# A Pilot Randomized Controlled Trial of a Guided Self-Help Intervention to Manage Chronic Orofacial Pain

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**Aims:** To conduct a pilot trial to test the feasibility of a guided self-help intervention for chronic orofacial pain. **Methods:** A pilot randomized controlled trial was conducted to compare the intervention with usual treatment. A total of 37 patients with chronic orofacial pain were randomized into either the intervention group (n = 19) or the usual treatment (control) group (n = 18). Validated outcome measures were used to measure the potential effectiveness of the intervention over a number of domains: physical and mental functioning (Short Form 36 [SF-36]); anxiety and depression (Hospital Anxiety and Depression Scale [HADS]); pain intensity and interference with life (Brief Pain Inventory [BPI]); disability (Manchester Orofacial Pain Disability Scale [MOPDS]); and illness behavior (Revised Illness Perceptions Questionnaire [IPQr]). Bootstrap confidence intervals were computed for the treatment effect (ES) posttreatment and at 3 months follow-up and adjusted for baseline values of the outcome measure by using analysis of covariance. **Results:** At posttreatment and the 3-month follow-up, 11 participants in the intervention group and 7 in the control group failed to complete outcome measures. The intervention was acceptable and could be feasibly delivered face to face or over the telephone. Although the pilot trial was not powered to draw conclusions about the effectiveness, it showed significant ($P < .05$) effects of the intervention on physical and mental functioning and treatment control. **Conclusion:** The self-help intervention was acceptable to patients and allowed them to better understand and self-manage chronic orofacial pain. It showed potential effectiveness on outcome domains related to functioning and illness perception. Further research is needed to understand the cost effectiveness of the intervention for chronic orofacial pain.
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**Keywords:** *behavioral, chronic orofacial pain, pilot trial, self-help intervention*

Chronic orofacial pain is common in the general population with a prevalence of 7%[1] and is a frequent cause of patients consulting outpatient clinics.[2] The role of psychosocial factors in the onset and maintenance of chronic orofacial pain is well established.[3–5] There is previous evidence from qualitative research that dental clinicians and patients recognize the role that psychological factors can play in developing and maintaining chronic orofacial pain[6]; however, management strategies are largely limited to biomedical interventions.[7,8] Achieving a diagnosis is problematic[9] but important for all parties in legitimizing symptoms.[6] Practitioners view chronic orofacial pain as a nondental problem and feel ill equipped to manage the condition.[6] Frustration at the current inadequacy of chronic orofacial pain management often leads to conflict with, or disengagement from, the clinician-patient relationship.[6] In cases of chronic orofacial pain where medical management is unsuccessful, psychosocial interventions may be helpful in re-engaging and motivating patients, particularly when they are in an established vicious cycle of negative thoughts and avoidance behaviors, which is not uncommon in patients with these long-term conditions.[10] Such interventions have the potential to be cost effective and available to a large number of patients.

A Cochrane systematic review[11] has shown that psychosocial interventions are effective in improving long-term outcomes for patients with chronic orofacial pain. However, this evidence was weak, given the

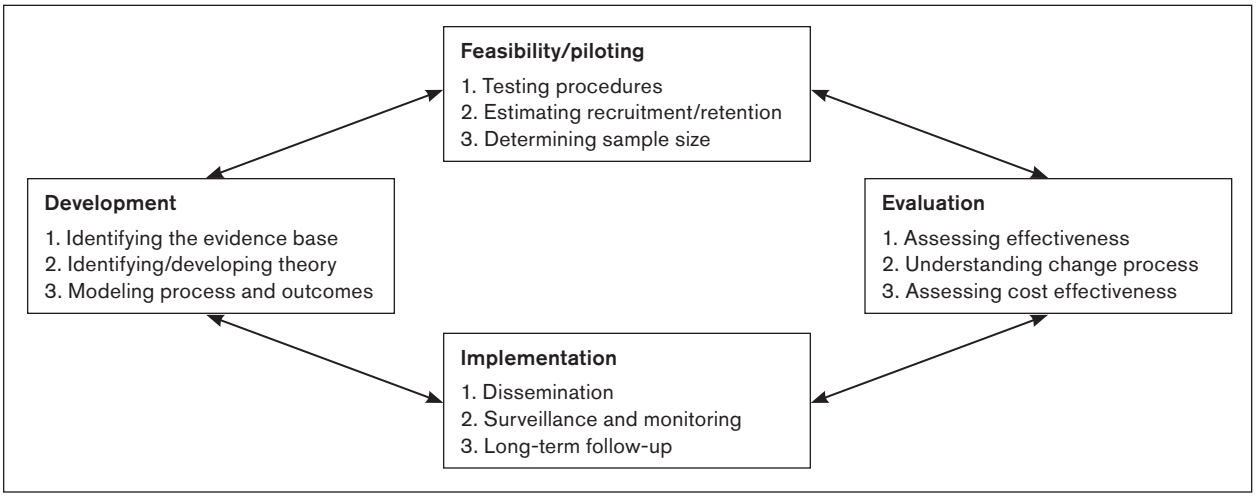


**Fig 1** Key stages in developing and evaluating complex interventions (Adapted from Craig et al[12]).

high risk of bias of the included trials. Furthermore, trials were poorly reported and specific components used within psychosocial interventions were unclear, as were the mechanisms by which the interventions brought about change in outcomes. The number of sessions and mode of delivery were often unreported. Interventions were designed for use in tertiary care and did not address important issues regarding feasibility and acceptability to both patients and clinicians.[11]

