Developing and evaluating a complex intervention to treat chronic orofacial pain

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Abstract

Introduction: Chronic orofacial pain (COFP) is distressing and disabling to sufferers and can be costly to patients, health services and society. Frequently, no underlying medical pathology can be found to account for the condition. Despite this, patients are treated according to a biomedical model, often by mechanistic and invasive procedures, which tend to be unsuccessful and not evidence based. Evidence suggests that cognitive behavioural therapy (CBT) based management may produce improved outcomes for patients. However, published studies can tell us little about which intervention components are effective, or recommend an optimum way for these components to be applied. Aim: To develop an evidence based intervention for the management of COFP that is feasible and acceptable to patients and practitioners. Method: The Medical Research Council’s guidelines for developing complex interventions were used as a framework for the research. Evidence from multiple sources was synthesised to produce the draft components of an intervention to manage COFP. An exploratory trial investigated preliminary outcomes, acceptability, feasibility and explored parameters for a full scale randomised control trial. Results: The intervention was acceptable to participants and could be feasibly implemented. No conclusions could be drawn relating to the effectiveness of the intervention. Participants were not affected at baseline for a number of outcomes, which implies that cut off points should be introduced into the inclusion and exclusion criteria of any future studies. Conclusion: The study produced an intervention which is acceptable and feasible to participants, however it is not known if it is effective. A number of recommendations are made for progression to a larger, definitive trial.
Declaration

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Dedication

This thesis is dedicated to my fiancée, Nick Wadeson and to my children, Ella and Joseph Jones, for all your love and for being my sanctuary.

The author

Joanna Goldthorpe has a BSc (Hons) in Psychology and Human Resource Management from Keele University and a Post Graduate Certificate in Research Methods from the University of Chester. She has worked in research since 2004, using mostly qualitative methods, until starting her current roles as Research Assistant and PhD student at the University of Manchester in 2009.
Introduction

Chronic Orofacial Pain (COFP) is pain or discomfort experienced in the face, mouth, teeth or jaws, for 3 months or longer. Frequently, no underlying medical pathology can be found to account for the condition. Current management of COFP has limited efficacy and is not evidence based. Evidence suggests that an intervention based on Cognitive Behavioural Therapy (CBT) may be effective in managing COFP. However, existing studies do not describe the active components of the interventions reported, examine the feasibility of delivering them or investigate their acceptability to patients and other stakeholders. The overall aim of this thesis is to chronicle the development and preliminary evaluation of an evidence based complex intervention to manage COFP.

Chapter 1 will provide some information relating to the epidemiology of COFP and discuss the unexplained nature of symptoms. In addition, it will examine evidence supporting the use of a CBT model to treat COFP.

Chapter 2 positions the research within a framework that will guide the thesis and describes the phases of the study.

Chapter 3 describes the mixed methodology that will be used to guide the study as a whole.

Chapter 4 reports on the first phase of developing the intervention, including synthesis of evidence and the development of a manual.

Chapter 5 provides a report of the quantitative element of phase 2; an exploratory trial of the intervention and includes an assessment of feasibility, examines intervention processes and investigates preliminary outcomes.

Chapter 6 presents the methods, analysis and findings of the qualitative work which contributed to phase 2, examining issues relating to acceptability of the intervention.

Chapter 7 includes a discussion of the overall findings, and aims to synthesise the results of the key pieces of work that contributed to this thesis.
Chapter 1 Background

1.1 Chronic Orofacial Pain

Chronic orofacial pain (COFP) is attributed to a number of disorders of the face, jaw and mouth, and is an encompassing term that includes clinical conditions such as temporomandibular joint disorder (TMD), burning mouth syndrome, atypical odontalgia and atypical facial pain. Although the site of the pain may differ, these clinical presentations display a common cluster of several symptoms, and a unified concept has been proposed based on their shared characteristics (Woda & Pionchon, 2000). Oral pain includes pain experienced in the mouth, gums and teeth, and facial pain includes pain originating below the orbitomeatal line, above the neck and anterior to the ears (Zakrzewska & Hamlyn, 1999). The condition is considered chronic or long–term when symptoms have been experienced for a period of three months or longer.

1.2 Prevalence

The prevalence of COFP in the UK has been estimated at between 7% (Aggarwal, McBeth, Zakrzewska, Lunt, & Macfarlane, 2006a) and 26% (Macfarlane, Blinkhorn, Davies, Kincey, & Worthington, 2002). This discrepancy is due to the use of multifarious definitions of the condition, and varied measurements and inclusion criteria. Macfarlane et al's (2002a) study included acute patients and patients with pain "in or around the eyes". This criterion may inadvertently have increased the number of cases due to the high number of people who suffer pain associated with headaches. Of these patients, 62% reported that their pain had started more than 3 months ago, making the prevalence of chronic pain in this sample approximately 16%. In comparison, Aggarwal et al., (2006) used a more stringent definition for oro-facial pain. This discrete definition may account for the lower prevalence found in the study and is likely to encompass the most severe and intractable cases. More women than men report symptoms associated with COFP, with 66% of reported cases attributed to female patients (Aggarwal et al., 2006a).

Temporomandibular joint disorder (TMD) is globally the most common orofacial pain condition and in the United States a prevalence of 6% in women and 3.5% in men has been reported (Lipton, Ship, & Larach-Robinson, 1993). The American Academy of Orofacial pain suggests that in any given year 10% of
women and 6% of men (approximately 20 million adults) have TMD pain (cited in Gatchel, Stowell, Wildenstein, Riggs, & Ellis, III, 2006).

1.3 Diagnosis and management

Due to the absence of an identified medical pathology, professionals find COFP difficult to diagnose. Current management is varied, often guided by the speciality or professional background of the treating physician, and often unsuccessful (Durham, Exley, Wassell, & Steele, 2007; Pfaffenrath, Rath, Pollmann, & Keeser, 1993; Ersasheed, Worthington, Ariaratnam, & Duxbury, 2004; Zebenholzer, Wober, Vigl, Wessely, & Wober-Bingol, 2005). Difficulties in diagnosing COFP, resulting from the unexplained nature of its symptoms are exacerbated by a lack of clear guidance. Evidence suggests that current guidelines for the diagnosis of COFP are inadequate; 28% (N=97) of patients suffering from facial pain could not be diagnosed according to the current (1988) International Headache Society classification (Zebenholzer et al., 2005).

Patients with COFP are likely to undergo multiple investigations to determine a physical cause for their symptoms and to consult frequently with medical professionals (Marbach, 1999) in a quest for diagnosis and effective treatment.

Agostoni, Frigerio, & Santoro (2005) describe treatment of atypical facial pain as “difficult and unsatisfactory”. Most chronic facial pain disorders are ultimately referred to, and treated by, dentistry and most patients undergo unnecessary dental procedures while a diagnosis is sought (Marbach 1999). Management of chronic and acute COFP tends to focus on correction of mechanical factors such as bruxism (teeth grinding) and malocclusion (irregular bite), using physical therapies such as splints, occlusion adjustment and surgery (Pfaffenrath et al., 1993). Evidence suggests that these invasive procedures show limited efficacy for chronic sufferers (Al-Ani, Gray, Davies, Sloan, & Glenny, 2005; Koh & Robinson, 2004) and research into the use of commonly used medical interventions to treat oro-facial pain has found that patients often report the same symptoms following invasive treatment (Dworkin et al., 2002; Gatchel et al., 2006). Studies on the use of splint therapy, a commonly used method to treat TMD, have found no evidence to suggest that it is beneficial in any way other than as a placebo (Dao & Lavigne, 1998; Slade et al., 2007; Al-Ani et al., 2005) and some forms of surgery, such as tooth extractions and the replacement of the temporomandibular joint with a prosthesis may result in
iatrogenic harm to patients (Pfaffenrath et al., 1993). There is therefore a lack of evidence to support the use of current dental treatments.

1.4 Impact of COFP

1.4.1 Quality of life
COFP can impact severely upon the lifestyle of patients and can result in the pursuit of costly treatment. A number of studies involving TMD patients have shown the financial costs suffered in terms of loss of homes, possessions and jobs after pursuing expensive treatments (Macfarlane et al., 2002). An adverse effect on the general quality of life of individuals suffering from the condition has been demonstrated (John, Miglioretti, LeResche, Von, & Critchlow, 2003; Locker & Grushka, 1987) with patients reporting disturbed sleep, avoiding certain foods and some social situations, depression and taking medication (Macfarlane et al., 2002a).

1.4.2 Cost
No definitive figures have been calculated for costs relating to COFP. However, given the pattern of frequent consultations and pursuing of costly treatment displayed by patients, it can be assumed that it is costly to the NHS, the individual and society. This assumption is supported by the international literature. For example, the American Academy of Orofacial pain estimates the direct costs of treatment for TMD of $2 billion within a six to 12 month period for treatment of more than 5.3 million people (Gatchel et al., 2006). Additionally, indirect costs impact on wider society and individual COFP patients. Unemployment and an increase in work absenteeism have been reported in orofacial pain patients (Von Korff, Ormel, Keefe, & Dworkin, 1992; Murray, Locker, Mock, & Tenenbaum, 1996). Patients suffering from COFP consult frequently with multiple professionals and undergo demonstratively ineffective, invasive treatment. GPs and dentists can find the condition time consuming and difficult to manage. General dental practitioners report little financial reward for the lengthy consultation time needed for TMD patients (Durham et al., 2007).

A considerable burden is therefore placed on already stretched health resources through repeated consultations and the use of treatments which are unsuccessful and not evidence based. There is consequently a need to
investigate alternative ways of managing patients through looking at COFP through the prism of an alternative model to the current mechanical or biomedical approach to treatment. One suitable approach may be to examine similarities with other conditions characterised by medically unexplained symptoms.

1.5 COFP as a medically unexplained symptom syndrome

Pain in the face or mouth in its acute form is most commonly related to periodontal disease and dental caries and, less frequently, damage or trauma to the teeth and mouth and can often be successfully treated by routine dental procedure. However when the condition presents as chronic, diagnosis, treatment and management become more difficult and inconsistent. Long term symptoms (experienced for more than more than 3 months) often cannot be attributed to pathological or medical origin by clinicians, or the original pathology has long since been resolved while symptoms remain (Macfarlane et al., 2002). COFP can be diagnosed according to distinct characteristics, many in common with other idiopathic (of unknown origin) disorders, differentiating it from other dental conditions for which a clear underlying pathology can be found in several ways. Symptoms are often reported in idiosyncratic ways with patients more likely to use pain descriptors such as burning, nagging, aching, and tingling (Marbach 1999). Stress is more likely to be reported as an exacerbating factor, the pain site is often described as poorly localised, and symptoms tend to remain for a persistent or chronic duration. Additionally disability, multiple consultations and co-morbidities, such as teeth grinding or clenching and reporting of other unexplained syndromes are reported frequently by COFP patients (Marbach, 1999; Aggarwal, McBeth, Zakrzewska, Lunt, & Macfarlane, 2008).

Other chronic conditions which are diagnosed by an assessment of symptoms, rather than detection of pathology include those characterised by pain (e.g. fibromyalgia and lower back pain), tiredness (e.g. chronic fatigue syndrome) and gastric discomfort (Irritable bowel syndrome). Medically unexplained symptoms (MUS) are common, with more than a quarter of primary care patients in England having unexplained chronic pain, irritable bowel syndrome or chronic fatigue syndrome and cause similar levels of disease and disability as conditions with an identifiable physical pathology (Hatcher & Arroll, 2008). Most medical
specialities have a diagnostic category for MUS, with common symptoms, epidemiology and responses to treatment. For example, gastroenterology has irritable bowel syndrome and rheumatology has fibromyalgia (Hatcher & Arroll 2008). There is evidence to suggest that COFP may be not only a dental MUS but part of a wider spectrum of unexplained disorders. Similar social, psychological and behavioural traits have been found in individuals suffering from other MUS conditions and COFP. High levels of health anxiety, reassurance seeking behaviour, reporting of recent adverse life events and illness behaviour congruent with features of somatisation (presentation of psychological dysfunction as physical symptoms) have been found in patients suffering from COFP, chronic widespread pain, irritable bowel syndrome and chronic fatigue (Aggarwal et al., 2006; Aggarwal at al., 2008). Psychological distress and other possible indicators of somatisation have been reported to be as common in patients with widespread body pain as those with orofacial pain (Macfarlane et al., 2002).

1.6 Psychological models of MUS conditions

The role of psychological factors in the development and maintenance of MUS has been hypothesised for decades (Deary, 1999) and more recently has been formally recognised. Predisposing factors, including prior learning and consequent behaviours relating to illness, have been proposed as basic components in the development of all chronic medically unexplained pain conditions (Flor & Hermann, 2004). Emotions, beliefs, attitudes, expectations, the meaning of pain to the individual and social and environmental factors can influence a person’s complex perceptual experience of pain and relate to how successfully an individual can adjust to life with illness (Turk & Okifuji, 2002). Social and psychological factors have also been specifically associated with COFP. A systematic review of 59 epidemiological studies looking at the antecedents of COFP identified that those affected by psychological factors such as stress, depression and anxiety are more likely to have symptoms associated with COFP (Macfarlane, Glenny, & Worthington, 2001) and associations have been shown between psychological dysfunction and COFP (Zakrzewska et al., 1999).
Mechanistic models proposed for the generation and maintenance of MUS generally focus on illness perceptions and attention. Somatisation and catastrophising are theoretical conjectures that are frequently cited to account for the perpetuating processes associated with MUS conditions and will be discussed in turn.

1.7 Somatisation

Somatisation describes a process of psychological dysfunction manifesting or interpreted as physical symptoms (Escobar, Burnam, Karno, Forsythe, & Golding, 1987). Elevated levels of somatising beliefs have been identified in COFP patients (Turner & Dworkin, 2004; Macfarlane et al., 2002). Individuals focus a high degree of attention on (often normal) bodily sensations and tend to interpret them as a sign of dysfunction or disease. Unhelpful behaviours can be adopted, based on the patient’s perception of how they should behave when ill, that reinforces their behaviour and experience. Particular patterns of dysfunctional illness perceptions can be formed due to earlier experiences of becoming unwell or being around others who are sick, and subsequent feedback relating to social norms of behaviour (Brown, 2004). For example, an individual may be advised to rest and withdraw from normal routines while recovering from an illness. The individual may subsequently feel better, and may have enjoyed some aspects of the period of rest. Consequently, for this person, illness becomes associated with behaviours relating to rest and withdrawal from normal routines.

1.8 Catastrophising

Catastrophising is a cognitive style that relates to the over interpretation of the severity or implications of physical symptoms. Individuals who catastrophise tend to focus a large amount of attention on perceived symptoms of ill health and experience a high degree of health–related anxiety (Jensen, Turner, & Romano, 2001). A tendency to catastrophise is central to most models of MUS and has been found to be associated with a number of MUS conditions, including chronic pain (Rief & Broadbent, 2007). Catastrophising has also been found to interfere with the positive analgesic effects of distraction on self reported levels of pain in both clinical and experimental settings (Campbell et al., 2010).
1.9 Summary

COFP can be positioned within a realm of medically MUS syndromes as the MUS of dentistry. Research has suggested that psychological factors play a part in the generation and maintenance of MUS conditions, including COFP. However COFP is currently treated mechanistically, according to a biomedical model. Concurrently, an examination of other literature and theoretical perspectives in the area of MUS syndromes and the use of relevant psychological treatments could be helpful in gaining an understanding of how an effective intervention for COFP might function.

1.10 Evidence for Cognitive Behavioural Therapy (CBT)

A number of systematic and critical reviews have found that interventions based on Cognitive Behaviour Therapy (CBT) have produced some evidence of effectiveness for chronic pain patients for a number of outcomes (Morley, Eccleston, & Williams, 1999; Hoffman, Papas, Chatkoff, & Kerns, 2007; Turner, Holtzman, & Mancl, 2007). Evidence from other studies further supports the efficacy of CBT in the management of a variety of chronic pain disorders, including TMD (Keefe, Rumble, Scipio, Giordano, & Perri, 2004; Turk et al., 2002; Kroenke & Swindle, 2000; Dworkin et al., 1994; Moore, Von Korff, Cherkin, Saunders, & Lorig, 2000; Speckens et al., 1995; van Tulder et al., 2001; Morley et al., 1999; Keefe, Dunsmore, & Burnett, 1992). Additionally, a review of 31 clinical trials of treatment for somatisation and MUS syndromes found that physical symptoms improved more following a CBT based intervention than for control groups in 71% of studies (Kroenke et al., 2000). Evidence suggests therefore that CBT may be an effective psychological intervention in improving outcomes for COFP.

1.11 Evidence supporting CBT as a treatment for COFP

There is specific evidence to suggest that a CBT intervention might be an effective way of managing COFP. A recent Cochrane systematic review (Aggarwal et al., 2011) found some evidence to support the use of CBT interventions for COFP. The studies included in this review were small and showed medium to high risk of bias, therefore results should be treated with
caution. It is difficult to ascertain from many studies of psychological interventions, which elements are effective and the mechanisms which could bring about changes in patients tend not to be addressed. Morley et al., (1999) note that the studies included in their systematic review of CBT for chronic pain in adults vary considerably in the quality and quantity of the interventions reported, with a lack of explicit accounts of the procedures involved. CBT is at tells us little about the specific mechanisms that bring about change.

Despite the weak evidence to support the use of CBT for COFP, Aggarwal et al., (2011) recommended that this type of non-invasive intervention should be considered in preference to other invasive and irreversible treatments currently used, which have limited or no efficacy. In concurrence with this conclusion, the theoretical significance of CBT models of treatment and its possible application to COFP will be considered.

1.12 Possible mechanisms of a CBT based intervention for COFP

CBT has been effective to varying degrees in managing mental health, MUS and chronic pain conditions. Treatment targets cycles of maladaptive cognitions (such as catastrophising) and unhelpful behaviours (Brewin, 1996), which are considered to be maintaining features of dysfunction which perpetuate an individuals’ experience of distressing symptoms. Deary et al., (2007) proposes a CBT model of MUS where predisposing factors (early adverse experiences, personality, genetics and life events) can result in a general inability to tolerate distress and a high sensitisation towards physiological sensations. Consequently, subsequent experiences of physical symptoms and general distress are augmented, resulting in normal or benign bodily sensations being perceived as signs of a more serious malaise. Furthermore, these heightened negative experiences are perpetuated by a combination of harmful physiological arousal (hypocortisolism), social factors (e.g. medical uncertainty), unhelpful cognitive processes (e.g. catastrophising) and negative behaviours (avoidance of symptoms, recuperative illness response). The mechanisms of this perpetual cycle is analogised with a self constructing and self maintaining biological system known as autopoiesis (Varela, Maturana, & Uribe, 1974). This work has largely been conducted in relation to other MUS and further research needs to be carried out before any mechanisms specifically relating to CBT for COFP can
be described. Nevertheless, this theoretical framework has been adapted to provide a basic model relating to COFP, and is illustrated in Figure 1.

**Figure 1 A cognitive behavioural model of COFP**

In this model, a maintaining cycle, or vicious circle is experienced, where unhelpful thoughts and behaviours relating to COFP interact to perpetuate physical and psychological symptoms. Negative cognitions relating to COFP might be worries that symptoms are signs of a more serious condition and feelings of failure or helplessness as withdrawal from normal routines takes place. Unhelpful behaviours might include avoiding certain social situations, avoiding hard foods, clenching and grinding of teeth and withdrawing from work and routine activities. A CBT based intervention would aim to break this cycle by utilising techniques which target behavioural factors and associated negative thoughts. It is assumed that breaking this negative pattern will have a positive effect on the remaining areas of the model, thus symptom severity will be reduced.

Kroenke and Swindle (2000) denote CBT related techniques for MUS conditions in relation to changing illness perceptions (also referred to interchangeably as illness representations, illness cognitions and illness beliefs) and adverse behaviours. Illness perceptions influence the type of related behaviours and
coping strategies adopted by patients which may affect or have implications for the severity of symptoms reported. Behavioural techniques may relate to behavioural activation for negative symptoms (such as withdrawal from normal activity) and modification techniques for positive symptoms (such as hyperactivity during periods of feeling well). A number of theories have been proposed to account for the efficacy of various techniques associated with changing illness perceptions. The common sense model and the theory of planned behaviour have been used to theoretically justify a number of CBT techniques, and will be discussed in turn.

### 1.13 Common sense model

The common sense model of illness representation proposes a maintaining cycle, where cognitive and emotional processing proceeds in a dynamic parallel, with each influencing the other (Leventhal, Meyer, & Nerenz, 1980). Information from various sources (both authoritative and lay), about illness and how the sick person should respond becomes assimilated with individual experiences. For example, an individual may be advised to take medicine and rest while the illness subsides. This may prove to be a successful strategy if the person becomes well after this period of rest. Consequently, illness becomes associated with medicine and interrupted functioning. People subsequently make sense and form representations of illness according to the nature and meaning of this information and experience (Hagger & Orbell, 2003). The common sense model is dynamic, as behaviours are constantly appraised in a process which may result in a modification of the illness representation. According to the CBT model, this should result in a (more desirable) replacement cognition or behaviour. A number of cognitive and behavioural techniques, such as behavioural experimentation, planning and goal setting and challenging cognitive processes are based on the common sense model which has been used to develop interventions for a variety of illnesses, including the MUS condition of chronic fatigue syndrome (Wearden & Peters, 2008).
1.14 Theory of planned behaviour

A central feature of theory of planned behaviour is the discrepancy between intention and action. The perceived degree of control (having the necessary resources and opportunities) over that action is a moderating feature of whether an intention is acted on. Intentions encompass an individual's motivation to perform the behaviour, and their willingness to carry out an action (Icek, 1991). If a situation is not viewed as being within a person's control, the intention and willingness to act may be sabotaged. The theory stipulates that an intention is more likely to be acted on when there is a perceived degree of control over the behaviour required. Behaviour change techniques aligned to this model focus on increasing the perceived degree of control held by an individual over a health enhancing behaviour (Conner & Abraham, 2001).

The above offers a valid theoretical framework for the use of CBT techniques to treat COFP, however we currently do not know which techniques produce effective results or what the exact mechanisms behind effective techniques might be. Further investigation is therefore needed and this will be addressed in later chapters of this thesis.

1.15 Summary

COFP is distressing and disabling for patients and is a costly burden to health care resources, patients, and professionals. It is routinely treated by mechanistic interventions as dentists manage the condition according to a biomedical model. These interventions are not evidence based and often do not improve outcomes for patients. Despite being managed biomedically, frequently no underlying pathology can be found to account for COFP. Studies have shown that COFP shares a number of risk factors and maintaining features with other medically unexplained conditions which are associated with psychological, social and behavioural dysfunctions.

Evidence from studies of COFP and other conditions associated with medically unexplained symptoms suggests that CBT may be effective in targeting maintaining features and producing positive outcomes for patients, and relevant theory is concurrent with this evidence and offers a model for bringing about change. However, these studies failed to identify the specific components used...
within the interventions, or precisely how they interact to produce effective outcomes. Little is known about the “active ingredients” that contribute to improving patients’ symptoms. The Medical Research Council (MRC) have published guidelines which recommend a phased approach to the development of interventions when there is ambiguity about current best practice (MRC 2000/2008). As current evidence concerning the best way to treat COFP is inconclusive and vague, MRC guidance will be used as framework to develop a new intervention. The next chapter will describe why this framework is important, and accordingly how the work that contributes to the main body of this thesis will be structured.
2 Chapter 2 Developing and evaluating evidence based intervention to treat Chronic Orofacial Pain – structure of the study

Exploratory research that aims to look at acceptability, feasibility and parameters to inform larger studies may also be referred to in academic journals as “pilot” or “feasibility” studies, or in the case of pharmacological studies, “proof of concept”. It is important to distinguish an exploratory study from a small, underpowered clinical trial which is generally accepted to be unethical, therefore pilot and feasibility studies should be very clear in describing their objectives (Arain, Campbell, Cooper, & Lancaster, 2010). This chapter will describe the overreaching aims and objectives of the study, and position the research within current guidelines for the development and evaluation of complex interventions within UK health services.

2.1 Aims and objectives

The aims and objectives of this thesis are as follows:

The overall aim of this study is to develop an evidence based intervention for the effective management of COFP, which is feasible and acceptable to patients and practitioners. The study was conducted over two phases.

2.1.1 Phase 1 (Development and piloting stage)

Aim:

To produce and develop a psychological intervention to manage COFP

Objective:

To synthesise good quality evidence from multiple studies:

1) **Survey of dentists’ experience of diagnosis and management of COFP** (Aggarwal, Joughin, Zakrzewska, Appelbe, & Tickle, 2011)

A quantitative analysis of the decisions clinicians make regarding the management of COFP compares the views of dental practitioners and specialists in current diagnosis and psychological managements of COFP and quantifies variation within the profession in the ways in which the condition is diagnosed and managed in the UK.
2) Qualitative studies of dentists, patients and GPs experiences of COFP (unpublished)
Semi structured interviews have been carried out in order to explore the views and preferences of patients, GDPs, dental specialists and GPs about their views on COFP.

3) Cochrane systematic review (Aggarwal et al., 2011).

The review has analysed the evidence on psychosocial treatments for COFP and reports their clinical effectiveness

N.B. The studies cited above were conducted by other researchers as part of a wider NIHR sponsored collaboration to collect evidence to specifically inform the development of this intervention and do not form part of this thesis. Presentations relating to these studies are provided in Appendix 1.

4) Component analysis (an exercise carried out as part of this thesis, see Chapter 4).

An analysis of the components used to comprise interventions reported in other studies where CBT had been used to treat COFP.

The results from these studies will be synthesised to produce the key components of a draft intervention for COFP, which will be further refined and modified through consultation with patients.

2.1.2 Phase 2 (Implementation and evaluation phase)

Aim:
To conduct an exploratory trial in order to assess:

- Interim benefits of the intervention to patients

- The best possible design for a future RCT to determine outcome measures, sample sizes and recruitment procedures.

- Feasibility of implementing the intervention
Objectives:

- To measure interim outcomes using established, reliable outcome measures and to investigate the usefulness of selected outcome measures to the trial.

- To inform the design of a possible later, larger scale RCT by investigating relevant features such as randomisation and recruitment procedures.

- To investigate attrition and fidelity to the treatment; this will inform investigations of feasibility.

- To carry out a qualitative study of acceptability of the intervention using semi-structured interviews.

The remaining chapters describe preliminary work that will deliver these aims and objectives, based on a phased approach. The following diagram summarises this endeavour (Figure 2).
Figure 2 study phases

**Phase 1**
- Synthesis of evidence: Core Components of intervention for Chronic Orofacial Pain
- Draft content of intervention including delivery and training

**Phase 2**
- Exploratory trial
  - Preliminary outcomes
  - Feasibility and intervention process
  - Acceptability

Results to inform larger scale RCT
2.2 Developing and evaluating complex healthcare interventions

One goal of healthcare research is to produce evidence of effectiveness through a “gold standard” randomised controlled trial (RCT) (Sackett, Haynes, & Tugwell, 1985; Charlton, 1991). Where the ultimate aim of a study is to produce evidence of effectiveness there is a danger of assuming that an intervention will work due to its inherent qualities, regardless of the context in which it was delivered (Blackwood, O’Halloran, & Porter, 2010). Previously, insufficient preparatory work has frequently been carried out and development and piloting work has been weak or absent (Hawe, Shiell, & Riley, 2004; Glasziou, Meats, Heneghan, & Shepperd, 2008). Trials that have failed to augment results through investigating processes and mechanisms may be underpowered, generate inaccurate conclusions from the results and increase the risk of a type 1 or 2 error (Campbell et al., 2007).

The Medical Research Council’s framework for “development and evaluation of RCTs for complex interventions to improve health” (Medical Research Council, 2000) was devised to help address weaknesses in previous trials of healthcare interventions. These guidelines can provide a model for this study to help ensure that an intervention for COFP is developed as rigorously as possible prior to testing in an RCT.

Complex interventions consist of several components which may interact or operate on a number of separate levels to produce outcomes. Several dimensions of complexity are considered: the number of interacting components within the experimental and control conditions; the number and difficulty of behaviours required by those delivering or receiving the intervention; the number of groups or organisational levels targeted by the intervention; the number and variability of outcomes and the degree of flexibility or tailoring of the intervention permitted (Craig et al., 2008).

When referring to behavioural interventions, the term “components” can be broadly defined to include aspects of the programme included within the intervention (for example, which techniques are to be used) and aspects of the delivery and implementation such as number and length of sessions, delivery location and characteristics of facilitator (Collins, Murphy, Nair, & Strecher,
Interventions which aim to alter human behaviour, whether at a population or individual level are therefore inherently complex and explanations for the outcomes observed will be multifarious.

Figure 3 shows the recommended phases to be completed in the development of a complex intervention (Medical Research Council, 2000). This study will incorporate the modelling and exploratory trial stages of the framework to develop an evidence based intervention for COFP. Modelling the intervention involves synthesising evidence and identifying core components and also looking at ways in which a new intervention might be delivered. The exploratory trial, in addition to describing and refining components and looking at parameters for a definitive RCT (phase 3) will look at feasibility and acceptability of a CBT based intervention for COFP to patients and other stakeholders.

Figure 3 MRC Framework for complex interventions (2000).

The 2000 guidelines were updated in 2008 (Medical Research Council, 2008) in response to feedback which suggested the original model was too linear and
that the importance of the modelling phase should be emphasised. The original
guidance had been based on a model used in pharmaceutical testing. A
consequence of this was that careful modelling processes, required to maximise
the success of implementing and trialling non pharmaceutical healthcare
interventions had frequently been overlooked resulting in premature or badly
conceived trials (Rowlands, Sims, & Kerry, 2005). An important aspect of
modelling, largely neglected in the original MRC guidance, is to investigate the
importance of the context in which an intervention is implemented (Campbell et
al., 2007). Context can mean aspects such as the ethnic and social background
of the population to receive the intervention, the healthcare setting and
structures in place and beliefs held by patients and practitioners. For example,
social context may obstruct patients’ ability to engage with the intervention. A
national evaluation of a pilot complex intervention found that the ability of
teens age parents to engage with the Family Nurse Partnership programme was
greatly compromised when essential needs such as housing, money and access
to health care were ongoing priorities (Barnes, Ball, Meadows, & Belsky, 2009).
Until these crisis situations were resolved, it was not possible for clients to
summon the time or the emotional investment needed to engage with the
programme, and family nurses’ time could be spent dealing with these
immediate issues, rather than on delivering the intervention.

Craig et al., (2008) describes the modelling process as cyclical, beginning with a
period of development, where the evidence base and guiding theory are
established, followed by feasibility and piloting stage, which should inform both
the development and evaluation of the intervention (see Figure 4). An iterative
development is recommended, where modelling processes continually inform
and are in turn, modified by the theory and exploratory trial stages (Campbell et
al., 2007).
2.3 Structure of work within MRC guidance

This thesis will describe work carried out for the development and feasibility and piloting stage. Table 1 shows the two phased structure of this work, organised according to MRC (2008) guidelines.

Phase 1: Intervention development.

The introduction, literature review and discussion of the theoretical rationale for the intervention (Chapter 1) comprise the pre-clinical phase. Synthesis of evidence from 4 studies specifically carried out to identify and develop intervention components, and the production of a treatment manual will be described in Chapter 4 and contributes to the modelling stage.

Phase 2: Exploratory trial

An exploratory trial will assess acceptability and feasibility of the intervention and investigate parameters for a larger RCT (Chapter 5).
2.4 Conclusion

MRC guidelines will be beneficial, however developing and evaluating a complex healthcare intervention to treat COFP patients of varying illness severity and longevity will be challenging. As discussed in the introduction to this thesis, published studies of psychological interventions for COFP are characterised by disparity in the reporting of the content and component parts. Consequently, there is little scope to replicate and further develop and evaluate an existing intervention. An opportunity therefore exists for the development of a new treatment which is evidence based and described in detail, therefore lending itself to rigorous evaluation. The remaining chapters describe work that will contribute to these aims and objectives, based on a phased approach.

<table>
<thead>
<tr>
<th>Stage of development &amp; evaluation</th>
<th>Procedure</th>
<th>Study phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Desk based exercise: review of relevant theories and literature</td>
<td>Phase 1</td>
</tr>
<tr>
<td>Development</td>
<td>Synthesis of evidence from previously conducted studies as described in phase 1 of this study. Production of treatment manual including user consultation.</td>
<td>Phase 1</td>
</tr>
<tr>
<td>Feasibility/ piloting</td>
<td>Acceptability, feasibility and identifying parameters for a full scale RCT</td>
<td>Phase 2</td>
</tr>
</tbody>
</table>
3 Chapter 3 Methodology

3.1 Mixed Methods

A mixed methods approach is recommended by MRC guidelines for the collection and interpretation of evidence to inform the development of a complex intervention (MRC, 2000, 2008). Mixed method studies have been defined as research which includes “at least one quantitative method (designed to collect numbers) and one qualitative method (designed to collect words) where neither type is linked to an enquiry paradigm” (Greene, Caracelli, & Graham, 1989, p36). Johnson & Onwuegbuzie (2004) argue that a pluralist stance results in superior research. By taking a “horses for courses” approach to research the method selected is lead by the research question without the confines of dualism (qualitative versus quantitative, positivist versus constructionist).

3.2 Pragmatic approach

Mixed methods research is not driven by the traditionally incompatible paradigms usually associated with qualitative and quantitative methods, but is conceptualised pragmatically and guided by purpose (Creswell, 2009; Newman, Ridenour, Newman, & DeMarco Jr., 2003). Patton (1990, cited in Creswell 2009) defines the philosophy of pragmatism as having “… a concern with applications; what works and solutions to problems (p215)”. The research problem is defined and appropriate approaches are utilised to understand the problem. A strength of this approach is that the domain of enquiry is not likely to be constrained by its method (Morse, 2003). Pragmatism is essentially a value driven approach, where the appropriate method is applied to provide the best way to answer the research question under consideration.
3.3 Purpose and rationale

The following 5 point framework to conceptualise purpose and rationale for mixed methods studies has been devised.

Table 2. Purpose and rationale for mixed methods studies (Greene, Caracelli & Graham 1989)

<table>
<thead>
<tr>
<th>Process</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triangulation</td>
<td>Comparison of findings derived from different methods to assess various dimensions of the phenomena, with a core premise that all methods have inherent biases and limitations.</td>
</tr>
<tr>
<td>Complementary</td>
<td>One method expands, illuminates and enhances the results of another.</td>
</tr>
<tr>
<td>Development</td>
<td>Methods implemented sequentially thereby allowing results of one method to inform the development of another method.</td>
</tr>
<tr>
<td>Expansion</td>
<td>Different methods utilised in to measure different phenomena according to appropriateness.</td>
</tr>
<tr>
<td>Initiation</td>
<td>To address divergence, paradox and contradiction different methods are used to compare various dimensions of the phenomena of interests.</td>
</tr>
</tbody>
</table>

3.4 Applying mixed methods within this study

(Tashakkori & Teddlie, 2003) recommend the formulation of one over arching research question (see Table 3), which can provide justification for mixing methods and guide the process of interpreting and integrating findings. From this follows a typology or ordering of purpose with mixed methods research and it is assumed that there will be an iterative process between purpose and methods (Newman et al., 2003).
The process of the study is shown in Table 3 and will involve 2 phases. Phase 1 of the development of the intervention the question; *What are the components of an evidence based, best practice manual for a CBT intervention for Chronic Oro-Facial Pain?* has been approached using qualitative methods that are complementary. A synthesis of the evidence collected to inform this intervention (systematic review of RCTs using CBT to treat COFP, dentists’ survey, interviews with patients and practitioners and a component analysis) provided the basis for the development of components for the intervention. The intervention components were refined in an iterative process, through consultation with patients. This enabled gaps in the findings to be addressed.
and feedback from potential users regarding the acceptability and usefulness of the draft intervention was gathered.

Phase 2 of the intervention employed an exploratory trial to determine feasibility and acceptability of the intervention, and to inform parameters for a future RCT. Interpretation of results from interviews (qualitative) and questionnaires (quantitative) will be enhanced and clarified through an increase in the meaning and validity of constructs in a way which is complementary. Concepts were expanded using the most appropriate methods (in depth interviews with patients to assess the complexities and nuances in their experience of receiving the intervention and short term outcomes assessed with validated measurement scales). Assessments of attrition and fidelity to treatment protocol complemented an appraisal of the overall acceptability of the intervention. Results from the phase 2 study can be used in the future to inform modification and adaptation of the intervention drafted for phase 1.

3.5 Conclusion

The MRC guidance will provide a framework for the study as whole, which will encompass the theory and modelling stages of developing a complex intervention. A mixed methodology will be guided by a pragmatic theoretical approach, applying the most appropriate methodology for each piece of research. The next chapter of this thesis describes phase 1 of the study: the identification and development of the intervention components.
4 Chapter 4 Phase 1: Developing a complex intervention to treat COFP

4.1 From evidence to intervention

Despite the emphasis placed on the iterative and cyclical nature of the modelling phase in the revised 2008 version, MRC guidance continues to pay more attention to the evaluation of complex interventions than to the initial key tasks and processes involved in their creation and development. Both versions of MRC guidance (2000 & 2008) recommend that a systematic review of current literature, combined with identification of relevant theory and some primary research, using qualitative and/or survey methods should take place to inform the intervention. However, a methodology for synthesising theory and evidence in order to develop or create a tangible first draft of an intervention prior to testing in an exploratory trial is not outlined.

National Institute for Health and Clinical Excellence (NICE) guidelines for behaviour change at population, community and individuals levels concluded that there is no evidence to recommend one particular behaviour change technique or psychological theory. Studies evaluating other behaviour change interventions are poorly designed and inconsistent in their reporting, often using multiple versions of certain models (NICE 2007). It may therefore be useful to incorporate multiple relevant theories within the development of a complex intervention, including a transparent mapping process of how they might relate to the intervention components (Michie, Johnston, Francis, Hardeman, & Eccles, 2008).

As reported above, many published papers describing complex interventions to change health related behaviours are characterised by sparse reporting of the interventions used. This relates not only to describing the individual components used, but also to the justification in including them, with regard to the theories and mechanisms by which they are hypothesised to work. (Michie & Abraham, 2004). The term “CBT” describes a number of discrete treatments rather than
one complete model. Describing an intervention merely as “CBT based” is insufficient in describing and justifying the inclusion of the individual therapeutic processes involved.

A thorough analysis of other relevant published interventions is therefore likely to be problematic. Inherent difficulties in replicating non-pharmacological treatments have been highlighted by Glasziou et al., (2008). Treatments described in 80 studies consisting of 55 randomised trials and 25 systematic reviews that had been reported over one year in established journals and databases were analysed. Elements of treatment were missing from descriptions in 41 of the original published studies (most often, a report of the process). Not only does this sparse reporting prohibit clinicians using these interventions in their clinical practice, (Glasziou et al., 2008) it prevents researchers from replicating them in different contexts.

Attempts have been made to provide a more standardised approach to describing and reporting techniques used in behaviour change interventions so that components of interventions might be more easily identified and replicated. Mitchie et al., (2008) carried out a systematic mapping of theory to behaviour change techniques by breaking down and analysing various techniques and components commonly employed, and using expert opinion to recommend ways of application (Michie et al., 2008). This can provide useful guidance for researchers creating and developing behaviour change interventions. An associated taxonomy of theory linked techniques used in behaviour change interventions was developed (Abraham & Michie, 2008) with the purpose of providing a standardised vocabulary for the intervention techniques identified, to add clarification to ambiguous terms and provide some definition and specificity to descriptions of behaviour change interventions.

Although potentially useful resources for intervention modelling, these papers focus specifically on applying psychological theory and matching to therapeutic techniques and tend to focus on behaviour change at population level (for example, larger public health campaigns) rather than patient focused help at an individual level. Other important components, such as intervention setting, number of sessions, who will deliver the intervention and what health technology is best employed cannot be adequately addressed through theoretical approaches. These aspects are heavily influenced by context, such as restraints
on resources and availability of patients and practitioners. An investigation of characteristics specific to the context of treating COFP is therefore necessary to elucidate these components. As a starting point to this endeavour, the following piece of work was carried out in order to scrutinise other interventions with some evidence of efficacy in the treatment of COFP.
4.2 Component analysis of existing interventions

4.2.1 Introduction

As recommended in MRC guidelines (2000, 2008) a systematic review of current non pharmacological interventions to treat COFP was carried out (Aggarwal et al., 2011). It concluded that Cognitive Behaviour Therapy (CBT) produced improved patient outcomes for activity interference, depression and pain intensity. Although the evidence for CBT was weak, it remains a preferable approach to current mechanical treatments as it is non invasive and unlikely to have side effects or cause harm (see Chapter 1).

A meta regression on data from studies in the systematic review was not possible due to the heterogeneity of the content of the interventions and the inconsistent way in which they were reported. This is often the case when pooling data relating to complex interventions for behaviour change (Michie, Fixsen, Grimshaw, & Eccles, 2009). Interventions are frequently poorly reported and terminology relating to different components can be ambiguous and inconsistent. Any contribution made to extending knowledge is therefore weakened and other researchers will find it difficult to replicate interventions and build on results.

As the statistical exploration of relationships between component characteristics of interventions reported was not possible, a qualitative analysis of the components used in previous CBT based interventions used to treat COFP was conducted. This exercise represented an attempt to unravel the interventions and provide a starting point for the identification of possible components.
4.2.2 Component analysis of CBT interventions for COFP (study 1b)

4.2.2.1 Aim
To analyse reports of CBT based interventions for COFP in order to break down component parts for delivery and therapeutic techniques and investigate their usefulness for inclusion in an evidence-based complex intervention.

4.2.2.2 Method
Relevant trials were identified based on a search strategy that had been recently applied to a Cochrane systematic review (Aggarwal et al., 2011). Trials that included “cognitive” and/or “behavioural” therapy in the title or abstract were included. Although the initial search strategy was the same, some studies included in this exercise were ultimately excluded from the systematic review. This is because the purpose of this exercise was to isolate the intervention components and to focus on an examination of the techniques used in the treatment for each study, rather than the studies’ design, methodology, or outcomes. The Cochrane systematic review criterion is strict and permits the inclusion of only randomised controlled trial that match a high standard of design. Hierarchies of evidence are not always appropriate as their application can lead to the rejection of knowledge (Glasby & Beresford, 2006), therefore the selection criteria was more inclusive for the purpose of this exercise.

Details of the components of the intervention were extracted from the methods section of the papers, and displayed in a matrix (Tables 4 & 5). The therapeutic components were summarised and grouped into 9 categorical headings. The frequency of use for each type of component was displayed visually and counted to see if there was a tendency for some components to be favoured more frequently than others.

4.2.3 Results

4.2.3.1 Component analysis – variation in delivery
Table 4 shows variations in the ways the interventions were delivered for each of the included research papers. Categories were: mode of delivery, number of sessions, duration, people present during sessions and approximate total contact hours. Specific treatment components displayed in Table 5 were: between session work, patient manual, relaxation, relapse prevention, education, cognitive therapy, behavioural therapy, coping and distraction.
For all 12 studies the setting for the delivery of the interventions was a secondary care or specialist pain clinic. The most common way (6 studies) of delivering the interventions was face to face sessions with a therapist and patient present, with another 2 following up a number of one to one sessions with telephone calls. Two out of twelve studies used group therapy only, with another 1 using groups and follow up telephone sessions. One paper (Stam McGrath & Brooke 1984) did not specify a mode of delivery.

Some sessions were delivered at irregular intervals rather than uniformly, 1 per week, for the duration of the intervention. Delivery could have possibly been according to patient demand or convenience; however none of the studies explore this aspect. The number of sessions comprising the intervention ranged from 4 to 5, and the duration in weeks for delivery was 4 to 15, however some interventions were delivered fortnightly for at least some of the programme (Turner et al., 2007) and (Gatchel et al., 2006). The length of each session was typically 1 to 2 hours.

Total contact time with patients varied widely, from 240 minutes (4 hours) to 1080 (18 hours), with the mean time for total contact 529.61 minutes (approximately 9 hours). Initial decision processes relating to contact time (“dosage”) were not explored in the studies.

