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Aggarwal, VR orcid.org/0000-0003-0838-9682, Wu, J orcid.org/0000-0001-6093-599X, Fox, F et al. (3 more authors) (2021) Implementation of biopsychosocial supported selfmanagement for chronic primary oro-facial pain including temporomandibular disorders: A theory, person and evidence-based approach. Journal of Oral Rehabilitation, 48 (10). pp. 1118-1128. ISSN 0305-182X

https://doi.org/10.1111/joor.13229

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Implementation of Biopsychosocial Supported-Self-Management for Chronic Primary Orofacial Pain including Temporomandibular Disorders: a Theory,

Person and Evidence-Based Approach.

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Running head: Supported Self-management for Chronic Orofacial Pain

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Abstract

Background:

Aims of the study were to:

- Implement supported self-management for chronic primary orofacial pain in a clinical setting.
- Evaluate its impact on consultation rates, pain-severity, interference-with-life and patient experience.

Methods: 66 patients with chronic primary orofacial pain received the intervention at a facial pain clinic at Leeds Dental Institute, UK. Brief Pain Inventory (BPI) scores measured pain-severity and interference-with-life before and after the intervention. Process mining outlined patient care pathways. Monthly consultation rates measured 12 months before and after the intervention were used to evaluate burden on healthcare services and economic impact. Patient feedback was assessed via Patient and Public involvement discussion groups.

Results

Mean BPI scores significantly improved after intervention - from 5.70 (SD 1.89) to 3.78 (SD 2.34) (P<0.001); mean pain-interference score reduced from 19.95 (SD 9.41) to 12.05 (SD 9.64) (p<0.001). Average monthly consultations significantly (p=0.001) reduced from 0.42/month before the intervention to 0.16/month after the intervention. Economic assessment showed cost savings of £293 per patient per year. Process mining showed high rates of service usage with 31 patients also attending 51 other specialist services between them. Patient and Public Involvement discussion groups with 5 patients identified that the intervention was a 'constant companion' and should be implemented at the outset in the care pathway.

Conclusion

Supported self-management for chronic primary orofacial pain has a positive impact on health outcomes (physical functioning, pain intensity and patient experience), as well as service usage and healthcare costs when implemented in a secondary care clinical setting. Reconfiguring current care pathways to upscale early implementation of such interventions should be a priority for future testing.

Keywords: chronic orofacial pain; Temporomandibular disorders; Self-management; burning mouth syndrome; biopsychosocial.

Introduction

Persistent pain in the face or mouth (orofacial pain) is a frequent cause for consultation in both primary dental and medical care and a substantial proportion of people (7% of the population) develop both chronic and disabling pain (1, 2). People with chronic orofacial pain also report an increase in pain levels and interference with life and are thus more likely to seek treatment and take medication (3).

Clinically, chronic orofacial pain is the characteristic feature of a number of conditions such as temporomandibular joint disorder (TMD), burning mouth syndrome, and persistent idiopathic facial pain that are difficult to diagnose and manage successfully (4, 5, 6, 7). The most recent IASP (international association for studies on pain) classification for ICD-11 (8) and the International Classification of Orofacial Pain (ICOP) (9) classified these chronic orofacial pain conditions as chronic primary pains defined as "chronic pain in one or more anatomical regions that persists or recurs for longer than 3 months and is associated with significant emotional distress and/or significant functional disability" (8). This has been confirmed by epidemiological evidence showing that chronic orofacial pain co-occurs with other chronic pain syndromes (2) and is associated with high levels of psychological distress of somatisation (1, 2) and that these psychological factors predict the onset and persistence of chronic orofacial pain (10).

Despite this, management of patients with chronic orofacial pain, in particular TMD, tends to focus on correction of local mechanical factors like teeth grinding and malocclusion rather than addressing underlying psychosocial factors which are aetiological. Cochrane systematic reviews have shown little or no beneficial effects of physical therapies such as irreversible occlusal adjustments (11) and oral splints

(12,13) that are targeted towards the correction of these factors.

Indeed, an audit of 101 consecutive referrals of patients with chronic orofacial pain to secondary care (14) showed that they had been treated in nine different hospitals; referred to fifteen distinct specialties, with a mean of seven consultations per specialty. Of 341 treatment attempts only 24% yielded a successful outcome and these did not account for natural remission or placebo response (14).

This imposes a huge burden on already stretched health care resources as current care pathways associated with multiple consultations in secondary care do nothing to improve pain (4, 5, 7).