The UK Medical Research Council (MRC) guidelines[12] (Fig 1) were therefore used to develop a complex intervention for chronic orofacial pain. For the development phase, evidence from a number of key studies was identified and synthesized in line with previous methodologic work in this area.[13] The Cochrane systematic review[11] was used to identify potential components of the intervention; qualitative work[6] and a national quantitative survey[14] provided an understanding of the needs of both patients and clinicians and addressed potential problems regarding acceptability and feasibility. The end product of the development phase was therefore a guided self-help manual for chronic orofacial pain, "Managing Chronic Orofacial Pain,"[15] and was similar in design to an intervention developed for the management of chronic widespread pain.[16] The aim of the current study was to conduct a pilot trial to test the feasibility of this guided self-help intervention for chronic orofacial pain. Specific objectives were to inform a future full-scale randomized controlled trial (RCT) to evaluate the cost effectiveness of the intervention to assess recruitment and randomization processes; to determine the most appropriate outcome measures and therefore inform sample size calculations for a full trial; to assess changes in outcome measures, follow-up response rates, and missing data at postintervention and at follow-up; and to determine the feasibility of delivering the intervention.

## Materials and Methods

### Design

The design of the study was a pragmatic pilot RCT. Acceptability of the intervention was also examined by using qualitative methods and has been reported in a separate paper.[17] The study was approved by the National Research Ethics Committee North West (Preston, UK) (reference 11/H1016/6) and was indemnified by the University of Manchester Committee on the Ethics of Research on Human Beings.

### Study Setting, Participants, and Recruitment Process

Given the pragmatic design, participants diagnosed with chronic orofacial pain and with no underlying medical pathology were recruited into the study. A diagnosis of chronic orofacial pain is predominantly made in secondary care once underlying medical conditions and pathology have been excluded. Quantitative[14] and qualitative evidence[6] in studies conducted while the intervention was developed showed that primary care practitioners felt that they did not have the skills or time to diagnose and manage chronic orofacial pain patients.[6] Furthermore, misdiagnosis was common in primary care[14]; underlying pathology was either missed or implicated when it was not present. Participants were therefore recruited from secondary care. To ensure that a range of chronic orofacial pain conditions and demographic areas were encompassed, recruitment was under-

taken at the temporomandibular disorders (TMD) and oral medicine clinics of the University of Manchester Dental Hospital (located in inner city Manchester) and the maxillofacial outpatient clinic at North Manchester General Hospital and Salford Royal NHS Foundation Trust (located in the suburbs of Manchester). The TMD department used the Research Diagnostic Criteria for TMD and the oral surgery and oral medicine departments also used appropriate criteria to diagnose other facial pains such as burning mouth syndrome and idiopathic facial pain. All clinicians who made the diagnoses were specialist consultants who had been trained to diagnose facial pains and received such training as part of their training to be accredited into their specialties. The diagnoses were therefore accurate, and patients were appropriately included into study groups. The diagnoses of the participants fell into broad categories of chronic TMD (excluding internal derangements and joint-related problems that had an obvious cause), burning mouth syndrome, and idiopathic facial pain (some cases had a neuropathic element). Participants were assessed for eligibility during appointments scheduled by their consultant, who took informed consent to pass their name and phone number to the research team. The research team then arranged to meet with the participant to take full informed consent. The following inclusion and exclusion criteria were used:

Inclusion criteria:

- Adults aged 18 and over
- Suffering from persistent pain in their face or mouth for 3 months or longer
- Sufficient level of English to complete questionnaires and take part in the guided self-help therapy

Exclusion criteria:

- Current treatment with a psychological therapy for oral or facial pain
- Current suicidal ideation (assessed at baseline by the Patient Health Questionnaire (PHQ-9).
- Commencement of a prescribed dose of antidepressants less than 3 months prior to the recruitment date

## Randomization and Masking

Randomization was undertaken independently by the Christie's Hospital Clinical Trials Unit. Minimization[18] was applied to reduce the risk of a particular group containing more patients with characteristics that may influence outcomes and was undertaken for age, gender, and referral clinic. Allocation occurred following baseline assessment and confirmation of patients' eligibility. The Christie's Hospital Clinical Trials Unit provided the allocation service by using stochastic minimization.[19] Participants were entered into the trial before the treatment allocation was divulged, as previously recommended.[20] It was not possible to blind participants due to the nature of the treatment; however, a researcher who was blind to allocation collected follow-up data.

**Table 1 Baseline Demographics of Control and Intervention Groups**

| | Intervention (n = 19) | Control (n = 18) |
|---|---|---|
| Gender | | |
| Female | 18 | 14 |
| Male | 1 | 4 |
| Mean age, y (range) | 52 (22–73) | 47 (21–66) |
| Ethnic origin | | |
| White British | 15 | 16 |
| Black British | 1 | 1 |
| British Asian | 1 | – |
| White other | 1 | 1 |
| Other | 1 | |
| IMD score based on postcode, mean (SD) | 25.6 (22.8) | 26.3 (16.1) |
| Social support, mean (SD) | 8.6 (2.1) | 7.9 (2.4) |

IMD = indices of multiple deprivation.

