# Development and validation of a Patient Reported Experience Measure (PREM) for patients with Temporomandibular disorders.

Submitted in fulfilment of the conditions governing

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**DOCTOR OF PHILOSOPHY**

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Oral Medicine

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# DECLARATION

This thesis describes research conducted in the UCL Eastman Dental Institute and Eastman Dental Hospital between 2018 and 2022 under the supervision of Dr Rachel Leeson, Professor Stefano Fedele, and Dr. Rícheal Ní Ríordáin. I certify that the research described is original and that I have written all the text herein and have clearly indicated by suitable citation any part of this thesis that has already appeared in publication.

Dina Taimeh.

## Abstract

Temporomandibular disorders are a group of conditions which affect the temporomandibular joint, surrounding muscles or both. They can manifest in an array of symptoms such as persistent pain, joint noises, alteration in mandibular movement and limitation in mouth opening. Patient Reported Experience Measures (PREMs) are validated questionnaires that reflect the patient experience while receiving healthcare and aim to capture the experience of the patients to ascertain whether specific aspects of care have or have not occurred. They can be tailored for use in specific settings and conditions such as mental health, rheumatoid arthritis and Parkinson's disease. A comprehensive search of the literature revealed that no such instrument exists for patients with TMD or indeed chronic facial pain.

The aims of this project were: 1. To explore the experiences of temporomandibular disorder patients with the public healthcare services in England. 2. To develop a Patient Reported Experience Measure (PREM) designed for use in a cohort of patients with pain-related temporomandibular disorders. 3. To evaluate the validity and reliability of the designed instrument.

A mixed method study was designed to achieve the outlined aims. A qualitative study was conducted in collaboration with 15 TMD patients to explore their experiences with the NHS when seeking treatment for their symptoms. The arising results helped generate the items of the questionnaire. A subsequent series of interviews with seven patients and six healthcare providers evaluated the suitability, relevance and comprehensibility of the suggested items. The following phase was a quantitative prospective study of 139 patients which investigated the structural validity, internal consistency and test-retest reliability of the new tool.

The newly developed questionnaire consisted of 21 items and was based on the NHS patient experience framework. Factor analysis revealed a suitable five-factor structure for the instrument, Cronbach-α was 0.7285 indicating good internal consistency, and interclass correlation coefficient was 0.732 indicating good test-retest reliability.

PREM-TMD is a brief measure to evaluate the experience of adult patients with pain related TMD within the healthcare services. It can be useful in service evaluation schemes, audits, and clinical research. The outlined psychometric properties are satisfactory, and hence support its use to evaluate the experience of TMD patients in a valid and reliable manner.

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warm and big-hearted mother, Ziad, Zeina, Hala, Alex, Sophia, Julia and Julien. I am very fortunate to have such a wonderful, caring and loving family and I am certain I could not have done it without them.

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## Impact statement

Over the past few decades, growing emphasis had been placed on the importance of the clinical experience for patients. It was announced as a pillar of the NHS alongside clinical effectiveness and safety. One of the suggested methods to evaluate the clinical experience is through the use of Patient Reported Experience Measures or PREMs. The present study describes a mixed method approach to create and validate a PREM for patients with temporomandibular disorders.

In preparation for the clinical study, qualitative evidence synthesis was conducted to explore the recorded experiences of TMD patients in the literature. The review not only helped in understanding the struggles of TMD patients in negotiating the healthcare systems, but also highlighted which aspects of care are important. Such qualitative evidence is a useful addition to the literature, where healthcare professionals and organisations alike can be guided in their efforts to make the clinical experience more pleasant for this group of patients.

A series of focus groups also shed light on the experience of this group of patients within NHS-England specifically. The results obtained complemented the findings of the qualitative systematic review and helped generate the items of the new PREM. Several discussions with domain experts who deal with TMD patients regularly and subsequent cognitive testing with a sample of the target population, ensured the content and face validity of the new tool and confirmed the suitability, relevance, comprehensibility and comprehensiveness of the items included.

Later, the structural validity, internal consistency and test-retest reliability of the new instrument were investigated. All the results were satisfactory and provided positive evidence for its use in a valid and reliable manner. PREMs have several potential

applications in research and clinical settings such as audits, quality improvement schemes, performance benchmarking and comparisons. This PREM can be a useful tool for units which deal regularly with TMD patients and can be helpful in achieving these purposes.

A comprehensive review of the literature also identified the Patient Reported Outcome Measures (PROMs) commonly used in TMD studies, and examined the psychometric properties attached. The findings of this study can be a helpful guide to orientate researchers regarding the most suitable PROMs for their own research. Furthermore, an additional cross sectional study provided psychometric evidence for the suitability of four PROMs for use in a TMD population. Again, the provided evidence could be a valuable addition to the literature, especially since the four tested PROMs are commonly used tools.

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## List of abbreviations

| | |
|---|---|
| 5-HT | 5-hydroxytryptamine |
| A&E | Accident and emergency |
| ACE | Angiotensin converting enzyme |
| CASP | The Critical Appraisal Skills Programme checklist |
| CBT | Cognitive behavioural therapy |
| CFA | Confirmatory factor analysis |
| CFI | Comparative fit index |
| CNS | Central nervous system |
| COFP | Chronic orofacial pain |
| COMT | Catechol-O-methyltransferase |
| COPD | Chronic obstructive pulmonary disease |
| COSMIN | COnsensus-based Standards for the selection of health Measurement Instruments |
| CPI | Characteristic pain intensity |
| CS | Central sensitisation |
| DC/TMD | Diagnostic Criteria for Temporomandibular Disorders |
| DDwR | Disc displacement with reduction |
| DOH | Department of Health |
| EBCD | Evidence Based Co-Design approach |
| EFA | Exploratory factor analysis |
| FA | Factor analysis |
| FDA | Food and drug administration |
| GAD | General anxiety disorder |

| | |
|---|---|
| GCPS | Graded chronic pain scale |
| GDP | General dental practitioner |
| GP | General practitioner |
| HRA | Health research authority |
| HTM | High-threshold mechanoreceptors |
| IA | Intra-articular involvement |
| IASP | The International Association for the Study of Pain |
| IBS | Irritable bowel syndrome |
| ICC | Interclass correlation coefficient |
| IMMPACT | Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials |
| IS | Interference score |
| JFLS | Jaw functional limitation scale |
| KMO | Kaiser-Meyer-Olkin Measure of Sampling Adequacy |
| MAOI | Monoamine oxidase inhibitors |
| NHS | National health service |
| NICE | The National Institute for Health and Care Excellence |
| NQB | NHS National Quality Board |
| NRM | Nucleus raphe magnus |
| NRS | Numeric rating scale |
| NSAIDs | Non-steroidal anti-inflammatory drugs |
| OBC | Oral behaviours checklist |
| OHIP | Oral health impact profile |
| OPPERA | Orofacial Pain: Prospective Evaluation and Risk Assessment study |

| | |
|---|---|
| PAG | Periaquaductal grey |
| PCC | Patient centred care |
| PHQ | Patient health questionnaire |
| PMN | Polymodal nociceptors |
| PREM | Patient reported experience measure |
| PREM-TMD | Patient reported experience measure for patients with temporomandibular disorders |
| PROM | Patient reported outcome measure |
| QI | Quality improvement |
| RA | Rheumatoid arthritis |
| RCDSO | Royal College of Dental Surgeons of Ontario |
| RCSE | The Royal College of Surgeons England |
| RDC/TMD | Research Diagnostic Criteria for Temporomandibular Disorders |
| REC | Research ethics committee |
| RMSEA | Root mean square of error approximation |
| SB | Sattora-Bentler adjustment |
| SD | Standard deviation |
| SNPs | Single-nucleotide polymorphisms |
| SRMR | Standardized root mean squared residual |
| SSRIs | Selective Serotonin Reuptake Inhibitors |
| S-W | Shapiro Wilkes test for normality |
| TCAs | Tricyclic Antidepressants |
| TLI | Tucker-Lewis index |
| TMD | Temporomandibular disorders |
| TMJ | Temporomandibular joint |

| | |
|---|---|
| TML | Temporomandibular ligament |
| VAS | Visual analogue scale |
| WHO | World health organisation |
| α | Cronbach’s alpha coefficient |

# Chapter 1: Literature review and introduction

## 1.1 Temporomandibular disorders

### 1.1.1 The anatomy of the temporomandibular joint

The temporomandibular joint (TMJ) is an articulating connection between the mandible and the cranium. This articulation is achieved by two joints -right and left TMJs - which are classified as synovial hinge joints despite the fact that some translatory or gliding movements also occur. In fact, the movements performed by the TMJ are considered the most complex joint movements in the human body (Wang et al., 2015)

The bony components of this joint consist of the mandibular condyle, the glenoid (mandibular) fossa and the articular eminence. The latter two components are a part of the temporal bone. Separating the bony components is an articular disc which is made up of dense fibrous connective tissue and separates the joint space into upper and lower compartments. The joint is also surrounded by a fibrous capsule and ligaments, which help stabilise the joint and reduce the extent of mandibular movements (Alomar et al., 2007).

#### 1.1.1.I. Mandibular condyle

The mandibular condyle measures about 15-20 mm from side to side, and 8-10 mm from front to back. The articular surface of the head of the condyle is the anterior and upper surface. When viewed from the front, the condylar head is divided into a medial pole and a lateral pole by a prominent crest, and both poles are roughened for the attachment of various structures. The medial pole serves as an attachment for the articular disc, and the lateral pole for the articular disc and the temporomandibular ligament (TML).

1.1.1. II. Glenoid (mandibular) fossa and articular eminence

- The glenoid fossa is a concavity within the temporal bone that secures the condylar head. The anterior wall of this fossa is formed by the articular eminence, which is a squamous part of temporal bone, and the posterior wall is formed by the tympanic plate, which is the anterior wall of the external acoustic meatus. A fissure called the tympanosquamous fissure separates the squamous portion and the tympanic portion.
- The articular eminence is a transverse bar of dense bone. During wide opening of the mouth, the condyle and disc complex move past the summit and onto the anterior slope of the eminence known as the preglenoid plane, which acts to facilitate posterior movement of this complex from such an anterior position.

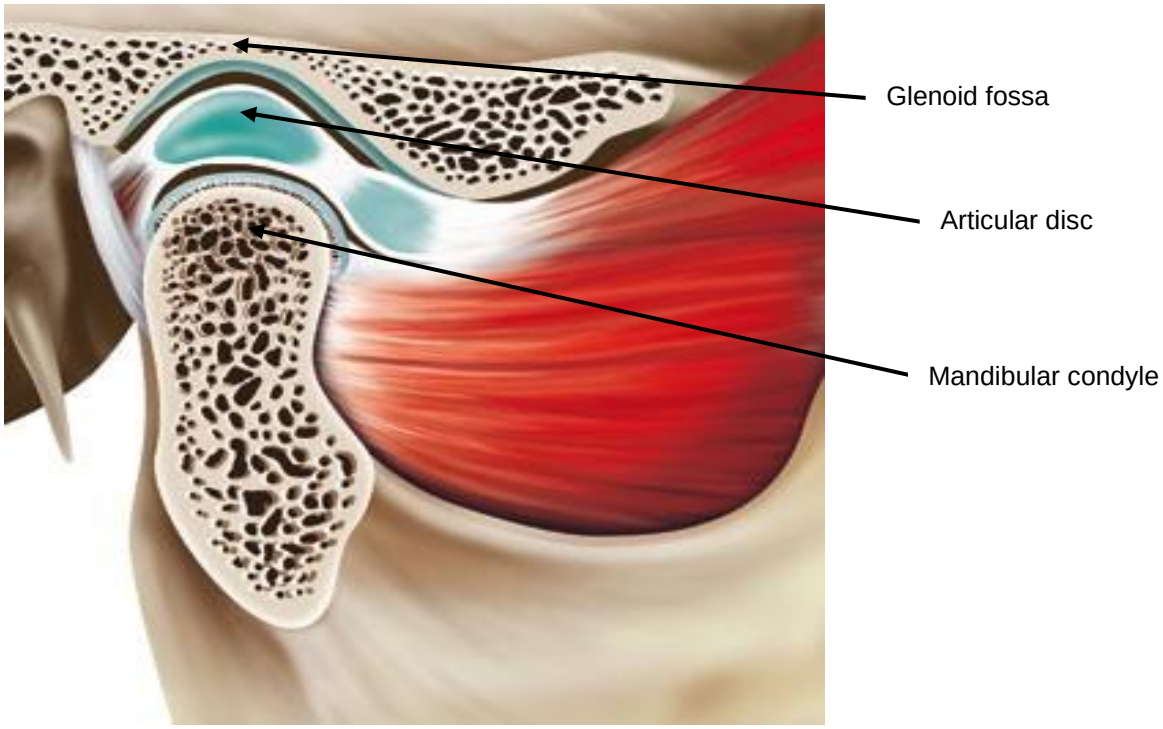
1.1.1.III. Articular disc

The articular disc is a firm, oval band of dense fibrous connective tissue, situated between the mandibular condyle and the articular fossa. Its central portion is the thinnest, and anteriorly it thickens to form the anterior attachment which is continuous with the capsule of the TMJ. Posteriorly, it forms the posterior attachment, which attaches to the condylar neck and the tempanosquamous fissure. The posterior attachment is profusely supplied with nerves and blood vessels. The main function of the articular disc has been suggested to be force distribution and stress reduction between the articulating surfaces of the joint.

1.1.1. IV. Articular capsule

A sleeve of tissue that completely surrounds the joint. The capsule is generally thin except for its lateral side which is thick and forms the TML.

Figure 1.1. The temporomandibular joint




Picture courtesy of www.nature.com/articles/sj.bdj.2013.950/figures/1

### 1.1.1.V. Temporomandibular ligaments

Temporomandibular ligament (TML): The TML is described to consist of two layers: a superficial broad fan-shaped layer, and a narrow deep portion.

Accessory ligaments: Two accessory ligaments have been described to support the TMJ, the sphenomandibular ligament and the stylomandibular ligament. The function of the sphenomandibular ligament is implied to be safeguarding the nerves and blood vessels passing into the mandibular foramen during opening and closing of the mandible. The stylomandibular ligament is tensed only when the mandible is protruded, which implies that it prevents excessive protrusive movement of the mandible.

### 1.1.1.VI. Muscles of mastication

Four main muscles are described in relation to the TMJ and mandibular movements. They are collectively called the muscles of mastication. These muscles are the Temporalis, Masseter, Lateral pterygoid and Medial pterygoid (van Gijn et al., 2022).

- Temporalis: This muscle originates from the surface of the temporal fossa and the temporal fascia and inserts deep to the zygomatic arch into the anterior portion of the coronoid process and the anterior border of the ramus.
- Masseter: This muscle consists of three portions; the superficial, the middle and the deep. The superficial portion of the muscle originates from the lower border of the anterior two thirds of the zygomatic arch and inserts into the lateral surface of the angle of the mandible. The deep portion originates from the inner surface and the lower posterior third of the zygomatic arch and inserts into the upper half of the ramus and the lateral surface of the coronoid process.
- Lateral pterygoid: It consists of two heads; the upper head which originates from the greater wing of sphenoid and the infratemporal crest, and the lower head which originates from the lateral surface of the lateral pterygoid plate. Both heads converge to be inserted on the anterior neck of the condyle and the articular disc and capsule.
- Medial pterygoid: It originates form the medial surface of the lateral pterygoid plate and the maxillary tuberosity. Its fibres pass to be inserted on the medial surface of the mandibular ramus and angle.

Mandibular movements are achieved by combining the actions of these muscles. The temporalis, masseter and medial pterygoid act together to raise the mandible against the maxilla. While the lateral pterygoid assists in mandibular opening, its main action is to bring the condyle and disc forward to achieve mandibular protrusion. The

posterior fibres of temporalis retract the mandible backwards. Furthermore, medial and lateral pterygoids are involved in side-to-side mandibular movements, such as those occurring during mastication of food.

The motor innervation of these muscles is the fifth cranial nerve (the trigeminal nerve) through its mandibular division (Akita et al., 2019). The blood supply to the TMJ mainly originates from the superficial temporal artery and the maxillary artery. Other vessels have also been described. These are small branches of the external carotid artery and of the facial or the ascending palatine artery (Cuccia et al., 2013, Ezure et al., 2011) .

### 1.1.2 Temporomandibular disorders

The term ‘temporomandibular disorders (TMD)’ is a general one which encompasses an array of conditions affecting the temporomandibular complex. Several definitions have been proposed, such as that of the American Dental Association “a set of diseases and disorders that are related to alterations in the structure, function, or physiology of the masticatory system and that may be associated with other systemic and comorbid medical conditions” (1983). Or the recent one proposed by the International Headache Society where “Temporomandibular disorders (TMDs) is a term used to describe a number of painful and non-painful disorders affecting the muscles of mastication, the temporomandibular joint (TMJ) and contiguous structures” (2020). Other terms previously used to describe TMD included “Temporomandibular joint dysfunction syndrome” (Shore, 1959), “Myofascial-pain dysfunction” (Laskin, 1969) and “Facial arthromylagia” (Harris, 1974).

The signs and symptoms were initially attributed to occlusal disharmony by Costen in 1934 (Costen, 1934), and similarly by Shore in the 1959 (Shore, 1959). In the 1980s,

however, the complex multifaceted biopsychosocial nature of TMD was recognised, and the new term ‘temporomandibular disorders’ was introduced by Bell (Bell, 1982).

This group of conditions can manifest in various ways, including pain in the joint, muscles of mastication or both, joint sounds such as clicking, popping or crepitus, restricted mouth opening, deviation in mandibular movements, headache in the temporal region, and earache (Palmer and Durham, 2021, Murphy et al., 2013). Other features include the psychological effects, which are suggested to be more prominent in patients experiencing chronic TMD. It is likely that the relationship is bidirectional, with chronic pain thought to contribute but also result in poor mental health (Von Korff et al., 1993).

### 1.1.3 Aetiology

Many theories have been suggested over the years to explain the aetiology of TMD. The prominent view at present suggests multifactorial and biopsychosocial risk factors, consisting of initiating, predisposing and perpetuating factors (Leeson, 2007, Suvinen et al., 2005)

#### 1.1.3.I. The anatomy and physiology of pain

The International Association for the Study of Pain (IASP) defines pain as ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage’ (1979). It is a subjective sensation usually associated with negative emotions and interpreted through the subject’s own experiences. Experience -rather than nociception- in this context is the keyword with which pain is described. While nociception is a natural process where signals are transmitted to the brain via certain pathways, pain is the product of a complex combination of signalling systems, higher centres modulation and the

individual's own interpretation (Steeds, 2009). The IASP definition avoids tying pain to a stimulus, as pain can be perceived in its absence.

Pain has multiple dimensions; sensory which encompasses the location and intensity of pain, emotional which projects the unpleasantness of the experience and cognitive which interprets the pain based on one's previous experiences (Crofford, 2015).

**Pain pathways**

Nociceptors are specialised peripheral nerve terminals, which receive input from painful stimuli and transmit them as electrical signals to the central nervous system (CNS) (Julius and Basbaum, 2001). Two types of these nociceptors are identified, high-threshold mechanoreceptors (HTM) which are activated by mechanical pressure, and polymodal nociceptors (PMN) which respond to tissue damaging inputs such as hydrogen ions, 5-hydroxytryptamine (5-HT), cytokines and bradykinin (Steeds, 2009).

Nociceptors can also be classified according to their fibre type into Aδ and C fibres. The differences between the two types are listed in table 1.1.

Table 1.1. Types of nociceptor fibres. (Steeds, 2009).

| Type | Aδ fibres | C fibres |
|---|---|---|
| Myelination | Myelinated | unmyelinated |
| Diameter | 2-5 μm | < 2 μm |
| Conduction velocity | 5–15 m $s^{-1}$ | 0.5–2 m $s^{-1}$ |
| Distribution | Body surface, muscles, joints | Most tissues |
| Pain sensation | Rapid, pricking, well localized | Slow, diffuse, dull, aching |

The dorsal root of the spinal cord is the main centre where the afferent neurons synapse with second order neurons. It is also where inhibitory and excitatory pathways interplay and where descending inhibitory neurons relay information from the higher centres in the brain (Yam et al., 2018, Steeds, 2009).

- Ascending pathways

The ascending second order neurons pass in the anterolateral white matter of the spinal cord via the spinothalamic and spinoreticular tracts.

- The brain

Axons travelling via the spinothalamic and spinoreticular tracts terminate in their respective nuclei in the thalamus, which is the main area in processing somatosensory information. Neurons then project into the insula, the anterior cingulate cortex and the prefrontal cortex (third order neurons). These areas interact with each other and with other areas in the brain to interpret pain.

- Descending tracts

These neuropathways have an important role in pain modulation. The principle inhibitory neurotransmitters involved are Noradrenaline and 5-HT, and two important areas responsible for the reduction of pain are the periaquaductal grey (PAG) and the nucleus raphe magnus (NRM). Both are found in the brain stem.

### 1.1.3. II. Acute vs chronic pain

Acute pain, often termed ‘nociceptive pain’ is that which “arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors.” That is, when pain signals originate from peripheral tissues, pass from the dorsal horn pain transmission neurons into the brain. When an identifiable lesion or disease affects the tissues of the somatosensory system, the term “neuropathic pain” is applied. Examples include stroke, vasculitis, shingles, or lesions identified by imaging or biopsy results (Crofford, 2015).