TMD alone is thought to cost the US 4 billion dollars annually (15). Whilst data is unavailable for overall economic cost in the UK, a study examining the costs to the UK National Health Service (6) showed that consultation costs comprised 75% of cumulative healthcare utilization costs, or an estimated £1,318 on average, for patients with persistent orofacial pain. Economic analysis for indirect and out-of-pocket costs show that patients with persistent orofacial pain have considerable out-of-pocket costs (£333 per person per 6-month period) and indirect (£1242 per person per 6-month period) costs related to lost time at work (16).

There is growing evidence from systematic reviews that self-management interventions incorporating a biopsychosocial approach are effective, in comparison to usual care, in improving outcomes (long term pain intensity and depression) in patients with orofacial conditions like TMD (17). Using synthesis of evidence from this review and further qualitative and quantitative (7, 17) work our team developed an evidence based biopsychosocial intervention for chronic orofacial pain (18) in accordance with the medical research council guidance on development of complex interventions (19). In

addition to synthesis of evidence from both quantitative (17) and qualitative studies (7) we adapted an existing manual, "Managing chronic widespread pain", which was shown to be both clinically and cost effective in a large randomised controlled trial for managing chronic widespread pain in primary care in both the short (6 months) and longer term (24 months) (20). We adopted a co-production and co-design approach with patient and clinician stakeholders to develop our intervention manual (21). This was evaluated in a proof-of-concept trial (18) which showed that the intervention was acceptable to patients (22) and could be delivered by telephone or face-to-face by facilitators from clinical and non-clinical backgrounds (18). Although the proof-ofconcept trial was not powered to measure effectiveness, there was significant improvement in some outcome measures indicating potential effectiveness (18). Additional components (posture control and habit reversal) were identified which led to further refinement of the intervention (23). Overall, the intervention incorporated a biopsychosocial approach with principles of cognitive behaviour therapy for the psychosocial components and posture control for physical self-regulation (23). This intervention aligns with recent recommendations by the US National Academies high profile international expert committee that advocated therapist-guided selfmanagement approaches that combine a psychoeducational rationale with techniques drawn from cognitive-behavioural therapy (CBT) and biofeedback for temporomandibular disorders (24).

Aims

The aim of the current investigation was to therefore to implement and evaluate our self-management intervention in a healthcare setting for patients with chronic orofacial pain.

Specific objectives were to:

- Assess the impact of the intervention on pain intensity and interference with life.
- Assess the impact of the intervention on consultation rates within medical and dental specialties.
- 3. Evaluate the economic impact of our intervention.
- 4. Evaluate patient feedback on their experiences with the intervention.

Materials and Methods

Study design: the study was a pragmatic prospective evaluation of our biopsychosocial supported self-management intervention (20). Patients were referred to a facial pain clinic which solely implemented the intervention and was located at Leeds Dental Institute, UK. Patients attended the clinic from October 2016 and were followed up from their first appointment up to and including December 2018. Anonymous data was extracted for these patients and their Dental Institute records were linked to their medical outpatient clinic records at Leeds General Infirmary. Both the Dental Institute and General Infirmary are part of Leeds Teaching Hospital Trust.

Participants: 66 patients attending the clinic were referred from the oral surgery, oral medicine and restorative dentistry departments at Leeds Dental Institute. Oral surgery and restorative dentistry included patients with chronic temporomandibular disorders (principally internal derangements and muscle disorders (myalgia and myofascial pain) (N= 46) whereas those from oral medicine had chronic burning mouth (BMS) or persistent idiopathic facial pain (N= 20).

Intervention: the intervention has been described previously (18). Briefly, up to 8 sessions of face-to-face or telephone supported self-management were offered over a period of up to 12 weeks and were delivered by a clinician from a dental background (VA) with training and prior experience in delivering the intervention. New patient appointments were allocated a 60min appointment while follow-up appointments were allocated a 40min appointment. All patients received the treatment guide (23) divided into 4 steps, and which is easy to read (age equivalent 12-13 years (Flesch-Kincaid level 6.4)), engaging and allows patients to personalise it to their needs:

- Step 1; What is "managing my chronic orofacial pain" all about? explanation
 of the origins of physical symptoms of subtypes of chronic orofacial pain and
 psychological processes involved in pain pathways using e.g. the gate control
 theory of pain. Introduces self-management, emphasizing the role of the
 patient as the agent of change/ taking control.
- Step 2; Understanding how the pain is affecting me Impact assessment and goal setting allows tailoring to the patient's needs.
- Step 3; My programme focuses on a biopsychosocial approach using three evidence-based interventions – posture control, behavioural activation and cognitive restructuring.
- Step 4; Continuing to manage my pain, and recovery techniques discusses episodic nature of pain and relapse prevention.