## Demographic Data

Demographic data relating to ethnic origin, indices of multiple deprivation (IMD), and social support were collected to enable an exploration of the characteristics of the sample and balance between groups after allocation (Table 1). The IMD score was identified by participants' postal codes and social support was assessed using three questions: *(1)* "How many people are so close to you that you can count on them if you have serious personal problems?"; *(2)* "How much concern do people show in what you are doing?"; *(3)* "How easy is it to get practical help from neighbors if you should need it?" These questions have been shown to have validity[21] and utility[22] for appraising social support.

## Treatments Provided

### *Guided Self-Help Intervention*

The intervention comprised a self-help manual, "Managing Chronic Orofacial Pain," that was supported and guided by a facilitator.[15] The manual guided self help by presenting a series of four steps, starting with understanding and legitimizing chronic orofacial pain by using patient experiences and stories and continuing with three further steps on goal setting, choosing the intervention, and techniques. The manual also included recovery stories to illustrate the techniques described. Techniques focused on three cognitive behavioral interventions: lifestyle changes

(managing sleep, irritability, fatigue, and other unhelpful habits; eg, teeth clenching), behavioral activation (increasing or decreasing activities, choosing a balance of routine pleasurable and necessary activities during the week), and cognitive restructuring (identifying and evaluating unhelpful thinking styles).

The intervention was delivered by two facilitators, a dentist and a psychologist, who attended a brief 2-day training program that focused on delivering the intervention. Training included initial assessment using impact and goal sheets followed by intervention techniques and the guiding of patients through to exit strategies and posttreatment relapse prevention. The training was delivered by an accredited cognitive behavioral therapist with previous experience in training practitioners for interventions of this type.

Facilitators were responsible for goal setting, conducting impact assessments and reviews, monitoring progress, and writing up case notes. The sessions with facilitators were predicted to take approximately 30 to 45 minutes, and a maximum of eight sessions were offered. Mode of delivery was either face to face or by telephone according to patient choice, which was offered to facilitate wider access to the intervention. Clinical supervision was provided to the facilitators by the accredited cognitive behavioral therapist for 1 hour every 2 weeks, or more frequently when considered necessary, and was provided either over the telephone or face to face.

***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. Usual care comprised oral splints, pharmacologic treatment, or counseling and education. These were provided alone or in combination.

***Outcome Measurements***

These were carried out at baseline, posttreatment, and at 3 months follow-up. Scores for participants in the treatment group were compared to those in the control group who received usual treatment from a secondary care provider.

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations for core outcomes in chronic pain clinical trials[23] cover key domains that have been shown to be relevant to patients, clinicians, and service providers.[24] Outcome measures chosen for the feasibility study therefore reflected these key domains as follows.

*Physical Functioning and Interference with Life.* Physical functioning and interference with life were assessed by using the physical component score for the Short Form (SF-36) questionnaire (Version 2),[25,26] the Brief Pain Inventory (BPI) interference with life subscale, and the Manchester Orofacial Pain Disability Scale (MOPDS), which is a specific measure for disability related to patients reporting orofacial pain. The SF-36 generates norm-based scores in which 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. Physical functioning was chosen as the primary outcome.

The MOPDS[27] comprises a 32-item, 3-point Likert scale. 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 physical and psychosocial disabilities specifically associated with pain in the orofacial region. The highest possible score is 64, which indicates the poorest possible outcome on the scale. A score of 32 indicates moderate disability, and a score of 0 indicates the least degree of orofacial pain–related disability.

The BPI was originally developed as a measure of cancer-related pain and has been validated for use with chronic nonmalignant pain.[28] It consists of 15 patient-rated visual analog scales and measures two dimensions: pain severity and pain interference. Four questions relating to pain severity over a varied period of time (in the past week [worst/least pain], on average, and at the time of rating) are presented. Pain interference is measured by using seven 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 pain interference 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.

*Emotional Functioning.* Emotional functioning was assessed by using the mental component score on the SF-36 and anxiety and depression scores on the Hospital Anxiety and Depression Scale (HADS). The HADS scale[29] contains a 14-item, 4-point Likert scale. The anxiety and depression 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.[29] The HADS is interpreted by using cut-off scores: raw scores of between 8 and 10 indicate mild cases, 11–15 moderate cases, and 16 and above severe cases of anxiety or depression.

*Pain Intensity.* Pain intensity was assessed by using the pain severity scores on the BPI, described above.

*Illness Behavior.* Illness behavior was assessed by using the Revised Illness Perception Scale (IPQr),[30] which is a valid and reliable measure of cognitive representations of illness and is scored by using 5-point Likert scales for each of the seven domains: consequences, timeline (acute/chronic), personal control, treatment control, cyclical control, illness coherence, and emotional representation. High scores for timeline, consequences, cyclical control, and emotional representation represent strongly held negative beliefs about chronicity, negative consequences, and the cyclical nature of illness. For personal control, treatment control, and illness coherence, high scores represent positive beliefs about the controllability and understanding of illness. Two additional dimensions, identity and causes, are included in the scale.