Chronic pain on the other hand, is usually defined as “pain lasting more than 3 months” and almost certainly has some, albeit variable, element of central sensitisation

(Crofford, 2015). It is a complex experience with sensory and emotional elements, often influenced by the psychological state of the person and context of pain to them (Bushnell et al., 2013, Villemure and Bushnell, 2009). These emotional and cognitive influences are linked on account of the connectivity of brain regions controlling pain perception and emotional states. Furthermore, considerable evidence has thus far been presented which demonstrates the alterations chronic pain casts on the brain regions involved in cognitive and emotional modulation of pain (Bushnell et al., 2013, Seminowicz et al., 2011, Apkarian et al., 2004). This complex interplay may explain the increased risk of psychological ill-health among chronic pain patients, but also why these psychological factors such as anxiety and depression are possible risk factors for chronic and central amplification of pain (Crofford, 2015).

#### 1.1.3.III. Central maintenance of pain

In many instances, notable disparities arise between the intensity of chronic pain as perceived by the patients, and that estimated by health care professionals (Puntillo et al., 2003, Prkachin et al., 2007). One proposed explanation of such discrepancy is the sensitisation processes and amplification of central excitatory signalling (Arendt-Nielsen et al., 2018).

The International Association for the Study of Pain (IASP) defines central sensitisation (CS) as 'Increased responsiveness of nociceptive neurons in the central nervous system to their normal or subthreshold afferent input' (2017). Accepted signs of CS include increased sensitivity outside the primary location of tissue injury, or the innervation district of a diseased nerve and increased sensitivity to sensory input in non-painful and healthy body parts (Nijs et al., 2021). Two mechanisms have been suggested to drive the development of CS: top-down and bottom-up theories. The Top-down theory suggests that the perception of pain is due to already existing

alterations within the CNS, whether peripheral noxious input is present or not (Harper et al., 2016) .The Bottom up theory suggests that excessive peripheral noxious input leads to CNS sensitisation, and subsequently pain is perceived even in the absence of a peripheral stimulus (Price and Gold, 2017). Both theories suggest that the changes in the CNS alter the way noxious stimulus is processed.(Eller-Smith et al., 2018).

The knowledge regarding central sensitisation, supported by systematic reviews and meta-analysis across several pain conditions, reveals a paradigm shift in the management, prognostic potential, and treatment outcome of chronic pain (Bartholomew et al., 2019, Tanaka et al., 2019, La Touche et al., 2018, Kaya et al., 2013, Meeus et al., 2012). CS, however, remains challenging to diagnose, given the lack of clear diagnostic and gold standards. Even more challenging is its treatment. Some preclinical data suggest that peripheral nociceptive input can induce and maintain CS (Woolf and Salter, 2000). Therefore, bottom-up treatments that reduce peripheral nociception, could potentially attenuate CS (eg. knee or hip replacement procedures). Alternatively, patients showing high levels of CS before physical treatments such as surgery, are more at risk of poor surgical outcomes, and therefore require approaches to attenuate central sensitisation (top–down treatment) (Nijs et al., 2021).

### 1.1.3. IV. Risk factors for chronic pain

A number of risk factors have been linked with the development of chronic pain, namely genes and environmental triggers. Pain sensitivity seemingly runs strongly in families, and a number of genes are culprit. For example, two major neurotransmitter pathways have been linked to musculoskeletal pain; the adrenergic pathway and the serotonin pathway (Diatchenko et al., 2013). In the former pathway, COMT -the gene

encoding the enzyme responsible for the catabolism of neurotransmitters such as epinephrine- is implicated. Additionally, increased risk of widespread pain has also been associated with β2-adrenergic receptor gene (ARDRB2; rs1042713 and rs1042714). As for the second pathway, specific genes include the 5-hydroxytryptamin receptor 2A (HTR2A) and 5HT transporter (SLC6A4) (Bondy et al., 1999, Nicholl et al., 2011).

Several environmental triggers have also been suggested in the transition of acute pain into chronic pain. Proposed factors include psychological distress such as depression and anxiety, history of childhood trauma and abuse, low educational attainment, social isolation, and sleep problems (Gupta et al., 2007, Nicholl et al., 2009).

All these factors come into play as part of the biopsychosocial model of pain, which posits that the experience of pain is a function of nociceptive input, psychological factors, and social contingencies such as expectations, family, and community influence (Blyth et al., 2007, Edwards et al., 2016)

#### 1.1.3.V. The biopsychosocial model of pain

Over the past few decades, medical views towards chronic pain have evolved. Where prior to the 1960s, it was regarded as a medical condition with clear pathophysiological bases handled with physical treatments such as medication, it is now progressively viewed in light of a biopsychosocial understanding (Jensen and Turk, 2014, Edwards et al., 2016). Collectively, the biopsychosocial model depicts pain as a reciprocating interplay among physiological, psychological, and social factors, eventually giving rise to complex pain syndromes such as fibromyalgia, temporomandibular disorders and back pain. Research has also supported a bidirectional link between mood disorders

and enduring pain. As pain persists, a higher risk of an effective disorder is expected, and similarly, psychosocial variables such as distress and anxiety are among the most robust predictors of the transition from acute to chronic pain (Edwards et al., 2016, Asmundson and Katz, 2009, Bair et al., 2003, Linton et al., 2011). A good deal of empirical evidence supports this argument and several reviews have highlighted the importance of such elements in shaping pain-related experiences and associated treatment outcomes (Pincus et al., 2002, Vissers et al., 2012). However, in practice, psychological components are often viewed as a reaction to the pain and are assigned secondary status (Edwards et al., 2016).

Despite its widespread support, this model does not come without criticism of its limitations. One of which is the ambiguity of the specific pathways of interaction and the blurred boundaries between the processes and constructs. Another is the involvement of multiple factors accounting for inter-individual variability of pain, rendering the hypothesis unfalsifiable by empirical research (Edwards et al., 2016, Gatchel and Turk, 2008, Weiner, 2008). Others have also noted that it may be too restrictive in some aspects of life, such as religion and spirituality. Biopsychosocial-spiritual model of chronic pain has since been proposed (Taylor et al., 2013). And finally, most studies do not routinely measure factors within the 3 domains. Indeed, psychosocial factors may be over-weighed, especially in the absence of anatomic pathology (Pincus et al., 2013, Weiner, 2008, Edwards et al., 2016).

### 1.1.3.VI. Aetiology of TMD and the OPPERA study

The underlying aetiology of TMD has been a cause for much debate over the past few decades, and many theories have been proposed throughout. Table 1.2 presents a few of the theories suggested.

Table 1.2. Theories suggested to explain the aetiology of TMD (Bhat, 2010).

| Name of the theory | Statements of the theory |
|---|---|
| Mechanical displacement (Costen, 1934) | Lack of posterior teeth support or occlusal contacts caused by parafunctional habits cause the condyle to be in an eccentric position; this leads to pain, and adverse muscle activity. |
| Trauma theory (Zarb and Speck, 1979) | TMD is caused by micro/macro trauma, either directly to the joint or muscles (macro-trauma) or by small forces repeatedly applied to the TMJ and surrounding structures (micro-trauma). |
| Biomedical (Reade, 1984) | TMD is initially caused by trauma, but in the presence of other factors such as malocclusion and parafunctional habits the condition progresses. Psychological factors are important influences. |
| Osteoarthric (Stegenga et al., 1989) | Osteoarthritis is the cause of TMD. Arthritic changes could be initiated by absolute or relative overloading. Absolute overloading occurs at the time of trauma, while relative overloading occurs when the adaptive capacity of the joint diminishes with inflammation or aging. |
| Muscle (Laskin, 1969) | Chronic myospasm secondary to parafunctional habits is the cause of myalgia in the facial region. Occlusal factors have no influence. |
| Neuromuscular (Ash and Ramjford, 1995) | Occlusal interferences are the primary cause of TMDs, as they cause altered proprioceptive feedback leading to muscle incoordination and spasm. |
| Psychophysiological (Reade, 1984, Zarb and Speck, 1979, Stegenga et al., 1989) | Psychological factors are more important than occlusal factors in initiating and propagating TMDs. Muscle spasm is caused by parafunctional habits which are a means to relieve stress, and the effect on the individual is determined by how they cope with stress. |
| Psychological theory (Grzesiak, 1991) (Greene, 1995, McNeill, 1997) | Emotional disturbance causes muscular hyperactivity, which in turns leads to parafunctional habits and consequently to occlusal abnormalities. Muscle contractility leads to pain. |

The current accepted view is that multiple factors act alone or in combination to cause painful TMD, therefore a single factor is unlikely to be discovered in a given case. Some domains of relevance are the psychological profile and state of pain

amplification (Slade et al., 2013b). Other predictors include number of co-morbid conditions such as irritable bowel syndrome (IBS) and other non-specific orofacial pain symptoms (Kapos et al., 2020). These specific factors are thought to be genetically regulated and influenced by environmental input as well (Maixner et al., 2011).

The aforementioned elements fall under either predisposing, initiating or perpetuating factors (Leeson, 2007). Predisposing factors are thought to be greater number of co-morbid conditions (IBS, fibromyalgia, depression and insomnia), non-specific orofacial pain symptoms (fatigue, soreness), geographic location (likely a representation of social and contextual factors), and pain interference. Other important predictors include number of oral parafunctional habits, limited mouth opening in the previous month, number of painful masticatory muscle sites on examination, age and somatic awareness (Bair et al., 2013, Kapos et al., 2020).

Initiating factors include jaw injury (such as yawning, dental treatment) (Sharma et al., 2019), migraine, headache frequency and worsening headache (Tchivileva et al., 2016).

Perpetuating factors include clinical measures of pain intensity, duration and frequency and co-morbidities (Meloto et al., 2019).

It is worth mentioning that a large-scale multicentre study was conducted in the US and sponsored by the NIH to identify risk factors that contribute to the development and persistence of TMD. The “Orofacial Pain: Prospective Evaluation and Risk Assessment” or OPPERA study received a grant from National Institute of Dental and Craniofacial Research, creating a $19.1 million project to meet those aims via four clinical studies (Dworkin, 2011b). An array of risk factors was investigated, ranging

from genetic and psychological factors to environmental influences. A decade later, 35 publications out and 4,346 patients enrolled, some of the findings of the study were:

- Somatic symptoms: The most important psychosocial predictor of TMD incidence.

The frequency of somatic symptoms such as dizziness and fatigue, is considered a strong predictor of TMD incidence. Smaller contributions were made from measures of psychological stress, anxiety, obsessive-compulsive feelings, and pain-coping strategies (Fillingim et al., 2013).

- Pain Thresholds: A consequence of TMD, not a predictor of it.

The OPPERA case-control study found that patients with TMD had an increased sensitivity to pressure pain, heat and pinprick stimuli for thresholds measured at trapezius and temporalis (Greenspan et al., 2011). Most of these measures, however, were not significant predictors to the incidence of TMD. The group argued that painful TMD increases the synaptic efficacy of neurons in the pathways involved in enhanced CS.

- Genetic associations were identified.

The case-control study evaluated the role of some genes in chronic TMD, using single-nucleotide polymorphisms (SNPs) representing genes involved in pain perception. Six SNP had strong associations. COMT genotype was also examined, and it was concluded that it modifies effects of stress on sensitivity to noxious stimuli and incidence of TMD.

- Oral parafunction and joint noises.

Participant-reported joint noises were a significant predictor of TMD incidence. Additionally, the risk of TMD was elevated in individuals reporting multiple oral behaviours occurring frequently (Slade et al., 2016).

- Sleep and TMD

The prospective cohort study explored sleep quality and risk of developing TMD. Their analysis showed that for each standard deviation decrement in sleep quality, the rate of first onset TMD increased 40% (Sanders et al., 2013). The deterioration in sleep quality was studied independently to other psychological or major TMD predictors.

### 1.1.4 Epidemiology

TMD represents the most common cause of chronic pain in the orofacial region and is the third most common cause of chronic pain after headaches and back ache (Dworkin, 2011b). It reaches peak incidence in the second and third decades of life with females more likely to develop persistent TMD (Palmer and Durham, 2021). The female: male ratio of 2:1 is reported in the general population; however, it is at least two folds higher in a clinical setting (Maixner et al., 2011, Leeson, 2007, Drangsholt et al., 1999, Bush et al., 1993)

Epidemiological reports show discrepancy as to the prevalence of the different TMD conditions under the broad general term. Lipton et al. (1993) report that 6-12% of the population report symptoms of TMD. Similar percentage was observed by LeResche (1997). While studies conducted in the 1980s report prevalence between 16-59% of the population (LeResche, 1997). The Royal College of Surgeons England (RCSE) report in their management guide that up to a third of the population could experience TMD (2013a).

Other studies revealed that around 60-75% of the population will manifest one TMD sign and 35% will express one TMD symptom (Karthik et al., 2017). Additionally, TMJ noises and clicking, are reported to be as high as 60% of the population. Discrepancies were also reported between populations, as shown by several studies conducted in

different countries (Johansson et al., 2003), (Macfarlane et al., 2002a), (Pow et al., 2001) and (Goulet et al., 1995).

### 1.1.5 Evaluation and diagnosis

As with any condition, a thorough history and examination are essential. A diagnosis is largely reached by comprehensive evaluation of the TMJ and surrounding structures, as the symptoms are often associated with pain in the preauricular, masseter or temporal areas on palpation, and/or upon jaw movements (chewing, yawning, talking... etc) (Gauer and Semidey, 2015). Additionally, other conditions with similar symptoms should be ruled out before reaching a diagnosis, such as odontogenic causes. The Royal College of Surgeons England (RCSE (2013a)), the Royal College of Dental Surgeons of Ontario (RCDSO) (2018) and the National Institute for Health and Care Excellence (NICE (2021)) provide checklists in their guidance to help obtain a comprehensive history. The checklists emphasise the importance of the overall medical history including injuries and trauma, pain location, character, onset, referral and associated alleviating/exacerbating factors. They also recommend questioning about any limitation in mouth opening and associated joint noises. Other aspects of relevance are any associated sensory alterations, hearing loss, tinnitus, parafunctional habits and sleep disturbances. Finally, all checklists recommend exploring any related mood or emotional changes such as feeling down or depressed.

The importance of a thorough examination is also highlighted in these guidelines, and checklists are provided for a systematic approach. Starting with the extraoral exam which includes the appearance and gait, as well as cranial nerves, lymph nodes and swellings/asymmetries. In patients over 50, the temporal vessels should also be carefully examined. The temporomandibular apparatus is probed closely next,

including the muscles of mastication, the TMJ, mouth opening, range of movement and joint noises. The intraoral examination inspects the state of the dentition, occlusion and soft tissue pathologies.

The role of imaging in the assessment of TMD has been examined by several studies (Crow et al., 2005, Epstein et al., 2001, Leon, 2004). The current trend suggests that imaging should be viewed as an adjunct to diagnosis rather than a definitive tool of diagnosis. Furthermore, it is prudent to recognise that many TMD conditions do not manifest as pathological changes, which cannot be assessed radiographically and would subject the patient to unnecessary radiation (RCSE (2013a). The need for imaging is usually dictated by the results of complete history and examination, however, radiographic investigation may be warranted if the following conditions are suspected (RCDSO (2018)):

1. Osseous abnormality in the jaw or the TMJ.

2. Internal derangement or disc displacement, if clinically significant or unresponsive to conservative treatment.

3. An extra articular disease, to rule out other potential causes.

4. Should the patient be unresponsive to initial conservative management.

Other laboratory investigations may be considered after history and clinical examination if an autoimmune or metabolic disorder is suspected, for example, rheumatoid arthritis. In some cases, consultation with other specialities may be also considered, for example, otolaryngologist, clinical psychologist or rheumatologist. (RCDSO (2018)).

It is worth mentioning that there are several suggested diagnostic systems for temporomandibular disorders, but currently, the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) seems to be the closest to a gold standard (Schiffman et al., 2014). The criteria, first proposed in 1992, was updated in 2014 following a series of international workshops, and consists of two axes. Axis I includes the physical assessment to reach a diagnosis using the provided algorithms and decision trees. Broadly, the system classifies TMDs into pain disorders and joint disorders. Pain related TMD include myalgia (local, myofascial pain and myofascial pain with referral), arthralgia, in addition to headache attributed to TMD. Joint disorders include intraarticular joint disorders (disc displacement with reduction, disc displacement with reduction with intermittent locking, disc displacement without reduction with limited mouth opening, and disc displacement without reduction without limited mouth opening), degenerative joint disease and subluxation. Axis II of the system evaluates the psychosocial status and pain-related disability in keeping with the biopsychosocial model of pain. Appendix 1 outlines the diagnostic decision trees.

Several screening instruments were also suggested in the past 30 years (Lundeen et al., 1986, Kleinknecht et al., 1986, Locker and Slade, 1989, Nielsen and Terp, 1990, Gerstner et al., 1994, Nilsson et al., 2006, Gonzalez et al., 2011).

### 1.1.6 Management

Pain seems to be the most common presenting symptom in TMD, including jaw pain, headaches and earache (Dimitroulis, 1998, Cooper and Kleinberg, 2007). The ability to cope with such painful symptoms varies among patients. Although most cope well with their symptoms, some might suffer from chronic TMD, and acute exacerbations of chronic disease. Furthermore, the quality of life could be affected as a result

(Burgess et al., 1988). Overall, however, around 5-10% of patients require treatment (Garefis et al., 1994).

The general consensus among several guidelines is that management should begin with conservative and reversible approaches. ‘First do no harm’ (NICE, RCSE, RCDSO). Non-surgical managements include reassurance and patient education, pharmacotherapy, occlusal therapy, physiotherapy, behavioural therapy, and psychotherapy. Surgical treatments include arthrocentesis, arthroscopy and arthrotomy.

A. Patient education and self- management

This is the key stone to all initial, non-invasive reversible management approaches. It is achieved first by giving the patient a clear diagnosis and educating them about their condition. Education often incudes motivation of patients toward self-care, alongside with providing them with strategies towards simple adjustment of everyday life, postural exercises and home exercises (Palmer and Durham, 2021). Active involvement of the clinician in patient care is recommended, as it aids in reinforcing their understanding of their condition and helps them have more control over their symptoms. It is also recommended that patients are made aware that their condition is of a fluctuating nature, and that acute flare-ups could be expected (RCSE (2013a)).

B. Physical therapy

Physical therapeutic strategies aim to correct muscle activity and improve joint function. The evidence regarding the techniques and the benefits is not yet well established, but it seems to suggest that the effect is generally short term (RCSE (2013a)) (La Touche et al., 2020) A Cochrane review studying the effectiveness of physical therapy in specific subgroups of TMD is forthcoming (Craane et al., 2018)

In a national survey conducted in the UK in 2013 (Rashid et al., 2013), it was reported that despite limited evidence, 72% of the survey responders considered physical therapy to be an effective approach to TMD management, with jaw exercises, manual therapy, ultrasound, laser therapy and acupuncture as the most effective modalities. It is also reported that physical therapy is among the 10 most commonly used treatment modalities for TMD (Medlicott and Harris, 2006).

Multiple techniques have been described, including jaw exercises such as stretching, relaxation, rotation, isometric and postural exercises, electro-physical modalities (ultrasound, low intensity laser, microwave and pulsed diathermy), massage, application of warm/cold compresses, manual therapy, acupuncture, electro-analgesic modalities (transcutaneous electrical nerve stimulation, interferential current and biofeedback), iontophoresis and phonophoresis (Armijo-Olivo et al., 2016).

Acupuncture is suggested to be effective in various chronic pain conditions such as: migraines, tension headaches and chronic daily headaches (Natbony and Zhang, 2020, Coeytaux and Befus, 2016). It seems that there is some supporting evidence for it as well in the case of myogenous TMD (Peixoto et al., 2021, Cho and Whang, 2010).

C. Pharmacology

The aim of pharmacological intervention is not curative, but it helps patients in managing pain and discomfort which may be associated with temporomandibular disorders (Dionne, 1997). A wide range of medications has been reported in managing TMD pain. Their effect has been examined in a Cochrane review by (Mujakperuo et al., 2010), and a review by the Canadian Dental Association (Ouanounou et al., 2017).

1. Non-steroidal anti-inflammatory drugs (NSAIDs)

NSAIDS can be used in mild to moderate acute inflammatory conditions, such as acute disc displacement without reduction or acute trauma. It is recommended that these medications be taken for two weeks for them to show an effect and at most four months in consultation with the patient's general practitioner (Wright, 2010). In a study by Ta and Dionne in 2004, Naproxen has shown to be superior to COX-2 inhibitor (celecoxib) and placebo in relieving TMD pain (Ta and Dionne, 2004). Whereas Diclofenac sodium showed no benefit in reducing daily experienced pain, pain at rest and palpation and severe and very severe symptoms (Ekberg et al., 1996). Other studies comparing ibuprofen with placebo failed to demonstrate a benefit of the drug in relieving TMD myogenous pain.(Singer and Dionne, 1997). Topical forms may be helpful in short courses. (Svensson and Arendt-Nielsen, 1995).

The most important side effect associated with the use of NSAIDs is GI risk of erosions and bleeding, which tend to occur more severely in elderly patients. In addition, NSAIDs have been shown to interact with various medications including lithium, methotrexate, ACE inhibitors, loop diuretics, and increase risk of serious bleeding if received with warfarin (Ouanounou et al., 2017).

