In addition, Donaldson (1994) did not find a positive effect for relaxation in the context of CLBP specifically. Similarly, this study, although not primarily concerned with the efficacy of relaxation, found that the mean scores of those participants who received relaxation did not improve significantly after treatment. The continued use of this treatment must surely be questioned. Of course it may be that relaxation per se is not effective, whereas it could be one of the necessary components of a multidisciplinary approach and thus work effectively in combination with other features of such treatment. Nonetheless, it would appear appropriate to further investigate the use of relaxation treatment for the management of pain. Similarly, data from the current study supports recent systematic reviews which argue that much of the usual care patients receive from their GP, for CLBP, has not been shown to be effective.

A number of previously identified relationships between the measured variables were confirmed by the results of the correlational analyses. Depression, catastrophising, pain, functioning, satisfaction with social support and general health status were all associated, which further reinforced the notion of CLBP as a complex biopsychosocial phenomenon. Though, it was not possible to determine the direction of these relationships, and for example, to ascertain whether the experience of CLBP had an effect upon depression, or vice versa. However, the fact that functioning as measured by the ODQ was predictive of pain after treatment suggested that failure to maintain the activities of daily living could exacerbate CLBP. Nevertheless, the direction of the relationship between these variables is still unclear, indeed it is possible that it is reciprocal. Therefore it is suggested that more research be conducted in order to ascertain the direction of some of these associations. For example, the use of path analysis could provide a means with which to assess the temporal and developmental aspects of these relationships.

5.1.8 Limitations of quantitative method

A number of limitations of the current investigation are apparent, some of which have been discussed already and will not be reiterated in depth here. Others are indicative of the types of limitations afforded by pragmatic RCT studies in general. However, these should be viewed within the parameters of the present study. CLBP is a 'real world' problem, and as such it necessitates the use of naturally occurring samples, such as patients from primary care, in order to evaluate 'real world' solutions. Thus it is pointed out that the methodology adopted here provided an ecologically valid means of assessing the efficacy of reflexology in practice, as opposed to a strict experimentally controlled assessment of reflexology which would have little relevance for its application in primary care.

Accordingly, this investigation is restricted in the extent to which the results are generalisable to the CLBP population as a whole. All participants were recruited from primary care sources, and it is recognised that those who present at primary care, are already a sub-sample of the total population of back pain sufferers (Walsh, 1992, Mason, 1994). In addition, GP's decided which patients conformed to the inclusion/exclusion criteria, and thus who could be referred, which may have biased the sample. Furthermore, some of the sample were self referring, via the poster, and this needs to be taken into account. However, the aim of the study was to ascertain whether and to what extent reflexology was effective in practice. Therefore it is argued that these limitations present less of a problem than may be anticipated, as they served to indicate the level of interest primary care patients have in reflexology, and provided an estimate of the potential uptake, should a reflexology service ever be offered.

Moreover, the inclusion criteria were broad i.e. back pain of greater than three months duration, and this may have resulted in a widely heterogeneous sample. A symptom based diagnosis was adopted in the current study (Croft et al., 1998) due to the difficulties inherent classifying subgroups of CLBP in any meaningful way, e.g. by aetiology (Croft et al., 1997). Nevertheless, it is possible that one 'type' of CLBP, for example that of less than 12months duration, could have responded more favourably than another 'type'. However, the lack of differences between participants at recruitment on a range of psychosocial dimensions, suggests that whatever the cause or duration of their back pain, their experience of having CLBP was initially broadly similar. Furthermore, as previously argued, evaluation of the therapy on a wide range of patients, enhanced the applicability of the trial results.

In common with other studies, attrition was a factor in the present study, and thus results should be interpreted with caution. In addition there was a small problem with participants reporting that they had completed and returned questionnaires which were never received. The study utilised the university freepost system which necessitates that envelopes are coded and returned to a central department by the post office. They are then sent on to individual staff members via the internal post system. Despite several discussions with the post room the situation did not improve. Furthermore, it was difficult to return to participants on more than one occasion requesting completion of another questionnaire, although participants generally complied with this request. However, a small number did not, thus it must be accepted that some were genuinely lost, while others may not have been returned in the first place. In addition, it was anticipated that participants who did not want to receive either reflexology or relaxation when it was offered would revert to the usual care group. This only happened on a couple of occasions, but those participants then failed to continue with completion of the questionnaires.

As previously stated, attrition led to uneven groups and the consequences of this for analyses of the post treatment data were considered. The data generally satisfied the necessary assumptions for ANOVA, i.e. normal distribution, homogeneity of variance and compound symmetry (Munro, 2001). However, Gatchel & Maddrey (1998) argue that ANOVA is relatively insensitive to violations of the normality assumption. Nevertheless, in those instances where Mauchley's test of sphericity was significant, the degrees of freedom were adjusted using Epsilon, and the Greenhouse Geisser results reported. In addition, it was recognised that repeated exposure to the questionnaire measures could have been a problem, as participants may have become sensitised to it. Although given the time intervals between each questionnaire (at least 6 weeks) and the relatively small improvements in the mean scores of each group this is unlikely to have been a significant issue.

It is apparent that the results of the present study would have been enhanced if the author had been blind to the treatment participants received. This was not possible due to the increased costs which this would incur. However, participants were only identifiable by trial number on the study database, and as there were over 240 of them the likelihood of the author recalling individual participants scores was slight. In addition, as the author is neither a reflexologist, relaxation therapist or GP it is argued that objectivity was maintained, and thus any threat to the internal validity of the trial was minimised.

Finally, the current study relied primarily on self report questionnaires. Turner & Jensen (1993) highlighted how demand characteristics could influence self report, and this may have occurred here. Indeed, factors such as the attention of the researcher or therapist, and acquiescence, are common features of outcome studies. However the usual care group who did not receive any additional intervention but who still completed the questionnaire should have controlled for this to some degree.

5.1.9 Recommendations for future research

The results of the present study indicated trends towards a more favourable outcome for those participants who received reflexology treatment. Thus it is apparent that reflexology was successful for some participants, and it is suggested that further exploratory analyses could determine whether there were any commonalities between such participants. For example the use of discriminant function analysis to identify whether those who experienced a reduction in pain had a different profile on the measured variables compared with those who did not may be useful. This could address the question of whether heterogeneity of the current sample had an effect on outcome. In addition it may provide valuable information to aid potential users/purchasers in their decision about whether to use the therapy or not.

As stated previously, the further confirmation of a relationship between depression and a number of other variables in this study is encouraging, particularly as a relatively new instrument was used to assess symptoms of depression (BDI II). However, given the lower levels of depression in the current sample, it is suggested that the use of this instrument warrants further investigation, as this would enable the extent to which scores may be potentially inflated by criterion contamination to be determined. Similar work completed on the BDI IA (Williams & Richardson, 1993; and Williams & Morley, 2000) with chronic pain patients yielded useful information, which aided clinicians in their interpretation of the scores on this instrument.

5.2 Interview One Discussion

Data from interview one revealed that approximately 50% of the sample had used some form of CM therapy before. This figure is higher than previous studies of CM use in the general population have estimated, e.g. 31% (Which? 1995), 34% (Eisenberg et al., 1993), 20% (White & Ernst, 2000) and 28.3% Thomas et al. (2001). It is also greater than the 34% reported by N=245 patients attending pain clinics. There are a number of possible explanations for this.

The first concerns the methodological quality of previous studies, in particular the definitions of CM employed. Harris & Rees (2000) conducted a systematic review of CM use and noted that differential definitions of CM severely restricted comparison between studies and therefore any conclusions they were able to make. Nevertheless they reported that a 'substantial proportion' of the population used such therapies, however it should be noted that none of the estimates were above the 50% recorded in the current study. The second relates to the current sample, i.e. patients with CLBP participating in a research project designed to evaluate a CM therapy. The highest users of CM are people with musculoskeletal pain (Thomas et al., 1991, 2001; Paterson, 1997; Paramore, 1997; Verhoef & Sutherland, 1995) and back pain has been found to be responsible for around half the cases of incapacity due to musculoskeletal problems (Rosen, 1994). Therefore it is perhaps to be expected that more of the current sample have utilised CM than the general population samples surveyed in previous studies. In addition, it is possible that patients with an interest in CM were more likely to take the opportunity to participate in this study when it was offered to them, than those who did not have such an interest. This factor could also account for the high rates of CM use reported here.

Reasons put forward for using CM also concur with those reported elsewhere (e.g. Vincent & Furnham, 1996, 1997; Sharma, 1992) the two primary ones being lack of OM provision and dissatisfaction with OM when it was provided. However this too needs to be viewed within the context of the previous treatment histories of the current sample. Many had experienced a variety of failed OM treatments over a long period of time. Moreover, it should also be recognised that CLBP is a complex and notoriously difficult condition to treat in primary care, which perhaps increases the likelihood that patients will seek alternative or complementary treatments.

Furthermore, a small number of participants referred to the fact that CM did not involve taking medication as something which had attracted them. Such instances lead one to question whether *any* other intervention, which did not include taking medication would have served the same purpose. Alternatively their use of CM may exemplify a 'pull' factor (Vincent & Furnham, 1996) that is, participants were more attracted to CM because of the natural systems of healing, rather than 'pushed' away from OM because of worries about the side effects of medication.

The ways in which users found, or were directed to particular therapists, appears to concur with previous research on pathways to CM (e.g. Sharma, 1992). Certainly recommendation of family, friends, GP and/or information on treatment from books, magazines and other media have been shown to be important determinants (e.g. Vincent & Furnham, 1994; Vincent & Furnham, 1997; Kristof et al., 1998). In the current study, 21% were recommended to try CM by their GP. This figure is similar to the number (25%) of GPs in Devon & Cornwall who stated they would advocate the use of such treatment (White et al., 1997). However, another study of CM users (Budd et al., 1990) found much higher rates: 83% of those visiting an osteopath and 58% of acupuncture users reported the treatment had been suggested by their doctor. Nevertheless, while these figures are incongruent with those found in the current study, they each demonstrate that the GP has a role to play in some patients' decision to consult a CM therapist.

This has important implications for GPs and other health professionals with whom patients consult for advice and/or information about particular CM therapies. GPs are often seen as gatekeepers to other health care services (BMA, 1993). In this respect, as Botting & Cook (2000) argue, doctors' views regarding CM are important because they may influence patients' decisions about utilising CM therapies. Indeed Thomas et al. (1995) reported 64% of people seeking CM had consulted their GP first. Similarly, Zollman & Vickers (1999) suggest that while GPs cannot be experts in all CM fields, they need to be able to offer clear and impartial advice on the safety and efficacy of CM treatments based on the evidence available to them.

In the current study, 3.5% of participants specifically stated they had not used CM because their GP had advised against it. The author is unable to comment upon the reasons these particular GPs had for this attitude. However, the recent CSAG report on services for patients with chronic pain (2000) found lack of evidence for the efficacy of CM was the main reason that 11% of GPs would not recommend it. Given the comment participants in this study attributed to their GPs it does not seem unreasonable that a similar explanation may be relevant here.

On the whole, participants' GPs were not negative about CM, indeed as stated previously, some had recommended it, and this would appear to concur with the existing literature. Reilly & Taylor (1993) found that 92% of 212 Scottish doctors they surveyed believed CM to be useful, whilst 76% said they had seen patients benefit from it. Furthermore, 63% of Scottish medical students were in favour of CM being included in the NHS (Halliday et al. 1993). Similarly, Furnham et al. (1999) in a study comparing attitudes to CM of medical and social science students, found that medical students appeared to have a positive and moderately sceptical attitude towards CM. This is encouraging for the future integration of CM into primary care. However it must be remembered that a relatively large proportion of the current sample had used CM before. Thus it is possible that these patients had GPs who were particularly positive and/or open minded about such treatments. In addition to which, patients with similar attitudes towards CM may have actively sought out GPs whose views were congruent with their own.

Moreover, participants' reports that advice from family and friends was a factor in their decision to use CM, and for some important in their choice of therapy, is in accordance with previous studies (e.g. Kristof et al., 1998). This, in combination with the other pathways to CM that users highlighted (GP, media, as an alternative to OM, or a last resort) demonstrates the complexity of the decision to choose and use a CM therapist. Sharma (1992) found that for most people, the initial visit to a CM therapist was prompted by a pragmatic desire to cure some intractable problem, whereas subsequent decisions to attend were influenced by the outcome of that first encounter. Similarly Furnham (1993) agreed that it is probably the continuation of a chronic illness with attendant pain and discomfort which may initially drive patients of OM to seek treatment elsewhere. However, Conroy et al. (2000) argued that the factors which influence choice of treatment are not only complex but may be qualitatively different depending upon the condition that requires treatment.

Helman (1990) agrees that the therapeutic choices of sick person are complex, and further points out that one should not necessarily differentiate between those who visit CM or OM. In addition, Helman suggests patients opt for a particular therapy based upon a number of issues such as chronicity of their complaint, demographic factors and advice of friends/family. Similarly Janz & Becker (1984) argue that people have a health model including these dimensions which determines whether or when they seek professional care for a health problem. Within OM, Elliot-Binns (1986) found that 96% of those who consulted their GP had only done so after discussion with family and/or friends beforehand, and just over half had treated themselves before going to see their doctor. Based on the data from this study it is apparent that decisions to use CM may also be influenced by such factors. In addition, choice must also be made on the basis of what is available (Furnham & Bhagrath, 1993, King et al., 1983), and this may in turn be influenced by financial factors (Klienman, 1988). Indeed Vincent & Furnham (1994) suggest that individuals may be 'judicious shoppers' using CM and/or OM dependent upon condition, need and availability.

The above discussion suggests that all patients are active in health care decisions. Data from the current study reveal that this may not be the case. A number of participants said they had not used CM because no one had ever asked them to, and that they just saw the doctor if they had a problem. This is congruent with the notion of the GP as 'gatekeeper' (BMA, 1993) who provides a pathway to different health care when they see it as appropriate. It is also perhaps indicative of an external locus of control (Rotter, 1954) in these particular participants, who place all their faith in the GP 'knowing what's right.' Furthermore it suggests that for individuals like these, CM will only ever be utilised at the behest of their GP. This has implications for the integration of CM into primary care, as if patients do not request it (or information about it), and the GP does not accept it as a valid addition to the services they provide, then potentially it will not be available in some primary care practices.

Unfortunately, five participants who had used CM experienced some negative effects of treatment. As stated, each of these instances concerned manipulative therapies. Shekelle et al. (1992) state that there are no published systematic reports on the frequency of complications from spinal manipulations, so it is not possible to determine whether this figure is high. Shekelle et al. notes that while serious complications including paraplegia and death have been reported along with other, less serious ones, levels of occurrence are not known, though he suggests they are probably low. The fact that there are little or no data on the potential complications of this or other types of CM therapy is something which warrants further investigation (White & Ernst, 2000), and it is suggested that potential side effects of treatment should be evaluated alongside the potential positive effects in any study concerning the efficacy of CM therapies.

The issue of efficacy was not only a factor which prevented GPs recommending CM treatment, it was also cited by non-users as something which had prevented their use of CM. Of course the only way to address this issue is to follow the example of the current study, and answer the numerous calls for more and better quality research into the effectiveness of CM (BMA, 1993, House of Lords report, 2000, White & Ernst, 2000). In addition, the results of such research would need to be widely disseminated in a format that was assessable to both to health professionals as well as 'lay' potential users.

However, concerns over efficacy were also entangled with issues around the cost of CM treatment for some participants. In a country where the majority of health care is free at the point of delivery it is perhaps understandable that individuals may be reluctant to fund the cost of their own treatment, particularly one that is 'unproven', or question continued personal expenditure for a treatment that no longer appears to be effective. This is congruent with the perception of CM as 'private medicine' and therefore a luxury item for those with less disposable income, although the cost of CM however, is actually quite modest when compared to that of private OM medicine (Wolsko et al., 2000). Nevertheless, in the current NHS climate, with the emphasis on evidence based medicine and where provision of CM is sporadic, it must be accepted that CM is for many a 'private medicine'

5.2.1 Summary

It is apparent that while participants in this study had been or were more frequent users of CM than the general population, their reasons for using CM were similar to those of previous studies. This lends further support to Vincent & Furnhams' (1996) thesis that patients are either 'pushed' or 'pulled' into using CM, because of their dissatisfaction with OM or because of the attractiveness of CM systems of healing. This similarity with previous samples is encouraging. The current sample were initially identified as patients from primary care with CLBP, rather than users/non-users of CM, yet when classified as such they appear typical of other survey populations. In addition, this study further highlights that while pathways to CM are complex, they may not be qualitatively different to those used when making decisions about OM.

5.2.2 Limitations of interview one

Limitations concerning the sample are similar to those highlighted in the first section of this discussion chapter, though it is recognised that some may be more pertinent here. They were all recruited from primary care sources to participate in a research study designed to evaluate a CM therapy, and this may have been a source of systematic bias. It is possible that the primary care sources who took part in the study were more open to CM than those that did not. Similarly, while precise figures are not known for all recruitment methods, the response rate to the letter of invitation was 29.4%. Potential participants with positive perceptions of CM may have been more likely to respond than those who had negative or neutral perceptions of CM.

As with all assessment tools, participants' responses to the interview questions could have been affected by a number of factors, including inaccurate recall. In addition it cannot be denied that the desire to provide socially acquiescent responses may have been greater in the context of a face to face interview than via the questionnaire. Furthermore, the interview was conducted before either the author or the participant was aware of the group to which the participant had been randomised. Therefore it is possible that the participant may have been more positive about CM treatment they had utilised previously in the hope that they would get more, or been negative about any past treatment in order to receive some additional treatment. However as the author informed all participants about the randomisation process, it is argued that they were aware that nothing they said at interview would affect the group to which they were randomised.

5.2.3 Recommendations for future research

This aspect of the study highlighted some of the different factors which influence individual's decisions about the health care they seek. Sharma (1992) argued that factors which lead a person to first visit to a CM therapist, may be different that those which result in future visits. Some participants in this study reported consulting more than one type of CM therapist. However, they were not asked to differentiate between the reasons which first led them to visit a CM therapist or those which led to subsequent visits. Thus it is suggested that it may be useful to look longitudinally at evolving attitudes to CM generally and factors which influence choice in particular. In addition, it would appear that a systematic survey of therapists and users to determine the nature and frequency of any negative effects is warranted.

5.3 Interview Two Discussion

Therapists and the therapeutic relationship were major themes referred to by all participants, regardless of whether they were in the reflexology or relaxation group. It is apparent that these factors were also related to other aspects of the treatment experience. It is argued the therapeutic relationship is central to the participants' experience and views of the therapy. Similar findings have been reported in previous studies of CM users which have found the nature of the relationship between CM therapist and patient to be important in terms of satisfaction with treatment and outcome (Sharma, 1992; Emanuel et al., 1996; Vincent & Furnham, 1996; Vincent & Furnham, 1997; Zollman & Vickers, 1999; and Luff & Thomas, 2000). In addition, these findings are analogous to data from research conducted specifically on users of reflexology (Trousdell, 1996; Coxon, 1998; and Launso et al., 1999). Indeed Launso et al. suggested that the therapist was the catalyst for change within patients, allowing them to exhert control over their 'illness-wellness' ratio. However it may not be the therapist per se but rather the interpersonal relationship between therapist and patient which is the primary instrument for change.