Sessions were delivered by practitioners who had obtained relevant qualifications or had been specially trained for the intervention. No interventions reported sessions involving family members, carers or more than one practitioner.
<table>
<thead>
<tr>
<th>Study</th>
<th>Mode of delivery</th>
<th>No of sessions</th>
<th>Duration</th>
<th>People present</th>
<th>Approx total contact hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turner, Mancl &amp; Aaron (2006)</td>
<td>Face to face</td>
<td>4 x fortnightly over 8 weeks = brief telephone calls to patients in the weeks between the personal sessions and at 2,4,8,12,16,20 &amp; 24 weeks after the 4th in person session</td>
<td>1:1 sessions 8 weeks, follow up calls to 24 weeks</td>
<td>Psychologists with prior experience of conducting CBT</td>
<td>(4 sessions x 90 mins + 7 sessions x 15 mins) 465</td>
</tr>
<tr>
<td>Turner, Holzman &amp; Mancl (2007)</td>
<td>Face to face with follow up phone calls</td>
<td>4 x fortnightly over 8 weeks = brief telephone calls to patients in the weeks between the personal sessions and at 2,4,8,12,16,20 &amp; 24 weeks after the 4th in person session</td>
<td>1:1 sessions 8 weeks, follow up calls to 24 weeks</td>
<td>Patient &amp; therapist</td>
<td>(as above) 465</td>
</tr>
<tr>
<td>Dworkin et al., (2002)</td>
<td>Face to face with follow up phone calls</td>
<td>6x visits, 3 telephone calls</td>
<td>Not reported</td>
<td>One joint session with dentist &amp; Psychologist, rest psychologist &amp; patient</td>
<td>(6 sessions x 90 mins + 3 sessions x 15 mins) 585</td>
</tr>
<tr>
<td>Dworkin et al., (1994)</td>
<td>Group sessions + telephone follow ups</td>
<td>2 x 2 hour sessions 1 week apart</td>
<td>3 weeks</td>
<td>Groups of around 2 to 7 (mode = 4) Team led by a study dentist &amp; study psychologist</td>
<td>(2 sessions x 120 mins) 240</td>
</tr>
<tr>
<td>Komiyama et al., (1999)</td>
<td>Group sessions + telephone follow ups</td>
<td>1 session + monthly follow ups for data collection</td>
<td>2 hours</td>
<td>Not specified</td>
<td>(1 session x120 mins) 120</td>
</tr>
<tr>
<td>Bergdahl, Anneroth &amp; Perris (1995)</td>
<td>Face to face</td>
<td>12-15 x 1 hr weekly</td>
<td>12-15 weeks with follow up at 6 months</td>
<td>2 x psychologists</td>
<td>(13 sessions average x 60 mins) 780</td>
</tr>
<tr>
<td>Gatchel et al.,</td>
<td>Face to face</td>
<td>12 x 1.5 hrs average length</td>
<td>8 weeks – twice a week for first 4</td>
<td>Psychologist &amp; patient</td>
<td>(12 sessions x 90 mins)</td>
</tr>
<tr>
<td>Date</td>
<td>Author(s)</td>
<td>Format</td>
<td>Duration</td>
<td>Frequency</td>
<td>Duration (mins)</td>
</tr>
<tr>
<td>-----------</td>
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<tr>
<td>(2006)</td>
<td>Gardea, Gatchel &amp; Misra (2001)</td>
<td>Face to face</td>
<td>12 x 1-2 hrs</td>
<td>8 weeks then weekly for remaining 4</td>
<td>1080</td>
</tr>
<tr>
<td>2001</td>
<td>Turk et al., (1996)</td>
<td>Face to face</td>
<td>6 Length of time not given</td>
<td>6 weeks</td>
<td>Not reported</td>
</tr>
<tr>
<td>1996</td>
<td>Turk et al., (1996)</td>
<td>Face to face</td>
<td>6 Length of time not given</td>
<td>6 weeks</td>
<td>Not reported</td>
</tr>
<tr>
<td>1994</td>
<td>Oakley et al., (1994)</td>
<td>Group</td>
<td>5 x 1.5 hour</td>
<td>5 weeks</td>
<td>Therapist + average of 3 patients</td>
</tr>
<tr>
<td>1994</td>
<td>Flor &amp; Birbaumer (1994)</td>
<td>Face to face</td>
<td>8 x 1 hour</td>
<td>Not reported</td>
<td>Not given</td>
</tr>
<tr>
<td>1979</td>
<td>Stenn, Mothersill &amp; Brooke (1979)</td>
<td>Face to face</td>
<td>8 sessions x 30 mins</td>
<td>Not reported</td>
<td>Psychologist &amp; patient</td>
</tr>
<tr>
<td></td>
<td>Mean total contact mins</td>
<td></td>
<td></td>
<td></td>
<td>529.61 mins</td>
</tr>
</tbody>
</table>

The total contact time is approximately 9 hours.
4.2.3.2 Therapeutic components

Table 5 shows that studies reported using the following techniques delivered in varying combinations: between session work, patient manual, relaxation, relapse prevention, education, cognitive therapy, behavioural therapy, coping and distraction.

Ten interventions have been broken down as some studies reported using the same treatment procedures. When studies used the same components, they have been placed together in the table. For these cases, treatment was delivered according to a previously published protocol with differences in modes of delivery and treatment duration reported. Komiyama et al., (1999) used an intervention published in Dworkin (1994) which was modified to include posture instruction and Gatchel et al., (2006) applied an intervention developed for chronic patients (Gardea et al., 2001) to acute pain patients.

All of the studies described contained a cognitive therapy, concerned with modifying negative thought processes relating to COFP and 6 out of 10 used a behavioural intervention. Distraction was used in 3 protocols and relapse prevention for only 2. When a distraction or a relapse prevention technique was used, a cognitive and a behavioural element to the therapy was also present in the intervention. Where coping was included (5 papers) a behavioural therapy was also present with the exception of one study (Stenn, Mothersill & Brooke 1979) and when coping was a strategy relaxation was always practised (7 studies).

Education was part of the treatment protocol for 6 of the studies and 5 protocols required patients to carry out between session work. For the more comprehensive treatment programmes, utilising 7 or 8 components out of the 8 displayed in the table, a patient manual was also used (3 protocols). These studies all contained a cognitive and behavioural therapeutic element, education, relaxation and between session work.
<table>
<thead>
<tr>
<th>Study Details</th>
<th>Between session work</th>
<th>Patient Manual</th>
<th>Relaxation</th>
<th>Relapse prevention</th>
<th>Education</th>
<th>Cognitive therapy</th>
<th>Behavioural therapy</th>
<th>Coping</th>
<th>Distraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turner, Mancl, Aaron (2006) Turner, Holzman, Mancl (2007)</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Dworkin, et al., (2002)</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Dworkin et al., (1999)</td>
<td></td>
<td></td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Bergdahl, Anneroth &amp; Perris (1994)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Used a combined CBT/Biofeedback treatments described in Mishra, Gatchel &amp; Gardea, “the relative efficacy of 3 CBT treatment approaches to TMD” (2000)</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td></td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Turk et al., (1996)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>Study</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----</td>
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<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>Oakley et al., (1994)</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stam &amp; McGrath, (1984)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flor &amp; Birbaumer (1993)</td>
<td></td>
<td></td>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stenn, Mothersill &amp; Brooke</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1979)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5</td>
<td>3</td>
<td>7</td>
<td>2</td>
<td>6</td>
<td>10</td>
<td>6</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>
4.2.4 Conclusion
Limited information could be gained from the systematic analysis of the components in the existing literature. It is not clear how important the components described in Tables 4 & 5 are to the intervention or how they interact within the treatment as a whole to affect outcomes for patients. A frequency count of the therapeutic components yielded little in terms of evidence for their selection in our intervention, however it showed that the most comprehensively reported interventions used a combination of the following: patient manual, cognitive and behavioural therapies, education, relaxation and between session work. The interventions used in the studies were not described to the extent that they could be replicated and some terms, such as, “relaxation”, “distraction” and “coping strategies” are ambiguous and undefined. For example, it is plausible that distraction and relaxation could be used as a coping strategy. As described previously, there is some evidence to suggest that a CBT based intervention may produce positive outcomes for COFP, however evidence to help make decisions regarding the inclusion of specific components was not found. A further exercise was conducted in order to aid decision-making.

4.3 SWOT analysis of components

4.3.1 Introduction
Although the component parts of the interventions were extracted, little is known about their individual roles regarding effectiveness and how they interact within the treatment as a whole to affect outcomes for patients. In light of this ambiguity, it would be possible to make a case for the inclusion of all the components, and to subsequently investigate their use and utility within the intervention. However, initial decisions regarding the potential usefulness and application of individual components when developing a manual for delivery of the intervention remains difficult. Consequently, there is a need to further explore the value of the components to make decisions about their use and relevance. The aim of this study is to develop an intervention that is developed in a rigorous and transparent way, using a methodology that can be replicated. The evidence synthesis meeting (p59, 4.4) afforded a timely opportunity to canvas the informed opinions of a group of experts, rather than relying on the decisions made by a single clinician or researcher. Therefore in order to focus the expertise of the group in an open and structured way, a SWOT analysis was conducted.
A SWOT analysis is commonly used in business development and aims to identify the strengths and weaknesses of an organisation and the opportunities and threats in the environment (Dyson, 2004). Although originating as an analytical tool for use in business, the SWOT framework can also be usefully applied to structure and guide endeavours in other fields (Rizzo & Kim, 2005).

4.3.2 Aim
To conduct a SWOT analysis in order to help make decisions regarding the inclusion of various therapeutic components of an evidence based complex intervention for COFP

4.3.3 Method
As part of a day-long meeting (Appendix 2) to synthesise evidence to develop the intervention, members of a multi disciplinary group (Appendix 3) considered each of the components systematically and assessed their potential usefulness in contributing to producing improved outcomes for COFP patients. Decision making was structured around perceived strengths, weaknesses, opportunities and threat (SWOT analysis), based on evidence presented from each of the key studies and the expertise and clinical experience of members of the group.

4.3.4 Results
The analysis is displayed in Table 6 below and summarised in Figure 5. For all of the components, more “strengths” and “opportunities” were found than “weaknesses” and “threats”. Although some weaknesses of both cognitive and behavioural therapy are reported, these are the components that have the highest evidence base in the existing literature, and either one or both of these were used by all the studies used for the component analysis. Weaknesses were mainly associated with the time and investment needed for training and supervision.

For distraction, education, relapse prevention and relaxation, an important weakness identified was the lack of evidence as a standalone component. These are strategies used commonly to support other techniques. However, these components were considered acceptable to patients by the group. Coping strategies are forms of self management and opportunities for relaxation and distraction refer to them as being “portable, cheap, easy to train and easy to practice” which suggests they are techniques patients might find acceptable. Furthermore, distraction is reported as being used already by patients in an existing repertoire of strategies. Education provides a way of informing patients of best current evidence about their condition, in
a way that is accessible, easy to produce and easy to access. However it may not be acceptable to patients if it does not fit their model of illness or conflict with information from other sources.
## Table 6 SWOT analysis

<table>
<thead>
<tr>
<th>Component</th>
<th>Behavioural Therapy</th>
<th>Cognitive therapy</th>
<th>Distraction</th>
<th>Coping strategies</th>
<th>Education</th>
<th>Relapse prevention</th>
<th>Relaxation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strengths</strong></td>
<td>Evidence base</td>
<td>Fits in with</td>
<td>People use it as a repertoire of strategies –</td>
<td>Build on patients own strategies (when they are helpful)</td>
<td>Can help to tackle health beliefs</td>
<td>Prevents relapse</td>
<td>Can be applied</td>
</tr>
<tr>
<td></td>
<td>Expertise</td>
<td>managing health</td>
<td>Has face validity</td>
<td>Focusses on pain</td>
<td>Legitimising health beliefs</td>
<td>Links with exacerbating factors</td>
<td>Can help other conditions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>beliefs and current policy for pain management</td>
<td>Easy technique</td>
<td>Can identify unhealthy coping strategies</td>
<td>Can be delivered through many mediums</td>
<td>Tool they can take away – carry on with techniques in intervention</td>
<td>Self management strategy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can be tailored to</td>
<td>Training inexpensive</td>
<td>Links with self management</td>
<td>Easily manualised</td>
<td>Exit strategy</td>
<td>Acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>individuals</td>
<td></td>
<td>Easy to rationalise/ explain/ understand/</td>
<td>Easily accessible</td>
<td>Emphasises ongoing self management</td>
<td>Link with condition/ can deliver a rationale/ fits with model of stress</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evidence base –</td>
<td>Onus on patient</td>
<td>Onus on patient</td>
<td>Opportunity to provide best evidence</td>
<td>Empowering</td>
<td>No specialised supervision needed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>wider: MUS</td>
<td>Links clearly with health beliefs</td>
<td>Links clearly with health beliefs</td>
<td></td>
<td>Visual representation of experience can be used</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expertise/ training</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>established</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lends itself to</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>different modes of delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Focuses on self</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Weaknesses</strong></td>
<td>Length of time</td>
<td>Training – time</td>
<td>Temporary</td>
<td>Focuses on pain</td>
<td>May not fit with patients’ health model</td>
<td>Responsibility of patient</td>
<td>Need space &amp; time</td>
</tr>
<tr>
<td></td>
<td>training</td>
<td>consuming &amp;</td>
<td>Short term</td>
<td>Simplistic</td>
<td>Weak evidence as a lone intervention</td>
<td>Not a standalone component</td>
<td>Absence of evidence as a component on its</td>
</tr>
<tr>
<td></td>
<td></td>
<td>difficult</td>
<td>Lack of evidence as a</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Supervision – time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>consuming</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Evidence base
- Expertise
- Techniques can be tailored to condition/behaviours/values
- Easy to teach
- Easy to incorporate into a manual
<table>
<thead>
<tr>
<th>Reductionist</th>
<th>Patients need to invest/ engage component on its own</th>
<th>Lack of evidence own</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Opportunities</strong></td>
<td>Self management</td>
<td>Policy/ funding/ could be applied potentially to other MUS May treat co-morbidities</td>
</tr>
<tr>
<td></td>
<td>Can be delivered in a variety of ways</td>
<td>Easily practised Self manage – cope with the pain rather than cure Can take it to others – can educate others</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can be delivered/ taught using many strategies, Portable, Cheap Easy to train</td>
</tr>
<tr>
<td><strong>Threats</strong></td>
<td>May change one behaviour for it to be replaced by another “all in their mind” May not be acceptable to patients – challenge their medical views Patients need to invest/ engage Finite duration</td>
<td>May isolate people Difficult to disseminate and include in a manual Implies can’t cope Onus on patient May conflict with patient’s preferred coping strategy Focus on cope with pain rather than cure; may have negative implications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Compliance – patients may not accept re education – may just want to be fixed May conflict with misinformation from other sources</td>
</tr>
<tr>
<td></td>
<td></td>
<td>May encourage avoidance of some behaviours Encourages monitoring/ health anxiety Contradicts distraction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>May suggest pain is “all in the mind”</td>
</tr>
</tbody>
</table>
Figure 5. Graph to show number of statements in each SWOT category

SWOT analysis of components

- Behavioural Therapy
- Cognitive therapy
- Distraction
- Coping strategies
- Education
- Relapse prevention
- Relaxation

Legend:
- Strengths
- Weaknesses
- Opportunities
- Threats
4.3.5 Conclusion
The SWOT analysis produced more positive statements (strengths and opportunities) than negative statements (weaknesses and threats). Distraction, education, relaxation and relapse prevention were not considered to be valid standalone components. These components could be included as supplementary or complementary to behavioural therapy and cognitive therapy, which have a supporting evidence base as key components within the wider literature. Distraction and relaxation techniques were often not defined and it is possible that these terms were used to describe similar coping strategies in some interventions. Coping strategies were also not clearly defined and it is possible that these components overlap. The component analysis produced a breakdown of the therapeutic components used in previous CBT interventions to treat COFP and, although useful, this exercise did not provide an insight into their individual effectiveness and has therefore proved to be of limited use.
4.4 Evidence synthesis

The process by which the components of an intervention and the underlying mechanisms that produce change are identified is described as modelling the intervention (MRC 2000). Despite being both influential and helpful in structuring and framing the development of complex interventions, both the original (2000) and revised (2008) MRC guidelines do not contain pragmatic directions on the optimum way to synthesise evidence so it can be applied to produce the intervention components. It is therefore necessary to utilise an additional methodology in order to enable decisions to be made regarding the application of evidence to produce a complex intervention prior to testing.

Initially, a Delphi consensus exercise was considered (Linstone & Turoff, 1975). The Delphi technique has been used widely in health services research, particularly for technology assessment and in developing clinical practice. It is a method for structuring a group communication process to aid decision-making and deal with complex problems. A group of individuals are involved in feeding back information and knowledge anonymously until a consensus is reached regarding a particular issue. The Delphi technique has been used widely in health services research, particularly for technology assessment and in developing clinical practice. The advantages of this approach are that it can be carried out over the internet, affording flexibility in terms of time and geographical position, and that views can be expressed impersonally. The aim was to seek the opinion of a number of experts including dental clinicians, CBT practitioners and patients. However, for pragmatic reasons, this approach was rejected. This was a time and resource limited study, and it did not prove possible to gain commitment from a significant number of possible protagonists to provide the necessary repeated input over a limited period of time.

Therefore a best evidence synthesis methodology which has previously been used successfully to develop complex interventions for depression (Lovell et al., 2008; Richards et al., 2006; Bradshaw et al., 2012; Bradshaw & Pedley, 2012) and healthy eating for people with early psychosis (Bradshaw et al., 2012) was selected. The following describes this process, applied to develop a complex intervention for COFP.
4.4.1 Process
Evidence from the results of the studies listed below was used:

- Survey of dentists’ experiences of diagnosis and management of COFP (study 1a).
- A qualitative study of the experiences of patients, dentists and general practitioners regarding COFP (study 1b).
- Cochrane systematic review which examines the quality and clinical effectiveness of CBT as a treatment for COFP (study 1c).
- Component analysis (study 1d).

The meeting was chaired by the author and organised around an agenda (Appendix 3). A room was booked for a full working day. A laptop computer and projector were used for the presentations. Proceedings were audio recorded, and further written records were made using the laptop.

4.4.1.1 Expert contributors
A multi-disciplinary group of six experts with a range of relevant experience and backgrounds contributed to the synthesis process, which involved a day – long meeting involving presentations, discussions and brainstorming exercises (Appendix 3).

4.4.1.2 Focus
Key findings from the four studies are presented in Table 4 (the presentations are produced in full in Appendix 1). Results from the four studies were combined and applied to a matrix relating to the core components. This matrix was used as the basis for decision making regarding how the components might be incorporated into the intervention.

Five components were considered:

- Content
- What should therapists be called?
- Setting of the intervention
- Number/ Duration of sessions
- Acceptability issues

The key task for the group was to make decisions regarding intervention content.
This was based on analysis of the evidence presented, expert opinion and reaching a consensus within the group.

4.4.2 Findings

4.4.2.1 Systematic review
The systematic review demonstrated that there is some weak evidence to suggest that a CBT based intervention may be helpful to COFP patients and the subsequent component analysis provided a cursory description of previously used interventions. It was not possible to ascertain which techniques produced a positive effect. Studies reviewed were poorly reported and the component analysis carried out in order to unravel and examine interventions proved to be largely descriptive.

4.4.2.2 Dentists survey
Although the survey of dentists was of limited use in identifying key intervention components, it did provide evidence that dentists were happy to refer patients to a talking therapy once pathology had been thoroughly investigated and that they were correctly able to diagnose COFP. This finding has specific implications for the recruitment of patients to an exploratory trial.

4.4.2.3 Interviews with patients and practitioners
The most useful evidence came from the qualitative study of patients and dentists which highlighted the importance of acknowledging varying medical models for the intervention to be acceptable. Possible sensitive areas are involved in moving away from models more commonly found in a medical context and towards a more holistic stance, incorporating psychosocial and biological factors.

4.4.2.4 Key findings
In Table 7, the rows list the active ingredients and the columns show how data from each of the studies relate to each component. The last column indicates decision making about how the evidence will relate to the draft intervention. There was not enough information available to make decisions regarding the setting, duration and number of sessions and a title for the therapists at this stage.
Table 7 Key findings from studies 1-4

<table>
<thead>
<tr>
<th>Systematic Review</th>
<th>Quantitative survey: dentists</th>
<th>Qualitative interviews with users and health professionals</th>
<th>Component analysis</th>
</tr>
</thead>
</table>
| CBT alone or in combination improved long term outcomes | Diagnosis was correct for majority | Dentists and GPs see these patients as challenging  
  • Dentists: volume and inability to manage mechanistically  
  • GPs: frustration over their relationship with dentists  
 Both view problem as non-dental  
  • Dentists: no obligation or desire for any role in COFP management  
  • GPs: accept they have a role in supporting patients and addressing psychological features of the condition  
 Patients want problem legitimated and to be believed  
 Many (but not all) patients recognise psychosocial aspects of their experience  
 Acceptability of psychological intervention depends on illness beliefs  
 Patients eager to self-manage  
 Illness severely impacts on several behaviours that could be targeted | Interventions vary in modes of delivery and content and scope of reporting in papers also varies.  
 Most common delivery method was face to face sessions involving patient and practitioner  
 Typically 1-2 hours long (approx 10 hrs total), 4-5 sessions, mean duration 6 weeks.  
 The most comprehensive (utilising the most components) protocols used patient manuals, cognitive and behavioural therapies, education, relaxation and between session work.  
 Most frequent components = Cognitive therapy, relaxation, behaviour therapy, education  
 Exclude distraction and coping strategies – these components are unspecific and poorly defined. There is no evidence of their effectiveness as standalone components. |
|                   | Variation in management – not evidence based |                                                         |                    |
|                   | Referral – variation and services unavailable |                                                         |                    |
|                   | Majority wanted to refer |                                                         |                    |
|                   | Length of chronicity predicted referral to psychological therapy |                                                         |                    |
Table 8 Synthesis of key components

<table>
<thead>
<tr>
<th>Component</th>
<th>Systematic review</th>
<th>Quantitative survey: dentists</th>
<th>Qualitative interviews with users and health professionals</th>
<th>Component analysis</th>
<th>Incorporated into the intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content</td>
<td>CBT alone or in combination improves a variety of outcomes</td>
<td>Pathology should be investigated prior to intervention</td>
<td>Legitimising condition is important for patient to engage Illness severely impacts on several behaviours and conditions that can be targeted. Patients want functional lives</td>
<td>All components have more positive attributes than negative. Some components should be used in conjunction with others; not “standalone” Some components may not be acceptable to some patients; a degree of flexibility is needed. Components have a good theoretical basis for inclusion</td>
<td>Cognitive and behavioural therapy based integrating education, relaxation and between session work. Content should legitimise the condition to patients</td>
</tr>
<tr>
<td>What should “facilitators” be called?</td>
<td>Not relevant</td>
<td>Not relevant</td>
<td>Element of dentistry/ facial pain/ teeth mouth/ oral however not acceptable for dentists to deliver intervention</td>
<td>Not relevant</td>
<td>Further evidence needed. Gain patients’ views</td>
</tr>
<tr>
<td>Setting of the intervention</td>
<td>All tertiary care settings</td>
<td>Dentists not wanting to manage COFP</td>
<td>Condition can be costly to patients, costs include travelling to appointments</td>
<td>Not relevant</td>
<td>Further evidence needed. Gain patients’ views</td>
</tr>
<tr>
<td>Number/duration of sessions</td>
<td>Not relevant</td>
<td>Not relevant</td>
<td>Not relevant</td>
<td>Typically 1-2 hours long Mean duration 6 weeks Mean total contact time, approx 9 hours</td>
<td>Further evidence needed. Gain patients’ views</td>
</tr>
<tr>
<td>Acceptability issues</td>
<td>CBT produced effective outcomes</td>
<td>Dentists more likely to refer long term patients Majority wanted to refer</td>
<td>Dentists do not want to manage COFP. Acceptance psychological features of the condition by dentists and GPs. Patients’ medical models are important. Patients accept self management.</td>
<td>Not relevant</td>
<td>CBT acceptable providing patients’ condition legitimised and their medical models acknowledged. Dentists are willing to refer to a CBT intervention and do not want to manage COFP themselves.</td>
</tr>
</tbody>
</table>
4.4.3 Conclusion
The results of four studies were synthesised to inform the components that will be used for a draft intervention for COFP. There is not enough evidence to make decisions regarding the length and duration of sessions, setting and what to call the therapists. Interim decisions were made pragmatically, based on a previous study of CBT to treat Chronic Widespread Pain (McBeth et al., 2011) that has produced effective results, and expert opinion. Further consultation with patients is needed to provide more evidence to aid decision making regarding these components and related issues will be explored in the acceptability interviews (Chapter 6). The next section describes how findings relating to content and acceptability were incorporated to produce a manual to guide the intervention.

4.5 Intervention Manual

4.5.1 Development of “Managing chronic orofacial pain”; a manual for guided self-help
The transcript of an existing self-help intervention based on CBT principles for chronic widespread pain titled “managing chronic widespread pain”, was obtained (Lovell et al., 2008). This intervention has produced recent evidence of efficacy and the techniques used have an appropriate theoretical basis (see below). It comprised of guided self help using a health technology (a manual) and a facilitator. Similarly to COFP, chronic widespread pain is characterised by medically unexplained symptoms and poor functioning and is associated with psychosocial factors. Using this manual as a template for a COFP intervention represents a parsimonious use of good quality resources. Results from the exercises reported above were used to adapt this manual and make it appropriate for treating COFP.

4.5.2 Mapping the synthesis evidence to the manual “managing chronic widespread pain”
The manual consists of guided self help, with a choice of therapies; lifestyle changes, behavioural activation and cognitive restructuring, supported by a facilitator. The manual is divided into 4 steps: Step 1; What is “managing my chronic orofacial pain” all about?, Step 2; Understanding how the pain is affecting me, Step 3; My programme, Step 4; Continuing to manage my pain and recovery stories.
Step 1 (“What is managing my chronic orofacial pain” all about) introduces guided self help, emphasising the role of the patient as the agent of change and in control of the direction of treatment as opposed to the facilitator taking the lead. A focus on strategies to increase the degree of perceived control over thoughts and behaviours is concurrent with the theory of planned behaviour (see Chapter 1). Case vignettes were used to demonstrate personal experiences of COFP.

Step 2 (“Understanding how the pain is affecting me”) helps the patient to highlight and understand the impact of their pain on loss of day to day functioning. Some information about COFP and chronic pain in general is given to help patients further understand the nature of their condition. Patients are encouraged to devise goals based on the outcomes they wish to achieve. Brief written exercises are offered in order to assist engagement and understanding.

Step 3 (“My programme”) is focused on three evidence based CBT derived interventions. They include a focus on lifestyle changes to help with the application and rationale of behavioural activation and cognitive restructuring and are techniques which are associated with changing illness perceptions in accordance with the common sense model (Leventhal et al., 1980, see Chapter 1). These interventions are also offered as additional methods of gaining control. Patients are able to select the interventions they feel would be most useful and a number of recovery stories are offered to assist patient selection. These stories are fictional but typical and based on actual patient experiences. They demonstrate patients’ experiences of chronic orofacial pain and its management using one of the interventions.

The results of the evidence synthesis were incorporated into the adaptation of “managing COFP” as shown in shown in Table 9.
Table 9 Adapting the intervention for COFP

<table>
<thead>
<tr>
<th>Component</th>
<th>Finding to be incorporated into the intervention</th>
<th>Adaptation of intervention</th>
</tr>
</thead>
</table>
| Content                    | Cognitive and behavioural therapy based  
Integrating education, relaxation and between session work.  
Content should legitimise the condition to patients                                                   | Step 3 – recovery stories changed to reflect experiences of COFP patients  
Step 2 (education) – information regarding COFP  
Step 3 (relaxation) – lifestyle changes to reflect issues associated with COFP  
Step 2 & 3 (between session work) – goal setting, written exercises  
Stories describe typical patient experiences based on qualitative interviews and user group experiences |
| Acceptability issues       | CBT acceptable providing patients’ condition legitimised and their medical models acknowledged                     | Case vignettes at the start of the manual reflect experiences of patients who hold both biopsychosocial and biomedical health models                                                                                          |
| What should therapists be called? | No evidence                                                                                                    | “Managing chronic widespread pain” uses the term “therapists”. We chose the term “facilitator” based on it’s neutrality and lack of association with psychological treatments. No negative comments about this term were made by the user group |
| Setting of the intervention | No evidence                                                                                                     | A choice of telephone and face to face delivery will be offered to patients                                                                                                                                           |
| Number/ duration of sessions | No evidence                                                                                                      | Based on the “managing chronic widespread pain” model, sessions will last approximately 30 -45 minutes per session over a period of up to 8 sessions. Decisions on the precise number and frequency of treatment sessions will be made according to clinical judgement made by the facilitator, in consultation with the patient |
4.5.3 Adapting the intervention

Column 3 of Table 9 shows how the components identified in the synthesis process were integrated into the intervention. The manual was based on CBT principles, and incorporated some of the techniques we had identified in the component analysis (study 1d); education, relaxation, between session work and manual based. The content of the patient stories and vignettes presented in the manual was based on transcripts of the qualitative interviews (study 1b) and input from a COFP user group (see below) and reflected patients’ experiences of living with COFP. Case vignettes at the start of the manual reflect patients’ dominant narratives of both biomedical and biopsychosocial models of illness and attitudes to psychological therapies.

The use of the term “facilitator” was chosen to replace the term “therapist” as the title for the person delivering support for the intervention. This decision was made in order to reduce the emphasis on the intervention as a psychological therapy, to increase the likelihood of its acceptance and to avoid misunderstandings as to the “facilitator’s” background and professional qualifications.

The most common way of delivering the interventions included in the component analysis was face to face, however “managing chronic widespread pain” has produced good preliminary results using telephone delivery exclusively. As there is a paucity of evidence to suggest the superiority of either mode of delivery, face to face and telephone delivery will be offered to patients in order to maximise patient choice and convenience and keep to patients’ costs to a minimum. As we also had little evidence on which to base decision making regarding the number and duration of sessions, the model used for “managing chronic widespread pain” was adopted: 30 - 45 minutes per session over a period of up to 8 weeks with judgement regarding the exact “dosage” to be made by the patient, facilitator and supervisor in consultation.

The style, layout and order of “managing chronic widespread pain” was retained. The content of the case vignettes, stories and educative material was changed to make the manual specific to COFP. The manual was written to engage patients, as though they were being “talked to” rather than “talked at”. Lay language, personal experience and metaphors are retained throughout to aid accessibility. The original manual obtained a Flesch-Kincaid level of 6.4, reflecting a reading ease of around 8th grade (age 12-13) and all changes made to the manual aimed to reflect a similar level and style of writing.
4.6 User group consultation

4.6.1 Introduction
Although the manual "Managing Chronic Widespread Pain" had produced some evidence of efficacy with a cohort of chronic widespread pain patients (McBeth et al., 2012), it was important to adapt the intervention specifically, so that it was appropriate for and acceptable to COFP patients. Therefore, a user group was recruited, comprising patients suffering from COFP. A consultation was conducted, to aid the adaptation of the intervention manual.

4.6.2 Aim and objectives

Aim

To involve COFP patients in producing material for the intervention manual which is authentic, reflecting patient experiences and which is acceptable.

Objectives

- To gather stories relating to patients’ experiences of living with COFP.
- To gain feedback on the content of the manual.

4.6.3 Method
A group of 5 patients (4 females, one male) aged over 18, who had suffered from pain in the face or mouth with no identifiable pathology for over 12 weeks were recruited from the TMD clinic at University Dental Hospital of Manchester. Participants were initially asked to provide narratives relating to their experiences of suffering from COFP, and were given a choice of participating by email, or through face to face or telephone semi structured interviews. One participant chose to provide a narrative of her experiences through email. The remaining participants chose to take part in telephone interviews which were audio recorded and transcribed verbatim. Participants were asked about the ways in which COFP affected their day to day routine and the resulting impact on their lives. Additionally they were asked to volunteer any insights into their condition such as exacerbating or
analgesic factors. General thoughts and feelings relating to their condition were recorded.

Participants’ experiences, drawn from completed narratives were incorporated into the vignettes and “stories” that form an important part of the treatment manual. Copies of a draft of the adapted version of the manual were then sent by email and members of the user group were invited to comment by return on their impressions of the manual generally and the authenticity of the content of the stories and vignettes specifically. They were also asked to comment on the use of the term “facilitator” to describe the individual delivering the intervention.

4.6.4 Results
One participant withdrew from the user group citing lack of time as the reason, with another becoming incommunicado.

The three remaining participants provided short narratives which focused on the cyclic nature of their pain and how stressful situations and facial movements involved in day to day activities, such as eating, talking and laughing could exacerbate their condition. The influence of these participants’ stories can be seen most clearly in the story of “Pearl” (page 15 “Managing Chronic orofacial Pain”) which contains a description of specific ways in which a woman’s life is affected by COFP. The “vicious circle of thoughts, physical symptoms and changes in behaviour” is depicted.

Two participants did not provide any comments on the manual content and were neutral regarding the use of the term “facilitator”. The third participant however was positive, stating that she “enjoyed reading it” and that the case studies would “make sufferers feel like they weren’t alone”. She felt that the exercises were easy to follow and that the three stories at the end of the manual offered good examples of how techniques could be used:

“Three stories at the end clearly showed how the different treatments could be undertaken” (us03).

Although the participant found the rationale behind CBT “easy to understand”, she suggested diagrams to supplement the descriptions of the vicious circle of pain and the recovery cycle. The basic structure of her diagrams was taken and embellished
and incorporated for use as supplementary materials to be used by facilitators at the first session to help explain the theory behind the treatment (below).

Figure 6 Vicious circle of pain and recovery cycle

**Physical symptoms:** Aching, stabbing, nagging, fatigue, poor appetite

**Doing:** Avoids doing activities, boom/bust behaviour, becomes withdrawn & isolated

**Feelings**

**Thoughts**

**Behaviours**

**Thinking:** I can't do anything because of this pain; I'm no good to anyone

**Revised thoughts**

**Changed behaviour**

**Altered feelings**
4.6.5 Conclusion
Although this was a brief exercise, involving a small number of participants, the consultation did provide some useful material that contributed to the adaptation of the intervention manual. Specifically it helped with the creation of appropriate stories and vignettes to illustrate patient’s experiences and to provide working examples of the therapeutic exercises described in the manual. The suggestion of a diagram to illustrate pain cycles and the mechanism of introducing a cognitive and/or behavioural therapy was adopted. This extra item may help to engage patients, introduce the intervention and illustrate its proposed mechanisms more clearly during the first session.

4.7 Phase 1 summary
Guidance for the modelling of a complex intervention to improve health outcomes focuses more on evaluation than development. Identifying relevant theory and evidence is a good starting point in the development of an intervention and can help to guide researchers towards appropriate therapeutic techniques. Decision making regarding appropriateness and utility of therapeutic components can be enhanced by convening expert opinion. “Expert opinion” could include patients and key personnel, for example, commissioners, practitioner and academics. Identifying key questions to be answered regarding the intervention can focus expert opinion, and provide a starting point in identifying the key components for a draft intervention, prior to testing in an exploratory trial. Some components of complex interventions, such as how and by whom sessions should be delivered are experientially influenced by context and the resources available.

Evidence from four specially conducted studies was synthesised using a best evidence synthesis methodology to produce the components of an intervention to treat COFP. The results of this exercise and the user group consultation were incorporated and used to create a draft manual based on a previous intervention which has produced some early evidence of efficacy. Phase 2 of this study will encompass an exploratory trial of the intervention.
Chapter 5 Phase 2: Exploratory trial

5.1 Introduction

A draft intervention to treat COFP was produced (Appendix 4), using methods described in the previous chapter. The intervention consists of guided self help supported by a manual; “Managing Chronic Orofacial Pain”. This book contains cognitive, behavioural and lifestyle changes supported by a health professional. Although previous research suggests an intervention of this type may help people with COFP, further evidence needs to be gathered to examine whether it is effective, acceptable and what possible reasons for the results observed might be. MRC guidelines for the development of complex interventions recommend conducting an exploratory trial as part of the intervention modelling phase, when insufficient evidence exists to conduct a randomised control trial. A phase 2 study was therefore carried out.

5.2 Aims and objectives

Aim
To develop an intervention for the management of COFP based on best evidence, which is feasible and acceptable to patients.

Objectives:
To carry out an exploratory trial in order to:

- Examine preliminary effects of a guided self help intervention for COFP
- Explore parameters for a future randomised control trial (RCT), including recruitment, randomisation, measures and sample size.
- Assess the feasibility of implementing the intervention
- Determine acceptability to patients
- Inform the content of the intervention
5.3 Design

An exploratory trial (sometimes referred to in the literature as a ‘pilot trial’) was conducted, using mixed methods for data collection and analysis. Validated quantitative outcome measures were combined with nested qualitative interviews which investigated acceptability (see Chapter 6). The study had a repeated measures design, where data was collected at two time points. The primary outcome was physical functioning, assessed by the SF36 questionnaire and measures were taken at baseline and at 8-10 week follow up time point. Scores for participants in the treatment group were compared to those in the control group who received usual treatment from a secondary care provider.

5.4 Inclusion criteria

Adults aged 18 and over with persistent pain in their face or mouth for 3 months or longer, which cannot be explained by pathology, who were referred to secondary care outpatient clinics in Salford and Central and North Manchester.

5.5 Exclusion criteria

- Current treatment with a psychological therapy for oral or facial pain.
- Current suicidal ideation (assessed at baseline by PHQ-9 questionnaire)
- Began a prescribed dose of anti depressants less than 3 months prior to recruitment date.
- Does not speak and understand a good level of English (Resources for interpretation and translation were not available within this exploratory study)

5.6 Recruitment

Participants were recruited from the TMD and oral medicine clinics of the University of Manchester dental hospital and the maxillofacial outpatient clinic at North Manchester General hospital and Salford Royal NHS Foundation Trust. Recruitment procedures were designed in a way that minimised the intrusion on patients’ time and ensured confidentiality.
Participants were approached in one of two ways:

1. The specialist clinician in the secondary care setting identified a suitable patient. At the end of the consultation permission was sought to refer the patient to a researcher on site. The researcher gave the patient an information sheet along with a brief verbal synopsis of the research. The patient was contacted by telephone after a period of 24 hours to answer any questions they had. If the patient agreed to participate, written informed consent was taken by a researcher at the first data collection session.

2. When a researcher was not on site, the clinician provided the patient with a patient information sheet and took written consent to pass the patient’s contact details on to a member of the research team. Patients were given a minimum of 24 hours to consider participating and written informed consent was taken by a researcher at baseline data collection.

For consent and baseline data collection, patients were given a choice of meeting a researcher at the University of Manchester Dental School, in a public venue of their choice or at their home. Follow up data collection could be completed either by post or over the telephone with a research nurse.

Figure 7 shows participants’ flow through the study, from identification at the clinic to acceptability interview or withdrawal.
Consultant identifies patient eligible for study, gives information sheet and takes consent to contact

Patient declines to become a participant in the study

After 24 hours, researcher contacts participant to answer any questions about the study and to make an appointment for baseline assessment and taking written consent

Patient agrees to be a participant

Researcher meets participant to take baseline measures and full consent

Participant withdraws from study

Excluded—no further contact

Patient is assigned to treatment group

Patient is assigned to control group

Outcome measures taken at baseline & 8-10 weeks later approx.

Participant withdraws from treatment

Researcher contacts participant for telephone or face to face interview about reasons for withdrawal. Follow up data completed.

Participant to receive intervention - up to 8 sessions total

Acceptability interviews conducted upon completion of intervention

Outcome measures taken at baseline & 8-10 weeks later approx.

Participant is assigned to treatment group

Participant is assigned to control group

Consultant identifies patient eligible for study, gives information sheet and takes consent to contact

Participant agrees to be a participant

Researcher meets participant to take baseline measures and full consent

Participant withdraws from study

Researcher contacts participant for telephone or face to face interview about reasons for withdrawal. Follow up data completed.

Participant to receive intervention - up to 8 sessions total

Acceptability interviews conducted upon completion of intervention

Outcome measures taken at baseline & 8-10 weeks later approx.
5.7 Intervention

The intervention comprised of a self help manual “Managing Chronic Orofacial Pain” supported and guided by a facilitator.

5.7.1 Manual
The manual consists of guided self help presented as a series of stages and recovery stories to illustrate the techniques described (see Chapter 4). Treatment focuses on three CBT based interventions (lifestyle changes, behavioural activation and cognitive restructuring).

5.7.2 Guidance
The guidance was delivered by two specially trained facilitators with a background in dentistry and psychology respectively. The role of the facilitators was to engage the participant with the intervention and guide them through the exercises in the manual, emphasising the pivotal role of the patient as the agent of change. Facilitators were responsible for conducting assessments and reviews, monitoring progress and writing up case notes. The sessions with facilitators were predicted to take approximately 30-45 minutes and be delivered over a period of up to 8 weeks.

5.7.2.1 Training programme
The facilitators (the author of this thesis and a member of the research team with a background in dentistry) attended a two day training programme and were provided with a training handbook. The training focused on delivering the intervention from the initial assessment through the interventions and guiding patients with the book through to exit strategies and maintaining health post treatment. The training was delivered by a highly experienced, accredited CBT facilitator with previous experience of training practitioners for interventions of this type, including the interventions on which “Managing Chronic Orofacial Pain” was based.

5.7.2.2 Clinical supervision
Clinical supervision was provided for one hour every 2 weeks, or more frequently when considered necessary, by an experienced accredited CBT practitioner. It was provided either over the telephone or face to face according to the preference and convenience of the parties involved.
5.8 Control – Usual care

All participants continued to receive usual care as decided on by their specialist or consultant in secondary care. The control group received usual care without the intervention. Information about the patient’s care and treatment was gathered from the appropriate clinician at the end of the trial. This information is important because it shows any potential treatment overlaps and confounding issues that could possibly affect results. The following Table (10) summarises the treatment pathway commonly followed in each outpatient clinic (information provided by consultants working in relevant clinics);

**Table 10 Usual care for each clinic**

<table>
<thead>
<tr>
<th>Clinic</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMD Clinic</td>
<td>• Explanation and reassurance</td>
</tr>
<tr>
<td></td>
<td>• Limited advice on Stress Management</td>
</tr>
<tr>
<td></td>
<td>• Suggest enrolment on mindfulness course</td>
</tr>
<tr>
<td></td>
<td>• Advice on the use of Warm Compresses</td>
</tr>
<tr>
<td></td>
<td>• Exercise to stretch Lateral Pterygoid</td>
</tr>
<tr>
<td></td>
<td>• Referral for Physiotherapy</td>
</tr>
<tr>
<td></td>
<td>• Occlusal Splint:</td>
</tr>
<tr>
<td></td>
<td>1. Soft Bite Guard</td>
</tr>
<tr>
<td></td>
<td>2. Stabilisation Splint</td>
</tr>
<tr>
<td></td>
<td>3. Localised Occlusal Interference Splint</td>
</tr>
<tr>
<td>Oral Medicine</td>
<td>• Exclusion of a tooth-related cause and a medical cause from other head and neck structures.</td>
</tr>
<tr>
<td></td>
<td>• Follow the care pathway principles outlined in the 2010 NICE clinical guideline 96 – Neuropathic pain. The pharmacological management of neuropathic pain in adults in non-specialist settings.</td>
</tr>
<tr>
<td></td>
<td>• Use of a tricyclic or pregabalin/gabapentin as principle treatments. Of the tricyclics, there is a tendency to prescribe nortriptyline rather than amitriptyline unless the patient has difficulty sleeping.</td>
</tr>
<tr>
<td>Oral surgery</td>
<td>• Course of Tricyclics increasing the dose according to the response and side effects.</td>
</tr>
<tr>
<td></td>
<td>• If this was not satisfactory, go on to use Gabapentin or Pregabalin.</td>
</tr>
<tr>
<td></td>
<td>• Recommend courses of acupuncture or meditation.</td>
</tr>
<tr>
<td></td>
<td>• Occasionally refer patients to the Breathworks course at the Buddhist centre</td>
</tr>
</tbody>
</table>
A placebo group was not used for a number of reasons. Firstly, as argued in previous chapters, it is not clear which components of a complex psychological intervention are effective and which are not. It is therefore difficult to identify a useful and plausible placebo treatment. Secondly, the use of a placebo group in research into psychological therapies may be inappropriate. Practically and methodologically, there are difficulties in developing a covert psychological intervention that would be acceptable to therapists, and be implemented in any meaningful way (O'Leary & Borkovec, 1978).

5.9 Outcomes

The primary outcome was physical functioning as assessed by the SF36 (Version 2). It is an appropriate primary measure because the intervention focused specifically on changing patients’ behaviour and increasing their level of normal functioning. Behavioural outcomes may be the most relevant when assessing health care interventions, particularly those that seek to change behaviour according to psychological models of health (Kaplan, 1990). Patient functioning and quality of life are vitally important constructs in terms of both human value and cost effectiveness due to the impact on patients’ abilities to fulfil their social, family and working roles (Brazier et al., 1992; Jenkinson, Coulter, & Wright, 1993).

A mixture of relevant generic and illness specific measures were used. Garratt (1993) recommends inclusion of the SF36 as part of a portfolio of outcome measures. Facial pain specific disability, pain intensity, anxiety and depression and illness perception were secondary outcome measures. Generic measures of general health, sensitive to a range of illnesses are appropriate to measure outcomes such as day to day functioning, overall well being and mental health and are necessary when patients have more than one condition affecting their overall health (Brazier et al., 1992). Additionally, data taken from generic measures can be compared with similar data from healthy populations or other illness samples (Garratt, Ruta, Abdalla, Buckingham, & Russell, 1993).