2. Paracetamol

When paracetamol is used with a weak opioid or an NSAID, it seems to be more effective than when used alone. A mild to moderate effect on pain relief was reported when using paracetamol (Wänman et al., 2016).

3. Corticosteroids

These potent anti-inflammatory drugs have been described in managing TMDs. In a study investigating patients with TMJ arthritis, a single intra-articular

methylprednisolone injection diluted with lidocaine was delivered, and it was found to have a significant effect in reducing pain for 4-6 weeks (Alstergren et al., 1996). In other studies, 1 ml of triamcinolone acetonide combined with local anaesthetic was found to significantly reduce pain and improve function (Fredriksson et al., 2005, Arabshahi et al., 2005). When comparing intra-articular steroid injections, hyaluronic acid and placebo, it was demonstrated that all groups showed improvement, but the first two groups showed a greater improvement in inter-incisal opening and reduction of the number of painful muscles (Kopp et al., 1991).

Although this management method has been described in the literature, it is not widely used given the adverse side effects associated with repeated corticosteroid injections, such as damage to the fibrous layer and bone resorption (Ouanounou et al., 2017).

4. Antidepressants

Antidepressants have been widely used in the management of TMD pain over the past 30 years, despite the limited evidence. Their use in this context may have stemmed from their efficacy in the management of other chronic pain conditions (Chan et al., 2009). Tricyclic Antidepressants (TCAs) and Selective Serotonin Reuptake Inhibitors (SSRIs) have been commonly linked to orofacial pain reduction and are suggested to be effective first-line medications in cases refractory to other treatment options (Rizzatti-Barbosa et al., 2003, Inagaki et al., 2007). Moreover, they seem to improve disturbed sleep patterns, an added benefit for many chronic pain patients (Ouanounou et al., 2017). An initial dose of 10 to 25 mg taken at night time is recommended. It can be gradually titrated up in 10 to 25 mg steps every 3–7 days in one to two divided doses to an effective dose or the person's maximum tolerated dose (no higher than 75 mg a day) (NICE, 2022).

TCAs are associated with an array of side effects, including sedation, dry mouth, dizziness, constipation, and blurred vision. These drugs should be avoided in patients taking Monoamine Oxidase Inhibitors (MAOI), as the combination could lead to a severe reaction consisting of fever, ataxia, confusion, and severe hypertension, known as “Lethal serotonin syndrome”. SSRIs are also reported to cause side effects, such as GI disturbances, headache, dry mouth, sexual dysfunction, and sweating (Ouanounou et al., 2017).

5. Anticonvulsants

This class of drugs such as gabapentin and pregabalin has been widely described for the management of neuropathic pain and various chronic pain conditions, as these agents are theorised to inhibit excitatory neurons and enhance such inhibition (Taylor et al., 1998).

The side effects of these drugs are dose dependant and are mild to moderate in severity, making them well tolerated in general. Dizziness and somnolence are the most frequently reported, with dry mouth, weight gain, inability to concentrate and blurred vision less commonly reported. It has been suggested that anticonvulsants may be useful as adjuvant therapy to other medications particularly in cases of unremitting pain and failed TMJ surgeries (Ouanounou et al., 2017).

6. Muscle relaxants

Muscle relaxants act by reducing skeletal muscle tone and therefore may be helpful in managing some forms of TMDs. Most common muscle relaxants are: carisoprodol, cyclobenzaprine, metaxalone and methocarbamol. Many consider cyclobenzaprine to be the drug of choice in managing chronic pain conditions. Its use, however, in managing TMDs has been debatable. A previous randomised controlled trial

concluded that cyclobenzaprine had an added benefit over placebo when it is combined with education and self-care (Herman et al., 2002).

These drugs should be used with caution as they cause profound sedation. Additionally, they should be avoided in patients with congestive heart failure, hyperthyroidism and those receiving MAOI and tramadol. Low doses, however (10 mg at bedtime), are shown to have a positive effect on sleep physiology and pain alleviation (Ouanounou et al., 2017).

7. Benzodiazepines

Benzodiazepines are widely used for the management of sleep disorders and acute muscle spasms. Their use however has been discouraged for chronic pain conditions, as the potential side effects associated with this class of drugs are too substantial to justify their use in this context. These include drowsiness, confusion, amnesia, incoordination, physical dependence, tolerance, and multiple drug interactions such as calcium channel blockers, antifungals and erythromycin (Ouanounou et al., 2017). In the guidance of the Royal College of Surgeons England, their use is only appropriate in an acute phase of myogenous TMD such as myofascial pain with limited mouth opening (RCSE (2013a)).

8. Botulinum toxin injections

Botulinum is a neurotoxin produced by anaerobic, gram positive, rod bacteria called *Clostridium botulinum*. The therapeutic use of botulinum toxin in humans was first suggested by Scott (1980) for the treatment of strabismus. Since then, it has been shown to be effective in the management of multiple conditions such as: blepharospasm, oromandibular dystonia and spasmodic dysphonia. Its mechanism of action involves transient paralysis of skeletal muscles by blocking the release of

acetylcholine from motor nerve endings (Simpson, 1981) and as some TMD conditions are muscular in origin, it has been rationalised that it could be used in the management of such cases. Additionally, it has been suggested that it causes reduction of sensory feedback and the inhibition of pain neurotransmitters release such as glutamate and substance P (Gobel and Jost, 2003).

Several systematic reviews have examined the evidence supporting its use in the context of TMD (Patel et al., 2019, Awan et al., 2019, De la Torre Canales et al., 2019). While some primary studies indicated improvements in pain scores, this finding was not reported consistently (la Fleur and Adams, 2020), and the evidence was found to be of low quality so far (Al-Moraissi et al., 2020). Additionally, the effects of Botox injections could be difficult to separate from placebo or indeed dry needling (essentially acupuncture) (RCSE, (2013a)).

Reported side effects in association with this type of injection include temporary regional weakness, tenderness over the site of injection, asymmetric smile and difficulty swallowing (la Fleur and Adams, 2020).

D. Occlusal interventions

Occlusal interventions described in association with TMD treatment include occlusal splints, occlusal adjustments, and orthodontic therapy.

1. Occlusal splints are any removable artificial occlusal surface affecting the relationship of the mandible to the maxilla used for diagnosis or therapy (Singh et al., 2017). They are the most common treatment approach, with benefits reportedly stemming from dental and non-dental origins (Singh et al., 2017, Zhang et al., 2020). Dental causes include alteration of occlusal relationship, increase in vertical dimension of occlusion and alteration of condylar position. Non-dental reasons

include: cognitive awareness, placebo effect and increased peripheral input to the CNS leading to decreased motor activity (Okeson, 2003). A recent network meta-analysis suggested that the treatment effects of stabilisation appliances extend beyond placebo (Alkhutari et al., 2021).

2. Occlusal adjustments: the theory proposes that by eliminating centric and protrusive interferences, disocclusion time is reduced, which in turn may lead to reduction of muscular hyperactivity and myofascial pain (Kerstein, 1992, Kerstein, 1993, Thumati et al., 2014). Occlusal equilibration is an irreversible intervention with no satisfactory evidence and fraught with potential difficulties and adverse effects, hence it is not a routinely recommended treatment approach. It may have a role in very specific corrections of a single obvious occlusal interference, or an acute occlusal change, i.e. new filling (RCSE, (2013a)).
3. Orthodontic therapy: it is proposed that by treating malocclusion, TMJ will undergo remodelling, which overrides new functional needs and allows normal function to continue (Moss and Salentijn, 1969). However, the current evidence is insufficient to recommend orthodontic treatment to treat or prevent TMDs (Manfredini et al., 2017) (Machado et al., 2012).

E. <u>Behavioural therapy and psychological interventions</u>

Multiple treatment modalities have been described in the literature including education, relaxation training, stress management, biofeedback, and cognitive behavioural therapy (CBT). CBT, notably, has been reported to give some long-term benefit in pain-related cases. It may also have a positive impact on depression and activity interference (Aggarwal et al., 2011, Aggarwal et al., 2010). Given these benefits, the RCSE recommends CBT among the initial treatment approaches of patients complaining of significant chronic pain (RCSE, (2013a)).

TMJ and maxillofacial surgery

Surgical intervention in TMD treatment is often considered a last resort. However, it is sometimes the only suitable treatment for some conditions. Laskin et al have divided the temporomandibular joint conditions into conditions that are primarily treated medically, primarily treated surgically and conditions that are treated medically initially but may need surgical intervention should the medical intervention fail (Roy, 2006). Conditions that may need surgical intervention primarily include:

1. Mandibular growth disturbances such as unilateral condylar hyperplasia, condylar agenesis, and condylar hypoplasia

2. Ankylosis of the TMJ if the aetiology was traumatic, congenital, or neoplastic in origin. Inflammatory ankylosis is often managed medically initially.

3. Tumours of the TMJ may require surgical management whether they were benign or malignant.

When conservative treatment is used for the remaining conditions, TMJ surgery is rarely indicated. Studies have shown that only 5-10% of TMD patients need surgical intervention with arthrocentesis being the most performed procedure (Dimitroulis, 2018). The choice of the procedure will vary according to the patient's history, clinical signs and symptoms, clinician skills and experience, and backed by radiographic investigations (Wright, 2010). Other indications for TMJ surgery include chronic severe limited mouth opening, and gross mechanical obstruction such as painful clicking and crepitus that does not respond to conservative management. The RCSE recognises the role of arthrocentesis in non-myogenous TMD with a significant functional problem (2013a). Other indications include recurrent TMJ dislocations, with a catalogue of

possible management procedures ranging from autologous blood injections to open surgery such as eminectomy (RCSE, (2013a)).

## 1.2 Patient experience and person-centred care

Person-centred (PC) care is defined as “treating the patient as a unique individual” (Redman, 2004). It demonstrates the intention of respecting the patients and allowing them to be a part of a shared decision-making process. It considers the uniqueness of the individuals and accounts for their circumstances, respective needs, wishes and expectations of treatment (Paparella, 2016). The concepts of PC care have been alluded to since the 1800s (Nightingale, 1992). However, it is only in the recent few decades that governing bodies and policy makers have started to shift the focus to rely not only on the traditional measures of healthcare such as physiological measures, but also on patients’ input and belief of effectiveness (Paparella, 2016).

PC care is viewed as a way to empower patients and expand their role in healthcare. The basis of this approach is to provide patients with reassurance, comfort, support, legitimacy and confidence (Fulford et al., 1995). It therefore assumes that they are capable of deciding what happens to their own bodies, and the role of clinicians is to support them with advice and deliver healthcare in line with their wishes and needs (Lutz and Bowers, 2000).

One of the leading institutes in Europe studying patient centred care is the Picker’s Institute. This charity has worked closely with prominent healthcare systems such as the National Health Service (NHS), to influence policy and practice to increasingly revolve around patients’ needs and feedback. The key components of PC care as proposed by the Picker’s Institute are:

1. Fast access to reliable health advice
2. Effective treatment delivered by trusted professionals
3. Continuity of care and smooth transitions

4. Involvement of, and support for, family and carers
5. Clear, comprehensible information and support for self-care
6. Involvement in decisions and respect for preferences
7. Emotional support, empathy and respect
8. Attention to physical and environmental needs

In 2011, the NHS National Quality Board (NQB) adopted these elements and made them the basis of a framework that details the elements which are critical to the patients' experiences within the NHS (NHS, 2011). The framework is outlined as follows:

- **Respect for patient-centred** values, preferences, and expressed needs, including cultural issues; the dignity, privacy and independence of patients and service users; an awareness of quality-of-life issues; and shared decision making
- **Coordination and integration of care** across the health and social care system
- **Information, communication, and education** on clinical status, progress, prognosis, and processes of care in order to facilitate autonomy, self-care and health promotion
- **Physical comfort** including pain management, help with activities of daily living, and clean and comfortable surroundings
- **Emotional support** and alleviation of fear and anxiety about such issues as clinical status, prognosis, and the impact of illness on patients, their families and their finances
- **Welcoming the involvement of family and friends**, on whom patients and service users rely, in decision-making and demonstrating awareness and accommodation of their needs as caregivers.

- **Transition and continuity** as regards information that will help patients care for themselves away from a clinical setting, and coordination, planning, and support to ease transitions
- **Access to care** with attention for example, to time spent waiting for admission or time between admission and placement in a room in an in- patient setting and waiting time for an appointment or visit in the out- patient, primary care or social care setting.

Patient experience has several definitions such as ‘what the process of receiving care feels like for the patient, their family and carers. It is a key element of quality, alongside providing clinical excellence and safer care’ (2013), or the ‘feedback from patients on what actually happened in the course of receiving care or treatment, both the objective facts and their subjective views of it’ (Foster, 2010). Another definition is the one proposed by NHS National Quality Board ‘A patient’s direct experience of specific aspects of treatment or care’.

### 1.2.1. Rationale to measuring patient experience

Measuring the hospital experience and obtaining feedback offers meaningful insight into what matters most to patients. To rely only on mortality and survival rates to assess the impact of healthcare is partial and unsighted, as patients also care about their ability to lead normal lives and be active in society as well. The inclusion of patient experience as a pillar of quality could be justified by several reasons; the least of which is that providing a humane and empathetic care is expected and necessary (Doyle et al., 2013). Furthermore, the information obtained from patients’ feedback could be used meaningfully to:

1. Enable the understanding of problems faced when delivering care to patients.
2. Provide a tool that helps clinicians and healthcare teams reflect on their care and practice.
3. Monitor the impact of implemented changes.
4. Help achieve continuous improvement of the services.
5. Facilitate standardising care between different practices and organisations
6. Comparing organisations for performance assessment
7. Helping patients choose high quality care.
8. Allow for public accountability.

Over the past few decades, hospital experience has increasingly become crucial to clinical quality. It was declared as one of the main pillars of quality in the NHS, with equal importance to safety and clinical effectiveness (D.O.H, 2008a). The delivery of a clinically effective intervention is no longer viewed as a successful clinical experience for patients if it was not delivered in a timely manner, in poor clinical conditions or from uncompassionate clinicians (NHS Wakefield Clinical Commissioning Group, (2012c)) Therefore, healthcare services in England are now required to review patient experience as part of quality assessments, and funding to some services is tied to improvements to patient experience (D.O.H, 2008b) (2012c).

### 1.2.2. Acquiring patient input

The national health policy in England accepts patient experience as an equal component in care quality alongside safety and clinical effectiveness, with the priority always being “putting the patient first” (2012b). Currently, the challenge lies in

determining the best approach to measure the patient experience and using the data in implementing changes to areas of concern (Skipper, 2014).

Patients' views about the received care in general can be obtained in several ways:

1. Questionnaires
   A. Satisfaction surveys: these are already in place across a range of healthcare services under the National Survey Programme implemented by the NHS. This programme enables health authorities to build a wide picture of the nation's views regarding care in the NHS and provide comparisons of the performance of different organisations over time and between different patient groups. An example being The Cancer Patient Experience Survey which collects data under the National Survey Programme and is helping in exploring how patient experience can be improved by The Cancer Patient Experience Advisory Group and the Macmillan Cancer Support (Skipper, 2014).
   B. Patient-Reported Outcome Measures (PROMs): these measure various patient-perceived parameters, such as health status, quality of life and effectiveness of treatment. The information collected from these questionnaires are an indication to the quality of care delivered to patients (Darzi, 2007). The national PROMs programme led by NHS England has imposed the routine collection of PROMs in certain clinical areas since April 2009. The PROMs currently in place are for four elective surgical procedures: hip replacement surgeries, knee replacements, groin hernia and varicose veins (Skipper, 2014).
   C. Patient-Reported Experience Measure (PREMs): are validated questionnaires that reflect the patient experience while receiving healthcare. They aim to capture the experience of the patients, to ascertain whether specific aspects of care have or have not occurred. They are a useful way to measure Patient

Centeredness (Christalle et al., 2018), and have the potential to provide policy makers with valuable information on patients' care and support, in conjunction with clinical audits and organisational data (Skipper, 2014).

2. Evidence Based Co-Design approach (EBCD): in this approach, staff members are shown recorded interviews with the patients where they describe their experience. Action groups identify areas of concern and suggest improvements. Later, they would receive patient feedback regarding these changes. (Pickles et al., 2008, Tsianakas et al., 2012).
3. Shadowing of patients by empathetic observers. These observers then produce a report of the patient experience, highlighting the areas which require attention. The report is then presented to clinicians, to identify and discuss areas of improvements (DiGioia and Greenhouse, 2011).

### 1.2.3 PROMs, PREMs, and satisfaction surveys

Experience has traditionally been measured by satisfaction surveys. The Care Quality Commission have released a number of satisfaction surveys for different settings (outpatient, inpatient, mental health, emergency care… etc) as part of the National Patient Survey Programme. Satisfaction surveys are useful sources for public accountability purposes and to give an impression of the 'bigger picture'. However, they could be insensitive to some problems faced in healthcare. If users are found to be dissatisfied, it is not immediately clear which aspects they are dissatisfied with. (NHS England Clinical Programmes and Patient Insight Analytical Unit (2018). Furthermore, these types of surveys tend to elicit ceiling effects (Coulter et al., 2002). Additionally, satisfaction is very subjective and highly influenced by the users, their expectations, attitudes, past experiences, age, and social class (Fitzpatrick and Hopkins, 1983). This leads to the idea of measuring patient-reported experience.

Rather than asking service users to give subjective ratings of their satisfaction with the service, PREMs give more focus to objective, measurable and actual experiences. For example, asking “Did your physician give you enough information about your medication?” or “Where you involved in the decision-making process?”. This approach provides more interpretable and actionable data than satisfaction surveys (Skipper, 2014, Cleary, 1998) .

PREMs are validated questionnaires, and typically measure the aspects of care that are most important to patients (Graham and Woods, 2013). The information gathered from such measures could be used in research, clinical performance evaluation, quality improvement schemes, improve patient-centred care, clinical practice benchmarking and performance comparisons. (Christalle et al., 2018, Kingsley and Patel, 2017). PREMs have become increasingly popular in recent years, with around 20% of the existing ones developed after 2015 (Bull et al., 2019). Bull et al, were able to identify 88 PREMs in their review of the literature, spanning different settings and conditions such as cystic fibrosis (Homa et al., 2013) and Parkinson’s disease (van der Eijk et al., 2012).

In contrast to Patient Reported Outcome measures (PROMs), PREMs do not measure the outcome of the treatment, but the impact of the process of care from the patients’ prospective, such as communication with the treating physician, empathy from the working staff, and involvement in decision making. (Kingsley and Patel, 2017).

PROMs are also validated questionnaires completed directly by the patients and measure treatment outcome, quality of life, symptoms severity, health and functional status. As with other outcome measures (including PREMs), they have a rigorous development process and robust psychometric properties (Smith et al., 2005).

While there are many advantages to the use of PREMs, they come with some limitations as well. Firstly, critics of PREMs point out the aforementioned issue that patient experience may be seen as congruent with terms such as “patient satisfaction”, therefore subtracting from its value as an indicator of quality. Secondly, PREMs may be confounded by factors other than the actual care experience, such as the outcome of treatment. And finally, they may be a reflection of the patients’ ‘ideal’ care rather than the actual care (Bull et al., 2019, Manary et al., 2013). However, despite these limitations. they continue to gain recognition as a source of patient-level information that can dictate quality improvement initiative, and a comprehensive insight into the care experience (Bull et al., 2019)

### 1.2.4 Barriers and facilitators to the routine use of experience questionnaires

The examination of the organisational factors that promote meaningful use of the collected data is important to ensure that it is properly used to entice changes within the service (Rozenblum et al., 2013, Byron et al., 2014, Gleeson et al., 2016).

Several barriers are identified to hinder the routine collection of this type of questionnaires, some of them are:

1. Lack of time and resources to collect, analyse and act on the data (Byron et al., 2014, Gleeson et al., 2016) (Gleeson, 2016)
2. Competing priorities within the service, for example the number of patients seen or financial plans. These priorities might hinder the staff’s commitment in engaging fully in quality improvement initiatives (Davies and Cleary, 2005, Gleeson et al., 2016).
3. Lack of data management systems in some settings (Bastemeijer et al., 2019).

4. The possibility of low response rates owing to a range of causes, such as patients being too ill, or the added burden of answering a questionnaire (Skipper, 2014).

On the other hand, various facilitators could be employed to promote their use:

1. Quality improvement interventions might be easier to implement if the management was committed to that goal (Ugarte, 2015, Reeves et al., 2013, Bastemeijer et al., 2019).
2. Involvement of staff into the collection process gives them insight into interpretation of the experience scores. Therefore, staff should be supported by means of coaching, education and multi-disciplinary collaborations (Bastemeijer et al., 2019, Indovina et al., 2016, Reeves et al., 2013).
3. Another facilitator could be the involvement of the patients in designing such initiatives, as getting that insight might shed light on what is and is not appropriate and acceptable (Indovina et al., 2016, Maqbool et al., 2016, Bastemeijer et al., 2019).
4. Continuous monitoring of patient experience is important as it enhances the culture of change within healthcare (Bastemeijer et al., 2019, Wilson et al., 2017).