Congruence with former research findings is encouraging when one considers that previous studies have generally surveyed users of private CM therapists, who it is argued may view their experience of the treatment more positively because of their financial investment in the therapy (Bandolier, 2000). However, Luff and Thomas (2000) conducted a survey with a group of patients (N=49) who were receiving CM therapy on the NHS. They too found that patients perceived the therapist as caring, and valued the development of a therapeutic relationship within which they were valued as a person. The current sample likewise received treatment at no financial cost to themselves, albeit within the context of a research study, yet they appear to have similar perceptions of treatment to Luff and Thomas's sample. These perceptions are not qualitatively different to those of the self-funding users surveyed in earlier studies.

The specific positive qualities of the therapeutic relationship identified by participants concerned its egalitarian nature and being valued as an individual, not a disease. In addition the empathy, understanding and generally caring demeanour of the therapist were emphasised. All or any of these may have facilitated a positive response to the treatment. Certainly previous research has demonstrated that the consultation process and holistic approach adopted by CM therapists makes people feel more in control of their illness (Austin, 1998 and Lewith, 1998). In addition, Trousdall (1996) found 'being heard and taken seriously' were aspects of reflexology treatment which patients perceived to be beneficial. Similarly in OM, patients' organisations have found that patients value a relationship with the doctor based on mutual trust and respect between two equal partners (De Ridder et al., 1997). This need to be taken seriously may be particularly relevant in the current sample of CLBP sufferers. As the data from interview one indicated, in common with other CLBP patients, many participants had experienced a series of consultations with a variety of different health professionals in their search for relief from the pain. Indeed as other authors have found, they considered themselves to be 'in the system' (Walker et al. 1999), which may be one of the reasons participants valued the quality time spent with the reflexologist or relaxation therapist.

Furthermore, Waddell (1992) has emphasised that treatment for back pain needs to be directed at the patient rather than the spine, and recommended that patients should be active in the management and maintenance of their own health, something which the prescriptive nature of OM often fails to achieve. It is apparent that many participants in the current study were accepting of this type of responsibility, and enjoyed the partnership with the therapist, although it is recognised that not all CLBP sufferers may welcome this approach. However, it is suggested that the adoption of a more egalitarian and holistic style of consultation could enhance the opportunities within any CLBP treatment to develop this notion of active engagement on the part of the patient and therefore facilitate shared responsibility.

It should be appreciated that while some participants in the current study explicitly compared consultations with their GP unfavourably to those they had experienced with the therapist, for the majority criticism was more implicit, as they highlighted all the positive aspects of their CM treatment experience. However, Hewer (1983) found that over 90% of OM patients are satisfied with their GP. In addition Baker & Streatfield (1995) have shown that patient satisfaction is greater in primary care practices with personal lists, where patients generally see the same GP at each visit. This last point indicates that it is the development of a continuing relationship with the same practitioner, similar to the one that participants enjoyed with therapists in this study, which is an important factor for patients. Nevertheless, it would be inaccurate to assume that all CM consultations share the same characteristics as those described by participants in this study, or conversely that all GP/patient consultations are the opposite. Indeed it is accepted that variation in practitioners and consultation styles exists within both types of therapy.

A number of authors (e.g. Fulder & Munro, 1982; Furnham & Kirkcaldy, 1996 and Luff & Thomas, 2000) have argued that CM users' perceptions of their GPs as poor listeners who are disinterested in them as individuals, may be a function of consultation time as opposed to inadequate communication skills. Certainly the hour that participants spent with the therapist was considerably longer than the average few minutes of the GP consultation. Thus participants and therapists had a greater opportunity to develop the therapeutic relationship. Joyce & Richardson (1997) similarly found that CM users especially appreciated individualised treatment and hour long sessions. However, as Vincent & Furnham (1997) point out, Tate (1983) argued that consultations which and are longer and more time consuming may lead to greater patient satisfaction and compliance, but they do not always equate to better clinical outcomes.

This latter point is important in the context of the current study. Analysis of the questionnaire data revealed a main effect of pain reduction over time, but no significant differences between groups. Yet the data from interview two demonstrated that participants reported that they experienced many positive effects from treatment. This incongruence between the two sets of results leads one to question the validity of each. This point will be further discussed in the final sections of this chapter where the implications of both the quantitative and qualitative results are examined in combination. However, this current section is concerned with the results from interview two, thus the validity of this data specifically will be considered.

First, to reiterate, the majority of participants interviewed reported a transient reduction in pain, feeling less tense, more relaxed and better able to cope with their pain on a daily basis. In addition, these positive aspects of treatment were generally discussed in the context of their interpersonal relationship with the therapist. This data was derived from interviews conducted with a small sub sample of participants (n=22) at the end of the treatment phase. It needs to be considered whether the results could be influenced by 'response bias' and/or Hawthorne Effect whereby participants felt they ought to have improved because of the effort the researcher, therapist and they themselves have put into the treatment. Indeed, as Turk et al. (1993) noted, some pain patients are likely to conform to the role of dismissing symptoms at the end of treatment, and it is possible that this occurred here.

A number of factors may account for this phenomenon. Sitzia & Wood (1997) suggest that 'cognitive consistency theory' provides an explanation of why patients report they are satisfied with treatment. This theory posits that patients need to justify the time and effort they have invested in treatment, so are likely to report a positive outcome. Related to this is cognitive dissonance theory (Festinger, 1957). Participants may have had a strong investment psychologically in the treatment, either because of its novelty or because it offered increased hope for relief in the absence of their current treatment being effective. According to cognitive dissonance theory, when experience is incongruent with existing attitudes, knowledge or affect, then distress may result. It is suggested that individuals attempt to alleviate this by reinterpreting or distorting the incongruent information. In the context of treatment outcome, if no improvement occurs after committing time and effort to the treatment (and possibly adopting its philosophical foundations in the case of CM) this could result in internal disharmony. Therefore rather than admit to others that treatment was ineffective, some individuals may report positive treatment effects.

However, as previously reported the quantitative results of this study revealed a significant main effect of pain reduction over time, regardless of the treatment received. Therefore it cannot be denied that for many participants pain reduced throughout the duration of the study. The reasons for this are not known, although it may be due to the natural variability of the condition. However, given the long standing nature of CLBP reported by many participants this is unlikely to have occurred. Nevertheless, it is possible that participants in the reflexology and relaxation groups attributed their reduction in symptoms to the treatment, rather than considering that other factors may have been responsible. In retrospect, it would perhaps have been useful to interview some of the usual care group to ascertain whether they also attributed any improvement they experienced to the treatment they received.

This leads on to another issue, i.e. the role of expectations. In outcome research patient expectations have received considerable attention (Flood et al., 1993), not least in the study of the placebo effect (e.g. Richardson, 1994, 1995; Turner et al., 1994). While the placebo effect has been demonstrated in numerous studies, it is not well understood theoretically (Simmonds & Kumar, 1994). However it is argued that positive expectations of treatment can have a significant effect on outcome (Skevington, 1995; Richardson, 1997; von Korff et al., 1998). In addition it is recognised that the expectations of the therapist are also likely to be important. Nevertheless, when participants in the current study were asked what they expected of the treatment, none referred to the expected outcome, but instead spoke of expectations in terms of the 'mechanics' and process of treatment. Of course this needs to be viewed within context. Participants were fully informed of the purpose of the study prior to giving their consent. Therefore they were aware that while reflexology was used by many CLBP sufferers, one of the aims of the project was to determine whether or not it was effective. Thus those interviewed were perhaps unlikely to hold highly positive expectations about treatment outcome. However it is accepted that attending treatment in the first instance may indicate some expectation of benefit by the participant, otherwise one could argue that they would not bother to attend at all. In addition, as Vincent & Furnham (1996) argue, the actual experience of CM therapy may in turn have developed a commitment to it, and thus influenced expectations of its outcome.

Interestingly, there were few differences between themes expressed by participants from either group. Thus it is suggested that any treatment effects perceived to have occurred were not due to the either reflexology or relaxation treatment, but rather to a number of 'non-specific' effects operating within the context of the therapeutic encounter. This is in partial agreement with the conclusion put forward by Ernst & Koder (1997) in their overview of research into reflexology, and is related to work by others attempting to explain the 'placebo effect' in CM generally (e.g. ter Riet et al., 1994, Kleijnen, 1994; Kleijnen & de Craen, 1996; Ernst, 1996; Di Blasi et al., 2001). Von Korff et al. (1998) argued that 'non-specific' effects in treatment for chronic pain may be related to: attention; interest; the expense or impressiveness of the intervention; patient or provider expectations or the characteristics of the setting in which treatment is provided. Despite this, little research attention has gone beyond the simple labelling of such factors as non-specific and focused specifically on their role in relation to outcome of CM treatment.

Data from the current study however provided some indication of the specificity of these non-specific factors in CM treatment, and point towards avenues for future research endeavour. It is apparent, given the perceptions of participants, that the therapeutic relationship or therapeutic alliance warrants detailed consideration. In addition it needs to be recognised that outside the sphere of CM therapy, this has already undergone some scrutiny.

Eysenck's critique (1952) that two thirds of neurotics who received psychotherapy improved substantially, while an equal proportion of those who did not receive psychotherapy also improved, prompted a great deal of research into the therapeutic relationship in psychotherapy. More recently Stiles et al. (1986) proposed the possibility that different psychotherapies may be broadly equivalent in their outcomes due to the overriding effects of common factors, a conclusion referred to as the 'equivalence paradox' for which the therapeutic alliance between therapist and patient is thought to be responsible.

A positive therapeutic alliance, defined as a positive and collaborative relationship between patient and therapist has been found to be associated with a positive clinical outcome across a range of psychological therapies and clinical conditions (Cape, 2000). In particular the therapeutic alliance in psychotherapy is generally considered to include the positive bond between patient and therapist, as well as their mutual collaboration concerning the goals of treatment. (Gaston, 1990; Hovarth & Luborsky, 1993). The similarities between this definition and the nature of the relationship between CM practitioner and patient are inescapable.

In addition, the importance of the doctor patient relationship and its therapeutic potential has long been recognised in general practice (e.g. Balint, 1964; Ley, 1988). Furthermore, studies of patient satisfaction in general practice have distinguished between procedural and affective aspects of the therapeutic encounter (Cape, 2000). Participants in the current study similarly separated these two aspects of the therapist's role. Thus it is suggested that, rather than replicate previous work, the existing large body of evidence available on aspects of the therapeutic relationship within the OM, counselling and psychotherapy literature be considered, in order to appropriately focus research in this area within CM therapy.

To some extent the foundations for this type of work may have already been laid. Mitchell & Cormack (1998) bring together a selection of literature from the aforementioned disciplines in order to describe the therapeutic relationship within CM therapy. Indeed they describe a model of the relationship which summarises aspects of treatment seen to be important, i.e. mutuality, trust, challenge and care. The model was first proposed by Mitchell (1995) and is perhaps best described as a series of waves, through which a relationship develops. Thus each component is seen in the context of all other aspects of treatment in a cyclical fashion. However, while the model has face validity, it has yet to be tested. Hence, at present, it is best viewed as a useful descriptive framework for future study of the therapeutic relationship.

In addition, while not solely concerned with the therapeutic relationship, Long et al. (2000) are currently in the process of developing a tool to measure holistic practice. Qualitative interviews and focus groups have been conducted with CM therapists and their patients' to determine which aspects of the CM intervention are defined as holistic. However, while a small pilot study has been conducted, no details of the instrument they have devised are provided, and Long et al. report that further validation is required.

There is however, also a need to appreciate the role of intrapersonal factors within the context of the therapeutic relationship. For example, the results of this study revealed one participant whose perceptions concerning the efficacy of reflexology did not change with his experience of the therapy. Indeed he displayed scepticism throughout, and his beliefs did not concur with those of the therapist, which may have acted as a barrier to him fully engaging with either the therapy or the therapist. Certainly consideration of the quantitative data from this particular participant supported this, as there were no improvements on the primary outcome measures (SF36 Pain and ODQ). In contrast, it is possible that participants with enhanced interpersonal skills who are less sceptical are able to forge a better therapeutic alliance with the therapist, or perhaps perceive it as such, and thus improve clinically more quickly than those who have not. Similarly, while a number of participants reported that internal or external factors distracted them from engaging in the treatment on occasion, others did not. Thus it is suggested that some individuals may have been more practised in the skills necessary to control their reaction to environmental and/or personal distractions. This perhaps enabled them to immerse themselves completely in the treatment process, and so optimise its potential.

The issue of environmental factors has implications for the integration of CM therapies into primary care. In keeping with the pragmatic nature of the trial, treatment sessions in this study were provided at participating GPs' surgeries. As well as being more geographically convenient for participants, it was also considered that this would provide some indication of uptake should the service be offered to patients, were it demonstrated to be effective. However, the general level of noise etc within the surgery was highlighted by a number of participants. Therefore it is suggested that this be taken into account when providing a CM service in a primary care setting. As the experience of one participant demonstrated, simply providing such a service at times when the surgery is quiet, e.g. Saturday morning, would address this to some extent, and potentially ameliorate the perceived effects of treatment.

If one accepts that intrapersonal factors can affect an individual's experience of treatment per se, it must be recognised that they may explain some of the variation in reported outcome to such treatment. Indeed, it is apparent that a number of participants in the current study accepted this, as is demonstrated in their attempts to explain their response to treatment. In particular, those who did not experience any long lasting positive effects blamed themselves for this. They were not dismissive of treatment, indeed they were reluctant to suggest that the treatment itself was ineffective and suggested it may help others. Of course, it is possible that this too may be explained by cognitive dissonance theory. Whereby participants cannot say it worked, as clearly it did not, yet they cannot deny it might, as they had attended all the sessions and the therapist told them it had worked for others. Furthermore, as previously mentioned, the background of previous treatment failures reported by many needs to be considered.

Moreover, there were some participants with positive treatment outcomes who adopted an 'explanatory model' (Klienman, 1988) in which the effects they experienced were considered to be the result of psychological mechanisms. This is congruent with Frankel's (1997) notion of a psychological theory for how reflexology works, and similarly supports the idea that the relaxation may be work by distracting the person from the pain (e.g. Seers, 1993; Vasterling et al., 1993). Furthermore, it could indicate that some participants were themselves aware that the effects of treatment were determined by the therapeutic relationship rather than the therapy itself. An alternative explanation for those in the reflexology group is also possible. Attributing the effects to psychological mechanisms may be understandable for therapies that defy logical explanations and 'fly in the face of science.' Participants who found it difficult to connect specific massage of the foot with effects in distance parts of the body may have been susceptible to this. In addition, it needs to be recognised that not all participants attempted to explain how the treatment had worked for them. For these people it was simply enough to have found something that 'worked for me.'

In a similar way, any reduction in pain was viewed positively by all participants, no matter how transient it was. This is in contrast to the findings of Emanuel et al. (1996) who interviewed patients with musculoskeletal pain referred by their GPs to complementary therapists. They found that while some would consider any relief a good outcome, others would view transient relief very negatively. Nevertheless, in the current study, pain reduction, even of limited duration, was seen to be desirable. This reinforces the notion that patients are more interested in relief, rather than management of pain, which is perhaps why treatments often appear to 'fail' from their viewpoint (Turk & Rudy, 1990). In addition, it illustrates the importance of gaining patients' perspectives of treatment outcome in order to ensure that realistic expectations are fostered by the treatment provider.

The positive effects of treatment expressed by participants in this study reflect those of previous studies. With regard to pain relief, both Seers (1993) and Philips (1988) found a short-term decrease in pain after relaxation. Similarly, in the study by Launso et al. (1999) 23% of headache patients said they were cured after reflexology treatment while a further 53% said they experienced relief after treatment. Furthermore, reports of feeling less tense, more relaxed and better able to cope with their pain on a daily basis provides support for Tiran's (1996) thesis that reflexology may be beneficial as it helps to relax and de-stress the patient, enhancing their coping ability. In addition it is in keeping with Seers (1993) notion that relaxation works by reducing muscle tension and provides a coping mechanism, which once taught to patients can be used independently to deal with pain.

The only negative experiences of treatment occurred in the reflexology group and were reported by two participants. They may have been indicative of a 'healing crisis' which reflexologists report may occur as a response to treatment (e.g. Mackereth, 1999). However there is no hard data on the frequency or duration of such events. Indeed where they are mentioned in practitioner handbooks or patient information leaflets, details are at best described as vague. Nevertheless, the negative effects endured by participants, while unpleasant, were short lived and did not discourage them from continuing with treatment. In addition, each referred to the therapist as reassuring them that they were common, and nothing to worry about, this further reinforcing the power of the therapeutic alliance between therapist and patient.

What is perhaps interesting in the accounts of treatment is the absence of any reference to touch from participants in the reflexology group. Touch is the medium via which reflexology is practised, whereas this is not the case for relaxation. Lack of reference to touch may not mean that it did not impact on treatment, just that it was not articulated by participants. Perhaps it is such an integral part of reflexology it was taken for granted, and participants did not consider it necessary to mention. Alternatively, it may have been perceived as secondary to the relationship with the reflexologist. However, touch may be considered a primitive form of communication that can produce a sense of reassurance and calm in a patient (Campbell, 2000). This has also been shown in studies of a particular type of 'hands on' therapy: therapeutic touch (e.g. Krieger, 1993). In addition, Fishman et al. (1995) in an experimental study found that physical contact was associated with significant decreases in heart rate and pain ratings. Therefore, although participants did not discuss touch specifically, it is possible that it is a factor which could account for some of the relaxation effect experienced by those in the reflexology group. Of course in the absence of any data to support this hypothesis, at this time it remains conjecture.

The remaining theme, common to participants from both the reflexology and relaxation groups, concerned their intention to use the therapy they had received again. It is suggested that this may be seen as an objective test of treatment efficacy from the individual's perspective. Certainly it is not unreasonable to conclude that those who intend to continue with the therapy are likely to have perceived that they derived some benefit from it. Although it is has to be accepted that this may be divorced from their CLBP. In addition, there are other factors, independent of efficacy, which may influence future use. The financial burden of accessing treatment privately was mentioned by more than one participant, and, as the data from interview one demonstrated, was a primary reason why some participants had not used any type of CM before. This raises a potential ethical question for the current study, which concerns the provision of treatment that patients perceive to be effective, followed by its withdrawal after six sessions. However, this issue is not peculiar to this study, but concerns all RCTs where treatment is provided for the duration of the evaluation only (Prescott et al., 1999). Nevertheless, as all participants were fully informed before being recruited to the study, it is suggested that any distress experienced by those who were denied further free access to treatment should have been minimal.

Related to this is the problem of participants not receiving their preferred treatment. Of those interviewed, three participants in the relaxation group expressed regret that they had not been randomised to the reflexology group. However, they went on to describe how they had enjoyed relaxation and been pleasantly surprised by its effects. It would appear therefore that for these participants, relaxation did not initially have the same face validity as reflexology. But this perception altered with their experience of the treatment, as Sharma (1992) suggests may occur with any patient new to CM. As previously stated, these conclusions are based upon data gathered from N=22 interviews with participants who had received relaxation or reflexology treatment as part of the main study. Therefore generalisation of the results is limited. Nonetheless, as data from the main study demonstrates, compared with the reflexology group, attrition was greater in the relaxation group and greater still in the usual care group. Thus, it is suggested that one possible explanation for this is failure to receive one's preferred treatment. This issue of preferences and their relationship to outcome is explored further in the discussion of the quantitative results (see section 5.1.5).