### Sample Size

This trial was carried out to test the feasibility and acceptability of the intervention as well as trial procedures including recruitment, randomization, and follow-up, and to provide information on parameters required for sample size calculation in a full study. For this reason, sample size was not determined to test effectiveness of the intervention.

### Statistical Analyses

Design parameters for a future trial were determined, including recruitment and follow-up rates. Outcome data were also presented as summary statistics of this analysis, which are important for future trial design. Treatment effects were estimated according to the intention-to-treat principle, subject to the availability of data. Inferential analyses were also presented to highlight the uncertainty in treatment effect estimates due to small sample size. Bootstrap confidence intervals were computed for the treatment effect (ES) posttreatment and at the 3-month follow-up and adjusted for baseline values of the outcome measure by using analysis of covariance. The standardized effect size (SES), determined as the adjusted ES divided by the pooled standard deviation (SD) at that time point, was also presented to aid interpretation of potential effects of treatment on outcomes. This study was clearly not adequately powered to detect plausible ES sizes at the conventional significance level of 5% with a two-tailed test. Following the suggestion of Schoenfeld,[19] it was felt that *P* values may have some relevance in pilot trials interpreting potential efficacy, but any inference regarding potential efficacy should be based on a larger significance level, as one does not wish to reject potentially efficacious interventions. Schoenfeld[19] suggests using a 25% level one-tailed test. While this may be overly formal, a *P* value, being a measure of strength of evidence against the null, can be useful in considering whether to take forward a treatment for further study.

## Results

### Recruitment and Randomization

The flow of participants through the study is displayed in Fig 2 (Consolidated Standards of Reporting Trials [CONSORT] flowchart). A total of 74 patients were deemed eligible by recruiting consultants and gave consent to be contacted regarding enrollment in the study. A total of 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. Despite this, recruitment was on target as planned, although monthly recruitment numbers were initially lower than predicted (Fig 2).

Of the 37 participants who gave consent, 19 were allocated to the intervention group and 18 to the control group. In the intervention group, four participants withdrew: two due to ill health, one due to caring responsibilities, and one because of work commitments. At posttreatment, a further three participants were lost to follow-up; ie, failed to complete outcome measures. Only one participant in the control group did not complete outcome measures. Therefore, final numbers for analysis at posttreatment were 12 participants in the intervention group and 17 in the control group. At a further 3-month follow-up, another four participants in the intervention group and six in the control group failed to complete outcome measure questionnaires. Therefore, final numbers for analysis at 3-month follow-up were 8 participants in the intervention group and 11 in the control group (Fig 2). The numbers analyzed in Table 2 for some outcome measures were lower than this final figure due to attrition and missing data for some outcome measures. Some outcome measures were not fully completed, and therefore scores could not be calculated where there was missing data.

### 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.[12] A total of four participants withdrew and did not complete treatment at the pilot stage. 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 in the study and completed follow-up data and interviews. This enabled continued gathering of