### 1.2.5. Hospital experience and chronic pain

Chronic musculoskeletal pain in general is one of the most significant causes of suffering in the United Kingdom and the second most common cause for sick leave (Dewar et al., 2009). It is a complex condition, making its management a challenge as patients often present with psychosocial distress (Campbell and Guy, 2007). In addition to the impact chronic pain has on several aspects of life, some research also

suggests that patients might find some difficulty articulating their pain experience to doctors, potentially leading to uneasy relationships (Wolf et al., 2008, Durham et al., 2013b)

Chronic pain places a large burden on the NHS in England (Outlaw et al., 2018). In the national pain audit in 2012, 20% of the respondents reported attending A&E for pain management in the previous 6 months (2012a). It was also estimated that 4.6 million appointments in primary care involved chronic pain patients in 2004 (Outlaw et al., 2018). Other reports reviewed the financial impact TMD has on patients in the northeast of England and found that the total costs per 6 months range from £321 to £519 per individual (Slade and Durham, 2020). Several direct and indirect costs were implicated, such as specialist consultation costs, employer-related costs due to work loss and presenteeism.

One element consistently appearing in the literature is the frequent engagement of chronic pain patients with the healthcare services, possibly indicating that the previous visits have been unsuccessful in some aspect or another (Toye et al., 2013b, Campbell and Guy, 2007). It has been suggested that although clinicians adhere to guidelines in their management of pain, they may not always consider patients' views on management strategies (Bergman et al., 2013), leading in consequence to unmet patients' expectations and excessive use of the services to help cope with the pain. A qualitative study exploring the experience with a chronic pain service also reported that the staff often misjudged what was important to patients, and the patients were poorly informed of what to expect from the pain service (Outlaw et al., 2018). In a similar manner, the care pathways for chronic orofacial pain also seem to have some existing problems, namely the length of time to receive a diagnosis, the persistence to

attending appointments in search of effective treatments and the inconsistent patterns of referral from primary care (Breckons et al., 2017).

The financial implications of a better and more efficient clinical experience are positive (D.O.H, 2013). Likewise, patient related outcomes may also benefit. In a study by Larson et al, (1996) studying patients admitted due to acute myocardial infarction, the group found that good communication between the clinician and the patient resulted in better health related quality of life (correlation co-efficient of 0.33). Similarly, in studies by Black, (2014), and Slatore et al, (2010), studying elective surgery and COPD patients, respectively. In fact, Doyle et al conducted a systematic review to study the relationship between patient experience and clinical effectiveness. The systematic review summarised evidence from 55 studies concerned with a wide range of disease areas, settings, and study designs. Overall, it demonstrated a positive association between patient experience, clinical effectiveness, and patient safety. Arguments explaining this effect include that a positive clinical experience promotes adherence to treatment instructions, compliance with medication, better recall, and better use of preventive services (Doyle et al., 2013). Further evidence was presented by Kelley et al (2014), who conducted a systematic review and meta-analysis of randomised controlled clinical trials which are concerned with the effect of the clinician-patient relationship on healthcare outcomes. Observed effect sizes for the individual studies ranged from d =-.23 to .66. Using a random-effects model, the estimate of the overall effect size was small (d = .11), but statistically significant (p = .02). The group argued that effect sizes in medicine are generally small, as there are many factors accounting for healthcare outcomes such as the natural course of the disease, disease severity and overall health. Other reviews by Griffin et al (2004), Di Blasi et al, (2001),

and Stewart (1995) also suggested that physicians who are warm and caring, may be more effective and show promise in improving patient health.

The previously presented arguments may well apply to chronic pain and TMD as well. Providing such evidence can be facilitated by having valid and reliable measures of clinical experience and patient reported outcomes.

## 1.3 Knowledge gap

Multiple international (WHO, Picker's institute, FDA) and national (NHS) organisations have highlighted the importance of a pleasant patient experience in healthcare services. Several PREMs have already been developed to capture this experience in many fields, such as cancer (Taylor et al., 2015), sickle cell disease (Chakravorty et al., 2018), mental health (Fernandes et al., 2019) and Rheumatoid arthritis (Bosworth et al., 2015). However, there remains no valid and reliable instrument intended purposefully for use in a TMD population to measure their experiences when frequenting healthcare services. The proposed instrument in this study will be designed to fulfil this purpose.

## 1.4 Aims and objectives of the research

Primary objectives

1. To explore the experience of temporomandibular disorder patients with the public healthcare services in England.
2. To develop a Patient Reported Experience Measure (PREM) designed for use in a cohort of patients with pain-related temporomandibular disorders.
3. To evaluate the validity and reliability of the designed instrument.

Secondary objectives

1. Identify the commonly used PROMs and classification systems in temporomandibular disorders studies.
2. To explore the associations between the hospital experience as measured by PREM-TMD, demographic characteristics and psychological co-morbidities.

# Chapter 2. A comprehensive review of the commonly used PROMs and classification systems in TMD studies.

## 2.1 Introduction

Traditionally, healthcare has been assessed in terms of the technical and physiological outcomes of treatment, such as survival rates or laboratory markers (Coulter et al., 2002). In more recent times however, healthcare organisations are striving to achieve services that are not only clinically effective and evidence-based, but also beneficial and effective to patients as judged from their own perspective (Coulter et al., 2002, Jenkinson and McGee, 1998). Despite the best of intentions, physicians may be overburdened with the administrative aspect of patient care so that some questions may be left unasked. In an attempt by Paul Ellwood to increase efficiency without decreasing the humanity of the patient encounter, he proposed the use of Patient Reported Outcome Measures (PROMs) (Ellwood, 1997). PROMs are “standardised, validated questionnaires that are completed by the patients to ascertain perceptions of their health status, perceived level of impairment, disability, and health-related quality of life” (Kingsley and Patel, 2017). These questionnaires could be a very powerful tool to bridge the need for gathering information in an efficient manner, complement the clinical decision making, and enhance communication between patients and physicians (Griggs et al., 2017). Some are generic, which are used in a wide range of conditions and settings, and some are condition-specific, which are designed specifically for the use of certain populations (Coons et al., 2000).

The use of PROMs may be more prominent in some aspects of health such as pain assessment, as it is a subjective experience difficult to be measured by the physician. It is what the sufferer says it is, therefore, it is widely accepted that pain is measured by self-report (Robinson-Papp et al., 2015). Numerous PROMs are used in trials

concerning chronic pain. However, such variability may have a hindering impact in terms of evaluating the efficacy of different treatments. In recognition of this, the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommended core outcome domains and measures for clinical trials of chronic pain, to facilitate pooling of information, and to make meaningful comparisons of different treatments (Dworkin et al., 2005). A similar set of PROMs was also suggested for temporomandibular disorders. This set, known as the Research Diagnostic Criteria, was first proposed in 1992 by Dworkin et al following international expert recommendations (Dworkin and LeResche, 1992). It was updated in 2014 to become the Diagnostic Criteria (DC/TMD) (Schiffman et al., 2014). The main rational, however, for this set was to offer a diagnostic and classification system for the subtypes of temporomandibular disorders by proposing two axes. Axis I offers a classification system obtained from a thorough history and an examination checklist. Axis II contains a set of PROMs to record some parameters, including pain intensity, jaw function, psychological status and psychosocial function. (Dworkin, 2010).

Despite the efforts of IMMPACT and DC/TMD, there appears to be a lack of consistency regarding the PROMs used in TMD clinical trials.

### 2.1.1. Psychometric properties of PROMs

Health measurement instruments have many applications in clinical research and practice, based on which, treatment decisions may be made. Hence, it is important that these instruments are well-designed and psychometrically sound. This is usually demonstrated by providing sufficient evidence of a rigorous development process and satisfactory psychometric properties such as validity and reliability (Mokkink et al., 2010b).

The COSMIN initiative (COnsensus-based Standards for the selection of health Measurement Instruments) aims to improve the selection of PROMs and harmonise the approach to their assessment. A taxonomy list and definition of the measurement properties are provided as part of the initiative. The key properties are reliability, validity, responsiveness (Mokkink et al., 2010c).

1. Reliability is defined as “The degree to which the measurement is free from measurement error”. It determines the extent to whether a PROM yields consistent and reproducible results. Reliability is a parent concept, with several aspects to it, namely internal consistency reliability and test-retest reliability.
   a. Internal consistency is defined as “The degree of the interrelatedness among the items of the PROM”. It evaluates the homogeneity of the scale and the consistency of the responses (Terwee et al., 2007). The commonly used method to assess internal consistency is by calculating Cronbach α. The values range from 0 to 1 indicating non correlation to complete correlation (Tavakol and Dennick, 2011).
   b. Test-retest reliability is the reliability of the instrument selected over time (Mokkink et al., 2018a). In general, it is evaluated by administering the PROM at two points in time. If the final score of the instrument is a continuous variable, the interclass correlation coefficient (ICC) is used to assess this aspect of reliability. The COSMIN guidance recommends a cut-off point of 0.70 (Terwee et al., 2007). Weighted Kappa is used for ordinal variables.
2. Validity is “The degree to which a PROM measures the construct(s) it purports to measure. It consists of the following aspects:
   a. Content validity: “The degree to which the content of a PROM is an adequate reflection of the construct to be measured”. It is considered the most important

measurement property, and lack thereof can affect all other properties (Terwee et al., 2018). Content validity also includes face validity.

b. Construct validity: “The degree to which the scores of a PROM are consistent with hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups) based on the assumption that the PROM validly measures the construct to be measured”. According to the COSMIN guidance, construct validity consists of structural validity (which can be explored using factor analysis), hypotheses testing, and cross-cultural validity.

c. Criterion validity: “The degree to which the scores of a PROM are an adequate reflection of a ‘gold standard’.” It may be difficult to assess, as a ‘gold standard’ often does not exist (Mokkink et al., 2010a)

3. Responsiveness: “The ability of a PROM to detect change over time in the construct to be measured”. Should changes occur in the construct, the tool should be able to detect these changes. Therefore, responsiveness can be considered as a measure of longitudinal validity (Terwee et al., 2007).

Another relevant aspect of an instrument is interpretability which is “The degree to which one can assign qualitative meaning - that is, clinical or commonly understood connotations – to a PROM’s quantitative scores or change in scores”. It is not a measurement property per se, but it is an important characteristic (Mokkink et al., 2010c).

## 2.2. Aims and objectives

1. To identify the range of PROMs and classification systems used in clinical studies of TMD patients.

2. To review which PROMs have undergone psychometric testing in a TMD population in order to provide some guidance for the selection of such measures.

## 2.3. Materials and methods

A comprehensive review was conducted in January of 2019 to retrieve the published articles that are concerned with the patient reported assessment of the effects of temporomandibular disorders. The articles were retrieved from 3 databases: Medline, Embase, and Web of Science. The employed search strategy consisted of the following MeSH terms and keywords:

1. patient-reported outcome/

2. Outcome assessment/

3. "Quality of life"/

4. (patient reported outcome measures or quality of life or treatment outcome or patient centred outcome or patient reported outcomes or patient defined outcome or outcome measurement or outcome assessment or subjective outcomes or health related quality of life).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]

5. Treatment outcome/

6. 1 or 2 or 3 or 4 or 5

7. Temporomandibular joint disorder/

8. Myofascial pain/

9. (Temporomandibular disorders or temporomandibular joint dysfunction syndrome or myofascial pain syndrome or TMD or TMJD or facial myalgia or facial arthralgia or temporomandibular joint derangement or temporomandibular disc displacement or temporomandibular joint degeneration or temporomandibular joint subluxation).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]

10. 7 or 8 or 9

11. 6 and 10

12. Limit 11 to (human and english language and last 10 years)

A substantial rise in the development and validation of PROMs occurred since 1990 (Garratt et al., 2002). Due to the vast number of articles retrieved, the review scope

was refined to the time period between 2009-2018. No time restriction was used when retrieving articles that assessed the validity of the PROMs.

### 2.3.1 Inclusion and exclusion criteria

The included studies were clinical trials and observational studies of TMD (cross sectional and longitudinal) containing at least one PROM, articles reporting on the development or psychometric testing of a PROM in a TMD population, and finally, articles published in peer reviewed journals in the English language. The exclusion criteria eliminated studies containing clinical or radiological outcomes only, studies containing PROMs that report on the side effects after a specific intervention (e.g., complications of surgery), systematic and literature reviews, case reports, book chapters, conference proceedings, commentary or author opinion, animal studies, and studies with full text unavailable.

### 2.3.2. Data extraction

A study-specific Excel spreadsheet was used to aid with consistent data extraction. The following information was extracted: Study design, type of intervention (if any), number of participants, age range (or mean age), type of TMD, classification system used, the PROM used, the follow up time point (if any). Additional data were also extracted from studies that assess the psychometric properties of the PROMs in a TMD population, such as measures of validity, reliability, interpretability, and responsiveness.

## 2.4. Results

The initial search of the 3 mentioned databases yielded 3452 articles in total. After applying the exclusion criteria, 517 articles containing at least 1 PROM remained. See Figure 2.1 for details of the filtering process.

### 2.4.1. Patient Reported Outcome Measures commonly used in TMD

A total of 106 PROMs were identified after examining the included studies. The PROMs fell into 3 categories: PROMs describing the severity and improvement of symptoms, PROMs describing the psychological status and satisfaction, and PROMs describing the quality of life and general health. See table 2.1 for the identified PROMs and the frequency of use.

Figure *2.2*. Flow chart showing the search results for each database and the subsequent exclusion process.

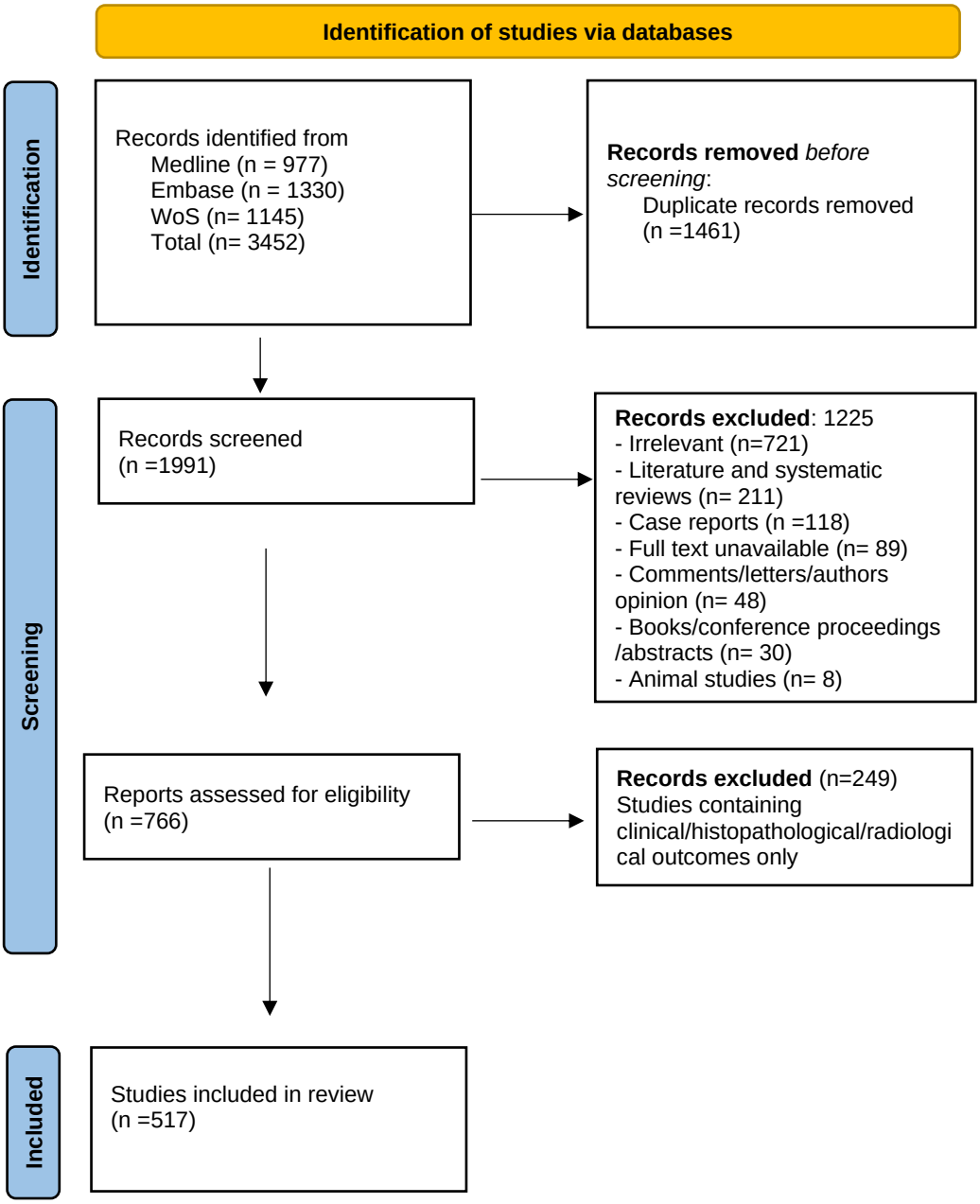


Table 2.1. PROMs identified and their frequency of use in TMD studies.

| Name of PROM | Frequency of use |
|---|---|
| **Severity of symptoms and improvement** | |
| Visual Analogue Scale (VAS) | 308 |
| Point Scales | 103 |
| Numeric Rating Scale (NRS) | 64 |
| Symptom Checklist-90 (SCL-90) | 45 |
| Graded Chronic Pain Scale (GCPS) | 42 |
| Jaw Functional Limitation Scale (JFLS) | 16 |
| Mandibular Function Impairment Questionnaire (MFIQ) | 16 |
| McGill Pain Questionnaire | 13 |
| Fonseca anamnestic index (FAI) | 12 |
| The West Haven-Yale Multidimensional Pain Inventory (WHYMPI) | 12 |
| Adjectival scale | 12 |
| RDC/TMD Axis II | 11 |
| Verbal Rating Scale | 10 |
| Helkimo anamnestic dysfunction index | 10 |
| Jaw Disability Checklist (JDC) | 9 |
| Symptom Severity Index (SSI) | 8 |
| Brief Pain Inventory (BPI) | 7 |
| Neck Disability Index | 6 |
| Characteristic Pain Intensity (CPI) | 4 |
| 3Q/TMD | 3 |
| Brief Symptom Inventory (BSI) | 3 |
| The Pain Related Self-Statement Scale | 3 |
| Chronic pain grade | 2 |
| Coloured Analogue Scale (CAS) | 2 |
| Headache Impact Test-6 | 2 |
| Limitations in Daily Functions-Temporomandibular Disorders Questionnaire (LDF-TMDQ) | 2 |
| Manchester Orofacial Pain Disability Scale (MOPDS) | 2 |
| Pain Stages of Change Questionnaire (PSOCQ) | 2 |
| ProTMDMulti | 2 |
| The Oral Behaviour Checklist (OBC) | 2 |
| Tinnitus Handicap Inventory | 2 |
| Widespread Pain Index (WPI) | 2 |
| Craniofacial Pain and Disability Inventory | 1 |
| Food Intake Ability (FIA) index | 1 |
| Mann assessment of swallowing ability (MASA) score | 1 |
| PRISM (Pictorial Representation of Illness and Self-Measure) | 1 |
| Screening for Somatoform Symptoms (SOMS-7) | 1 |
| Symptom Interference Questionnaire – Revised (SIQR) | 1 |
| The Battery for Health Improvement | 1 |
| The Gracely Pain Scale | 1 |
| the Jaw Pain and Function (JPF)-Questionnaire | 1 |
| The Pain Behavior Questionnaire | 1 |
| The Patient Specific Functional Scale (PSFS) | 1 |
| The Universal Pain Assessment Tool (UPAT) | 1 |
| Visual Faces Pain Scale (FPS) | 1 |
| Zerssen complaint list | 1 |

| **Quality of Life, general health and effect on daily life questionnaires** | |
|---|---|
| Oral Health Impact Profile-14 (OHIP-14) | 29 |
| Pittsburgh Sleep Quality Index | 17 |
| The Short Form 36 Health Survey (SF-36) | 14 |
| Oral Health Impact Profile (OHIP) | 9 |
| General Health Questionnaire-7 (GHQ-7) | 7 |
| The Short Form 12 Health Survey (SF-12) | 5 |
| Epworth Sleepiness Scale | 4 |
| TMJ-Surgical-Quality of Life (TMJ-S-QoL) | 4 |
| WHO QoL- brief | 4 |
| EQ-5Dm | 3 |
| Health Assessment Questionnaire | 2 |
| OHQoL-UK | 2 |
| Oral Health Impact Profile-OFP (OHIP-OFP) | 2 |
| RAND-36 health survey | 2 |
| University of Washington QOL (UW-QOL) | 2 |
| Youth Self report | 2 |
| Child Perception's Questionnaire | 1 |
| General Oral Health Assessment Index (GOHAI) | 1 |
| Insomnia Severity Index (ISI) | 1 |
| Michigan Oral Health-related Quality of Life Scale – Child Version (MOHRQoL-C) | 1 |
| The Flanagan Quality of Life Scale | 1 |
| The Life Experiences Survey (LES) | 1 |
| The Multidimensional Fatigue Inventory-Short Form | 1 |
| The Sleep Assessment Questionnaire (SAQ) | 1 |
| **Psychological Status and Satisfaction** | |
| Beck Depression Inventory (BDI) | 11 |
| Pain Catastrophizing Scale (PCS) | 10 |
| Hospital Anxiety and Depression Scale (HADS) | 8 |
| State-Trait Anxiety Index (STAI) | 8 |
| Patient Health Questionnaire-9 (PHQ-9) | 7 |
| Generalised Anxiety Disorder-7 (GAD-7) | 6 |
| Centre for Epidemiological Studies Depression scale-20 (CESD) | 5 |
| Coping Strategies Questionnaire (CSQ) | 5 |
| PTSD Check List–Civilian (PCL-C) | 5 |
| The Perceived Stress Scale (PSS) | 4 |
| Beck Anxiety Inventory (BAI) | 3 |
| Chronic Pain Self-Efficacy Scale (CPSS) | 2 |
| Eysenck Personality Questionnaire-Revised (Short Form, EPQ-R) | 2 |
| Life Orientation Test 12-Revised | 2 |
| Lipp's Stress Symptoms Inventory for Adults (LSSI) | 2 |
| Sense of coherence-29 (SOC-29) | 2 |
| The Pennebaker Inventory of Limbic Languidness: The Kohn Reactivity Scale | 2 |
| Behavioral Rating Scale (BRS) | 1 |
| Columbia Classification Algorithm of Suicide Assessment (C-CASA) | 1 |
| Coping Pain Questionnaire (CAD) | 1 |
| Dental Anxiety Scale (DAS) | 1 |
| Depression, Anxiety and Stress Scales-21 (DASS-21) | 1 |

| | |
|---|---|
| Fear Avoidance Belief Questionnaire (FABQ) | 1 |
| Illness Perception Questionnaire –Revised (IPQ-R) | 1 |
| Irrational Attitudes Questionnaire | 1 |
| Miller Behavioural Style Scale [MBSS] | 1 |
| Millon Behaviour Medicine Diagnostic survey | 1 |
| Minnesota Multiphasic Personality Inventory (MMPI) | 1 |
| NEO-Five Factor Inventory (NEO-FFI) | 1 |
| Pain Coping and Cognition List (PCCL) | 1 |
| Screening for Somatoform Symptoms (SOMS-7) | 1 |
| Survey of Pain Attitude (SOPA-35) | 1 |
| Tampa Scale for Kinesiophobia (TSK-11) | 1 |
| The Group Health Association of America (GHAA) Consumer Satisfaction Survey | 1 |
| The Profile of Mood States-Bipolar (POMS-Bi) | 1 |
| The Satisfaction With Life Scale | 1 |

The most commonly used PROM was the Visual Analogue Scale with 59.5% (n=308) of the trials using this instrument. However, various verbal descriptors were employed, such as: pain intensity, subjective chewing efficiency and quality of life. See table 2.2. The length of the VAS used also varied, with trials reporting results on a 100mm scale, 10cm scale, 0-3, 0-4, 0-5, 0-6, and -5-5 VAS scales.