5.3.1 Summary

It is evident that participants' experiences of reflexology and relaxation shared many common features, most noticeably reference to the therapeutic relationship between themselves and the therapist. It is similarly apparent that few comments related specifically to physical aspects of either therapy per se. Thus it is suggested, as others have, that any perceived benefits of treatment reported by participants may be more suitably accounted for by the range of non-specific factors that are also common to both treatments. These aspects of CM generally, and reflexology in particular, require further investigation, in order to delineate which, if any, non-specific factors are necessary for a positive therapeutic outcome.

Of particular interest is the therapeutic relationship. It is probable that a CM therapy which involves relatively long consultation and treatment times, tailored to the individual's needs, delivers more than simply the therapy in question. The therapeutic alliance may provide a 'legitimate' means for people who perhaps would not ordinarily engage formally in this type of relationship to do so. Thus, while it could be argued that the development of such a relationship with any health professional and/or therapist, especially a counsellor or psychotherapist, could result in similar positive outcomes, it is suggested that this may not be the case. Individuals who consult reflexology or relaxation therapists do so because of the therapy and what it may offer, not to engage in psychotherapeutic work. However, As Mackereth (1999) illustrated in a case study, the reflexology session does provide the potential for this to occur, and this aspect of treatment warrants further investigation.

The six main themes generated from particpants interview data, were considered to represent their experience of the treatment. Indeed, the aim of the interview was to enable the process and outcome of treatment to be explored from the perspective of the participant. However examination of the six themes: therapist/therapeutic relationship; environmental factors; role of self; effects; explanatory models; and future use, revealed similarities with the taxonomies of patient satisfaction proposed by Ware et al (1983) and Fitzpatrick (1990). Thus participants may have been expressing satisfaction with treatment as opposed to reflecting on their experience of treatment, and the two may be qualitatively different. Alternatively it is possible that the themes highlighted by participants are those that were important to them, which would obviously be in accordance with aspects of treatment they would evaluate to describe their satisfaction. In addition, it should be recognised that patient satisfaction is a notoriously difficult concept to assess (Van Campen, 1998). Instruments which purport to measure it may be subject to demand characteristics and a tendency towards positive scores (Williams et al., 1993). Therefore they often reflect highly skewed results, with over 90% of responders satisfied with their health care (Van Campen, 1998), which does not reflect everyday experiences. Moreover, it is apparent that high satisfaction is not always associated with a positive treatment outcome, indeed as previously stated satisfaction may actually overrate treatment effectiveness (Sitzia & Wood, 1997). Thus, given the experience of participants in this study, the possibility remains that their views were a reflection of their satisfaction with treatment rather than its outcome.

The data from this interview study suggest that there are few differences between reflexology and relaxation from the perspective of the participant, with each experiencing some degree of relaxation and transient pain reduction. Therefore the notion that reflexology is effective over and above the non-specific effects of treatment cannot be supported. This is in agreement with the conclusions of Ernst & Koder (1997). However, Tiran's (1996) premise that reflexology induces relaxation would also appear to be supported. Similarly the results offer tentative support for Trousdell's (1996) argument that reflexology appears to work because it meets emotional needs.

Finally, the results of this interview highlight the fact that outcome for participants is, or may be, expressed in different terms to that of researchers or service providers. These latter groups may place inappropriate emphasis on specific magnitudes of change on objective measures, while participants appear to be encouraged by more subtle changes. Asking participants for their views provides an indication of their perceptions of outcome which may help to inform the clinical versus statistical significance of change debate. This is an issue which is expanded upon further in the final sections of this chapter where related points from the results of each method of data collection are discussed collectively.

5.3.3 Limitations

A number of limitations of the post treatment interview are apparent, some of which have already been highlighted in the preceding discussion and will not be expanded upon further here.

No claim is made that the sample here is representative of all patients with CLBP who attend reflexology or relaxation therapy. Certainly it is accepted that the extent to which the results may be generalised to other populations of CM users or CLBP sufferers is limited. However, every effort was made to ensure participants were randomly selected from the study population (N=234), and that they were representative of it. Furthermore, the interview and analysis process was iterative and continued until analysis of the data reached saturation point, i.e. when no new themes emerged from the data.

All interviewed participants had completed the treatment phase of the study. It has to be accepted that this may have introduced some bias into the sample. Participants who failed to attend treatment or dropped out of treatment after a few sessions did not take part, and it is possible that they may have reported differently. Another potential source of bias could have included participants providing socially acquiescent responses, being selective in their recollections, and/or overestimating the efficacy of treatment in the hope that this may lead to continued provision. Moreover it is recognised that the data collection and analytic procedures are each susceptible to the author's reconstruction of events and therefore bias. However, attempts were made to ensure this was reduced. The purpose of the interview was outlined comprehensively to participants and the author's interpretation of the data was verified by interviewees as well as another member of the research team. As discussed previously, this was not to ensure that a 'single truth' emerged, but rather to check that the conclusions of the author were supported by the data.

The absence of any data from the therapists limited examination of the process of treatment. An attempt was made to collect this type of data, via therapists' record sheets, but variance in the quality of this information rendered it unsuitable for analysis. Nevertheless it is recognised that this information would have provided another useful perspective on the treatment process as well as outcome.

In retrospect, the fact that interviews were conducted only after treatment may have been an oversight. The interviews asked participants to review their experience retrospectively. This meant that no firm conclusions could be drawn concerning the (potential) causal mechanism of the therapeutic relationship on treatment outcome. Indeed, while the interview data provided an indication of the process of treatment, a more comprehensive understanding might have been gained by interviewing participants before and after the treatment phase. It is argued that this would have provided a more valid assessment and allowed any changes that occurred throughout the duration of the therapy to be determined.

5.3.4 Recommendations for future research

The nature of the therapeutic relationship in CM warrants further and more detailed study. It is recognised that evaluation of this aspect of CM will be complex and difficult, not least because of variation in the ways that individuals interpret experience. However it is suggested that the use of a variety of methods could aid deconstruction of the encounter between patient and therapist. For example a measure of the encounter itself via observation or tape recording could be combined with pre and post session in-depth interviews of the patient and/or therapist. The results of this type of research might indicate which aspects of the encounter, if any, are essential for a positive treatment outcome and this in turn could inform, and potentially enhance the future practice of CM therapists.

The aspects of treatment highlighted by this interview data may be utilised to develop a questionnaire. This would allow examination of the extent to which the themes described by the current sample, are generalisable to other users of CM (both NHS and private).

5.4 General Discussion and Conclusions

5.4.1 Introduction

The previous three sections of this chapter have discussed the results of the analysis performed on the data collected via the questionnaire, interview one and interview two. In this, the final section, the results of both the quantitative and qualitative analysis are considered together. In addition, the implications of this for future research into CM therapy are discussed, and some recommendations for practice made. First however the strengths of the methodological approach adopted in the current study are outlined.

5.4.2 Strengths of study

The present study was designed to address a number of the problems associated with previous studies into CM generally, and reflexology in particular, which were identified in chapters one and two. Thus the primary strength of the study was its methodological rigour. A RCT design was utilised, commonly perceived to be the most powerful tool for evaluating health care interventions (e.g. Prescott et al., 1999). Participants were randomised, using a minimisation technique to one of three groups: reflexology, relaxation or maintain usual care. This ensured the groups differed only by chance, and that the minimisation factors were distributed evenly throughout, thereby reducing bias. Moreover, the use of three groups meant that reflexology was not only compared with usual care, but also with relaxation, which controlled for the reported relaxation effect of reflexology as well as attention from the therapist.

Standardised, previously validated outcome measures designed to reflect the biopsychosocial nature of CLBP were incorporated into the design to enable a critical evaluation of a holistic therapy such as reflexology. In addition changes in the primary outcome parameters were stated *a priori* and the size of sample required to determine such effects calculated, and recruited. This represents a considerable achievement when one considers that it has been estimated around half of clinical trials fail to reach their planned size (Easterbrook & Matthews, 1992). However, it should be recognised that the development of additional recruitment methods during the initial stages of the study, along with the broad inclusion criteria facilitated recruitment.

The pragmatic nature of the present investigation was also seen as a strength, as it ensured that the question practitioners are interested in, i.e. does the therapy work in practice? could be answered. Indeed the protocol was designed to ensure compatibility with normal practice. The value of this type of research on real life clinical populations in real world settings, with its attendant methodological difficulties, is increasingly recognised (Knottnerus & Dinant, 1997). In addition, whilst the pragmatic RCT did not allow blinding of the participants or the therapist to the treatment, it did enable contextual factors to be taken into account and some ethical issues to be addressed. Therapists were not required to provide sham treatment, and participants were fully informed of the treatment under scrutiny and the trial protocols before giving their consent.

Previous studies in reflexology have been criticised because the person who delivered the therapy also evaluated it (e.g. Fosholt, 1992). However this did not occur in the current study as treatment outcome was evaluated by the author. It is argued that this ensured that objectivity was maintained during the analyses and reporting of results. Of course, as previously stated, results would have been enhanced had the author been blind to the treatment condition.

In addition to all the advantages of the RCT design, the present study addressed issues surrounding treatment process as well as treatment outcome via the use of qualitative interviews. These were conducted after the treatment phase with a subsample of participants which enabled their perceptions of the treatment experience as well as outcome to be explored in depth. Furthermore, the semi-structured interview carried out with the whole sample (N=234) at recruitment provided participants with the opportunity not only to say whether they had used CM before, but also to describe their reasons for this. Participants' treatment preferences were also elicited at this interview. Thus the range of data collected throughout the duration of the study and at follow up represented a comprehensive overview of treatment from a number of perspectives.

5.4.3 Comparative evaluation of qualitative and quantitative results

As the preceding sections of this discussion chapter have shown, the results of the pre-post treatment analysis on the questionnaire data were not entirely congruent with those derived from the post treatment interview with a sub-sample of participants. However, each did demonstrate trends in the same direction. To recap, quantitative data analysis revealed a main effect of pain reduction over time, with no differences between groups, though this was not considered to be indicative of a clinically significant change. The qualitative data showed that participants experienced a generally transient reduction in pain. Thus it is apparent that the question of whether reflexology is effective depends not only on the particular perspective taken, but also on the level of specificity employed in defining 'therapeutic success.'

For the purposes of the present study the author defined a successful outcome in terms of participants' improvement levels on the two primary outcome variables. It was apparent however, that interviewed participants were less precise in their definition of therapeutic efficacy, and appeared to be satisfied with a more subtle reduction in pain, whatever its duration. This raises the question of whether therapists, participants and the author had different ideas of a positive outcome to reflexology or relaxation, which in turn has implications for the conclusions which can be drawn from the data. A question raised in chapter one with regard to the Petersen et al. (1992) study, is also relevant here, should the participants' view of efficacy be negated because the 'scientific' parameters showed no effect? Or, should the appropriateness of those parameters be questioned because they are not congruent with the participants' idea of efficacy? Furthermore, it is recognised that health care purchasers and providers concerned at the rising cost of providing treatment for CLBP may express additional, different views when defining a successful treatment outcome. Thus it is suggested that these differing levels of analysis be taken into account when evaluating treatment, and that outcome is defined in terms that have currency for both providers and consumers alike.

This is not a new idea. As long ago as 1977, Strupp & Hadley noted that the definition of what constitutes a successful outcome will depend upon who is asked: patient, practitioner or provider. Furthermore, Melles et al. (1995) argued that success in terms of treatment outcome for pain is difficult to define and is not homogeneous, a view supported by the present author. Nevertheless, it is argued that the pragmatic approach adopted in the current study addressed this issue to some extent. It was recognised that individuals can vary in their response to treatment. However, it has to be accepted that the average budget holder is generally concerned with the effect that a given treatment will have upon a given type of patient population, not with individual differences. The use of mixed methods in the current study enabled outcome to be considered from the perspective of both the participant and the researcher. Thus it is argued that aspects of the results of the study may potentially have currency for purchasers, practitioners, prospective individual users, and health care personnel faced with enquiries for information about reflexology.

The use of more than one method is demanding and taxing on the skills of the researcher (Poole et al., 1999). Nevertheless, it is argued that the variety of data generated is more informative than that which would result from the use of either method alone. In addition to offering tentative support for the trends apparent in the questionnaire data, and therefore providing a modicum of convergent validity between the two sets of results, the qualitative aspect of the study also addressed some of the limitations inherent in the quantitative methods (Duffy, 1987). In particular, these related to participants' perceptions of the treatment itself. The RCT provided one of the best ways to determine cause and effect (e.g. Vickers, 1996). However, it failed to take into account what happened during treatment, i.e. between the 'before' and 'after' measurements. This information was accessed via the post treatment interview. Furthermore, the questionnaire data revealed slight improvements across all groups, and this indicated one shortcoming with the qualitative method. That is, it might have been more informative had some of the participants from the usual care group been interviewed as well as those from the reflexology and relaxation groups. This would have enabled the author to determine to what they attributed positive changes in their condition.

Consideration of the data from both aspects of the study leads one to further question whether the variables measured by the questionnaire were legitimate for the more general, subjective effects of a therapy such as reflexology. However, the measures employed in the current study are commonly used to evaluate outcome to treatment for CLBP (Deyo et al., 1998; PMP Consensus Meeting, 2000) and have previously been used to assess the efficacy of CM therapies in this domain (e.g. ODQ-Meade et al., 1990; SF36-Brown et al., Thomas et al., 2000). Therefore it is suggested the measures were legitimate, and they were able to demonstrate some changes over time. Nonetheless, it is appreciated that the magnitude of change considered by participants in this study to be clinically significant was less than the figures derived from previous research (e.g.Fisher & Johnston, 1996; MacPherson et al., 1995).

While not conclusive, the data from interview one which reflected on participants past experience of OM and CM, may have provided an indication of why some of them did not attend all therapy sessions, i.e. treatment was either not, or had ceased to be, effective. If one assumes that those who stopped attending did so because the therapy was not effective, then one must accept that those for whom it was effective may be over represented in the remainder. Therefore it is suggested that in future studies of this nature some attempt is made to follow up non-attendees and ascertain their reasons for continuing with the treatment.

In the absence of any definitive evidence for the efficacy of reflexology, consideration of how it works may seem inappropriate. However, some participants did benefit from the treatment, and the findings of interview two echo those of previous researchers (e.g. Trousdell, 1996; Mackereth et al., 1999). Thus it is suggested that any positive effects may be explained by non-specific factors, such as those surrounding the therapeutic relationship. Indeed, reflexology may respond to patients 'felt needs' and in this regard, a psychological theory (Frankel, 1997) may most suitably explain how it works.

5.4.4 Implications of results for reflexology and relaxation

Based upon the evidence of the current study, the author cannot recommend reflexology as an effective treatment for CLBP, nor sanction its widespread use or funding within the NHS for this condition. However there is a caveat. Whilst reflexology did not demonstrate efficacy over and above that of usual care or relaxation for the group in this study, it was effective for some individuals. Therefore, if an individual patient with CLBP expressed an interest in reflexology, it is suggested they try it, as although it does not work for everyone, it is a seemingly safe therapy, and some benefit may be gained from it. In addition, failure of the pragmatic RCT to demonstrate that reflexology is effective does not mean that it is ineffective. Indeed, as previously stated, it simply points to the need for further research.

Similarly, this study has done little to clarify the debate on the efficacy of relaxation for CLBP. Those in the relaxation group did not improve as much as those in the reflexology group on the primary outcome measures. However, participants who were interviewed found relaxation to be beneficial. This suggests it was as effective as reflexology from the participants' perspective. Relaxation was provided in very small groups, it was therefore a less expensive alternative than reflexology, which was given on an individual basis. Such factors would need to be considered by service providers if the participants' view of a successful outcome was accepted as evidence for efficacy.

The reader is reminded however, that reflexology and relaxation are both commonly used therapies. Furthermore, the results of this study need to be considered in the wider context. As chapter one demonstrated, many OM and CM treatments for CLBP have not been shown to be effective, yet they continue to be requested, prescribed or accessed privately. In terms of provision with the NHS, this suggests that the concept of evidence based practice has not been adopted universally. Harrison (1998) argued that clinicians are more likely to be influenced in their choice of intervention by either their own experience with similar types of patients or vicariously via the experiences of colleagues. In addition, Hicks et al. (1996) have suggested that a contributory factor to the lack of impact of initiatives such as the Cochrane Collaboration may be that health professionals have '...fundamental and deep-seated attitudes which are resistant to research' (p1033). Whilst not an ideal situation, these factors suggest that along with many other treatments, relaxation and reflexology will continue to be available as long as people want to use them, no matter what the evidence for their efficacy suggests.

5.4.5 Implications for practice

A number of implications which arose from the current study have been highlighted already within the preceding sections on each aspect of the study (5.1, 5.2 & 5.3) and will therefore not be reiterated here. Nevertheless, the following additional observation is made.

Many aspects of the therapeutic relationship were found to be influential to treatment outcome. This may be one of the reasons why people opt for private CM therapy, as rather than addressing their clinically determined health care needs, it addresses their desire to be listened to (Murray & Shepherd, 1993). In the context of primary care, Little et al. (2001) recently reported that patients preferred a 'patient centred' approach which encompasses good communication and partnership. Of course the time required to develop this type of relationship is seldom available in primary care settings, and this has implications for both CM and OM therapists. CM therapists seeking to integrate themselves into primary care will have to resist pressure to conform with shorter NHS consultation times (Luff & Thomas, 1999). On the other hand, OM practitioners who are interested in capitalising on the positive effects of the therapeutic relationship will need to negotiate increased contact time with patients.

It is recognised that increased time with a patient does not necessarily equate with a more positive outcome (Tate, 1983). Nevertheless, it is argued that in the current climate of patients demanding more information, and increased participation their own treatment, longer consultation times will become essential. Thus it is suggested that it may be useful to try to determine the optimum consultation time required for different types of therapy, in order to inform the practice of both CM and OM for CLBP.

5.4.6 Implications for Research

The type of design, i.e. pragmatic RCT, used in the current project has been successfully employed previously to evaluate outcome to treatment for CLBP (e.g. Meade et al., 1990; Klaber Moffatt, 1999). Furthermore, in the present study, the incorporation of qualitative data collection techniques enhanced the design and enabled another perspective of efficacy, as well as information on the treatment process, to be obtained. An additional benefit was that the pragmatic nature of the trial enabled therapists to treat participants as they would in their everyday practice. Therefore, the author would recommend a similar design for future studies to evaluate the efficacy of CM therapies. However, based on the experience of conducting this study, it is suggested that attention be paid to the sample size throughout the study, in particular the level of attrition.