However, it is important to also assess illness-specific variables in order to look at clinically relevant issues (Riazi et al., 2003). The extent to which patients are affected can differ considerably within specific diagnoses (Kaplan, 1990). For Chronic
Orofacial Pain patients, pain episodes and symptoms related to orofacial discomfort and functioning, such as difficulties with mouth opening, talking and eating are specific to their condition (Aggarwal, Lunt, Zakrzewska, Macfarlane, & Macfarlane, 2005) and therefore are important to investigate when evaluating an intervention that seeks to specifically treat COFP. Additionally, psychological variables are associated with the onset and maintenance of COFP (Aggarwal & MacFarlane, 2006b). Illness models and related behaviours have been hypothesised as mechanisms involved in the maintenance of all chronic pain and MUS conditions (Flor et al., 2004) and perceptions of pain and illness can affect the way an individual copes with the symptoms of chronic illness (Turk et al., 2002). An examination of multiple outcomes may give an indication of the mechanisms operating within the intervention and allow for an analysis of wider effects.

5.10 Questionnaires

5.10.1 SF36 version 2

The SF36 (Appendix 5) measures constructs relating to overall quality of life. It has been found to be a reliable and valid measure for use with populations aged 18-65 (Brazier et al., 1992; Jenkinson et al., 1993). It is widely used, increasing the appropriateness for inclusion in meta analyses with other studies and has been found to have reliability and validity for both self report and interviewer administration (Bowling, Bond, Jenkinson, & Lamping, 1999). It generates norm-based scores, where each scale is scored to have the same average (50) and the same standard deviation (10), meaning each point equals one-tenth of a standard deviation. A score of 50 therefore delineates normal functioning, with scores below 50 showing abnormal functioning and above 50 indicating an above average outcome. Licensed scoring software was obtained (Quality Metric Incorporated, License number QM008052) that utilised pre-programmed algorithms to calculate scores from raw data.

The SF36 measures 3 main areas comprising 8 dimensions and two summary components (see Table 11).
Table 11 Constructs measured by the SF36

<table>
<thead>
<tr>
<th>Area</th>
<th>Dimension</th>
<th>Number of questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Status</td>
<td>Physical Functioning</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Social functioning</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Role limitations (physical problems)</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Role limitations (emotional problems)</td>
<td>3</td>
</tr>
<tr>
<td>Wellbeing</td>
<td>Mental health</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Vitality</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Pain</td>
<td>2</td>
</tr>
<tr>
<td>Evaluation of health</td>
<td>General health perception</td>
<td>6</td>
</tr>
<tr>
<td>Overall physical component</td>
<td>Combination of questions used to assess physical health status</td>
<td>21</td>
</tr>
<tr>
<td>Overall mental component</td>
<td>Combination of questions used to assess physical health status</td>
<td>15</td>
</tr>
</tbody>
</table>

5.10.2 Manchester orofacial pain disability scale
The Manchester orofacial pain scale (Aggarwal et al., 2005) comprises a patient–rated, 32 item, 3 point Likert type scales (Appendix 6). It has been found to be valid and reliable for use with a UK population. The total disability score is the sum of scores for each item of the scale. The scale measures anatomic, physical and psychosocial disabilities specifically associated with pain in the orofacial region, such as eating, talking and mouth opening. The highest possible score is 64, which indicates the poorest possible outcome on the scale. A score of 32 indicates moderate disability, with 0 indicating the least degree of orofacial pain related disability.

5.10.3 Brief Pain Inventory (BPI)
The Brief pain inventory (Appendix 7) was originally developed as a measure of cancer related pain and has been validated for use with chronic non malignant pain (Tan, Jensen, Thornby, & Shanti, 2004; Keller et al., 2004). It consists of 15 patient–rated visual analogue scales. It measures two dimensions: pain severity and pain
interference. Four questions relating to pain severity are positioned over a period of time: in the past week, on average and at the time of rating. Pain interference is measured by looking at 7 quality of life domains: general activity, mood, walking ability, normal work, relations with other persons, sleep and enjoyment of life. Outcome domains of pain severity and interferences are scored by calculating the mean rating for each domain. Poorer outcomes are indicated on a continuum from the average to the maximum score possible, whereas scores below the mean show above average outcomes.

5.10.4 Hospital Anxiety and Depression Scale (HADS)
The HADS scale (Zigmond & Snaith, 1983) contains 14 item, patient- rated, 4 point Likert type scales (Appendix 8). The anxiety and depressive subscales are valid measures of the severity of emotional disorders. This scale has been validated for use in community and primary care in addition to hospital settings (Snaith & Zigmond, 1986). Unlike other anxiety and depression scales, the HADS does not include physical symptoms. Consequently, it is particularly useful for assessing levels of depression and anxiety in physical conditions. The HADS is interpreted using “cut off” scores: raw scores of between 8 and 10 indicate mild cases, 11-15 identify moderate cases and severe cases score 16 and above (Crawford, Henry, Crombie, & Taylor, 2001).

5.10.5 The revised Illness Perception Questionnaire (IPQr)
The revised illness perception questionnaire, (Moss-Morris et al., 2002) is a valid and reliable measure of cognitive representations of illness, scored using five point Likert type scales (Appendix 9). Seven domains measured by the IPQr will be included: timeline (acute/ chronic), consequences, personal control, treatment control, illness coherence, timeline cyclical and emotional representation. High scores for timeline, consequences, cyclical and emotional representation represent strongly held negative beliefs about chronicity, negative consequences and the cyclical nature of illness. For personal control, treatment control, and coherence, high scores represent positive beliefs about the controllability and understanding of illness. Two additional dimensions (identity and causes) are included in the scale. However these scales have not been included in analysis as they require that the data be categorised, and are not suitable for use with smaller samples.
Table 12 Domains measured by the IPQr included in analysis

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Number of questions</th>
<th>Highest score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timeline (acute/chronic)</td>
<td>6</td>
<td>35</td>
</tr>
<tr>
<td>Consequences</td>
<td>6</td>
<td>35</td>
</tr>
<tr>
<td>Personal control</td>
<td>6</td>
<td>35</td>
</tr>
<tr>
<td>Treatment control</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Illness coherence</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Timeline cyclical</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>Emotional representations</td>
<td>6</td>
<td>35</td>
</tr>
</tbody>
</table>

5.10.6 Piloting
These questionnaires were piloted together for feasibility for use in this study and took an average of 35 minutes to self-complete and around 50 minutes to complete when researcher-administered. A convenience sample of 5 individuals (1 male, 4 female) aged between 11 and 60 years participated in the pilot.

5.10.7 Baseline
Baseline data was collected face to face with participants at their home, Manchester Dental Hospital or on the University of Manchester campus, or in a suitable public venue of their choice (usually a café close to participants’ home or place of work). Demographic data and some information relating to the individual patient’s COFP treatment history, social support and general health were additionally collected at baseline (see Appendix 10).

5.10.8 Follow up
Paper copies of questionnaires were sent out to participants at around 8 to 10 weeks following baseline, giving them the choice of self-completion and return by post in a stamped addressed envelope or over the telephone with a researcher. If the questionnaires were not returned by 10 weeks, a researcher telephoned the participant as a reminder and to offer an appointment to complete the questionnaire over the telephone.
5.10.9 Administration
Participants were given a choice of answering questionnaires through either self completion or via a researcher, both at baseline and follow up. There are benefits and disadvantages to both methods. Although researcher completed measures may suffer from social desirability bias (King & Bruner, 2000) there are advantages of offering the choice of having an interviewer administer questionnaires. (Garratt & Ruta, 1999) recommends that for a portfolio of mixed questionnaires, a generic measure should be administered before disease specific scales to minimise bias from order effects. For the order of completion to be ensured, a researcher needs to control administration of questionnaires. Participants may have literacy issues, disabilities or other barriers to engaging with self-complete materials and returning postal questionnaires (Johnson, Goodman, & Master, 2007). The inclusion of an interviewer-administered method of completion helps to ensure that a wider, more representative population can be included in research.

5.11 Sample
Clinicians sometimes find that an effect size statisticians claim to be small may, in some circumstances be clinically significant and an effect size considered statistically large may similarly be deemed trivial when translated in to practice (Kraemer et. al., 2006). One approach to determining sample sizes in pilot studies is to set effect size levels for power calculations according to a “degree that would imply clinical or practical significance” (Kraemer et. A., 2006, p484).

As well as testing the feasibility of the intervention and study procedures, the trial aimed to detect a potential effect of the intervention, which would have some clinical relevance. As mentioned previously, this exploratory study does not aim to extrapolate results to a general population. For this reason, it has been designed using one-sided significance level of 0.25 instead of the usual two-sided 0.05 (Schoenfeld 1980) so that the study has a reasonable power to detect potential effects within the small sample.

5.11.1 Examining effects in small samples
This study has a small sample, powered to detect some indication of effect rather than aiming to be representative of a population. Due to the size of the sample, a large significant effect is not expected, and if it were found that those in the intervention group did worse, the same action would occur than if no difference were
found: it would be concluded that the intervention did not produce a positive effect. In cases such as this, a one tailed test of significance, where the direction of the effect under investigation (whether the intervention produced improved outcomes for participants) is stated prior to analysis is the most appropriate (Schoenfeld, 1980; Bland & Altman, 1994; Schoenfeld, 1980).

The comparison with an exploratory or pilot study with a conventional, larger scale trial is notable. The aim of a larger trial would be to extrapolate the results to a larger population. Tests of significance in this situation start with the null hypothesis that there is no difference between both the groups in the study, and the population from which the data came. If this hypothesis is not true, then the alternative hypothesis (that there is a difference) is correct. Neither of these hypotheses stipulates the direction of effect (whether the intervention makes participants better or worse) and therefore a two sided test of significance is used (Bland & Altman, 1994). The direction of effect is examined during analysis, rather than being stated a priori as is the case for one sided tests.

5.12 Randomisation

Patients were allocated to either the intervention or control group (treatment as usual) by the trials unit at Christies Hospital. A clinical trials unit was employed independently of the exploratory trial team to undertake the randomisation in order to reduce bias.

5.12.1 Sequence generation
As this is a small, exploratory trial, we cannot assume that participant characteristics across the two groups will be balanced by simple randomisation. Minimisation (Pocock, 1983) was applied to reduce the risk of a particular group containing more patients with characteristics which may influence outcomes.

5.12.2 Minimisation
Minimisation is a largely non-random method of participant assignment, where running totals of participant characteristics in each group are kept. The first participant (or a small number of participants) is randomly allocated to a group at the start of the process. Subsequent enrolment is balanced between groups according to predetermined factors or patient characteristics which may affect outcomes (Altman & Bland, 2005). For the purpose of this study gender, age, clinic, and severity of condition as measured by degree of impaired function were the minimisation factors.
Females and younger adults are significantly more likely to report symptoms of COFP than males and those in their mid 40s and older (Aggarwal, Macfarlane, Farragher, & McBeth, 2010; Aggarwal, McBeth, Lunt, Zakrzewska, & Macfarlane, 2005). The referring clinic was a minimisation factor to ensure that patients with a range of COFP diagnoses were recruited and patient functioning was assessed by the BPI activity interference score, to ensure that groups contained a balanced number of patients with varying degrees of illness severity. BPI interference score was chosen as a measure of baseline functioning for pragmatic reasons; it was quick and simple to score (mean score of 7 items) and did not require any specialised software to compute.

5.12.3 Justification for using non random allocation
A criticism of minimisation is that it does not control for bias on unknown factors (Schulz & Grimes, 2002b), however for smaller studies where participant numbers are too small to eliminate bias through randomisation, minimisation may be a sound, if imperfect, method of balancing groups. The use of managed rather than random allocation is in practice, compatible with standard statistical analysis (Pocock, 1983) and is appropriate for use in this small, exploratory trial. Simple randomisation is recommended for allocation to treatment groups in clinical trials which are statistically powered to generate results that can be considered representative of a sample’s population, and will often achieve well-balanced groups when the numbers of participants are high enough (Scott, McPherson, Ramsay, & Campbell, 2002). However simple randomisation only reduces the chances of imbalance between groups in larger trials of around 200 participants or more and is therefore inappropriate for smaller studies or pilot trials. It is therefore appropriate to use minimisation for a smaller, exploratory trial of the type proposed for this study.

Despite the suitability of minimisation for smaller trials, it may be prudent to take a cautious approach and introduce an element of chance to reduce the (however unlikely) risk of investigators keeping records of past assignments and predicting the next allocation (Pocock, 1983). Consequently, stochastic minimisation (Schoenfeld 1980) was used for this study, which introduces some element of chance when allocating participants to study arms. Probability is weighted in favour of a managed, rather than randomised method of allocation, while allowing for a smaller, pre-defined degree of chance assignment. A weighted probability of 70:30, when minimisation factors have been considered was the ratio of allocation by minimisation to allocation
according to chance in this study. As an additional measure of providence, the first ten participants recruited were allocated using simple randomisation only.

5.13 Allocation concealment

Inadequate blinding and allocation concealment can result in bias, which adversely affects the results of trials, and any subsequent meta-analyses that include them. Trials that do not address allocation concealment tend to exaggerate treatment effects (Schulz & Grimes, 2002a) Biases associated with poor allocation concealment may be greater when an attempts are made to assess patients’ prognosis at the time of recruitment (Wood et al., 2008). Although some clinicians may have attempted to decipher allocation sequences in previous trials, (Schulz et al., 2002a) researchers do not always deliberately introduce bias. Studies are also at risk of unconscious bias, where researchers inadvertently treat participants differently based on their known or expected group allocation (Altman & Schultz 2001).

Allocation occurred following baseline assessment and confirmation of patients’ eligibility. Christie’s Hospital Clinical Trials Unit (CTU) provided the allocation service using stochastic minimisation (Schoenfeld 1980). A researcher telephoned Christie’s CTU and gave details of patient initials, date of birth, gender, referring clinic, and baseline BPI interference score. Participants were subsequently allocated by computer to either intervention or control group and a trial identification number was generated. Wherever possible, researchers carrying out recruitment and deciding eligibility should be blind to the allocation sequence and as separate as possible from those who allocate participants to a group (Altman & Schultz, 2001). As this was a small study administered by one investigator (the author of this thesis) who was also involved in providing treatment to patients, allocation concealment from researchers was not fully possible; however participants were entered into the trial before the treatment allocation was divulged, as recommended by Altman and Schultz (2001).

5.14 Blinding

In a blinded study, steps are taken to prevent researchers and participants becoming aware of key aspects of the study which may, consciously or unconsciously, affect results. This is done to reduce the chance of a number of detrimental effects, such as Hawthorne or placebo effect, observer bias, researcher bias or conscious deception
Biases associated with poor blinding strategies tend to exaggerate estimates of intervention effects and these effects may be greater in trials with subjectively assessed outcomes (Wood et al., 2008).

It was not possible to blind participants and researchers to group allocation due to the nature of the treatment and the multiple roles of researchers working on the study; however steps were taken to reduce the risk of bias during the collection of follow up data. A researcher was employed specifically to collect follow up data and had no other involvement in the study. The group allocation of participants was concealed from this researcher and she had access only to a spreadsheet containing patient contact details and the dates that follow up data were due to be received. However, we were unable to control or determine, whether participants chose to disclose which group they had been allocated to during the course of follow up data collection.

5.15 Statistical Methods

5.15.1 Statistical Analysis
An intention to treat analysis was carried out, subject to the availability of data. Analysis by intention to treat includes all participants who were randomised, regardless of whether they received treatment, withdrew from treatment and/or the study itself or deviated from the study protocol (Newell, 1992). This process is preferred over the exclusion of deviant participants as firstly, it provides more valid results and secondly assessments of treatment efficacy relate more closely to clinical practice (Pocock, 1983). The main assumption of the random allocation process is that groups are similar, apart from random variation (Hollis & Campbell 1999). This assumption also applies to allocation by minimisation. If analysis is not performed on groups that resulted from the original allocation process, this feature could be lost. Additionally, deviations from protocol can occur in normal practice, therefore they should be included in the analysis to provide a more realistic and pragmatic estimate of change in a routine clinical setting (Hollis & Campbell, 1999).

5.15.2 Missing data
There is no consensus about precisely how to handle missing data in intention to treat analyses, and different approaches may suit different situations (Hollis & Campbell 1999). Where there was no data for outcome measures or less than half
the items for an individual domain had been completed, data was classed as missing and the outcome measure or domain was omitted from the final intention to treat analysis. Where more than half of the values were available for a single domain on an outcome measure, pro rating calculation was used. Pro rating (or simple mean imputation) is a method that assumes that data collected for a certain domain has some inherent meaning which relates to the intended outcome; therefore missing values are calculated using the mean scores of items completed for each domain. For example, if an outcome domain consisted of data from five questions and a participant had completed only four, the remaining value would be completed using the mean score of the four completed items. This approach is not appropriate for categorical variables and may dilute associations or regression coefficients. It is however preferable to using “last observation carried forward”, where the last item response is carried forward to replace the missing value. Scoring methods are not always the same for each item response and mean and covariance structure can be seriously distorted (www.missingdata.org.uk).

Analysis of contingency tables examined the pattern of missing data for cases where pro rating was not possible due to missing more than 50% of data for an outcome measure or domain.

5.15.3 Data checks
Data cleaning checks were made as the baseline and follow-up data accumulated blind to allocation group. Further data cleaning analysis was carried out on the final dataset. Data was checked for accuracy by taking four randomly generated participant identification numbers using a randomisation website (www.randomnumber.org.uk) and comparing entered data with completed questionnaires. Once this was complete the group allocation was added to the dataset for the analysis of outcome.

5.15.4 Analysis of measures of central tendency
Statistical analysis of continuous outcome was based on a comparison of the change in scores from baseline to post treatment between the control and intervention groups. Although the study had a repeated measures design, where data was measured at two time points (baseline and post treatment), the analysis was carried out on a single separate independent variable that measured change during these time points (post treatment scores – baseline scores). Consequently, it was appropriate for the statistical analysis to be carried out using procedures suitable for an independent design.
5.16 Ethical Issues: Potential Burdens and risks to participants

The study was given a favourable ethical opinion by the National Research Ethics Committee North West (Preston) on 24 February 2011 (reference 11/H1016/6) and the University of Manchester Committee on the ethics of Research on Human Beings. All participants who were involved in the study received usual routine care, so no conventional treatment was compromised. Participants in the intervention group received a copy of the intervention manual and support and encouragement in implementing the strategies from their facilitator. All changes were patient led and it was the intention of the study to improve the ability of participants to manage their COFP. It was not anticipated that the participants in the research would experience any pain, discomfort or distress from taking part in the study or that the intervention would pose a risk or burden to them. However, to minimise the potential for both, the following steps have been taken:

5.16.1 Burdens

1. All participation was completely voluntary and did not affect the individual patient's usual care and treatment. This was made clear in written and verbal communication. Participants opted to take part in a study in which they were supported in making lifestyle changes in a way which suited them.

2. All participants were free to withdraw from the study at any point without giving a reason.

3. A decision to cease participation at any point during the study did not affect the usual provision of care for the participant and this was made clear at the point of initial recruitment and during the informed consent process.

4. Participants were asked to give up some of their time for the collection of data. To minimise the burden to participants, appointments for baseline data collection were made at a time and location to suit the participant. Participants additionally had the option of completing questionnaires over the telephone for the follow up data collection.

5. Participants who took part in the intervention were offered the choice of face to face or telephone interviews, to minimise their costs and travelling time and these options were also available for those who took part in qualitative interviews.
5.16.2 Risks
6. Participants randomised to the control group were not exposed to a level of risk beyond that which is normally present in their routine care. However, we understood that participants allocated to the usual care group may have felt disappointed, given that psychological interventions are not routinely offered for COFP. To minimise the potential for disappointment, we offered participants in the usual care group a copy of the intervention manual at the end of the study, to go some way to counteract any negative effects of being allocated to the control group.

7. Participants were assessed for suicidal ideation using the PH9 patient health questionnaire at baseline, prior to data collection. If a risk was established, the patient was excluded from the study and their GP and referring practitioner contacted immediately in writing and by telephone. The intervention supervisor was contacted to offer support to the participant and facilitator. The facilitator provided the participant with a 24 hour helpline number and literature giving details of support services.

8. There was some potential for participants who were involved in the intervention to become distressed or upset during the course of their treatment. Arising and ongoing issues were addressed during supervision which took place every two weeks, or more frequently when required. If a risk to the physical or mental health of a participant was suspected, any issues were discussed with a senior mental health practitioner attached to the study and the participant’s GP and referring clinician was identified immediately in writing and by the telephone.

9. Lone worker procedures were devised and implemented to ensure researchers were put at the least amount of risk possible during the course of the study.

Literacy issues
If a patient was identified as having literacy difficulties, the patient information sheet was read aloud by the researcher or clinician. All participants were given the option of having questionnaires administered by a researcher or to self-complete (during the course of the study, it became clear that having a researcher administer the questionnaires had benefits for patients who had difficulty concentrating, in addition to those with literacy difficulties).
5.16.3 Informed consent
Written informed consent was taken by a researcher at the appointment for, but prior to, baseline data collection.

5.17 Results

5.17.1 Recruitment
The flow of participants is displayed in Figure 8 (CONSORT flowchart). 74 individuals were deemed eligible by recruiting consultants and gave consent to be contacted with a view to enrolling in the study. 37 gave full consent and 19 were allocated to the intervention group, 18 to the control arm. In the intervention group, 7 participants were lost to follow up, with 4 withdrawing from treatment: Two participants withdrew from treatment due to ill health, one due to caring responsibilities and one because of work commitments. Only one participant in the control group was lost to follow up.
**Figure 8 Participant flow (CONSORT 2010 Flow Diagram)**

- **Enrolment**
- **Assessed for eligibility (n=74)**
  - Excluded (n=37)
    - Not meeting inclusion criteria (n=2)
    - Declined to participate (n=16)
    - Other reasons (n=17)

- **Randomized (n=37)**
  - Allocated to intervention (n=19)
    - Received allocated intervention (n=15)
    - Did not receive allocated intervention (withdrew) (n=4)
  - Allocated to control (n=18)

- **Follow up**
  - Lost to follow-up (n=7) (Did not complete post treatment questionnaires)
  - Discontinued intervention (n=4) (2 = ill health, 1 = caring responsibilities, 1 = too busy)
  - Lost to follow-up (n=1) (Did not complete post treatment questionnaires)

- **Analysis**
  - Analysed (n=12)
    - Excluded from analysis due to lost to follow up (n=7)
  - Analysed (n=17)
    - Excluded from analysis due to lost to follow up (n=1)
Table 13 Baseline characteristics of control and intervention groups

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=19)</th>
<th>Control (n=18)</th>
<th>Total (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender: Female</td>
<td>18</td>
<td>14</td>
<td>32</td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Age (yr): Mean</td>
<td>52</td>
<td>47</td>
<td>37</td>
</tr>
<tr>
<td>Range</td>
<td>22-73</td>
<td>21-66</td>
<td>21-73</td>
</tr>
<tr>
<td>Ethnic origin:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>15</td>
<td>16</td>
<td>31</td>
</tr>
<tr>
<td>Black British</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>British Asian</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>White other</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>IMD score based on postcode: Mean</td>
<td>25.57</td>
<td>26.32</td>
<td>N=36</td>
</tr>
<tr>
<td>SD</td>
<td>22.79</td>
<td>16.13</td>
<td></td>
</tr>
<tr>
<td>Social support: Mean</td>
<td>8.63</td>
<td>7.89</td>
<td>N=37</td>
</tr>
<tr>
<td>SD</td>
<td>2.11</td>
<td>2.42</td>
<td></td>
</tr>
</tbody>
</table>

*N=36

5.17.2 Characteristics of the sample

Demographic data relating to ethnic origin, indices of multiple deprivation (IMD) and social support was collected to enable an exploration of the characteristics of the sample and balance between groups after allocation (Table 13). Data was assessed using the Index of Multiple Deprivation 2010 (IMD) which is used widely by a variety of organisations to analyse patterns of deprivation. IMD data is calculated using a number of social, economic and housing issues for England and is compiled by the UK Department for Communities and Local Government ([http://www.communities.gov.uk/com](http://www.communities.gov.uk/com)). Geographical localities are divided into 32,482 lower super output areas and data allows each area to be ranked according to relative level of deprivation. IMD score was identified by participants’ postcodes, using an online tool provided by the National Perinatal Epidemiology Unit ([https://www.npeu.ox.ac.uk/birthplace/lcm/imd](https://www.npeu.ox.ac.uk/birthplace/lcm/imd)).
Social support was assessed using 3 questions (“How many people are so close to you that you can count on them if you have serious personal problems?, How much concern do people show in what you are doing?, How easy is it to get practical help from neighbours if you should need it?”). These questions have been shown to have validity (Dalgard, Bjork, & Tambs, 1995) and utility (Lehtinen et al., 2003) for appraising social support.

The control and intervention groups were well balanced for the above demographic variables with no significant differences between the two groups, although there were more males (5) in the control group than the intervention group (1). Males were under-represented in the sample as a whole (ratio of 6.4 females: 1 male) which generally reflects the gender disparity of COFP sufferers in the general population (see Chapter 1). The intervention group was slightly more ethnically diverse and one participant in the intervention group spoke English as a second language.

5.18 Outcomes

5.18.1 Introduction
For the purposes of this thesis, the results will be described in two ways. Firstly, data will be interpreted in the conventional way as if the study had been powered to produce generalised results that can be assumed to be representative of a given population (as would be the case for a randomised control trial). P values from a two tailed test, which does not predict the direction of the test (scores can either improve or decline), will be interpreted using the conventional 0.05 level of significance. The null hypothesis in this case is that there will be no significant difference in outcomes between the intervention and control groups. Secondly, the results will be discussed in the context of this exploratory trial, which has a small sample, powered to detect some indication of effect rather than aiming to be representative of a population. A one tailed test will be used, where the stated direction is that participants in the intervention group will show improvements on outcome measures post treatment. The directional hypothesis for the exploratory interpretation is that those in the intervention group will have improved outcomes post treatment compared to participants in the control group. The rationale for this is provided earlier in this chapter (5.11.1). The reason for describing the results in this dual way is to display an understanding of the conventional way in which results would usually be interpreted for appropriately powered studies, and to compare this with the application of results for this exploratory study.
5.18.2 Distribution of data
The data was plotted on a separate histogram for each outcome measure domain. The histograms revealed that the distribution of scores was not normal (they did not follow a bell-shaped curve pattern). Further exploration of skewness and kurtosis confirmed that data did not meet the assumptions for parametric tests. If the assumption of a normally distributed population is not met, then the rationale for hypothesis testing becomes flawed (Field 2005) and a parametric analysis of mean scores is not appropriate.

5.18.2.1 Non-parametric tests
Non parametric tests make fewer assumptions about the type of data to be analysed. Most non-parametric tests rank data, where higher scores are given higher ranks, and vice versa for lower scores. The analysis is then carried out on the ranks given to the data, rather than the original scores (Field, 2005). For non parametric tests, the median (the score ranked in the middle) is the main measure of central tendency.

5.18.3 Descriptive data
Tables 14-18 show the median, minimum, maximum, mean, standard deviation and number of cases analysed for the control and intervention groups at baseline, post treatment and the change between data collection time points. The Mann Whitney test was used to look at differences between the intervention and control groups for change in the baseline and post treatment scores. The significance value of the Mann Whitney test indicates the probability that the test statistic is a chance result. This is displayed for both the two tailed probability, for which no prediction is made about which group will produce the highest change in scores, and the one tailed probability, where the assumption is that the intervention group will experience a higher, positive change in outcomes.

Baseline scores for cases that have a complete set of post treatment data have also been displayed (baseline with patient data) for comparison with the main intention to treat analysis. This has been included to allow exploration of the results to see if there are any inherent differences in scores for those that did not provide at data post treatment. Although non-parametric analyses have been conducted, the mean and standard deviation is also displayed. This extra descriptive information has been
provided to allow for a full and transparent exploration of the results, in accordance with the aims and objectives of this exploratory study.
Table 14 SF36

<table>
<thead>
<tr>
<th>SF36</th>
<th>Control</th>
<th>Intervention</th>
<th>Mann-Whitney</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
<td>Min</td>
<td>Max</td>
</tr>
<tr>
<td>Physical Functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>95.00</td>
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<tr>
<td>Baseline with pt data</td>
<td>90.00</td>
<td>5.00</td>
<td>100.00</td>
</tr>
<tr>
<td>Post treatment</td>
<td>92.59</td>
<td>10.00</td>
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</tr>
<tr>
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<td>Role Physical</td>
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<td>Baseline</td>
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<td>56.25</td>
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<td>Post treatment</td>
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<td>Change</td>
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<tr>
<td>Bodily Pain</td>
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<td>100.00</td>
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<td>Baseline with pt data</td>
<td>46.00</td>
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<td>100.00</td>
</tr>
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<td>Intervention</td>
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* Higher score indicates an improvement
**Direction for one tailed significance = improvement in outcome
5.19 Primary outcome

5.19.1 Physical functioning (SF35)
Both groups showed high levels (a score between 50 and 100 indicates normal functioning, with scores of 0-49 showing a level of functioning considered to be below normal) of physical functioning both before and after treatment (control group: med = 95, mean = 79.29, intervention group: med = 85.00, mean = 72.73). There was little change in scores between baseline and post treatment for both the control group (med = 0.00, mean = 79.29) and the intervention group (med = -10.00). The Mann Whitney test revealed that this change is not significant at the 0.05 level for the two tailed significance (P=0.33) and there was no evidence to indicate a potential effect at the one tailed significance of 0.83 (p>0.25).

Baseline scores with complete post treatment data (row 2 of each table). Similar scores were shown when only cases with a full set of follow up data were included. For the remainder of this section, these scores will be commented on only if there is an indication that these data are different from those used for the main intention to treat analysis.

5.20 Secondary outcomes

5.20.1 Role physical (SF36)
Both groups produced scores which indicated a good level of functioning (>50) at baseline and post treatment. No median change was shown (0.00 for the control and intervention group) with mean change low (control 6.69, sd 12.14, intervention 0.57, sd 38.57). No significant change was shown by the Mann Whitney test at the two tailed level of significance (p>0.05) and no indication of potential effect was demonstrated at the one tailed level (p>0.25).

5.20.2 Bodily pain (SF36)
Bodily pain scores were lower than average (control: med = 41.00, mean = 47.79, intervention: med = 22.00, mean=33.55), at baseline for the control and intervention groups, suggesting that pain interfered with patients functioning. Changes for both groups were small (control group: med = 5.00, mean = 6.64, intervention group: med = 10.00, mean = 6.18. No significant change was shown by the Mann Whitney test at the two tailed level of significance (p>0.05) and no indication of potential effect has been demonstrated at the one tailed level (p>0.25).
5.20.3 General health (SF36)
Scores were higher for the control group (med = 72.00, mean = 61.22, sd 32.31) than for the intervention group (med = 52.00, mean = 49.18, sd 19.62) at baseline. For the control group, scores for general health decreased from baseline to post treatment, (med change = -6.50), with no median change (0.00) for the intervention group. No significant difference was shown for the Mann Whitney two tailed test of significance (p>0.05). However, some indication of a positive effect is shown by the one tailed directional test of significance (p<0.25).

5.20.4 Vitality (SF36)
Both groups showed below average scores at baseline (control; med= 40.62, mean = 43.75, sd 28.90, intervention; med= 43.75, mean= 39.77 sd 20.59). At post treatment the median score for the intervention group increased to 50.00, however the mean score remained just below normal (although showing an increase) at 45.45. No significant difference was shown for change scores at the two tailed test of significance (p>0.05). However, some indication of a potential effect favouring the intervention group was shown by the one tailed directional test of significance (p<0.25).

5.20.5 Social functioning (SF36)
The control group scores were higher at baseline (med = 62.50, mean = 65.18 sd 32.21) than the intervention group scores (med = 50.00, mean 54.55 sd 36.77). Median change was 0.00 for both groups, with no significant change shown for the Mann Whitney test at the two tailed level of significance (p>0.05) and no indication of potential effect was demonstrated (p>0.25) at the one tailed level.

5.20.6 Role emotional (SF36)
Baseline scores were higher in the intervention group (med = 83.33, mean 73.81 sd 31.49) than for the control group (med = 58.33, mean=61.36 sd 33.80). Mean change at post treatment was 0.00 for both groups. The Mann Whitney test showed no significance at the two tailed level (p>0.05) and no indication of potential effect has been demonstrated at the one tailed level of significance (p>0.25).

5.20.7 Mental Health (SF36)
Baseline scores were similar for both groups. For the control group, med = 62.50, mean = 62.86 and the intervention group showed med = 55.00, mean 51.82. Median change for both groups was 0.00, with no significant change shown for the Mann Whitney test at the two tailed level of significance (p>0.05) and no indication of potential effect was demonstrated at the one tailed level (p>0.25).
5.20.8 Physical component (SF36)
Baseline data was similar for both groups, with little change shown at post treatment (med = 0.41, mean = 1.04 for the control group, med= -1.72, mean = 4.02). The Mann Whitney test showed no significant difference between groups at the two tailed level of significance (p>0.05) and no indication of potential effect was demonstrated at the one tailed level (p>0.25).

5.20.9 Mental component (SF36)
Scores for both groups were slightly below normal at baseline with the control group showing slightly higher scores (Med=46.64, mean 41.) than the intervention group (med = 37.18, mean = 36.73). A negative change was shown for the control group over time (med = -2.77, mean = 4.02) and a slight improvement was shown for the intervention group (med = -1.33, mean = -0.49). The Mann Whitney two tailed test showed no significance between groups (p>0.05). However, some indication of a potential effect favouring the intervention group is shown by the one tailed directional test of significance (p<0.25).
Table 15 Manchester Orofacial pain disability scale

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<th>Mann Whitney</th>
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*Lower score indicates improvement
**Direction for one tailed significance = improvement in outcome
5.20.10 Manchester Orofacial pain disability scale

Scores were similar at baseline for both groups. There was a slight improvement (lower scores) in the control group scores at post treatment (median change = -1.00, mean change = -0.71 sd 8.03) compared to the intervention group (median change = 1.00, mean change = 0.91 sd 4.81), however the Mann Whitney test showed no significant difference between groups (p>0.05) for the two tailed score and no indication of a potential effect for the one tailed test (p>0.25).
Table 16 Brief Pain inventory

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*Lower score indicates improvement

**Direction for one tailed significance = improvement in outcome
5.20.11 Pain severity (Brief pain inventory)
Scores were slightly higher for the control group (med = 5.62, mean = 5.19) than for the intervention group (med = 3.50, mean = 4.64) at baseline, which means that the intervention group overall reported less pain than the control group. At post treatment, small positive changes were shown over time (med = -0.75, mean = -0.82 sd 2.57 for control group, med = -0.32, mean = -0.39 sd 1.64 for intervention group). The changes were not significant however; the Mann Whitney test showed no significant difference between groups (p>0.05) for the two tailed score and no indication of a potential effect for the one tailed test (p>0.25).

5.20.12 Activity Interference (Brief Pain inventory)
Scores were similar for both groups at baseline. Very small positive median changes were shown for both groups, (control: med = -0.57, mean = 0.63 intervention: med = -0.12, mean = 0.45). No significant differences were detected by the Mann Whitney test for the two tailed test (p>0.05) and there was no indication of a potential effect for the one tailed test (p>0.25).
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*Identity, timeline, consequences & cyclical dimensions: High scores represent strongly held beliefs about chronicity, negative consequences, negative emotional representations & cyclical nature. Low score = improvement
Personal control, treatment control & coherence: High scores represent positive beliefs about controllability and understanding of illness. High score = improvement
**Direction for one tailed significance = improvement in outcome
5.20.13 Timeline (IPQr)
Median scores were similar at baseline (Control group: median = 23.00, mean = 22.57, intervention: med=19.00, mean = 20.18) and small change scores over time were revealed (control: med = -1.00, mean = 0.57, intervention: med = 0.09, mean = 4.09). The Mann Whitney test showed no significant difference between groups (p>0.05) for the two tailed score and no indication of a potential effect for the one tailed test (p>0.25).

5.20.14 Consequences (IPQr)
Scores were slightly lower at baseline for the control group (med = 17.50, mean = 17.71) than the intervention group (med = 19.00, mean = 19.82) indicating that the intervention group’s views regarding the consequences of their illness were more negative. At post treatment, scores had decreased (indicating an improvement) in the control group (change scores: med = -1.00, mean = -1.71) but had increased slightly (indicating a further negative change) in the intervention group (change scores: med = 0.09, mean = 0.09). However, the Mann Whitney test revealed no significant difference between groups (p>0.05) for the two tailed score, and there was no indication of a potential positive effect for the one tailed test (p>0.25).

5.20.15 Personal control (IPQr)
At baseline both scores showed very similar levels of personal control (intervention group: med = 16.00, mean = 16.45, control: med – 16.00, mean = 16.43). Both groups showed some improvement in post treatment scores, with a slightly higher change for the intervention group (med = 3.00) than the control group (med = 1.00). The Mann Whitney test showed no significant difference between groups (p>0.05) for the two tailed score, however some indication of a potential positive effect was shown for the one tailed directional test for improvement (p<0.25).

5.20.16 Treatment control (IPQr)
Scores for treatment control were very similar at baseline for both groups (intervention: med = 16.00, mean= 166.09, control: med =16.50, mean = 15.86). The control group showed a small negative change (Med = -1.00) and a positive change for the intervention group (med = 2.00). The Mann Whitney test showed no significant difference between groups (p>0.05) for the two tailed score, however some indication of a potential effect was shown for the one tailed directional test for improvement (p<0.25).
5.20.17 Illness coherence. (IPQr)
Illness coherence was slightly higher in the intervention group at baseline (med = 11.50, mean = 12.00 than the control group (med = 10.00, mean = 12.43). There was a slight improvement for intervention group scores (med = -1.00) compared with control group scores (med = 2.00), however the difference was not significant (p>0.05) for the two tailed score, and the Mann Whitney tests did not provide an indication of a potential positive effect for the one tailed test (p>0.25).

5.20.18 Timeline cyclical (IPQr)
Intervention group scores were slightly higher (high scores indicate strongly held beliefs about the cyclical nature of illness) at baseline (med = 14.00, mean = 14.0 sd 3.16). ) compared to the control group (med = 11.50, mean = 12.00 sd 3.70). There was a very slight improvement for the intervention group which was shown in the change scores (med = -1.00, mean = 0.03) compared to the control group in which scores changed very little over time (med = 0.00, mean = 0.79). No significant difference is shown for the Mann Whitney two tailed test of significance (p>0.05) and no indication of potential effect was found for the one tailed directional test (p>0.25).

5.20.19 Emotional representation (IPQr)
At baseline, the intervention group scores higher (med = 21.00, mean = 21.27, sd 3.74) than the control group (med = 18.00, mean = 18.00, sd 6.88). This indicates that the intervention group experienced more negative emotions regarding illness at baseline. A slight improvement was shown for the intervention group (med = -2.00) and the control group (med = -0.50). These differences were not however shown to be significant by the Mann Whitney two tailed test (p>0.05) and no indication of a potential positive effect was provided for the one tailed test (p>0.25).
Table 18 HADS

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*Lower score indicates improvement
**Direction for one tailed significance = improvement in outcome
5.20.20 Anxiety subscale (HADS)
Those in the control group, overall appeared to be suffering from mild anxiety (med = 7.50, mean 7.71, sd 4.83) compared to the intervention group who showed mild to moderate levels of anxiety (med = 10.00, mean = 11.18, sd 5.08) at baseline. At post treatment, there was a positive change (med -1.00, mean = 1.91) for the intervention group compared to a negligible change in the control group (med = 0.00, mean = 0.14). A Mann Whitney two tailed test did not reveal a significant change (p>0.05) in anxiety, however an indication of potential effect was found for the one tailed test (p<0.25).

5.20.21 Depression subscale (HADS)
There was a very small difference in scores for both the control (med = -0.05, mean = 6.00) and intervention groups (med= 5.00, mean = 6.00 ) at baseline. There was little difference shown by change scores for both groups (control: med = -0.50, mean = -0.36, intervention: med = 0.00, mean = -0.36) . The Mann Whitney two tailed test did not show a significant change (p>0.05) for depression and no indication of a potential effect was found for the one tailed test (p<0.25).
5.21 Missing data

It is important to acknowledge and deal with gaps in the data. Participants allocated to a treatment group should be analysed together (Newell, 1992) and a complete data set will provide more accurate results. Pro rating calculations were used to estimate missing values where more than half the values for each outcome or domain were present (described earlier in this chapter). However, some participants provided no post treatment data at all, for reasons that are unknown. An investigation of the characteristics of those who did not provide any follow up data may be useful for future trials involving COFP patients. For example, extra support could be provided in a targeted way in order to encourage questionnaires to be returned.

Eight participants did not complete outcome measures post treatment. Seven of these were in the intervention group, with only one participant in the control group not providing post treatment data. Characteristics (age group, gender, physical functioning at baseline and allocation) of those that did not provide post treatment data were investigated using Fisher’s exact test, which is a test of statistical significance used to examine the association between categorical data in the analysis of contingency tables. No significant associations were found between any of the participant characteristics and having missing data at post treatment. Although more participants in the intervention group did not complete post treatment outcome measures, no significant association was present.

5.22 Discussion

This discussion focuses specifically on the findings of this quantitative piece of work and will be expanded in Chapter 7, which addresses the implications for the study as a whole in more detail.

5.22.1 Effectiveness
As discussed in previous chapters, this was a small, exploratory trial that did not aim to look for a precise estimate of effect. Therefore, as expected, no significant results were found at the conventionally used 0.05 level.

5.22.2 Primary outcome
No indication of a potential effect was found for the primary outcome which was physical functioning as assessed by the SF36. Participants in the control and
intervention groups showed above normal levels of functioning both at baseline and post treatment.

5.22.3 Secondary outcomes
For the SF36, no indication of a potential effect was found for role physical, bodily pain, social functioning, role emotional, mental health or overall physical component. Some indication of a potential effect was however found for general health, vitality and overall mental component. The Manchester orofacial pain disability scale and the brief pain inventory also produced no evidence of a potential effect. Evidence of a potential effect was shown for the HADs anxiety subscale and the IPQr personal and treatment control dimensions.