Likert Point Scales and Numeric Rating Scales were relatively commonly used also (19.9%, n=103 and 12.4%, n=64 respectively). Similar to the VAS, the word descriptors varied for these PROMs, as did the length of the scales. See tables 2.3 and 2.4. The Point Scale mostly ranged from 3 to 7 points; however, 5 studies have used an 11-point scale. For the NRS, the lengths of the scales included 0-10, 0-3, 0-5, 0-6 and 1-4. Among the other commonly used PROMs were the Symptom Checklist-90 (SCL-90), and the Graded Chronic Pain Scale (GCPS) with 8.7% (n=45) and 8.1% (n=42) of the studies using these tools, respectively. Most of the other PROMs described the characteristics of pain, and the functional limitations incurred. A few PROMs described other symptoms associated with TMD, such as the Neck Disability Index (n=6) Tinnitus Handicap Inventory (n=2), Headache Impact Test-6 (n=2) and Food Intake Ability (FIA) index (n=1).

Table 2.2. Word descriptors used with the VAS in TMD studies

- Pain intensity ± on palpation, TMJ pain intensity ± on palpation, pain during function, TMJ discomfort, pain severity, pain at rest, during function; while eating/chewing, pain sensitivity, pain unpleasantness, headache severity, Pain interference with daily activity, work activity, social life, spontaneous pain, neck pain, ear symptoms
- Diet consistency tolerated, dietary restrictions.
- Functional disability, physical function, subjective chewing efficiency, speech, mandibular function (chewing and biting off, talking, and moving), facial symmetry, subjective malocclusion, teeth clenching, difficulties for mastication, self-perceived joint noise
- Psychosocial influence of TMJ disorder, patient satisfaction with treatment, postoperative improvement, anxiety levels, treatment beliefs (credibility of treatment), perceived need for treatment.
- Quality of life, sleep quality, analgesic activity.

Table 2.3. Word descriptors used with the NRS in TMD studies.

- Pain intensity ± on palpation, pain at rest, maximum mouth opening, at chewing, movements, degree of unpleasantness due to TMD pain, jaw fatigue, facial tension, temporal headaches, and neck pain
- TMJ sounds and noises
- Limitation of mouth opening, difficulty in eating or chewing, clenching difficulty, jaw function, diet, disability.
- Quality of life, impact of TMJ pain on abilities to perform daily activities, sleeping difficulty.
- Pain-related worry, anxiety, perceived tension and stress, satisfaction with treatment, treatment motivation and credibility before treatment.

Table 2.4. Word descriptors used with the point scales in TMD studies.

- Muscle and TMJ pain intensity ± on palpation, frequency of pain, jaw fatigue, severity of discomfort, headache intensity, distress due to headaches, frequency of headache, improvement in overall subjective symptoms
- Feelings of depression, general stress, nervous tension, fear of movement, satisfaction with the outcome/treatment/ improvement, subjective treatment effectiveness, tolerability of treatment, Patient Global Impression of Change (PGIC)
- Difficulty in chewing, diet consistency tolerated, joint noises, frequency of locking, severity of locking (duration of locking), limitation in mandibular movements/ mouth opening, tinnitus, frequency of clicking, grinding, and clenching at night/day, perceived alterations in chewing capacity, aesthetics, open bite deformity, impact on talking, yawning, activity, recreation, mood the shape of their faces, frequency of dislocation
- Quality of life, interference with daily life, patients' general health status, appetite, quality of sleep, effectiveness at work, analgesic consumption, school absence, treatment compliance, self-perceived oral health status, extent to which pain interfered with work, TMD-related limitation of daily functions (LDF-TMD).

As for the PROMs assessing the quality of life, the Oral Health Impact Profile-14 was most frequently employed (5.61%, n=29). The Short Form 36 Health Survey (SF-36)

and the Pittsburgh Sleep Quality Index (PSQI) were also frequently used generic PROMs with 2.71% (n=14) and 3.29% (n= 17) of the studies, respectively, using them. Most of the PROMs used to describe the quality of life were generic, with the exception of TMJ-Surgical-Quality of Life (TMJ-S-QoL) which is specific for TMD.

In total, 36 PROMs which describe the psychological status of the participants were identified. The most frequently used PROM describing psychological distress was the Beck Depression Inventory (2.13%, n=11), followed by the Pain Catastrophizing Scale (1.93%, n=10).

### 2.4.2. Classification systems and clinical indices

The most frequently used TMD classification system was the Research diagnostic Criteria/TMD axis I (RDC/TMD axis I). Approximately half of the examined studies (50.68%, n=262) have confirmed the diagnosis of TMD using this system. Other commonly used classification systems include the Wilkes classification of TMJ internal derangement (n=41) and the American Academy of Orofacial Pain Criteria (n=9). Classification systems for other symptoms associated with TMD were also used, such as the International Classification for Headache Disorders-2 (n=6). See table 2.5 for the frequently used classification systems.

Table 2.5. The common classification systems used in TMD studies

| Classification system | Frequency of use |
|---|---|
| RDC/TMD axis I | 262 |
| Wilkes classification | 41 |
| American Academy of Orofacial Pain Criteria | 9 |
| International Classification for Headache Disorders-2 | 6 |
| International League of Associations for Rheumatology (ILAR)-for JIA | 5 |
| Surgical classification by Dimitroulis | 3 |
| American association of Maxillofacial surgeons' criteria for success of treatment | 3 |
| International Association for the Study of Pain (IASP) criteria for TMD | 2 |

Other clinical and radiological classification systems included: Sawhney classification for bony ankyloses, Spiessl classification for mandibular condylar fracture, and Turlington–Durr classification for TMJ ossification.

Clinical indices for the assessment and determination of the severity of TMD included the Helkimo Clinical Dysfunction Index (n=15), Craniomandibular Index (n=6), Temporomandibular Index (n=1), the Protocol of Orofacial Myofunctional Evaluation with Scores (OMES) (n=2), the patient reported Fonesca Questionnaire (n=2), and 3Q/TMD (n=3)

### 2.4.3. Psychometric properties of PROMs used in TMD

Several PROMs identified in the current search have some evidence of psychometric testing in a TMD population. The PROMs identified and their relevant psychometric evidence are detailed in table 2.6. The Research Diagnostic Criteria (RDC) Axis II tools and the Oral Health Impact Profile (OHIP) were the instrument most repeatedly tested in a TMD population and undergone cross-cultural validation into several languages. The search also identified a TMD-specific variant of OHIP; OHIP-TMD. The reported psychometric properties were internal consistency (Cronbach's α= 0.94), test-retest reliability (Intraclass correlation coefficient= 0.805), convergent validity, content validity, known groups validity and responsiveness to change. One other variant was also suggested for orofacial pain, where the authors omitted 10 items from the original tool and added two items relevant to facial pain patients (Cronbach's α= 0.97).

## 2.5. Discussion

The recent growth of the adoption of PROMs into healthcare reflects the emphasis placed by health institutes of the importance and relevance of the patient perspective

in improving the quality of healthcare. They are a shift from the traditional indicators of treatment success such as mortality rate, post-surgical infection rates and re-admissions (Devlin et al., 2010). Although PROMs are now commonly incorporated in the scientific literature, as outcomes in clinical trials concerning TMD for example, a uniform set of outcomes or instruments is not routinely used. This limits our ability to compare outcomes of these clinical trials across the various studies conducted.

Kavchak et al provided an assessment of the psychometric properties of some tools in a TMD population in 2014. The group was able to identify 13 papers describing some form of psychometric analysis for 8 tools. They reported in their review that few PROMs reported for use in TMD patients have undergone rigorous analysis and with complete psychometric properties established (Emerson Kavchak et al., 2014). Aguiar et al, also examined the psychometric properties of 10 common condition-specific PROMs and had similar conclusions where they note the need for further studies on psychometric properties (Aguiar et al., 2021).

In the present review of 517 studies, we identified 106 PROMs that were used to assess the effects of TMD on patients, and an additional 58 papers that tested the psychometric properties of some tools in a TMD population including cross-cultural adaptation. The most used PROM is the Visual Analogue Scale. The pain VAS mimics the continuous visual analogue scales developed to measure well-being in the psychology domain (Aitken, 1969). It is relatively acceptable to patients (Joyce et al., 1975), and widely used in diverse adult populations (Huskisson, 1974). Other reviews of the literature have also reported that VAS was the most widely used PROM in Oral Medicine populations (Ni Riordain et al., 2015) such as Oral Lichen Planus (Wiriyakijja et al., 2018) and Burning Mouth Syndrome (Ni Riordain and McCreary, 2013). This widespread use can be rationalised in light of the relative ease of administration, low

administrative burden required and acceptability to patients (Hawker et al., 2011). The wide variety of word descriptors associated with it as seen in table 2.2, however, could result in heterogeneity of the results, and difficulty of data pooling.

The most frequently used oral-health quality of life PROM in our review was the Oral Health Impact Profile-14. The items for OHIP were generated following interviews with patients from private dental practice, primary care clinics and prosthetic clinics in a dental hospital (Slade and Spencer, 1994), therefore, it may not be specific enough for patients with TMD to detect the impact of the condition on their daily lives. The TMD variant (OHIP-TMD) has very good internal consistency reliability, test-retest reliability and content validity according to the COSMIN criteria (Mokkink et al., 2018b). First proposed in 2011 (Durham et al., 2011b) with further validation presented in 2015 (Yule et al., 2015), this measure is still relatively new compared to OHIP-14, which might explain the popularity of the latter in TMD research so far.

The current search has highlighted the scarcity of TMD-specific quality of life and psychological status PROMs. Several have been created to describe the symptoms of TMD, such as Jaw Functional Limitation Scale (JFLS), Mandibular Function Impairment Questionnaire (MFIQ), Jaw Disability Checklist (JDC), and the Jaw Pain and Function (JPF)-Questionnaire. However, PROMs describing other dimensions of the condition are still lacking and most clinical trials have used generic PROMs to describe the quality of life and psychological status of the patients. Condition-specific PROMs are more sensitive and with greater discriminatory ability to detect small changes over time (Dijkers, 1999, Allen et al., 1999).

Numerous PROMs were used to describe the impact of TMD on patients. Such variability may limit the ability of researchers and clinicians to evaluate the efficacy of

different treatments, data pooling and making meaningful comparisons. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) tried to address this issue in chronic pain trials (Dworkin et al., 2005). The initiative recommends evaluating the following aspects: pain intensity, physical functioning, emotional functioning, participant ratings of global improvement and satisfaction with treatment, symptoms and adverse events, and participant disposition. It also recommends the use of certain PROMs to unify the results among clinical trials.

The Research Diagnostic Criteria has also been proposed to provide a comprehensive diagnostic and classification system for the subtypes of temporomandibular disorders. The criteria, first proposed in 1992 (Dworkin and LeResche, 1992), was updated in 2014 following a series of workshops to include an expanded taxonomic classification structure to include common and less common TMDs. Additionally, its second axis was expanded by adding new instruments to evaluate pain behaviour, psychological status, and psychosocial functioning (Schiffman et al., 2014). At the moment, it is the closest to a gold standard in terms of classification systems. Our results have highlighted that this system is popular among researchers, as 50.68% of the studies confirmed the diagnosis of TMD based on axis I of these criteria. However, fewer studies used the complete list of PROMs recommended in axis II. The number of the proposed questionnaires may discourage some researchers, as the following questionnaires are proposed for research purposes: DC/TMD Symptom Questionnaire, Pain Drawing, Graded Chronic Pain Scale (GCPS), Jaw Functional Limitation Scale (JFLS-20), Patient Health Questionnaire 9 (PHQ-9), General Anxiety Disorder 7 (GAD-7), Patient Health Questionnaire 15 (PHQ-15) and Oral Behaviours Checklist (OBC). In addition to length of the recommended questionnaires, the primary objective of a trial might involve other clinical or radiological outcomes, therefore, a

comprehensive evaluation of psychosocial functioning may not be crucial to the researchers. It is worth mentioning that the initiative has also put forward a shorter list of questionnaires for clinical and screening purposes consisting of pain drawing, GCPS, PHQ-4, JFLS-8 and OBC.

Interestingly, the psychometric properties of PHQ-9, PHQ-15 and GAD-7 do not seem to have been rigorously tested in a TMD population. They have been extensively validated in the general population and in a variety of other conditions (Lamela et al., 2020, Johnson et al., 2019, Cano-García et al., 2020), but one paper was identified to report on some psychometric properties in TMD patients (Hietaharju et al., 2021). PROMs are often tested in a specific population to study the acceptability of their behaviour and performance in that population, as it cannot be assumed that they will perform well across all cohorts. For example, an instrument which measures depression or health-related quality of life may require modifications to its factor structure or standard cut-off points (Dyer et al., 2016). Therefore, it is recommended to attain further proof of validity of these three questionnaires (PHQ-9, PHQ-15, and GAD-7) in a TMD population.

The GCPS, OBC and JFLS, on the other hand, have evidence of validity in a TMD population (Sharma et al., 2021, Barbosa et al., 2018, van der Meulen et al., 2014, Xu et al., 2020, Fetai et al., 2020, Ohrbach et al., 2008a, Ohrbach et al., 2008b). The GCPS displayed high Cronbach α for pain intensity and interference (0.87 and 0.94, respectively), indicating very good internal consistency. It also demonstrated high temporal stability (CPI (intraclass correlation coefficient (ICC)=0.91), interference (ICC=0.85), and CPG (weighted kappa=0.88) (Sharma et al., 2021). The structure of JFLS-20 was also explored using factor analysis, proposing a 3-factor solution. In

addition, it showed high internal consistency (Cronbach α >0.8) (Xu et al., 2020, Fetai et al., 2020, Ohrbach et al., 2008a, Ohrbach et al., 2008b).

Limitations

The present review was limited to studies in the English language found in the three mentioned databases. Indeed, the results of the search might be different should studies in other languages be included, or the search expanded to other databases with no time restrictions.

## 2.6. Conclusions

Condition specific PROMs to assess the psychological status and quality of life of TMD patients are needed. The scarcity of such measures is reflected by the popularity of generic PROMs used in TMD research. While these may be useful in comparisons between different populations, they may lack the sensitivity and discriminatory ability in specific conditions. The use of a collection of concise and psychometrically sound measures may also promote consensus in TMD literature and provide a more robust basis for comparisons and data pooling.

Table 2.6. Summary of the psychometric properties of identified PROMs in a TMD population.

| PROM | Author and year | Number of TMD patients | Psychometric testing |
|---|---|---|---|
| **Central Sensitization Inventory (CSI)- Italian** | (Chiarotto et al., 2018) | 37 | Cross-cultural adaptation<br>Structural validity: Exploratory factor analysis<br>Construct validity: Pearson's correlation with 11-point NRS for pain intensity =0.427, SF 36= −0.479, HADS=0.706, Pain Self-Efficacy Questionnaire= −0.618. All have significant correlations.<br>Internal consistency: Cronbach's α= 0.87 |
| **Centrality of pain scale- Chinese** | (Wang et al., 2019) | 166 | Cross cultural adaptation<br>Internal consistency: Cronbach's α= 0.942<br>Test-retest (30 patients- 1week): ICC= 0.815 - 0.929.<br>Construct validity: Exploratory factor analysis (EFA)- 1 factor<br>Convergent validity: Pearson's correlation with: Catastrophizing Scale (r=0.57) and Pain Self-Efficacy Questionnaire (r= –0.42). Both have significant correlation. |
| **Child perception questionnaires**<br>**CPQ 8-10 (years)**<br>**CPQ 11-14 (years)** | (Barbosa et al., 2011) | 547 | Criterion validity: Spearman's correlation with pain scores (obtained from Question 3 of the RDC/TMD Axis II). CPQ 8-10: r= 0.18/ non sig, CPQ 11-14: r=0.32/sig.<br>Discriminant construct validity<br>Correlational construct validity<br>Internal reliability (internal consistency)- CPQ 8-18: Cronbach's α= 0.93, CPQ 11-14: Cronbach's α= 0.94 |
| **Craniofacial Pain and Disability Inventory (CFPDI)- Spanish** | (La Touche et al., 2014) | 192 | Test-retest reliability (106 patients, 12 days): ICC= 0.90<br>Internal consistency: Cronbach's α= 0.88<br>Construct validity by exploratory factor analysis: 2 factors<br>Responsiveness: SEM= 2.4<br>Convergent validity: Pearson's correlation with VAS= 0.46, PCS (r=0.46), TSK-11 (r=0.40), NDI (r=0.65), HIT-6 (r= 0.38). All have significant association. |
| **Craniofacial Pain and Disability Inventory- Brazilian Portuguese** | (Greghi et al., 2018) | 100 | Cross cultural adaptation<br>Internal consistency: Cronbach's α= 0.77-0.86<br>Construct validity: Pearson's correlation with PCS (0.69), TSK-TMD (0.68), NDI (0.40), MFIQ (0.74), and pain-related disability (0.75). All have significant correlation<br>Structural validity: Confirmatory Factor Analysis- 3 factors<br>Test retest (60 patients- 1 week): ICC= 0.97 |
| **EQ-5D-5L** | (Durham et al., 2015) | 66 | Convergent validity- Spearman's Rho with MPI for each subscale. |