With regard to the definition of a successful outcome, as previously stated this will depend upon who is asking the question and why. There is no definitive answer, though it may be better to adopt a broader definition to take into account the psychosocial factors surrounding CLBP. It is argued that asking participants, either via the questionnaire or interview, whether they considered the outcome was successful and why, would be informative. In this study it would have allowed the author to determine whether participants' ideas of a clinically significant difference were congruent with those defined *a priori*, based on previous research. Thus it is suggested that future research projects address this issue. It is possible, for example, that smaller or larger changes in scores on the SF36 are indicative of significant clinical changes from the patients' point of view, and this would have obvious implications for the interpretation of results.

Study of therapeutic process in CM has been recommended (Mitchell & Cormack, 1998), and a number of narratives and case studies have appeared. However, whilst these provide a useful description, a more systematic evaluation of the therapeutic process is required. This would perhaps allow the specific components of treatment which patients perceive as effective, to be identified. Such information could then be used to enhance treatment efficacy.

A longitudinal study of the evolving attitudes and perceptions of patients regarding CM is recommended. As Sharma (1992) argued, what drives an individual to access CM initially may be qualitatively different than the subsequent reasons they use. For example, it would have been useful to interview participants in the current study before and after treatment, in order to 'map' changes in their perceptions over time. As well as questioning users of CM generally, it may be more informative to ask specific groups of patients, and note any differences between them dependent upon their condition. Interview one revealed that many patients with CLBP had used a variety of CM practitioners over a period of time in a search for relief from their pain, and highlighted a number of reasons for their choice of therapy/therapist. However this information was entirely retrospective, and it is argued that more valid and reliable data may be gained using a prospective design.

Additional suggestions for the direction of future research are provided at the end of each of the previous sections (5.1, 5.2 & 5.3).

5.4.7 Final Summary

CLBP is recognised as one of contemporary societies major health problems, and it is estimated that the cost of direct healthcare in 1998 was £1632 million (Maniadakis &

Gray, 2000). Both OM and CM provide a numerous options for the management of CLBP, though evidence for the effectiveness of many remains equivocal. The current study was concerned with the evaluation of reflexology for the management of CLBP. A recent English survey on CM use by Thomas et al. (2001), suggested that reflexology was used more frequently than acupuncture (4.33 and 3.14 million visits per year respectively). Yet it was estimated that only £3.1 million per year was spent on reflexology in the NHS compared to £25.9 million on acupuncture. Thus it would appear that the majority of visits to reflexologists are private, and this supports the notion of a 'lay' perception of reflexology as an effective therapy.

However, as the report from the House of Lords Select Committee on CM (2000) report, quoted 'any therapy that makes specific claims for being able to treat specific conditions should have evidence of being able to do this above and beyond the placebo effect. This is especially true for therapies which aim to be available on the NHS.' Prior to the current study, evidence for the efficacy of reflexology in the context of CLBP was primarily anecdotal or derived from case studies. This study represented the first RCT of reflexology in this domain.

The results indicated that reflexology was not effective for CLBP, although there was a trend towards increased pain reduction for participants in the reflexology group. Therefore, the universal adoption of reflexology for CLBP, centrally funded within the NHS cannot be condoned based on this evidence. However, it would appear that reflexology treatment addressed some of the requirements of patients, and they were very satisfied with it. In particular, via the development of an egalitarian, empathic relationship with the therapist, patients' desires to be seen and treated as an individual rather than simply a person with CLBP were met. It is argued therefore that a person who expressed an interest should not be discouraged from trying what appears to be a seemingly safe therapy. In addition, the incongruence between results raises important questions for the design of research studies into the efficacy of CM therapies. Should the patient's view of efficacy be negated because 'objective' measures showed no effect, or the appropriateness of the scientific parameters be questioned because they are in conflict with the patient's notion of efficacy? Whatever the verdict, it is apparent that studies which consider treatment outcome need to define that outcome in terms which have currency for providers and consumers alike.

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Appendix 9 Table

Appendix 10

A10.11 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Ability to Control Pain (CSQ Control)

A10.12 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Ability to Decrease Pain (CSQ Decrease)

A10.13 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Catastrophising (CSQ C)

A10.14 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Praying and Hoping (CSQ PH)

A10.15 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Ignoring Sensations (CSQ IS)

A10.16 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Coping Self Statements (CSQ CSS)

A10.17 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Beck Depression Inventory II (BDI II).

A10.18 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Current Pain as measured by VAS (VAS1 Pain)

A10.19 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Seven day average pain as measured by VAS (VAS2 Pain)

A10.20 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Mean Number of Social Supports

A10.21 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Mean satisfaction with social supports

Appendix 11

A11.1 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Functioning as measured by the ODQ (Oswestry Disability Questionnaire).

A11.2 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = pain as measured by the SF36 Pain scale.

Appendix 12

A12.1 Repeated measures ANOVA. Comparison of treatment group, usual care group and time variables. Dependent variable = SF36 Pain

A12.2 Repeated measures ANOVA. Comparison of treatment group, usual care group and time variables. Dependent variable = Function measured by ODQ

Appendix 13

A13.1 Number of participants in each group who consulted/did not consult their GP during the baseline phase (i.e. between Time 1 & Time 2)

A13.2 Number of participants in each group who consulted/did not consult their GP during the treatment phase (i.e. between Time 2 & Time 3)

Appendix 14

A14.1 One way ANOVA for SF36 percentage change in pain at Time 3

Appendix 15

A15.1 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 General Health Perception

A15.2 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Role limitations Physical (SF36RP)

A15.3 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Mental Health (SF36 MH)

A15.4 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Energy/Vitality (SF36 EV)

A15.5 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Social Functioning (SF36 SF)

A15.6 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Role Limitations Emotional (SF36 RE)

A15.7 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Physical Functioning (SF36 PF)

A15.8 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Reinterpreting the pain sensation (CSQ RPS)

A15.9 Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Diverting attention (CSQ DA)

Appendix 16

Referral Form

Appendix 1

Patient Name **Date**

Address

Telephone Home : **Work:**

Presenting complaint and date of onset

Current Medication (include doses)

Signature **GP Name**

Address

Please send completed form to H Poole, School of Health, Liverpool John Moores University, 79 Tithebarn Street, Liverpool, L2 2ER.

Letter of invitation

Appendix 2

Dear Sir/Madam

This letter has been sent by your GP, on behalf of The School of Health at Liverpool John Moores University. The School of Health are conducting research into the effectiveness of reflexology and relaxation for chronic low back pain.

Your GP has identified you as a someone who suffers from chronic low back pain, and I would like to invite you to take part in the research.

Attached is an information sheet with some brief details about the research. I would welcome the opportunity to talk to you about it in more detail before you make up your mind.

Please complete and return the form below in the envelope provided (no stamp needed) and I will contact you within the next few days. In the meantime if you have any questions you may contact me, Helen Poole, on 0151 231 4120.

I would like to emphasise once again that this letter has been sent on my behalf by your GP. I do not have access to your name or address, and therefore require the details you provide on the reply slip to contact you.

Many thanks for taking the time to read this letter. I look forward to hearing from you soon.

Best wishes

Helen Poole (Research Associate)

I am/am not* interested in hearing more details about the research project (* delete as appropria

Name

Address

Telephone

Patient Information Sheet   Appendix 3

Here is some brief information about the research.

What is it about? This research is being carried out by The School of Health at Liverpool John Moores University and is designed to try and find out whether reflexology and relaxation therapy are effective in treating low back pain. Approximately 240 people, aged between 18 & 65, with low back pain will be invited to take part in the study. Some of these will be offered reflexology or relaxation treatment while others will continue with the care they are currently getting. All those taking part will have the opportunity to talk about their experience of back pain. If you are offered reflexology or relaxation you will have the choice of whether to accept it or not. The research team will then compare the effects of each type of treatment. It is hoped that the results of this study will inform future treatment choices for patients with back pain.

What will reflexology or relaxation treatment entail? During reflexology treatment the therapist uses their hands to apply pressure to your hands or feet. Relaxation treatment requires you to take part in progressive muscle relaxation. This involves gently tensing then relaxing all the major muscle groups of the body. Reflexology and relaxation sessions will last about 50 minutes. If you accept treatment when it is offered, you will be required to attend six sessions over a six week period (i.e. on a weekly basis). These will be **free of charge** and take place at your GPs surgery.

Will my decision to take part or not affect the treatment I am getting already? No. Participation in this research is entirely **voluntary** and your decision to take part or not will have **no effect** whatsoever on your current treatment. **Any information you give to the researchers will remain strictly confidential.**

What will I have to do? First of all you will be seen by Helen Poole, a researcher from the University, who will explain the study in more detail. If you decide you want to take part, you will be asked to sign a consent form. Then you will be asked to fill in some questionnaires about yourself and about the way back pain affects your day to day life. The questionnaires will take around 25 minutes to complete.

What will happen next? If you are interested in hearing more about the research, complete the form and post it in the envelope provided. Helen will contact you within the next few days to arrange an appointment, when you will be able to discuss any questions you may have.

Thank you for taking the time to read this information.

Appendix 4

Patient Number ☐☐☐☐

Liverpool John Moores University

The Efficacy of Reflexology in the Management of Chronic Low Back Pain

Questionnaire

Please read each question carefully and ensure that ALL questions have been answered.

Helen Poole
Liverpool John Moores University
School of Health and Human Sciences
79 Tithebarn Street
Liverpool
L2 3ER

[redacted]

THE SHORT FORM 36 HEALTH SURVEY QUESTIONNAIRE (SF-36™)

The following questions ask for your views about your health, how you feel and how well you are able to do your usual activities. If you are unsure about how to answer any questions please give the best answer you can and make any of your own comments if you like. Do not spend too much time in answering as your immediate response is likely to be the most accurate.

1 In general, would you say your health is:

(Please tick one box)

Excellent ☐

Very good ☐

Good ☐

Fair ☐

Poor ☐

2 Compared to one year ago, how would you rate your health in general now?

(Please tick one box)

Much better than one year ago ☐

Somewhat better than one year ago ☐

About the same ☐

Somewhat worse now than one year ago ☐

Much worse now than one year ago ☐

3 **HEALTH AND DAILY ACTIVITIES**

The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?

(Please tick one box on each line)

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a)	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b)	Moderate activities, such as moving a table, pushing a vacuum, bowling or playing golf	☐	☐	☐
c)	Lifting or carrying groceries	☐	☐	☐
d)	Climbing several flights of stairs	☐	☐	☐
e)	Climbing one flight of stairs	☐	☐	☐
f)	Bending, kneeling or stooping	☐	☐	☐
g)	Walking more than a mile	☐	☐	☐
h)	Walking half a mile	☐	☐	☐
i)	Walking 100 yards	☐	☐	☐
j)	Bathing and dressing yourself	☐	☐	☐

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(Please answer Yes or No to each question)

		Yes	No
a)	Cut down on the amount of time you spent on work or other activities	☐	☐
b)	Accomplished less than you would like	☐	☐
c)	Were limited in the kind of work or other activities	☐	☐
d)	Had difficulty performing the work or other activities (eg it took more effort)	☐	☐

[redacted]

5 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(Please answer Yes or No to each question)

		Yes	No
a)	Cut down on the amount of time you spent on work or other activities	☐	☐
b)	Accomplished less than you would like	☐	☐
c)	Didn't do work or other activities as carefully as usual	☐	☐

6 During the past 4 weeks, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

(Please tick one box)

Not at all ☐

Slightly ☐

Moderately ☐

Quite a bit ☐

Extremely ☐

7 How much bodily pain have you had during the past 4 weeks?

(Please tick one box)

None ☐

Very mild ☐

Mild ☐

Moderate ☐

Severe ☐

Very Severe ☐

8 During the past 4 weeks how much did pain interfere with your normal work (including work both outside the home and housework)?

(Please tick one box)

Not at all ☐

A little bit ☐

Moderately ☐

Quite a bit ☐

Extremely ☐

YOUR FEELINGS

9. These questions are about how you feel and how things have been with you during the past month. (For each question, please indicate the one answer that comes closest to the way you have been feeling).

(Please tick one box on each line)

	How much time during the last month:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a)	Did you feel full of life?	☐	☐	☐	☐	☐	☐
b)	Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c)	Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d)	Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e)	Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f)	Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g)	Did you feel worn out?	☐	☐	☐	☐	☐	☐
h)	Have you been a happy person?	☐	☐	☐	☐	☐	☐
i)	Did you feel tired?	☐	☐	☐	☐	☐	☐
j)	Has your health limited your social activities (like visiting friends or close relatives)?	☐	☐	☐	☐	☐	☐

HEALTH IN GENERAL

10. Please choose the answer that best describes how true or false each of the following statements is for you.

(Please tick one box on each line)

		Definitely true	Mostly true	Not sure	Mostly false	Definitely false
a)	I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b)	I am as healthy as anybody I know	☐	☐	☐	☐	☐
c)	I expect my health to get worse	☐	☐	☐	☐	☐
d)	My health is excellent	☐	☐	☐	☐	☐

SF36 is a trade mark of the Medical Outcomes Trust

This questionnaire has been designed to give us information as to how your back or leg pain has affected your ability to manage in everyday life. Please answer every section and mark in each section ONLY THE ONE BOX which applies to you. We realise that you may consider that two of the statements in any one section relate to you, but PLEASE JUST MARK THE BOX WHICH MOST CLEARLY DESCRIBES YOUR PROBLEM.

Section 1 - Pain intensity

☐ I have no pain at the moment
☐ The pain is very mild at the moment
☐ The pain is moderate at the moment
☐ The pain is fairly severe at the moment
☐ The pain is very severe at the moment
☐ The pain is the worst imaginable at the moment

Section 2 - Personal care (washing, dressing etc)

☐ I can look after myself normally without causing extra pain
☐ I can look after myself normally but it causes extra pain
☐ It is painful to look after myself and I am now slow and careful
☐ I need some help but manage most of my personal care
☐ I need help every day in most aspects of self care
☐ I do not get dressed, wash with difficulty and stay in bed

Section 3 - Lifting

☐ I can lift heavy weights without extra pain
☐ I can lift heavy weights but it gives extra pain
☐ Pain prevents me from lifting heavy weights off the floor but I manage if they are conveniently placed e.g. on a table
☐ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
☐ I can only lift very light weights
☐ I cannot lift or carry anything at all

Section 4 - Walking

☐ Pain does not prevent me walking any distance
☐ Pain prevents me walking more than 1 mile
☐ Pain prevents me walking more than 1/2 mile
☐ Pain prevents me walking more than 1/4 mile
☐ I can only walk using a stick or crutches
☐ I am in bed most of the time and have to crawl to the toilet

Section 5 - Sitting

☐ I can sit in any chair as long as I like
☐ I can sit in my favourite chair as long as I like
☐ Pain prevents me from sitting more than 1 hour
☐ Pain prevents me from sitting more than 1/2 hour
☐ Pain prevents me from sitting for more than 10 minutes
☐ Pain prevents me from sitting at all

Section 6 - Standing

☐ I can stand as long as I like without extra pain
☐ I can stand as long as like but it gives me extra pain
☐ Pain prevents me from standing for more than 1 hour
☐ Pain prevents me from standing for more than 30 minutes
☐ Pain prevents me from standing for more than 10 minutes
☐ Pain prevents me from standing at all

Section 7 - Sleeping

☐ My sleep is never disturbed by pain
☐ My sleep is occasionally disturbed by pain
☐ Because of pain I have less than 6 hours sleep
☐ Because of pain I have less than 4 hours sleep
☐ Because of sleep I have less than 2 hours sleep
☐ Pain prevents me from sleeping at all

Section 8 - Sex life (if applicable)

☐ My sex life is normal and causes no extra pain
☐ My sex life is normal and causes some extra pain
☐ My sex life is nearly normal but is very painful
☐ My sex life is severely restricted by pain
☐ My sex life is nearly absent because of pain
☐ Pain prevents any sex life at all

Section 9 - Social life

☐ My social life is normal and causes me no extra pain
☐ My social life is normal but increases the degree of pain
☐ Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport, etc
☐ Pain has restricted my social life and I do not go out as often
☐ Pain has restricted my social life to home
☐ I have no social life

Section 10 - Travelling

☐ I can travel anywhere without pain
☐ I can travel anywhere but it gives me extra pain
☐ Pain is bad but I manage journeys over two hours
☐ Pain restricts me to journeys of less than 1 hour
☐ Pain restricts me to short journeys of under 30 minutes
Pain prevents me from travelling except to receive treatment

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness
0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time.
3 I am so sad or unhappy that I can't stand it.

2. Pessimism
0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure
0 I do not feel like a failure.
1 I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure
0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings
0 I don't feel particularly guilty
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time
3 I feel guilty all of the time

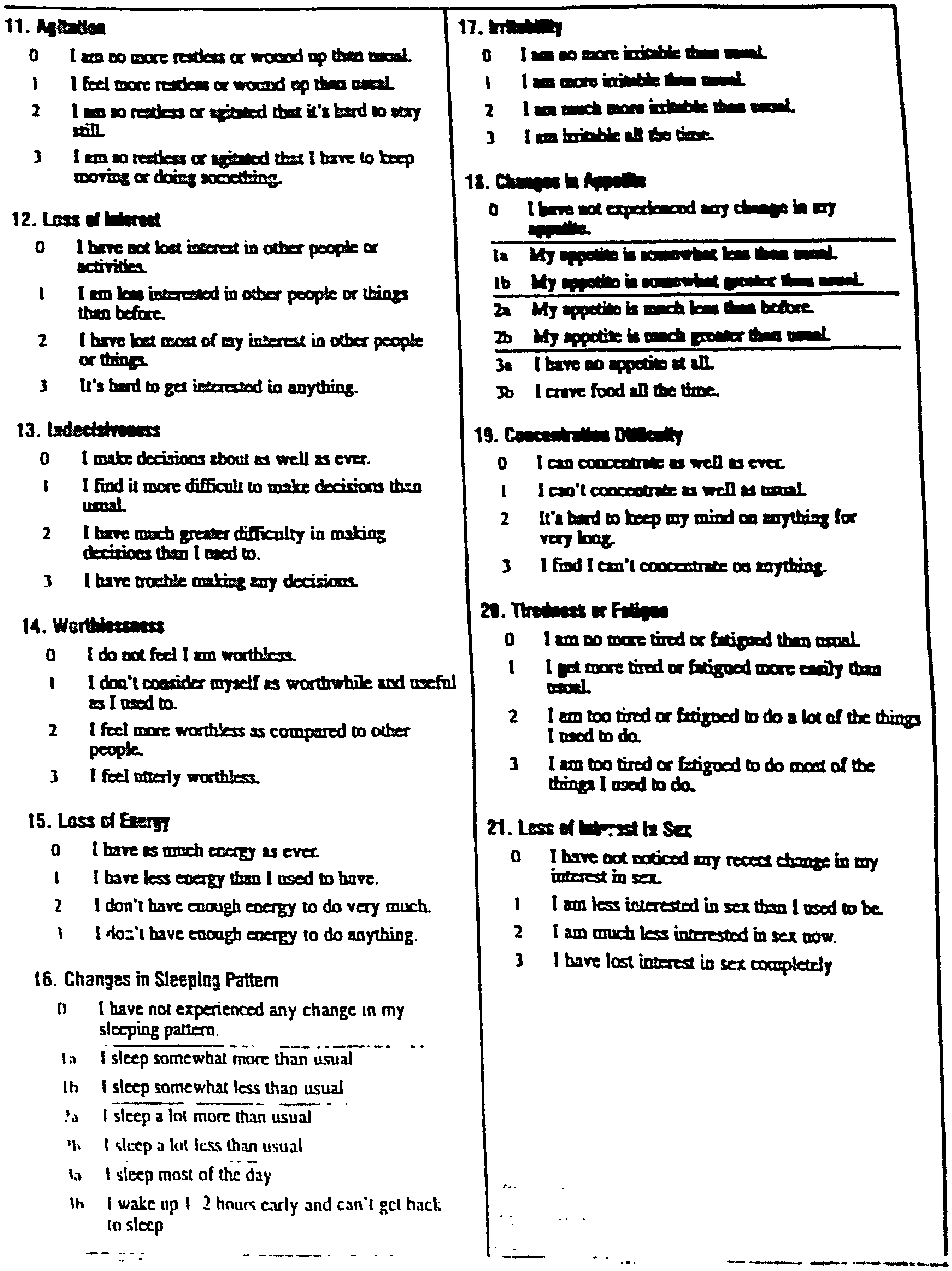
6. Punishment Feelings
0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike
0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness
0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes
0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying
0 I don't cry anymore than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.