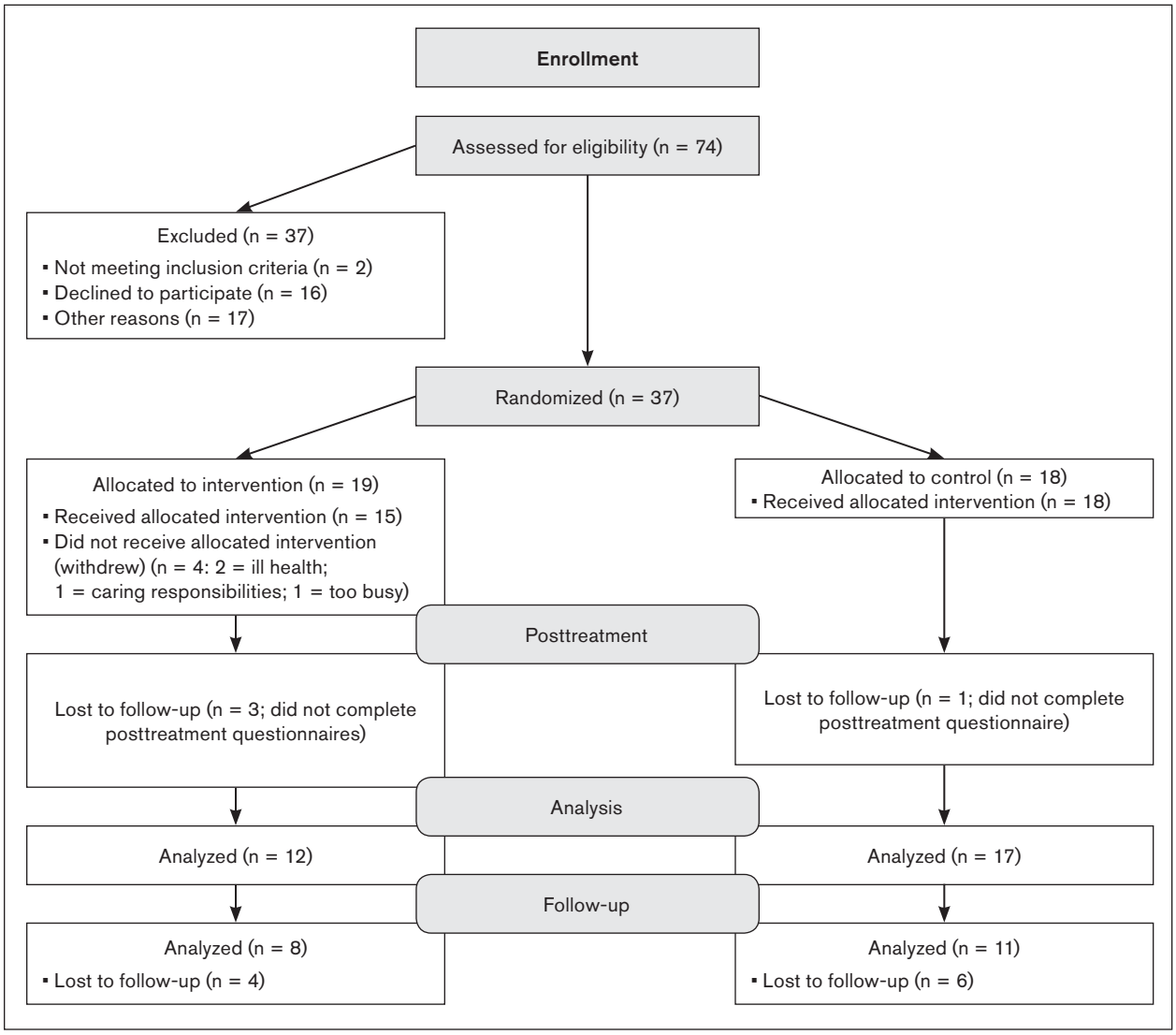


**Fig 2** Participant flow (CONSORT 2010 Flow Diagram).

follow-up data (important for an intention-to-treat analysis) and also completion of acceptability interviews.

## Characteristics of the Sample

The control and intervention groups were well balanced for demographic variables related to age, ethnic origin, sociodemographic profile, and social support, with no significant differences between the two groups (Table 1). However, there were more males in the control group than in the intervention group, and males were underrepresented in the sample as a whole (female-male ratio of 6.4:1), which reflects the general gender disparity of chronic orofacial pain sufferers in the general population.

## Outcome Measures

### *Physical Functioning (SF-36)*

There was a positive direction of effect of treatment on physical functioning (Table 2), with improvement both posttreatment (ES = 3.26; 95% confidence interval [CI] = −5.92, 12.43) and at the 3-month follow-up (ES = 8.35 95% CI = −0.06, 16.76). The SES also indicated improvement posttreatment (SES = 0.24; *P* =.49) and at the 3-month follow-up (SES = 0.63; *P* = .05). Higher scores on the SF-36 are indicative of improvement.

### *Mental Functioning*

*SF-36.* Similarly, there was a positive direction of effect of treatment on mental functioning at the 3-month follow-up (SES = 0.63; *P* = .05) (Table 2). The posttreatment effect on mental health showed slight deterioration, although this effect was not significant.

*HADS Anxiety.* There was a positive direction of effect of treatment on anxiety at the 3-month follow-up (SES = −0.13), although the effect was not significant (*P* = .71) (Table 2). The posttreatment effect on anxiety showed deterioration that was significant but did not continue at follow-up.