5.22.4 Overall direction of scores
The Mann Whitney tests of significance determined which outcome domains produced some evidence of a potential positive effect at the one tailed 0.25 level of significance. However, this is an exploratory trial in which significance levels are less important than in larger, sample size defined RCTs (Arain et al., 2010). It may therefore be interesting to examine the overall direction of effects found by each outcome domain, regardless of significance. One way of doing this is by a comparison of standard mean differences. The standardised mean difference is calculated by dividing the mean by the standard deviation, and is used for comparing the effect size between any two groups where the data is continuous (www.cochrane.net.org). Data from each outcome were entered into “Review Manager”, software used by the Cochrane collaboration. The output from this software is used most commonly in meta analyses to compare the means between two treatment groups for a number of studies. In this case, it facilitated comparisons between the outcome measures to see whether change scores favoured the control or intervention groups. Data are displayed in a table and in a forest plot (Figure 9).
### Figure 9: Comparison of standard mean difference to show the direction of scores for outcome measures

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Std. Mean Difference</th>
<th>Std. Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean  SD</td>
<td>Mean  SD</td>
<td>IV, Fixed, 95% CI</td>
<td>IV, Fixed, 95% CI</td>
</tr>
<tr>
<td>a. Physical function</td>
<td>-5  22.5</td>
<td>-9.63  15.48</td>
<td>0.23 [-0.50, 0.95]</td>
<td></td>
</tr>
<tr>
<td>b. Role physical</td>
<td>6.69  12.13</td>
<td>0.57  38.57</td>
<td>0.22 [-0.50, 0.95]</td>
<td></td>
</tr>
<tr>
<td>c. Bodily Pain</td>
<td>6.64  24.27</td>
<td>6.18  19.3</td>
<td>0.02 [-0.70, 0.74]</td>
<td></td>
</tr>
<tr>
<td>d. General Health</td>
<td>-4.14 10.83</td>
<td>2.73  13.51</td>
<td>-0.55 [-1.29, 0.18]</td>
<td></td>
</tr>
<tr>
<td>e. Vitality</td>
<td>1.34  12.05</td>
<td>5.68  15.68</td>
<td>-0.31 [-1.03, 0.42]</td>
<td></td>
</tr>
<tr>
<td>f. Social Functioning</td>
<td>0.89  23.75</td>
<td>-7.95  28.65</td>
<td>0.33 [-0.40, 1.06]</td>
<td></td>
</tr>
<tr>
<td>g. Role emotional</td>
<td>0.6  18.62</td>
<td>6.82  28.09</td>
<td>-0.26 [-0.99, 0.46]</td>
<td></td>
</tr>
<tr>
<td>h. Mental Health</td>
<td>-2.14 12.51</td>
<td>8.18  14.71</td>
<td>-0.74 [-1.49, 0.01]</td>
<td></td>
</tr>
<tr>
<td>i. Physical component</td>
<td>1.04  5.31</td>
<td>2.07  8.04</td>
<td>-0.15 [-0.87, 0.57]</td>
<td></td>
</tr>
<tr>
<td>j. Mental component</td>
<td>-0.49  6.92</td>
<td>4.02  10.1</td>
<td>-0.52 [-1.26, 0.22]</td>
<td></td>
</tr>
<tr>
<td>k. Manchester OFP scale</td>
<td>0.91  4.81</td>
<td>0.71  7.5</td>
<td>0.03 [-0.69, 0.75]</td>
<td></td>
</tr>
<tr>
<td>l. BPI Pain severity</td>
<td>-0.39  1.64</td>
<td>-0.82  2.09</td>
<td>0.22 [-0.51, 0.94]</td>
<td></td>
</tr>
<tr>
<td>m. BPI interference</td>
<td>0.45  2.36</td>
<td>-0.63  1.3</td>
<td>0.57 [-0.16, 1.31]</td>
<td></td>
</tr>
<tr>
<td>n. IPQr Timeline</td>
<td>0.27  4.98</td>
<td>-0.36  4.47</td>
<td>0.13 [-0.59, 0.85]</td>
<td></td>
</tr>
<tr>
<td>o. IPQr Consequences</td>
<td>0.09  2.91</td>
<td>-1.71  2.64</td>
<td>0.63 [-0.11, 1.38]</td>
<td></td>
</tr>
<tr>
<td>p. IPQr Personal control</td>
<td>0.57  5.88</td>
<td>4.09  3.27</td>
<td>-0.69 [-1.44, 0.05]</td>
<td></td>
</tr>
<tr>
<td>q. IPQr Treatment Control</td>
<td>-1.36  4.31</td>
<td>1  3.07</td>
<td>-0.60 [-1.34, 0.14]</td>
<td></td>
</tr>
<tr>
<td>r. Illness coherence</td>
<td>0  4.74</td>
<td>2  4.57</td>
<td>-0.42 [-1.15, 0.31]</td>
<td></td>
</tr>
<tr>
<td>s. IPQr Timeline cyclical</td>
<td>0.03  2.83</td>
<td>-0.79  3.83</td>
<td>0.23 [-0.49, 0.96]</td>
<td></td>
</tr>
<tr>
<td>t. IPQr Emotional rep</td>
<td>-1.55  3.98</td>
<td>-0.29  4.97</td>
<td>-0.27 [-0.99, 0.46]</td>
<td></td>
</tr>
<tr>
<td>u. Anxiety</td>
<td>-1.91  3.05</td>
<td>0.14  2.35</td>
<td>-0.75 [-1.50, 0.00]</td>
<td></td>
</tr>
<tr>
<td>v. Depression</td>
<td>-0.36  4.06</td>
<td>-0.36  2.82</td>
<td>0.00 [-0.72, 0.72]</td>
<td></td>
</tr>
</tbody>
</table>

---

Favours experimental Favours control
The forest plot displayed in Figure 9 shows the direction of mean differences for each outcome measure or domain. The small boxes in the centre of each line on the plot depicts the standard mean difference for each outcome level, and the “whiskers” running either side of the boxes indicate the length of the confidence intervals. The line running down the centre of the plot indicates no effect. The boxes and whiskers situated to the left of this line represent cases where the outcome favours the intervention group, those to the right of the line show cases of outcomes favouring the control group. Eleven outcomes favour the intervention group, 9 favour the control group and two studies show no effect.

The forest plot shows that overall, outcome measures slightly favour the intervention compared to usual treatment. It is difficult to interpret outcome measure results in small, exploratory studies (Arain et al., 2010) therefore no definitive conclusions can be drawn by a comparison of standard mean differences. However, this exercise provides a useful summary of the overall findings of the study.

5.22.5 Baseline characteristics
It was notable that the results indicated that participants had good levels of physical, social and emotional functioning and low levels of pain and ill health at baseline for many outcome domains, for a number of reasons. The outcome measures had been selected carefully for use, based on the findings of previous research (particularly epidemiological studies) involving COFP patients (see Chapter 1). The generic questionnaires (SF36, BPI, IPQr and HADS) have been widely used in health services research and demonstrated validity and reliability for use with a number of primary and secondary care populations (see page 73). The Manchester OFP disability scale was developed especially for use with a clinical COFP population based on specific epidemiological research and had also been found to have reliability and validity (Aggarwal et al., 2005). Furthermore, consultants working at the study’s referring clinics had informally indicated that COFP patients in secondary care generally tend to present with low levels of physical and social functioning and high levels of both mental and physical ill health.

The primary outcome (physical functioning as assessed by the SF36) produced scores that represented above normal (>50) levels of functioning both at baseline and post treatment. Similar high levels of functioning were indicated by the SF36 for role physical, role emotional and mental health. Contrastingly, dimensions that showed some indication of potential effect on the SF36 (general health, vitality and
overall mental component) were amongst those that yielded scores that indicated participants were functioning at below normal levels at baseline (others were bodily pain and overall physical component). The Manchester orofacial pain scale and the brief pain inventory subscales showed low levels of disability, pain severity and pain interference at both time points respectively. The HADS scale indicated that participants were not depressed at both time points. However the intervention group showed moderate anxiety at baseline, which became mild at post treatment.

The IPQr does not use cut off points to interpret scores. High scores denote a more chronic and cyclical timeline, greater perceived negative consequences, greater perceived personal control and belief in treatment, and a sense of having a less coherent understanding. Zero is the lowest score possible, and Table 12 (page 80) indicated the highest score possible for each of the dimensions. This can be used as a guide for constituting what represents a comparatively high or low score.

Participants tended to score higher at baseline and post treatment in both groups for negative beliefs relating to timeline, consequences, timeline cyclical and emotional representation and score lower for positive beliefs relating to control, and coherence.

5.22.6 Baseline scores and direction of effect for outcome domains

The low impact at baseline shown for many outcome domains may have implications for the validity of the selected outcome measures within this study’s sample. Validity is the degree to which an instrument measures what it aims to measure and it is important that an outcome has relevance to the population being tested (Kirshner & Guyatt, 1985). A visual examination of the overall direction of scores indicated that outcome domains that favour the control group overall tended to have low impact on both treatment groups at baseline. In order to explore this finding further, Table 19 was created to provide an overall summary of the direction of scores combined with levels of good or poor performance at baseline on specific outcome domains.

Rudimentary good or poor levels of performance were determined based on the mean and median scores for both groups displayed in Tables 14-18, using cut off points where appropriate. Where cut off points were not specified, scores that were higher than the median possible score for each outcome measure determined high scores and those lower than the median were classified as lower scores.
Table 19 Overall performances at baseline and direction of SMD scores

* Some evidence of potential effect found at 0.25 one tailed level of significance

<table>
<thead>
<tr>
<th>Baseline score</th>
<th>Favours intervention</th>
<th>No effect</th>
<th>Favours control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication of good baseline</td>
<td>General Health</td>
<td>Depression</td>
<td>Physical</td>
</tr>
<tr>
<td>performance</td>
<td>Role emotional</td>
<td></td>
<td>functioning</td>
</tr>
<tr>
<td></td>
<td>Mental Health</td>
<td></td>
<td>Role physical</td>
</tr>
<tr>
<td></td>
<td>*Treatment control</td>
<td></td>
<td>Social functioning</td>
</tr>
<tr>
<td></td>
<td>Illness control</td>
<td></td>
<td>Manchester</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OFP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>BPI severity</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>BPI interference</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Consequences</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Timeline</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>cyclical</td>
</tr>
<tr>
<td>Indication of poor baseline</td>
<td>Vitality</td>
<td>Bodily</td>
<td>Timeline</td>
</tr>
<tr>
<td>performance</td>
<td>Physical component</td>
<td>pain</td>
<td>(chronicity)</td>
</tr>
<tr>
<td></td>
<td>*Mental component</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Personal control</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Emotional</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>representation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Anxiety</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The majority (eight out of 9) of domains that favoured the control group showed good levels of performance at baseline. Out of the domains that favoured the intervention group, five revealed a good level of baseline performance and six showed indications of poor levels of functioning at baseline. Out of the 6 domains that showed some evidence of potential effect at the 0.25 level of significance, four favoured the intervention and two implied poor performance at baseline. The two outcome measures that produced no direction of effect were split equally between displaying good and poor indications of performance. There is therefore an indication that those outcomes that do not negatively impact on participants at baseline do not produce a positive effect that favours the intervention. Domains that favour the intervention
show more varied distribution between good and poor performance at baseline, however more domains that provided some indication of potential effect at the 0.25 level indicated poor baseline performance (4) compared to showing good baseline performance (2). This exercise therefore indicates that outcomes show a slight overall trend towards favouring the intervention when baseline performance is poorer.

5.22.7 Missing data
Missing data can reduce the power of a study to produce realistic effect sizes and can result in biased data (Hutton & Williamson 2000). A total of 8 complete sets of data were lost to follow up. A visual comparison of median and mean scores at baseline for both complete data sets, and those included in the intention to treat analysis revealed small differences which should not have significantly affected any final results. No significant associations were found between participants’ characteristics (age group, gender, primary outcome at baseline and allocation) and not providing follow up data. Possibly more resources could be allocated to obtaining follow up data in any future studies trials to try to alleviate this potential problem.

5.22.8 Strengths of the study
Recruitment was successful and attrition was low. The intervention could be feasibly implemented within a secondary care sample. The modelling phase was completed thoroughly, using up to date evidence and drawing on current MRC guidance. The results are presented in a thorough and transparent manner, and an intention to treat analysis was carried out. Patterns of missing data were investigated and reported in full. The components and content of the intervention were reported thoroughly and the study should be easily replicable.

5.22.9 Limitations of the study
We do not know the reasons why patients did not give consent to contact following the initial introduction to the study by their consultant, or why many individuals ultimately did not provide full consent to participate. Consequently, participants who agreed to take part in the study may have been self-selecting or not representative of people suffering from COFP generally. During post treatment data collection, participants may have disclosed which group they had been allocated to during telephone conversations with a researcher, introducing bias to the data. Some participants chose to complete post treatment
outcome measures themselves, whilst others chose to have a researcher administer the questionnaire. The way post treatment measures were administered may have affected the way participants responded, however a subgroup analysis was not possible due to the small sample size.

It was not possible to include longer term follow–up data, due to constraints in time and resources. Consequently this study was unable to report on the sustainability of or changes in potential effects over time.

5.23 Summary
The quantitative study did not produce evidence of potential effects for the primary outcome measure or dimensions that measured physical or social functioning or pain. It did however show potential to positively affect general health, vitality (energy and a sense of wellbeing), mental health, anxiety and control. The overall direction of scores favoured the intervention group. Baseline scores indicated that participants were performing well on many outcomes prior to treatment. The implications of these findings will be discussed in more detail in Chapter 7.
5.24 Feasibility and intervention processes

5.24.1 Feasibility
One purpose of conducting an exploratory trial is to collect information relating to the feasibility of delivering the intervention and acceptability to patients and other stakeholders (Campbell et al. 2000). Key factors to consider when assessing feasibility are recruitment and attrition (Craig et al., 2008). Within the context of “Managing COFP” it is important to ensure that specialist clinicians in secondary care are able to appropriately diagnose and refer patients to the new intervention so that there will be sufficient numbers to ensure an appropriate trial sample. Furthermore, clinicians need to feel comfortable with the possibility that their patients may be allocated to the control group, which places demands on individuals without the incentive of possible benefit from the intervention.

5.24.2 Recruitment activity
38 participants (19 in each group) needed to be recruited to ensure that the study had sufficient power to estimate effect sizes. This was almost realised, with 37 participants ultimately taking part (n=19 intervention group, n=18 control group). The graph below (Figure 10) shows the pattern of recruitment from April 2011 to January 2012. Recruitment fell short of monthly targets and took slightly longer than predicted. Originally, the aim was to recruit 7 participants during April and May 2011, with a further 6 participants per month the target for June through to October. A reduction in referrals was experienced in August (likely due to participants and clinicians taking holidays) which meant that there was a drop in recruitment which continued through to October. Consequently the recruitment period was extended through to January 2012.
Figure 10 Number of participants recruited per month from April 2011 to January 2012

A total of 74 patients gave consent to contact at their consultation at one of the recruiting clinics. 37 participants gave full consent to take part in the exploratory trial. This represents a 50% yield or one in every two patients showing an initial interest in entering the study and ultimately providing full consent to participate. Out of the remaining 37, those who could be contacted and chose not to participate in the study often volunteered explanations for declining and these were recorded. A content analysis of reasons for non participation was carried out and a summary of the results are displayed below (Table 20).
Table 20 Content analysis of reasons for not participating in the exploratory trial

<table>
<thead>
<tr>
<th>Reason for non participation</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unable to contact</td>
<td>1</td>
</tr>
<tr>
<td>Too busy to commit</td>
<td>4</td>
</tr>
<tr>
<td>Pending and on going medical investigations/ surgery</td>
<td>2</td>
</tr>
<tr>
<td>Ineligible for intervention</td>
<td>2</td>
</tr>
<tr>
<td>Withdrew consent</td>
<td>1</td>
</tr>
<tr>
<td>Managing COFP adequately; feels no further intervention needed</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
<tr>
<td>No reason given</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>37</strong></td>
</tr>
</tbody>
</table>

Just over half (19 from a total of 37) of those who expressed an interest in participating at the referral stage could not be contacted further. Commonly in these cases, phone calls went unanswered and voicemail message were not returned rather than numbers being unobtainable. A cut off point of 5 attempts at contacting an individual was set due to time constraints. Four potential participants said busy lifestyles and other commitments (for example, hospital visits for other conditions and work) took up all their time and that they could not find time for another commitment. A small number (2) declined to participate on the grounds that they were awaiting the results of related medical investigations or treatment such as tooth extraction. Two patients were ineligible for the intervention and excluded, due to having an identifiable pathology to account for their complaint (osteoarthritis in the jaw). Three participants felt that their COFP was adequately managed or relatively unproblematic, and thus had little motivation for trying an alternative treatment and a further 3 gave no reason for declining to participate. Other explanations (7th row) included a young person citing her mother as not wanting her to be involved in the exploratory trial, concerns the intervention may interfere with religious observance and an imminent move to another country. Consent was withdrawn in one instance prior to randomisation taking place, as a participant wished to avoid disclosure of involvement in the study to a GP.

37 participants were recruited over a 10 month period (one fewer than the target sample) using clinicians to screen for appropriate patients. Recruitment was
successful, despite monthly recruitment numbers being initially lower than predicted. Suitable participants can therefore be appropriately identified by specialist clinicians and recruited from secondary care outpatient clinics to a trial for a guided self help intervention based on CBT principles to treat COFP.

5.24.3 Attrition in the intervention group

High attrition can result in lower than expected effect sizes, however if detected during the pilot stage, factors affecting attrition can be investigated and study design amended accordingly (Craig et al., 2008). A total of four participants did not complete treatment. Only two participants in the intervention group left the study completely, (ceased treatment and involvement in any further data collection); one prior to receiving any intervention sessions and one following the first session. Reasons cited for withdrawal were illness in the family and receiving a diagnosis of a serious health problem, respectively. Two further participants withdrew from the intervention but chose to remain part of the study, completing follow up data and interviews. This enabled continued gathering of follow up data (important for an intention to treat analysis) and also completion of interviews (see Chapter 6).

5.25 Intervention processes

5.25.1 Implementation

Monitoring and assessment of treatment fidelity is important in large clinical trials as it helps to increase confidence in the treatment effects and improve internal and external validity of findings (Borrelli, 2011). However, as this work formed part of a smaller exploratory trial that contributed to modelling the intervention, the broader issue of how treatment could be implemented in practice was of more interest than the extent to which facilitators adhered to a pre defined protocol. Treatment was guided by a manual, however dosage was not pre determined and a patient-centred approach was taken in order to investigate acceptable levels of treatment intensity. Although clinical notes were kept by facilitators, monitoring of treatment implementation could have been more rigorous if sessions had been recorded and assessed by a third party.

Data relating to the number and length of sessions and mode of delivery was recorded and the results are displayed below.
19 participants were allocated to the intervention group. Based on the model used by the MUSCIAN study (McBeth et al., 2012) it was decided that the intervention sessions should last between 30 - 45 minutes (see Chapter 5) and that a minimum of four sessions would need to be completed for a participant to have complete treatment (three sessions or fewer were considered non - completion). The total number of sessions received by each participant was determined by patient preference and clinical judgement, however a maximum of eight sessions was imposed. Two participants dropped out of the intervention prior to receiving any treatment and two participants withdrew after the first session. In line with the patient – centred approach of the intervention, participants were given a choice of either face to face or telephone delivered sessions (or a combination of both). The following Table (21) describes implementation in practice.

### Table 21 Implementation of treatment sessions

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean number of sessions per participant</td>
<td>5.06 (SD 1.95)</td>
</tr>
<tr>
<td>Mean contact time per participant</td>
<td>4 hours (241.06 minutes) (SD 1.82)</td>
</tr>
<tr>
<td>Mean number of minutes delivered per session</td>
<td>44.56 (SD 7.08)</td>
</tr>
<tr>
<td>Total number of telephone- delivered sessions</td>
<td>48</td>
</tr>
<tr>
<td>Total number of face to face sessions</td>
<td>54</td>
</tr>
</tbody>
</table>

A total of 102 sessions were delivered to 19 participants by both facilitator (facilitators treated 9 and 10 participants respectively). The mean number of sessions received per participant was 5. Mean contact time per participant was around 4 hours (241 minutes), with each session lasting an average of 43 minutes. This shows compliance with the a priori decisions made regarding dosage and is concurrent with the protocol used for telephone delivered CBT based treatment for the MUSCIAN study (McBeth et al., 2012). Similar numbers of sessions were delivered both by telephone (48) and face to face (54) indicating no overall preference for method of delivery. The mean number of sessions received per participant is around 5. Table 22 shows this data in more detail.
Table 22 Number of intervention sessions completed

<table>
<thead>
<tr>
<th>Number of sessions</th>
<th>Number of participants (N=19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td>5</td>
</tr>
</tbody>
</table>

Four participants did not complete treatment, attending fewer than three sessions, however the majority of participants (N=15) successfully completed treatment. The highest number of participants (5) completed the maximum number of 8 sessions.

5.25.2 Participants’ treatment priorities

Participants receiving the intervention were asked to set goals relating to their priorities (essentially, what “getting better” means to them). The mean number of goals set per participant was 2.23. Table 23 shows the types of goals set by participants. Individuals are asked to set very specific goals during treatment so for ease of analysis data has been categorised into more general groups. This data is useful for investigating the priorities COFP patients have regarding changes they wish to make and the ways their lives are affected by their illness.

Table 23 Participants’ goal setting

<table>
<thead>
<tr>
<th>Goal type</th>
<th>Number of goals set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase exercise</td>
<td>10</td>
</tr>
<tr>
<td>Improve social contact</td>
<td>5</td>
</tr>
<tr>
<td>Lifestyle changes (e.g. sleep hygiene, cooking meals)</td>
<td>9</td>
</tr>
<tr>
<td>Changes in daily routine</td>
<td>5</td>
</tr>
<tr>
<td>Reduce medication</td>
<td>2</td>
</tr>
<tr>
<td>Personal improvement (education)</td>
<td>1</td>
</tr>
<tr>
<td>Habit reversal</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
</tbody>
</table>

Priorities for the majority of the participants centred on increasing exercise and lifestyle changes such as improving the amount of sleep they had and cooking meals from scratch. Improving social contact was also a priority, possibly due to
idiosyncratic difficulties associated with the mouth and jaw such as eating and talking. Changes in daily routine focused on scheduling time for relaxation or pleasurable activities and one participant wanted to introduce a regular time for showering and getting dressed. Habit reversal goals again were concerned with reductions in behaviours idiosyncratic to COFP, such as jaw clenching and teeth grinding. Other priorities (bottom row) encompassed non–routine activities including buying a hair care item, tidy a specific area of the house, to go out for a drive in the car when feeling ill and to apply for a new job. Only participants who had a supervisor with a clinical background set goals regarding reduction in medication, which has implications for future training of facilitators.

5.25.3 Discussion
In practice, the intervention can be feasibly delivered and implemented as intended (based on McBeth et al., 2012) within a sample of secondary care patients. Attrition was low, with only four participants failing to complete treatment. A majority of participants (5) completed the maximum eight sessions, with a mean number of 5 sessions delivered per participant. Similar numbers of sessions were delivered using both face to face and telephone and these lasted for an average of 43 minutes. Therefore no changes to the implementation protocol should be made.

Participant’s priorities focused on increasing exercise and lifestyle changes. A primary outcome of physical functioning appears to be appropriate and congruent with the priorities of participants. Goals included reduction of medication which has implications for participants’ usual care. Training of facilitators without clinical backgrounds should incorporate seeking advice from consultants, or instructing participants to liaise with the appropriate doctors or dentists who prescribed the medication.

Although feasibility has been established, there is a need to research issues relating to acceptability of “Managing COFP” to participants. Key areas to investigate include the ability of COFP patients to engage with the intervention, perceived benefits or harm resulting from treatment and associated underlying mechanisms.
Chapter 6 Acceptability: Qualitative Study

6.1 Introduction

This chapter describes the methods, design and analysis of the qualitative element of for this mixed methods study (see Chapter 3). The results and implications of this study are also discussed.

Qualitative interviews were conducted to explore acceptability of the new complex intervention (“Managing chronic orofacial pain”) and to assess the potential for the intervention to bring about change. Assessment of participant acceptability is both scientifically useful and allows service users to be integrated into research (Paley & Shapiro, 2002). The importance of integrating consumers in health services research is widely recognised and has potential benefits for policy making, research, practice, improved implementation, better care and better health (Nilsen, Tinderhold, Johansen, Oliver, & Oxman, 2006). Furthermore, patient participation is desirable within a wider professional and philosophical context as it can promote transparency, accountability and a sense of participative democracy (World Health Organisation 1978, cited by Nilsen et al., 2006).

When developing and evaluating complex interventions, it is necessary to establish some degree of acceptability to those who may benefit from it (Craig et al., 2008; Campbell et al., 2000). Patients will only be able to experience the potential benefits of any treatment if they are able to engage with its components (see Chapter 2 for expansion on this topic) therefore any potential barriers to acceptability should be highlighted as soon as possible. Findings from this piece of work are additionally important both for creating a deeper understanding of how “Managing COFP” might help participants and to inform modification and improvements to the intervention. Individual qualitative interviews were chosen in order to gain an in depth view of participants’ experiences in a confidential setting. Group interviews were not considered as the research sought to examine the views of individuals rather than observe interactions between participants in a group setting.
6.2 Sampling

The qualitative study was nested within the exploratory trial. Chapter 5 provides a detailed account of recruitment and allocation methods, including identifying potential participants, how they were allocated into study groups and a description of the sample as a whole. The original intention was to use purposive sampling for this study (Coyne, 1997), in order to gain the views of participants from varying backgrounds. Purposive sampling aims to reflect variation within a specific group of participants rather than seek to extrapolate results to a general population (Barbour, 2001). However, during the early stages of the study a decision was made to interview as many participants from the intervention group as possible, soon after treatment ended. This decision was based on pragmatic reasons following a lull in recruitment and a wish to minimise the amount of time elapsed between completing treatment and participating in the interview.

6.3 Participants

Participants had been previously allocated to the intervention group (see Chapter 5). They had either completed the intervention (taken part in 3 sessions or more) or dropped out (had fewer than 3 sessions). A total of 14 participants took part in the interviews. Two participants had dropped out of the study (and requested no further contact) at the time the interviews were conducted and a further three could not be contacted. Table 24 describes the characteristics of participants by sex, age, number of intervention sessions received and mode of delivery (phone or face to face). This table has been included in order to describe the sample and also to provide clarification and context for participants quoted in the results section (below).
Table 24 Characteristics of qualitative study participants

<table>
<thead>
<tr>
<th>Participant number</th>
<th>Sex: f/m</th>
<th>Age</th>
<th>No. of sessions</th>
<th>Mode of delivery (Phone/ face to face)</th>
<th>Background of facilitator</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>f</td>
<td>64</td>
<td>7</td>
<td>Phone &amp; face to face</td>
<td>Psychology</td>
</tr>
<tr>
<td>*3</td>
<td>f</td>
<td>72</td>
<td>1</td>
<td>Face to face</td>
<td>Dentistry</td>
</tr>
<tr>
<td>4</td>
<td>f</td>
<td>49</td>
<td>8</td>
<td>Phone &amp; face to face</td>
<td>Psychology</td>
</tr>
<tr>
<td>5</td>
<td>f</td>
<td>32</td>
<td>7</td>
<td>Phone</td>
<td>Dentistry</td>
</tr>
<tr>
<td>6</td>
<td>m</td>
<td>34</td>
<td>5</td>
<td>Face to face</td>
<td>Dentistry</td>
</tr>
<tr>
<td>7</td>
<td>f</td>
<td>36</td>
<td>8</td>
<td>Face to face</td>
<td>Psychology</td>
</tr>
<tr>
<td>8</td>
<td>f</td>
<td>49</td>
<td>8</td>
<td>Phone</td>
<td>Psychology</td>
</tr>
<tr>
<td>9</td>
<td>f</td>
<td>66</td>
<td>4</td>
<td>Phone</td>
<td>Dentistry</td>
</tr>
<tr>
<td>*10</td>
<td>f</td>
<td>54</td>
<td>0</td>
<td>N/A</td>
<td>Psychology</td>
</tr>
<tr>
<td>11</td>
<td>f</td>
<td>65</td>
<td>8</td>
<td>Phone</td>
<td>Psychology</td>
</tr>
<tr>
<td>12</td>
<td>f</td>
<td>47</td>
<td>8</td>
<td>Phone &amp; face to face</td>
<td>Psychology</td>
</tr>
<tr>
<td>13</td>
<td>f</td>
<td>64</td>
<td>5</td>
<td>Face to face</td>
<td>Dentistry</td>
</tr>
<tr>
<td>14</td>
<td>f</td>
<td>50</td>
<td>5</td>
<td>Phone</td>
<td>Dentistry</td>
</tr>
<tr>
<td>19</td>
<td>f</td>
<td>21</td>
<td>4</td>
<td>Face to face</td>
<td>Dentistry</td>
</tr>
</tbody>
</table>

*Participants 3 and 10 did not complete the intervention. Data from these interviews were included in the analysis as a whole; however during the process of coding and categorising data, researchers were mindful that they represented potentially deviant cases (see ‘Validity’ below).

The mean age of interviewees was 50, with 71% (10 out of 14) participants aged >40. The majority of the participants (13 out of 14 or 92.9 %) were female. There was no preference for mode of delivery for this group of participants: three participants chose a combination of phone and face to face sessions, 5 interviewees chose phone only and 5 preferred face to face delivery exclusively.

6.4 Interviews

Interviews were semi structured with interviewers (researchers) using topic guides as prompts, (Appendix 11) but allowing for exploration of participant generated issues in a bottom – up approach to data generation. Topics for discussion were identified through reviewing relevant literature, issues arising from the evidence synthesis exercise (Chapter 4) and discussion with the supervisory team. Subjects of particular interest were explored further as they arose during the interviews, in addition open ended questions were used to encourage participants to elaborate on relevant topics.
Topics covered in the guide included:

- Background prior to involvement in the study
- Content of the intervention
- The facilitator
- The intervention manual
- General comments and suggestions for improvement

Interviews took place over the telephone or face to face on the University of Manchester campus and lasted approximately 35 minutes (range = 11.45 - 47.5 minutes). They were audio recorded and transcribed verbatim as soon as possible after the interview had taken place. Two participants requested to be interviewed in their own homes, and one participant requested an interview in a coffee shop near to her place of work.

A conversational style was used throughout the interviews order to place the participant at ease and elicit a richer response; however in practice this may not have been successful for every interview. The interviewers were a female postgraduate student with a background in psychology (the author) and a male academic dentist. The participants came from a variety of backgrounds. It should be noted that interviewers and interviewees may have not shared the same assumptions and perspectives relating to issues such as class, status, education and culture. This has implications for establishing a setting in which participants are able to comfortably articulate their experiences. The notion of a friendly conversation implies an established relationship with some form of reciprocity (Grbich, 1999) so time was spent at the start of the interview explaining the purpose of the interview and trying to build a friendly rapport in an attempt to minimise these potential factors.

6.4.1 Interviewer considerations
A further issue concerning the interviewer/ interviewee relationship is that the interviewers also had responsibility for delivering the intervention and had been involved in the design of the intervention and the inception and implementation of the study as a whole. It is likely that a number of participants were aware of this as interviewers (in particular the author) were involved in recruitment and obtaining informed consent. Grbich (1999) states that an assumption underpinning the interview process in qualitative data collection is that a response to a question will represent the participant’s views and knowledge on an issue, and a “truth” relevant to
their understanding will emerge. Although researchers did not interview participants they had previously treated, implications for possible effects on ability to capture a “truth” during these interviews exist. The expression of private views may have been inhibited or experiences may have been reconstructed to favour responses participants think the researcher is seeking (Myers & Newman, 2007). Taking these issues into account, participants were reminded at the start of each interview that the interviews were confidential and transcripts would be anonymous, and similar details were provided on the participant information sheet (Appendix 12).

The analysis was carried out by the author of this thesis and checked with a member of the supervisory team. When the initial thematic structure had been developed, it was periodically checked with the wider research team. Participant identifiers for transcripts were changed from those used in other areas of participant data management, in an attempt to introduce anonymity during analysis. In practice, this endeavour had limited success, as the interviewers were able to identify interviewees from the transcripts. All transcripts were read by at least two members of the research team, including one member of the supervisory team, who was blind to case histories.

### 6.5 Analysis

The data was interrogated using two approaches. Firstly, qualitative description was used to categorise data according to a priori defined topics. Secondly, a more in depth thematic analysis was carried out in order to explore the data for relevant and emerging themes and subthemes.

#### 6.5.1 Qualitative description

Qualitative description (Sandelowski, 2000; Sandelowski, 2010) is an appropriate method to be used when a comprehensive summary of pre defined undertakings is needed. Data is not deliberated further than its surface meaning and the endeavour is to describe and categorise rather than interpret and find meaning. This method is widely used in health services research, particularly nursing (Sullivan-Bolyai, Bova, & Harper, 2005) and offers a pragmatic approach to organising data. Data was scrutinised in a deductive way, with a view to being organised into a pre-defined schema. This schema was derived from gaps in evidence highlighted by a previous evidence synthesis exercise (see Table 8, Chapter 4) related to delivery of the
intervention. Participants' views were required in relation to the number and duration of sessions received, mode of delivery and setting of the intervention and the facilitators (what they should be called and the importance of their professional background).

6.5.2 Thematic Analysis
Thematic analysis (Braun & Clarke, 2006) was used to identify emerging issues and themes from the data using an inductive approach. This is a flexible way of analysing qualitative data that can be used to answer a number of research questions across a range of theoretical approaches. It aims to develop an understanding of the data, rather than just knowing and describing the data. A theme is therefore more than just a descriptive code. Braun and Clarke (2006 p82) define a theme as something which “captures something important about the data in relation to the research question, and represents some level of patterned response or meaning within the data set”. Themes may be manifest (obvious or superficial) or latent (hidden and concealed).

6.5.3 Selecting a method for analysis
Qualitative description and thematic analysis were considered appropriate for investigating acceptability and processes of a complex intervention in the context of this study for the above reasons. Alternative methods considered were framework analysis, interpretive phenomenological analysis, discourse analysis and grounded theory. These will now be discussed in turn, in order to justify their rejection and the use of the selected methods.

Framework analysis
Framework analysis would be an appropriate method for analysis within this study, as it allows the merging of a deductive and inductive approach, including a priori objectives, with themes grounded in the data (Pope, Ziebland, & Mays, 2000). Framework analysis is often used for applied policy research, where results are to be used to address specific objectives. Although some a priori objectives were set, it was decided to keep this descriptive aspect of the investigation separate from a more in depth, explorative approach. As little is currently known about the experiences of participants taking part or how the intervention might be positioned within conventional treatment, the methods selected may be of more value to the explorative endeavour of modelling a new complex intervention.
Discourse analysis

Discourse analysis, phenomenology and grounded theory were readily discounted. Discourse analysis requires interrogating the way language is used and the way individual’s use language and storytelling to construct meaning (Starks & Brown Trinidad, 2007). While this approach could well have produced some interesting accounts, an examination of content that has a general resonance amongst participants is of more use to an exploratory trial than individual accounts and the ways in which they were articulated.

Interpretative phenomenological analysis

Phenomenology contributes to an understanding of specific experiences by exposing presumptions surrounding individuals’ ways of knowing. A common essence or core structure of a specific experience is consequently exposed (Starks and Brown Trinidad 2007). This approach is incongruent with the objectives of this particular piece of research, which is to explore wider issues concerned with many issues concerning acceptability of “Managing COFP”, rather than an identified specific phenomenon.

Grounded theory

Grounded theory attempts to understand meaning derived from social interaction (Starks et al., 2007). The process of analysing data is similar to that of thematic analysis in that it involves an inductive method of constant comparison in order to examine relevant themes. The ultimate aims of the two methods do however differ. The intention of grounded theory is to produce an exploratory theory of social processes, grounded in the context in which the data is collected (Glaser & Strauss, 1967). Although the thematic analysis carried out for this piece of work does examine possible processes of change related to the intervention, focusing entirely on the development of an over arching theory would have narrowed the scope of the analysis. The aim was to look at a wider range of issues related to acceptability of a new complex intervention.

6.6 Process of analysis

Categories and memos were coded into a series of documents that were continually refined and elaborated. Three members of the PhD supervisory team, two of whom had not been involved in delivering treatment to participants, interrogated the transcripts as the analysis developed to check for reliability. It was important to have individuals who had not been involved in intervention delivery included in the
analytical process to ensure that developing themes were grounded in the data, rather than inferred from previous experiences. Discussion between the researcher and supervisory team focused the analysis and helped to move it beyond a description of the data to generate a developing account of recurring patterns in the data. Themes were verified and modified, returning to the data when necessary in a process of constant comparison.

6.7 Reliability

Reliability in the context of qualitative research is the extent to which the process of analysis was carried out in a consistent and valid way (Mays & Pope, 1995). Different observers should be able to draw similar conclusions about the assignment of data to categories or themes. Independent assessment of transcripts by three other experienced researchers (members of the supervisory team) helped to ensure reliability. Analysis was subject to discussion and dissent and concurrence were explored, in order to seek agreement and generate a reliable account of participants’ experience.

6.8 Validity

Validity within qualitative research relates to the content of the analysis and the extent to which the researcher explains the phenomena under investigation in a way that would be plausible and credible to participants and other observers (Mays et al., 1995). Reporting of qualitative research can often appear to rely on a series of anecdotes rather than representing a thorough analytical approach (Silverman, 2000; Sandelowski, 2010). Qualitative research assumes that the researcher cannot attempt to operate in a purely objective way (Bowling, 1997). Data analysis and reporting will inevitably be filtered through the researcher’s perspective and will involve an interpretative element. However, a number of methods can be used that may ensure that the finished report contains a valid account of the phenomena under investigation in the sense that it can be seen as plausible and credible, and clearly evidenced by the data.
6.8.1 Constant comparison
Use of the constant comparative method (Glaser, 1964) can help to ensure that an analysis is consistent and based on the data. Coding and analysing data is carried out continuously, with the researcher returning to texts to compare incidents for each theme. Categories were collapsed and widened as new data emerged, rather than beginning with a rigid set of themes and selecting data that fits.

6.8.2 Examination of deviant cases
Mays and Pope (1995; 2006) state that there is a danger in assuming that participants have a general “common sense” consensus and that capturing this is therefore the essence of validity. This type of assumption should be balanced with some other evidence of an account, as groups of individuals are likely to have differing perspectives (Mays et al., 1995). Consequently any negative or deviant cases which did not fit the researcher’s explanations of the data or contradicted an overriding argument were examined and acknowledged. Any findings of this nature will be discussed later in this chapter.

6.8.3 Triangulation
Triangulation describes a method by which evidence is sought from a wide range of sources to support an assertion or argument (Silverman, 2000; Mays et al., 1995). Evidence used can result from various approaches, methodologies and paradigms. Conclusions drawn from this analysis were compared with existing theory and evidence from relevant studies, to identify patterns of concurrence or contradiction. This should help to ensure that any arguments are plausible and appear well supported.

6.8.4 Reflexivity
Reflexivity involves acknowledging how the researcher and the process of conducting research influences data collection and analysis. Attention should be drawn to researcher reactions to participants and their responses (Mauthner & Doucet, 2003). The effects of personal characteristics (for example, gender, professional status, age) and personal and professional biases should be made explicit. Researchers should attempt to be aware of the extent to which it is possible to maintain a professional distance when interpreting and analysing data (Mays & Pope, 2000). A diary of thoughts and observations made was kept throughout the study and regular meetings with other research team members provided an opportunity to be reflexive about the interviews and analysis.
Examination of deviant cases and triangulation will be presented in the discussion section towards the end of this chapter. A reflexive account appears after the findings below.

6.9 Findings

This section of the chapter is divided into two main parts. Firstly, descriptive data relating to participants’ views on the delivery of “Managing COFP” are presented. This was guided by the priori themes included in the topic guide, based on questions arising from the evidence synthesis (Table 8, Chapter 4). The second section presents results from the thematic analysis, which is more in depth and represents an iterative approach, where themes grounded in the data are identified. This part is organised around two main themes;

- Views on engagement with the intervention
- An exploration of change processes.

Descriptions of findings are presented under subheadings, and illustrated with quotes from participants. The relevant participant identifier and transcript line number are provided in brackets at the end of quotes.

6.9.1 Views on delivery of “Managing COFP”

6.9.1.1 Contact time

Issues regarding the duration and number of sessions to be delivered for “Managing COFP” were discussed with the supervisory team. It was decided that a minimum of three and maximum of eight sessions would be used as a guideline, based on findings from the MUSICIAN trial (McBeth et al., 2012), which produced beneficial outcomes for participants (see Chapter 4). A strict regimen was not imposed however, and a patient-centred approach was adopted. Ultimately, decisions regarding contact time were made based on consultation with participants and clinical judgement, supported by supervisory sessions. This flexibility permitted exploration of the amount of contact time deemed appropriate and acceptable to participants.

Participants received between four and eight (mean = 5) sessions and expressed overall satisfaction with the number of sessions they received. It should be noted that although initially some participants were a little reticent regarding the prospect of
committing to up to 8 weeks of treatment, they were ultimately happy with the number of sessions received;

Well at first I thought it was going to be too much really. But then I realised that you do actually start digging a bit deeper and different things come out in each session, so I was quite happy to have the 6 in the end. They lasted about half an hour to 45 minutes, which is long enough, I think. (p14 254-270)

The intervention protocol suggested that the first session should last 45 minutes, allowing 30 minutes for subsequent sessions. In practice, facilitators were flexible with the amount of time taken in the sessions, again, being receptive to the needs of participants. Unequivocally, participants were satisfied with the length of their sessions (average of 43 minutes per session).

The length of time was fine, sometimes I didn’t realise the time has passed. The number of sessions, I think it was 5, was fine for me. (P13 l38-39)

6.9.1.2 Mode of delivery and setting (telephone and face to face)
Participants were offered face to face or telephone sessions. Face to face sessions took place in a quiet room on the University of Manchester campus, which proved to be an acceptable setting. One participant requested sessions in her home and another in a city centre café. These meetings were accommodated as they were practical in terms of facilitator travelling and convenience. When travel and accessibility was not problematic, participants tended to prefer face to face sessions. Reasons for this were largely concerned with wanting visual contact with facilitators in order to gain feedback from body language and a perception that face to face sessions would facilitate a better relationship. A small number of participants also valued the fact that face to face sessions could provide motivation to leave their house to make the appointment, and afforded a change of environment.

I think I was, you know a bit more relaxed in a change of scenery, you know, take me out of my comfort zone”. (P05 399-402, sessions took place at the University of Manchester)

However, where telephone sessions were more convenient for participants and improved access to the intervention, no barriers to effective delivery were reported. For example, this participant had initially expressed a preference for face to face
sessions, but as time went on she had found the necessary journey wearing and switched to telephone sessions:

*The telephone was alright, the face-to face was … sometimes it was a bit of a drag coming all the way from Stockport on the bus to there (p12 206-208)*

### 6.9.1.3 Facilitators

Participants were positive regarding facilitators. Facilitators had worked to establish a rapport with participants and typically, they were described as “nice”, “easy to talk to”, “good listeners” and individuals felt able to engage with them. Facilitators were perceived as knowledgeable and their feedback was seen as credible. However it is important to bear in mind that many participants were aware of the interviewer’s involvement in the study and professional contact with their facilitator (see *Interviews* above).

Participants had been informed during their first session of the professional background of their facilitator, and that they had been specially trained in delivering the intervention. It was important to participants that facilitators had a good degree of knowledge about COFP. The background or profession of the facilitator seemed less important to participants than a perception of plausible information coming from a knowledgeable individual.

*Of course you need someone who knows what they are talking about to tell you that. (p9 114-115)*

The individuals delivering “Managing Chronic Orofacial Pain” were referred to as ‘facilitators’. During the interviews, participants were asked for their views on the title “facilitators” to describe those delivering “Managing Chronic Orofacial Pain” and if they felt it adequately described the role. This issue had been identified during the evidence synthesis exercise (Chapter 4) and was deemed important for the acceptability of a new practitioner. For example, participants involved in a study for a guided self help intervention for depression had drawn an analogy with their therapists and a personal trainer and this finding was subsequently incorporated into the intervention (Lovell et al., 2008). Results were however inconclusive; participants had inconsistent opinions regarding the use of the term. Some participants felt that “facilitator” was acceptable;
I think ‘facilitators’ is a good name because they are not actually telling you what to do they are more helping you decide what you think is best for yourself (p 19 381-383)

However, a small number of participants did not understand the term or felt it unnecessarily abstract:

Yeah what does it mean that word, “facilitators”? (p5 412)

Participants did struggle in attempts to suggest a more concise or appropriate way to describe the role;

I don’t know what you’d call them? Not really no. erm no I can’t. Not, like, ‘mediator’? No, that is a bit thingy isn’t it? (p5 421-426)

‘Counsellors’ was suggested as an alternative to ‘facilitators’. Some participants felt that a substantial amount of time was taken talking through problems and issues they faced and that participation in the intervention was similar to either an experience or perception of counselling. However a participant with experience of counselling felt that this description was incongruent with the support she had experienced;

A support role that rather than a counselling … it’s kind of not one sided, I don’t know how to explain it really, this is much more practical. (p27 360-364)

6.10 Engagement with and processes of “Managing Chronic Orofacial Pain”.

Two primary themes emerged from the data relating to engagement with “Managing COFP” and mechanistic processes of change following engagement with the intervention. These were further categorised into secondary themes which are positioned within the two discourses of engagement and processes. Themes relating to features and barriers to engagement included identification with the intervention, feeling believed and understood, obtaining a plausible explanation and effort required. Acceptance of having a chronic condition and receiving demonstrative positive feedback were associated with both primary themes. Additional processes associated with change were related to identifying unhelpful patterns, control and distraction. It should be noted that the themes presented are not mutually exclusive. There are overlaps, where themes can act as engaging feature, but sometimes
become present during the course of treatment. For further clarification, the organisation of the analysis is shown below in Figure 11.
Figure 11 Themes arising from qualitative data

- **Primary themes**
  - Identification with “managing COFP”
  - Feeling believed and understood
  - Obtaining a plausible explanation
  - Effort required
  - Acceptance of chronic condition
  - Receiving demonstrative positive feedback
  - Identifying unhelpful patterns
  - Control
  - Distraction

- **Secondary themes**
6.10.1 Identification with “Managing Chronic Orofacial Pain (COFP)”

Identification with “Managing Chronic Orofacial Pain” refers to the extent to which participants identified with the treatment model underpinning the intervention and other COFP patients. These were important factors influencing engagement with the intervention initially, at the referral stage and for sustaining engagement.

6.10.1.1 Identifying with the treatment model.

The intervention was described on the participant information sheet as “guided self help using a talking therapy”. Recruiting consultants had been given a short presentation on the intervention prior to this study commencing and as a consequence, would often describe the intervention as based on Cognitive Behavioural Therapy (CBT) principles during the recruitment process. Additionally, facilitators would explain the CBT model of treatment in relation to Managing COFP in the first session. The extent to which participants identified with both their prior ideas of what these descriptions meant, and their subsequent experience of taking part impacted on their ability to engage. Some patients felt at the referral stage that the intervention was not appropriate for them, particularly when they could not reconcile their impressions of the intervention and its treatment model with their own condition and symptoms.