11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I don't consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.
1a I sleep somewhat more than usual
1b I sleep somewhat less than usual
2a I sleep a lot more than usual
2b I sleep a lot less than usual
3a I sleep most of the day
3b I wake up 1 2 hours early and can't get back to sleep

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.
1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.
2a My appetite is much less than before.
2b My appetite is much greater than usual.
3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely

Individuals who experience pain have developed a number of ways to cope or deal with their pain. These include-saying things to themselves when they experience pain, or engaging in different activities. Below are a list of things that people have reported doing when they feel pain. For each activity, I would like you to indicate, using the scale below, how much you engage in that activity when you feel pain. An 0 indicates that you never do that activity when you are experiencing pain, a 3 indicates you sometimes do it when you are experiencing pain, and a 6 indicates you always do it when you are experiencing pain. Remember, you can use any point along the scale. Write the appropriate number in the box beside each question.

0	1	2	3	4	5	6
Never do			*Sometimes do that*			*Always do that*

When I feel pain . . .

☐ 1. I try to feel distant from the pain, almost as if the pain was in somebody else's body.
☐ 2. I leave the house and do something, such as going to the cinema or shopping.
☐ 3. I try to think of something pleasant.
☐ 4. I don't think of it as pain but rather as a dull or warm feeling.
☐ 5. It is terrible and I feel it is never going to get any better.
☐ 6. I tell myself to be brave and carry on despite the pain.
☐ 7. I read.
☐ 8. I tell myself that I can overcome the pain.
☐ 9. I count numbers in my head or run a song through my mind.
☐ 10. I just think of it as some other sensation, such as numbness.
☐ 11. It is awful and I feel that it overwhelms me.
☐ 12. I play mental games with myself to keep my mind off the pain.
☐ 13. I feel my life isn't worth living.
☐ 14. I know someday someone will be here to help me and it will go away for a while.
☐ 15. I pray to God it won't last long.
☐ 16. I try not to think of it as my body, but rather as something separate from me
☐ 17. I don't think about the pain.
☐ 18. I try to think years ahead, what everything will be like after I've got rid of the pain.
☐ 19. I tell myself it doesn't hurt.
☐ 20. I tell myself I can't let the pain stand in the way of what I have to do.
☐ 21. I don't pay any attention to it.
☐ 22. I have faith in doctors that someday there will be a cure for my pain

When I feel pain . . .

☐ 23. No matter how bad it gets, I know I can handle it.
☐ 24. I pretend it is not there
☐ 25. I worry all the time about whether it will end.
☐ 26. I replay in my mind pleasant experiences in the past.
☐ 27. I think of people I enjoy doing things with.
☐ 28. I pray for the pain to stop.
☐ 29. I imagine that the pain is outside of my body.
☐ 30. I just go on as if nothing happened.
☐ 31. I see it as a challenge and don't let it bother me.
☐ 32. Although it hurts, I just keep on going.
☐ 33. I feel I can't stand it any more.
☐ 34. I try to be around other people.
☐ 35. I ignore it.
☐ 36. I rely on my faith in God.
☐ 37. I feel like I can't go on.
☐ 38. I think of things I enjoy doing.
☐ 39. I do anything to get my mind off the pain.
☐ 40. I do something I enjoy, such as watching television or listening to music.
☐ 41. I pretend it is not part of me.
☐ 42. I do something active, like household chores or projects.

Based on all the things you do to cope or deal with your pain, on an average day, how much control do you feel you have over it? Please circle the appropriate number. Remember, you can circle any number along the scale.

0	1	2	3	4	5	6
No control			*Some control*			*Complete control*

Based on all the things you do to cope or deal with your pain, on an average day, how much are you able to decrease it? Please circle the appropriate number. Remember, you can circle any number along the scale.

0	1	2	3	4	5	6
Can't decrease it at all			*Can decrease it somewhat*			*Can decrease it completely*

Instructions

The following questions ask about people in your environment who provide you with help or support. Each question has two parts. For the first part, list all the people you know, excluding yourself, whom you can count on for help or support in the manner described. Give each person's initials and their relationship to you (see example). Do not list more than one person next to each of the numbers beneath each question. Do not list more than nine people per question.

For the second part, using the scale below, circle how satisfied you are with the overall support you have.

6	5	4	3	2	1
Very satisfied	*Fairly satisfied*	*A little satisfied*	*A little dissatisfied*	*Fairly dissatisfied*	*Very dissatisfied*

If you have no support for a question, tick the words 'No one', but still rate your level of satisfaction. The example below has been completed to help you. All your responses will be kept confidential.

Example

Who do you know whom you can trust with information that could get you in trouble?

(a) No one
1) TEN (Brother)
2) LM (Friend)
3) ASS (Friend)
4) PEN (Father)
5) LM (Employer)
6)
7)
8)
9)

(b) How satisfied? 6 5 [✓ 4] 3 2 1

2

(1) Whom can you really count on to distract you from your worries when you feel under stress?

(a) No one	3)	6)	9)
1)	4)	7)	
2)	5)	8)	

(b) How satisfied? 6 5 4 3 2 1

(2) Whom can you really count on to help you feel more relaxed when you are under pressure or tense?

(a) No one	3)	6)	9)
1)	4)	7)	
2)	5)	8)	

(b) How satisfied? 6 5 4 3 2 1

(3) Who accepts you totally, including both your worst and best points?

(a) No one	3)	6)	9)
1)	4)	7)	
2)	5)	8)	

(b) How satisfied? 6 5 4 3 2 1

(4) Whom can you really count on to care about you, regardless of what is happening to you?

(a) No one	3)	6)	9)
1)	4)	7)	
2)	5)	8)	

(b) How satisfied? 6 5 4 3 2 1

(5) Whom can you really count on to help you feel better when you are feeling generally down-in-the-dumps?

(a) No one	3)	6)	9)
1)	4)	7)	
2)	5)	8)	

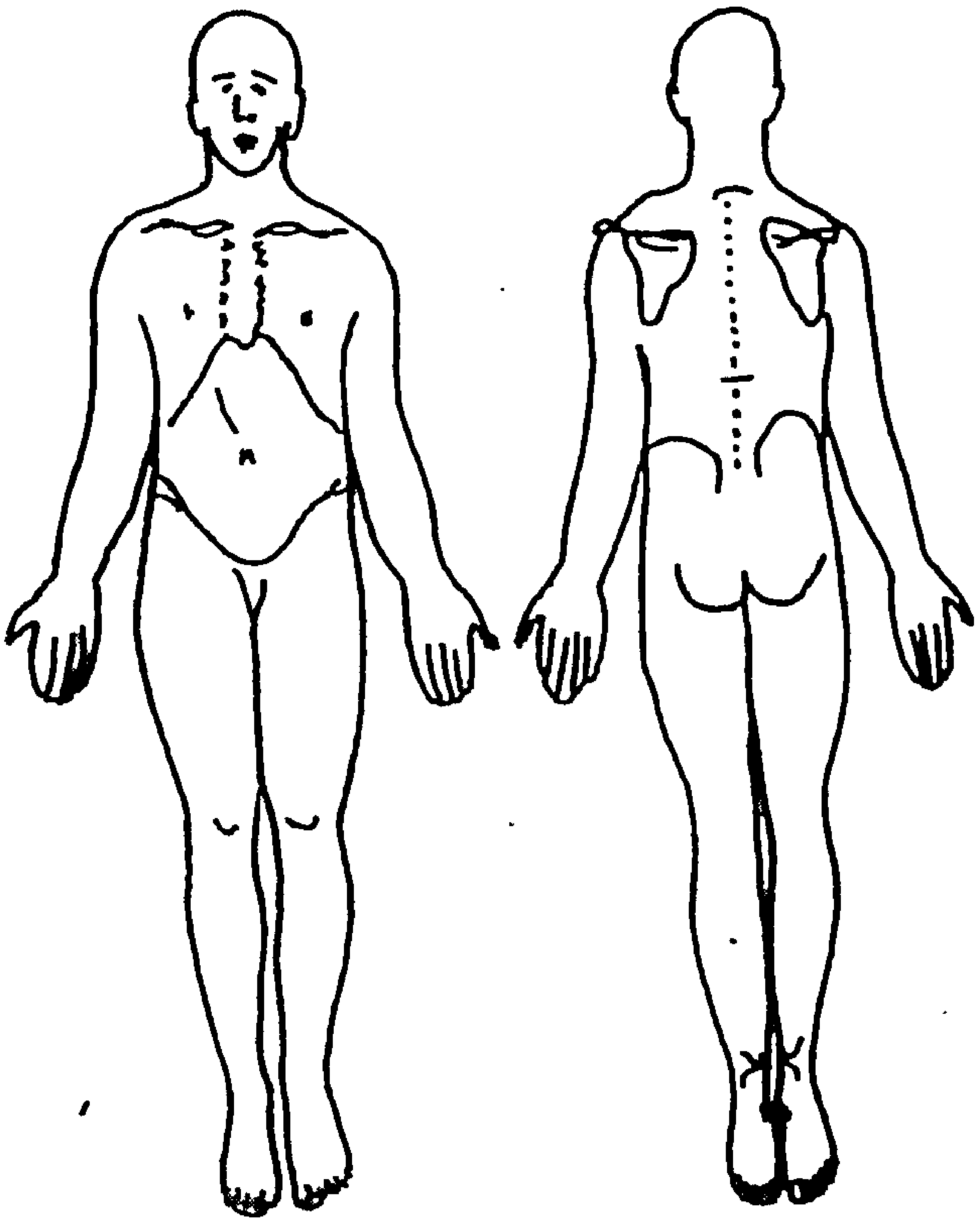
(b) How satisfied? 6 5 4 3 2 1

(6) Whom can you count on to console you when you are very upset?

(a) No one	3)	6)	9)
1)	4)	7)	
2)	5)	8)	

(b) How satisfied? 6 5 4 3 2 1

Please mark clearly on the drawings below the area(s) where your usual pain is



Please use the following lines to indicate with a cross the level of pain (associated with your back) that you feel.

For Example: Please mark on the line with a cross the level of your present pain.

If you felt very little pain at the moment you would mark the line like this:

0 —X———————————————— 100

No pain Worst pain possible

OR if you felt a great deal of pain at the moment you would mark the line like this:

0 ————————————————X— 100

No pain Worst pain possible

Please mark the line with a cross to indicate your present level of pain

0 ————————————————— 100

No pain Worst pain possible

Please mark the line with a cross to indicate your average level of pain during the last week

0 ————————————————— 100

No pain Worst pain possible

Please give details of the medications you are currently taking for your back pain (include doses)..

Have you visited your GP about your back pain since the last time you completed this questionnaire ? ....

If so, how many times ? ....
....

Have you visited any other doctors or therapists about your pain since the last time you completed this questionnaire?
....

If so, please give details ....
....
....
....
....
....
....
....
....
....
....
....

Thank you for taking the time to complete this questionnaire, and for your continued interest and support in the project.

Interview One Schedule

First appointment

Trial Number

History of back pain and treatment

When did it start?	Cause
When did you first visit the GP about it?	
What treatment was prescribed?	Was it effective
Subsequent treatment from GP/hospital	
Was it effective?	
Current medication/treatment? e.g.prescribed drugs, OTC meds, physio	List all
Is it effective? reduces pain?	
How often visit GP in last year?	Visit or repeat
Ever used complementary therapies for your back pain ? or anything else? e.g. homeopathy, chiropractic, acupuncture etc	**Yes** Describe Any particular reason for choosing that therapy, eg recommended by friend, GP, read about it Did you have to pay Was it effective **No** Any particular reason why not
Why interested in taking part in the study ?	
Group preference?	

Interview 2 Schedule

Questions and prompts

- What did you think of the treatment?
        - enjoy it - why
        - did it help - can you describe how

- Did you expect anything from the treatment?
    - what did you think it would be like to have reflexology/relaxation
    - did you think about the effect it might have...?
        - less pain (more/same)
        - less medication (more/same)
            - increased function - more able to do things you like

- Anything liked/disliked about the treatment?
    - effects/side effects
    - therapist
        - venue/room
        - actual physical treatment

- How did it make you feel?
    - comfortable/relaxed, in what way - physically, mentally....
    - what about the pain - did it change - how
    - any discomfort
    - **Changes** - if any, gradual or instant

- Sessions?
        - gaps between sessions
        - effects the same

- Therapist?
    - did she explain everything or just get on with it
    - did you get along - approachable
        - talk during session

- Would you have more of the treatment if offered?
    - worked / worthwhile
        - pay for it

- Any other comments you would like to make?

Appendix 7

Therapists record **Session Number**_______

Client's Name ________________________________ **Date**_______________

Comments

Record how client has been since last treatment (include any positive and negative after effects) ....
....
....
....
....
....
....
....

Client's expectations of, and attitude towards treatment (in particular any changes reported since the last session, if applicable) ....
....
....
....
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....
....

Flexibility ....
....
....

Posture ....
....
....

Treatment given ....
....
....
....
....
....
....

How effective do you think the treatment was?..
....
....
....
....

Name ____ Date __________

Please use the following lines to indicate with a cross the level of pain (associated with your back) that you feel.

For Example: Please mark on the line with a cross the level of your present pain.

If you felt very little pain at the moment you would mark the line like this:

0 **100**

No pain Worst pain possible

OR if you felt a great deal of pain at the moment you would mark the line like this:

0 **100**

No pain Worst pain possible

Please mark the line with a cross to indicate your present level of pain

0 **100**

No pain Worst pain possible

Please mark the line with a cross to indicate your average level of pain during the last week

0 **100**

No pain Worst pain possible

Please Note: On the original forms, space was provided to answer the following questions:

- Please give details of the medications you are currently taking for your back pain (include doses)
- Have you visited your GP about your pain since the last session ?

  If so, how many times ?
- Have you visited any other doctors or therapists about your pain since the last session?

<u>If so, please give details</u>

Appendix 8

Preliminary list of themes from initial analysis of reflexology interviews

Note: codings comprise participant number, followed by the line number, which represents the beginning of the excerpt relating to the specific code

Role of self in treatment

- **expectations**

-outcome 0001:65, 0004:311, 0074:11, 0163:41, 0173:143, 0180:51 (GP),
-process 0004:94, 0157:66, 0163:303, 0207:146,

- **treatment**

-open minded 0004:311, 0074:11, 0074:208, 0155:212, 0157:139, 0157:140, 0163:68, 0173:135, 0180:234,
-positive 0163:69, 0163:312 (vicarious) 0180:11,
-neutral 0001:65,
-negative/cynical/sceptical 0074:208 (little), 0087:143, 0173:195, 0226:35, 226:60, 0226:234,

- **beliefs**

-comparing own with therapists/others 0087:126, 0226:35, 0226:65, 0226:234, 0226:272,

- **comparison with others/previous self/disabled self** 0001:336, 0001:380, 0001:452, 0001:508, 0001:603, 0004:52, 0004:112, 0004:132, 004:182, 0004:206, 0004:262, 0074:249, 0155:88, 0157:154, 0163:148, 0173:261, 0180:294, 0207:251, 0207:274, 0226:125, 0226:243, 0226:254, 0226:282,

- **self criticism/blame** 0004:126, 0074:43, 0074:83, 0074:148, 0155:30, 0163:42, 0163:85, 0207:253, 0207:268, 0226:35, 0226:182, 0226:226, 0226:250,

- **self worth** 0004:11, 0004:198, 0163:25, 0229:109,

- **self help techniques**

-used 0074:28, 0074:53, 0074:150, 0087:14, 0087:90, 0173:64, 0180:202, 0180:339, 0207:56, 0207:251*, 0229:26, 0226:223*,
-non compliance (physical limitations) 0001:277, 0004:64,

Reflection/explanatory models

- **Mechanisms of effect**

-psychological/distraction 0004:88, 0173:70, 0173:290, 0180:209, 0229:58,
-not important (effect is, mechanism isn't) 0229:64,
-unable to explain 'v' credible 0001:327, 0001:420, 0074:15, 0087:125, 0087:142, 0155:171, 0163:126, 0226:131,

-**physical/distraction** *0004:253, 0074:179, 0229:53,*
-**manipulation-** 0074:177, 0155:206,

- **Rationalising**

-**treatment effects/non-effects related to condition variability?** 0001:245, 0001:327, 0087:194, 0155:188, 0157:146, 0157:152, 0157:230, 0180:76, 0180:139, 0180:285, 0180:382, 0207:20, 0226:77, 0226:125,

- **Diagnostic efficacy**

-**challenged preconceptions** 0087:75, 0087:145, 0163:151, 0173:196, 0173:240, 0180:255,

-**confirmed relationship between foot and body** 0074:189, 0087:65, 0155:115, 0155:127, 0155:206, 0163:115, 0173:202, 0180:182,

-**experience changed belief** 0074:15, 0074:198, 0173:202,

-**incredulous (positive and negative)** 0074:199, 0180:193, 0226:65, 0226:216, 0226:237,

Therapist/Therapeutic Relationship

- **Therapist**

-**expert in field** (some no name) 0001:409, 0074:29, 0074:62, 0074:98, 0074:161, 0163:16, 0163:183, 0163:311, 0226:17

-**beliefs/models of treatment, condition** 0173:195, 0226:35, 0226:65, 0226:237, 0226:272,

-**listening** 0074:189, 0087:163, 0157:208, 0163:18, 0163:140, 0229:68,

-**concern/reassurance** 0087:41, 0155:56, 0155:65, 0157:200, 0163:35, 0180:18, 0180:171, 0180:264, 0207:79,

- **Relationship** (*cf* GP/OM)

-**egalitarian** 0001:189, 0173:48, 0180:302,

-**social interaction (valued, not X with pain)** 0001:192, 0004:177, 0074:64, 0074:155, 0087:161, 0155:200, 0157:80, 0163:27, 0163:171, 0173:30, 180:110, 0180:302, 0207:61, 0207:186, 0229:68, 0226:66 (nice), 0226:288,