Outcome measures and data analysis:

 Pain severity and interference with life. This was measured using the Brief Pain Inventory (BPI) (25) which includes patient-rated visual analogue scales and measures pain location, intensity (least, worse and average over the past week) and interference with activities of daily-living. It is recommended by IMMPACT (26) core outcomes measures for chronic pain trials. BPI was completed blind and independent of the treatment provider by patients before their first appointment and similarly after their last appointment. All scores were calculated and entered into the dataset also blind and independent of the treatment provider. For the purpose of analysis, means and standard deviations of BPI scores were compared before and after treatment. The paired sample t-test was used in all comparisons as we tested the pre- and post- treatment BPI scores for each patient. Statistical significance was set at p<0.05.

- 2. Consultation rates: Average monthly consultation rates were measured before and after the intervention to assess impact on consultations both within dental and medical specialities at the Dental Institute and Leeds General Infirmary respectively. Average monthly consultations were used to account for the differing pre-clinic and post-clinic attendance times. Consultation rates before the intervention were measured in the 12 months prior to the first facial pain clinic appointment and appointments after were measured for the 12 months after the final facial pain clinic appointment (or the data cut-off date of December 2018 if sooner). The paired sample t-test was used in all comparisons as we tested the pre- and post- treatment consultation rates for each patient. Statistical significance was set at p<0.05.</p>
- 3. Economic analysis We estimated hospital costs for each appointment in our data, before and after the intervention, based on the NHS Specialty Code specified for the appointment (28). We estimated all planned appointments irrespective of whether the patient attended or ultimately failed to attend.

- 4. Care Pathways: Process mining, an emerging data analysis technique, was used to map care-pathway to illustrate the most common sequences of treatment experienced by the patient cohort in the hospitals' dental and medical specialities. Its purpose is to rapidly deliver comprehensive representations of care pathways and, for this case, revealing new insights to the utilisation of services. The process mining tool selected was Disco (27) and the data used is detailed in the study design above.
- 5. Subgroup analysis we investigated differences in consultation rates for those with TMD (N=46) and BMS (N=20) separately to determine whether the intervention had different effects on consultation rates, pain intensity and pain severity for subtypes of chronic orofacial pain. Paired sample t-test were used in these comparisons as we tested the pre- and post- treatment consultation rates and pain severity and interference for each patient. Statistical significance was set at p<0.05.</p>
- 6. Patient feedback and experience was elucidated through Patient and Public Involvement (PPI) meetings where five patients shared their lived experience of chronic orofacial pain including their experiences of using our supported self-management intervention. All patients consented to participation at the meetings (N=3) and transcription and publication of audio recordings.

Ethical approval:

Ethical approval for a larger project 'Linking dental and medical patient records for research' was used to conduct the current study. Approval for that project was granted by HRA and HCRW (IRAS ref: 277767; Research Ethics committee ref: 20/WM/0127).

Results

Pain outcomes

Of 66 patients who attended the clinic, 22 completed the Brief Pain Inventory (BPI) before and after clinical consultation. For these patients, mean pain severity scores and mean pain interference scores were calculated before and after treatment using the standard BPI scoring (25). Mean follow-up time was 384.82 days (SD 197.16). This showed that mean pain severity scores significantly reduced (p<0.001) from 5.70 pre-treatment (standard deviation (SD) 1.89) to 3.78 (SD 2.34) post-treatment. Mean pain interference score also significantly reduced (p<0.001) from pre-treatment scores of 19.95 (SD 9.41) to 12.05 (SD 9.64) post-treatment.

Consultation rates and cost savings:

Average monthly specialist clinic visit reduced from 0.23/month before the intervention to 0.15/month after the intervention (p-value = 0.008) measured over a 12-month period before and after the intervention. Mean follow-up time was 384.82 days (SD 197.16).

An initial comparison of average monthly costs observed 12 months before and 12 months after the patient's consultations yielded a large fall in those observed afterwards (£69.85 before vs £21.50 after, p<0.001, n=66). Over a full 12-month period this represents a cost saving of £580 per patient.