_Erm, well I didn't really know anything about Cognitive Behaviour therapy and I didn’t really think that just sitting around talking about it would help really...I suppose I'd read a bit about it, it's here and there about Cognitive Behaviour Therapy and I don’t know, I think I just formed an opinion that is what happened and nothing much else happened, you just chatted and that was it (p14 29-43)_

However, this barrier to engagement at the referral stage could be overcome for a number of reasons. Some participants had been visiting the same hospital for a number of years, sometimes having more than one regular consultant, and had built up relationships with practitioners. If the patient trusted in or felt an obligation to, the referring institution they may consent to become participants in the study despite feeling sceptical of the intervention model. They also expressed altruistic feelings towards organisations that had helped them in the past.

_Well I will be absolutely honest with you, I didn’t think it was for me, because I’ve heard of CBT for people with depression … but I didn't want people to think that I was being offered help and not take it and I will be honest, that’s the only reason that_
I thought well, “If I’m also helping somebody else with the study”. You know, the dental hospital have tried to do a lot for me over the years (p04 15-28)

A positive view of CBT and talking therapies could facilitate engagement even if there was some scepticism about the appropriateness of the treatment model for COFP in particular. Participants could see some potential value in the intervention if they had received affirmative reports of similar treatment in other contexts. The following quote is from a participant who is studying psychology had an understanding of the varied applications of CBT based treatment:

I know that it is an effective technique with like, lots of different disorders but I wasn’t too sure what it could do for my jaw because when I first started I felt it was nothing I could do to prevent my pain (p19 172-175)

Some participants had been receiving standard mechanistic and pharmacological treatment from the same institution for a number of years. Consequently, the offer of a psychological based treatment could be unexpected. Therefore, an elaboration of the participant information sheet, providing detailed clarification of what the intervention involved was sometimes required before participants felt able to give full consent and engage in the intervention:

I don’t know what I was expecting; I mean Dental Hospital to me means going to have your teeth out (p02 40-42)

When participants were feeling benefits resulting from a traditional treatment, the “managing COFP” model of treatment could seem unnecessary. There appeared to be few benefits to investing in understanding and engaging with an alternative treatment model, when the current regimen seemed beneficial.

I can’t see therapy would actually help that tooth. Yes, I mean wearing the splint seems to have helped the actual jaw area and the face, so really what are we trying to achieve? (p03 254-26)

Some participants had other conditions that were physically more debilitating than their COFP, and symptoms of co-morbid illnesses often seemed overwhelming. Consequently, the management of these problems were prioritised. This could mean
that they were disinclined to engage with a treatment that they felt specifically related
to COFP symptoms.

*My life is ruled by my back, definitely, my life is ruled completely as to what we do …
What I am saying is, I have this whiplash in my neck since last November, these are
problems that are overriding even though the toothache is there, they are overriding
the toothache, do you understand that?* (p03-31-45 dropped out after 1 session)

6.10.1.2 Identification with “people like me”
Participants highly valued stories relating to others’ experience of COFP. They often
had not heard of people with similar symptoms prior to their involvement in this
intervention. This could cause participants to feel isolated and anxious about their
symptoms, which were perceived to be uncommon and peculiar to them. It could be
reassuring and comforting to know that other people suffered from the same
condition.

*I thought I was isolated and it was only me and I couldn’t understand why I was going
through this and thought, “it could have been just I was ill”, whatever, a multitude of
things. But then I realised it’s a condition that is not widely recognised, but there are
people who have it”* (p8-54-57)

An interest and enthusiasm for finding out about people with the same condition
could influence initial consent to become a participant. In many cases, discovering
that there were other people with COFP was fundamentally important.

*I was just interested to find out …. About other people who had the same jaw
problem as me because up until then I didn’t know other people could you know, sort
of have it* (p02-26-29)

Case studies allowed information about COFP to be presented in a way which was
often novel to participants. Background, symptoms, impact and techniques to
improve symptoms were presented in the narratives, which appears to offer an
engaging way of delivering material. Identification with the stories seemed to offer
countenance to participants, facilitating an environment in which they felt able to talk
about their condition.
I thought the book was very good, you know reading peoples’ cases studies, case histories … because you do feel, especially my problem, you do feel freaky and I know that if I go and research it on the internet there is a lot of people with my problem …, but I have never actually read someone’s case history like in the book, …sometimes because you feel that’s all you ever talk about (p04 412 -424)

Ability to relate to others with COFP through reading the case studies and vignettes was a feature in sustaining engagement during the first stages of the intervention, through registering similarities between participants’ symptoms and those of other patients.

… I found it really, really interesting because I was reading it and I was reading all the you know all the tips, and then as I said the different stories of the 3 people I could relate to, you know, their behaviours and the problems they had, I could actually relate so some of what, you know, what all three said (p12 258-261)

However, participants could find the stories disengaging if their experiences of COFP were dissimilar or less debilitating than those depicted. A sense that the intervention is inappropriate for people with a background that is different to the stories’ protagonists was reported; participants therefore felt no motivation to engage with the techniques.

I don’t even get headaches or anything. You know its not causing any you know, any sort of undue effect on my life whatsoever and therefore having to sort of work on all these goals and everything is just too much pressure (p10 107-110)

It was noted that even if some participants did not relate to the characters in the manual, they could value the opportunity to read about different experiences of COFP and could often identify with some, if not all of the experiences presented;

Well a lot of them are far worse than I’ve ever been. But things like the negative thoughts and that, and being able to deal with those and sorting their lives out a bit and being able to prove that is it. I think the stories in the book are based on real people, and it’s interesting to see how it relates to other people. (p14 397- 405)
Identifying with others with COFP may be sufficiently important as to warrant the incorporation of a group session into the intervention which may act as a supportive space for patients and a forum in which they could exchange information.

*I think maybe, perhaps do a group session or something because it's quite good to meet other people with the same sort of problems and maybe discuss amongst yourselves, you know with a professional there. ..I think, it's just reassurance, you know, that there is people like you and I think you know, you could pass on things that have worked for you, and you know, and they'd pass on things to you* (p14 428-440).

6.10.2 Feeling believed and understood

Participants had often experienced repeated investigations and consultations in unsuccessful quests to find an underlying cause for their condition. As a result, some participants felt they were seen as disingenuous or prone to psychological problems. Consequently, participants felt stigmatised and that they were not believed by others (clinicians, family members, friends and acquaintances) when they talked about their COFP. Feeling believed and understood was important for participants to feel comfortable talking about their symptoms and to be able to engage with the intervention.

*I'd seen all the medical at the doctors, consultants and everything ... I think it was just talking to someone who won't judge you. You know that type of thing. It just seems like .. I don't know how to describe it really ... to be able to tell somebody what was going on and not them saying “it's in your head” which I have been told before. (p05 160 – 174)*

After feeling that their symptoms may have been met with some scepticism from others, participants were often relieved the find that they were believed and their symptoms were understood within the context of the intervention. This could be their primary reason for engaging with the study.

*I just wanted someone to tell me it wasn't all in my mind and do something for me* (p09 156)
It was important to participants that their families and friends believed that COFP symptoms were legitimate. The existence of a specific intervention for COFP and the managing COFP manual could act as evidence that participants were suffering from a condition that the medical profession took seriously:

*I gave to read this to my husband for example, he sees that I am not the only one so it is this problem for other people as well, so it is an illness, some sort of illness* (p7 71-72)

Participants reported avoiding those close to them when their symptoms flared up for fear of being negatively judged. A consequence of this was that they had limited opportunities in every day life to allow an understanding or empathic exchange to take place in which they could feel believed.

*You do feel that because it dominated your life that you don’t want to talk about it sometimes because you feel that’s all you ever talk about. And I do feel that, what does my family think? … You know I don’t want people to think I’m a whinger because I’m not really* (p4 371-382)

Sessions within the intervention offered an opportunity to establish a relationship where an understanding of how participants are affected by COFP can take place. This could contrast with participants’ accounts of experiences during previous consultations. Participants saw the facilitator as somewhat removed from the situation personally and this helped to assist the progress of developing an accepting environment.

*For me, because I have got these negative thoughts, just having someone who doesn’t have to solve your problems, just having someone to listen just helps, I think anyway. Yeah, just that [facilitator] believes me, is a lot of the time, you know, because it is such an abstract thing talking about pain, you know some people tend to brush you aside I think, not that I think they mean to but I think that.* (p14 320-331)

Being understood and believed by someone seen as knowledgeable about COFP, can act as an endorsement that participant’s symptoms are legitimate. The fact that facilitators have already encountered other COFP patients encouraged some participants to feel they would be believed and the use of appropriate anecdotes could be reassuring.
That’s another thing about the facilitator, he said you know, about this, it happens to a lot of people and you know, you’re not alone sort of thing, so sort of reading about other people and how they’ve coped and what they did, that all helped…. just that someone will believe you again, because you’re not the only one coming up with these sort of symptoms and that they’ve seen it all before and they can help you (p14 371-393)

Talking is a predominant and necessary part of the intervention; it is essentially a talking therapy. Participants sometimes talked in a negative way about the ‘counselling’ element of the intervention. However, once a relationship had been established between patient and facilitator, the talking element could become an engaging feature that served as a way to facilitate an accepting and understanding relationship.

At first I wasn’t sure what to expect and when they started going about the you know like behaviour therapy and how to manage… it reminded me of when I went to see a counsellor at one point … I just remember thinking it’s just going to be a waste of time, but in the session, it actually helped, because I could talk more about how I actually, actually felt (p12 72-78)

Participants generally valued the ability to talk about their illness. They liked the fact that the intervention was structured and focused around their concerns. Managing COFP sessions were seen as different to counselling however, as there was an expectation that participants were going to generate plans for change in addition to discussing relevant issues.

You know in a general way, the counselling is more airy fairy … I’m sure there is a place for it, …but the actual ideas of what you are going to do, what you are going to change comes from you, comes from the person (p11 362-373)

6.10.3 Obtaining a plausible explanation for symptoms

Participants could become frustrated and distressed when repeated investigations failed to reveal an underlying physiological problem to account for their COFP. The invisible and often cyclic nature of their symptoms and a lack of a clear explanation for a cause of their condition could be confusing and distressing to patients. It was
important for participants to receive a plausible explanation for their symptoms, or feel that they had reached a satisfactory understanding of what may have caused their illness. Participants had generally received a diagnosis in secondary care, however they required an acceptable, credible sounding narrative to account for the label given to their illness. They felt that such accounts could be used to mitigate future circumstances where their COFP symptoms might be met with scepticism.

*I couldn’t understand it but like now I understand it is some form of condition which before you couldn’t really describe to anybody can you? Nobody else would understand what you’re going through so you just can’t explain. If you have a broken limb people could see that, couldn’t they? (p8 66-70)*

Participants have received unsatisfactory and ambiguous explanations for their COFP in the past, which can be unsettling and lead to a lack of confidence in their dentists;

*There was always that uncertainty before I went to the dental hospital … I was always told, “there must be a little bit of root showing; there was always a same reason of a bit of root showing and whatever (p6 272-274)*

Although a definitive cause for COFP has not been found (it is a medically unexplained condition, see Chapter 1), possible causal models for symptoms were sometimes discussed during “Managing COFP” sessions. The facilitators tended to centre these discussions on participants’ medical backgrounds and case histories, drawing on current evidence. They generally centred around two main narratives. Firstly, a stress related habitual behaviour such as jaw clenching or teeth grinding, can create muscle tension which in turn causes pain. A second common explanation was that a nerve had become sensitive due to previous dental work or a now resolved pathology and continued to keep “firing” although the original stimulus had since gone. Participants generally accepted explanations based on these models. It seems that a plausible explanation does not however need to encompass great detail or an in depth understanding; it can be enough that the explanation is sensible and meets with the beliefs and expectations of the participants.

*So I suppose someone explaining it to you, and that it does happen to a lot of other people and they think this is the cause, which seems quite a sensible cause and you think, “this seems quite logical” (P6 255-265)*
It is possible that participants could be less likely to engage when they had already accepted an established explanation for their COFP. This may be associated with having an existing treatment regimen that seems congruent with their understanding of the condition.

“I had this thing [splint] for my gritting … not so much grinding but gritting my teeth and it was causing the sort of extensive dryness and a strange sort of sensation in my mouth” (p10 28-35: dropped out prior to first session)

6.10.4 Effort required
Two participants who had provided full consent and been allocated to the intervention group, then later decided to withdraw from treatment, agreed to be interviewed. Participant 10 withdrew from the intervention after receiving and reading the treatment manual, and participant 3 decided not to continue with the sessions after taking part in the initial consultation. The main reasons cited focused on a perception that participation in both the intervention and the study itself was overwhelmingly effortful and time consuming. Participants had conflicting lifestyles and other priorities that were seen as incompatible with the intervention.

“To be honest it just seemed … an awful lot of work … and at the time I think I didn’t think that it would be that sort of involved. You know its bad enough getting me to get on with my own work (P10 64-89)

A few participants who chose not to consent to the exploratory trial of “managing COFP” cited similar reasons, summarised in Table 20 as “too busy to commit”. These patients felt that they had insufficient spare time to commit to either the intervention, or the study itself. Particularly when participants’ COFP symptoms are perceived as mild, the intervention can seem too intensive and incongruous with their condition.

“It’s probably absolutely fantastic for people that are suffering badly with pain but its just too in depth for those like myself who aren’t … here its sort of steps to recovery I think or steps to coping and do I need to take those steps?… something that asks me to keep a diary on what I’m doing or things like that it’s just like a quick turn off. (p10 135-160)
Other, more debilitating illnesses could undermine participants’ abilities to engage with “Managing COFP”. This could make certain aspects of the intervention, such as the treatment manual unappealing due to the effort needed to concentrate on reading the manual and to engage in sessions with a facilitator.

*It is still concentration on having to read things, it’s just concentration at the moment, I just cut off completely, this is where the difficulty is.* (p3 187-189)

### 6.10.5 Acceptance of having a chronic or long term condition

An important part of participants being able to engage with “Managing COFP” appeared to involve an acceptance that their illness was long term and that symptoms could be managed over a longer period of time. An adjustment from the acute model of illness, specifically involving temporary withdrawal from normal activity, rest and awaiting the short term results of medical intervention was needed in order to engage with the intervention and accept some of the techniques.

Sometimes, this acceptance had been reached by the point of referral and therefore the timing was right to accept the offer of the intervention

*I had in the back of my mind that kind of hope that every time I would go [to the dental hospital] there would be something else they could try … It would be a magic wand and it would all go away … I had a lot more time to think and suddenly I realised it’s not, this isn’t going to happen …. I think the timing was good, I was ready to take control instead of waiting for medication and “take this and everything will go away”* (p11 304-322)

Participants talked about the cyclic nature of COFP, involving periods of remission followed by flare up and this could be incorporated into a treatment plan, once recognised.

*You know this is a pattern for you now unless for some unknown reason things might change and things get better so you have to plan around that … Which I do now …I will get until sort of like up to three weeks and then feel things really going down again, so I’ve started to plan ahead* (p29 239-253)
COFP symptoms were interpreted by some participants as indications of more threatening, acute conditions which could in turn cause stress, therefore exacerbating symptoms and associated worry. Revising their interpretation of reoccurring, repetitive symptoms as being part of a chronic illness could help to allay fears of a more sinister cause.

*And now I know I’m not going to have a stroke or heart attack which I thought I was initially going to have … I think if I was going to have a stroke, as [facilitator] quite rightly pointed out, it would have happened a long time ago, and obviously it didn’t* (p8 31-38)

Those participants who successfully engaged with the intervention had often tried a number of previous treatments. Typically these were analgesics, anti-depressants and splints, often used over a number of months or years. A repeated lack of effective results from traditionally prescribed interventions could result in frustration and despair and “Managing COFP” intervention offered an alternative they found acceptable:

*Yeah well, I’d just tried everything, so I’d just give up trying basically, you know, after just running into brick walls all the time (p5 45-46)*

It was noted that not all participants need to have tried several medical and pharmacological treatments in order to find “Managing COFP” acceptable. Some participants may have been amenable to considering guided self help at an early stage of their illness, provided plausible justification is given:

*I think, if my dentist would have said 12 months before he took my teeth out, “look, I can’t find anything wrong with this but I’m aware there is this type of treatment that’s been quite successful” I’d have been totally willing to do it, because rather than having another tooth out I’d definitely been, embraced it, gone on it, but it was the fact I wasn’t aware, I had no awareness whatsoever* (p06 280-285)

For some participants engaging with “Managing COFP” provided an acceptable explanation for the unpredictability of symptoms experienced by sufferers of a chronic condition. This is associated with justification for self-management and increasing activity levels.
It kind of explained that it may always be there or sometimes it disappears for no reason but I would be able to manage it and cope better and certainly get back into, you know more realistic day to day activity level (p11 40-42)

Techniques modelled by the treatment manual included goal setting that focuses on personal accounts of what it means to become well and resuming previously abandoned activities and return to a normal routine. Participants generally accepted these types of techniques, and the focus on managing rather than curing symptoms:

We set some objectives. I said, “I’d like to get to the point where I wasn’t noticing the toothache and I didn’t want to be taking medication for it” (p06 18-20)

6.10.6 Demonstrative positive feedback
Demonstrative positive feedback (as opposed to encouraging words from a facilitator or significant other) could contribute to changing attitudes towards certain behaviours. Participants found it engaging and encouraging when the techniques they used were perceived as working and symptoms seemed to be improving.

Several participants described how the use of diaries, and scoring symptoms according to severity could demonstrate positive feedback. For example, looking back over pain scoring entries could provide reassurance that a flare up would be followed by a period of remission or decreased pain. Diaries could be returned to during unsettling periods to provide reassurance that symptoms could subside.

I started to put on a pain score which for me was between 1 and 8 because 8 was for me the pain I’d most felt, and I think, “hold on a minute I think it was bad a few days ago”, oh well no it wasn’t, it was actually well over a week ago … but looking at that, as well as it showing the activities I was doing, it was also showing me how I was improving on that level, on the pain level so again, that was reassurance (p11 122-139).

In addition to being an engaging factor, obtaining demonstrative positive feedback could affect patients’ thoughts and beliefs about their illness. When participants tried new activities or conducted behavioural experiments, outcomes could be unexpected.
Well, I started doing a lot more exercise and it just makes me feel better in general, I don't feel as tired and I just think, 'get on with it now'. I used to think it made it worse, being tired, and that exercise will make it worse when actually it doesn't, it makes me feel a lot better in yourself really, just generally” (p14 79-82)

Goal setting (see Chapter 5 for more detail regarding participants’ goals) appears to be a useful way to facilitate activities which lead to positive demonstrative feedback and changes in attitudes towards certain behaviours

So what started off as me kind of making myself try and do something, over time I was doing I know some of the things I didn't really want to ..I made myself, even just getting out of the house and you know go for a long walk. I started off doing it because I'd put it down I was going to do it, so I'd get my coat on and go, but after a few times I was actually wanting to do that without feeling it was something I had to do, but wanted to do (27 75-87)

6.10.7 Identifying unhelpful patterns

Participants often had established disadvantageous patterns of thoughts or behaviours (or both) relating to their COFP and for these to be changed, it was necessary that they were first acknowledged. Techniques such as behavioural activation and cognitive restructuring could be introduced appropriately by the facilitators once unhelpful patterns had been elicited. The materials included in the intervention, such as the impact sheets which participants used to note the impact their illness had on their lives could serve as useful tools to aid recognition of negative ways of thinking or behaving that had become habitual.

Impact sheets and things like that, it really brought home for me how everything was different to how it used to be and I can't really explain – it just like a sudden awareness thinking, 'this is common sense – you know why didn't I think of this… it was very insidious. .. Not just because I was feeling the pain was worse for longer periods but also because I'd cut down doing things, seeing people very, very slowly (p11 46-60)
In addition to withdrawing from activities, participants could experience cycles of behaviour where patterns of increased activity during periods of feeling well were followed by prolonged periods of withdrawal and unpleasant symptoms. This meant that activities carried out by participants were controlled according to the severity of COFP symptoms.

*And it [intervention] got me doing more, and I was doing things that I didn't have a routine at all. And that's what I wanted, I'd stay up until 5 or 6 o'clock …And I was aching and tired and wanted to stop and couldn't stop (p2 316-322)*

Facilitators encouraged the introduction of new routines to try to break established unhelpful patterns. Making such changes or introducing routine into a more chaotic lifestyle could be motivating to participants and provide a clear course of action to help bring about change

*No I had got stuck in a rut, you know being where I were and everything and just like trying to get back to normal a bit so it did help to push me a bit for that, I think it was what I needed you know, more than everything … something to give me a bit of a push you see. (p5 150-166)*

Jaw clenching and teeth grinding, are particular habitual behaviours associated with COFP, which participants tended to associate with stress. Once exacerbating patterns were identified, habit reversal techniques could be introduced. Participants were able to identify the contribution of habitual mechanical patterns of behaviour, in exacerbating and possibly causing their COFP.

*Mine wasn't like a constant pain, it would just come in cycles … but now like, I can tell when I am going to clench and it goes like when I use the techniques I don't clench and the pain is at zero. … It's usually when you're stressed. I can feel it, like the tension in my jaw… I didn't know there were particular things that I could do to help so I used to clench and then suffer in the morning (p19 184-188)*

6.10.8 Control

Participants talked about wanting to have more control over their COFP and going through a process of taking control over symptoms. Having control over COFP
meant that participants were more able to engage with normal day to day functioning, such as work in and outside the home. Techniques suggested and modelled by the intervention could result in participants reporting a sense of greater control over symptoms and a reduced impact on normal functioning.

Because initially when I started I thought that there was nothing I could do to help prevent the pain but then when I found out there were techniques I could do, that gave me a bigger sense of control over the pain. (19 57-160)

Reducing or discontinuing analgesic medication in the form of antidepressants or pain killers and reducing visits to clinicians were sometimes cited as objectives when participants described goal setting exercises. To some participants, gaining control of symptoms meant relying less on medication and techniques modelled in “Managing COFP” could help with this.

I thought there was nothing I could do, I’d have to go to my dentist, I’d have to get other people to treat I and that actually I thought there was nothing I could do, now I know there are things I can do and now I can really help. That aspect of having control over things that is kind of a big deal for me it did hurt and when it was bad it was really bad and it was just knowing that there is something that you can do and you don’t feel as sense of like basically, up against it (19 207-232)

Scheduling activities and ensuring planned tasks were still carried out when mild symptoms were experienced seemed to help with improving feelings of general wellbeing. Participants could feel as if their lives were dominated by COFP or co-morbid conditions such as back pain and chronic fatigue because they had regularly cancelled or changed plans in the past due to feeling unwell.

So that you sort your life out a bit so that you can fit in … I wanted to do more exercise because I always felt tired and I felt like it was hard to fit it in but just doing these plans, these schedules to fit things in just sort of put things into perspective really, so you did have time to do some and I could do it and it wouldn’t affect my tiredness either really. (014 53-57)

A number of repetitive negative thoughts were reported by participants during the intervention sessions. These could be related to illness itself, or other areas of the participant’s life. For example, a few participants were worried that symptoms would
get worse or were a sign of a more malevolent underlying disorder such as a stroke. Participants were also concerned that others did not believe their illness (as reported earlier). Where the worries and concerns were not directly related to illness they tended to focus around three main areas: travel, work and family. When negative thoughts occurred, they resulted in feelings of stress and anxiety, often exacerbating symptoms or making them harder to cope with. Participants reported benefits in becoming able to recognise and gain some control of their negative thoughts.

*I think well, look, this is the first time this has happened in 5 days and so, you know, just get on with whatever you are doing, and don’t be overwhelmed by it which is what was happening before, it was like ‘oh god no’, you know, “this is never going to go away”. I do try and look at the positive things a lot more, you know, even if I’m out and it’s raining, it’s raining, I’m walking, I’m getting wet, so what, it doesn’t matter* (27 489-493)

6.10.9 Distraction

Many participants reported using distraction as an effective technique for managing COFP either prior to becoming involved in the intervention. This provided a useful platform on which to build during the course of their sessions. Others adopted distraction as a technique during the course of their sessions. Distracting activities were introduced at times when participants tended to dwell on symptoms. For example, listening to music while walking to work or reading in bed had been tried. Participants often talked of feeling much better when in a complete change of surroundings and routine, such as being on holiday;

*I was going on holiday and it was a difficult thing because I’d noticed if I kept myself very busy and I’m away then the pain seemed less* (27 107-109)

Similarly, when symptoms of COFP or other illnesses became debilitating, a simple change of environment could provide a useful distraction.

*You know, sat in the house and all that, and you’re just brooding about it and everything. If you can get out and about doing different things, I think it does, you know take your mind off it, and doing it that way. (p5 354-359)*
Undertaking other activities in a familiar environment can be easily implemented were seen as useful in helping to allay any unhelpful and distressing preoccupation with symptoms. This could take the form of even the most routine and familiar activities, such as gardening or watching something engaging on television.

To fill my time so that it took my mind off, you know, not just sitting down and thinking “I can’t do anything” . . . just general things around the house, going out to see somebody, doing some sort of sewing or reading or watching a programme, keeping busy basically. (p9 8-26)

Taking part in intervention sessions could paradoxically offer distraction from COFP symptoms, providing an unexpected benefit through a change in routine and giving participants a focus for their attention. When sessions took place face to face, some participants reported valuing the distracting effect of getting ready for and travelling to the setting.

Well it made me more relaxed and not focusing on one certain thing and getting myself worked up and it was something different itself, you know coming out to Manchester, you know doing it that way. I suppose it was just getting me out and about. (05 122-125)
6.11 Intervention model

From the above analysis, a model for “Managing COFP” incorporating these themes is proposed (Figure 12). The larger ovals in the centre of the diagram show how some features of the model can be both engaging and act as a mechanism for facilitating change. The horizontal arrow along the bottom delineates how the themes are not mutually exclusive, and can impact on each other. Engagement with the intervention is associated with identification with the treatment model and others with COFP, feeling believed and understood and obtaining a plausible explanation for symptoms. Acceptance of suffering from a long term condition can be an engaging feature, either prior to starting the intervention or reached during participation. Participants can experience a change in their illness models during the treatment and develop an understanding that withdrawal from normal activity is not a helpful approach in managing COFP. Once engaged, participants can implement techniques modelled in the manual to activate processes for change. Positive demonstrative feedback acts to reinforce new thoughts and behaviours and augment engagement. The right hand side of the diagram illustrates the process of change, once patients are engaged with the intervention. When unhelpful patterns have been identified, strategies for control and distraction can be employed as appropriate.
Figure 12 Model of factors relating to “Managing COFP”

Features of engagement

- Identification with intervention
- Feeling believed & understood
- Obtaining a plausible explanation
- Low perceived effort

Factors relating to engagement & processes

- Acceptance of chronic condition
- Demonstrative positive feedback
- Identifying unhelpful patterns
- Control
- Distraction
6.12 Implications of findings

The following Table (25) summarises the practical implications of the findings for moderating and adapting the intervention. The finding, taken from the results section is presented in the first column, the intervention component it impacts on is presented in the second column and the implications and suggestions and how they relate to for “Managing COFP” is described in the third column.
<table>
<thead>
<tr>
<th>Finding/ theme</th>
<th>Intervention component</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier to delivery - Some participants found the effort required to participate in the intervention overwhelming (interviews)</td>
<td>All</td>
<td>Investigate convenient ways of delivery using different health technologies.</td>
</tr>
<tr>
<td>Qualitative description - Participants satisfied</td>
<td>Number and length of sessions</td>
<td>Keep number and length of sessions as currently implemented</td>
</tr>
<tr>
<td>Qualitative description – both face to face and telephone delivery are acceptable</td>
<td>Method of delivery</td>
<td>Keep choice of delivery method as currently implemented</td>
</tr>
<tr>
<td>Qualitative description - Professional background did not make a difference</td>
<td>Facilitators</td>
<td>Facilitators do not need a dental back ground. Look at who might deliver “Managing COFP” in the long term.</td>
</tr>
<tr>
<td>“Facilitator” mostly acceptable however some participants do not understand the term</td>
<td>Title for individuals delivering intervention</td>
<td>Adequate replacement for “facilitator” difficult to find – add definition and ‘job description’ to manual and ensure facilitators explain what their role is</td>
</tr>
<tr>
<td>Demonstrative positive feedback</td>
<td>Diary keeping/ stories.</td>
<td>Some participants found scoring symptom severity useful. Add scale for symptom severity (e.g pain, sleeplessness). Model use of scales through stories and vignettes.</td>
</tr>
<tr>
<td>Identifying unhelpful patterns</td>
<td>Manual, training and stories</td>
<td>Introduce habit reversal techniques formally, in training and manual. Model through stories and vignettes.</td>
</tr>
<tr>
<td>Distraction</td>
<td>Face to face sessions, manual, training and stories</td>
<td>Face to face sessions can be a distracting feature. Good techniques for introducing distraction in place. Participants sometimes already use for self – management. Possibly emphasise role of distraction more in stories.</td>
</tr>
<tr>
<td>Identifying with “Managing COFP”</td>
<td>Recruitment and early engagement</td>
<td>Those who do not identify with the treatment model may decline treatment or disengage early. This may be overcome if the patient identifies with another aspect of the recruitment process, for example the referring practitioner or clinic or is interested in hearing about others with COFP.</td>
</tr>
<tr>
<td>Identifying with others with COFP</td>
<td>Number and type of sessions, engagement</td>
<td>Participants valued hearing about others with the same condition. Investigate the plausibility of introducing one</td>
</tr>
<tr>
<td>Feeling believed and understood</td>
<td>Recruitment, engagement and training</td>
<td>Emphasise how participants are believed and understood within the intervention and acknowledge that this may be in contrast to experiences in other contexts.</td>
</tr>
<tr>
<td>------------------------------</td>
<td>-------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Reasons for non participation</td>
<td>Difficulties contacting patients after consent to contact given</td>
<td>Ensure different types of contact details (address, email) are taken at referral stages</td>
</tr>
</tbody>
</table>
6.13 Reflexive statement.

This reflexive account has been included to discuss the influence of the researcher on data collection and analysis. Practising reflexivity involves an assumption that the researcher is part of the research process and that subjectivity does not hinder the production of credible accounts of the data but adds transparency and understanding to the findings and interpretation (Finlay, 2002). Situating oneself socially and emotionally in relation to respondents is an important element of reflexivity however other features of researchers’ influence on research should also be considered (Mauthner et al., 2003). This account focuses mainly on how the multiple role of the interviewers within the study may have influenced data collection and analysis, because this was a main area of concern for the author.

The author of this thesis (the “I” referred to in the first person voice below) and a senior member of the supervisory team with a vested interest in the research (the funding grant holder) were required to both deliver the intervention and conduct interviews with participants whom they did not treat. Additionally, both individuals had been involved in recruitment and baseline data collection. This had involved discussing some aspects of the intervention and study in more detail and building relationships with participants. Consequently, participants may have (correctly) concluded that interviewers and facilitators knew each other professionally, and as a result of this, expression of some private views may have been inhibited (Grbich 1999). Additionally, some unconscious bias (Quinn Patton, 1990) towards favourable accounts of themselves and the intervention may have affected the interview process. As both interviewers also held dual roles as facilitators, questions may have been framed to favour positive responses, despite an attempt on behalf of interviewers to be transparent and practice reflexivity in accordance with a qualitative approach to health research (Dingwall, 1992).

An example of an issue relating to the dual role of interviewers is highlighted in the case of participant number 3. This participant had a number of co morbid health conditions and had requested a substantial amount of information concerning the study and the intervention prior to giving consent. During a visit to her home to collect baseline data, she had asked further questions regarding my role and information about the facilitators, which I had provided. However, this meant that during the interview I eventually conducted with her not only did she have knowledge of the
working relationship between myself and the facilitator, there were a number of facts and assumptions, established during previous exchanges, that were not explicit in the interview transcript. This meant that there was a danger that I may have drawn conclusions based on these previous exchanges, rather than an examination of interview data. Ideally, interviews would have been carried out by people who were not directly involved in treating participants, and additional interviews would have been conducted with facilitators to gain their impressions of the intervention. However given the small size of this study and number of resources available this was not possible.

Involvement in delivering “Managing COFP” meant that I had already began to form impressions of the ways in which participants were responding to the intervention and often these impressions could be consolidated further during supervision. It was therefore difficult to separate subjective opinions formed during the treatment stage from impressions formed from the interview data during the thematic analysis. Consequently my own narrative regarding how participants related to the intervention may have been projected on to my interpretation of participants’ accounts, as given in the interviews.

I additionally felt that some interviews with participants’ revealed accounts that were at odds with impressions I had formed during intervention sessions. For example, one participant seemed to be well engaged with the intervention, for example she had attended all eight sessions. However, this participant had told me that she had withdrawn from the treatment plan we had made as she was unwilling to become more active for reasons not directly related to her illnesses (she had multiple co morbidities). This was at odds with the account she had given during the interview, where she had described ways in which she had become more active as a result of using techniques learned during the intervention. This issue is however difficult to explore further. In the absence of other evidence, participants’ accounts can only be taken at face value.

Checks were however made by two experienced qualitative researchers (members of the supervisory team) who had not been involved in treatment which helped to counteract issues highlighted above. A consensus on themes grounded in the interview data was reached in an iterative process which added to the reliability of findings.
An important and interesting finding concerned the degree of acceptability for the intervention, which essentially targets functional and psychological issues. It seemed surprising that such acceptance for a non medical approach was expressed by participants who had initially presented with pain symptoms, which are traditionally treated by drugs or surgery. This finding is discussed in more detail below, however it would have been interesting to have interviewed those who did not consent to take part, and conducted an in depth comparative study that investigated the views of both groups of patients. In the meanwhile, one can only speculate on the characteristic differences between these two groups.

6.14 Discussion

6.14.1 Introduction
The main finding from this study is that “Managing Chronic Orofacial Pain” was generally acceptable to participants. The findings from the descriptive section (“Views on delivery”) show that in practice, contact time, mode of delivery and setting was compatible with the parameters initially set for the treatment (based on McBeth et al., 2012). Participants expressed positive views regarding the facilitators. The professional background of facilitators did not appear to affect how they were perceived by participants.

Two over arching themes, “engagement” and “processes”, emerged from the thematic analysis. Engagement with the intervention was affected by the degree to which participants identified with the treatment model and other COFP patients, felt believed and understood, obtained a plausible explanation for symptoms and the degree of perceived effort required from them. Processes that were helpful to participants during the course of treatment were identification of unhelpful patterns of behaviour or thoughts, control and distraction. Acceptance of having a long term or chronic illness and receiving positive feedback were both engaging features, and processes which could occur during treatment. The above findings will now be discussed in more detail and placed within the context of other relevant literature.

6.14.2 Characteristics of the sample
It is important to consider the potential influence of the characteristics of the sample on the findings. Although there are more females (66%) than males (34%) in the UK general population with COFP symptoms (Aggarwal et al., 2006b), this sample was
disproportionately female (just over 93% of participants). Therefore these findings may represent a predominantly female perspective. However it was not possible to conduct more interviews with men as only one male participant was assigned to the intervention group. Larger trials can try to redress the balance of participant characteristics in qualitative studies through using purposive samples however it was not possible in this small sample.

It is possible that COFP patients who could not identify with or accept a psycho social model of their illness did not consent to be in this study, therefore this sample reflects the views of a self selecting group who inherently found the prospect of a self help intervention acceptable in principle. Additionally, it is important to bear in mind that these participants were recruited from secondary care clinics, and had already undergone a number of investigations and examinations. All participants had experienced symptoms for at least three months, many for a number of years. It is possible that this sample may have distinct characteristics that separate them from primary care and acute patients. For example, Durham et al., (2011) explored the journey through care of TMD patients (the most common diagnosis within the COFP spectrum). They found that primary care clinicians found the condition was difficult to diagnose and that general dental practitioners found management problematic. Consequently primary care patients tended to be preoccupied with seeking a diagnosis. However, most participants in this study received a satisfactory diagnosis from secondary care clinicians (often after a substantial period of waiting for an appointment) and subsequently prioritised obtaining treatment rather than finding a label for their condition.

6.14.3 Components relating to implementation
The majority of participants interviewed completed treatment (between four and eight sessions), with two interviewees dropping out after completing none and one session respectively (a more thorough description of intervention implementation in practice is provided at the start of Chapter 5). Although some preference was expressed for face to face sessions, where travel to and from the setting was implausible or inconvenient telephone based delivery was acceptable and no barriers were identified. This is in accordance with findings from the MUSICIAN study (McBeth et al., 2012), in which delivery of CBT based guided self help was carried out exclusively by telephone and found to be acceptable to chronic widespread pain patients.
6.14.4 Facilitators
Feedback regarding the facilitators was positive and participants appeared to have successfully engaged with participants and formed good relationships. However, participants’ disclosure of favourable views may have been influenced by an awareness of the working relationship existing between interviewer and facilitator (see reflexive statement, page 164). The professional background of the facilitator did not appear to impact on the degree to which participants engaged with the intervention. This is important because previous studies (e.g. Durham et al., 2007) have found that most dentists do not want to deliver psychological interventions for COFP. The findings from this study suggest that COFP patients will accept guided self help delivered by a facilitator without a dental background.

Some participants cited withdrawal from prescribed drugs as one of their treatment goals. This was possibly related to having a facilitator who had been clinically trained and could confidently provide direct advice and guidance in relation to this subject. In contrast, participants assigned a facilitator with a non clinical background did not have advice relating to prescribed drugs directly available. This issue should be addressed in the future training of facilitators and guidance and recommendations relating to withdrawal from commonly prescribed drugs for COFP (mainly analgesics and anti-depressants) and other medical devices (such as splints and mouth guards) should be given.

6.14.5 Engagement with “Managing COFP”
The main themes to emerge from the interviews were associated with engagement with the intervention and processes associated with managing illness. For participants to engage with the intervention, it was important that they could identify both with the notion of guided self help based on CBT principles, and with other COFP patients. Both participants who dropped out of the intervention expressed some degree of disassociation with the treatment model, (“what are we trying to achieve?”), however the majority of participants were able to accept and engage with “Managing COFP”. In contrast, a resistance to psychological interventions and non medical approaches to treatment has been identified in participants with a variety of MUS conditions, for example Chronic Fatigue Syndrome (CFS)/Myalgic Encephalomyelitis (ME) e.g. (Nettleton et al., 2005, Peters et al., 2011, Wearden and
Chew-Graham (2006) and Chronic Pelvic Pain (McGowan et al., 2007) and this will be discussed in more detail below.

6.14.6 Feeling believed and understood
The stigma of suffering from an illness that does not have an identified medical cause was felt keenly by participants, and it was important for them to feel believed and understood by those responsible for treating them. COFP participants reported a feeling that others could view their illness as “all in the mind”. Similarly, Burbaum et al., (2010) found that patients with a variety of MUS conditions felt that they were not taken seriously by physicians and the reality of their symptoms had been questioned. Practitioners’ response to and interaction with patients has been found to be highly important in other studies. For example, a recognised diagnosis and association with a physical cause could be less important to neurology patients with unexplained symptoms than feeling that their symptoms are being taken seriously by practitioners (Nettleton, 2006).

6.14.7 Plausible explanations
Although COFP participants in this study did not challenge their diagnoses, they often did not possess a satisfactory explanation for causal or perpetuating factors. In the absence of a medical explanation they required a plausible narrative to account for their symptoms. Explanations acceptable to participants tended to encompass at least one mechanistic factor, such as teeth grinding, jaw clenching or nerve sensitivity. This mechanistic or physical element could plausibly be exacerbated and perpetuated by psychological factors such as stress or traumatic life events or physiological responses such as fatigue. This type of mechanistic explanation incorporating both physical and psychological elements may be more acceptable to participants than a purely psychological model. Similarly, Burbaum et al., (2010) found that patients from secondary care internal medicine and neurology with unexplained symptoms sought causal narratives to account for their illness. Understanding psychosomatic attributions (psychological basis for illness) was connected to professionals offering this concept within an acceptable model.
Therapists in this study highlighted information offered by patients and used it as evidence to formulate an explanation. When explanations were framed in a sensitive, discrete way, participants who were initially reluctant to accept an alternative to a medical model could change their views over time. This finding reflects findings relating to CFS patients who were initially reluctant to accept a psychological
treatment. It was found that some nurse therapists were able to engage them over the course of the intervention (Peters et al., 2011).

Some narratives found to be acceptable to participants in this study also seemed to lend themselves to self management. For example, teeth grinding can be treated by recognition of triggers and implementing habit reversal techniques. This is in contrast with the findings of Peters et al. (1998) who found that although MUS patients may have a connective mind-body model that they can understand, understanding did not lead to acceptance. In addition, participants in this study rarely cited explanatory mechanisms that they can take responsibility for or that lend themselves to self management.

A model that incorporates both psychological and mechanistic features may be more readily available to COFP participants in this study than to some other MUS patients. Although one participant talked about the hidden nature of COFP (if you had a broken limb people could see that) Durham et al., (2011) point to a number of visual features and auditory cues available for TMD patients, such as clicking jaw, teeth worn as a result of grinding, tense muscles of mastication (used for chewing) and reduced jaw opening. In contrast the site of discomfort for conditions such as Irritable Bowel Syndrome, (IBS) and Chronic Pelvic Pain are hidden to the extent that invasive exploration is needed to investigate physiological symptoms. Additionally, the lack of visible symptoms in Fibromyalgia has been found to contribute to a stigmatising effect (Mengshoel & Heggen, 2004) and McGowan et al., (2007) highlight problems inherent in communicating chronic pelvic pain, due to its invisible nature.

Participants in this study did not appear to be resistant to either their diagnoses or the notion that psychological factors may play a part in either exacerbating or maintaining their symptoms. In comparison, a number of studies involving individuals with MUS conditions have found that many participants can find it difficult to accept explanations based on psychological approaches. For example, Wearden and Chew-Graham (2006) found that a number of primary care Chronic Fatigue Syndrome (CFS) participants were resistant both to their diagnoses and the possibility that psychological factors may be associated with their illness. Further research is needed to explore potential explanations for this finding and a myriad of possibilities relating to individual differences, such as personality types could be proposed. Additionally, this small sample may not reflect the views of COFP patients generally
(see “characteristics of sample” earlier in the discussion) and those resistant to psychological explanations or models may not have consented to participate in the study. It should also be noted that there is an ongoing medical debate within the field of CFS/ME in terms of the origins and subsequent labelling of the condition. Psychological versus viral explanations for the causes of the condition are highly contested and patient groups have organised campaigns against the promotion of and research into psychological treatments (Nigel 2011). These campaigns have also been highly publicised (e.g. The Guardian, 21 August 2011). In contrast COFP patients in this sample often had not heard of other people with similar conditions and consequently had not been exposed to such polarisation of views regarding their illness.

6.14.8 Accepting long term illness and self management

When COFP was recognised as being a long term illness with cyclical features, participants reported better engagement with and more benefits from the intervention. This appeared to be associated with a move away from a sick role. A “sick role” incorporates characteristics that are similar to the usual response to acute illness, involving withdrawal from normal routine, rest and treatment seeking. This type of behaviour in long term illnesses is associated with somatisation where individuals focus a high degree of attention of bodily sensations and interpret them as a sign of malaise. A tendency to somatise is associated with a number of MUS conditions and psychological dysfunction such as anxiety and stress (Brown 2004). This is also consistent with the common sense model of illness representation (Leventhal et al., 1980). The common sense model (outlined in Chapter 1) suggests that people respond to illness in different ways, based on prior experiences. Targeting behaviour based around a “sick role” may help patients respond to their conditions in ways that break perpetuating cycles of illness. For example, many techniques used in “Managing COFP” such as planning and goal setting are based on the common sense model (Weardon & Peters 2008). Additionally, it has been proposed that withdrawing from normal activity over a period of time may interfere with acceptance of self management (Mengshoel and Hedden 2004, Nettleton et al., 2005).

Although a complete cure was the preferred main outcome for participants, they could generally recognise value in managing symptoms over a period of time whilst attempting a return to a normal routine. Similarly, Mengshoel and Hedden (2004)
found that fibromyalgia patients who had accepted the fluctuating severity of their symptoms over a period of time were open to the idea of self – management. This could be viewed as an acceptable ‘second best’ to a complete cure.

6.14.9 Helpful processes and techniques
Once unhelpful patterns of behaviour relating to COFP had been established, participants were able to introduce appropriate techniques, under the guidance of facilitators. Effective techniques were associated with gaining control and distracting behaviours or activities. Previous research and theoretical models support the idea that control and distraction are important concepts in managing conditions with medically unexplained symptoms, and the two techniques may interact in a complimentary way.