-**time/relaxed** 0004:397, 0163:16,

-**interactive** (not passive for all) 0155:210, 0163:88, 0229:70,

-**information giving** – **procedural** 0001:554, 0074:18, 0074:62, 0157:69, 0163:121, 0173:25, 0173:59, 0180:93, 0180:179, 0207:69, 0207:168, 0229:71, 0226:95, 0226:219,
- **emotional** 0074:62, 0173:25,

-**educational** (self/sig others/social) 0001:267, 0004:65, 0004:78, 0004:177, 0004:327, 0074:32, 0074:155, 0087:9, 0163:20, 0163:172, 0180:339, 0229:16,

Effects

-**immediate** 0004:35,

-**gradual** 0001:87, 0001:151, 0001:424, 0004:109, 0074:73, 0074:245, 0087:28, 0180:17, 0180:140,

-**continuous** 0074:143,

- **Pain**

-**no difference** 0157:16, 0157:31, 0157:256, 0173:9, 0173:99, 0226:32

-transient reduction 0004:38, 0004:253, 0004:394, 0155:30, 0155:39, 0155:80, 0180:26, 0180:36, 0180:72, 0207:20, 0207:176, 0226:85,
-reduction 0001:40, 0001:525, 0074:59, 0087:20, 0087:90, 0229:12,
-worse 0163:30, 0163:155,
-changed/more localised 0001:40, 0001:362,

- **Functioning**

-increased 0001:32, 0001:343, 0004:37,

- **Fear- reduced** 0001:32,

- **Coping –improved** 0001:18, 0001:430, 0155:40, 0173:277, 0173:293, 0173:305, 0229:28,

- **Relaxing** 0001:183, 0001:197, 0004:35, 0004:57, 0004:420, 0074:28, 0074:66, 0087:168, 0087:187, 0155:20, 0155:144, 0157:72, 0157:95, 0157:112, 0157:175, 0163:94, 0163:105, 0163:346, 0173:12, 0173:55, 0173:70, 0173:135, 0173:157, 0173:306, 0180:32, 180:121, 0180:284, 0207:242, 0229:11, 0229:42, 0229:83, 0226:119,

- **General Well Being**

-better 0001:87, 0001:161, 0001:534, 0001:550, 0001:591, 0001:601, 0004:246, 0074:73, 0155:63, 0157:13, 0173:138, 0180:282, 0207:15, 0229:80, 0226:77,
-sleep pattern improved 0001:444, 0001:525, 0173:173, 0207:273,
-reduced blood pressure 0180:40,
-sinus 0173:218,
-improved mood 0155:23, 0155:40, 0180:1322,

- **Medication**

-reduced 0087:85, 0207:94, 0229:13,
-self-controlled/necessary evil 0001:467, 0001:566, 0157:192, 0163:287, 0173:93, 0180:269,
-side effects 0074:102, 0074:213, 0155:244,

- **NOT Medication-compared to OM**

-natural 0004:358, 0074:119, 0155:253, 0173:296, 0180:385,
-no gastric side effects 0001:101,
-not so easy as popping a pill 0074:222,
-awakened interest in CM 0001:205, 0001:237, 0004:358, 0155:212, 0180:214, 0229:32,
-social/GP interest confirms credibility 0001:228, 0180:51,

- **Adverse Effects**

-increased pain 0001:80, 0001:369, 0001:540, 0087:36, 0157:19, 0157:187, 0163:31, 0163:155, 0163:202, 0180: 22, 0180:167,
-increased urination 0087:47, 0155:226,
-low affect 0155:50,

-none 0004:28, 0207:134, 0229:79, 0226:136,

Treatment/Sessions

- **Experience**

-pleasant 0004:102, 0004:321, 0004:422, 0074:174, 0155:15, 0157:210, 0173:259, 0180:395, 0207:79, 0229:42, 0226:234,
-uncomfortable position/feet 0004:252, 0155:111, 0163:113, 0226:99,
-tactile not visual 0004:407, 0226:40, 0226:74,
-aware of lumps/bumps 0001:390,
-strange 0226:24, 0226:187,

- **Passive** 0004:62, 0087:55,

- **Session spacing**

-difference 0001:135, 0001:540, 0087:132, ?0163:223, 0180:86,
-no difference 0004:340, 0157:92 (no treat effect), 0163:401, 0173:84, 0207:120, 0229:91, 0226:173,

- **Venue**

-medicalised (connotations) 0163:248, 0163:251,
-distractions (within self/from outside) 0087:170, 0087:201, 0163: 268,
-quiet/cosy/welcoming 0163:243, 0173:120, 0180:309, 0207:189, 0226:178,

- **Flexibility - self/others/location** 0001:128, 0163:371,

- **Continued use of reflexology**
  -intended 0001:199, 0004:426, 0074:239, 0155:148, 0163:336, 0163:358, 0180:241, 0180:362, 0207:179, 0229:117,

- **Cost**

- prohibitive 0001:201, 0001:633, 0074:35, 0173:189, 0180:295
-cost/benefit analysis 0074:42, 0180:249, 0180:284, 0207:179, 0229:115

- **Convenience** 0163:350, 0180:324,

- **Recommend to others** 0074:32, 0157:160, 0180:277, 0226:227,
- negative re:questionaire 0207:219,

Preliminary list of themes from relaxation group

Note: codings comprise participant number, followed by the line number, which represents the beginning of the excerpt relating to the specific code

- **Expectations**

- don't know 0171:25, 0212:80, 0187:28, 0187:158, 0150:108, 0231:8,
- open minded 0171:35, 0144 (positive), 0016:191, 0231:14,
- disappointed not to be in reflexology group 0171:269, 0195:430, 0144:11, 0016:76,
- negative (sceptical) 0195:171, 0195:436, 0187:22, 0187:219,
- last resort 0195:354,

- **Comparing self with others/previous self/,** 0195:248, 0195:327, 0144:314, 0096:398, 0187:163, 0187:211, 0187:379,

- **Comparing with previous treatments** 0195:54, 0195:380, 0096:351, 0212:112,

- **Self blame** 0195:64, 0195:190, 0195:423, 0144:95, 0212:22, 0016:17, 0016:163, 0187:21,

- **Comparing current pain episode with previous episodes** 0171:119, 0171:238, 0144:223,

- **Commitment to course of treatment** 0171:41, 0171:319, 0171:351, 0144:374, 0144:394, 0016:176, 0016:185, 0187:129, 0150:83,

- **Explanation of effects**

- Psychological 0171:123, 0195:226, 0195:262, 0195:335, 0096:476 (relaxed), 0150:26,
- don't know 0171:188, 0144:318,
- treatment effect 'v' variance in condition 0171:178, 0171:385, 0195:327, 0144:15, 0144:92, 0144:289, 0096:51, 0096:80,
-

- **Therapist- personal qualities**
- Empathy/concern/reassurance/understanding 0171:10, 0171:136, 0171:410, 0171:477, 0195:11, 0195:306, 0144:113, 0212:88, 0212:128, 0016:102, 0187:18, 0187:93, 0187:130, 0150:166, 0231:21, 0231:93,
- Voice/calming 0212:37, 0150:63, 0231:78,
- Information giving- procedural 0195:13, 0195:322, 0144:128, 0096:185, 0212:149, 0016:107, 0016:194, 0187:172, 0187:230, 0150:20, 0150:60, 0150:178, 0231:10,
- Educational 0144:412, 0096:185, 0212:14, 0016:46,

- **Therapist/social Interaction –general** 0171:14, 0171:280, 0171:410, 0195:309, 0144:113, 0096:185, 0212:89, 0212:128, 0187:19, 0187:79, 0150:175, 0231:88, 0231:121,

- **Treatment**

- Enjoyed 0171:64, 0171:275, 0096:16, 0096:253, 0212:17, 0016:11, 0016:175, 0187:14, 0150:12, 0150:56,

- Venue 0195:250, 0096:257, 0187:31, 0187:255, 0187:314, 0231:100,
- Actively engaged in treatment 0171:434, 0144:115, 0096:167,
- Comfortable *0171:161, 0231:99,*
- Individual 'v' group 0171:19, 0144:153, 0144:186, 0144:457, 0096:162, *0096:175,* 0212:80, 0016:69, 0016:117, 0187:45, 0187:274, 0150:60,

- **Difficult** 0171:44, 0195:104, 0195:283, 0212:50, 0187:100,
    - Practise made easier 0171:60, 0171:174, 0171:359, 0171:446, 0144:67, 0144:119, 0212:51, 0212:166, 0187:100,
    - Easy 0150:62, 0150:92, 0150:185, 0231:102,
- **Breathing exercises boring** 0195:28, 0195:282,
- **Distractions**
    - Internal 0171:41, 0171:338, 0195:43, 0195:240 0144:503
    - External 0171:52, 0171:306, 0195:21, 0144:160, 0144:503, 0096:167, 0096:193, 0187:36, 0187:335,
- **Time out** 0171:373, 0195:215, 0096:254, 0016:178,
- **Self help (continue at home)**
    - effective 0171:217, 0144:68, 0212:54, 0150:24, 0150:81, 150:126, 0231:62,
    - taught others 0150:83, 0150:131, 0150:186,
    - Ineffective 0195:93, 0187:210,
    - needs therapist to guide 0171:196, 0171:213, 0144:143 (prefer) 0187:197, 0231:72,
    - external demands 0195:33, 0195:361, 0144:438, 0096:229, 0212:206, 0016:19, 0016:66, 0016:159,
    - internal distractions 0195:62, 0096:36, 0096:117, 0187:235 (motivation),
    - preferred first mode of treatment now 0144:75,

- **Session spacing**
    - No difference 0171:257, 0195, 0144:100, 187:186, 231:105,

- **Effects**

- **Relaxation (less tense, more calm)** 0171:74, 0171:94, 0171:380, 0171:449, 0195:26, 0195:48, 0195:62, 0195:221, 0144:39, 0144:318, 0096:254, 0096:477, 0212:14, 0212:71, 0016:12, 0016:150, 0187:75, 0150:16, 0150:46, 0150:120, 0150:178, 0231:33, 0231:80, 0231:124,

- **Relaxation –transient** 0195:85, 0144:208, 0096:61, 0212:194, 0187:192, 0231:50,

- **Pain**
  - No difference over all 0171:103, 0195:51, 0212:15, 0212:60, 0016:10, 0187:14, 0187:230, 0231:46,
  - More pain 0187:252 (on occasions)
  - Reduced during session (distraction) 0171:114, 0171:142, 0016:29, 0187:63, 0231:47,
  - Transient reduction 0096:23, 0096:61, 0096:153,
  - Reduced 0144:15, 0144:48, 0144:276, 0144:379 (catalyst), 0150:18, 0150:46,

- **Increased general well being** 0171:95, 0144:31, 0144:57, 0144:276, 0096:30 (cope), 0096:142, 0096:268, 0016:95, 0150:146,

- **Improved affect** 0144:22,

- **Sleep**
  - During session 0144: , 0096:263 (?), 0096:294, 0212:31, 0150:112,
  - Improved 0144:269

- **Compared to hypnotic state** 0171:89, 0171:431, 0195:41, 0150:115,

- **Increased knowledge/interest in complementary therapy** 0144:7, 0144:40, 0096:320,

- **Medication**
  - Reduced 0144:91, 0144:210, 0150:154,
  - Same 0171:231, 0096:96, 0187:245, 0231:114,
  - More
  - Side effects 0195:194, 0212:112,

- **Continue with treatment**
  - No intention 0195:376, 0016:82
  - Intention 0171:265, 0144:151, 0144:450, 0096:196 (possibly), 0187:216, 0212:184, 0187:376, 0150:149, 0231:118,
  - Cost a factor 0171:266,
  - Cost/benefit analysis 0195:377, 0096:201,

Table A8.1: Master list of themes

Theme	Reflexology- preliminary themes	Relaxation- preliminary themes
Therapist/therapeutic relationship	• expert in field • listening, concern, reassurance, calm • therapists beliefs • social interaction (valued, not x in pain) • egalitarian • information giving: procedural/'feelings' • educational	• empathy, reassurance, concern, understanding • voice calming • educational • social interaction • information giving: procedural
Environmental/treatment factors	• discomfort • pleasant/enjoyed • tactile not visual (touch) • passive • session spacing • venue: distractions, medical connotations • flexibility/convenience	• enjoyed • comfort/discomfort • active engagement • venue: distractions • individual v group • difficult/easy • practice makes easier • breathing exercises boring • session spacing
Effects	• pain: no difference, transient reduction, reduction, worse • increased functioning • increased coping ability • relaxation • general well being • sleep • medication: same, more, reduced, SE/GI • adverse effects: increased pain, increased urination, low affect • increased interest in CM	• pain: no difference, transient reduction, reduction, worse • relaxation: transient • general well being • sleep • hypnotic state • medication: reduced, same, SE/GI • increased interest in CM
Explanatory models	• mechanisms of effect: psychological, not important, manipulation, unable to explain v credible • treatment effects v condition variability • diagnostic efficacy	• mechanisms of effect: psychological, unable to explain • treatment effects v variance in condition
Role of self	• comparison with others, previous self, previous treatment, previous pain • self criticism/blame • self worth • self help techniques • committed to course of treatment • distractions: internal/external • expectations: process and outcome • treatment: positive, negative, neutral	• comparison with others, previous self, previous treatment, previous pain • self criticism/blame • commitment to course of treatment/research • distractions: internal/external • time out • self help • disappointed not in reflexology group • expectations: process and outcome • treatment: positive, negative, neutral
Future use	• intention • cost: prohibitive • cost/benefit analysis • recommend to others	• no intention/intention • cost • cost/benefit analysis

Appendix 9

Tables related to analysis between completers and non completers

A9 Whole Group

Table A9.1: Differences at Time 1 between those who did and those who did not complete questionnaires 1, 2, & 3 (Whole group, N = 234).

Scale	**Complete**		**Incomplete**			
	Mean	SD	Mean	SD	T	*p*
SF36 Subscales						
Physical functioning	50.25	29.06	51.96	29.45	-0.408	.684
Social functioning	60.47	29.74	57.49	31.13	0.690	.491
Role limitations (physical)	30.94	41.25	40.94	43.08	-1.661	.098
Role limitations (emotional)	60.29	44.82	56.52	45.48	0.582	.561
Pain	39.73	21.01	40.58	25.34	-0.265	.791
Mental Health	60.74	20.38	59.59	21.17	0.386	.700
Energy/vitality	42.38	21.89	37.61	22.70	1.498	.135
General health perception	54.64	22.91	51.50	24.67	0.928	.355
CSQ Subscales						
Diverting attention	1.40	1.34	1.39	1.28	0.048	.962
Reinterpreting the pain sensation	0.91	1.20	0.83	1.06	-0.529	.597
Catastrophising	1.65	1.34	1.55	1.47	0.503	.616
Ignoring sensations	2.10	1.30	2.05	1.53	0.261	.794
Praying/hoping	1.68	1.40	1.84	1.43	-0.792	.429
Increased behavioural activity	2.01	1.31	1.95	1.16	0.307	.759
Coping self statements	3.32	1.45	3.12	1.39	0.937	.350
Ability to control pain	3.04	1.29	3.04	1.40	-0.028	.978
Ability to decrease pain	2.69	1.22	2.68	1.37	0.074	.941
Oswestry Disability Questionnaire	34.18	18.09	34.25	19.96	-0.026	.979
Beck Depression Inventory II	13.32	9.74	14.20	10.95	-0.606	.545
Mean number of social supports	2.74	1.90	2.54	1.78	0.741	.459
Mean satisfaction with social support	5.26	1.02	5.04	1.03	1.411	.160
VAS1 Current pain intensity	39.93	26.28	36.97	28.05	0.759	.449
VAS2 Seven day mean pain intensity	50.15	25.01	50.82	28.17	-0.176	.860
Age	48.64	10.31	41.94	11.01	4.415	**.000**
Duration of pain (months)	134.29	112.45	91.06	91.60	2.799	.034
When finished full time education	16.72	4.23	16.49	3.38	0.411	.681

Table A9.2: Number of male and female participants who did/not not complete questionnaires 1, 2, & 3.

	Complete	Non complete	Total
Male	67	28	95
Female	98	41	139
Total	165	69	234

There was no relationship between gender and compliance with completion of questionnaire 1, 2, and 3 ($\chi^2 = .000$, df = 1, $p = .997$).

Table A9.3: Number of participants who had used/not used CM previously in each of the three groups.

	Complete	Incomplete	Total
Used CM	95	24	119
Not used CM	70	45	115
Total	165	69	234

There was a significant relationship between previous use of CM and compliance with completion of questionnaires 1, 2, & 3 ($\chi^2 = 10.14$, df = 1, $p = .001$).

Table A9.4: Participants expressed treatment preference and comparative numbers for each group

Treatment preference	Complete	Incomplete	Total
Reflexology	92	36	128
Relaxation	15	2	17
Reflexology or Relaxation	26	12	38
No preference	32	19	51
Total	165	69	234

There was no significant relationship between treatment preference and compliance with completion of questionnaires 1, 2 & 3 ($\chi^2 = 4.242$, df = 3, $p = .236$).

Table A9.5: Comparative number of participants from social classes II - V in each group

Social class	Complete	Incomplete	Total
II	39	11	50
IIInm	20	9	29
IIIm	58	23	81
IV	26	13	39
V	22	13	35
Total	165	69	234

There was no significant relationship between social class and compliance with completion of questionnaires 1, 2 & 3 (χ^2 = .3.163, df = 4, p = .531).

Table A9.6: Comparative number of participants who did/did not complete questionnaires at Time 1, 2 & 3 and their vocational status.

	Complete	Incomplete	Total
Unemployed	16	11	27
Retired	26	4	30
Off sick due to pain	22	7	29
Student	2	0	2
Homemaker	13	8	21
Employed	86	39	125
Total	165	69	234

There was no significant relationship between vocational status and compliance with completion of questionnaires 1, 2 & 3 (χ^2 = .7570, df = 4, p = .182)[1].

Table A9.7: Reported qualifications for participants who completed Time 1, 2 & 3 questionnaires and those who did not.

	Complete N	Incomplete N	Total N
No qualifications	62	32	94
CSE, GCSE, O Level	37	15	52
A Level, GNVQ	44	18	62
Graduate	22	4	26
Total	165	69	234

There was no significant relationship between qualifications and compliance with completion of questionnaires 1, 2 & 3 (χ^2 = .3.442, df = 3, p = .328).