The average number of sessions per patient of the facial pain clinic were 2.73 (SD 1.66 range 1-7). These are presented in figure 1 which shows number of patients

attending that range (1-7) of sessions. The average tariff per patient for a consultant led face-to-face new patient consultation in an oral medicine setting is £123.07 and for a consultant led face-to-face review is £95.13 (based on local tariff rates at Leeds Dental Institute). These were the costs applied to facilitator time. For 2.73 sessions this gives a total consultation cost of £287. Based on cost saved from consultation rates above (£580), this represents a cost saving of (£580 - £287) or £293 per patient per year.

Service Usage and co-morbidities: Patients with chronic primary orofacial pain had high rates of service usage attending 51 different clinic services within both dental and medical specialties. Figure 2 shows services that had more than 10 consultations. Not surprisingly, the most common services were dental and included oral surgery (ORAL), oral medicine (DMS), our pain clinic (VA-M) and restorative dentistry (RDEN) in descending order. The most frequent procedure in the oral surgery clinic was Botox injections with 81 consultations. Medical services included those to which comorbid pain conditions present. A total of 48 (73%) of patients had co-morbidities with the most frequent co-morbidity clinical services attended out-with dentistry being: Gynaecology (GYNA for chronic pelvic pain), Rheumatology (RHEU for fibromyalgia), and Gastroenterology (GAST for irritable bowel syndrome) conditions that frequently co-occur with chronic orofacial pain (2). Figure 3 shows the pathway and number of patients who attended each of these services. The process model clearly shows the 66 patients attending the pain clinic (VA-M) and the total number of attendances to be 180. It also shows that 25 of these patients came from 'ORAL' and 32 came from 'DMS'. These pathways are indicated by red arrows in Figure 3. Attendance at services such as PAIN (pain management) and PHYS

(physiotherapy) included those patients that were managed by multiple services and others such as ENT, Audiology and Ophthalmology where patients are referred for multiple investigations to exclude an organic cause.

Attrition

There were 16 (24%) patients who attended one session on the pain clinic (figure 1). Of these 7 needed further appointments but did not attend. The attrition rate was therefore 7/66 (11%).

Subgroup Analysis

Differences in consultation rates for TMD (n=46) and BMS (n=20) are presented in figure 4. This shows consultation rates dropped significantly (p<0.01) for TMD patients from a mean of 0.48 (SD 0.30) before the intervention to 0.18 (SD 0.36) after the intervention. Similarly for BMS consultation rates dropped significantly (p<0.01) from a mean of 0.29 (SD 0.16) before the intervention to 0.11 (SD 0.27) after the intervention.

Pain severity for TMD also significantly (p<0.01) improved after the intervention from a mean BPI of 6.4 (2.0) before to 3.4 (2.3) after the intervention (figure 5). However, whilst there was a drop in pain intensity for BMS patients with mean 5.8 (2.1) before to 5.4 (2.7) after the intervention (figure 5) this was not statistically significant (P=0.39).

Pain interference for TMD improved after the intervention from a mean BPI of 4.7 (2.7) before to 2.7 (3.2) after the intervention although not statistically significant (p=0.069) (figure 6). There was also improvement in pain interference for BMS

patients with mean 5.4 (2.7) before to 3.2 (2.1) after the intervention (figure 6) but this was not statistically significant (P = 0.42).

Patient feedback

Patient and Public Involvement (PPI) meetings (N=3) were attended by 5 patients and one lay chair who had previous expertise in patient involvement in research. Patient feedback related to three key domains: personal experiences, experiences of the current healthcare system and experiences of the supported self-management intervention. Table 1 shows the key domains along with corresponding feedback. Chronic orofacial pain affected every aspect of patients' lives and suffering was both physical and psychosocial. Experiences of the current healthcare system involved multiple referrals and invasive and irreversible treatments which did nothing to improve symptoms, imposed financial burden on the patients and produced harmful side-effects and addiction.

Patients reported that the intervention improved their understanding of the pain and could readily be shared with their work and social networks to allow them to understand the pain which resulted in more empathy. Patients were able tailor the intervention as needed according to their symptom severity and use what worked for them. All five patients found it to be a constant 'support' and recommended its use at the onset of symptoms.

Discussion

To our knowledge this is the first successful implementation of a biopsychosocial intervention that targets chronic primary orofacial pains and allows the patient to take control and self-manage their pain. The intervention had positive impact on pain intensity and quality of life measured using the Brief Pain Inventory subscales. It also reduced the burden on health care services by reducing consultation rates within both medical and dental specialties and subsequent costs to the healthcare service. Expert patient feedback recommended use of the intervention at the outset and as a first-line treatment. Patients in the Patient and Public Involvement (PPI) group reported that the intervention could be tailored to their needs and the patient manual was a 'constant companion' to self-manage exacerbations in symptoms particularly during the ongoing COVID-19 pandemic. The intervention could also be delivered flexibly either face-to-face or remotely by telephone – the latter being particularly useful during the current pandemic.