The analgesic effects of distraction on pain have been well documented (e.g. Cambell et al., 2011). However, catastrophising (see Chapter 1) has been found to interfere with the ability to use distraction as an effective technique in pain management (Campbell et al., 2010). Increasing the amount of perceived control over a situation has potential to reduce the tendency to catastrophise (Reif and Broadbent 2007, Campbell et al., 2010), which could in turn facilitate the use of distraction techniques. In addition, increasing participants’ perception of control over their heath may have more general value. The degree of perception of control over a situation is a central feature of the theory of planned behaviour (Icek 1991) and many behavioural change techniques have focused on increasing the perceived degree of control over health related behaviours (Conner and Abraham 2001).

6.14.10 Examination of deviant cases
The two participants who dropped out of the intervention had uniquely cited concerns regarding the time and effort involved in participating. This decision was made by participant 10 after receiving the intervention manual by mail prior to telephone sessions. She explained that her job and lifestyle meant she had too little spare time to devote to participating in the intervention. Participant 3 cited Illnesses and family worries as contributing to a feeling of being overwhelmed by the only session she took part in. She also expressed difficulty concentrating on some of the materials included in the intervention, such as reading the manual and diary keeping. Contrastingly, those who completed the intervention did not report finding participation effortful. The other interviewees appeared to have similar
characteristics, such as having full time jobs, co morbidities and available social support therefore it is unclear why these participants in particular found “Managing COFP” effortful.

One possible approach to overcoming barriers associated with the perception that the intervention may be effortful could be, to investigate the use of other health technologies for delivering the techniques modelled in the intervention manual. This would allow participants to access guided self help when appropriate and convenient to them. An internet based intervention, for example, may be more acceptable to those who have little free time. Patients who have access to the internet could then engage with the intervention when, and for how long they choose. Further research is needed to explore different ways in which “Managing COFP” might effectively and acceptably be delivered.

6.14.11 Strengths of this study
Fourteen out of a possible seventeen (83%) participants took part in the study. Out of the three who did not take part, two could not be contacted and one could not be interviewed within the time period allocated. This is a good response rate and participants generally found participation in the semi structured interviews acceptable. Although the study was limited in resources, three experienced qualitative researchers (the author and two senior members of the supervisor team) were closely involved in the analysis and two other supervisors provided further analytical support. This helped to ensure that the findings of the study were robust. The findings are additionally supported by a number of other studies relating to MUS conditions and psychological interventions and are supported by theories relevant to health psychology such as the theory of planned behaviour and the common sense model. This suggests that the findings do have validity. Furthermore, two deviant cases that did not support the main finding (that “Managing COFP” is acceptable to participants) were examined. As a result, suggestions were made for further research and possible modification of the intervention in its current form.

Interviews were conducted approximately 2 weeks following completion of the intervention therefore participants should have a good level of recall of events. The data was analysed in two ways. Firstly, descriptive data was used to answer previously identified questions relating to the intervention. Secondly, a more in depth thematic analysis was conducted in an attempt to allow participants’ views to be
elicited organically, rather than according to themes defined a priori by the researchers. This flexible approach means that research methods have been applied pragmatically, in a way that is relevant to the research questions. This is compatible with the mixed methods approach that guides the whole thesis (see Chapter 2).

6.14.12 Limitations of this study
Limited resources meant that interviewers had multiple roles in the research. This meant that inherent biases and previously established relationships may have impacted on the data in a number of ways. Participants’ responses may have been inhibited by knowledge that interviewers knew facilitators, and that they had a personal interest in the research. Similarly, the interviews may have been affected by inherent bias towards the intervention held by those who were also involved in its delivery. This is discussed in more detail in the reflexive statement presented earlier in this chapter. Any larger scale trials of this intervention should separate the roles of researchers and individuals who deliver the interventions to try to minimise such potential issues.

It was possible only to interview one male participant. This means that the findings may reflect a gendered female perspective. However as only one male was assigned to the intervention group it was not possible to include more men in the study. Further research should attempt to recruit more male participants to try to address the balance of gender. A more balanced perspective may then be generated. Data relating to longer term management and relapse prevention was not captured in this study. This was due to limited time and resources available. Consequently, the results are limited to representing a ‘snapshot’ of participants’ views, given shortly after completing treatment.

6.14.13 Conclusion
The intervention, “Managing COFP” was acceptable to participants and the findings are supported by a number of studies involving MUS patients participating in psychological interventions, and theory from the field of health psychology. Other studies of CBT based treatments for COFP patients have not investigated acceptability, which limits their potential to be implemented more widely and incorporated into clinical guidelines (see Chapter 1). Therefore, a strength of this study as a whole is that acceptability amongst participants has been established. Findings suggest that features of engagement should be enhanced, and a strategy to overcome barriers, such as the perceived effort involved, could be developed and put
in place. This may result in increased recruitment to a future randomised control trial and a decrease in attrition. It was also possible to propose a model of processes involved in the treatment, which offers explanations for how the components might interact to bring about change. This is in accordance with MRC guidance for developing and evaluating complex interventions and represents a further strength of the study as a whole.

Data from quantitative interviews may reflect a predominantly female perspective, as it was only possible to include one male participant. It is not known why some patients decided to not participate in the trial, therefore the data may reflect a narrow set of opinions, which may not apply to COFP patients generally. As the study was limited in resources, researchers had multiple roles which may have limited the findings. This issue should be addressed when considering future study designs and the role of researcher and facilitator should be separated.
Chapter 7 Overall discussion.

7.1 Introduction
The overall aim of this thesis was to develop a feasible and acceptable evidence based intervention to treat COFP and to investigate parameters for a larger, definitive trial. Work towards these aims was carried out using a phased approach, based on the modelling stage described in the latest MRC guidance. Phase one encompassed the development of the intervention “Managing Chronic Orofacial Pain” through conducting a synthesis of evidence from multiple sources. Phase 2 involved two main studies, one quantitative and one qualitative, which formed the basis of an exploratory trial which was conducted to evaluate the intervention. Findings relating to the qualitative and quantitative studies have been discussed separately within the appropriate chapters. This chapter will synthesise the findings of these studies, the strengths and weaknesses of the research carried out and implications for further development and evaluation of the intervention.

7.2 Principal findings

7.2.1 Phase 1
Work conducted for phase 1 resulted in the production of an intervention to treat COFP, based on current evidence from specially conducted studies and the wider relevant literature. There is no current guidance on how to carry out an evidence synthesis to produce a complex intervention. The methods applied in this study were effectual and resulted in the production of a comprehensive treatment manual, which included content and materials to help facilitate delivery, and a comprehensive protocol.

7.2.2 Phase 2
The findings from phase 2 suggest that the components of the intervention are generally feasible and acceptable to participants. The findings of the qualitative study enabled barriers and facilitators to engagement to be identified and a preliminary model of therapeutic processes to be developed. In addition, the analysis produced some suggestions for slight modifications to the treatment manual. Recruitment to the exploratory trial was successful, attrition in the intervention group was low therefore findings suggest that the protocol for delivery should remain unchanged.
The primary outcome produced no indication of showing a potential effect. Additionally, only six out of 21 secondary outcome domains produced evidence of potential effect at the 0.25 one tailed level of significance. However, a visual analysis of standard mean differences (SMDs) showed an overall (non significant) trend that slightly favours the intervention group. In addition the majority of outcome domains that favoured the control group (including the primary outcome) were not negatively affecting participants at baseline. The implications of these findings will be discussed later in the chapter.

### 7.2.3 Support for findings
A number of findings from this study, particularly those relating to illness beliefs, control and anxiety about health, are supported by other research. Control was found to be an important theme arising from the qualitative study and both the treatment control and personal control subscales of the IPQr produced indications of potential effect. A recent Swiss study (Galli et al., 2010) used the IPQr to measure changes in illness beliefs and found that beliefs in low personal control and chronic timeline explained a small proportion of the variance of treatment effect and that beliefs about pain are important predictors of treatment outcome. Similarly, Turner et al., (2007) found that control beliefs and self efficacy were mediators that predicted effects on outcomes at one year. In addition, the notion of control is central to the theory of planned behaviour and is incorporated into many CBT techniques (Chapter 1, page 22).

Small differences in self reported TMD pain following a brief CBT intervention were associated with changes in cognitions and coping behaviours (Litt et al., 2009). A subsequent investigation of treatment moderators by the same research group (Litt, Shafer, & Kreutzer, 2010) did not detect effects for the treatment group on depression scores or pain related interference (in line with findings from the quantitative study) however high self efficacy and readiness to accept the treatment were associated with positive outcomes. The negative findings relating to depression and pain were attributed to the use of non-sensitive measures, which highlights the importance of selecting outcome measures that have appropriate levels of validity and sensitivity. Barriers to readiness to accept treatment were associated with high somatisation and an associated degree of recalcitrance found in participants. This finding also underscores the need to assess barriers to recruitment to studies of
psychological interventions to treat pain and other physical symptoms and to investigate the characteristics of patients who chose not to participate.

7.3 Strengths of the study

A phased approach was taken to the development and evaluation of the intervention, based on current guidelines (MRC 2000 & 2008). The intervention was based on current evidence and the methodology used to develop it has been reported in a thorough and transparent manner. The intervention now has potential to be modified further, based on information gleaned from participants. Acceptability and feasibility has been investigated and the intervention has undergone a process of thorough modelling. The iterative nature of the research means that findings can be applied to improve and further develop the intervention prior to testing in a definitive trial. Findings from the exploratory trial have highlighted modifications that should be made to the study protocol prior to conducting a larger, definitive RCT.

This approach to modelling and reporting CBT based interventions to treat COFP is in contrast with previous studies, which have been characterised by sparse reporting of intervention components and evidence underpinning their use (see Chapter 1). In addition, previous research has not addressed issues relating to stakeholder acceptability and feasibility of implementation. Studies of CBT based treatments for COFP carried out since the commencement of this study appear to be few in number and based outside of the UK (Litt et al., 2009; Galli, Ettlin, Palla, Ehlert, & Gaab, 2010). Although one pilot study has been conducted in Brazil (Calderoni et al., 2011) the focus of the research was on investigating effect sizes, despite randomisation of only a small number of participants (N=47). These new studies do not report intervention modelling procedures or the components of interventions used in treatment and omit investigations of acceptability and feasibility. The tendency for trials involving CBT based treatment for COFP to lack detail when reporting key processes relating to modelling, development and delivery appears to continue to date.

7.4 Limitations of the study

An exploration of this study’s limitations can provide important information which can be used to refine the design of any subsequent, definitive trials. This was a small, resource limited study, which impacted on the design. Potential issues arising from the multiple roles of researchers are highlighted in the discussion of the qualitative
findings (Chapter 6). In addition, it was not possible to carry out interviews with facilitators to investigate their views of delivering the intervention. Both facilitators were involved with, and had a vested interest in, the study as a whole. If the intervention is ultimately tested on a larger cohort, facilitators will need to be recruited from a wider skill base and it will be important to gain their views regarding the acceptability of delivering the intervention, particularly in light of employment-related factors such as the current changes being applied to NHS structures and possible secondment from their usual roles. The views of those who did not provide consent to participate were also not sought (although reasons volunteered were noted and summarised, see Table 20). This meant that potential barriers to participation could not be fully explored.

MRC guidelines (2000, 2008) recommend that an analysis of cost effectiveness be incorporated into evaluations of complex interventions. Although the resources were not available to incorporate a cost effectiveness analysis into this study, findings from this research can be used to inform a future cost effectiveness analysis, which could be included in a larger, definitive trial.

**7.4.1 Indication of effect**

Findings from the analysis of outcome measures were difficult to interpret. The main reason for this is that a small, exploratory study was conducted, powered to produce an indication of potential effect, rather than to provide evidence based on statistical measures of treatment effect. There is no established convention for the interpretation of quantitative outcomes in exploratory or pilot studies, although Arain et al., (2010 page 4) cite guidelines suggesting that the “characteristics” of proposed outcome measures should be investigated. The primary outcome and many secondary measures did not produce any indication of potential effect. However the finding that outcome domains overall slightly favour the intervention group suggests that the treatment may in fact have the potential to be effective. These conflicting findings mean that there is a high risk of making a type one or type two error when interpreting the results.

**7.5 Outcome measures**

Difficulties in drawing conclusions based on outcome results were further compounded by the finding that participants were not affected at baseline by many of the constructs measured by the outcome domains, which has implications for both the validity of their use with this sample and recommendations for use in a larger trial.
Furthermore, the intervention has potential to improve some outcomes that are negatively affecting COFP patients prior to treatment, suggesting these domains may be more valid for use. It is important however, to guard against selecting outcome measures that only produce positive effects. Selective reporting can cause results to be misinterpreted and may lead to incorrect clinical guidance being given (Hutton & Williamson 2000). Additionally, when results from trials that have been selectively reported are included in systematic reviews the data may be biased and estimates of effect and significance levels can be misrepresented (Hutton & Williamson, 2000; Kirkham et al., 2010).

The section of the study that investigated feasibility and intervention processes (5.24.2) cited the treatment goals of participants that took part in the intervention. The majority of goals set focused on improving physical and social functioning, such as increasing exercise, improving social contact, lifestyle changes and changes in routine (Table 23). This finding suggests that the primary outcome measure of physical functioning, along with many secondary outcomes, such as social functioning and role limitations do reflect the desired outcomes of participants and therefore may have validity for use with COFP patients. It may be the case that the sample recruited to this study represented a particularly high functioning cohort and this was reflected in the baseline scores. Consequently, a major recommendation for any future studies would be to introduce a suitable cut off point based on the primary (and possibly a number of secondary) outcome measures to ensure that the sample consists of participants who have the potential to gain the most benefit from the intervention. However, this has implications for the inclusion and exclusion criteria of any future studies and could consequently affect recruitment rates.

7.6 Conclusion

This research represents a preliminary stage in modelling a complex intervention (MRC 2000,2008). Although it is not possible to draw conclusions relating to the efficacy of the intervention, feasibility and acceptability has been established and participants have had considerable input into the development of the intervention. In contrast with reports of similar interventions, “Managing COFP” has undergone a considerable degree of modelling and development. Therefore, the author of this thesis advocates that research progresses to the next stage of evaluation and that a
definitive trial should commence, taking into account a number of caveats and recommendations based on the findings of this exploratory study.

7.6.1 Recommendations for the intervention

- The treatment manual should be updated and modified based on implications gleaned from the qualitative study and displayed in Table 25.

- The training manual should also be updated to incorporate guidance relating to participants who wish to reduce or cease their medication.

- The possibility of providing a flexible version of the intervention, perhaps through the use of an accessible, complimentary health technology, or by provision of only a manual could be investigated in order to facilitate access to those who might find the intervention as a whole prohibitively effortful.

- Findings suggest that a dental background is not needed to deliver the intervention however it was not within the realms of this study to identify a suitable skill base from which to recruit facilitators. Consequently, a larger number of facilitators from differing professional backgrounds should be recruited to deliver the intervention as part of a more comprehensive study, in order to determine how the intervention might be rolled out and implemented in the long term. The views of facilitators from a wide variety of backgrounds should be sought and analysed.

- The treatment protocol should remain unchanged. A measure of fidelity to the treatment protocol should be developed and incorporated into the study.

7.6.2 Recommendations for trial design

- Attention should be given to decisions regarding the selection of appropriate outcome measures, particularly for the primary outcome. Measures of a number of constructs including physical and social functioning, pain, mental health, anxiety and illness beliefs should be retained unless patient preference is established and indicates omission.
• Appropriate cut off points should be introduced to the inclusion and exclusion criteria so that participants who might most benefit from the intervention are recruited. Implications for recruitment should be noted as numbers may decrease due to the use of more stringent criteria.

• The views of those who decline to participate in the study should be sought in order to fully investigate barriers to acceptability of the intervention.

• Outcome assessors should be given separate roles to facilitators and those involved in recruitment of participants. In addition, they should be unaware of randomisation outcomes and maintenance of “blinding” should be assessed at the end of the study.

• Data from this study should be used to aid a full cost effectiveness analysis, which should form an important part of a definitive trial.
Reference List


Arain, M., Campbell, M., Cooper, C., & Lancaster, G. (2010). What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Medical Research Methodology, 10,* 67.


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Appendix 1 Presentations of evidence from contributing studies

COFP – Qualitative Studies: Perspectives of patients, dentists and GPs
Sarah Peters
Beth King

Synthesis day
11th June 2010

• Aims of Qualitative Studies

• To understand the patient perspectives of COFP – the condition and the experience of living with it

• To explore dentists and GPs views of COFP and their role in it’s management

Method
• Dentists and Patients
  – Manchester sample (Cheryl McElroy – dental nurse)
  – Newcastle sample (Justin Durham – dentist)

• GPs
  – Manchester sample (Beth King – psychologist)

Final sample comprised
  – Patients (n=23)
  – Dentists (n=26)
  – GPs (11 – recruitment on going)

• Qualitative approach

Semi structured, face-to-face audiotaped interviews
Manchester studies
  – Analysis of transcripts was iterative approach to identify emerging themes
  – Schedules developed to test emerging hypotheses in light of the preliminary data

Newcastle study
  – secondary analysis of transcripts to develop analysis of Manchester findings to inform development of a psychological intervention
Patient & Dentist Perspective

GP perspective

- Patient Sample (N=23)
  Recruited from 2 Manchester 2ndry care clinics and Newcastle TMD clinic
  - pain >3 months
  - no underlying pathology
  - Diagnosis of TMD (Newcastle only)

- Manchester patients – consecutive referrals, assessed for suitability from case notes

- Newcastle patients – assessed for suitability by researcher (dentist)

- Dentist Sample (N=26)
  - Recruited from Manchester and Newcastle
  - Purposive sample
  - Sampled for range of discipline/experience
    - General Dental Practitioner (GDPs) n=9
    - Secondary care Dentists Consultants n=17

1. Findings for Dentists & Patients

Similar themes emerged for patients and dentists:
Illness perceptions about COFP
Importance of a Diagnosis
Impact of the condition
Managing the problem
Clinical Relationships

- i. Illness perceptions of COFP

- Patients’ principle illness belief was **biomedical**
  - Malocclusion, physical trauma, dental damage

- Illness beliefs were rich and many incorporated a role for **stress**
  *some of it is...because I am stressed, I clench and that results in pain (patient 106/506)*

- Dentists’ beliefs were similar
  - **biomedical** (e.g. muscular, nerve damage)
  - **psychological**
stressful job, difficult lifestyle, lots of children to juggle at home…it can sometimes be quite difficult to cope with all these things at once…making your facial pain worse (dentist 201/201)

Both parties recognised variety of exacerbating factors
- stress, driving, cold temperatures facial movement, (eating, talking, singing)
- ii. Importance of a Diagnosis
  Viewed by both dentists and patients as important
  - Legitimised their experiences
  ‘I’m in this much pain it must be called something’ (patient 104)
  - Accessed referral pathways
  - Dentists perceived it communicated their competence
  - Provided therapeutic benefits
  ‘Had a lot of improvement after knowing the diagnosis, I think it’s very crucial’ (dentist 203)

Dentists were confident excluding pathology, but less confident in positively diagnosing COFP
‘Oral facial pain is often used to describe patients where we don’t know…where we think there is a problem somewhere in the oral facial region but we don’t know where it is or what is causing it’ (dentist 201)

Lack of a diagnosis was a key source of frustration
I can’t give them a diagnosis so I don’t feel I can help them and that makes the whole consultation quite difficult and strained sometimes (dentist 201)

- iii. Impact of the condition
  It affected all aspects of patients’ lives
  Work

Sleeping

Social interactions (eating, talking)

‘It effects everything…effects me being able to talk…eating is exhausting and the pain, it like pulls me down and makes me tired’ (patient 103)

- Financial
  ‘I have had to pay for everything, virtually I am bankrupt trying to get to the bottom of it’ (patient 104)

- iv. Managing the problem - dentists

Dentists treated mechanistically (splints/extractions) despite being aware it was ineffective
I made a lower soft splint…really I think they are a placebo if they do work (dentist 208)
Limited attempts to intervene psychologically
   — information, ‘explain’, ‘reassure’

However, psychological intervention viewed as outside their expertise & remit
I don’t think it is appropriate to be treating unexplained pain at all (C201)

Not what they were paid for
You might get one [Unit of Dental Activity]… for an emergency, for
doshing out a painkiller or something, but if it is an ongoing problem… got
to get something sorted out and get them referred off (dentist 207)

— iv. Managing the problem - patients
— Patients described varied attempts to self-manage
   — psychological coping strategies (e.g. distraction)
   — social support
Looked on the internet to see what I could find…it’s really helpful. It takes
the stress away, you know, you’re not a one off” (patient 015)
   — physical interventions (e.g. warmth, ice, pressure/massage)
   — self-surgery
‘I know what makes it better. I physically actually moved my teeth…so I
literally got a pencil…onto the canine and started pushing it, towards out,
to where it should be’ (patient 107)

— Patient choices preferences depended on their illness beliefs
   — biomedical mechanistic/physical
   — Psychosocial psychological intervention

— 5. Clinical Relationships
— Dentists found patients demanding
I just don’t feel I’m qualified and they can be quite terrifying at times
(dentist j5)
I find it much more tiring myself than dentistry  (dentist 206/118)

— Patients found dentists unsupportive
It’s almost as if you are sort of fighting the world…you are having to sort
of fight your corner (patient 106)

— Narratives described having reached a clinical impasse
This is is an immeasurable problem for me…I would say they are picking
around the edges rather than addressing the real issue because I initially
went to the dentist when I was about 20 odd for the initial searing pain in
my teeth (patient c107)
They view that I have not understood what their problem is… we seem to go over the same ground a lot when we recover the same incident many times, as if I have not understood the first time round (consultant c201)

2. Findings from GPs

— Poorly defined cohort
  — uncommon
  — variable duration of pain
  — Don’t coexist with other chronic conditions (apart from other pain)
  — Generally viewed as being caused/exacerbated by psychological problems – ‘she just seemed sort of, blank’

— Labels of pain
  — Multiple labels given (e.g. unexplained pain, somatisation, TMJ problems)
  — Diagnosis not necessarily beneficial
  — Trigeminal neuralgia
    • sometimes viewed as unexplained (‘diagnosis by exclusion’)
    • or explained (nerve pain)

— Treatment options
  • Refer for additional treatment and support/confirm diagnosis
    — Primary care dentists (non attendance)
    — Secondary care dental or medical services
      • TMJ injections, surgery, splints
    — Pain clinic
    — CBT, but delays make this unfeasible option
  • Psychological iatrogenesis of secondary care referral

• GP management – largely viewed as successful
  ‘For 9 out of 10 people I think I could find a positive solution’
  — Pharmacological
    • Analgesia, antidepressants, anticonvulsants, antibiotics, non-steroidal anti-inflammatory (for dental problems)
  — Psychological
    • counselling, relaxation, advice
  — Acupuncture
  — ‘watch and wait’

— Role of the GP

— COFP
  — Viewed as psychological rather than dental problem, hence part of their job
  — Confident with dealing with psychological problems
Main focus is changing patient expectation from cure > long term management

Managing dental problems
- Many inappropriate dental presentations
- Accept signposting responsibility
- Feel responsible for patient, even if problem is dental rather than medical
- Unconfident in managing dental problems

What do GPs want?
- Better communication with dental services
  ‘The way I approach the job is that the we get is through our referrals. You build up a real picture and it is help from both ends. You really appreciate the difficulties and you work with each other to help the patient’
- Awareness of individual’s specialist interests
- Clarity over dentists roles and responsibilities
- Improved dental access
- Time with patients
- Training
  - Common dental problems GPs could manage
  - Inexplicable pain

Summary of main barriers to management
- Patients not clearly identified or defined cohort
- No specialist service in either dental, medical or mental health services. No continuity of care.
- Lack of clarity over whose role COFP is
- Unavailability of effective treatments
- Uncertainty over diagnosis and aetiology: confusion about terminology
- Lack of clinicians’ expertise in explaining problem adequately to patients
- Poor communication between dental and medical services
- Key Messages

Dentists and GPs see these patients as challenging
- Dentists: volume and inability to manage mechanistically
- GPs: frustration over their relationship with dentists

Both view problem as non-dental
- Dentists: no obligation or desire for any role in COFP management
— GPs: accept they have a role in supporting patients and addressing psychological features of the condition
Patients want problem legitimated and to be believed

Many (but not all) patients recognise psychosocial aspects of their experience

Acceptability of psychological intervention depends on illness beliefs

Patients eager to self-manage

Illness severely impacts on several behaviours that could be targeted
Chronic Orofacial Pain

Chronic Oro-Facial Pain: Epidemiology to Evidence Based Management
Vishal Aggarwal

Overview
TMJ pain (facial arthromyalgia)
Atypical facial pain
Burning mouth syndrome

Systematic Review
CBT alone or in combination improved long term outcomes:
Pain intensity (dwokin 2002 self care)
Pain to muscle palpation (dwokin 2002 self care)
Activity interference (dwokin 2002 self care)
Depression

However no standardised protocol for delivery
Appendix 2 Synthesis day agenda

Evidence synthesis day – 11 June 2010
Turing room, Coupland 1, Psychology
Agenda

Attendees
Karina Lovell, Vishal Aggarwal, Linda McGowan, Sarah Peters, Joanna Goldthorpe, Beth King

9.30am Introduction and definition of COFP: Vishal

9.45am. Quantitative Presentation: Vishal

10.00. Qualitative Presentation:
GPs – Beth
GDPs – Sarah
Patients - Sarah

10.45. Systematic review – Vishal

11.00. Coffee & cakes

11.15 CBT components – Joanna

11.30. Completing Table 1

Table 1: Key findings from studies 1-4

<table>
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<tr>
<th>Systematic Review</th>
<th>Quantitative survey: dentists</th>
<th>Qualitative interviews with users</th>
<th>Qualitative interviews with health professionals</th>
<th>Component analysis</th>
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<tr>
<td></td>
<td></td>
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<td>GPs</td>
<td>GDPs</td>
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12.30. Lunch

1.00pm. Completing Table 2

<table>
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<td><strong>Component</strong></td>
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<td>---------------</td>
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<td>Content</td>
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<td>Mode of delivery</td>
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<td>Who should deliver the intervention</td>
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<td>Setting of the intervention</td>
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<tr>
<td>Number/duration of sessions</td>
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<td>Acceptability issues</td>
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</table>

2.30. Coffee break

2.45. Finish completing tables, identify unanswered questions.
### Appendix 3 Synthesis day expert contributors

<table>
<thead>
<tr>
<th>Contributor</th>
<th>Details</th>
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<tbody>
<tr>
<td>Contributor 1</td>
<td>Author of this thesis. BSc (hons) in Psychology and Human Resource Management (1997). PGcert Research methods (2003). 8 years experience in social and health services research. Conducted the component analysis (study 1b)</td>
</tr>
<tr>
<td>Contributor 2</td>
<td>Qualified in dentistry in 1998 then embarked on a 2 year general professional training scheme involving rotations within general practice, maxillofacial surgery and clinics at the Manchester dental hospital. Undertook an epidemiological investigation to classify Chronic orofacial pain and identify risk factors, obtaining a PhD in 2006. Previous clinical role as a general dental practitioner. Lead researcher for the survey of dentists (study 1b) and systematic review (study 1c)</td>
</tr>
<tr>
<td>Contributor 3</td>
<td>Professor of Mental Health, RN, BA (hons), Pgdip (ED), MSc, PgD, Accredited Cognitive Behaviour Therapist, Experienced researcher, completed a range of research including case studies, systematic reviews, RCTs and qualitative studies.</td>
</tr>
<tr>
<td>Contributor 4</td>
<td>Senior lecturer in health psychology (PhD awarded 2001) and a practising Health Psychologist (HPC registered). Expertise in doctor-patient communication and specialises in medically unexplained symptoms. Lead researcher and conducted the analysis for the qualitative study of patients and practitioners (study 1b).</td>
</tr>
<tr>
<td>Contributor 5</td>
<td>Clinical background in nursing and midwifery, and a PhD in Health Psychology. Experience conducting of both systematic reviews and meta-analysis since completing a PhD in 1998. Has published several reviews and is currently Unit Lead for a Masters level module - Critical Appraisal and Evidence Synthesis.</td>
</tr>
<tr>
<td>Contributor 6</td>
<td>A psychology researcher, completed an MRes in 2010 for which her dissertation was a qualitative study of GPs views of chronic oral facial pain. Conducted interviews with GPs and carried out analysis for study 1b.</td>
</tr>
</tbody>
</table>
Managing Chronic Orofacial Pain

Karina Lovell, David Richards, Phil Keeley, Joanna Goldthorpe, Vishal Aggarwal.
Acknowledgements:

We would like to thank all the patients with chronic orofacial pain who have helped us to produce this book by sharing their experiences with us. Their insights have been invaluable.

We would also like to thank the research team working on the MUSICIAN study at the University of Manchester for providing the manuscript from which this book was adapted.

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## Step 2

**Understanding how my orofacial pain is affecting me**

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## Step 3:

**Ways of managing my pain**

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## Step 4:

**Managing my chronic orofacial pain in the long term**

| Stories: |
|---|---|
| Ali | 42 |
| Maria | 46 |
| Sara | 57 |
Step 1: What is “managing my chronic orofacial pain” all about?
Introduction.

Our world can be a hectic and challenging place. Despite modern conveniences and advances, many of us find it a difficult place to be. For people with chronic orofacial pain it can be even more challenging and we can become overwhelmed by our world. Yolanda and Jack feel overwhelmed with their pain and how it affects their lives and their worlds. These are their stories:

Yolanda:

I am 28 and I work at a garden centre. I live on my own but I might be moving in with my boyfriend soon. I've had a clicking in my jaw ever since I had a tooth removed 5 years ago and find it difficult to open my mouth wide, for instance when I yawn. I also get a terrible nagging pain in my jaw and over the past few months this has got worse to the point where I have to take time off work because of the pain. I have even more days off sick when it is cold because bad weather seems to make the pain worse.

I find that other things also make the pain worse, for example when I have to lift heavy things at work. Although my colleagues can do a lot of this for me, I would rather do it myself and when I can’t, I feel embarrassed and not good at my job. Although my boss is very understanding, I worry that I will get the sack. I really need to keep my job as my bank account is overdrawn. My pain is much worse when I get stressed, for example when my boyfriend wants to talk about buying a house together. I am worried I won’t be able to afford to pay the mortgage and the bills if my facial pain continues to affect my job. My pain also affects our relationship. One of the problems is that I never know when the pain is going to flare up, so we’re always cancelling plans with friends at the last minute because I don’t feel up to going out, and now it’s getting to the stage where we just don’t make plans at all. We rarely see our old group of friends, and my boyfriend tends to go out on his own now while I stay in and go to bed early. I don’t want to talk to him about the pain and how it affects me as I don’t think he will understand. The doctors and dentists don’t know what causes my pain, so I don’t know what to tell him about my condition.

Over the years I have seen 5 different dentists at 3 different dental practices to try to find out what is causing the pain. Eventually I was referred to a specialist who made a soft splint for me to wear over my teeth at night. The pain did go away for a short while but after a few
days the throbbing sensation returned. Sometimes I worry that the pain will always be this bad and that makes me feel down. When I feel fed up, I feel even less like going out or doing anything much and that makes me focus on the pain more, I feel like I'm in a vicious circle.

I have heard that chronic orofacial pain is related to stress and I can actually relate to that. I know I felt much better when I had a proper break in Spain for a fortnight, my orofacial pain did not flare up at all when I was away from the usual routine, and money and relationship worries. I would like to be able to manage the pain better, but I'm not sure how.

Jack:

I am 55 and divorced with 3 grown up children. I live on my own since my son got married and left home about 3 years ago. Shortly after he left, I had a car accident, which left me with whiplash. The time after the accident was stressful for me because I was left with this pain, and struggled to get compensation from the insurance company. As well as the terrible nagging pain I get in my face, I also suffer from lower back pain so about a year ago I took early retirement from my job as a transport manager. I take a lot of painkillers but they don't seem to do much to help. I did have physiotherapy, and the exercises they gave me to do can make me feel a bit better, but sometimes the pain in my face is so bad, it feels like nothing can relieve it.

I used to do a lot of gardening, go to my son and daughter in law for lunch every Sunday and out for a pint and a curry on a Friday night with some of the drivers from where I used to work, but that has stopped now. I don't sleep well because of the pain so I don't have the energy to do much and I don't like eating in front of other people. This is because I have to cut my food up really small so I don't need to chew much, so it can take me ages to eat a meal. Sometimes I stop for a break to rest my jaw. If I get something too chewy like some fatty meat, I can't cope with it and have to spit it out into a napkin. It's just embarrassing and if I chew for too long, it makes my facial pain worse.

It might sound funny, but since the accident, I've felt like my teeth don't fit together properly. I've been to 2 different dentists, but they both say that my teeth haven't moved and there is nothing wrong with them. Although I'm sure the dentists and doctors I've seen are good, I've been looking on the internet and I've read that you can pay for an operation to
correct the way your teeth fit together. If nothing else works, I might just be tempted to cash in some savings to give it a try because I'm fed up and exhausted and will try anything right now.

I also read that talking to someone can help with chronic pain, but I'm not sure I believe in all this psychological stuff. I know all this pain is not just in my head, and if they had to put up with it, they would think differently. I don't really want to spend a fortune on an operation that might not work, or carry on seeing different doctors and dentists. I would like to get to grips with this facial pain a bit better and stop it from taking over my life, but I'm not sure where to start.

**How could we describe Yolanda and Jack's problems?**

If anything about the way Yolanda or Jack are feeling sounds like some of your own feelings, this book could help you. In fact we have tried to write this book so that people learn how to deal with these kinds of feelings. Of course, everyone is an individual. Everyone is different. Even if you share some of Yolanda and Jack’s feelings, you will also have very different feelings of your own.

In this book we have included advice about using cognitive behavioural therapy (CBT) techniques that have been developed from medical research. However, we have also included things that people with chronic orofacial pain themselves have told us they have found useful. We believe that the combination of both will produce the most informative and practical guide to help people manage their pain. We hope you will manage to find all the information helpful. Most of all, we hope you will put some of these suggestions into practice.

At this point we want to reassure you that you are not on your own. We don’t want you to use the book without support from other people. Managing your chronic pain is a team effort; a partnership. So first of all, let’s meet the team. The team includes you, this book, your facilitator and your friends and family.

**Meet your team**

**You:** You are the most important person in the team. Only you know what you feel like at the moment. And only you can take the steps that are needed to get back to the way you want to be. Actually, you are the only person that really knows what this feels like. You are the expert in how you feel. Receiving help can be hard to do. There is no shame in doing so and you must have had real courage to seek assistance. It’s a tough decision to admit you need help. We all like to think that we are invincible but the bravest people are those who know when to get help. Nothing in this book will take your strength away; in fact we have designed this book to support you as you take steps to help you to manage your chronic orofacial pain better.
However, as we said earlier, this is a team effort. Although you are the person in charge of your own recovery, you are not alone. The next important member of this team is this book.

**This book:** This book will help you manage situations which you are finding difficult at the moment. When you are in pain, concentration can be affected and so we have tried to keep this book as friendly as possible. The book is based on cognitive behaviour therapy (CBT). Before we explain more about the book, let us explain what CBT is.

Cognitive behaviour therapy (CBT) is a treatment which helps people to manage a wide range of difficulties. It was first used to help people who were experiencing anxiety and depression but over the last few years it has been successfully used in many other areas, for example, obesity, sleep problems, chronic pain and other medical conditions.

CBT is a “talking therapy” based on a view that the way we act (behaviour) and our thoughts (cognitions) and our physical sensations (feelings) are all interlinked and change what we do. CBT helps to identify the unhelpful and helpful feelings, behaviour and thinking that you have. It can help you to change the way you think and act and in doing so reduce the impact that these problems have on your life. CBT is about working in partnership with you and together looking at and trying the best solutions. CBT is an umbrella term and there are many interventions that can be used. With a facilitator you choose the intervention that you think best suits you.

Some people feel that having a talking therapy means that their pain or condition is not believed by health professionals or that they believe the pain has psychological origins. This is not true, pain is very real and there are many reasons why pain occurs, but what therapy can help with is learning techniques that help you to manage the pain and importantly, to reduce the impact it has on your life.

This book is divided into steps:

Step 1: “What is managing my chronic orofacial pain all about?” (This section)
Step 2: “Understanding how my chronic orofacial pain is affecting me”.
Step 3: “Ways of managing my pain”
Step 4: “Continuing to manage my pain”.
Stories: Ali, Maria and Sara

Steps 1 and 2 are important for everyone to deal with. Step 3 is different. In it, we describe ways to manage your pain. In this step you can make choices between the different things described to help you. When you are managing your pain better, step 4 looks at things you can do to continue to manage your pain when the programme has finished.

We have used stories to illustrate how you can use the different techniques we describe in the book. These stories are about ordinary people. They show how real people with real problems can manage their chronic pain. Before we
wrote these stories we talked to a lot of people who have experienced chronic orofacial pain about what should go in the book and the stories are based on real experiences. We have also asked doctors, dentists and other health professionals for their advice.

This book has been written by a team of researchers working in the NHS and universities. Our team includes dentists, nurses, psychologists and health researchers. All of us are committed to making life better for people who struggle with chronic orofacial pain. Everything we suggest in the book is something that we know someone else has found useful, or we have personally found helpful. All the techniques are things we would do ourselves. We would feel very happy recommending them to our own friends and relatives.

Your facilitator: Your facilitator will be someone who is trained in cognitive behaviour therapy (CBT) and have specific knowledge about chronic orofacial pain. Their role is to support you as you learn to manage your pain. They will help you to understand your feelings and the impact it has on you. Most importantly, they will help you to choose the most useful exercises for you in the book. Managing chronic pain can be tough. So when you feel discouraged, your facilitator will give you advice and offer you support.

Your facilitator is a really important part of your programme. Think of them like a personal fitness trainer. If you go to the gym or play sports personal fitness trainers don’t do the actual work of getting fit, that is up to the individual. However, the trainer will develop a fitness plan, monitor your progress and keep encouraging you when the going gets tough. Your facilitator will do the same; they are there to support you.

Your friends and family: for many of us, our friends and families are the people we are closest to. They can see when a person they know is acting differently. Sometimes we try to hide how we feel from those closest to us. We might feel embarrassed or we might want to protect them from how bad we feel.

Often we try to hide our feelings and put on a brave face. Sooner or later though, the people that know us well do see changes in us. They see the pain and tiredness; they experience the results of our irritability. Many of us do not want to admit how we are feeling because we are embarrassed or worry that others will not understand. However, if we do talk about how we are feeling with those closest to us then we usually find that they are concerned and supportive.

We believe that families and friends are very important in helping to manage chronic orofacial pain. Everyone must make their own choices about what they say to whom. In general however we would encourage you to discuss both the way you are feeling and the programme in this book with at least one person you are close to.
Tips for helping you to manage your pain.

To help you with your programme, here are some tips that have helped people manage their pain.

**Good and bad days:** You are going to have some good days and some bad days. On bad days you will avoid looking at the book. You might even avoid speaking to your facilitator. You will probably feel guilty about this. However, remember that this is what it feels like to be down. Sometimes we just want to avoid important things. If you put the book down for a while or miss a session with your facilitator, don’t feel guilty about it. Contact your facilitator again. If you really don’t feel able to make an appointment, just ring them and rearrange. They will understand and support you.

**Keeping notes:** Because having chronic pain affects our concentration it is a really good idea to write things down. Keep a record of what you are doing, the exercises and plans you have made. When you begin to manage your pain, you can look back at these and see just what progress you are making.

**Make a step by step plan:** At first it can seem very daunting to work on your problems. Step by step plans break down your recovery into manageable chunks. Doing little and often is the best way to manage your pain.

**Do something every day:** Just like trying to get physically fit, the best programmes involve regular activity. Try to do something from your recovery programme each day, even if it is just one thing. But remember, if you have a bad day it is not the end of the world. Tomorrow is an opportunity to try again.

**Talk to friends, family and your facilitator:** support from friends, family and your facilitator is vital. Keep talking to them. Let them know how you are doing.

**If something is not working, try another thing:** the book is full of different ideas and exercises. Some may not work for you. If this is the case, try another one. Make sure you discuss this with your facilitator. She or he will help you to make the right choices.

There are a number of ways that we know we can help people with chronic orofacial pain – what you need to do is look through the different techniques (your facilitator will help you to do this) and then work on this with you. But perhaps the best way to start is to ensure that you understand what pain means to you and how it affects your life.
Step 2: Understanding how my orofacial pain is affecting me
How is your chronic orofacial pain affecting you?

Many people with chronic orofacial pain have had the condition for months or years, sometimes with pain-free periods in between. People tend to have tried lots of things to make the pain go away, like having surgery on their teeth, using splints or taking painkillers. Often, these things don’t work or only work for a short time before the pain comes back. It can be frustrating to have to attend lots of appointments and still not feel any better.

When most people with chronic orofacial pain are asked how their pain is affecting them, the most common answer they give is how much the pain impacts on their daily lives. For example, people say that some of the most enjoyable aspects of their lives are being avoided or curtailed because of the pain. This was highlighted in Yolanda’s and Jack’s stories in the first section of this book. Being unable to deal with the pain usually means that people stop doing things that they were doing before the pain started. This can be things that are a part of their daily routine such as housework, working, childcare, personal hobbies and interests and socialising with other people. Chronic orofacial pain often means that we stop working or that working becomes a struggle and it also affects our social lives and all the things that we enjoyed doing. Chronic orofacial pain can have an impact on all areas of people’s lives.

Before you choose some of the exercises that you will work through with your facilitator, we need you to do two things. You and your facilitator need to understand the impact that your pain is having on your life and also you may need to know a bit more about orofacial pain.

What is the impact of orofacial pain on your life?

Many people with chronic pain find that writing down the impact of their problems on their life is the first step towards managing their condition. Although it can be quite distressing to list all these things, writing them down can give us something to aim for.

Your orofacial pain may affect your home life, your social life, your work and your personal relationships with partners, families and friends. The things you identify now are the things you really want to change. With your facilitator discuss and write them down on the sheet below.

- What exactly do you find difficult?
- Where and when is this difficult?
- Are the difficulties associated with specific situations or people?

The impact sheet will help you decide what to write. Your facilitator will help you to use this sheet to choose an exercise to help you manage your orofacial pain.
IMPACT SHEET

Home Things around the house, such as housework, cooking, etc.
The things to do with home I find difficult because of my pain are:
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Work Paid, self-employment, home working or caring for others:
The things to do with working that I find difficult because of my pain are:
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Relationships Family and close relationships with others:
The things to do with relationships with others that I find difficult because of my pain are:
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Social Activities Being with other people
The things to do with being with others that I find difficult because of my pain are:
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Personal Activities Doing things alone which you enjoy, such as reading
The things to do with personal activities that I find difficult because of my pain are:
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Some information about chronic orofacial pain.

There is no way of knowing whether one person’s experience of pain is the same as another’s, however most people report their pain as unpleasant – leading to a loss of function in their lives. Pain is the most common reason for people going to see their GP. Sometimes there are obvious reasons for a person presenting to their GP or dentist with pain, for example in the case of a fractured arm or broken tooth; however sometimes the cause is unclear. This is more often the case with chronic conditions, for example, chronic orofacial pain. Often, people with chronic orofacial pain are frustrated that tests and examinations have been unable to find the cause of their problem.

Throughout this book we will use the term “chronic orofacial pain”. This term relates to a number of diagnoses used by dentists and doctors. A doctor or dentist might have called your condition “temporomandibular joint disorder”, “burning mouth syndrome”, “a typical facial pain”, “myofascial pain”, “atypical odontalgia” (toothache) or something similar.

There are many theories about why people develop chronic orofacial pain however at this time we do not know exactly what causes it and there are no known cures.

What most people with chronic orofacial pain want is to decrease the impact that the pain has on their everyday life. An important first step in managing pain better is to have knowledge about what is happening to us. There is no single way a person who is in pain feels. It is an individual experience. However, there are many similar feelings which people have. The following section describes a model that many people use to help them understand and manage their pain better.

Pain has an effect on three different parts of us:

- Things we feel physically (the physical feelings of pain)
- Things we do or stop doing
- Things we think

**Things we feel physically** include the physical sensations you experience with pain. These may include sensations such as shooting, nagging, dull aching types of pain, but may also include difficulty sleeping, sleeping too much, exhaustion, fatigue, poor concentration, tearfulness and poor appetite.

**Things we do or stop doing** include avoiding things because we feel they might be too difficult or because we fear they will cause more pain. We end up not doing things that we previously enjoyed and often our daily routine becomes disrupted.

**Things we think** include worthless or angry thoughts which make us feel less confident. People might have thought that the pain will get worse and they will
end up dependent on others, or that it is a sign of a more serious disease. Some people have thought that life is not worth living, whilst others might have definite thoughts of killing themselves.

**Vicious circle of chronic orofacial pain.**

Things we feel, do and think are all related to each other. For example, our physical feelings can lead to changes in the way we do things and the way we think. If we stop doing things we can feel worse physically and have very negative thoughts. These thoughts can mean that we stop doing things and make our physical feelings worse.