**Table 2 Clinical Outcome Measures by Treatment Group at Baseline, Posttreatment, and 3-Month Follow-up**

| | Control | | | Intervention | | | Treatment effect | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| PCS | Mean | SD | n | Mean | SD | n | ES | (95% CI) | *P* | SES |
| PCS | | | | | | | | | | |
| Baseline | 45.15 | 10.60 | 18 | 43.97 | 13.11 | 19 | | | | |
| Posttreatment | 41.13 | 14.20 | 17 | 43.97 | 12.37 | 12 | 3.26 | (–5.92, 12.43) | .49 | 0.28 |
| 3-mo follow-up | 49.36 | 9.32 | 11 | 47.49 | 9.42 | 8 | 8.35 | (–0.06, 16.76) | .05 | 0.63 |
| MCS | | | | | | | | | | |
| Baseline | 40.51 | 13.51 | 18 | 39.25 | 13.25 | 19 | | | | |
| Posttreatment | 42.97 | 13.42 | 17 | 39.43 | 14.51 | 12 | –2.72 | (–13.02, 7.58) | .60 | –0.21 |
| 3-mo follow-up | 40.43 | 15.26 | 11 | 45.22 | 13.21 | 8 | 8.35 | (–0.03, 16.74) | .05 | 0.63 |
| Anxiety | | | | | | | | | | |
| Baseline | 3.44 | 1.98 | 18 | 3.47 | 1.07 | 19 | | | | |
| Posttreatment | 3.17 | 1.92 | 18 | 5.74 | 2.64 | 19 | 2.57 | (1.15, 3.99) | .00 | 1.65 |
| 3-mo follow-up | 2.73 | 1.56 | 11 | 2.88 | 0.83 | 8 | –0.21 | (–1.28, 0.87) | .71 | –0.13 |
| Depression | | | | | | | | | | |
| Baseline | 3.28 | 1.96 | 18 | 3.16 | 0.96 | 19 | | | | |
| Posttreatment | 3.28 | 1.87 | 18 | 5.00 | 3.21 | 19 | 1.73 | (0.13, 3.34) | .03 | 1.15 |
| 3-mo follow-up | 2.91 | 1.64 | 11 | 2.63 | 0.92 | 8 | –0.19 | (–0.88, 0.49) | .58 | –0.13 |
| Disability score | | | | | | | | | | |
| Baseline | 15.06 | 7.61 | 18 | 15.00 | 10.68 | 19 | | | | |
| Posttreatment | 14.44 | 9.14 | 16 | 17.08 | 11.98 | 13 | 0.33 | (–4.69, 5.35) | .90 | 0.04 |
| 3-mo follow-up | 12.27 | 11.37 | 11 | 11.00 | 9.02 | 8 | –2.96 | (–9.26, 3.34) | .36 | –0.32 |
| Pain interference | | | | | | | | | | |
| Baseline | 3.79 | 1.92 | 18 | 3.36 | 2.66 | 19 | | | | |
| Posttreatment | 3.72 | 2.89 | 17 | 4.13 | 3.24 | 13 | 0.65 | (–1.07, 2.37) | .46 | 0.28 |
| 3-mo follow-up | 2.94 | 2.52 | 10 | 2.20 | 2.02 | 8 | –0.56 | (–2.03, 0.90) | .45 | –0.24 |
| Pain severity | | | | | | | | | | |
| Baseline | 4.99 | 2.19 | 18 | 4.32 | 2.43 | 19 | | | | |
| Posttreatment | 4.65 | 2.17 | 17 | 4.37 | 2.26 | 13 | –0.13 | (–1.50, 1.24) | .85 | –0.06 |
| 3-mo follow-up | 3.77 | 2.20 | 11 | 4.28 | 2.18 | 8 | 0.78 | (–1.07, 2.63) | .41 | 0.34 |
| Timeline | | | | | | | | | | |
| Baseline | 21.94 | 4.61 | 18 | 20.58 | 4.19 | 19 | | | | |
| Posttreatment | 22.24 | 3.38 | 17 | 20.45 | 4.37 | 11 | –1.14 | (–4.26, 1.98) | .47 | –0.26 |
| 3-mo follow-up | 22.73 | 4.31 | 11 | 21.25 | 3.11 | 8 | 0.19 | (–2.44, 2.82) | .89 | 0.04 |
| Consequences | | | | | | | | | | |
| Baseline | 17.94 | 5.30 | 17 | 18.74 | 5.05 | 19 | | | | |
| Posttreatment | 16.71 | 5.23 | 17 | 20.25 | 6.09 | 12 | 1.94 | (–0.74, 4.63) | .16 | 0.38 |
| 3-mo follow-up | 15.18 | 5.64 | 11 | 17.00 | 6.05 | 8 | 1.09 | (–1.66, 3.84) | .44 | 0.21 |
| Personal control | | | | | | | | | | |
| Baseline | 16.88 | 5.22 | 17 | 16.53 | 3.69 | 19 | | | | |
| Posttreatment | 16.71 | 6.05 | 17 | 19.67 | 4.42 | 12 | 3.04 | (–0.44, 6.52) | .09 | 0.69 |
| 3-mo follow-up | 15.82 | 4.69 | 11 | 18.50 | 3.63 | 8 | 2.39 | (–1.40, 6.18) | .22 | 0.54 |
| Treatment control | | | | | | | | | | |
| Baseline | 3.56 | 1.58 | 18 | 2.89 | 0.88 | 19 | | | | |
| Posttreatment | 3.28 | 1.60 | 18 | 5.05 | 3.19 | 19 | 1.80 | (0.28, 3.32) | .02 | 1.39 |
| 3-mo follow-up | 2.64 | 0.92 | 11 | 2.75 | 0.46 | 8 | 0.12 | (–0.49, 0.72) | .71 | 0.09 |
| Illness coherence | | | | | | | | | | |
| Baseline | 12.47 | 5.51 | 17 | 13.05 | 5.21 | 19 | | | | |
| Posttreatment | 12.18 | 5.64 | 17 | 16.00 | 5.46 | 12 | 3.15 | (–0.37, 6.67) | .08 | 0.60 |
| 3-mo follow-up | 11.55 | 5.09 | 11 | 14.50 | 5.50 | 8 | 2.87 | (–0.76, 6.51) | .12 | 0.54 |
| Emotional representation | | | | | | | | | | |
| Baseline | 18.12 | 6.90 | 17 | 19.84 | 4.23 | 19 | | | | |
| Posttreatment | 17.93 | 6.02 | 15 | 20.17 | 4.88 | 12 | 0.21 | (–2.97, 3.40) | .90 | 0.04 |
| 3-mo follow-up | 17.55 | 7.13 | 11 | 17.63 | 3.46 | 8 | –0.81 | (–4.67, 3.05) | .68 | –0.14 |

ES = the treatment effect of intervention compared to control adjusted for baseline value of outcome; SES = the standardized effect size calculated as ES/SD where SD is the pooled baseline standard deviation. PCS = physical component summary scores; MCS = mental component summary scores.

*HADS: Depression.* There was a positive direction of effect of treatment on depression at the 3-month follow-up (SES = –0.13), although the effect was not significant (*P* = .58) (Table 2). The posttreatment effect on depression showed deterioration that was significant but did not continue at follow-up.

