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“I just wanted someone to tell me it wasn’t all in my mind and do something for me”: Qualitative exploration of acceptability of a CBT based intervention to manage Chronic Orofacial Pain.

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Abstract

Introduction: Evidence suggests that psychosocial management may produce improved outcomes for patients suffering from Chronic Orofacial pain (COFP), when symptoms can not be attributed to pathology. A complex intervention, based on Cognitive Behavioural Therapy (CBT) was developed by a multi- disciplinary team, using evidence synthesis. An important element of developing and evaluating complex interventions is to establish acceptability to stakeholders; therefore qualitative interviews with patients were carried out. Objectives: To explore levels of acceptability of a complex intervention to manage COFP. Method: Semi-structured interviews were carried out with 17 participants who had been referred to the intervention. Thematic analysis was used to identify emerging issues and themes from the data.
Results: Themes relating to processes of engagement with the intervention emerged. Important processes were: identification with the intervention, feeling believed and understood, obtaining a plausible explanation for symptoms, degree of perceived effort required to engage, acceptance of having a long –term condition and receiving demonstrative, positive feedback. Conclusion: Patients presenting with unexplained COFP in a secondary care setting are able to accept a CBT based intervention to manage their condition. Findings may offer guidance for dentists who are unused to referring patients to psychosocial interventions and inform the way dentists communicate the nature of unexplained symptoms to patients.

Introduction

Chronic Orofacial pain (COFP) is distressing and disabling to sufferers and can be costly to patients, health services and society. 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 (1). Consequently, diagnosis tends to be made by assessment of symptoms. Despite this, patients tend to be treated according to a biomedical model, often by mechanistic and invasive procedures, which do not have a strong evidence base (2–4). Limited evidence suggests that cognitive behavioural therapy (CBT) based management may produce improved outcomes for patients. However published studies are few in number and do not contain detailed accounts of interventions used or guidance on how they should best be delivered (5).

A guided self management intervention was developed based on CBT principles, using Medical Research Council (MRC) guidance for the development and evaluation of complex interventions (6,7).The intervention was developed using findings from a best evidence synthesis of 3 specially conducted studies (systematic review, (5) survey of dentists (8) and a qualitative study of dentists, GPs and patients (9). A full review of this process is available (10). The resulting intervention consisted of a manual and a facilitator and was entitled “Managing Chronic Orofacial Pain”. An existing manual for the management of chronic widespread pain (11), which produced evidence of positive effects for patients, was adapted for use with COFP patients. Two researchers (dentist and psychologist) were trained as facilitators for the intervention and supervised by an experienced CBT therapist.

As part of a mixed- methods exploratory study to assess potential for the intervention to bring about positive change and to investigate parameters for a larger randomised control trial (10), interviews were conducted with participants to explore acceptability of this new complex intervention. 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 (12,13). When developing and evaluating complex interventions, it is necessary to establish some degree of acceptability to those who may benefit from it and to explore the context in which it is delivered (6,7). Patients will be able to experience the potential benefits of any treatment only if they are able to engage with its components. For this qualitative piece it was important to explore if patients presenting with physical symptoms of oral or dental pain at a secondary care setting would engage with an intervention that aimed primarily to improve psychosocial outcomes. Therefore the aim of this study is to explore acceptability of this CBT based intervention to manage Chronic Orofacial Pain.

Methods

The study received ethical approval 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. Informed consent was obtained for all participants.

Participants and recruitment

Participants were recruited from the temperomandibular disorder, oral surgery and oral medicine clinics of three secondary and tertiary care settings in Northwest England. Patients were randomised to either intervention or control group (treatment as usual) by an independent trials unit, using stochastic minimization (14).

Adults aged 18 and over with persistent pain in their face or mouth for 3 months or longer, which cannot be explained by pathology, referred to secondary care outpatient clinics were included. Participants currently receiving psychological therapy for pain, taking a prescribed dose of anti depressants less than 3 months prior to recruitment or current suicidal ideation (assessed at baseline by PHQ-9 questionnaire) were excluded, as were those who did not have sufficient level of English to take part in the trial.

Nineteen participants were allocated to the exploratory study intervention group. They had either completed the intervention (taken part in > 2 sessions) or dropped out (< 3 sessions). Six participants completed >6 sessions (the maximum number being eight) sessions, of which the psychologist facilitated five. Fourteen participants (74% of the total intervention group) took part in the interviews. Two participants dropped out of the study and a further three could not be contacted. Table 1 describes the characteristics of participants by sex, age, number of intervention sessions received and mode of delivery.