This “vicious circle” of unhelpful thoughts, changes in behaviour and physical symptoms can make the pain less manageable. Here is an example:

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**Pearl**

*Pearl has been experiencing episodes of chronic orofacial pain for 3 years. She describes stiffness in her jaw and a dull, throbbing pain in her cheeks. This is accompanied by feelings of exhaustion, which is made worse by the fact she is unable to get a good night’s sleep.*

*On a bad day (usually about 3-4 times a week) she does not go out or see anyone. She does not open her mouth, other than to drink and eat soup or soft foods like mashed potato and will not speak to anyone as she feels the pain will become worse. She can only manage a few light household tasks, as she finds that lifting heavy items such as the vacuum cleaner causes a painful pulling sensation on her jaw. Pearl does not like to drive on a bad day because she finds concentrating and sitting in the driving position for more than a few minutes makes the pain worse. The painkillers she takes to try to ease the pain don’t make much difference. Pearl does not feel that she can be herself properly. She is constantly aware of physical actions of the mouth, face and jaw and adjusts her behaviour to reduce the pain and discomfort. She feels that things like singing and laughing have to be controlled, and can no longer be done spontaneously. Because she prefers to keep her jaw clamped shut, Pearl rarely leaves the house. She has no social life and is becoming more dependent on others to help her out. She feels guilty and angry that she cannot do more for herself and suffers from lack of confidence and low mood. Often she thinks that things will never get better, and that she will never be her old sociable, happy self again. That makes her feel very sad. The more Pearl has these thoughts, feelings and behaviours the worse her pain is and the less control she has over her pain. This ‘vicious circle’ of thoughts, physical symptoms and changes in behaviour is making the pain worse.*

*For example, because Pearl tightly clenches her teeth together, the muscles around her jaw become tense. She is so afraid of opening her mouth wide she clamps and clenches her jaws shut. This increases her physical experience of facial pain, which evokes more feelings of desperation and guilt. This leads to her becoming more withdrawn and isolated. This and other vicious circles are keeping Pearl feeling less and less in control of her pain.*
Your own personal feelings, behaviours and thoughts.

Now let’s think about you. What are your physical feelings, behaviours and thoughts? Here is a copy of a sheet which you can use to write down how your pain is affecting you. Just jot down the main area where your physical feelings, the things you do and the way you think are a problem for you.

It can be very difficult to write these things down. It is like bringing everything out into the open. Your facilitator will help you with this during the first or second session.

My feelings

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Things I do or things I have stopped doing

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Your own feelings, behaviours and thoughts and how they are linked.

Have a look at your list. Can you identify how the three areas are linked? Write this in the space provided. Once again, your facilitator can help you with this. You might like to discuss it in your next session.

My feelings, behaviours and thoughts are linked in the following ways:

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Setting some goals.

Now you understand how the times or occasions when your physical feelings, your behaviours and your thoughts fit together you can use this knowledge to choose some treatments and activities from this book.

**Setting some goals**

You already know how your mood affects your life from writing it down on the impact sheet. Many people find it a really good idea to set some goals when starting to manage their pain. You should base these goals around the areas where your life is affected by your orofacial pain. That way, you can do something really positive to overcome the impact of your pain. Remember, your facilitator will help you with this.

**Goals in detail**

You are the person who can decide what you want out of your treatment. These will be your goals. Goals will help you to:

- Keep focused on managing your pain
- Be clear about what you want to achieve
- Give you feedback on your progress

A goal is what you want to be able to do at the end of your treatment programme. You should be as clear as you can. You may want to “feel better” or “feel less pain” but ask yourself what “feeling better” means you will be able to do.

Examples of a person’s specific goals:

- To go out for a meal once a week and not worry about whether I will be able to eat the food
- To get to sleep in 30 minutes, six times weekly
- To go for a bike ride three times a week

**Your goals**

What are your goals? We have provided some sheets for you to write this down.

Working with too many goals can be confusing. We would advise you to work with between one and three goals. Here is some advice for setting your goals:

Ask yourself what you want to be able to do

Be as specific as you can by stating how often you want to do something

Set realistic goals, things you want to do in the future or used to do in the past
State goals positively, start with “to be able to …”, rather than, to stop …”.

You can ask your facilitator to go through this with you.

Goals are things to aim for. Pick things that your chronic orofacial pain is getting in the way of. Because of this they should be things you are struggling with at the moment. The techniques in this book are designed to help you reach your goals. So that you know how you are doing, we have written down a simple scale underneath each goal. Circle one of the numbers for each one. This will tell you how difficult you find each goal.

At the moment you should choose goals that are difficult. As time goes by however, we hope that the techniques you try will help you to find it easier to achieve your goals. Re-rating them using the same scale every now and then is an excellent way to monitor your own personal progress. Aim to do this at least monthly during your recovery programme. Your facilitator will be able to do this with you.
## My Goals

### Goal number 1

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Step three: Ways of managing your pain.
There are a lot of different things you can do to manage your pain and reduce the impact it is having on your life. Probably the last thing you want to do right now is make a choice from a great long list of options. This is where your facilitator comes in.

A few pages ago you saw Pearl’s experience of living with chronic orofacial pain. You also looked at your own feelings, behaviours and thoughts. There was a very good reason for this.

This treatment can be divided into techniques designed to improve our physical symptoms, strategies to alter our behaviours and ways to get us to think differently. The idea is to get the vicious circle working in reverse. If our behaviours and thoughts can change for the better, our physical symptoms can improve. If we choose a technique to change our behaviours, thoughts and physical symptoms can improve. Your vicious circle can be turned into a “recovery circle”.

Now is the time to step into your recovery circle. In the following pages we describe a number of useful ways of improving the way you feel. They are not in any particular order of helpfulness, some people use one technique; other people like to try a number of them.

Your facilitator will help you decide which of these techniques might be the best place to start. However, to help you make a choice we have collected some recovery stories for you to read. They are stories about ordinary people who have used some of the ideas in the book to cope with their orofacial pain.

**Improving the way I feel physically**

In the next few pages we have listed the common physical symptoms experienced by many people with chronic orofacial pain. These are the symptoms that can really interfere with your daily lives. We have written down some ideas which you could use to help you to improve these symptoms. If they sound like the kind of thing you would like to try, you should discuss them with your facilitator.

**Poor sleep.**

People with chronic orofacial pain often have disturbed sleep. Sleep problems can take many forms. Some people have difficulty getting off to sleep. Some people wake up early in the morning and are unable to get back to sleep. Some people wake frequently in the night whilst others sleep but wake up without feeling rested. Some people sleep too much, sleeping throughout the day. This can be because they feel so bad and they think that sleep will help or give them some respite from their pain. Other people sleep a lot because they feel so tired and have lost energy.

**If your sleep is disturbed here are some useful dos and don’ts about sleep which you could find helpful**
- Try not to sleep in the day. The problem with not sleeping at night is that we feel down, tired and washed out. This tempts us to nap in the day. Unfortunately napping in the day just creates another vicious circle. The more we take daily naps the harder it becomes to sleep at night.

- Ensure that you prepare yourself for sleep before going to bed. Try to relax for an hour or so before going to bed. Some people find it useful to have a warm bath or a milky drink.

- Eating large meal in the evening may prevent sleep so try to eat earlier.

- Don’t drink tea or coffee before going to bed. Tea and coffee contains caffeine. Caffeine is a stimulant and will keep you awake.

- If you cannot get to sleep, try to relax your body and mind. Focus on resting rather than sleeping. For some people, doing some mental relaxation exercises can help.

- Try to go to bed and get up at the same time each day. Keeping to the same routine every day is more likely to restore your sleeping pattern. Avoid those long lie ins if at all possible.

- Try to do some exercise every day. This could be a brief walk or some gardening. “Little and often” and “start small” are good pieces of advice. A ten minute walk every day is a great start.

**Problems with eating**

Some people with chronic orofacial pain have problems with eating. Because the pain is in their face and mouth people are sometimes scared that eating will make their pain worse. This can make eating a distressing experience. Another problem with suffering from chronic pain is that sometimes, cooking just feels like too much effort. We stop bothering to cook, shop or prepare a meal. If our appetite is poor or we are feeling fed up with the pain, it can seem like there is little point in making an effort. When our mood is low, even if we are tempted to eat, we can tend to choose convenience or junk food.

**If your chronic orofacial pain is causing you a problem with eating, here are some useful do’s and don’t which you may find helpful.**

- Try to eat small meals regularly. It is often easier to face small amounts of food rather than a huge meal all at once.

- If you don’t want to make a lot of effort to prepare food, try to buy healthy food that doesn’t need too much preparation. Fruit, yoghurt, soup and fish are examples of foods which are easy to prepare and easy to eat.
- Try to avoid too much comfort eating – it rarely feels comfortable in the end. It is easier not to buy comfort food at all when you go shopping than to resist eating it when it is in the cupboard.

**Feeling irritable**

Feelings of irritability, frustration, stress and anger are a common experience for people suffering from chronic pain. We can become intolerant of people and snap at them. We do this even with people we don’t know. In turn, this can make us feel guilty about the way we are behaving. Guilty thoughts are common when we are feeling down. They can make us feel even worse.

If irritability is one of your orofacial pain symptoms here are some dos and don’ts which you could find very helpful indeed.

- Try reminding yourself that the way you are feeling is because of your chronic orofacial pain. This is not the “real you”. It is a symptom.

- Get your facilitator and other supportive people on board. Explain to your family and friends that chronic pain is associated with low mood and how that affects people. You could ask them to read this book. The main idea is for you to help your family and friends understand that your irritability is a symptom of your pain.

- Many people find they need to relax. Some simple relaxation exercises might help. Listening to your favourite music is another good way to relax.

- From time to time, even the most placid person needs to take time out. Many people experiencing chronic orofacial pain find that one thing that helps is to have some respite from their day to day lives. Respite can be anything. Mostly it will include something that you find pleasurable, something just for you. This could involve a simple activity such as having a relaxing bath or listening to some favourite music. Other people find that telephoning a friend or going out with friends or family a way to distract themselves.

**Lack of concentration.**

Experiencing difficulties with concentration can be a very distressing symptom of chronic pain. Many people find that they can not pick up a book or a newspaper or concentrate on tasks at work. Our memories seem to deteriorate and we can forget what we have just read or heard. This can also happen in conversation with people.

Actually, our concentration may not be as bad as we fear. Suffering from a chronic pain condition can mean we tend not to listen as we normally do. Because we don’t listen clearly we don’t remember information properly. We
then end up worrying about our concentration. Once we start to worry, our concentration gets worse. It’s another vicious circle.

**If concentration is a problem for you here are a couple of useful ideas which you may find helpful to try**

- One useful suggestion is to write things down. It can be very helpful to keep a list of important things to do. Sometimes repeating what somebody has said either out loud or in our head can help with remembering things.

- Because our concentration can be affected when we are feeling down we often stop doing things like reading. One solution is to read regularly but for small periods of time. Alternatively we could read something that is slightly easier to digest than the material we are used to.

**Fatigue and exhaustion**

Fatigue and exhaustion are very common for people who experience chronic orofacial pain. People experience a loss of energy. Loss of energy is a key symptom of pain and is closely linked to tiredness or fatigue. Energy loss is another vicious circle. The less we do, the less we want to do.

However some people with pain experience bursts of energy and want to take advantage of this feeling. They therefore overdo it and consequently feel much worse the next day. Some people become fatigued because of “booms and busts”, which is when people do lots on one day but then feel exhausted for the next few days. A good way of managing this is explained in the next section.

**If fatigue and exhaustion is a problem for you here is a useful idea which you may find helpful to try**

Although it sounds very difficult to do at first, taking some exercise will actually help with loss of energy. The idea is to break the vicious circle of tiredness followed by inactivity and more tiredness. You should try and plan some exercise into your day every day. This might be a walk, a slow swim or anything that involves even a small amount of movement. An important thing to remember is that exercise is unlikely to make you any more tired than you already feel.

Pacing your activity is very helpful for people who alternate between resting some days and overdoing it on others. Pacing yourself means structuring your day so that it is balanced by activity periods followed by rest period.
Exercise worries

Some people who suffer from chronic orofacial pain worry that exercising will make their pain worse and lose confidence in their ability to move in certain ways. For chronic orofacial pain, this could mean moving the jaw, face or mouth in certain ways, lifting things, altering their posture or exercise in general. Most people who avoid certain activities still find that their pain does not go away as a result.

In fact, avoiding certain movements or exercise can result in muscles becoming weak and the pain becoming worse. We can also feel down about not being able to do the things we’d like to do. Another vicious circle can be created. If your doctor or dentist has not told you to avoid certain movements it is unlikely that they will make your pain any worse even though it might not feel better immediately. Some techniques in the next section might help you to start to gain confidence to move in ways in which you have previously avoided.
Changing the things I do

Behavioural activation.

In this book we have discussed how chronic pain can consist of feeling painful sensations, being physically unwell, feeling tired, thinking unhelpful thoughts and changes in the way we behave. As we have shown, these feelings, thoughts and behaviours are all linked. They end up in a vicious circle where we withdraw or avoid doing the normal things we do.

When we have chronic pain, it is often the pain that controls what we do or don’t do. Generally we do one of two things; either we stop/avoid or greatly reduce all of the things we used to do, or we wait for the pain to become more tolerable and rush around to get as much done as possible (but this often results in us feeling much worse later on). This is referred to as “boom and bust” behaviour. Although the reasons we do this are understandable, it can cause problems for us because the level of pain we are feeling determines our activities and our life. Our lack of control can make us feel hopeless, unhappy or anxious.

Some of the things we avoid are regular, routine activities such as cleaning the house, washing up, cooking a meal etc. Our routines also become disrupted. We change the time we go to bed or get up, when we eat, how we cook and care for ourselves. Although we often moan about our daily routines they do make us comfortable in our surroundings.

Other activities that get disrupted are the things we do for pleasure. These can include seeing friends, enjoying a meal out with our families, reading or doing whatever interests we have. These are the things that in normal circumstances we find pleasurable. They are necessary breaks from our routine.

The third area where we can end up avoiding activities are important, necessary things such as paying bills or confronting difficult situations at work, home or in close relationships. Although the consequences of not doing these things can be quite serious, when we suffer from chronic pain and feel down we can often avoid doing them. Going back to work after a period of sickness can be one such difficult but necessary activity.

Behavioural activation is a technique where we focus on establishing our daily routines, increase our pleasurable activities and do things that are necessary for us. It can help you to be more in control of your pain by planning, pacing and structuring your activities differently and making sure that there are planned rest periods. Research into pacing has shown that this technique makes you feel more in control of your pain, can help to reduce the amount of medication that you take, but most importantly helps to increase the things you want to do. Your facilitator will discuss behavioural activation in more detail with you, but basically it means planning, structuring and pacing your activities as well as incorporating planned rest periods and gradually building them up to a level that is right for you.
How do I start to do this?

There are 4 stages to behavioural activation. If you chose to try it, your facilitator can help you to make start.

Stage 1: is to make a weekly diary of what you are doing now.

Stage 2: is to think about activities that you would like to start doing again. Some of these things will be routine things. Other things will be pleasurable activities such as going out and meeting people and some things will be important activities that may need to be dealt with quickly.

Stage 3: is to make a list of many of these different activities. You will write the most difficult things at the top of the list and the easiest activities at the bottom. When making the lists it is a good idea to make sure that you have some routine, some pleasurable and some necessary activities evenly spread throughout.

Stage 4: is doing the behavioural activation diary to plan out how to start doing these things. You can do this by starting with the easiest activities first and adding activities from higher up your list as time goes on.

At each stage you will be able to discuss your plans and activities with your facilitator. If you wish to read a story of someone who has chosen behavioural activation as part of their programme, then go to page 46.

Stage 1

Take a blank behavioural activation diary.

Each day, write down what you do. Even if you think that you have done nothing, make a note, this is all helpful information. When you record your activities write down some details about what exactly you have done. It can be helpful to record details such as where you were, when you did things and if you were with anyone.
## Behavioural activation diary

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Stage 2.

Think about the things that you wanted to do. Some of these things will be activities that you have stopped doing since the start of your orofacial pain but might contain new activities. This will be discussed in detail with your facilitator.

Remember to include routine activities which need to be done such as shopping and cooking. Also include pleasurable activities that you would normally enjoy. Finally try to think of things that are necessary such as paying bills, dealing with conflict or activities associated with work.

Use worksheet A to list all these activities. Put them down in any order you like.
**Behavioural activation worksheet A**

Write down your routine activities here e.g. cooking, cleaning and shopping

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Write down your pleasurable activities here e.g. going out, visiting friends

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</table>

Write down your necessary activities here e.g. Paying bills

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<th>Activity</th>
<th>Activity</th>
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</table>
Stage 3.

Use worksheet B to organise all these different things into a list, with the most difficult activities at the top of the list and some easier activities at the bottom. Try to make sure that you mix up routine, pleasurable and necessary activities in the bottom, middle and top of the list.

**Behavioural activation worksheet B**

Now try to put your list in order of difficulty

<table>
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<th>Most difficult</th>
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Stage 4.

In this last stage you should take a blank diary sheet to plan out how to start doing some of your activities. Take some routine, pleasurable and necessary activities from near the bottom of the list and write in your diary when you would like to do them. Try to include sufficient rest periods.

Once again, being specific is helpful. Write down what the activity is, where it is done, when it will be done, how it will be done and if it includes other people who it can be done with. Writing things down this clearly will help you when you actually come to do the activity.

Try to schedule something at least once a day, more if you wish, but for most people it is best if they start small.

When you have tried to do some of the activities you have listed, discuss your progress with your facilitator. Over time you can move up your list to do other things. You can go at your own pace and your facilitator will support and encourage you.

For many people even doing what were once pleasurable activities may not bring immediate pleasure. To start with, people often feel a sense of achievement rather than actual pleasure. As the weeks go on you should find that you get back to either your old routine or you develop new ones. The main thing with behavioural activation is to plan carefully and keep going.
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Changing the way I think

Cognitive restructuring.

Cognitive restructuring is a way of changing our unhelpful thoughts by looking at them and challenging them. When we are suffering pain and feeling down we have many unhelpful thoughts such as “I am no fun to be around, I can’t go out for meals or talk and have a laugh anymore”, “I’m in so much pain I can’t do anything in case it gets worse”. They maybe thoughts about the stigma of pain and illness like, “I can’t tell people how bad it is because they will think I am complaining”, “people don’t understand what it is like to have this pain”. There may be thoughts about how to control the pain, such as, “when I have a good day I pay for it the next”, “I just need to take the opportunity of not having pain today” or “resting will help me to get better”. Other thoughts might be linked to emotions such as anger or despair; “why me?” guilt; “I am a burden on others, I don’t want to become dependent” or anxiety and worry; “If I do anything physical it will make the pain worse”.

These unhelpful thoughts often stop us doing things that we want to do. The more unhelpful thoughts that we have the less confident we become. The less confident we become, the less we do which increases the amount of physical pain we experience. We can then have even more unhelpful thoughts. It is yet another vicious circle.

The features of unhelpful thoughts are:

- These are automatic. We don’t think them on purpose, they just appear in our heads
- They seem believable and real at the time they appear
- They are the kind of thoughts that would upset anybody.

You can use cognitive restructuring to help you put your thoughts in perspective. An example of how this is helpful is given in one of the recovery stories on page 57 of this book. If you want to use this technique your facilitator can give you some support.

The stages of cognitive restructuring.

There are three stages to cognitive restructuring.

Firstly, you need to identify exactly what the content of your unhelpful thoughts are.
Secondly, you do something to help you examine the thought more objectively. Sometimes this includes collecting evidence as to how accurate the thought really is.

Finally, you reconsider the thought in light of the evidence you have collected. You can then put the thought into perspective.

**How do I do cognitive restructuring?**

If you want to do some cognitive restructuring you can use a thought diary to collect and write down your thoughts.

**Stage 1**

Each time you feel sad, depressed, frustrated, anxious, guilty, worried or irritable:

- Write down in the first column of your thought diary a brief description of the situation where the thought occurred. You should write down where you were and what you were doing.

- In the second column write down the actual feeling you had. This may be sad, anxious or angry. Also record how bad that feeling was on a scale of 0-100%. 0% is not at all. 100% is I totally believe this thought. An example can be found on the thought diary.

- For the time being, ignore the last 2 columns as you start the diary.

**Thought diary**

<table>
<thead>
<tr>
<th>Situation</th>
<th>Feeling (rate how bad it was 0-100%)</th>
<th>Thought (rate how much you believe this thought 0-100%)</th>
<th>Revised thought (rate how much you believe this thought 0-100%)</th>
<th>Feeling (How bad was it? 0-100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: Sitting doing nothing</td>
<td>Example: Sad 70%</td>
<td>Example: Things will never get better for me 90%</td>
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</table>
We suggest you collect your thoughts for 2 weeks in this way. At the end of two weeks, look at your diary. Preferably also talk to your facilitator about what you have written in the diary. Often these thoughts might all be about a similar topic such as guilt or feeling a failure. Such thoughts are very common when we are feeling unwell and our mood is low.

Stage 2.

Stage 2 is all about collecting some kind of evidence to see if your thought is accurate or not. There are many ways to collect this evidence. Some are more difficult than others. In this book we have described one of the most common ways to do this. It is also one of the most straightforward to do yourself.

We suggest that you examine a frequent thought in more detail from the ones you have collected. To do this, take one thought that you have rated yourself as believing in at least 60% and which is causing you distress.

Write the thought down on top of the “evidence table”. Add in your percentage of how much you believe it. In the evidence table, one column is labelled “evidence for” and one column is labelled “evidence against”.

Next, imagine that you are the judge in a court where the evidence for and against the truth of your thought is being examined. Write down the evidence for and against the thought being true. Remember that you are the judge and you need to present the full picture so that a fair decision is made.

<table>
<thead>
<tr>
<th>My thought</th>
<th>My % belief</th>
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<tbody>
<tr>
<td>Evidence for</td>
<td>Evidence against</td>
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</table>
Sometimes people find this quite difficult. People particularly find it difficult to come up with evidence that the thought is not true. To help you give your thought a “fair trial”, think about the following questions:

- **If my best friend or partner were giving evidence, what would they say for and against this thought?**

- **If you rate the belief in your thought as 75% then there is a 25% chance of the thought you do not believe to be true. Ask yourself what makes up this 25%.**

**Stage 3.**

Now you need to reconsider the thought in light of the evidence you have collected. You should be able to come up with a revised thought. Use the fourth column of the thought diary to write down this new thought. You should also rate how much you believe the revised thought.

In the final column rate your feelings again using the same 0-100% scale. Note how by changing your thought your mood has also changed. This is the way cognitive restructuring can really work to change the way you feel.

**Here are some tips to make cognitive restructuring easier**

- Unhelpful thinking takes time to change. Often you will need to challenge your thoughts several times before change takes place.

- Ask a friend you trust to help you look for evidence for and against your unhelpful thoughts.

- Practice cognitive restructuring with other thoughts. Use your evidence table to judge them.

- As you become more expert in this, try to catch the thoughts and judge them as they actually occur.

- Carry your diary with you so that you can catch and challenge your thoughts straight away.

- Your facilitator will also show you some other techniques to help you. He/she will show you how to carry out some “experiments” to test out whether your beliefs are valid. For example, the person who feels that they are not able to do anything might, with support from their facilitator test this thought out by trying something new.
Step 4: Managing my chronic orofacial pain in the long term
Many people ask what happens when their programme has finished. We would suggest that it is your programme and you should continue with it, including keeping your diaries until you feel that your new routines have become fully incorporated into your lifestyle.

Your facilitator will discuss in detail with you before the end of the session how to keep your routine going and how to cope with “bad days”. With your facilitator you will devise a plan of how to help you continue with your progress.

There are two ways to increase the chances of you staying well.

- Keeping a healthy lifestyle
- Continuing to build on the progress you have made

A healthy lifestyle.

We know that what we do in our lives has an important effect on our health and mood. Lifestyle activities such as regular exercise, positive relationships with other people and making sure we allow some time in our lives for things that give us pleasure all help to keep our health stable. A balanced diet is another important factor in staying well.

We suggest that toward the end of this programme you have a look at your overall lifestyle. See if you wish to identify any changes that could help. Pay attention to exercise, scheduled rest periods, diet, sleep, your balance between duties and pleasures and your close relationships. Is there anything you could do to make any of these aspects of your life more positive? If there are, it could be a really good idea to make some positive changes in the next few weeks.

Continuing to build on the progress that you have made

During your programme, you will have discussed what to do if you start to fall back into your unhelpful routines. With your facilitator you will have written down a plan in case this happens. This plan will be individual to you. It will include monitoring your plan, recognising if problems are happening again and dealing with setbacks. However, we have outlined the basic principles below:

During this recovery programme you have probably learnt a lot about the way you feel about your pain. You will have understood your pain in terms of the way that it makes you feel, the things you have stopped doing and the things you think. We suggest that you pay attention to these aspects of yourself on a regular basis. Notice if you begin to experience any of these feelings again. These could be potential early warning signs that you have stopped managing your pain as well as you had been.
Stories: Ali, Maria and Sara.
Stories

Ali
Ali’s story is about someone who used a technique from the book which is aimed at improving some of the physical consequences of chronic orofacial pain.

Ali is a 42 year old man who works as a maths teacher. In 2003, he began to experience a clicking in his jaw when he tried to bite and chew certain hard foods, such as baguettes. Despite avoiding difficult to eat food, about a year later his jaw became intermittently painful, which he later put down to grinding his teeth at night. Over the years the pain had become increasingly severe and persistent and he also began to develop irritable bowel syndrome. He tried acupuncture, physiotherapy and mouth splints however he still described his facial pain as “unbearable at times”. He does not like to take painkillers, and chose to take ibuprofen only when the pain was most severe; however he found that this only slightly eased the pain, and the effects were short lived.

Ali is married with young children, and although his family were supportive, he felt he was not putting enough back into family life. He felt like he was barely getting by at work, and turned down an opportunity to be considered for promotion to head of department. This was because he was finding it difficult to concentrate, marking and lesson plans were always done at the last minute and he did not feel he would be able to cope with the extra responsibility. Ali had always found that his pain was a lot less severe during the summer break; however last year, just after going back after summer he needed to take a week off when his facial pain and irritable bowel syndrome flared up badly. Ali found that one of his major problems was fatigue, and that if he could just get a good night’s sleep, he would be able to cope better with his facial pain. He said at the time, “The combination of pain and lack of sleep makes me feel a lot less tolerant, more ratty, you know? It makes me feel exhausted, often I am too tired to read my children a bed time story, or spend time with my wife and that can be hard for all of us. I think the stress goes with my job; sometimes I worry a bit more about things though, especially at night which keeps me awake, so I feel even worse the next day”. He tried sleeping tablets a few years ago and they helped a lot but after a few months they stopped working.

Ali had difficulty getting off to sleep and woke often. He reported having about 4 hours sleep a night. He described feeling exhausted when he wakes in the morning and at the end of the working day. He often lay down on the sofa and napped when his children had gone to bed. He had stopped putting them to bed, because he would often fall asleep on his daughter’s bed whilst reading a bedtime story. He took naps during the day at weekends to try to catch up with some sleep. After his naps, he would wake and drink coffee to help to wake himself up again. Once he had woken up, he often found it hard to wind down again, and regularly stayed up late watching television. He would frequently wake up in the night and struggle to get back off to sleep. When this happened he would usually go downstairs to have a cigarette out of the back door. His tiredness and grumpiness caused friction with his wife. They argued over the amount of help he gave her around the house and she felt that Ali was not making any effort to spend time with her and the children. In many ways, Ali found the exhaustion had more of a negative impact on his life than the pain.

With the help of his facilitator, Ali decided on the following goals:
My Goals

Today’s date ………………..

Goal number 1

To sleep for 6 hours a night ………………….. ……………………..

I can do this now (circle a number)

Not at all     Occasionally     Often     Anytime

Goal number 2

To put my children to bed and read to them 3 nights a week without falling asleep

I can do this now (circle a number)

Not at all     Occasionally     Often     Anytime

Goal number 3

To spend an hour in the evening on weekdays catching up with marking and planning

I can do this now (circle a number)

Not at all     Occasionally     Often     Anytime
Ali read some of the techniques in his manual and decided that he would like to do something to improve his sleep. His facilitator suggested that he kept a sleep diary. Ali recorded the following:

- What time he went to bed
- What time he fell asleep
- What time he woke up
- Details of other times of the day that he slept and for how long

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<th>Sun</th>
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<tbody>
<tr>
<td>Woke at 4.45am,</td>
<td>Woke up at 5.30am</td>
<td>Woke up at 4.30am</td>
<td>Woke up at 5.45am</td>
<td>Day off sick.</td>
<td>Woke up at 5.30</td>
<td>Woke up at 7am</td>
</tr>
<tr>
<td>got up at 6.30am</td>
<td>didn’t go back to</td>
<td>didn’t go back to</td>
<td>lay there until</td>
<td>Slept from 11am</td>
<td>got up at 7.30</td>
<td>at 7am, got up at</td>
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<tr>
<td>Fell asleep on the</td>
<td>sleep properly then</td>
<td>sleep at all.</td>
<td>alarm went off at</td>
<td>until 2pm</td>
<td>Went to sleep at</td>
<td>7.30</td>
</tr>
<tr>
<td>sofa at about 8.10pm</td>
<td>alarm went off at</td>
<td>Really bad night</td>
<td>6.30am</td>
<td>2pm</td>
<td>2.30pm, woke up at</td>
<td>Fell asleep on the</td>
</tr>
<tr>
<td>Woke to bed at</td>
<td>6.30am</td>
<td>smoked 2 cigarettes</td>
<td>Short nap on the</td>
<td>4pm, had nap with the</td>
<td>at 4pm, went back</td>
<td>sofa from 9pm to</td>
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<tr>
<td>01.15pm</td>
<td>for about half an</td>
<td>gave up trying at</td>
<td>sofa about 8.30pm to</td>
<td>the baby</td>
<td>to sleep at about</td>
<td>10.45pm</td>
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<td>Fell asleep around</td>
<td>hour</td>
<td>5.45am.</td>
<td>9pm</td>
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<td>5.45</td>
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<td>2.30am</td>
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<td>Fell asleep on the</td>
<td>Went to bed at</td>
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<td>sofa from 8pm to</td>
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<td>Went to bed at</td>
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<td>12.30, went to sleep</td>
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<td>Woke up at 12.30am</td>
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<td>Fell asleep at about</td>
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<td>1.00am</td>
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<td>Woke up about 3.15</td>
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<td></td>
<td></td>
<td>could not get back</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>to sleep at all</td>
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</tbody>
</table>

At the next session with his facilitator, Ali discussed his sleep diary. He was able to see clearly that his sleep pattern was probably not helpful. He was surprised at how infrequently he even tried to go to bed or miss an evening nap.

Ali tried to change his sleeping routine. With the help of his facilitator they agreed that for the 1st week, Ali would go to bed every night, rather than falling asleep on the sofa. He agreed that he would go to bed at 11.00pm every night. He would also not nap on the sofa after work. At the next appointment with his facilitator, Ali had managed to do this every night. It was still taking him an hour or so to get to sleep and he still woke early, around 5.00am, but this regular 5 hours sleep was a great improvement. Although he slept less in the afternoons he found he was much less
tired than he had been previously. Over the next few weeks, Ali developed his sleep pattern so that it allowed him to structure his days better. As he was less exhausted he started to be more active after work. When he got home, he played with his children for half an hour, then sat down at the dining room table rather than the sofa and caught up with some work. He put the children to bed and read to them on Fridays and at the weekend and started to cook the family’s weekend meals. Ali felt that he was less irritable and felt like he played a much more active role in his family. He and his wife get along much better and, although he still had bad facial pain days he felt that overall his pain had reduced and he could manage the pain much better now that he was less exhausted. Six months later, Ali was still working full time, could not remember the last time he had a day off sick, enjoying reading to his children regularly in the evening and felt that work was no longer getting on top of him.

Ali scored his goal sheet again several times during his programme. His ratings went up as he began to feel better and achieve his goals. These are detailed in Ali’s goal summaries:
My Goals

Goal number 1
To sleep for 6 hours a night

I can do this now (circle a number)

0 1 2 3 4 5 6

Not at all Occasionally Often Anytime

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Goal number 2
To put my children to bed and read to them 3 nights a week

I can do this now (circle a number)

0 1 2 3 4 5 6

Not at all Occasionally Often Anytime

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Goal number 3
To spend an hour in the evening on weekdays catching up with marking and planning

I can do this now (circle a number)

0 1 2 3 4 5 6

Not at all Occasionally Often Anytime
**Maria**

Maria’s story is about someone who used behavioural activation, a technique from the book which is aimed at increasing the things people stop doing because of their chronic orofacial pain by helping them to pace their activities and including planned rest periods.

Maria is 58, divorced with 4 grown up children and 2 grandchildren and works part time as a receptionist in a hotel. About 4 years ago she was diagnosed as having chronic myofascial pain by a dental specialist; however she has been experiencing severe throbbing pains around her face and mouth intermittently for about the past 9 years. Over the previous year the pain had become “impossible to cope with” and Maria does not like to open her mouth or use her jaw for too long as she finds it makes the pain much worse. Because her job involves answering the telephone and talking to hotel customers, she reduced her hours to 3 half days per week, however she has been thinking of changing to an office job where she would not need to talk so much. She has also become depressed and has been taking anti depressants as well as a number of painkillers. She has suffered from a low mood in the past, but now feels that because of the pain, it has spiralled out of control.

Maria feels that much of her life is controlled by her facial pain. She is struggling financially because of her reduced working hours, and because she has spent a large proportion of her income on visiting private dentists, alternative practitioners and remedies sold over the internet, in an unsuccessful search of a cure for her facial pain. She generally manages to hold down her job, but after work on bad days she does nothing else. Maria states “I try to make the most of my good days by catching up and cramming everything in. This feels great at the time, but afterwards I am usually in agony and have to rest more”. She feels she does not have any routine in her life and is unable to plan anything because she can not predict how she will be feeling and what she will be able to do. She had lots of thoughts such as “what if the symptoms are a sign that something much worse is wrong with me” and “I want to live a normal life but I can’t manage it with this pain in my face”. Since the pain became severe she had lost contact with many of her friends and began to spend more time using the internet instead. She felt ashamed of her inability to cope with her pain and did not think her friends would understand. She no longer went swimming or for the walks and pub lunches she used to enjoy regularly with friends. Maria had always enjoyed preparing big family meals, but as eating caused her great discomfort, she stopped planning meals and now eats mostly cereal and soup. Maria’s children visited regularly however she often didn’t want them to stay for long as talking made the pain worse. This was particularly tough for her eldest daughter, who was going through relationship problems, and had always come to Maria for chats and advice. They had always been very close, but Maria felt as if she was pushing her away. Although she slept reasonably well, she often went to bed very early, as the evenings seemed unbearably long. She often found it hard to concentrate on the television or a book and she found sleep to be a respite from the pain.

Maria felt that these problems were having an impact on her life in many ways. She wrote on her impact sheet that a big problem was that she was lonely and she wanted to see more of her family and meet with her friends again, even though she did not feel like talking much. She also felt that she would like to start swimming again. A big problem was that she could not afford the repayments on her car. She was getting letters from the finance company and was worried that soon the car would be repossessed. She could not sell it as the car belonged to the finance company until the loan was repaid. This was causing her a worry and she had kept this a secret from her children.
With the help of her therapist, Maria decided on the following goals:

**My Goals**

Today’s date ……………….

Goal number 1
To have a conversation that lasts over 15 minutes with my daughter 4 times a week
I can do this now (circle a number)

0                1              2                 3               4                5              6
Not at all                 Occasionally                     Often                      Anytime

Goal number 2
To go swimming at least once a week …………………

I can do this now (circle a number)

0                1              2                 3               4                5              6
Not at all                 Occasionally                     Often                      Anytime

Goal number 3
To sort out my car repayments
I can do this now (circle a number)

0                1              2                 3               4                5              6
Not at all                 Occasionally                     Often                      Anytime
First of all, Maria completed stage 1 of behavioural activation which involved completing a weekly diary of her current activities. She felt that it had been a typical week. As can be seen by the diary on the next page, Friday had been a good day, but she had suffered for it the next day.
| Time    | Monday                                                                 | Tuesday                                                                 | Wednesday                                                              | Thursday                                                               | Friday                                                                 | Saturday                                                              | Sunday                                                                 |
|---------|------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------|
| Morning | Work                                                                    | Did some shopping on the internet so I don’t have to talk to anyone    | Work                                                                   | Tidied up                                                              | Work                                                                   | Slept in to 10.30am.                                                   | Looked at the news on the internet                                    |
|         | What                                                                    | Where                                                                  | When                                                                   | Who                                                                    |                                                                       |                                                                       |                                                                        |
|         | Where                                                                   | Work                                                                   | Surfed the internet                                                   | Work                                                                   | Work                                                                   | Felt dreadful, in pain went back to bed.                              |                                                                        |
|         | When                                                                    | Who                                                                    |                                                                       |                                                                       |                                                                       |                                                                       |                                                                        |
|         | Who                                                                     |                                                                       |                                                                       |                                                                       |                                                                       |                                                                       |                                                                        |
| Afternoon| Felt fed up, sat watched tv                                            | Filled up the car with petrol at pay at pump so didn’t have to talk   | Nothing – felt fed up                                                | Surfed the internet                                                   | Made a batch of soup for freezing because I eat it all the time       | Had a bath                                                            | Went to see my younger daughter. She invited me for lunch but didn’t feel like eating what she was having |
|         | What                                                                    | Where                                                                  | When                                                                   | Who                                                                    |                                                                       |                                                                       |                                                                        |
|         | Where                                                                   | Work                                                                   | Surfed the internet                                                   |                                                                       |                                                                       |                                                                       |                                                                        |
|         | When                                                                    | Who                                                                    |                                                                       |                                                                       |                                                                       |                                                                       |                                                                        |
|         | Who                                                                     |                                                                       |                                                                       |                                                                       |                                                                       |                                                                       |                                                                        |
| Evening | Had a microwave fish pie – easy to eat.                                | Ate soup,                                                               | Dozed on the sofa, ate soup                                           | Ate porridge                                                         | Made a chicken casserole with mash for my daughter & me, ate lots    | Sat with a heat pack on my face – made no difference to the pain. Had cup a soup | Looked at facial pain support forums on the internet, ate soup          |
|         | What                                                                    | Where                                                                  | When                                                                   | Who                                                                    |                                                                       |                                                                       |                                                                        |
|         | Where                                                                   | Had a microwave fish pie – easy to eat.                                | Ate soup,                                                               |                                                                       |                                                                       |                                                                       |                                                                        |
|         | When                                                                    | Who                                                                    | Dozed on the sofa, ate soup                                           |                                                                       |                                                                       |                                                                       |                                                                        |
|         | Who                                                                     |                                                                       | Ate porridge                                                         |                                                                       |                                                                       |                                                                       |                                                                        |
|         | Went to bed at 8pm                                                     | Went to bed at 8.30pm, read a few pages of my book                     | Watched tv, went to bed at 8.15pm                                     | My son came over with his children – was ok, they did all the talking! | Emma (eldest daughter) came round, had bottle of wine & good chat until 10.30 | Had soup + extra painkillers and went to bed at 7.30pm.               | Watched tv for a bit, fell asleep on the sofa. Went to bed at 8.45pm   |
|         | What                                                                    | Where                                                                  | When                                                                   | Who                                                                    |                                                                       |                                                                       |                                                                        |
|         | Where                                                                   | Went to bed at 8pm                                                     | Read a few pages of my book                                           |                                                                       |                                                                       |                                                                       |                                                                        |
|         | When                                                                    | Who                                                                    |                                                                       |                                                                       |                                                                       |                                                                       |                                                                        |
|         | Who                                                                     |                                                                       |                                                                       |                                                                       |                                                                       |                                                                       |                                                                        |
|         | Bed at 9.30pm                                                          |                                                                       |                                                                       |                                                                       | Bed at 11.00pm                                                         |                                                                       |                                                                        |
Maria also completed the worksheets from stages 2 and 3 of behavioural activation. She made lists of routine, pleasurable and necessary things in her life. When she discussed these with her facilitator, it was clear that sorting her car repayments out was very important.

**Behavioural activation worksheet A**

**Write down your routine activities here e.g. cooking, cleaning and shopping**

I don’t really have a routine, although I would like to.
I would like to be able to enjoy doing something fun in the evenings instead of just going to bed early.
I used to enjoy the ladies only swimming sessions every Monday, Wednesday and Friday afternoons but I hardly go any more.
I love cooking but I’m fed up of making soup all the time. But it’s so easy to eat because I don’t have to open my mouth wide.

**Write down your pleasurable activities here e.g. going out, visiting friends**

I would like to start contacting my old friends and speak to people instead of going on the internet. I would like to be more of a help to Emma.
I used to enjoy walks with a pub lunch at the end
I like spending time with my children and catching up on their news

**Write down your necessary activities here**

I must sort my car payments out. My son works in a bank and he thinks it’s best to get a bank loan over a longer period of time so the payments won’t be as high then I can pay off the car and they won’t be able to repossess it. If I don’t get a move on though he said my credit rating will be too bad for a bank loan.
<table>
<thead>
<tr>
<th>Behavioural activation worksheet B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Now try to put your list in order of difficulty</td>
</tr>
</tbody>
</table>

**Most difficult**
- Sorting out my car payments
- Meeting friends - especially chatting to them for a long time and having meals.
- Going back to work.

**Medium difficulty**
- Having long chats with Emma
- Finding something I feel like doing in the evenings
- Starting up regular swimming again
- Spending more time with my children and being more involved with my grandchildren.

**Easiest**
- Not going on the internet as much
- Cooking different types of food
Maria and her facilitator discussed the behavioural activation sheet 2 and planned some of the activities that she could do. One of the important things the facilitator discussed with her was to do the activities she had planned regardless of the level of pain. With routine activities she decided she would not go to bed before 9.30pm and begin to go swimming again every Monday afternoon. She would arrange to do things with friends that required less talking, such as cinema visits and card games. Maria planned to also consult her cook books and start to prepare more adventurous meals that could easily be cut up into small pieces, and planning for plenty of time to eat the meal.

Maria noticed that some of the things she found most pleasurable, such as eating and conversation were the main things she had started to avoid because of her facial pain. These were the things that had made up her social life, and missing out on them had led to her feeling more depressed. With her facilitator, Maria planned to call her closest friend, and arrange a card game, explaining that she would not be able to chat for more than 10 minutes at a time to begin with. The facilitator stressed that Maria should chat for no longer than 10 minutes at a time, even if she felt like continuing. For the necessary activity, Maria agreed to sit down and complete a budget planner, working out how much she could afford per month for her car. To ensure that Maria paced her activities, rest periods were built in. Maria’s stage 4 behavioural activation diary is shown here. It has a range of activities including routine (red), pleasurable (purple), necessary (blue) and rest periods are yellow.
<table>
<thead>
<tr>
<th>Time</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Morning</strong></td>
<td><strong>What</strong></td>
<td><strong>Where</strong></td>
<td><strong>When</strong></td>
<td><strong>Who</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>work</td>
<td>Chores</td>
<td>work</td>
<td>Chores</td>
<td>work</td>
<td>Fill in budget sheet from bank statements</td>
<td>Fill in budget sheet from bank statements</td>
</tr>
<tr>
<td></td>
<td>work</td>
<td>30 mins rest</td>
<td>work</td>
<td>30 mins rest</td>
<td>work</td>
<td>30 mins rest</td>
<td>30 mins rest</td>
</tr>
<tr>
<td><strong>Afternoon</strong></td>
<td><strong>What</strong></td>
<td>30 mins rest</td>
<td>Walk to the local butchers</td>
<td>30 mins rest</td>
<td>Look after son's baby for an hour</td>
<td>30 mins rest</td>
<td>Visit son</td>
</tr>
<tr>
<td></td>
<td>Swimming</td>
<td>Arranite card game with Joan</td>
<td>30 mins rest</td>
<td>30 mins rest</td>
<td>Ask Emma to go to the cinema next week</td>
<td>30 mins rest</td>
<td>30 mins rest</td>
</tr>
<tr>
<td><strong>Evening</strong></td>
<td><strong>What</strong></td>
<td>Plan a meal for tomorrow</td>
<td>Eat something new</td>
<td>Plan a meal for tomorrow</td>
<td>Eat something new</td>
<td>Plan a meal for tomorrow</td>
<td>Eat something new</td>
</tr>
<tr>
<td></td>
<td>Stay up until at least 9.30pm</td>
<td>Stay up until at least 9.30pm</td>
<td>Stay up until at least 9.30pm</td>
<td>Card game with Joan</td>
<td>Stay up until at least 9.30pm</td>
<td>Stay up until at least 9.30pm</td>
<td>Stay up until at least 9.30pm</td>
</tr>
</tbody>
</table>
Maria told her facilitator the following week that she had managed to do most of the things in the diary. On the Monday she had been in pain and had gone to bed 8pm but for the rest of the week she had gone to bed at 9.45pm. However, despite the pain, she had still managed to go swimming and visit family. She had found filling in the budget sheet very difficult, but established that she could afford £115 per month for a loan. Despite a difficult week, Maria was pleased with what she had done. She enjoyed the rest periods more than she had before, because she felt they gave her ‘permission’ to rest.