The intervention has several strengths. First, we used an evidence-based approach (17). Second, the self-management intervention model (biopsychosocial) aligns with recommendations both within the United Kingdom (NICE guidance (29)) and internationally (24) for management of chronic primary orofacial pain including TMD which advocate therapist-guided self-management approaches that combine a psychoeducational rationale with techniques drawn from cognitive-behavioural therapy (CBT) and biofeedback for chronic primary orofacial pain (29) and temporomandibular disorders (24). Third, we incorporated a theoretical (biopsychosocial) and methodological framework (19) in developing the intervention which involved synthesis of evidence from both quantitative (17) and qualitative (7) studies and adaptation of an existing intervention (20) which had been shown to be

cost-effective for chronic widespread pain. We optimised the design using a coproduction approach with patient and clinicians and the findings of our pilot trial (18) showed that the intervention was acceptable to patients and could be feasibly delivered face-to-face or by telephone by healthcare workers from dental and psychology backgrounds. The intervention theory, design, content and evaluation are presented in the logic model in figure 7. Through PPI meetings, we captured actual patient experience as they travelled through their care pathway and this showed how patients are passed from pillar to post and undergo multiple invasive and irreversible treatments that are harmful - findings shared by previous research (5,7,13). Our intervention was seen as a first step by patients to improving their care as they were able to tailor it to better meets their needs. They suggested prioritisation of early selfmanagement throughout chronic orofacial pain care pathways to prevent pain negatively impacting their lives. From a commissioning perspective, our intervention not only has a sound evidence base but is safe and efficient to deliver and positively impacts on the emotional experience of delivering and receiving care. In addition, the intervention saves consultation costs although the cost savings of the intervention (£293 per year per patient) are likely an under-estimate as we only included costs of face-to-face consultations (whereas the intervention can be delivered by telephone) and additional procedures such as botox, splints and surgery that were undertaken for patients in other clinics prior to attending our pain clinic were not included. A telephone only service which has been the alternative during Covid would result in a consultation cost saving of £511 per patient per year (consultation savings £580 minus telephone costs $25.24 \times 2.73 = \text{\pounds}68.90$) based on a $\text{\pounds}25.24$ tariff for a telephone consultation. In addition, we did not include primary care costs (from where patients were initially referred) as these were unavailable. Whilst this affects the

generalizability of the findings, the cost savings are likely to have been an underestimate as prior primary care consultation and treatment costs would have increased consultation costs pre-intervention.

Our study was limited as there was no control group which would be only possible in a randomized controlled trial that would require substantial resources. In our pragmatic study the best we could achieve was using patients attendance and BPI scores before being referred to the clinic as a proxy for a control group and compare this to attendance and BPI scores after receiving the intervention. Whilst consultation data was available for all patients, not everyone completed BPIs which was another limitation. BPIs were incomplete as those who were discharged from the clinic at the last appointment were not required to attend again and therefore if they did not return their BPIs after discharge, we could not get hold of the patients. Finally, the PPI groups by their very nature, were made up of those who wished to contribute to inform further development of the intervention by sharing of their experiences of using it. This group did not include non-responders for whom the intervention may not have been effective. Previous research has shown that non-responders to psychosocial management of TMD using cognitive behaviour therapy accounted for 16% of the sample and although they did not differ from treatment responders on demographics or temporomandibular joint pathology, they reported more psychiatric symptoms, poorer coping, and higher levels of catastrophizing (30). These patients may be vulnerable to seeking alternative treatments and unnecessary investigations that not only burden health care services but more importantly expose patients to potentially harmful treatment. Future research therefore needs to understand the long term needs of non-responders so as to avoid referrals or exposure to ineffective treatments, unnecessary investigations and/or potentially harmful medication (e.g.

opiates). Strategies to increase patient engagement in focus groups particularly from non-responders have been previously described and need to be implemented in future research evaluating interventions such as ours (31). Our subgroup analysis showed that the intervention was potentially more effective for TMD patients compared with BMS patients. Apart from pain severity for BMS (which only reduced by 0.4 points on the BPI), all other values for pain severity and interference for TMD and pain interference for BMS improved by greater than 1 point on the BPI which is deemed clinically significant by IMMPACT (26). Lack of statistical significance is likely to be down to the small number of BMS patients (n=20).