Table 1. Participants

Participant number	Sex: f/m	Age	No. of sessions	Mode of delivery (Phone/ face to face)	Background of facilitator
2	f	64	7	Phone & face to face	Psychology
*3	f	72	1	Face to face	Dentistry
4	f	49	8	Phone & face to face	Psychology
5	f	32	7	Phone	Dentistry
6	m	34	5	Face to face	Dentistry
7	f	36	8	Face to face	Psychology

8	f	49	8	Phone	Psychology
9	f	66	4	Phone	Dentistry
*10	f	54	0	N/A	Psychology
11	f	65	8	Phone	Psychology
12	f	47	8	Phone & face to face	Psychology
13	f	64	5	Face to face	Dentistry
14	f	50	5	Phone	Dentistry
19	f	21	4	Face to face	Dentistry

* Participants who subsequently withdrew from the study

Interviews

Interviews were semi structured with interviewers (researchers) following topic guides as prompts, but allowing for exploration of participant generated issues in a participant - centred approach to data generation. Topics for discussion were identified through reviewing relevant literature and discussions with the multi-disciplinary research team. These included: patient experience prior to taking part in the trial; content of the intervention; views of the facilitator and intervention manual; suggestions for improvement. Areas of relevance to the research question were explored as they arose during the interviews and open-ended questions were used to encourage participants to elaborate on relevant topics.

Interviews were conducted approximately 2 weeks following completion of the intervention. They took place over the telephone or face to face at a university setting and averaged 35 minutes (range = 11.45 - 47.5 minutes) and. They were audio recorded and transcribed verbatim, at which point any identifying information (e.g. names and places) was removed.

The interviewers were a female postgraduate student with a background in psychology (JG) and a male academic dentist (VA). Interviewers had not previously treated participants. A conversational style was used throughout the interviews order to place the participant at ease and elicit a richer response. However, the notion of a friendly conversation implies an established relationship with some form of reciprocity (15) 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.

Analysis

Thematic analysis (16) 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. Use of the constant comparative method (17) helped to ensure that the analysis was consistent and based on evidence from the data. Categories and memos were coded into a series of documents that were continually refined and elaborated. Coding and analysing data was carried out in parallel with completion of interviews. Categories were collapsed and widened as new data emerged with the researcher returning to texts to compare incidents for each theme. Analysis was completed when no further themes emerged from the data (data saturation was reached). The analysis was conducted initially by JG and validated through discussion with the wider research team over a course of five meetings.

Results

The findings revealed six themes relating to engagement with the intervention: identification with the intervention, feeling believed and understood, obtaining a plausible explanation, effort and conflict, acceptance of having a chronic condition and receiving demonstrative positive feedback. Each are described below and supported by illustrative data.

Identification with “Managing Chronic Orofacial Pain (COFP)”

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

Identifying with the treatment model.

The extent to which participants identified with both their prior ideas of what the intervention involved and what was expected of them, and their subsequent experience of taking part impacted on their ability to engage. Some patients initially felt 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.

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, and had built up relationships with practitioners. Participants also expressed altruistic feelings towards organisations.

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*”* (p04 15-28)

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, 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 (p03 31-45 dropped out after 1 session)

Identification with “people like me”

Discovering that there were other people with COFP was fundamentally important. Participants were generally positive about stories and vignettes contained in the manual, relating to others’ experience of COFP. 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 *… But then I realised it’s a condition that* is not widely recognised, but there are people who have i*t” (p8 54*-57)

The vignettes 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. Identification with the stories seemed to offer countenance to participants, facilitating a good therapeutic environment.

I thought the book was very good, *reading peoples' cases studies, …* you do feel *freaky … but I have never actually read someone's case history like in the book (p04* 412 -424)

Feeling believed and understood

Participants had often undergone repeated investigations and consultations to find an underlying cause for their condition. Consequently, participants felt stigmatised, and 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 think it was just talking *to someone who won't judge you … 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 their symptoms may have been met with some scepticism from others, participants were often relieved the find that their accounts were accepted within the context of the intervention.

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 was evidence that participants were suffering from a condition that the medical profession took seriously:

I gave this to my husband to read 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)

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 to receive a plausible explanation for symptoms. Participants had generally received a diagnosis in secondary care, however they required a credible 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 understand it is some form of condition, which before *you couldn't really describe to anybody can you? If you have a broken limb people could see that, couldn't they* ?(p8 66-70)

Participants had 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)

Possible causal models for symptoms had been offered and were sometimes discussed during “Managing COFP” sessions. Discussions tended to focus 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, creates muscle tension which in turn causes pain. A second explanation was that a nerve had become sensitive due to previous dental work or a now resolved pathology. These accounts appeared sensible to participants and compatible with their current beliefs and expectations around COFP.