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| **Fonseca anamnestic index (FAI)** | (Rodrigues-Bigaton et al., 2017) | 94 | Structural validity: Exploratory factor analysis<br>Overall correlation between items : Spearman's correlation- Some items showed good correlation, but not all items were correlated, suggesting more than one dimension in the FAI.<br>Internal consistency: Cronbach's α= 0.7<br>Rasch analysis |
| | (Campos et al., 2014) | 700 – normal population, assuming 40% are TMD | Confirmatory Factor Analysis (CFA)<br>Convergent validity - The average variance extracted (AVE)= 0.513, The composite reliability (CR)= 0.878<br>Internal consistency: Cronbach's α = 0.745<br>Reproducibility (62 patients- 1 week): Kappa = 0.89<br>Concurrent validity- Correlation analysis with MFIQ: r = 0.66<br>(Questions 8 and 10 were below the adequate values. Thus, these questions were excluded from the original model) |
| **Jaw Disability Checklist**<br>**Characteristic Pain Intensity (CPI)**<br>**Symptom Checklist 90-Revised (SCL-90-R)**<br>**Oral Health Profile-14 (OHIP-14)- Turkish**<br>**Short Form 36 Item Health Survey (SF-36)-Turkish** | (Balik et al., 2019) | 104 | Internal consistency: Cronbach's α<br>JDC= 0.76<br>CPI= 0.79<br>SCL-90-R- somatisation= 0.87<br>SCL-90-R- depression= 0.93<br>OHIP-14= 0.86<br>SF 36- physical health= 0.83<br>SF-36- mental health= 0.82 |
| **Jaw Function Limitation Scale-20,8 (JFLS-20, 8)** | (Ohrbach et al., 2008b) | 31 | Fitness of model/ item reliability: Rasch methodology<br>Temporal stability (1-2 weeks): concordance correlation coefficient- JFLS 20= 0.87, JFLS 8 = 0.81<br>Internal consistency: Cronbach's α- JFLS 20 = 0.95, JFLS 8= 0.87<br>Correlation of Subscales: JFLS 20= 0.9422 |
| | (Ohrbach et al., 2008a) | 219 | Factor analysis<br>Model fitness: Rasch methodology<br>Construct validity: correlation with Jaw Symptom Index = 0.57, SCL-90= 0.02, GCPS Pain Interference = 0.26, GCPS Characteristic Pain Intensity = 0.49 CPI, and STAI= 0.17 |
| **Jaw pain and function (JPF)-German** | (Undt et al., 2006) | 137 | Cross cultural adaptation<br>Concurrent construct validity (97 patients) - Pearson's correlation with maximum inter-incisal distance, r= -0.213. Significant correlation.<br>Test-retest reliability (40 patients- 1 day and 1 week) - Pearson's correlation, 1 day: r= 0.91, 1week: r=0.93. Both are significant. |

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| | | | Internal consistency of verbal subscales- Cronbach's α: Pain score = 0.85, ADL score = 0.94, function score = 0.68. |
| **Manchester Orofacial Pain Disability Scale** | (Aggarwal et al., 2005) | 171 | Internal consistency- Cronbach's α: Physical disability construct = 0.78, psychosocial disability construct= 0.92<br>Item correlation: values between 0.43 and 0.80<br>Construct validity<br>Factor analysis: 2 factors |
| | (Kallas et al., 2013) | 50 | Cross cultural validation<br>Internal consistency: Cronbach's α = 0.9<br>Test retest (reproducibility)- 15-20 days: ICC = 0.924<br>Criterion validity- Correlations with OHIP-14, r= 0.857 and VAS for pain intensity, r= 0.758. Both are significant.<br>Inter-item correlation<br>Factor analysis: 2 factors |
| **Mandibular Function Impairment Questionnaire (MFIQ)** | (Stegenga et al., 1993) | 95 | Convergent validity<br>Internal consistency: Cronbach's α= 0.63 to 0.95.<br>Factor analysis: 3 factors |
| **MFIQ- Chinese** | (Xu et al., 2016) | 352 | Cross-cultural adaptation<br>Internal consistency: Cronbach's α for factor 1: 0.925, for factor 2= 0.72<br>Test retest (78 patients - 7days): ICC for factor 1= 0.895, for factor 2= 0.720<br>Content validity: evaluated by twenty dentists and five physical therapists.<br>Construct validity: exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) - 2 factors.<br>Face validity: consensus between 8 specialists |
| **MFIQ- Portuguese** | (Campos et al., 2012) | 249 | Factorial validity- confirmatory factor analysis: 2 factors<br>Internal consistency: Cronbach's α for functional capacity dimension= 0.874, for feeding dimension= 0.918.<br>Intra-rater reproducibility (62 patients – 1 week): ICC for functional capacity dimension 1 = 0.895, for feeding dimension= 0.825.<br>Temporal stability (test-retest reliability): Pearson's correlation for dimension 1 r= 896, for dimension 2 r= 0.826.<br>Face validity: evaluated by six dentistry professionals (specialists on temporomandibular disorders) and three experts of the English language.<br>Content validity: assessed by 21 dentists with expertise in temporomandibular disorders.<br>Convergent and discriminant validity were assessed, respectively, by the average variance extracted (AVE), composite reliability (CC) and bivariate correlations between factors. |

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| **Multidimensional Pain Inventory (MPI)- Spanish** | (Andreu et al., 2006) | 114 | Cross-cultural adaptation<br>Internal consistency: Cronbach's α > 0.7 for all items.<br>Confirmatory Factor Analysis |
| **MPI - Brazilian** | (Zucoloto et al., 2015) | 31 | Convergent validity: Average variance extracted and composite reliability<br>Internal consistency: Cronbach's α= 0.80–0.94<br>Content validity ratio (CVR): 15 experts in the field of dentistry.<br>Construct validity- confirmatory factor analysis |
| **Oral Behaviour Checklist- Portuguese** | (Barbosa et al., 2018) | 120 | Cultural adaptation<br>Test retest (120 patients- 2 weeks )- ICC= 0.998<br>Temporal stability: weighted Kappa = >0.946<br>Item agreement between English and Portuguese OBC: weighted Kappa = >0.934<br>Internal consistency: Cronbach's α= 0.64<br>Convergent and discriminant validity |
| **OBC- Dutch** | (van der Meulen et al., 2014) | 155 | Cross cultural validity<br>Test-retest reliability (35 patients- 2weeks): ICC= 0.86<br>Concurrent validity: Spearman's correlation with Dutch Oral Parafunctions Questionnaire r = 0.757, RDC- CPI r= 0.069, Dutch SCL-90 Depression r= 0.485, somatisation r= 0.312, anxiety r= 0.448, Stress 7 item questionnaire r= 0.433. All have significant correlations except with RDC-CPI.<br>Correlations between individual items: 0.389 to 0.892 |
| **Oral Health Impact Profile-49 (OHIP-49)- German** | (John et al., 2002) | 67 | Cross cultural validation<br>Groups validity: Point-biserial correlations<br>Responsiveness (1 month): Effect size calculation by paired t-test. |
| **OHIP- 5,14,21-German** | (John et al., 2006b) | 175 | Validity and internal consistency: Cronbach's α = 0.65–0.92<br>Responsiveness: standardized effect size = 0.55-0.95<br>Construct validity: Point-biserial correlations |
| **OHIP-49- Swedish** | (Larsson et al., 2004) | 30 | Test-retest reliability: ICC= 0.87-0.98<br>Construct validity: Spearman's correlation with JFLS (r= 0.76), SCL-90 (r= 0.65), self-reported health (r= 0.61).<br>Internal reliability: Cronbach's α = 0.83-0.91 |
| **OHIP- Italian** | (Segu et al., 2005) | 124 | Cross-cultural validation<br>Content validation: group of experts<br>Internal consistency: Cronbach's α= 0.71-0.86 |

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| | | | Construct validation: known-groups analysis<br>Criterion-related validation<br>Exploratory factor analysis: 7 factors |
| **OHIP-5,14,48-Dutch** | (Van der Meulen et al., 2012) | 245 | Internal consistency: Cronbach's α- OHIP-48= 0.96, OHIP-14= 0.9, OHIP-5= 0.67<br>Test-retest reliability (64 patients- 2 weeks): ICC- OHIP-48= 0.82, OHIP-14= 0.8, OHIP-5= 0.69<br>Construct validity<br>Convergent validity: Spearman's rho with Pain-related disability score- OHIP-48= 0.46, OHIP-14= 0.46, OHIP-5= 0.39, and Self-reported oral health status- OHIP-48= 0.28, OHIP-14= 0.19, OHIP-5= 0.21<br>Group validity: T tests between patients with and without complaints, and Spearman's rho (with CPI and biting activities) |
| **OHIP-30-OFP** | (Murray et al., 1996) | 121 | Internal consistency: Cronbach's α= 0.97 |
| **OHIP-TMD** | (Durham et al., 2011b) | 110 | Convergent validity: Spearman's Rho correlation with MPI = 0.751, VAS = 0.576. Without the 2 new items. Both are significant.<br>Internal consistency: Cronbach's α= 0.942. Without the 2 new items. |
| **OHIP-TMD** | (Yule et al., 2015) | 76 | Face and Content validity: Focus groups of patients and a panel of specialists.<br>Content validity index= 0.64 for patients, 0.82 for professionals.<br>Known groups validity: t-tests of the means between patients and controls.<br>Responsiveness to change: Paired, two tailed, t-tests to calculate effect size (OHIP-TMDs versus OHIP-49)<br>Test-retest reliability: ICC= 0.805<br>Internal consistency: Cronbach's α = 0.95 at baseline, 0.96 at follow up. |
| **OHIP- TMD-Chinese** | (He and Wang, 2015) | 156 | Cross cultural validation<br>Internal consistency Cronbach's α = 0.917<br>Test retest (30 patients - 2weeks): ICC= 0.899<br>Structural validity: Factor analysis- 5 factors<br>Convergent validity: Global rating of oral health question= 0.548.<br>Significant correlation. |

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| **Pain Disability Index** | (Bush and Harkins, 1995) | 197 | Factor structure |
| **Pain related limitations of daily functions (LDF-TMDQ)- Japanese** | (Sugisaki et al., 2005) | 456 | Factor validity- Exploratory factor analysis: 3 factors<br>- Confirmatory factor analysis<br>Convergent validity<br>Discriminant validity: Spearman correlations with Pain VAS, Japanese dental version of McGill Pain Questionnaire, HADS, Eysenck Personality Questionnaire short form and Diet VAS.<br>Internal consistency: Cronbach's α = 0.81, and split-half estimation (Guttmann method) r = 0.76, (P < 0.05) |
| **Pain resilience scale- Chinese** | (He et al., 2018) | 152 | Cross cultural validity<br>Confirmatory Factor Analysis: 2 factors.<br>Internal consistency: Cronbach's α = 0.92<br>Test retest (30 patients - 2weeks): ICC = 0.92<br>Convergent validity: Spearman's correlation with Connor-Davidson Resilience Scale = 0.61 to 0.65 and TSK-TMD= -0.46 to -0.41 |
| **Pain-Related Control Scale (PRCS)** | (Flor et al., 1993) | 44 | Internal consistency: Cronbach's α = 0.83, 0.77<br>Convergent validity<br>Discriminant validity<br>Factor analysis<br>Stability (Test-retest): PRCS-Helplessness= 0.86, PRCS-Resourcefulness= 0.88 |
| **Pain-Related Self Statements Scale (PRSS)** | (Flor et al., 1993) | 44 | Internal consistency: Cronbach's α= 0.92, 0.88.<br>Convergent<br>Discriminant validity<br>Factor analysis<br>Stability (Test-retest): PRSS-Catastrophizing= 0.87, PRSS-Coping= 0.77 |
| **Pittsburgh Sleep Quality Index (PSQI)** | (Rener-Sitar et al., 2014) | 609 | Exploratory factor analysis: 1 factor<br>Model fit: Confirmatory factor analysis<br>Internal consistency: Cronbach's α= 0.75<br>Inter-item correlation: Pearson correlation coefficients = 0.3<br>Test-retest reliability: ICC= 0.86<br>Convergent validity: Spearman's rho coefficient with questions from the GHQ, Q1= 0.43, Q2= 0.48. |
| **PRISM (pictorial representation of illness and self-measure)** | (Streffer et al., 2009) | 70 | Construct validity: Pearson's correlation with GCPS (disability subscale) = –0.60, GCPS (PI subscale) = –0.55, HADS-D= –0.21, HADS-A= –0.21, Insomnia Severity Index = –0.41. Significant correlation with GCPS subscales and the ISI. Nonsignificant correlations with HADS subscales |

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| **PRISM (German to Portuguese)** | (Lima-Verde et al., 2013) | 42 | Cross cultural translation<br>Content validity: Pearson correlations with Numerical Pain Scale (NPS) 0-10 (moderate – 0.42), Insomnia Severity Index (week –0.24), HADS-A (week –0.25), HADS-D(week – 0.22),<br>Temporal stability (30 patients- 3days): ICC= 0.991 |
| **ProTMDMulti** | (de Felicio et al., 2009) | 30 | Criterion Validity: Spearman R with Helkimo Di = 0.65. Significant correlation<br>Construct Validity: Comparison results between pre- and post-treatment and comparing the TMD group to the control group |
| **RDC/TMD- Axis II** | (Dworkin et al., 2002) | 362 | Concurrent validity of SCL-90- depression: Pearson correlations with BDI= 0.69, and Centre for Epidemiologic Studies for Depression= 0.78<br>Internal consistency reliability: Cronbach's α, SCL90= 0.91, Non- Specific Physical Symptoms= 0.82, CCPS= 0.71.<br>Construct validity of the Non-Specific Physical Symptoms Scale: Exploratory factor analysis- 2 factors<br>Clinical utility: sensitivity of 0.91 and specificity of 0.41. |
| **RDC/TMD Axis II** | (Ohrbach et al., 2010) | 626 | Internal consistency: Cronbach's α SCL-90-Depression= 0.91, Nonspecific Physical Symptoms, with pain items= 0.84, GCPS-CPI=0.84, GCPS- Activity Interference 0.95.<br>Convergent validity: SCL-90- Depression: Lin's correlation concordance coefficient (CCC) with The Centre for Epidemiologic Studies-Depression instrument (CESD) = 0.85, and with SF12 = −0.70.<br>SCL-90 Non- Specific Physical symptoms: CCC with GHQ-28= 0.45 and CESD= 0.56.<br>GCPS-CPI: CCC with MPI= 0.65.<br>GCPS- Activity Interference: CCC with MPI= 0.52<br>Test-retest reliability (75 patients-2 weeks): SCL-90-Depession: CCC= 0.63- 0.78.<br>SCL-90 Non- Specific Physical symptoms: CCC= 0.63 – 0.78.<br>GCPS-CPI (3 days): CCC= 0.91.<br>GCPS- Activity Interference: CCC = 0.89<br>GCPS-Chronic pain grade: weighted kappa = 0.87<br>Discriminant validity: Lin's correlation concordance coefficient with MPI.<br>Criterion validity<br>Clinical utility of the Depression instrument by calculating PPV, NPV |
| **RDC/TMD Axis II- Portuguese** | (de Lucena et al., 2006) | 155 | Internal consistency: Cronbach's α= 0.72<br>Reliability: Kappa, 0.73 to 0.9 |

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|---|---|---|---|
| | | | Test retest (45 patients- 2 weeks): Cohen Kappa scale/ for axis 1. Spearman's rank correlation = 0.727-0.821.<br>Concurring validation: Spearman's correlation with Oral Impacts on Daily Performances= 0.306-0.602, OHIP-14= 0.336- 0.598 |
| **RDC/TMD axis II - German** | (John et al., 2006a) | 378 | |
| **RDC/TMD axis II Malay** | (Khoo et al., 2008) | 40 | Cross cultural adaptation<br>Test-retest reliability (27 patients- 1-2 weeks): ICC- Jaw Disability List (JDL)=0.76, GCPS= 0.92<br>Internal consistency: Cronbach's α- JDL= 0.72, GCPS = 0.88.<br>Construct validity: Rank correlation with self-reported oral health, OHIP-G, self-report of oral habits, MPI |
| **Multimedia Version of the RDC/TMD Axis II- Portuguese** | (Cavalcanti et al., 2010) | 30 | Cross cultural validity<br>Internal consistency: Cronbach's α- GCPS= 0.77, Nonspecific Physical Symptoms= 0.71, Depression= 0.88.<br>Test-retest reliability (40 patients - 1 week): ICC- GCPS = 0.97, Nonspecific Physical Symptoms= 0.94, Depression= 0.95.<br>Discriminant validity: t test of means between patients with pain symptoms and symptoms free. SEM |
| **Screening for Somatoform Symptoms (SOMS-7)** | (Shedden Mora et al., 2013) | 58 | Internal consistency: Cronbach's α = 0.88<br>Internal consistency: Cronbach's α = 0.94<br>Convergent validity: Spearman's rank correlation<br>Reproducibility (1 day): Spearman´s rank correlation test= 0.670-0.913. |
| **Self-medication questionnaire** | (Dias et al., 2019) | 110 | Face validity (content validity): interviews with 10 patients and expert opinion.<br>Internal reliability: Cronbach's α =0.844<br>Exploratory factor analysis: 2 factors<br>Reproducibility (11 patients-15 days): weighted Kappa coefficient=0.81 |
| **Short Form 36 Item Health Survey (SF-36)** | (Deli et al., 2009) | 146 | Correlation of the SF-36 versus the Axis II scales: Spearmen coefficient (r). All items and subscales are significantly correlated with the exception of the jaw disability checklist when crossed with the mental scales of SF-36. |
| **Social support and Pain Questionnaire (SPQ)- Chinese** | (He and Wang, 2017) | 118 | Translation and cross-cultural adaptation<br>Internal consistency: Cronbach's α = 0.926<br>Test-retest reliability (2 weeks): ICC= 0.784 |

| | | | |
|---|---|---|---|
| | | | Construct validity: Exploratory factor analysis- 1 factor model<br>Convergent validity: Spearman's rank correlation with Global oral health question = 0.624. Significant correlation. |
| **Social Support Scale** | (Funch et al., 1986) | 92 | Internal consistency: Cronbach's α =0.39-0.73<br>Criterion validity<br>Construct validity: Correlation with The Centre for Epidemiologic Studies Depression Scale (CESD), Profile of Mood States (POMS), The Taylor Manifest Anxiety Scale (TMAS) |
| **Symptom severity index- modified (SSI)** | (Nixdorf et al., 2010) | 108 | Internal consistency: Cronbach's α = 0.96<br>Dimensionality- exploratory factor analysis: 2 factors<br>Test-retest reliability (55 patients- 2–48 hours): ICC= 0.97<br>Between-item correlation: substantial but variable |
| **Tampa scale for kinesiophobia (TSK-TMD)- from original Dutch to English** | (Visscher et al., 2010) | 301 | Cross cultural adaptation<br>Factor structure- Confirmatory factor analysis: 2 factors<br>Test-retest reliability (4 weeks-58) : ICC= 0.73<br>Convergent validity: Pearson Correlation with the Catastrophizing scale of the Coping Strategies Questionnaire (Dutch version) = 0.23<br>Internal consistency: Cronbach's α = 0.83 |
| **TSK-TMD- Chinese** | (He et al., 2016) | 160 | Translation and cross-cultural adaptation<br>Internal consistency: Cronbach's α =0.919<br>Test-retest reliability (30 patients- 2 weeks): ICC= 0.797<br>Content validity: Interviews with patients and an expert panel<br>Construct validity: exploratory factor analysis (EFA)- 2 factors<br>Convergent validity: Pearson Correlation with Global oral health question =0.458–0.563 |
| **TSK-TMD-Brazilian** | (Aguiar et al., 2017) | 100 | Cross cultural validity<br>Internal consistency: Cronbach's α = 0.78<br>Test retest: ICC= 0.51-0.75<br>Structural validity: confirmatory factor analysis- 2 factors<br>Construct validity: Spearman's rank correlation with PCS= 0.48, PHQ-8= 0.38, MFIQ= 0.43<br>Convergent validity/ Discriminant validity: Average variance extracted |
| **The TMJ Scale** | Lundeenet al, Levitt at al Full texts unavailable | - | Internal reliability<br>Test-retest reliability |
| **TMD-Pain Screening Instrument Long Version (LV) Shot Version (SV)** | (Gonzalez et al., 2011) | 504 | Internal reliability: Cronbach's α, LV= 0.93, SV= 0.87<br>Rasch analysis<br>Sensitivity =99 % and Specificity =97% |

| | | | |
|---|---|---|---|
| | | | Exploratory-factor analysis (EFA) - LV: 2 factors, SV: 1 factor.<br>Temporal stability: ICC- LV= 0.79, SV= 0.83. |
| **VAS score of the PSA (Patient specific activities)** | (Rollman et al., 2010) | 132 | Reproducibility: ICC= 0.72<br>Responsiveness<br>Sensitivity = 0.85%, specificity= 0.84% |
| **WHO-5 well-being index** | (Ismail et al., 2018) | 92 | Internal consistency: Cronbach's α = 0.883<br>Concurrent validity: Spearman correlation with OHIP-49, r = 0.705. Significant association. |

# Chapter 3: Factor analysis and internal consistency of four patient reported outcome measures (PROMs) in a TMD population: PHQ-8, GAD-7, PHQ-15 and JFLS-20.

## 3.1. Introduction

In recent years, growing emphasis has been placed on the patients' evaluation of clinical care. High quality care involves exploring patients' opinions on how they perceive their health, symptoms, and treatment effects. Patient Reported Outcome Measures (PROMs) are efficient tools for this purpose. The selection of appropriate PROMs, whether for use in clinical research or in quality improvement schemes requires consideration of some issues, namely validity and reliability (Weldring and Smith, 2013). One aspect of validity is structural validity, which the COSMIN initiative defines as "the degree to which the scores of a health-related patient reported outcome instrument are an adequate reflection of the dimensionality of the construct to be measured" (Mokkink et al., 2010c). According to the guidance of the same initiative, one way to explore the factor structure of an instrument is to conduct exploratory (EFA) or confirmatory factor analysis (CFA) (Mokkink et al., 2018a, Terwee et al., 2018, Prinsen et al., 2018). Another aspect of interest for the purpose of this study, is internal consistency reliability, which is "a measure of the degree of interrelatedness between the items of an instrument" (Mokkink et al., 2010c).