***Orofacial Pain Disability***

There was a positive direction of effect of treatment on disability at the 3-month follow-up (SES = −0.32), although the effect was not significant ($P$ = 0.36) (Table 2). The posttreatment effect on disability showed deterioration that was not significant and did not continue at follow-up.

***Interference with Life***

There was a positive direction of effect of treatment on interference with life at the 3-month follow-up (SES = −0.24), although the effect was not significant ($P$ = .45) (Table 2). The posttreatment effect on interference showed deterioration that was not significant and did not continue at follow-up.

***Pain Intensity***

There was a positive direction of effect of treatment on pain intensity posttreatment (SES = −0.06), although the effect was not significant ($P$ = .85) (Table 2). However, at the 3-month follow-up, the effect was not sustained, and there was a deterioration that was not significant.

***Illness Behavior Domains***

There was a positive direction of effect of treatment on personal control (SES = 0.69), treatment control (SES = 1.39), and illness coherence (SES = 0.60) posttreatment, and the effect for treatment control was significant ($P$ = .02) (Table 2). These effects were sustained at the 3-month follow-up, although the effects were not significant.

The intervention did not have any effects on emotional representation, timelines, or consequence of illness.

***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.[31] Key factors to consider when assessing feasibility are recruitment and attrition.[12] Within the context of "Managing Chronic Orofacial Pain," it was important to ensure that specialist clinicians in secondary care were able to appropriately diagnose and refer patients to the new intervention so that there were sufficient numbers to ensure an appropriate trial sample. Furthermore, clinicians needed 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.

In practice, the intervention could be feasibly delivered by a dentist and a nonclinical psychologist and implemented either face to face or over the telephone within a sample of secondary care chronic orofacial pain patients. Suitable participants could be appropriately identified by specialist clinicians and recruited from secondary care outpatient clinics to receive the intervention. Attrition was low, with only four participants failing to complete treatment.

The total number of intervention sessions delivered to the participants was 102, and sessions were delivered to the participants by both facilitators (facilitators treated 9 and 10 participants, respectively). The mean number of sessions received per participant was five, and mean contact time per participant was around 4 hours (241 minutes), with each session lasting an average of 43 minutes (Table 3). This showed compliance with the a priori decisions made regarding dosage and was concurrent with the protocol used for telephone-delivered cognitive-based therapy (CBT) for the MUSICIAN study.[16] Similar numbers of sessions were delivered by telephone (48 sessions) and face to face (54 sessions), indicating no overall preference for method of delivery.

Four participants did not complete treatment, attending fewer than four sessions; however, the majority of participants (n = 15) successfully completed treatment. The highest number of participants (five) completed the maximum number of eight sessions (Table 4).

### Participants' Treatment Priorities

Participants receiving the intervention were asked to set goals relating to their priorities (essentially, what "getting better" meant to them). The mean number of goals set per participant was 2.23. Table 5 shows the types of goals set by participants.

This data was useful for investigating the priorities that the chronic orofacial pain patients had regarding changes they wished to make and the ways their lives were affected by their pain.

Priorities for the majority of the participants centered on increasing exercise and on 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. Habit reversal goals again were concerned with reduction in behaviors idiosyncratic to chronic orofacial pain such as jaw clenching and teeth grinding. Other priorities encompassed nonroutine activities such as larger domestic tasks and applying for work. Only participants who had a supervisor with a clinical background set goals regarding reduction in medication, which has implications for future training of facilitators.

## Discussion

The main findings of this study were that patients with chronic orofacial pain could be successfully identified and recruited to take part in a trial for the

guided self-help intervention that was developed. Furthermore, the intervention could be feasibly delivered either face to face or by telephone by a dentist and a psychologist. The findings also showed that those receiving the intervention improved on a number of outcome measures posttreatment and at the 3-month follow-up. Physical and mental functioning were improved on the SF-36 domains. The intervention also had positive effects on treatment control, personal control, and illness coherence, although the effects were only significant for treatment control posttreatment. That being said, the feasibility study was not powered to establish effectiveness, and further work is needed to assess both long-term effects of the intervention and its cost effectiveness. The feasibility study also identified a number of shortcomings that need to be taken into account when conducting a definitive trial. These are related to the following:

**Table 3 Implementation of Treatment Sessions**

| | |
|---|---|
| Mean number of sessions per participant (SD) | 5.06 (1.95) |
| Mean contact time per participant (SD) | 4 h (241.06 min) (1.82 h) |
| Mean number of minutes delivered per session (SD) | 44.56 (7.08) |
| Total number of telephone-delivered sessions | 48 |
| Total number of face-to-face sessions | 54 |

**Table 4 Number of Intervention Sessions Completed**

| No. of sessions | No. of participants (n = 19) |
|---|---|
| 0 | 2 |
| 1 | 2 |
| 4 | 3 |
| 5 | 3 |
| 6 | 2 |
| 7 | 2 |
| 8 | 5 |

**Table 5 Participants' Goal Setting**

| Goal type | No. of goals set |
|---|---|
| Increase exercise | 10 |
| Improve social contact | 5 |
| Lifestyle changes (eg, sleep, hygiene, cooking meals) | 9 |
| Changes in daily routine | 5 |
| Reduce medication | 2 |
| Personal improvement (education) | 1 |
| Habit reversal | 4 |
| Other | 3 |