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)

Effort and conflict

Two participants who later withdrew 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 (P10 64-89)

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* (p10 135-160)

Other, more debilitating illnesses could undermine participants’ abilities to engage with “Managing COFP”.

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)

Acceptance of having a chronic or long term condition

An important part of engaging with “Managing COFP” was an acceptance that this illness was long term. 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.

Some participants were happy to self – manage their symptoms and felt 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 ... 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 (p29* 239-253)

Participants who successfully engaged with the intervention had often tried a number of previous treatments, typically analgesics, anti-depressants and splints, often used long -term. Lack of effective results could result in frustration and despair and “Managing COFP” intervention offered an acceptable alternative:

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)

Demonstrative positive feedback

Demonstrative positive feedback (as opposed to encouraging words) was helpful to participants, who found it encouraging when techniques worked and symptoms seemed to be improving. Use of diaries, and scoring symptoms according to severity could provide reassurance that a flare up would be followed by a period of remission or decreased pain.

I started to put on a pain score 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 … it was also* showing me how I was improving on the pain level so again, that was reassurance (p11 122-139).

Discussion

The main finding from this study is that “Managing Chronic Orofacial Pain” is an acceptable intervention. Participants in this study were able to accept and engage with the intervention and were generally positive about their treatment.

Engagement with the intervention was initially 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 sustaining engagement during the course of treatment were acceptance of having a long term or chronic illness and receiving positive, demonstrative feedback.

Participants in this study were not 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 medically unexplained symptoms have found that many participants can find it difficult to accept explanations based on psychological approaches. For example, Wearden and Chew -Graham (2006) (18) 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. However, this may be due to a fear of being dismissed or having all their concerns attributed to mental health problems, rather than a lack of understanding of the relevance of psychological symptoms (19). It seems that the approach taken in this intervention, in particular feeling listened to and understood, may have facilitated these discussions and helped patients trust their practitioner with this information. Further research is needed to understand how this patient group in particular became engaged with psychological services, and the roles that dental practitioners and medical practioners may play in supporting this during consultations. 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.

The background of the facilitator did not impact on the ability of the participants to engage with the intervention or perceived satisfaction with their progress. This suggests that this intervention does not need to be delivered by a dentist to have credibility with patients. Therefore there is scope for investigating the involvement of professionals from a variety of sources and agencies in long-term implementation of this intervention.

Sample characteristics

Although there are more females (66%) than males (34%) in the UK general population with COFP symptoms (20), our sample was disproportionately female (just over 93% of participants).

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 small sample may have distinct characteristics that separate them from patients presenting in primary care and acute settings.

Strengths and limitations of the study

This study offers a valuable insight into ways in which psychological interventions can be introduced to patients and how engagement might be sustained. It is the first to explore the acceptability of a psychological intervention for this patient population and the findings have implications for offering similar approaches in other settings.

The 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 particular study.

Limited resources meant that interviewers had multiple roles in the research. This may have allowed inherent biases and previously established relationships to have impacted on the data in a number of ways. Interviews may have been affected by inherent bias towards the intervention held by those who were also involved in its delivery. The backgrounds of the facilitators (dentistry and psychology) may have influenced the lines of questioning pursued, for example the dentist may have been more interested in clinical outcomes, and the psychologist inclined towards issues of psychological wellbeing. However, three experienced qualitative researchers were closely involved in supporting the analysis and two other researchers provided further analytical support. This helped to ensure that the data and findings of the study had credibility.

Some participants perceived participation with the intervention to be prohibitively effortful, and conflicted with lifestyles. Other medical conditions could be perceived as more serious or debilitating and their management was prioritised over COFP. As a result, suggestions can be made for possible modification of the intervention in its current form. Use of other health technologies could be investigated for delivering techniques modeled 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. Further research is needed to explore different ways in which “Managing COFP” might effectively and acceptably be delivered.

It is possible that COFP patients who could not identify with or accept a psychosocial model of their illness did not consent to be in this study. This small sample may therefore reflect the views of a self-selecting group who found the prospect of a self help intervention acceptable, possibly through previous engagement.

An exclusion criteria of this study was that participants had a sufficient level of English languages skills. This was a pragmatic decision, based on resources available for this small study. There are an estimated 200 languages spoken in Greater Manchester (21) therefore health literacy issues of non- English speaking populations may impact on both the implementation of findings in a clinical context and initial recruitment. Interpretation and translation resources should be identified prior to a larger clinical trial of the intervention.

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.

It is not known why some patients decided against participating 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.

Conclusion

Findings show that the intervention, “Managing COFP” was acceptable to participants. In comparison, 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. Findings suggest that features of engagement, such as accepting the long term nature of symptoms, 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 widening access to the intervention, in addition to increasing recruitment to a future randomised control trial of the intervention, and improving attrition rates.

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