A generic PROM is often tested in a specific population to study the acceptability of its behaviour and performance in that population, as it cannot be assumed that it will perform well across all cohorts. For example, an instrument which measures depression or health-related quality of life may require modifications to its factor structure or standard cut-off points (Dyer et al., 2016). Common generic PROMs found in the TMD literature are the Patient Health Questionnaire-8 and 15 (PHQ-8, PHQ-15)

and General Anxiety Disorder-7 (GAD-7). Although these PROMs are widely used in the literature and extensively validated in various populations (Lamela et al., 2020, Johnson et al., 2019, Cano-García et al., 2020), very few papers reported on their psychometric properties in a TMD population (Hietaharju et al., 2021), and none was found to explore the structural validity in such a sample. Regarding the JFLS-20, only two studies were located to describe the factor structure of the scale in a TMD sample (Fetai et al., 2020, Xu et al., 2020).

## 3.2. Aims and objectives

1. To explore the structural validity and internal consistency of PHQ-8, GAD-7, PHQ-15 and JFLS-20 in a TMD population
2. To investigate the associations between the psychological comorbidities, pain levels, functional limitation, and demographic data in patients with pain related TMD.

## 3.3. Materials and methods

### 3.3.1. Study design

This was a questionnaire-based study with a cross sectional design. It received ethical approval from the Southeast Scotland Research Ethics Committee 1 (REC reference:19/SS/0130). See appendix 2 for the REC and Health Research Authority (HRA) approvals.

### 3.3.2. Participants

The participants were approached after their routine clinical appointments in the oral surgery and facial pain departments at the Eastman Dental Hospital. They were informed about the study orally and provided with a patient information sheet (PIS). Participants who showed interest, were invited to sign 2 copies of an informed consent

form (CF) and given a set of questionnaires to complete. See appendices 3 and 4 for copies of the PIS, CF and study questionnaires.

The sample size was determined according to the COSMIN guidance, where an adequate sample when performing factor analysis would be 4-6 participants per item and at least 100 in total (Mokkink et al., 2018a, Terwee et al., 2018, Prinsen et al., 2018).

Patients were eligible to participate if they were adult patients (>18) having a diagnosis of TMD with associated pain according to the DC/TMD criteria, with pain being the main complaint for attendance to clinic. Patients having at least one of the following diagnoses were eligible: myalgia (local myalgia, myofascial pain, myofascial pain with referral), arthralgia and headache attributed to TMD. Additionally, they should have had a good command of the English language and were able to give informed consent.

Patients were excluded if they had any of the following: diagnoses of intra-articular TMD with no pain symptoms, recent history of trauma or surgery to the head and neck area, poor command of the English language, inability to give informed consent and if they were under the age of 18.

### 3.3.3. Procedure

A comprehensive clinical exam was carried out to confirm the diagnosis of TMD and classify the participants according to the DC/TMD criteria (Schiffman et al., 2014). The participants were then asked to complete a set of questionnaires after concluding their routine clinical visits. The forms completed were:

1. A demographics form with the following variables: age, sex, ethnicity, smoking status, alcohol consumption, education level, employment status, medical co-morbidities including other systemic chronic pain conditions.

2. Graded Chronic Pain Scale (GCPS) version 2.0: This scale is a composite score which takes into account the characteristic pain intensity (CPI) and interference score (IS). Two versions exist, 6-month and 1-month versions. The 1-month version was chosen as we think it is a better representation of the patients' pain intensity closer to the actual clinical appointment. It is also suggested that the accuracy of pain report worsens with longer recall period, meaning that the 6-month scale may not represent the current situation accurately (Sharma et al., 2021, McGorry et al., 1999). In addition, axis 1 of the DC/TMD criteria is based on a 1-month reference, therefore, this version would be consistent with the classification system used. Previous findings have shown good psychometric properties for this scale in a TMD population. The 1-month version outperforms its 6-month counterpart in terms of reliability for pain intensity and pain interference and is equally valid for those constructs. The pain disability classification, based on only a 1-month window, does not have similar evidence, however (Sharma et al., 2021).

   GCPS scores were split into 2 categories in this study: high pain-related impairment (grades 3 and 4) and low disability or no disability at all (grades 0,1, and 2). (Manfredini et al., 2011, Manfredini et al., 2010)

3. Patient Health Questionnaire-8 (PHQ-8) is a measure of depressive disorders. This scale is one of the most commonly used tools in research and healthcare setting worldwide (Mitchell et al., 2016, Lamela et al., 2020). It was developed as a screener of the depressive symptoms as specified by the Diagnostic and Statistical Manual of Mental Disorders IV-TR (Kroenke et al., 2001). The scores range from 0-24, with values of 5, 10, 15, and 20 representing cut-off points for mild, moderate, moderately severe, and severe depression, respectively. A 10-point cut off score

was used in this study to indicate clinically relevant depression, hence categorising the scores into a binary variable (<10 and >=10) (Pieh et al., 2020, Feingold et al., 2017). This scale has been tested repeatedly in various populations, with several alternative factor structures suggested, including one-factor, 2-factor and bifactor models. (Chilcot et al., 2013, Krause et al., 2011, Granillo, 2012).

4. General Anxiety Disorder-7 (GAD-7): this tool is a simple and short questionnaire which was developed to increase recognition of general anxiety disorder in primary care (Spitzer et al., 2006). It has shown good reliability and validity by repeated testing in various populations (Kertz et al., 2013, Löwe et al., 2008, Johnson et al., 2019). Scores range from 0-21, and values of 5, 10, and 15 represent cut-off points for mild, moderate, and severe anxiety. Similar binary categorisation was applied to the scores with a 10-point cut off value to indicate clinically relevant anxiety (Pieh et al., 2020, Feingold et al., 2017). Akin to PHQ-8, GAD-7 has more than one suggested factor solution found in the literature.

5. Patient Health Questionnaire-15 (PHQ-15): developed by Kroenke et al as a brief and self-reported PROM to screen and monitor somatisation and somatic symptom severity (Kroenke et al., 2002). Several studies have examined the psychometric properties of the scale, contributing to support its validity and reliability in various settings (van Ravesteijn et al., 2009, Han et al., 2009, NORDIN et al., 2013, Hyphantis et al., 2014). Scores range form 0-30, with scores of 5, 10, and 15 represent cut-points for low, medium, and high physical symptoms, respectively. Similar to the previous 2 scales, a 10-point cut-off score was applied to establish patients with somatisation disorder (Bierke et al., 2016, North et al., 2019).

6. Jaw Functional Limitation Scale-20 (JFLS-20): this instrument assess disability related to facial pain and covers a range of activities such as eating foods of various consistencies, yawning, kissing, and laughing (Ohrbach et al., 2008a, Ohrbach et al., 2008b). Two papers were identified exploring the factor structure of this instrument in the literature, and both showed a three-domain solution (Xu et al., 2020, Fetai et al., 2020). A single global score of "jaw functional limitation" can be computed as the mean of the available items or by computing the mean of the 3 subscale scores (*Mastication*: mean of items 1-6, *Mobility*: mean of items 7-10, and *Verbal and non-verbal communication*: mean of items 13-20).

### 3.3.4. Statistical analysis

The statistical analysis was performed using STATA version 17 (StataCorp, College Station, TX, U.S.A.). Descriptive analysis was first conducted to summarise the demographics and outcome scores of the sample. The normality of distribution of the data was also tested using the Shapiro-Wilkes test.

#### 3.3.4.I. Structural validity and factor analysis

The structural validity is the degree to which the scores of a health-related PROM are an adequate reflection of the dimensionality of the construct to be measured (Mokkink et al., 2010c). The structural validity of PHQ15, PHQ8, GAD7 and JFLS20 was explored in this study by conducting confirmatory factor analysis (CFA). Where the factor solutions proposed in the literature did not suit any of the PROMs, exploratory factor analysis (EFA) was conducted.

The following fit indices were used to judge the suitability of the proposed models: root mean square of error approximation (RMSEA), standardized root mean squared residual (SRMR), comparative fit index (CFI) and Tucker-Lewis index (TLI). RMSEA

and SRMR values <0.5 are indicative of a good fit, and values <0.8 of an acceptable fit. CFI and TLI values greater than 0.95 are considered acceptable (Hu and Bentler, 1999). Sattora-Bentler correction was applied to account for non-normality in the data, as some of these indices are affected by it especially in small to medium sample sizes (Satorra and Bentler, 2001, Brosseau-Liard and Savalei, 2014, Pagán-Torres et al., 2020, Nima et al., 2020, Frazier et al., 2018).

### 3.3.4. II. Internal consistency reliability

This aspect of reliability reflects the degree of inter-relatedness between the items (Mokkink et al., 2010c). The COSMIN guidance recommends using Cronbach α to measure the internal consistency, with a minimum cut-off point of 0.7 as an acceptable value (Terwee et al., 2007, Mokkink et al., 2010b). George and Malley propose the following criteria as well: values >0.9 are excellent, >0.8 are good, >0.7 are acceptable, >0.6 are questionable, >0.5 are poor and <0.5 are unacceptable (George and Malley.).

### 3.3.4.III. Cross sectional analysis of the associations between pain, functional limitation, anxiety, depression, and somatisation.

The associations between the various PROMs and corresponding demographic data were explored by running bivariable analysis using Mann-Whitney rank sum test, Kruskal-Wallis test and Spearman's correlation for continuous variables, and chi-square and Fisher's exact tests for categorical variables. All tests were two-tailed and p-values < 0.05 were considered statistically significant.

### 3.3.4. IV. Missing values

PHQ-8: there were 4 missing values for 4 participants, making up 0.3% of the data set. These missing values were replaced by mean imputation, where the mean of the

rest of the items in the scale for each participant was used to estimate the missing value. The integer mean value was used.

GAD-7: there were 3 missing values for 3 participants, making up 0.3% of the data set. The missing values were treated similarly to PHQ-8.

PHQ-15: 21 values were missing for 11 participants, making up 1% of the data set. However, 1 participant had 8 values missing, therefore was excluded from factor analysis. The rest of the missing values were handled similarly to the previous scales.

JFLS-20: 46 values were missing for 20 participants, making up 1.8% of the data set. 3 participants, however, had over 6 values missing and were excluded from factor analysis. In subsequent analysis, the missing overall scores for these participants were replaced by the mean value of the scores of the rest of the participants for this scale.

## 3.4. Results

### 3.4.1. The participants

129 participants took part in this cross-sectional study. The mean age was 39.8 years (median =37) and ranged from 18-74. 82.17% (n=106) were females and 17.83% (n=23) were males. The mean duration of onset of symptoms was 7.5 years (±7.9 SD) with a range of 0.05 to 38 years. All the participants had at least one diagnosis with pain symptoms; 100% (129) had myalgia, 10.1% (n=13) of those additionally had headache attributed to TMD and 10.9% (n=14) had arthralgia. 49.6% (n=64) of the participants additionally had intraarticular (IA) joint involvement with 38% (n=49) having disc displacement with reduction, 7.8% (n=10) having disc displacement without reduction with limited mouth opening and 3.8% (n=5) having degenerative joint disorder. See table 3.1 for a full description of the participants' details.

Table 3.1. Descriptive statists of the demographic variables of the study participants.

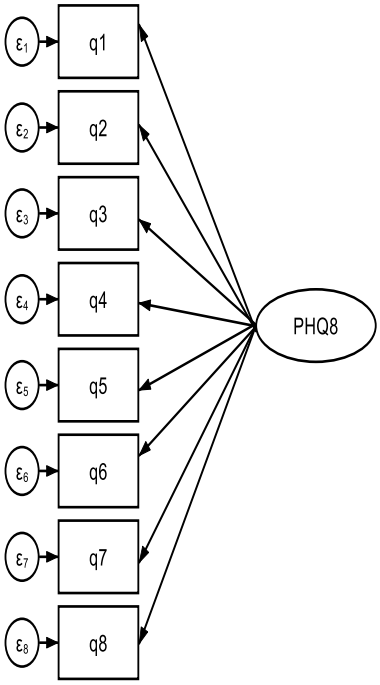
| **Gender** | N (%) |
|---|---|
| Female | 106 (82.14%) |
| Male | 23 (17.83%) |
| **Ethnicity** | |
| White | 84 (65.1%) |
| Asian | 27 (20.9%) |
| Black | 9 (6.98%) |
| Mixed | 5 (3.88%) |
| Other | 4 (3.10%) |
| **Smoking status** | |
| Never smoked | 84 (65.1%) |
| Previous smoker | 31 (24%) |
| Current smoker | 14 (10.9%) |
| **Alcohol consumption** | |
| Non-drinker | 69 (49.64%) |
| Drinker | 70 (50.36%) |
| **TMD symptoms** | |
| Pain only symptoms | 65 (50.4%) |
| Pain+ IA involvement | 64 (49.6%) |

### 3.4.2. PHQ-8

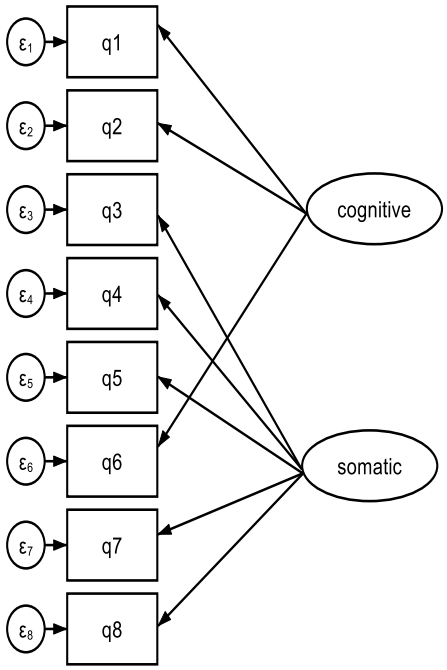
Confirmatory factor analysis

Several factor solutions were described in the literature (Chilcot et al., 2013, Lamela et al., 2020, Pagán-Torres et al., 2020, Krause et al., 2011). Four of those were tested for this scale to identify a suitable fit in a TMD sample. See figure 3.1 for some of the tested models. The fit indices result for each solution are shown in table 3.2.

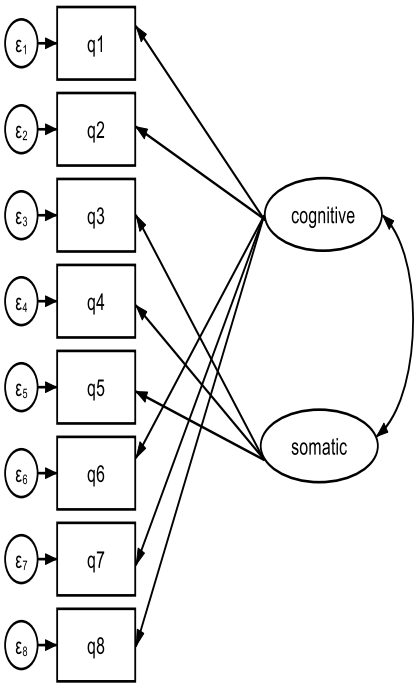
Figure 3.1. Structural models applied in confirmatory factor analysis for PHQ-8 in a TMD cohort.



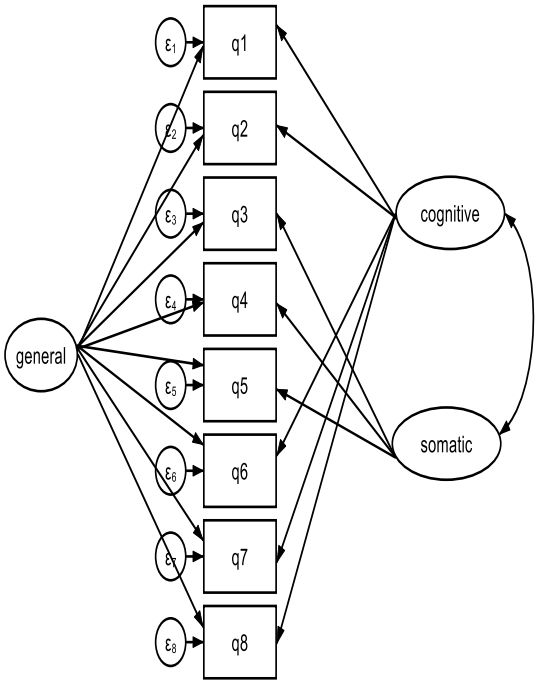

Solution 1. One factor model.




Solution 2. Two-factor model.




Solution 3. Two-factor model




Solution 4. Bifactor model.

Table 3.2. Confirmatory factor analysis fit indices for the models suggested- PHQ-8

| **Solution 1. One-factor model** (Lamela et al., 2020) | |
|---|---|
| RMSEA (CI) | 0.176 (0.142-0.211) |
| *RMSEA-SB* | *0.146* |
| CFI | 0.874 |
| TLI | 0.824 |
| *CFI-SB* | *0.897* |
| *TLI-SB* | *0.856* |
| *SRMR* | *0.061* |

| **Solution 2. Two-factor model*** (Pagán-Torres et al., 2020, Lamela et al., 2020) | |
|---|---|
| RMSEA (CI) | 0.092 (0.05-0.132) |
| *RMSEA-SB* | *0.067* |
| CFI | 0.968 |
| TLI | 0.952 |
| *CFI-SB* | *0.980* |
| *TLI-SB* | *0.970* |
| *SRMR* | *0.044* |

| **Solution 3. Two-factor model** (Lamela et al., 2020, Chilcot et al., 2013) | |
|---|---|
| RMSEA (CI) | 0.144 (0.108-0.181) |
| *RMSEA-SB* | *0.118* |
| CFI | 0.920 |
| TLI | 0.882 |
| *CFI-SB* | *0.937* |
| *TLI-SB* | *0.907* |
| *SRMR* | *0.067* |

| **Solution 4. Bifactor model** (Lamela et al., 2020) |
|---|
| No convergence achieved. |

*: Suitable solutions. RMSEA: Root mean square of error approximation. CI: 90% Confidence interval. SB: Sattora-Bentler adjustment. CFI: Comparative fit index. TLI: Tucker-Lewis index. SRMR: Standardized root mean squared residual.

Based on the results displayed in table 3.2, solution number 2 seemed to give the best fit model (RSMEA-SB=0.67, CFI-SB=0.980, TLI-SB=0.970, SRMR=0.044). RSMEA-SB and SRMR values fell under the acceptable cut-off point of 0.08 and CFI-SB and TLI-SB over 0.95. This model suggested a two-factor solution, with items 1,2 and 6 comprising a cognitive component, and items 3,4,5,7 and 8 comprising a somatic component.

Internal consistency reliability

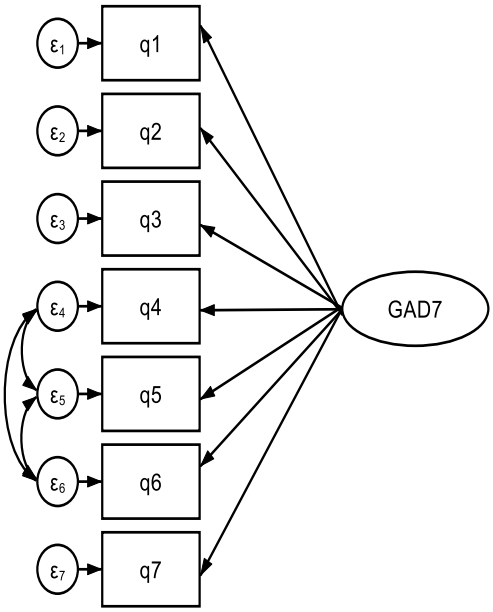
Cronbach α was subsequently calculated based on this model. Alpha for the items all together was an excellent 0.91. Alpha for the first factor (items 1,2 and 6) was 0.89 and for the second factor (3,4,5,7 and 8) was 0.86. Both values were good and fell above the acceptable cut-off point of 0.7.

### 3.4.3. GAD-7

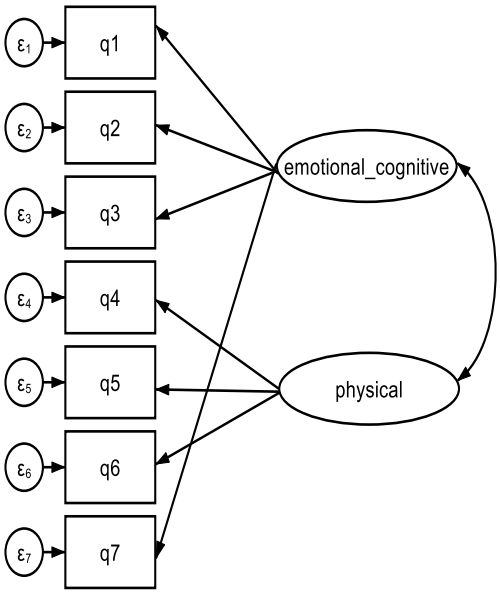
Confirmatory factor analysis

Akin to the other scales, GAD-7 was also tested for its factor structure several times in different populations (Johnson et al., 2019, Terrill et al., 2015, Löwe et al., 2008, Kertz et al., 2013). One and two-factor solutions were tested to assess the best fit model. Figure 3.2 and table 3.3 describe the suggested solutions and associated CFA results.

Figure 3.2. Structural models applied in confirmatory factor analysis for GAD-7 in a TMD cohort.




Solution 1. One-factor model.