Reflexology group

Table A9.8: Differences between those who did and those who did not complete questionnaires 1, 2, & 3 (Reflexology n = 77)

Scale	Complete		Incomplete			
	Mean	SD	Mean	SD	T	*p*
SF36 Subscales						
Physical functioning	50.63	29.35	44.61	31.26	.666	.507
Social functioning	58.16	29.88	59.83	34.41	-.179	.858
Role limitations (physical)	34.77	43.78	44.23	45.82	-.705	.483
Role limitations (emotional)	61.46	44.13	64.10	41.86	-.199	.843
Pain	38.89	20.86	35.90	32.12	.427	.671
Mental Health	60.00	20.98	58.15	25.54	.278	.782
Energy/vitality	42.22	20.43	40.77	26.29	.222	.825
General health perception	55.25	21.54	49.25	27.90	.843	.402
CSQ Subscales						
Diverting attention	1.61	1.15	1.58	1.58	-1.104	.273
Reinterpreting the pain sensation	0.70	0.93	1.64	1.80	-2.731	.008
Catastrophising	1.67	1.33	1.24	1.51	1.023	.310
Ignoring sensations	1.96	1.28	3.38	1.79	-3.372	**.001**
Praying/hoping	1.61	1.46	1.47	1.21	.302	.764
Increased behavioural activity	2.03	1.37	2.55	1.11	-1.283	.204
Coping self statements	3.09	1.42	3.99	1.32	-2.084	.041
Ability to control pain	2.92	1.44	3.62	1.26	-1.617	.110
Ability to decrease pain	2.59	1.27	2.77	1.96	-.405	.686
Oswestry Disability Questionnaire	32.63	17.14	34.54	23.34	-.344	.732
Beck Depression Inventory II	12.79	8.69	13.31	9.88	-.192	.849
Mean number of social supports	5.14	1.01	5.32	0.94	-.566	.574
Mean satisfaction with social support	2.66	1.86	2.55	1.42	.185	.854
VAS1 Current pain intensity	40.22	26.96	51.00	37.22	-1.158	.251
VAS2 Seven day mean pain intensity	50.77	25.33	57.27	35.98	-.738	.463
Age	48.88	9.86	39.85	8.91	3.056	**.003**
Duration of pain (months)	129.89	117.44	75.62	89.93	1.571	.121

Table A9.9: Number of male and female participants who did/not not complete questionnaires 1, 2, & 3 (Reflexology group)

	Complete	**Non complete**	**Total**
Male	24	5	29
Female	40	8	48
Total	64	13	77

There was no relationship between gender and compliance with completion of questionnaires 1, 2 and 3 ($\chi2$ = .004, df = 1, p = .948)

Table A9.10: Number of participants who had used/not used CM previously in the reflexology group.

	Complete	Incomplete	Total
Used CM	25	7	32
Not used CM	34	11	45
Total	59	18	77

There was no significant relationship between previous use of CM and compliance with completion of questionnaires 1, 2, & 3 ($\chi^2 = .295$, df = 1 , $p = .587$).

Table A9.11: Participants expressed treatment preference and compliance for reflexology group

Treatment preference	Complete	Incomplete	Total
Reflexology	34	7	41
Relaxation	5	0	5
Reflexology or Relaxation	11	2	13
No preference	15	3	18
Total	65	12	77

The above table is for illustrative purposes only. Chi Square for participants preference is not reported for the reflexology group, due to the small drop out rate, 50% of the cells have expected count of less than 5.

Relaxation Group

Table A9.12: Differences between those who did and those who did not complete questionnaires 1, 2, & 3 (Relaxation Group, n = 82).

Scale	Complete		Incomplete			
	Mean	SD	Mean	SD	t	*p*
SF36 Subscales						
Physical functioning	54.73	29.26	60.77	28.90	-.871	.386
Social functioning	62.10	28.33	61.54	35.17	.078	.938
Role limitations (physical)	29.72	39.55	49.04	44.99	-1.950	.055
Role limitations (emotional)	56.17	46.16	60.26	47.16	-.368	.714
Pain	42.46	22.03	46.58	25.92	-.745	.459
Mental Health	62.29	20.86	59.08	23.36	.624	.534
Energy/vitality	43.55	21.83	35.96	22.72	1.441	.154
General health perception	54.54	24.26	46.77	25.32	1.331	.181
CSQ Subscales						
Diverting attention	1.62	1.35	1.21	1.47	1.216	.228
Reinterpreting the pain sensation	0.88	1.02	0.65	0.95	.975	.333
Catastrophising	1.62	1.35	1.43	1.43	.585	.560
Ignoring sensations	2.10	1.30	1.84	1.46	.795	.429
Praying/hoping	1.77	1.35	1.77	1.34	.004	.997
Increased behavioural activity	2.09	1.32	1.78	1.34	.974	.333
Coping self statements	3.34	1.44	2.81	1.59	1.480	.143
Ability to control pain	3.26	1.22	2.92	1..53	1.062	.291
Ability to decrease pain	2.89	1.21	2.69	1.12	.697	.488
Oswestry Disability Questionnaire	33.86	19.06	31.65	21.70	.466	.642
Beck Depression Inventory II	14.02	11.22	12.46	12.10	.570	.570
Mean number of social supports	5.22	1.24	4.98	1.20	.018	.968
Mean satisfaction with social support	2.86	2.02	2.85	2.08	.754	.453
VAS1 Current pain intensity	38.46	24.71	31.83	21.38	1.143	.256
VAS2 Seven day mean pain intensity	49.59	24.72	41.42	28.64	1.291	.200
Age	47.66	11.49	41.15	11.96	2.356	.021
Duration of pain (months)	148.11	114.07	88.15	66.95	2.474	.016

Table A9.13: Number of male and female participants who did/not not complete questionnaires 1, 2, & 3 (Relaxation group).

	Complete	Non complete	Total
Male	18	11	29
Female	38	15	53
Total	56	26	82

There was no relationship between gender and compliance with completion of questionnaires 1, 2 and 3 ($\chi 2$ = .803, df = 1, p= .257)

Table A9.14: Number of participants who had used/not used CM previously and complied with completion of questionnaires at Time 1, 2 & 3 (Relaxation group).

	Complete	Incomplete	Total
Used CM	38	9	47
Not used CM	16	19	35
Total	54	27	82

There was a significant relationship between previous use of CM and compliance with completion of questionnaires 1, 2, & 3 ($\chi^2 = 12.83$, df = 1, $p = .0005$).

Table A9.15: Completers and non-completers expressed treatment preference in the relaxation group (Relaxation group).

Treatment preference	Complete	Incomplete	Total
Reflexology	34	10	44
Relaxation	6	1	7
Reflexology or Relaxation	8	5	13
No preference	9	9	18
Total	57	25	82

There was no significant relationship between treatment preference and compliance with completion of questionnaires 1, 2 & 3 ($\chi^2 = 5.741$, df = 3, $p = .125$).

Usual Care Group

Table A9.16: Differences between those who did and those who did not complete questionnaires 1, 2, & 3 (Usual Care Group, n = 75).

Scale	**Complete**		**Incomplete**			
	Mean	SD	Mean	SD	t	*p*
SF36 Subscales						
Physical functioning	44.13	27.92	46.97	28.14	-.432	.667
Social functioning	61.11	32.67	54.55	25.36	.951	.345
Role limitations (physical)	26.25	39.20	32.58	40.74	-.674	.502
Role limitations (emotional)	62.60	46.06	52.53	44.90	.946	.347
Pain	38.10	20.26	36.70	20.69	.293	.770
Mental Health	59.80	19.86	60.61	16.80	-.185	.854
Energy/vitality	40.98	25.08	38.18	20.87	.513	.610
General health perception	55.50	23.38	54.30	22.96	.220	.827
CSQ Subscales						
Diverting attention	1.43	1.40	1.52	1.26	-.268	.790
Reinterpreting the pain sensation	.097	1.30	0.82	0.94	.553	.582
Catastrophising	1.55	1.32	1.90	1.49	-1.069	.289
Ignoring sensations	2.28	1.36	1.73	1.17	1.805	.075
Praying/hoping	1.63	1.36	2.09	1.59	-1.304	.197
Increased behavioural activity	1.77	1.14	1.94	1.12	-.612	.542
Coping self statements	3.59	1.51	3.09	1.14	1.588	.117
Ability to control pain	2.89	1.18	2.93	1.27	-.153	.879
Ability to decrease pain	2.55	1.18	2.67	1.27	-.393	.696
Oswestry Disability Questionnaire	36.60	18.49	36.64	16.93	-.010	.992
Beck Depression Inventory II	13.12	9.57	15.91	9.93	-1.232	.222
Mean number of social supports	2.59	1.80	2.46	1.75	.294	.770
Mean satisfaction with social support	5.44	0.71	5.01	0.91	2.226	.029
VAS1 Current pain intensity	41.42	27.71	35.97	28.24	.828	.410
VAS2 Seven day mean pain intensity	49.95	25.46	55.81	23.38	-1.01	.316
Age	50.07	9.56	43.41	10.61	2.832	.006
Duration of pain (months)	125.56	107.24	100.72	105.97	.987	.327

Table A9.17: Number of male and female participants who did/not not complete questionnaires 1, 2, & 3 (Usual care group)

	Complete	**Non complete**	**Total**
Male	23	14	37
Female	19	19	38
Total	42	33	75

There was no relationship between gender and compliance with completion of questionnaires 1, 2 and 3 ($\chi2$ = .1.125, df = 1, p= .289)

Table A9.18: Number of participants who had used/not used CM previously (Usual care group).

	Complete	Incomplete	Total
Used CM	28	12	40
Not used CM	15	20	35
Total	43	32	75

The relationship between previous use of CM and compliance with completion of questionnaires 1, 2, & 3 was not significant ($\chi^2 = 5.652$, df = 1, $p = .017$).

Table A9.19: Participants expressed treatment preference and comparative numbers (Usual care group).

Treatment preference	Complete	Incomplete	Total
Reflexology	24	19	43
Relaxation	4	1	5
Reflexology or Relaxation	7	5	12
No preference	8	7	15
Total	43	32	75

There was no relationship between treatment preference and compliance with completion of questionnaires 1, 2 and 3 ($\chi 2 = 1.194$, df = 3, p= .755)

Appendix 10

Tables related to the repeated measures ANOVA on the secondary outcome measures

Please note: Associated Means/SDs at Times 1, 2 & 3 for each questionnaire variable contained within the following analyses can be found in tables 4.4, 4.5 & 4.13 respectively

Table A10.1: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 General Health Perception

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	81.164	2	40.582	.029	.972
Error 1	213955.36	152			
		Within subjects			
SF 36 GHP	719.411	2	359.706	3.450	.033
SF36 GHP* Treatment Group	1104.310	4	276.078	2.648	.034
Error 2	31699.062	304	104.273		

Note: Total N= 155 entered into analyses

Table A10.2: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Role limitations Physical (SF36RP)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	7330.976	2	3665.488	1.037	.357
Error 1	536878.18	149	3536.095		
		Within subjects			
SF36 RP	4820.128	1.911	2521.764	3.159	.046
SF36RP* Treatment Group	6926.104	3.823	1811.777	2.270	.065
Error 2	227331.02	284	798.212		

Note: Total N= 152 entered into analyses. Greenhouse Geisser corrected results reported.

Table A10.3: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Mental Health (SF36 MH)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	48.776	2	24.388	.025	.975
Error 1	152042.13	155	980.917		
		Within subjects			
SF36 MH	2222.093	2	1111.046	7.130	.001
SF36 MH * Treatment Group	510.447	4	127.612	.819	.514
Error 2	48304.878	310	155.822		

Note: Total N= 158 entered into analyses

Table A10.4: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Energy/Vitality (SF36 EV)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	2616.535	2	1308.267	1.153	.319
Error 1	174947.37	154	1135.048		
		Within subjects			
SF36 EV	573.430	2	286.715	1.882	.154
SF36 EV* treatment Group	718.667	4	179.667	1.179	.320
Error 2	46932.394	308	152.378		

Note: Total N= 157 entered into analyses

Table A10.5: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Social Functioning (SF36 SF)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	3545.869	2	1772.934	.847	.431
Error 1	326478.49	156	2092.811		
		Within subjects			
SF36 SF	1791.849	1.881	952.443	3.616	.031
SF36 SF * Treatment Group	2253.324	3.763	598.868	2.274	.065
Error 2	77299.109	293.486	263.383		

Note: Total N=159 entered into analyses Greenhouse Geisser corrected results reported.

Table A10.6: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Role Limitations Emotional (SF36 RE).

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	700.382	2	350.191	.088	.916
Error 1	597082.03	150	3980.547		
		Within subjects			
SF36 RE	3448.641	2	1724.321	1.707	.183
SF36 RE * treatment group	6159.810	4	1539.953	1.524	.195
Error 2	303087.62	300	1010.292		

Note: Total N= 153 entered into analyses

Table A10.7: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Physical Functioning (SF36 PF)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	7163.332	2	3581.666	1.553	.215
Error 1	352792.22	153	2305.832		
		Within subjects			
SF36 PF	915.424	2	457.712	4.815	.009
SF36 PF* Treatment Group	251.044	4	62.761	.660	.620
Error 2	29085.708	306	95.051		

Note: Total N=156 entered into analyses

Table A10.8: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Reinterpreting the pain sensation (CSQ RPS)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	14.826	2	7.413	2.294	.105
Error 1	449.130	139	3.231		
		Within subjects			
CSQ RPS	3.971	1.856	2.139	4.378	.016
CSQ RPS * Treatment Group	2.862	3.713	.771	1.578	.185
Error 2	126.090	258.043	.489		

Note: Total N= 142 entered into analyses. Greenhouse Geisser corrected results reported.

Table A10.9: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Diverting attention (CSQ DA)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	33.416	2	4.228	.016	
Error 1	553.245	140	3.952		
		Within subjects			
CSQ DA	3.195	2	1.597	2.814	.062
CSQ DA * Treatment Group	.709	4	.177	.312	.870
Error 2	158.920	280	.568		

Note: Total N=143 entered into analyses

Table A10.10: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Increased Behavioural Activity (CSQ IBA)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	21.940	2	10.970	3.533	.032
Error 1	431.540	139	3.105		
		Within subjects			
CSQ IBA	1.230	1.863	.660	1.071	.340
CSQ IBA* Treatment group	1.516	3.726	.379	.660	.620
Error 2	159.581	258.974	.616		

Note: Total N=142 entered into analyses. Greenhouse Geisser corrected results reported.

Table A10.11: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Ability to Control Pain (CSQ Control)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	4.786	2	2.393	.623	.538
Error 1	557.025	145	3.842		
		Within subjects			
CSQ Control	.323	2	.161	.211	.810
CSQ Control* Treatment group	.750	4	.187	.245	.912
Error 2	221.575	290	.764		

Note: Total N=148 entered into analyses

Table A10.12: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Ability to Decrease Pain (CSQ Decrease)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	9.895	2	4.947	1.600	.206
Error 1	445.370	144	3.093		
		Within subjects			
CSQ Decrease	3.075	2	1.537	2.029	.133
CSQ Decrease* Treatment group	4.068	4	1.017	1.342	.254
Error 2	218.218	288	.758		

Note: Total N= 147 entered into analyses

Table A10.13: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Catastrophising (CSQ C)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	2.388	2	1.194	.301	.741
Error 1	555.337	140	3.967		
		Within subjects			
CSQ C	2.476	2	1.238	2.228	.110
CSQ C* Treatment group	2.113	4	.528	.950	.435
Error 2	155.623	280	.556		

Note: Total N=143 entered into analyses

Table A10.14: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Praying and Hoping (CSQ PH)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	11.591	2	5.795	1.307	
Error 1	629.710	142	4.435		
		Within subjects			
CSQ PH	1.841	2	.921	1.633	.197
CSQ PH* Treatment group	.926	4	.232	.411	.801
Error 2	160.100	284	.564		

Note: Total N=145 entered into analyses

Table A10.15: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Ignoring Sensations (CSQ IS)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	12.914	2	6.457	1.530	.220
Error 1	591.013	140	4.222		
		Within subjects			
CSQ IS	.625	2	.313	.460	.632
CSQ IS * Treatment Group	1.678	4	.419	.617	.650
Error 2	190.207	280	.679		

Note: Total N= 143 entered into analyses

Table A10.16: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Coping Self Statements (CSQ CSS)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	14.924	2	7.462	2.094	.127
Error 1	498.862	140	3.563		
		Within subjects			
CSQ CSS	2.546	2	1.273	1.567	.210
CSQ CSS * Treatment Group	1.308	4	.327	.403	.807
Error 2	227.398	280	.812		

Note: Total N=143 entered into analyses

Table A10.17: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Beck Depression Inventory II (BDI II).

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	227.777	2	113.888	.427	.653
Error 1	41374.529	155	266.932		
		Within subjects			
BDI II	28.250	1.713	16.491	.642	.504
BDI II* Treatment group	115.300	3.426	1.311	.266	
Error 2	6816.121	265.526	25.670		

Note: Total N=158 entered into analyses. Greenhouse Geisser corrected results reported.

Table A10.18: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Current Pain as measured by VAS (VAS1 Pain)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	1650.629	2	825.314	.535	.587
Error 1	232754.12	151	1541.418		
		Within subjects			
VAS1 Pain	2580.950	2	1290.475	4.438	.013
VAS1 Pain* Treatment Group	2635.383	4	658.846	2.266	.062
Error 2	87807.994	302	290.755		

Note: Total N=154 entered into analyses

Table A10.19: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Seven day average pain as measured by VAS (VAS2 Pain)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	1522.899	2	761.449	.497	.610
Error 1	234546.63	153	1532.985		
		Within subjects			
VAS2 Pain	1956.195	2	978.098	3.155	.044
VAS2 Pain* Treatment Group	2233.498	4	558.374	1.801	.128
Error 2	94853.267	306	309.978		

Note: Total N=156 entered into analyses

Table A10.20: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Mean Number of Social Supports

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	5.903	2	2.951	.385	.681
Error 1	957.457	125	7.660		
		Within subjects			
Number of social supports	3.618	1.656	2.185	2.488	0.96
Number of social supports * Treatment Group	3.034	3.313	.916	1.043	.386
Error 2	181.815	207.039	.878		

Note: Total N=128 entered into analyses. Greenhouse Geisser corrected results reported.

Table A10.21: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Mean satisfaction with social supports

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	11.784	2	5.892	2.544	.083
Error 1	250.146	108	2.316		
		Within subjects			
Mean satisfaction with social support	.151	2	7.533	.221	.802
Mean satisfaction with social support* Treatment Group	1.500	4	.375	1.102	.357
Error 2	73.504	216	.340		

Note: Total N=111 entered into analyses

Appendix 11

Repeated measures ANOVA. Missing data inputted with estimated means.

Table A11.1: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Functioning as measured by the ODQ (Oswestry Disability Questionnaire).

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	1081.199	2	540.600	.682	.507
Error 1	183125.71	231	792.752		
		Within subjects			
Function (ODQ)	259.397	1.92	134.96	1.655	.193
Function (ODQ) * Treatment Group	462.566	3.844	120.336	1.475	.211
Error 2	36216.646	443.976	81.57		

Note: Total N= 234 entered into analyses. Greenhouse Geisser corrected results are reported.

Table A11.2: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = pain as measured by the SF36 Pain scale.

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	1758.642	2	879.321	.891	.412
Error 1	227970.31	231	986.884		
		Within subjects			
Pain	5921.762	2	2960.881	12.912	.0005
Pain* Treatment Group	1426.558	4	356.640	1.555	.185
Error 2	105946.32	462	229.321		

Note: Total N=234 entered into analyses

Repeated measures ANOVA for treatment versus usual care groups

Table A12.1: Repeated measures ANOVA. Comparison of treatment group, usual care group and time variables. Dependent variable = SF36 Pain

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	1167.961	1	1167.961	.948	.332
Error 1	192113.281	156	1231.495		
		Within subjects			
Pain	2332.953	1.911	1220.927	5.347	.006
Pain * Group	351.393	1.911	183.898	.805	.448
Error 2	68064.505	298.086	228.339		

Note: Total N=158 entered into analyses. Greenhouse Geisser corrected results reported.