With her facilitator, Maria planned next week’s diary. She had enjoyed swimming and planned to go on both Monday and Friday next week. She also planned to call her friend and ask her round for another game of cards. This had been very successful, as there were natural intervals between talking when they concentrated on the game. She also planned a menu for the week comprising more adventurous meals that were still easy to eat. Maria also decided to look at some of the menus for the local pubs and restaurants to see where there were meals she could eat easily and with less embarrassment, with a view to asking some friends to meet for lunch. She also planned to ring her bank manager about making an appointment for the loan.
Maria’s second behavioural activation diary.

<table>
<thead>
<tr>
<th></th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morning</td>
<td>Work</td>
<td>Chores</td>
<td>Work</td>
<td>Chores</td>
<td>Work</td>
<td>Take suit to dry cleaners</td>
<td>Walk to newsagents for newspaper</td>
</tr>
<tr>
<td></td>
<td>work</td>
<td>chores</td>
<td>work</td>
<td>Chores</td>
<td>work</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A week later, the facilitator rang Maria. On 6 of the 7 days, she had gone to bed after 9.30 and had made an appointment at the bank the following week. She was delighted with her progress and had started to develop a routine. Although her pain levels were no different, she felt the pain was more controllable. As can be seen by the diary below, Maria decided to go to bed later in the evenings, see her friend.
again, arrange a short walk and lunch with friends and go to the bank for her appointment. With the help of her facilitator, she also planned a menu for her evening meals next week consisting of a variety of easy to eat foods.

<table>
<thead>
<tr>
<th>Maria’s 3rd behavioural activation diary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Morning</strong></td>
</tr>
<tr>
<td>What</td>
</tr>
<tr>
<td>Who</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Who</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Afternoon</strong></td>
</tr>
<tr>
<td>What</td>
</tr>
<tr>
<td>Who</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Evening</strong></td>
</tr>
<tr>
<td>What</td>
</tr>
<tr>
<td>When</td>
</tr>
<tr>
<td>Who</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
The following week, Maria discussed her progress with her facilitator. Maria had been successful, and had began to get DVDs and books from the library to enjoy in the evenings. She had stuck to the new menu and enjoyed every meal, allowing herself permission to take her time to cut up her food into smaller pieces. She had found that her friends and family understood better than she had thought that sometimes talking was uncomfortable for her, and did not mind if she went quiet for a while. She had been to the bank and sorted out a loan over a longer period of time for her car. This now meant that her car could not be repossessed, and as she owned it outright she could sell it if she decided to and use the money to pay off the loan. The thing she was most pleased about was seeing more of Emma, her daughter, and apologising for not being there for her when she needed to talk. She was surprised to find that Emma was only upset that Maria had not told her how much the pain had affected her.

Over the next few sessions Maria’s routine became more established, she started seeing her friends and family regularly and her pain improved. She also agreed to let Emma move in with her for a while, so she could afford to go back to do a university course. Although talking and eating was still painful, Maria found that she noticed it a lot less than she used to.

Maria’s final diary example shows how much progress she had made in establishing a routine and doing more pleasurable activities with regularly planned rest periods. Maria’s manager, had offered her a different job at the hotel doing office work 3 full days per week. After some discussion with Emma, she had decided she was ready to take up this offer. Maria still had days where her pain was severe, but she felt much more in control of her life.

Maria scored her control sheet again several times during her programme. Her ratings went up as she started to do more with scheduled rest periods.

**Maria’s goal summaries:**

| Goal number 1: To have a conversation over 15 minutes long with my daughter |
|---|---|---|
| Time 1: 1 | Time 2: 2 | Time 3: 5 |
| Goal number 2: To go swimming at least once a week |
| Time 1: 1 | Time 2: 3 | Time 3: 6 |
| Goal number 3: To sort out my car repayments |
| Time1 0 | Time 2: 3 | Time 3: 6 |
Sara
Sara’s story is about someone who used cognitive restructuring, a technique from the book which is aimed at changing the way we think.

Sara is 42 and lived alone with her son who is 17, following a difficult divorce 4 years ago. For the past 3 years Sara had suffered from a burning sensation on her tongue and mouth and a constant throbbing pain in her back teeth. She describes her face being so sore that she could not bear to touch it in some areas and had brought a child’s toothbrush to make it easier to bear the pressure on her rear teeth and gums. Doctors and dentists diagnosed the burning sensation as ‘burning mouth syndrome’ however the pain in her teeth could not be explained, despite Sara having visited 3 different dentists and a specialist.

Sara’s facial pain had become worse when she was made redundant and started to set up her own business as a web designer. She found that her pain made her feel distracted and unable to concentrate on doing the things she needed to do to get the business up and running. Sara felt that the constant pain also caused her to be irritable and angry with herself and her son. She also had difficulty getting off to sleep and often woke in the night. She spent most of the day sitting and believed that resting would help her to recover. However, Sara also felt frustrated that she could not function as she had before. She had wanted to start up her own business for a while, and had felt that her redundancy money would allow her to finally achieve this ambition. However, she felt terrified that she would not be able to take on such responsibility because she would not be able to cope with her facial pain. She felt ashamed that she had only done one piece of work since starting her business and guilty that she was using up her redundancy money. There was tension in Sara and her son’s relationship and they argued frequently. Sara felt that her son disliked and resented her. Her son was learning to drive and wanted Sara to take him for a lesson in her car, but her pain made her impatient and she felt like she could not take him out in the car without becoming angry and tense and causing yet another argument. This made Sara feel like she was a bad mother. She felt ashamed of her condition and although she knew people believed how much pain she was in, she felt they did not understand her illness, and she thought they were always wondering when she was going to get better.

Sara felt that the pain impacted heavily on her life. Before the onset of her chronic orofacial pain, Sara had enjoyed Friday nights out with her friends and was very social. She enjoyed badminton and going to the gym. A friend had told her that one of her colleagues wanted to ask her for a date, but Sara had not been keen. She was worried she would have to cancel if it was a bad day for her pain, and she would make this man feel bad when that happened as he would not understand. She also felt that she was boring because she did not go out or enjoy her hobbies as much anymore and she felt unattractive on her bad days because she could not bear to touch her face to apply makeup or moisturiser.
With the help of her facilitator, Sara decided on the following goals:

<table>
<thead>
<tr>
<th>Goal number 1</th>
<th>To work on my business</th>
</tr>
</thead>
<tbody>
<tr>
<td>Today’s date</td>
<td></td>
</tr>
</tbody>
</table>

I can do this now (circle a number)

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Occasionally</th>
<th>Often</th>
<th>Anytime</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Goal number 2

| To take my son for a driving lesson in the car and keep calm… |

I can do this now (circle a number)

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Occasionally</th>
<th>Often</th>
<th>Anytime</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Goal number 3

| To do a class at the gym 3 times a week |

I can do this now (circle a number)

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Occasionally</th>
<th>Often</th>
<th>Anytime</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Sara felt that dealing with her thoughts would help her most. She felt that if she could feel less angry and frustrated, this would help her to do more things in her life. With the help of her facilitator, Sara learnt how to complete some thought diaries. These helped her to identify the exact type of thoughts she was having, the situations where these thoughts were occurring and how much she believed these thoughts to be true. To start with, Sara filled in these first three columns. An example of one of Sara’s thoughts diaries is shown below.

Sara’s first thought diary

<table>
<thead>
<tr>
<th>Situation</th>
<th>Feeling (rate how bad it was 0-100%)</th>
<th>Thought (rate how much you believe this thought 0-100%)</th>
<th>Revised thought (rate how much you believe this thought 0-100%)</th>
<th>Feeling (How bad was it? 0-100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting at home watching to my son asks me when I’m going to feel well enough to take him out in the car. I shout at him, “probably never so ask your dad for more money for lessons!”</td>
<td>Angry 60% Guilty 40%</td>
<td>I’m horrible and a bad mother, my son must hate me 80%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Friend texts to invite me on a night out</td>
<td>Sad 30% Frustrated 70%</td>
<td>I don’t go out anymore, I’m boring now, they probably didn’t want me to go anyway 90%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Watching dragon’s den</td>
<td>Frustrated 90% angry 85%</td>
<td>I’ll never make a go of my business. I bet those people didn’t have this pain. 75%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sara collected a week of diaries and discussed these at the next session with her facilitator. Through the diaries she saw the main type of thought she could recognise was “of no use to anyone and not doing anything with my life because of the pain”. She saw the link between her thoughts, her belief in how true they were and her mood and subsequent behaviour. She was able to identify the link with her relationship with her son. She understood that her guilt and frustration with her chronic orofacial pain led her to believe that her son disliked and resented her. The
more she believed that thought the more angry she became so she avoided spending time with him which led her to believe that she was a bad mother.

With help from her facilitator, Sara worked on the thought that she was a bad mother and her son disliked her. This was a distressing thought as she believed it to be 80% true. She looked at how true or false this really was. The way she did it was to imagine she was a judge in court where evidence for and against the truth of the thought was being examined. This is shown in Sara’s evidence table.

<table>
<thead>
<tr>
<th>My thought</th>
<th>My % belief</th>
</tr>
</thead>
<tbody>
<tr>
<td>My son doesn’t like me, and I am a bad mother</td>
<td>80%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evidence for</th>
<th>Evidence against</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have no patience with him</td>
<td>He offers to help me do things around the house when I have a bad day</td>
</tr>
<tr>
<td>I don’t do the things other parents do, like take him out in the car</td>
<td>When he played football for his school I came to watch him play nearly every match</td>
</tr>
<tr>
<td>We argue over everything.</td>
<td>He does say he loves me now and again</td>
</tr>
<tr>
<td>He will think I’m a failure because my I’ve not got my business going</td>
<td>My brother said that no one is a perfect parent and that teenagers are always difficult. He said I do a good job of bringing him up on my own. Jake (my son) said he was proud of me when I did that one job for my business</td>
</tr>
</tbody>
</table>

When Sara completed this exercise, she reconsidered her belief in her thought that her son disliked her and that she was a bad mother. She could see the evidence for believing the thought was fairly weak as it was based on feelings and assumptions rather than facts. Instead of believing it to be 80% true she decided that it was no more than 40% true. Because her belief was less, she felt less frustrated and angry when she had these thoughts. With her facilitator, she developed a new thought (called a revised thought) which was “Sometimes my son and I argue and get cross with each other on a bad day, but we have a normal relationship, I’m not a bad mother”. She rated this new thought at 75% and her anger and guilt reduced considerably. This example is shown in Sara’s second thought diary.
<table>
<thead>
<tr>
<th>Situation</th>
<th>Feeling (rate how bad it was 0-100%)</th>
<th>Thought (rate how much you believe this thought 0-100%)</th>
<th>Revised thought (rate how much you believe this thought 0-100%)</th>
<th>Feeling (How bad was it? 0-100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting at home watching tv my son asks me when I'm going to feel well enough to take him out in the car. I shout at him, &quot;probably never so ask your dad for more money for lessons!&quot;</td>
<td>Angry 60% Guilty 90%</td>
<td>I'm horrible and a bad mother, my son must hate me 80%</td>
<td>Sometimes my son and I argue and get cross with each other on a bad day, but we have a normal relationship, I'm not a bad mother 75%</td>
<td>Anger 10% Guilty 30%</td>
</tr>
</tbody>
</table>

Sara repeated this process a number of times with the same thought. She also tackled other thoughts, particularly about her belief that resting her body will help her facial pain. With support and encouragement from her facilitator Sara carried out some behavioural experiments. For example, one experiment was to rest for an entire day and rate her pain levels, the next day she was asked to do some mild activity and again rate her pain. She did this for six days and at the end of the experiment she discovered that her pain levels were less on the days she did some activity. Over the course of a few weeks, with challenging her thoughts and carrying out some behavioural experiments Sara felt that she was in more control of her pain. The more she challenged her thoughts the more confident she became and the more her behaviour changed as she started to do more. She felt much more confident and importantly her mood improved which led to her feeling less angry, which improved her relationship with her son. She allowed him to drive her car for half an hour along some country roads and found that she did not feel the need to prompt or instruct him too much. They did exchange cross words once, when he drove through a huge puddle of muddy water, but both of them managed to see the funny side. Sara started to go back to the gym, at first once a week, but is now managing to make it 3 times. She has just secured a contract to revamp the website for a small local restaurant chain, and is hopeful that this will lead to more work.

As with other recovery stories, Sara’s improvement was not immediate and she continued to have days where she was in pain. She knew that she needed to continue to challenge her thoughts and carry out experiments but she did feel that she managed her pain much better. She also recognised that she had been in a low mood, which had led to her feeling low in confidence, frustrated and angry. She felt that she could use the techniques she had learned to manage these emotions.

Sara scored her goal sheet again several times during her therapy. Her ratings went up as she started to feel better and achieve her goals. These are detailed in Sara’s summaries:
# My Goals

## Today’s date ………………

### Goal number 1

**To work on my business**

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Not at all | Occasionally | Often | Anytime

### Goal number 2

**To take my son for a driving lesson in the car and keep calm**...

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Not at all | Occasionally | Often | Anytime

### Goal number 3

**To do a class at the gym 3 times a week**

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Not at all | Occasionally | Often | Anytime
Appendix 5 SF36

SF-36v2® HEALTH SURVEY (FOUR-WEEK RECALL)

SCRIPT FOR INTERVIEW ADMINISTRATION

These first questions are about your health now and your current daily activities. Please try to answer every question as accurately as you can.

1. **In general, would you say your health is...**  
   [READ RESPONSE CHOICES]  
   (Circle one number)
   
   Excellent ................................................................. 1
   Very good ........................................................................ 2
   Good .............................................................................. 3
   Fair ............................................................................... 4
   or Poor ........................................................................... 5

2. **Compared to one year ago, how would you rate your health in general now? Would you say it is...**  
   [READ RESPONSE CHOICES]  
   (Circle one number)
   
   Much better now than one year ago 1
   Somewhat better now than one year ago ........................................... 2
   About the same as one year ago ......................................................... 3
   Somewhat worse now than one year ago ............................................. 4
   or Much worse now than one year ago .............................................. 5

Now I'm going to read a list of activities that you might do during a typical day. As I read each item, please tell me if your health now limits you a lot, limits you a little, or does not limit you at all in these activities.

3a. **First, vigorous activities, such as running, lifting heavy objects, participating in strenuous sports. Does your health now limit you a lot, limit you a little, or not limit you at all?**  
   [READ RESPONSE CHOICES ONLY IF NECESSARY]

   [IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]

   (Circle one number)
   
   Yes, limited a lot ........................................................................... 1
   Yes, limited a little ........................................................................ 2
   No, not limited at all ....................................................................... 3
3b. . . . moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES ONLY IF NECESSARY]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]
(Circle one number)

Yes, limited a lot ................................................................. 1
Yes, limited a little ............................................................. 2
No, not limited at all .......................................................... 3

3c. . . . lifting or carrying groceries. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES ONLY IF NECESSARY]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]
(Circle one number)

Yes, limited a lot ................................................................. 1
Yes, limited a little ............................................................. 2
No, not limited at all .......................................................... 3

3d. . . . climbing several flights of stairs. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES ONLY IF NECESSARY]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]
(Circle one number)

Yes, limited a lot ................................................................. 1
Yes, limited a little ............................................................. 2
No, not limited at all .......................................................... 3

3e. . . . climbing one flight of stairs. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES ONLY IF NECESSARY]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]
(Circle one number)

Yes, limited a lot ................................................................. 1
Yes, limited a little ............................................................. 2
No, not limited at all .......................................................... 3
3f. . . bending, kneeling, or stooping. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES ONLY IF NECESSARY]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]

(Circle one number)

Yes, limited a lot ........................................... 1
Yes, limited a little ........................................... 2
No, not limited at all ........................................ 3

3g. . . walking more than a mile. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES ONLY IF NECESSARY]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]

(Circle one number)

Yes, limited a lot ........................................... 1
Yes, limited a little ........................................... 2
No, not limited at all ........................................ 3

3h. . . walking several hundred yards. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES ONLY IF NECESSARY]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]

(Circle one number)

Yes, limited a lot ........................................... 1
Yes, limited a little ........................................... 2
No, not limited at all ........................................ 3

3i. . . walking one hundred yards. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES ONLY IF NECESSARY]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]

(Circle one number)

Yes, limited a lot ........................................... 1
Yes, limited a little ........................................... 2
No, not limited at all ........................................ 3
3j. . . . bathing or dressing yourself. Does your health now limit you a lot, limit you a little, or not limit you at all? [READ RESPONSE CHOICES ONLY IF NECESSARY]

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]

(Circle one number)

Yes, limited a lot .................................................................................................................1
Yes, limited a little ................................................................................................................2
No, not limited at all .............................................................................................................3

The following four questions ask you about your physical health and your daily activities.

4a. During the past four weeks, how much of the time have you had to cut down on the amount of time you spent on work or other daily activities as a result of your physical health? [READ RESPONSE CHOICES]

(Circle one number)

All of the time ......................................................................................................................1
Most of the time ..................................................................................................................2
Some of the time ................................................................................................................3
A little of the time ...............................................................................................................4
or None of the time ............................................................................................................5

4b. During the past four weeks, how much of the time have you accomplished less than you would like as a result of your physical health? [READ RESPONSE CHOICES]

(Circle one number)

All of the time ......................................................................................................................1
Most of the time ..................................................................................................................2
Some of the time ................................................................................................................3
A little of the time ...............................................................................................................4
or None of the time ............................................................................................................5
4c. **During the past four weeks, how much of the time were you limited in the kind of work or other regular daily activities you do as a result of your physical health?**

[READ RESPONSE CHOICES]

(Circle one number)

All of the time .................................................................................................1
Most of the time ................................................................................................2
Some of the time ................................................................................................3
A little of the time ..............................................................................................4
or None of the time ..........................................................................................5

4d. **During the past four weeks, how much of the time have you had difficulty performing work or other regular daily activities as a result of your physical health, for example, it took extra effort?** [READ RESPONSE CHOICES]

(Circle one number)

All of the time ................................................................................................1
Most of the time ................................................................................................2
Some of the time ..............................................................................................3
A little of the time ............................................................................................4
or None of the time .........................................................................................5

The following three questions ask about your emotions and your daily activities.

5a. **During the past four weeks, how much of the time have you had to cut down the amount of time you spent on work or regular daily activities as a result of any emotional problems, such as feeling depressed or anxious?** [READ RESPONSE CHOICES]

(Circle one number)

All of the time ................................................................................................1
Most of the time ................................................................................................2
Some of the time ..............................................................................................3
A little of the time ............................................................................................4
or None of the time .........................................................................................5
5b. During the past four weeks, how much of the time have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?  [READ RESPONSE CHOICES]  (Circle one number)

All of the time..............................................................................................................1
Most of the time ........................................................................................................2
Some of the time .......................................................................................................3
A little of the time .....................................................................................................4
or None of the time..................................................................................................5

5c. During the past four weeks, how much of the time did you do work or other regular daily activities less carefully than usual as a result of any emotional problems, such as feeling depressed or anxious?  [READ RESPONSE CHOICES]  (Circle one number)

All of the time..............................................................................................................1
Most of the time ........................................................................................................2
Some of the time .......................................................................................................3
A little of the time .....................................................................................................4
or None of the time..................................................................................................5

6. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? Has it interfered . . .  [READ RESPONSE CHOICES]  (Circle one number)

Not at all ..................................................................................................................1
Slightly .....................................................................................................................2
Moderately .............................................................................................................3
Quite a bit .................................................................................................................4
or Extremely ..........................................................................................................5

7. During the past four weeks, how much did pain interfere with your normal work, including both work outside the home and housework? Did it interfere . . .  [READ RESPONSE CHOICES]  (Circle one number)

Not at all ..................................................................................................................1
A little bit ..................................................................................................................2
Moderately ............................................................................................................3
Quite a bit .................................................................................................................4
or Extremely ..........................................................................................................5
8. How much bodily pain have you had during the past four weeks? Have you had . . .

[READ RESPONSE CHOICES]

(Circle one number)

None..........................................................................................................................1
Very mild...................................................................................................................2
Mild..............................................................................................................................3
Moderate....................................................................................................................4
Severe........................................................................................................................5
or Very severe ........................................................................................................6

The next questions are about how you feel and how things have been with you during the past four weeks.

As I read each statement, please give me the one answer that comes closest to the way you have been feeling; is it all of the time, most of the time, some of the time, a little of the time, or none of the time?

9a. How much of the time during the past four weeks . . . did you feel full of life? [READ RESPONSE CHOICES]

(Circle one number)

All of the time ........................................................................................................1
Most of the time .......................................................................................................2
Some of the time ......................................................................................................3
A little of the time ...................................................................................................4
or None of the time ...............................................................................................5

9b. How much of the time during the past four weeks . . . have you been very nervous? [READ RESPONSE CHOICES]

(Circle one number)

All of the time ........................................................................................................1
Most of the time .......................................................................................................2
Some of the time ......................................................................................................3
A little of the time ...................................................................................................4
or None of the time ...............................................................................................5
9c. **How much of the time during the past four weeks . . . have you felt so down in the dumps that nothing could cheer you up?** [READ RESPONSE CHOICES ONLY IF NECESSARY]

(Circle one number)

- All of the time .......................................................... 1
- Most of the time .......................................................... 2
- Some of the time ......................................................... 3
- A little of the time ....................................................... 4
- or None of the time ...................................................... 5

9d. **How much of the time during the past four weeks . . . have you felt calm and peaceful?** [READ RESPONSE CHOICES ONLY IF NECESSARY]

(Circle one number)

- All of the time .......................................................... 1
- Most of the time .......................................................... 2
- Some of the time ......................................................... 3
- A little of the time ....................................................... 4
- or None of the time ...................................................... 5

9e. **How much of the time during the past four weeks . . . did you have a lot of energy?** [READ RESPONSE CHOICES ONLY IF NECESSARY]

(Circle one number)

- All of the time .......................................................... 1
- Most of the time .......................................................... 2
- Some of the time ......................................................... 3
- A little of the time ....................................................... 4
- or None of the time ...................................................... 5

9f. **How much of the time during the past four weeks . . . have you felt downhearted and depressed?** [READ RESPONSE CHOICES ONLY IF NECESSARY]

(Circle one number)

- All of the time .......................................................... 1
- Most of the time .......................................................... 2
- Some of the time ......................................................... 3
- A little of the time ....................................................... 4
- or None of the time ...................................................... 5
9g. How much of the time during the past four weeks . . . did you feel worn out? [READ RESPONSE CHOICES ONLY IF NECESSARY] (Circle one number)

All of the time .................................................................................................................................................. 1
Most of the time ............................................................................................................................................... 2
Some of the time ............................................................................................................................................ 3
A little of the time ........................................................................................................................................... 4
or None of the time ....................................................................................................................................... 5

9h. How much of the time during the past four weeks . . . have you been happy? [READ RESPONSE CHOICES ONLY IF NECESSARY] (Circle one number)

All of the time .................................................................................................................................................. 1
Most of the time ............................................................................................................................................... 2
Some of the time ............................................................................................................................................ 3
A little of the time ........................................................................................................................................... 4
or None of the time ....................................................................................................................................... 5

9i. How much of the time during the past four weeks . . . did you feel tired? [READ RESPONSE CHOICES ONLY IF NECESSARY] (Circle one number)

All of the time .................................................................................................................................................. 1
Most of the time ............................................................................................................................................... 2
Some of the time ............................................................................................................................................ 3
A little of the time ........................................................................................................................................... 4
or None of the time ....................................................................................................................................... 5

10. During the past four weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends or relatives? Has it interfered . . . [READ RESPONSE CHOICES] (Circle one number)

All of the time .................................................................................................................................................. 1
Most of the time ............................................................................................................................................... 2
Some of the time ............................................................................................................................................ 3
A little of the time ........................................................................................................................................... 4
or None of the time ....................................................................................................................................... 5
These next questions are about your health and health-related matters.

Now, I'm going to read a list of statements. After each one, please tell me if it is definitely true, mostly true, mostly false, or definitely false. If you don't know, just tell me.

11a. I seem to get sick a little easier than other people. Would you say that's . . . [READ RESPONSE CHOICES]

(Circle one number)

Definitely true ........................................................................................................................................... 1
Mostly true ............................................................................................................................................... 2
Don't know ............................................................................................................................................. 3
Mostly false ............................................................................................................................................. 4
or Definitely false ........................................................................................................................................ 5

11b. I am as healthy as anybody I know. Would you say that's . . . [READ RESPONSE CHOICES]

(Circle one number)

Definitely true ........................................................................................................................................... 1
Mostly true ............................................................................................................................................... 2
Don't know ............................................................................................................................................. 3
Mostly false ............................................................................................................................................. 4
or Definitely false ........................................................................................................................................ 5

11c. I expect my health to get worse. Would you say that's . . . [READ RESPONSE CHOICES]

(Circle one number)

Definitely true ........................................................................................................................................... 1
Mostly true ............................................................................................................................................... 2
Don't know ............................................................................................................................................. 3
Mostly false ............................................................................................................................................. 4
or Definitely false ........................................................................................................................................ 5

11d. My health is excellent. Would you say that's . . . [READ RESPONSE CHOICES]

(Circle one number)

Definitely true ........................................................................................................................................... 1
Mostly true ............................................................................................................................................... 2
Don't know ............................................................................................................................................. 3
Mostly false ............................................................................................................................................. 4
or Definitely false ........................................................................................................................................ 5
DO NOT read the following text to the survey respondent

Important Instruction for Interviewer:

When using this script for interview administration of the SF-36v2 survey, note that items 7 and 8 from the Bodily Pain health domain scale are administered in reverse order from the way they appear on the printed SF-36v2 self-administered paper form. Reversing the order of the presentation of these two items facilitates the flow of the interview administration.

When recording responses from interview administration of the SF-36v2, the response to Item 7 from the interview script should be entered in the Item 8 response area on the paper form, and vice versa.

Note: All QualityMetric scoring solutions only support the scoring of items as ordered on the printed SF-36v2 self-administered paper form.
Appendix 6 Manchester orofacial pain disability questionnaire

Below are some statements about problems people have because of pain in their face, mouth or jaws.

*Because of pain in my face, jaws or mouth, during the past month this has applied to me:* (please tick appropriate statement)

<table>
<thead>
<tr>
<th>During the past month this has applied to me: (please tick on line under appropriate statement)</th>
<th>None of the time</th>
<th>On some days</th>
<th>On most/everyday( s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. I cannot open my mouth as wide as I could</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. I cannot touch my face</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. I have difficulty falling asleep</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. I wake up at night in pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. I cannot find a comfortable position in which to sleep</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. I cannot eat hard foods like apples or toast</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g. I take longer to finish my meals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. I no longer enjoy my food</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. I find it sore to kiss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>j. I find it difficult to smile or laugh</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>k. People find me difficult to live with</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>l. I have had to take time off work</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>m. I have lost earnings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n. I have found it difficult to concentrate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o. I have problems performing normal household tasks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p. I would rather be by myself</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>q. I find it difficult to talk for long periods of time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r. I have cancelled social activities and holidays</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>s. I am unable to eat out in restaurants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>t. I feel weary/tired</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>u. I am irritable, angry and easily frustrated</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>v. I cannot stop crying</td>
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<tr>
<td>w. I am worried that I may have a serious illness</td>
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<tr>
<td>x. I feel embarrassed and self conscious</td>
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<tr>
<td>y. I feel depressed</td>
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<td></td>
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<tr>
<td>z. I feel I no longer take any pleasure in life</td>
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</tbody>
</table>
Appendix 7 Brief Pain Inventory

Hunter Integrated Pain Service
Brief Pain Inventory
Dec 2006
Reproduced with acknowledgement of the Pain Research Group
The University of Texas MD Anderson Cancer Center, USA

Date: 
Name: 

1. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts most.

2. Please rate your pain by circling the one number that best describes your pain at its worst in the last week.

   0  1  2  3  4  5  6  7  8  9  10
   No pain  Pain as bad as you can imagine

3. Please rate your pain by circling the one number that best describes your pain at its least in the last week.

   0  1  2  3  4  5  6  7  8  9  10
   No pain  Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain on average.

   0  1  2  3  4  5  6  7  8  9  10
   No pain  Pain as bad as you can imagine

5. Please rate your pain by circling the one number that tells how much pain you have right now.

   0  1  2  3  4  5  6  7  8  9  10
   No pain  Pain as bad as you can imagine

6. What treatments or medications are you receiving for your pain?

Page 1 of 2
7. In the last week, how much relief have pain treatments or medications provided? Please circle the one percentage that best shows how much relief you have received.

<table>
<thead>
<tr>
<th>%</th>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relief</td>
<td>No relief</td>
<td>Complete relief</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. Circle the one number that describes how, during the past week, pain has interfered with your:

a. General activity
   - 0 1 2 3 4 5 6 7 8 9 10
   *Does not interfere*  *Completely interferes*

b. Mood
   - 0 1 2 3 4 5 6 7 8 9 10

c. Walking ability
   - 0 1 2 3 4 5 6 7 8 9 10

d. Normal work (includes both outside the home and housework)
   - 0 1 2 3 4 5 6 7 8 9 10

e. Relations with other people
   - 0 1 2 3 4 5 6 7 8 9 10

f. Sleep
   - 0 1 2 3 4 5 6 7 8 9 10

g. Enjoyment of life
   - 0 1 2 3 4 5 6 7 8 9 10
   *Does not interfere*  *Completely interferes*

---

**Brief Pain Inventory Scoring Instructions**

1. *Pain Severity Score*
   This is calculated by adding the scores for questions 2, 3, 4 and 5 and then dividing by 4. This gives a severity score out of 10.

2. *Pain Interference Score*
   This is calculated by adding the scores for questions 8a, b, c, d, e, f and g and then dividing by 7. This gives an interference score out of 10.
## Appendix 8 Hospital anxiety and Depression Scale

**Researcher initials:  _ _**  
**Date of Assessment: _ _ / _ _ / _ _ _ _**

Please read each item and tick the box which comes closest to how you have been feeling during the past week. Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought out response.

1. I feel tense or wound up:  
   - Most of the time
   - A lot of the time
   - From time to time, occasionally
   - Not at all

2. I still enjoy the things I used to enjoy:  
   - Definitely as much
   - Not quite as much
   - Only a little
   - Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen:  
   - Very definitely and quite badly
   - Yes, but not too badly
   - A little, but it doesn't worry me
   - Not at all

4. I can laugh and see the funny side of things:  
   - As much as I always could
   - Not quite as much now
   - Definitely not so much now
   - Not at all

5. Worrying thoughts go through my mind:  
   - A great deal of the time
   - A lot of the time
   - From time to time but not too often
   - Only occasionally

6. I feel cheerful:  
   - Not at all
   - Not often
   - Sometimes
   - Most of the time

7. I can sit at ease and feel relaxed:  
   - Definitely
   - Usually
8. I feel as if I am slowed down:
Nearly all the time
Very often
Sometimes
Not at all

9. I get a sort of frightened feeling like butterflies in the stomach:
Not at all
Occasionally
Quite often
Very often

10. I have lost interest in my appearance:
Definitely
I don't take as much care as I should
I may not take quite as much care as ever
I take just as much care as ever

11. I feel restless as if I have to be on the move:
Very much indeed
Quite a lot
Not very much
Not at all

12. I look forward with enjoyment to things:
As much as I ever did
Rather less than I used to
Definitely less than I used to
Hardly at all

13. I get sudden feelings of panic:
Very often indeed
Quite often
Not very often
Not at all

14. I can enjoy a good book or radio or TV programme:
Often
Sometimes
Not often
Very seldom
Appendix 9 Illness Perception Questionnaire (revised)

ILLNESS PERCEPTION QUESTIONNAIRE (IPQ-R)

___________________________________________  Date___________________________________________

YOUR VIEWS ABOUT YOUR ILLNESS
Listed below are a number of symptoms that you may or may not have experienced since your illness. Please indicate by circling Yes or No, whether you have experienced any of these symptoms since your illness, and whether you believe that these symptoms are related to your illness.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Have Experienced Since Illness</th>
<th>Symptom is Related to Illness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Nausea</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Breathlessness</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Weight Loss</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Stiff Joints</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sore Eyes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Wheeziness</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Headache</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Upset Stomach</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sleep Difficulties</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Dizziness</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Loss of Strength</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

We are interested in your own personal views of how you now see your current illness.

Please indicate how much you agree or disagree with the following statements about your illness by checking the appropriate box.

<table>
<thead>
<tr>
<th>VIEW ABOUT YOUR ILLNESS</th>
<th>STRONGLY DISAGREE</th>
<th>DISAGREE</th>
<th>NEITHER</th>
<th>AGREE</th>
<th>STRONGLY AGREE</th>
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<tbody>
<tr>
<td>191</td>
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</tbody>
</table>

287
<table>
<thead>
<tr>
<th>VIEWS ABOUT YOUR ILLNESS</th>
<th>STRONGLY DISAGREE</th>
<th>DISAGREE</th>
<th>NEITHER</th>
<th>AGREE</th>
<th>STRONGLY AGREE</th>
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<tbody>
<tr>
<td>My illness has major consequences on my life</td>
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<tr>
<td>My illness does not have much effect on my life</td>
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<tr>
<td>My illness strongly affects the way others see me</td>
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<td>My illness has serious financial consequences</td>
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<tr>
<td>My illness causes difficulties for those who are close to me</td>
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<tr>
<td>There is a lot which I can do to control my symptoms</td>
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<tr>
<td>What I do can determine whether my illness gets better or worse</td>
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<tr>
<td>The course of my illness depends on me</td>
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<td></td>
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<tr>
<td>Nothing I do will affect my illness</td>
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<tr>
<td>I have the power to influence my illness</td>
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<tr>
<td>My actions will have no affect on the outcome of my illness</td>
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<tr>
<td>My illness will improve in time</td>
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<tr>
<td>There is very little that can be done to improve my illness</td>
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<tr>
<td>My treatment will be effective in curing my illness</td>
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<tr>
<td>The negative effects of my illness can be prevented (avoided) by my treatment</td>
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<tr>
<td>My treatment can control my illness</td>
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<tr>
<td>There is nothing which can help my condition</td>
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<tr>
<td>The symptoms of my condition are puzzling to me</td>
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<tr>
<td>My illness is a mystery to me</td>
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<tr>
<td>I don’t understand my illness</td>
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<tr>
<td>My illness doesn’t make any sense to me</td>
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<tr>
<td>I have a clear picture or understanding of my condition</td>
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<tr>
<td>The symptoms of my illness change a great deal from day to day</td>
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<tr>
<td>My symptoms come and go in cycles</td>
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<tr>
<td>My illness is very unpredictable</td>
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<tr>
<td>I go through cycles in which my illness gets better and worse</td>
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<tr>
<td>I get depressed when I think about my illness</td>
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<tr>
<td>When I think about my illness I get upset</td>
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<tr>
<td>My illness makes me feel angry</td>
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<tr>
<td>My illness does not worry me</td>
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<tr>
<td>Having this illness makes me feel anxious</td>
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<tr>
<td>My illness makes me feel afraid</td>
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Appendix 10 Baseline demographic and clinical information

Evidence based management of COFP
Baseline demographic and clinical data.

Patient ID number ............................................................... 

Personal information

1. Date of birth .........................................................  2. Postcode 
..............................................................................

3. Gender:  Male ☐  Female ☐

4. How would you describe your ethnic status?

☐ a. White British ☐ b. White Irish ☐ c. White other (specify) .................

☐ d. Asian or Asian British, Indian ☐ e. Asian or Asian British, Pakistani

☐ f. Asian or Asian British, Bangladeshi ☐ g. Asian or Asian British other (specify) ........

☐ h. Black or Black British, Caribbean ☐ i. Black or Black British (African)

☐ J. Black or Black British other (specify) .... ☐ k. Chinese

☐ l. Mixed ethnicity (specify)  ........................................................................

☐ m. Other ethnic group (specify)
..............................................................................

5. Name of GP 
..................................................................................................................
..............................................................................

6. Address of GP practice 
.................................................................................................................. 
.................................................................................................................. 
.................................................................................................................. 

7. Do you live:
8. SOCIAL SUPPORT

1. How many people are so close to you that you can count on them if you have serious personal problems?

[ ] None
[ ] 1 or 2
[ ] 3 to 5
[ ] More than 5

2. How much concern do people show in what you are doing?

[ ] A lot of concern and interest
[ ] Some concern and interest
[ ] Uncertain
[ ] Little concern and interest
[ ] No concern and interest

3. How easy is it to get practical help from neighbours if you should need it?

[ ] Very easy
[ ] Easy
[ ] Possible
[ ] Difficult
[ ] Very Difficult

Financial burden

9. Are you currently working?

[ ] full-time
[ ] Yes, part time
[ ] No
10. How much do you estimate you have spent on pursuing treatment for your orofacial pain? Include items such as travelling to and from clinics, prescriptions and child care.

£ .......................................................... over (length of time) ..........................................................

11. What is your household income? We would be grateful if you could provide this information so that we can get some idea of the proportion of income people are spending on treatment for chronic orofacial pain.

a. ☐ Less than £60-£89 per week/ Less than £260-£389 per month/ Less than £3,100-£4,699 per year
b. ☐ £90-£199 per week/ £390-519 per month/ £4,700-£6,199 per year
c. ☐ £120-149 per week/ £520-£649 per month/ £6,200-7,799 per year
d. ☐ £150-£199 per week/ £650-£689 per month/ £7,800-£10,399 per year
e. ☐ £200-£249 per week/ £870-1,099 per month/ £10,400-12,999 per year
f. ☐ £250-£299 per week/ £1,100-£1,299 per month/ £13,000-15,599 per year
g. ☐ £300-£349 per week/ £1,300-£1,499 per month/ £15,600-£18,199 per year
h. ☐ £350-£399 per week/ £1,500-£1,699, per month/ £18,200-£20,799 per year
i. ☐ £400-£499 per week/ £1,700-£2,199, per month/ £20,800-£25,999 per year
j. ☐ £500-£599 per week/ £2,200-£2,599 per month/ £26,000-£31,199 per year
k. ☐ £600-£699 per week/ £2,600-£2,999 per month/ £31,200-£35,399 per year
l. ☐ £700 or more per week/ £3,000 or more per month/ £37,000 or more per year
j. ☐ Don’t know

Clinical information

12. Are you currently taking antidepressants?  Yes/ No

If yes:
When did you begin the current course?
..............................................................................................................

13. What prescribed drugs are you currently taking for your orofacial pain?
i. Name of product
..............................................................................................................................
........................................................................
Dosage .................................................................................................................. Date
treatment started ...........................................

ii) Name of product
..............................................................................................................................
........................................................................
Dosage .................................................................................................................. Date
treatment started ...........................................

iii) Name of product
..............................................................................................................................
........................................................................
Dosage .................................................................................................................. Date
treatment started ...........................................

14. **What other types of treatment** have you received for your **orofacial pain**?

Please give details:
..............................................................................................................................
..............................................................................................................................
..............................................................................................................................
..............................................................................................................................
..............................................................................................................................
..............................................................................................................................
..............................................................................................................................
..............................................................................................................................

Do you have any other chronic (experienced symptoms for longer than 3 months) medical conditions? Yes/ No

If yes, please give details

Diagnosis
..............................................................................................................................
..............................................................................................................................

Symptoms
..............................................................................................................................
..............................................................................................................................
..............................................................................................................................
..............................................................................................................................

Length of time you have had the symptoms
..............................................................................................................................

Treatment
..............................................................................................................................
..............................................................................................................................
..............................................................................................................................
..............................................................................................................................

Thank you
Appendix 11 Topic guide

Evidence based management of COFP

Acceptability of intervention: Topic guide

This guide is for participants who complete the intervention and those who leave after receiving at least one session.

What follows is a guide: some themes may emerge spontaneously so the order of the questions may vary as the interview develops. Probe and ask for examples as time permits.

History
1. Tell me about how you became part of this study
2. What did you think it would be like?
3. What kind of treatment did you want?

Intervention
4. What happened during the sessions?
5. How did that fit with what you were expecting?
6. What have you got out of being involved in the study?
7. What changes have you made due to being involved?
8. How did those changes affect you and others?
9. What are your views on the number and length of sessions you received?
10. What are your views on the way the intervention was delivered (telephone /face to face)

Facilitator
11. What was your facilitator like?
12. How does your facilitator compare with other people you have seen for your COFP?
13. We are trying to decide what to call the “facilitators” who deliver this intervention. How do you see their role, and what suggestions do you have?
Manual

14. How useful did you find the manual?

15. What did you think of the between session work?

General

16. If you could make any changes to the intervention, what would you do to make it better?

17. What treatment would you like for your COFP?

Is there anything else you would like to add?

Thank you for your time.
Appendix 12 Participant information sheet

Evidence based management of COFP

The University of Manchester
School of Dentistry
Higher Cambridge Street
Manchester
M15 6FH

The purpose of this information sheet is to explain a research project being carried out by the University of Manchester in partnership with your healthcare provider.

Background

Chronic orofacial pain is pain experienced in the face, mouth, teeth and/or jaws for 3 months or longer and is an important health problem for people. Evidence from other research suggests that guided self help, based on the principles of Cognitive Behavioral Therapy (CBT) could be effective in helping patients manage their orofacial pain. The aim of this study is to pilot an intervention we have developed.

Who will take part in the study?

Patients who have had orofacial pain that can not be explained by underlying pathology for 3 months or longer and aged over 18 years old.

What will this study involve?

You would be allocated randomly to either: take part in a guided self help intervention or receive usual care as prescribed by your specialist. We do not know which one is better.

Guided self help:

The intervention consists of guided self help using a talking therapy which will be delivered using a manual and face to face or telephone sessions with a specially trained facilitator. The face to face sessions will take place at Manchester Dental Hospital or on the University of Manchester Campus. The sessions will last about 45 minutes, over a period of up to 8 weeks. You will be asked to complete a questionnaire before the first session and after the last session. The questionnaire will take approximately 1 hour to complete. You may also be invited to take part in a short interview after you have completed the intervention, or if you decide to leave. Three months after you complete the intervention we will follow up your progress and you will be asked to complete the questionnaire again. You will continue to receive medical or dental treatment as usual.

Usual care

If you are allocated to receive usual care, you will be asked to complete a questionnaire shortly after you agree to take part, 8 weeks later and again after 3 months. The questionnaire will take approximately 1 hour to complete. You will continue to receive medical or dental treatment as usual.

We will ask you for permission to contact your specialist to find out details of any other treatment prescribed during the course of the study and to inform your GP that you are participating in this study.
Will it affect my medical/dental care?
You are completely free to agree or disagree to join the study. Whatever your decision, it will have no effect on your healthcare. Your comments about the treatment you receive for unexplained oro-facial pain during any interviews or conversations with the research team will not be discussed or passed onto your health care provider.

What information will be collected?
The questionnaires you will be asked to complete will be related to how your chronic orofacial pain affects your life and makes you feel. The information you provide for the interviews will be recorded and transcribed, but your name and details will not be used. Any notes will be used only by researchers from Manchester University. Dentists/doctors and hospital staff will not have access to them. The information will be kept in a locked filing cabinet at the University of Manchester Dental School. Direct quotations from your interviews may be used in the write-up of the study and where used, these will be anonymous. No individuals will be able to be identified and your privacy will be protected. If you divulge information which indicates a risk of self harm, or harm to others, we will have to refer the incident to the appropriate authority.

Can I leave the study?
You can withdraw at any time without giving reasons. You may be approached to ask for your reasons but you can decline to answer.

What should I do now?
Please carefully consider this request and the information given above. You will be contacted by a member of the research team after a period of 24 hours who will explain the project to you and answer any questions you might have, or you can contact us using the information given below. If you decide to participate, an appointment will be made for a time convenient for you to consent to the study and for you to complete the first questionnaire.

How can I find out more about the study?
If you have any queries about the study, please contact:
Dr Vishal Aggarwal / Ms Joanna Goldthorpe
Oral Health Unit
University of Manchester Dental School, Coupland 3 Building, Manchester, M15 6FH
Telephone: 0161 275 6623 / 3749
If you have concerns during or following your participation in the study please contact Professor Karina Lovell on 0161 306 7853

What if there is a problem?
Complaints
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance coordinator on 0161 2757583 or 0161 2758093 or by email to research-governance@manchester.ac.uk.

This project is sponsored by the University of Manchester
The research to be carried out has been approved by the Research Ethics Committee appointed by the Health Authority. This does not imply any endorsement.