Previous studies have successfully implemented behavioural interventions using trained dental nurses (32). Our intervention may be suitable for such pathways as we have shown that it can be delivered by trained healthcare workers from a dental background (18) and could fit the remit for extended roles (nurse practitioners / dental therapists) akin to those commonly used in medical care to manage long term conditions with nurse-led enablement of self-management (33, 34).

Future work therefore needs to investigate the cost-effectiveness (in a pragmatic randomised controlled trial) of our upscaling our intervention to re-configure current care pathways so that interventions such as ours are accessible across healthcare services to improve outcomes for patients with chronic primary orofacial pain (35). Future work also needs to explore mechanisms by which these interventions brings about change and understand characteristics of patients who respond to such treatments as well as those who do not as non-responders may be particularly vulnerable to seeking further unnecessary investigations and alternative (often harmful) treatments

Conclusions:

We have implemented, for the first time, a biopsychosocial intervention that supports patients to self-manage chronic primary orofacial pain. The intervention had a positive impact on both health outcomes (physical functioning, pain intensity and patient experience) and non-health outcomes (consultation rates and costs). Future work needs to upscale such interventions to explore whether early supported selfmanagement can improve outcomes for these patients by re-configuring current clinical pathways for optimal referral, triage and management of chronic primary orofacial pain within primary and secondary care services.

Funding sources: none

Acknowledgements

We would like to thank Dr Elizabeth Bradley for her help with data entry of BPI scores and transcription of PPI meetings. Thanks also goes to our patient user group who provided valuable feedback on their difficulties of accessing care and their experiences of self-management of chronic orofacial pain. Finally we would like to acknowledge the support received from staff at Leeds Dental Institute both in setting up and maintaining the facial pain clinical service and also for help with anoymising and extracting the data.

Figure Legends:

Figure 1: Bar chart showing number of sessions attended on the facial pain (OMPAIN) clinic (x-axis) plotted against the number of patients attending those sessions (y-axis).

Figure 2: consultations of the 66 patients (who received the intervention) across medical and dental services. The graph shows those with more than 10 consultations

per service. ORAL=oral surgery; DMS=Oral medicine; VA-M=facial pain clinic; RDEN=Restorative dentistry; GYNA=Gynaecology; PHYS=Physiotherapy; RHEU=Rheumatology; ENT=Ear, Nose and Throat; OPH=Ophthalmoloy; GAST=Gastroenterology; TRAU=Trauma; DERM=Dermatology; AUDI=Audiology; THOR=Respiratory medicine; NEUR=Neurology; COLO=Colorectal;PAIN=Pain management; OBST=Obstetrics;ODON=Orthodontics; ENDO=Endocrinology; DIAB=Diabetic medicine; UROL=Urology; CARD=Cardiology; CHMO=Medical oncology

Figure 3: Process mining care pathways of 66 patients attending the facial pain clinic (VA-M). 37 patients were discharged following attendance to the clinic represented by the stop symbol on the bottom left-hand corner. Key pathways to VA-M highlighted with red arrows. ORAL=oral surgery; DMS=Oral medicine; VA-M=facial pain clinic; RDEN=Restorative dentistry; GYNA=Gynaecology; PHYS=Physiotherapy; GYNA=Gynaecology; RHEU=Rheumatology; ENT=Ear, Nose and Throat; OPH=Ophthalmoloy;

GAST=Gastroenterology; TRAU=Trauma; DERM=Dermatology; AUDI=Audiology NEUR=Neurology; PAIN=Pain management; UROL=Urology;

Figure 4: Box-plots showing monthly consultation rates before and after the intervention for subtypes of Chronic orofacial pain. BMS = burning mouth syndrome; TMD = Temporomandibular Disorders

Figure 5: Box-plots showing pain severity scores measured using the Brief Pain Inventory before and after the intervention for subtypes of Chronic orofacial pain. BMS = burning mouth syndrome; TMD = Temporomandibular Disorders

Figure 6: Box-plots showing pain interference scores measured using the Brief Pain Inventory before and after the intervention for subtypes of Chronic orofacial pain. BMS = burning mouth syndrome; TMD = Temporomandibular Disorders

Figure 7: Logic model showing the process of intervention development including: theoretical underpinnings, methodological frameworks, process evaluation using co-production and co-design approaches; feasibility and pilot work; implementation and future upscaling based on patient input and current care pathways.

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