Table A12.2: Repeated measures ANOVA. Comparison of treatment group, usual care group and time variables. Dependent variable = Function measured by ODQ

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	679.800	1	679.800	.677	.412
Error 1	160670.737	160	1004.192		
		Within subjects			
ODQ	84.949	1.880	45.191	.937	.388
ODQ * Group	118.620	1.880	63.103	1.309	.271
Error 2	14503.812	300.764	48.22		

Note: Total N=158 entered into analyses. Greenhouse Geisser corrected results reported.

Appendix 13

Chi Square tables for GP visits

Table A13.1: Number of participants in each group who consulted/did not consult their GP during the baseline phase (i.e. between Time 1 & Time 2)

Group	No did not consult GP	Yes consulted GP	Total
Usual Care	33	18	51
Reflexology	48	21	69
Relaxation	49	14	63
Total	130	53	183
Chi Square = 2.458, df = 2, p = .293			

Table A13.2 Number of participants in each group who consulted/did not consult their GP during the treatment phase (i.e. between Time 2 & Time 3)

Group	No did not consult GP	Yes consulted GP	Total
Usual Care	20	20	40
Reflexology	36	19	55
Relaxation	46	12	58
Total	102	51	153
Chi Square = 9.209, df = 2, p = .010			

Appendix 14

SF36 Percentage change in pain

Table A14.1: One way ANOVA for SF36 percentage change in pain at Time 3

	SS	df	MS	F	p
Between Groups	14304.38	2	7152.19	1.550	.216
Within Groups	696834.0	151	4614.78		
Total	711138.4	153			

Note: Total N=154 entered into analyses

Appendix 15

Follow up comparisons between groups (Time 1, 2, 3 and 4 data) on secondary outcome variables

Please note: Associated Means/SDs at Times 1, 2, 3 & 4 for each questionnaire variable contained within the following analyses can be found in tables 4.4, 4.5, 4.13 & 4.16 respectively

Table A15.1: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 General Health Perception

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	75.509	2	37.754	.020	.980
Error 1	243944.224	132	1848.062		
		Within subjects			
SF 36 GHP	1313.615	2.581	509.012	3.871	.013
SF36 GHP* Treatment Group	1325.533	5.161	256.815	1.953	.083
Error 2	44795.623	340.654	131.499		

Note: Total N=135 entered into analyses. Greenhouse Geisser corrected results reported.

Table A15.2: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Role limitations Physical (SF36RP)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	8019.801	2	4009.901	.811	.447
Error 1	638187.585	129	4947.191		
		Within subjects			
SF36 RP	15967.614	2.897	5511.643	6.911	.0005
SF36RP* Treatment Group	4577.567	5.794	790.034	.991	.430
Error 2	298050.274	373.722	797.519		

Note: Total N=132 entered into analyses. Greenhouse Geisser corrected results reported.

Table A15.3: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Mental Health (SF36 MH)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	24.415	2	12.207	.009	.991
Error 1	172078.518	132	1303.625		
		Within subjects			
SF36 MH	2086.646	2.920	961.330	5.800	.001
SF36 MH * Treatment Group	1215.105	5.839	208.098	1.255	.278
Error 2	63876.629	385.380	165.750		

Note: Total N=135 entered into analyses. Greenhouse Geisser corrected results reported.

Table A15.4: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Energy/Vitality (SF36 EV)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	3333.100	2	1666.550	1.111	.332
Error 1	196567.134	131	1500.512		
		Within subjects			
SF36 EV	808.390	2.671	302.638	1.644	.184
SF36 EV* treatment Group	1274.916	5.342	238.646	1.296	.263
Error 2	64419.067	349.920	184.097		

Note: Total N=134 entered into analyses. Greenhouse Geisser corrected results reported.

Table A15.5: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Social Functioning (SF36 SF)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	3237.747	2	1618.874	.574	.565
Error 1	377782.045	134	2819.269		
		Within subjects			
SF36 SF	1967.661	2.588	760.234	2.406	.076
SF36 SF * Treatment Group	2142.937	5.176	413.977	1.310	.258
Error 2	109602.848	402	272.644		

Note: Total N=137 entered into analyses. Greenhouse Geisser corrected results reported.

Table A15.6: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Role Limitations Emotional (SF36 RE)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	275.262	2	137.361	.027	.973
Error 1	649597.381	128	5074.980		
		Within subjects			
SF36 RE	1399.716	3	466.572	.501	.682
SF36 RE * treatment group	10574.388	6	1762.398	1.8891	.081
Error 2	357907.528	384	932.051		

Note: Total N=131 entered into analyses.

Table A15.7: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = SF36 Physical Functioning (SF36 PF)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	8918.174	2	459.087	1.483	.231
Error 1	393.769	131	3005.871		
		Within subjects			
SF36 PF	1663.949	2.748	605.522	4.654	.004
SF36 PF* Treatment Group	648.181	5.496	117.939	.906	.484
Error 2	46837.267	359.983	130.110		

Note: Total N=134 entered into analyses. Greenhouse Giesser corrected results reported.

Table A15.8: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Reinterpreting the pain sensation (CSQ RPS)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	22.155	2	11.077	2.514	.085
Error 1	528.836	120	4.407		
		Within subjects			
CSQ RPS	2.610	2.807	.930	1.823	.147
CSQ RPS * Treatment Group	5.613	5.614	1.000	1.960	.076
Error 2	171.821	336.845	.510		

Note: Total N=123 entered into analyses. Greenhouse Geisser corrected results reported.

Table A15.9: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Diverting attention (CSQ DA)

Source	SS	*Df*	*MS*	*F*	*Sig*
		Between subjects			
Treatment Group	33.763	2	16.882	3.188	.045
Error 1	640.700	121	5.295		
		Within subjects			
CSQ DA	1.336	3	.445	.727	.537
CSQ DA * Treatment Group	1.418	6	.236	.386	.888
Error 2	222.484	363	.613		

Note: Total N=124 entered into analyses.

Table A15.10: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Increased Behavioural Activity (CSQ IBA)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	28.099	2	14.050	3.438	.035
Error 1	494.408	121	4.086		
		Within subjects			
CSQ IBA	.678	2.797	.242	.388	.748
CSQ IBA* Treatment group	2.742	5.595	.490	.784	.575
Error 2	211.524	338.485	.625		

Note: Total N=124 entered into analyses. Greenhouse Geisser corrected results reported.

Table A15.11: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Ability to Control Pain (CSQ Control)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	8.097	2	4.049	.852	.429
Error 1	612.636	129	4.749		
		Within subjects			
CSQ Control	1.968	3	.656	.855	.465
CSQ Control* Treatment group	1.921	6	.320	.417	.868
Error 2	296.975	387	.767		

Note: Total N=131 entered into analyses.

Table A15.12: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Ability to Decrease Pain (CSQ Decrease)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	13.013	2	6.507	1.731	.181
Error 1	477.364	127	3.759		
		Within subjects			
CSQ Decrease	4.873	3	1.624	1.992	.115
CSQ Decrease* Treatment group	4.963	6	.827	1.014	.415
Error 2	310.660	381	.815		

Note: Total N=130 entered into analyses.

Table A15.13: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Catastrophising (CSQ C)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	6.514	2	3.257	.574	.565
Error 1	686.760	121	5..676		
		Within subjects			
CSQ C	4.721	2.794	1.690	3.177	.027
CSQ C* Treatment group	2.365	5.587	.423	.796	.566
Error 2	179.803	338.015	.532		

Note: Total N=124 entered into analyses. Greenhouse Geisser corrected results reported.

Table A15.14: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Praying and Hoping (CSQ PH)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	23.381	2	11.691	2.118	.125
Error 1	679.018	123	5.520		
		Within subjects			
CSQ PH	1.924	3	.641	1.130	.337
CSQ PH* Treatment group	1.007	6	.168	.296	.939
Error 2	209.495	369	.568		

Note: Total N=125 entered into analyses.

Table A15.15: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Ignoring Sensations (CSQ IS)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	22.449	2	11.224	1.903	.154
Error 1	713.710	121	5.898		
		Within subjects			
CSQ IS	1.426	3	.475	.670	.571
CSQ IS * Treatment Group	7.090	6	1.182	1.665	.129
Error 2	257.618	363	.710		

Note: Total N=124 entered into analyses.

Table A15.16: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = CSQ Coping Self Statements (CSQ CSS)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	17.484	2	8.742	1.875	.158
Error 1	568.967	122	4.664		
		Within subjects			
CSQ CSS	3.388	3	1.129	1.395	.244
CSQ CSS * Treatment Group	2.716	6	.453	.559	.763
Error 2	296.192	366	.809		

Note: Total N=125 entered into analyses.

Table A15.17: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Beck Depression Inventory II (BDI II)

Source	SS	df	MS	F	Sig
		Between subjects			
Treatment Group	260.297	2	130.148	.358	.700
Error 1	48673.729	134	363.237		
		Within subjects			
BDI II	46.656	2.511	1.583	.688	.535
BDI II* Treatment group	112.807	5.021	22.466	.832	.528
Error 2	9086.087	336.430	27.007		

Note: Total N=137 entered into analyses.Greenhouse Geisser corrected results reported.

Table A15.18: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Current Pain as measured by VAS (VAS1 Pain)

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	1031.966	2	515.983	.256	.775
Error 1	266151.767	132	2016.301		
		Within subjects			
VAS1 Pain	2102.620	3	700.080	2.192	.088
VAS1 Pain* Treatment Group	2597.442	6	432.907	1.354	.232
Error 2	126593.254	396	319.680		

Note: Total N=135 entered into analyses. Greenhouse Geisser corrected results reported.

Table A15.19: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Seven day average pain as measured by VAS

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	1371.544	2	685.772	.348	.707
Error 1	258180.786	131	1970.846		
		Within subjects			
VAS2 Pain	2799.972	3	933.324	2.720	.044
VAS2 Pain* Treatment Group	2477.145	6	412.857	1.203	.304
Error 2	134852.622	393	343.136		

Note: Total N=134 entered into analyses.

Table A15.20: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Mean Number of Social Supports

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	13.202	2	6.601	.724	.487
Error 1	1002.219	110	9.111		
		Within subjects			
Mean number of social supports	3.971	2.423	1.639	1.344	.263
Mean number of social supports * Treatment Group	3.982	4.846	.822	.674	.639
Error 2	325.106	266.520	1.220		

Note: Total N=113 entered into analyses. Greenhouse Geisser corrected results reported.

Table A15.21: Repeated measures ANOVA. Comparison of treatment group and time variables. Dependent variable = Mean satisfaction with social supports

Source	SS	Df	MS	F	Sig
		Between subjects			
Treatment Group	7.683	2	3.841	1.909	.155
Error 1	171.076	85	2.013		
		Within subjects			
Mean satisfaction with social support	.420	2.771	.512	.448	.703
Mean satisfaction with social support* Treatment Group	.997	5.543	.180	.532	.770
Error 2	79.670	235.557	.338		

Note: Total N=88 entered into analyses. Greenhouse Geisser corrected results reported.

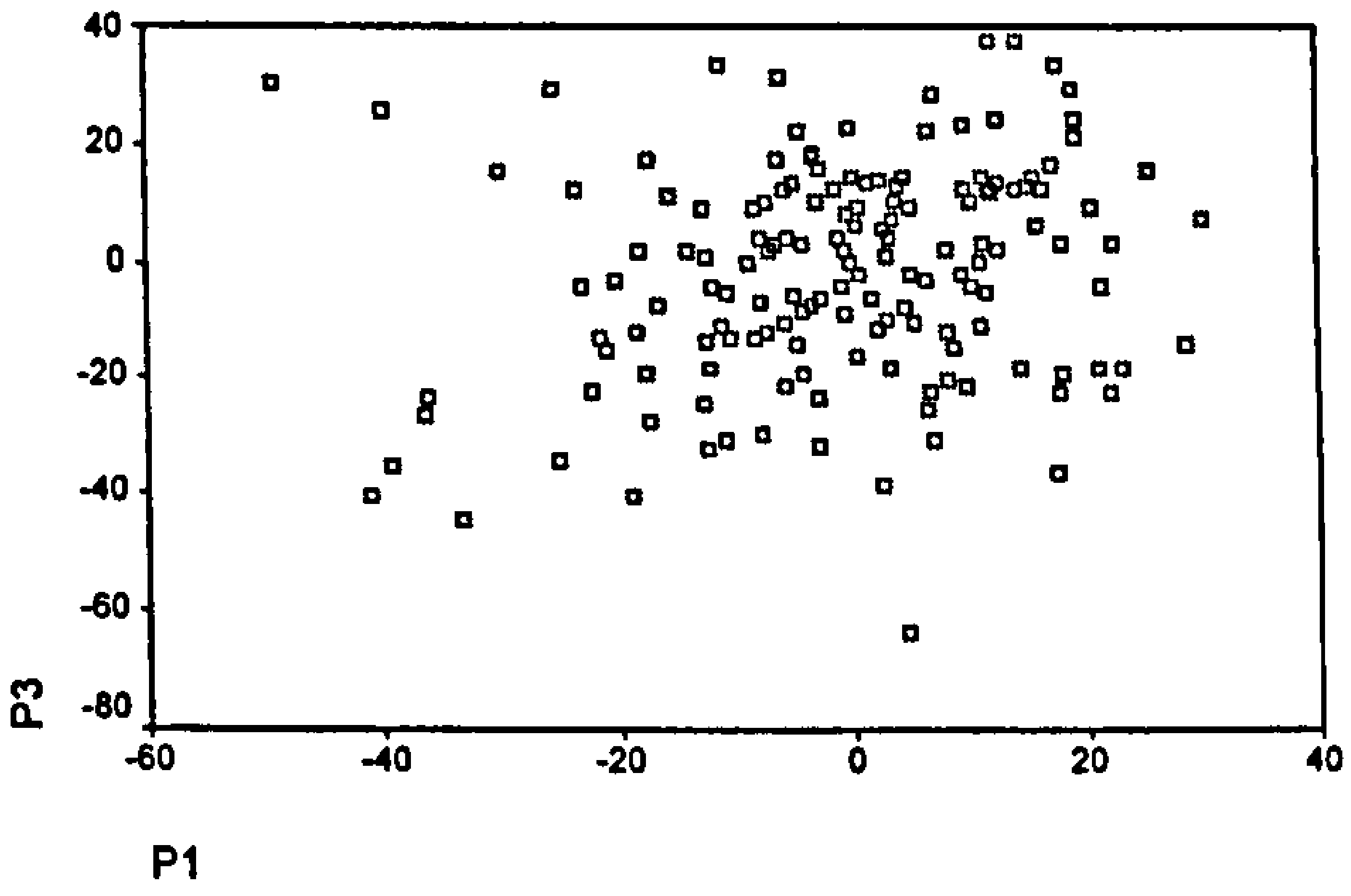
Re-categorisation to take account of group preference

Table A16.1 Group and preferred group categories.

Group	Preferred Group			
	Reflexology	Relaxation	Reflexology or Relaxation	No preference
Reflexology	Got preference	Did not get preference	Got preference	Got preference
Relaxation	Did not get preference	Got preference	Got preference	Got preference
Usual Care	Did not get preference	Did not get preference	Did not get preference	Got preference

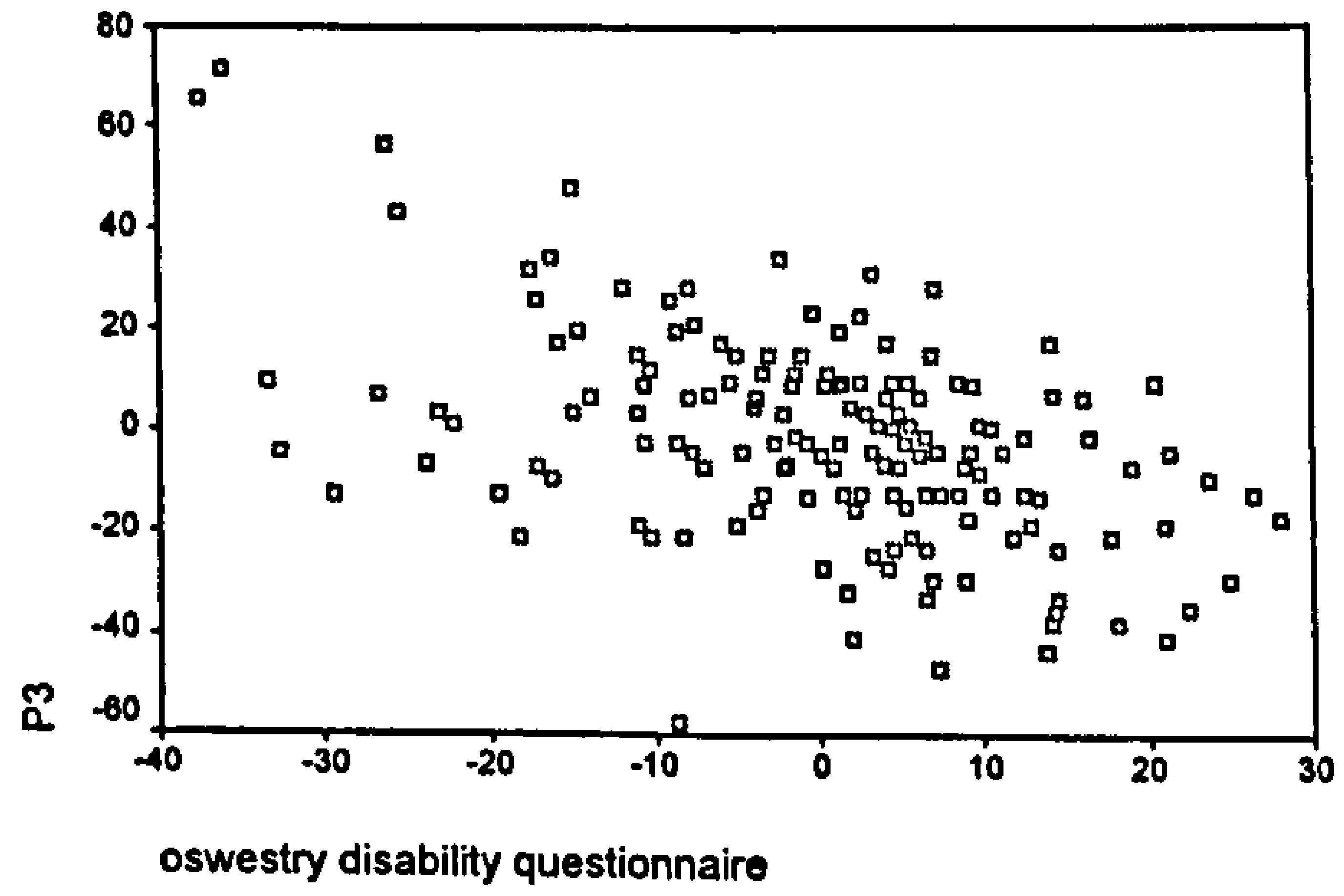
Appendix 17

Residual plots associated with Multiple linear regression (p126, see also discussion p171)



Scatterplot

Dependent Variable: P3



Scatterplot

Dependent Variable: P3