### Outcome Measures

The primary outcome chosen for the feasibility study was physical functioning; however, the study showed that the intervention had important directions of effect on other outcomes, particularly those related to emotional functioning. Since the study was conducted, recent research has shown[32] that a number of outcome domains, including physical and emotional functioning, are important in benchmarking psychological treatments for chronic pain. This study[32] relates benchmarking directly to core outcome measures adopted by IMMPACT for chronic pain trials. To ensure that future trials are comparable, core outcome domains and measures proposed by both this work[32] and IMMPACT[23] need to be adopted in a definitive trial of the guided self-help intervention developed in the current study. McBeth et al[16] recently conducted a trial to test the cost effectiveness of a similar intervention for chronic widespread pain. For this, the global rating of improvement using the Patient Global Impression of Change was used as a primary outcome. Given that the intervention in the current study was patient centered and showed the potential to improve a number of outcomes, a global rating of improvement may be an appropriate primary outcome measure for a future definitive trial. It will ensure comparability with previous work and align with IMMPACT recommendations for core outcome measures in chronic pain trials.

### Uptake of Intervention

Only 50% of those approached agreed to take part in the study. 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, remain unclear. Consequently, participants who agreed to take part in the study may have been self selecting; indeed, the acceptability interviews[17] revealed that engaging with the intervention involved patients accepting the treatment model. Once patients had consented, the attrition rates were low for completion of the intervention. Further research is required to understand why people are unwilling to take part in trials of psychological interventions for chronic pain and how those who participate differ from those who do not. This will provide valuable data for implementation of such interventions.

### Missing Data

While compliance with the intervention was high, there was a considerable amount of missing data from noncompletion of outcome measure questionnaires at the 3-month follow-up. The purpose of the feasibility study was to test a number of outcome measures to identify the most appropriate, and this therefore increased the number and length of outcome measures.

This in itself explains the high noncompletion rates. In addition, the primary outcome measure, SF-36, was long and difficult to complete. Nonresponse was higher in the intervention group when compared with the controls. This could be related to the intervention group being overburdened with questionnaires, as the intervention itself had a number of additional questionnaires, homework diaries, and acceptability interviews, which were conducted during the intervention and posttreatment. Attrition could be reduced by including further resources for staff to contact patients to complete the outcome measures rather than relying on postal deliveries.

### Feasibility

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

### Strengths of the Study

A phased approach was taken to the development and evaluation of the intervention, based on current MRC guidelines in the UK.[12] Feasibility of delivering the intervention was investigated and the intervention underwent a process of modeling. The iterative nature of the research meant that findings could be applied to improve and further develop the intervention prior to testing in a definitive trial. Findings from the current feasibility study have provided invaluable information about the design and logistic issues that will inform the design, set-up, and implementation of a larger, definitive RCT.

This approach to modeling and reporting CBT-based interventions to treat chronic orofacial pain is in contrast with previous studies, which have been characterized by sparse reporting of intervention components and evidence supporting their use. In addition, previous research has not addressed issues relating to stakeholder acceptability and feasibility of implementation. As part of the study, qualitative acceptability interviews were conducted with the patients who received the intervention.[17] Briefly, this showed that the intervention was acceptable to patients and engaging with the intervention involved patients accepting the treatment model, feeling believed and understood, and obtaining a plausible explanation.[17] Processes of change included gaining control, distraction, identifying unhelpful patterns, and accepting that the condition was long term.[17] This is supported by the findings of the pilot trial, which show that the intervention had an effect on treatment control, personal control, and illness coherence.

Studies of CBT-based treatments for chronic orofacial pain carried out since the commencement of this pilot trial appear to be few in number and based outside of the UK.[33,34] Although one pilot study has been conducted in Brazil,[35] the focus of the research was on investigating effect sizes despite randomization of only a small number of participants (n = 47). These recent studies did not report intervention-modeling procedures or the components of interventions used in treatment and omitted investigations of acceptability and feasibility.

### Implications for Future Research

Based on the findings of this feasibility study, the key changes required for a definitive RCT are as follows:

- Attention should be given to decisions regarding the selection of appropriate outcome measures, particularly for the primary outcome. A patient global rating scale may be the most appropriate primary outcome, although this needs to be assessed by using patient input. Measures of a number of constructs including physical and social functioning, pain, mental health, anxiety, and illness beliefs should be retained as secondary outcomes according to IMMPACT recommendations.
- Qualitative research to systematically examine the views of those who decline to participate in the study is needed to fully investigate barriers to acceptability and uptake of the intervention.
- A cost-effectiveness analysis needs to be incorporated into a definitive trial and should include discrete-choice experiments to assess clinicians' willingness to deliver the intervention and patients' acceptability of the intervention.

## Conclusions

The intervention developed in this study was acceptable to patients and allowed them to better understand and self manage chronic orofacial pain. The intervention showed potential efficacy on outcome domains related to functioning and illness perception. Further research is needed to understand cost effectiveness of the intervention for chronic orofacial pain.

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V.A., S.P., and K.L. conceived the idea. V.A., S.P., K.L., and L.M. supervised J.G., who conducted the study for her PhD. C.R. and I.N. independently analyzed the data and prepared the tables. J.G. drafted the paper. All authors reviewed and finalized the manuscript.

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