Solution 2. Two factor model

Table 3.3. Confirmatory factor analysis fit indices for the models suggested- GAD-7.

| **Solution 1. One factor model*** (Johnson et al., 2019) | |
|---|---|
| RMSEA (CI) | 0.103 (0.052-0.155) |
| *RMSEA-SB* | *0.069* |
| CFI | 0.981 |
| TLI | 0.963 |
| *CFI-SB* | *0.989* |
| *TLI-SB* | *0.979* |
| *SRMR* | *0.027* |

| **Solution 2. Two-factor model*** (Johnson et al., 2019) | |
|---|---|
| RMSEA (CI) | 0.105 (0.058-0.152) |
| *RMSEA-SB* | *0.067* |
| CFI | 0.0976 |
| TLI | 0.962 |
| *CFI-SB* | *0.988* |
| *TLI-SB* | *0.980* |
| *SRMR* | *0.033* |

*: Suitable solutions. RMSEA: Root mean square of error approximation. CI: 90% Confidence interval. SB: Sattora-Bentler adjustment. CFI: Comparative fit index. TLI: Tucker-Lewis index. SRMR: Standardized root mean squared residual.

As displayed in table 3.3, the fit indices for both solutions were suggestive of a good fit. The first solution suggested grouping all the items in one factor, with the residuals of items 4,5 and 6 allowed to correlate. In solution 2, the items were grouped in two factors: items 1,2,3 and 7 in an emotional and cognitive factor and items 4,5 and 6 in a physical factor.

Internal consistency reliability

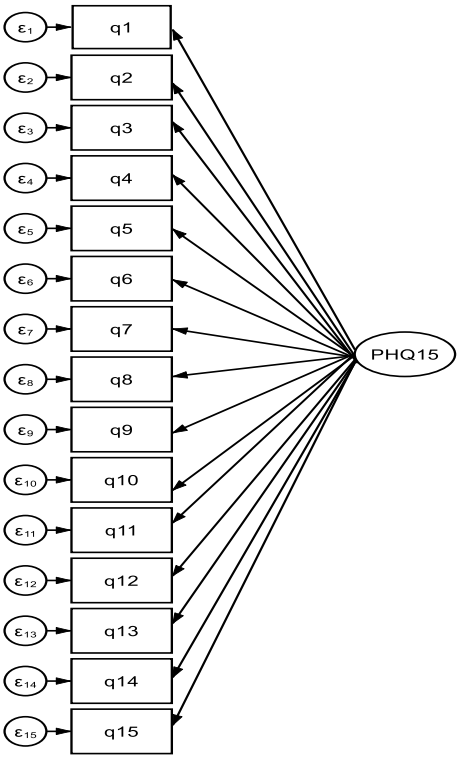
Cronbach α was calculated next and gave good results for both solutions as well. Alpha for solution 1 where all the items were grouped together was 0.93. Alpha for the emotional and cognitive factor of solution 2 was 0.91 and for the physical factor 0.84. All alpha values were good and above 0.7.

### 3.4.4. PHQ-15

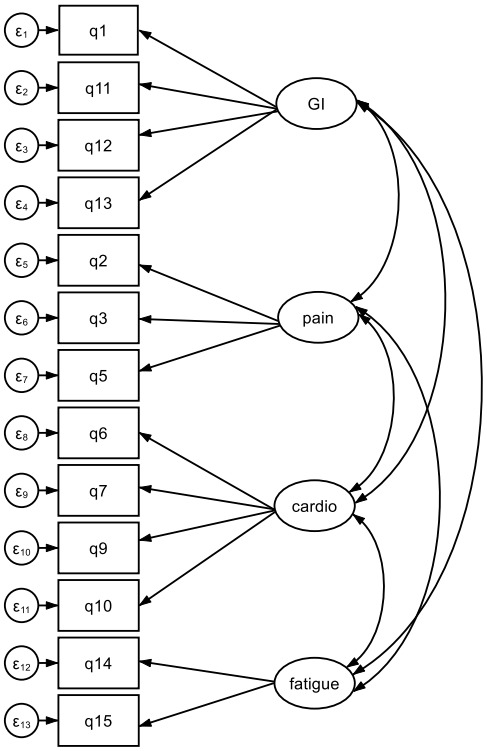
Confirmatory factor analysis

Studies exploring the factor structure of PHQ-15 were reported abundantly in the literature (Cano-García et al., 2020, Liao et al., 2016, Leonhart et al., 2018, Claassen-van Dessel et al., 2017). Hence, multiple models were tested to find the best fit. One, three, four and bifactor models were tested. See figure 3.3 and table 3.4 for results of the tested solutions. The suggested factors were gastro-intestinal, pain, fatigue, and cardiopulmonary.

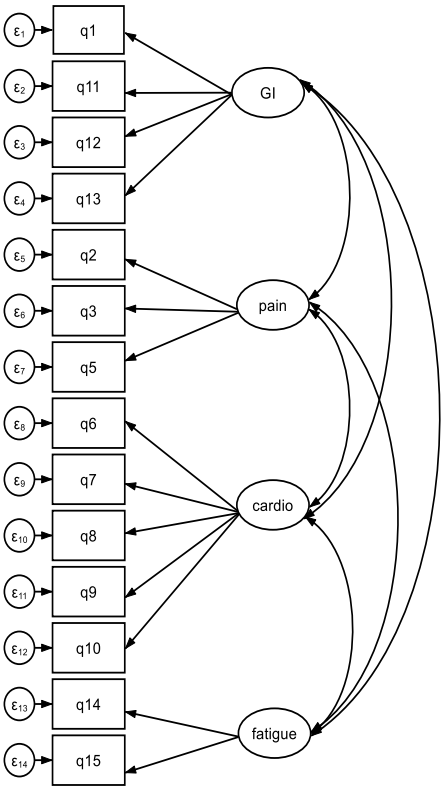
Figure 3.3. Structural models applied in confirmatory factor analysis for PHQ-15 in a TMD cohort



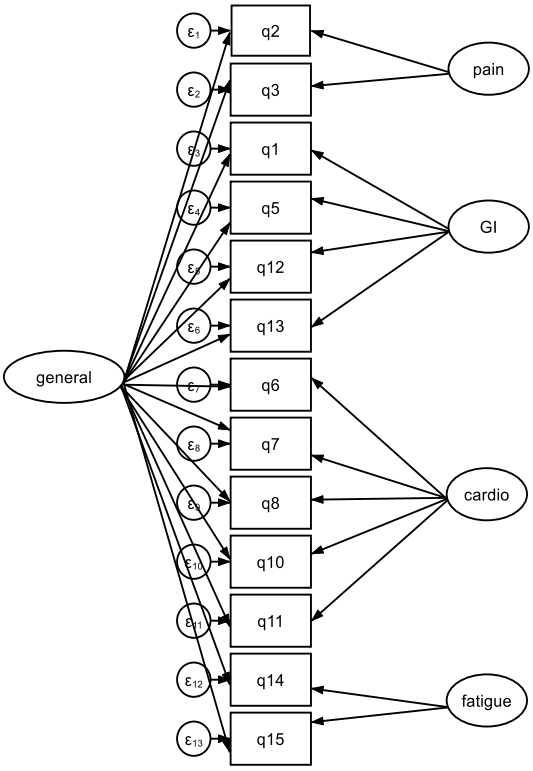

Solution 1. One-factor model.



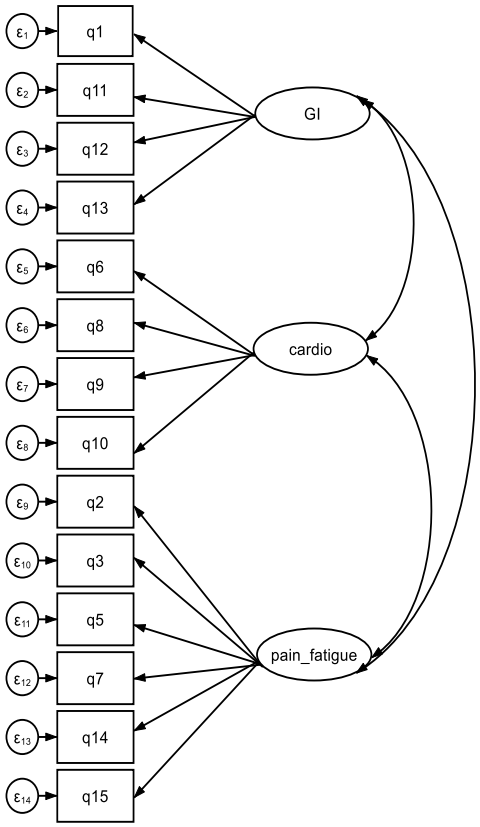

Solution 2. Four-factor model



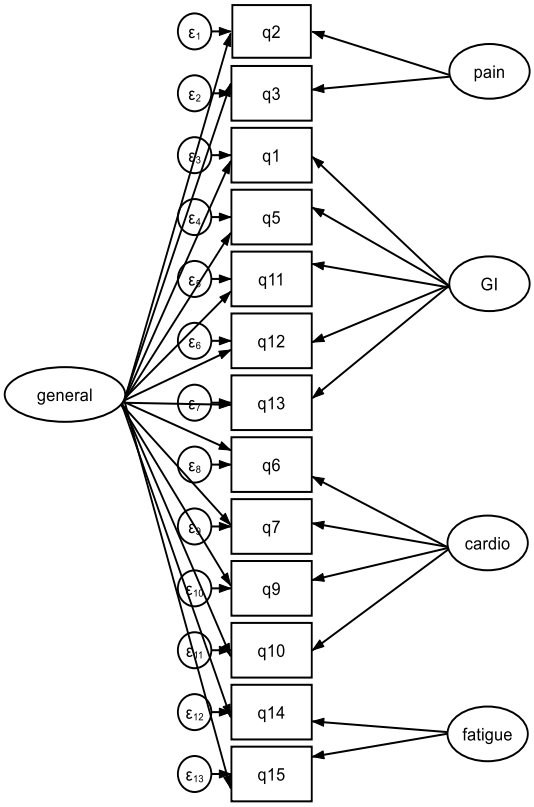

Solution 3. Four-factor model.



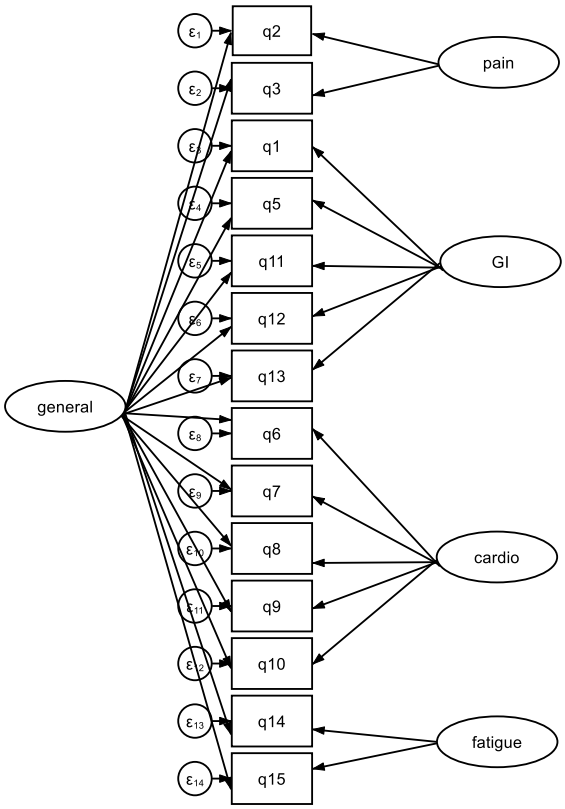

Solution 4. Bifactor model.




Solution 5. Three-factor model




Solution 6. Bifactor model.




Solution 7. Bifactor model.

Table 3.4. Confirmatory factor analysis fit indices for the models suggested- PHQ-15.

| **Solution 1. One-factor model** | |
|---|---|
| RMSEA (CI) | 0.095 (0.076-0.113) |
| *RMSEA-SB* | *0.087* |
| CFI | 0.772 |
| TLI | 0.734 |
| *CFI-SB* | *0.786* |
| *TLI-SB* | *0.751* |
| *SRMR* | *0.083* |

| **Solution 2. Four-factor model (- items 4,8)*** (Cano-García et al., 2020). | |
|---|---|
| RMSEA (CI) | 0.028 (0.000-0.063) |
| *RMSEA-SB* | *0.009* |
| CFI | 0.985 |
| TLI | 0.981 |
| *CFI-SB* | *0.998* |
| *TLI-SB* | *0.998* |
| *SRMR* | *0.050* |

| **Solution 3. Four-factor model (- item 4)*** (Cano-García et al., 2020). | |
|---|---|
| RMSEA (CI) | 0.050 (0.013-0.076) |
| *RMSEA-SB* | *0.042* |
| CFI | 0.948 |
| TLI | 0.933 |
| *CFI-SB* | *0.960* |
| *TLI-SB* | *0.949* |
| *SRMR* | *0.059* |

| **Solution 4. Bifactor model (- items 4,9)*** (Leonhart et al., 2018) | |
|---|---|
| RMSEA (CI) | 0.018 (0.000-0.060) |
| *RMSEA-SB* | *0.000* |
| CFI | 0.995 |
| TLI | 0.992 |
| *CFI-SB* | *1.000* |
| *TLI-SB* | *1.005* |
| *SRMR* | *0.047* |

| **Solution 5. Three-factor model.** (Liao et al., 2016) | |
|---|---|
| RMSEA (CI) | 0.072 (0.049-0.094) |
| *RMSEA-SB* | *0.064* |
| CFI | 0.888 |
| TLI | 0.862 |
| *CFI-SB* | *0.900* |
| *TLI-SB* | *0.877* |
| *SRMR* | *0.069* |

| **Solution 6. Bifactor model (- items 4,8)*** (Cano-García et al., 2020). | |
|---|---|
| RMSEA (CI) | 0.023 (0.000-0.062) |
| *RMSEA-SB* | *0.000* |
| CFI | 0.991 |
| TLI | 0.987 |
| *CFI-SB* | *1.000* |
| *TLI-SB* | *1.009* |
| *SRMR* | *0.046* |

| **Solution 7. Bifactor model (-item 4)*** (Cano-García et al., 2020). | |
|---|---|
| RMSEA (CI) | 0.040 (0.00-0.069) |
| *RMSEA-SB* | *0.027* |
| CFI | 0.971 |
| TLI | 0.958 |
| *CFI-SB* | *0.985* |
| *TLI-SB* | *0.978* |
| *SRMR* | *0.051* |

*: Suitable solutions. RMSEA: Root mean square of error approximation. CI: 90% Confidence interval. SB: Sattora-Bentler adjustment. CFI: Comparative fit index. TLI: Tucker-Lewis index. SRMR: Standardized root mean squared residual.

As described in the previous table and figure, the one and three-factor solutions yielded the poorest fit (solutions 1 and 5). The four-factor and bifactor solutions, however, gave a good fit to the data. A couple of points of note, however, were:

- Item 4 seemed to be omitted form CFA in most papers as it contains gender-specific content (menstrual problems). Therefore, most models in the literature did not have it in their suggested solutions.
- Another point of note was that in solution number 2, both items 4 and 8 were excluded from the analysis. This model was suggested by Cano-García et al, as item 4 contains gender-specific content (menstrual problems), and item 8 (fainting spells) had a very low base rate in their sample. This model gave very good results in the current sample as demonstrated in solution 2. If item 8 is included in the model as well, the results also seemed very good as demonstrated in solution 3. The bifactor counterparts suggested by Cano-García et al, yielded very good fit as well. See solutions 6 and 7.

The bifactor model suggested in Leonhart et al paper (solution 4), did not seem to converge with correlated factors in our sample. If, however, the factors were not allowed to correlate, the results for this model were also very good indeed. It is worth noting that items 4 and 9 were excluded in this model by Leonhart et al. If included in the analysis of our sample, convergence would not be achieved.

Internal consistency reliability

Cronbach α was calculated for the four-factor and bifactor models proposed in the previous section as they have the best fit indices. Alpha value for the overall scale with all items included was 0.83, and 0.84 with item 4 excluded as is the case in most models. See table 3.5 for alpha values in each scenario.

Table 3.5. Internal reliability estimates of the sub-scores of PHQ-15.

| **Solution 2** | **Cronbach α** |
|---|---|
| GI (1,11,12,13) | 0.72 |
| Pain (2,3,5) | 0.57 |
| Cardio (6,7,9,10) | 0.68 |
| Fatigue (14,15) | 0.73 |

| **Solution 3*** | **Cronbach α** |
|---|---|
| GI (1,11,12,13) | 0.72 |
| Pain (2,3,5) | 0.57 |
| Cardio (6,7,8,9,10) | 0.71 |
| Fatigue (14,15) | 0.73 |

| **Solution 4** | **Cronbach α** |
|---|---|
| Pain (2,3) | 0.58 |
| GI (1,5,12,13) | 0.67 |
| Cardio (6,7,8,10,11) | 0.67 |
| Fatigue (14,15) | 0.73 |

| **Solution 6** | **Cronbach α** |
|---|---|
| Pain (2,3) | 0.58 |
| GI (1,5,11,12,13) | 0.68 |
| Cardio (6,7,9,10) | 0.68 |
| Fatigue (14,15) | 0.73 |

| **Solution 7** | **Cronbach α** |
|---|---|
| Pain (2,3) | 0.58 |
| GI (1,5,11,12,13) | 0.68 |
| Cardio (6,7,8,9,10) | 0.71 |
| Fatigue (14,15) | 0.73 |

* Suitable solution

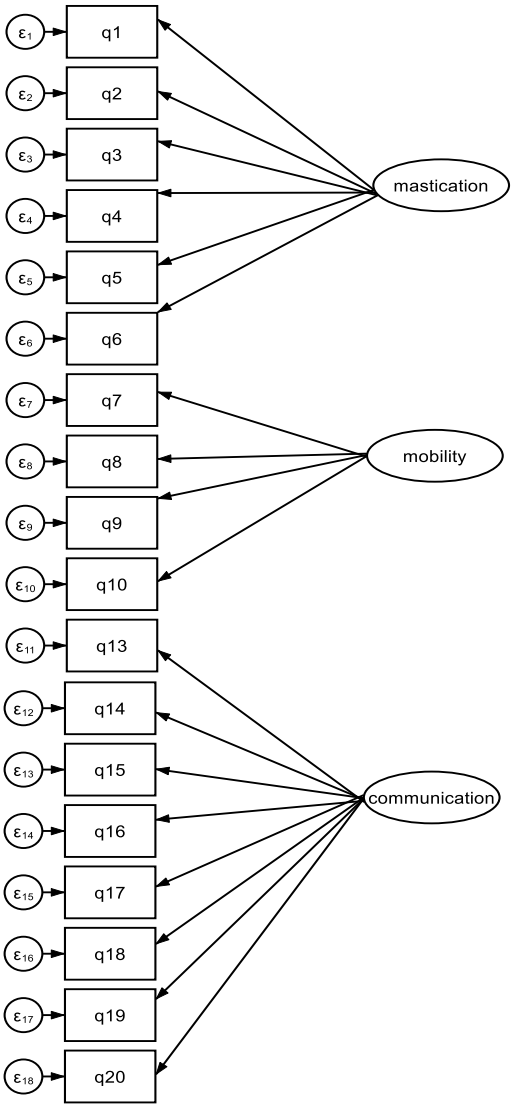
Based on the CFA and Cronbach α results displayed in the table 3.5, solution number 3 (four-factor model) seemed to give the most satisfactory results in both sets of statistics (factor analysis and Cronbach α).

### 3.4.5. JFLS-20

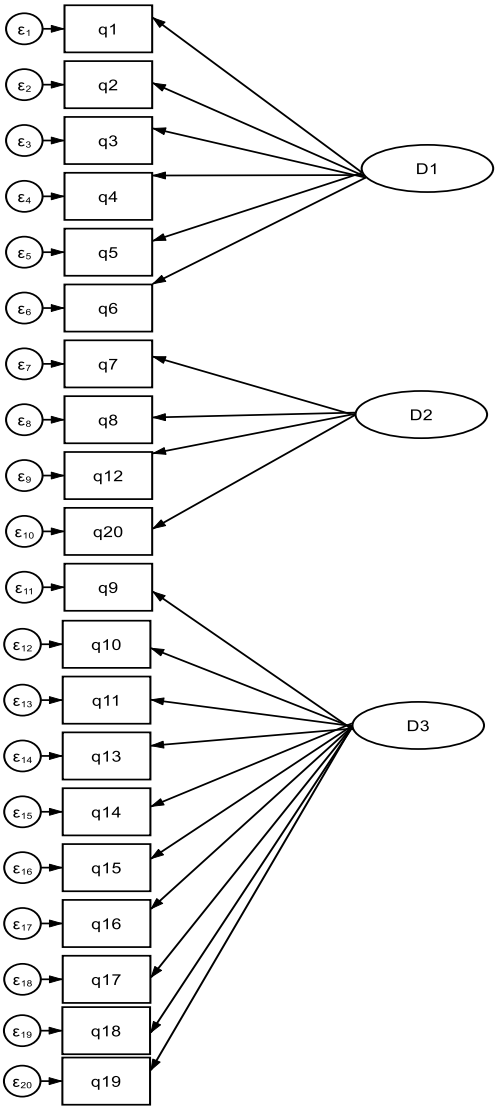
Confirmatory factor analysis

Very few studies in the literature explored the factor structure of JFLS-20. The original development papers used Rasch analysis to assess the relevance of the items, however, a clear factor structure was not described (Ohrbach et al., 2008a, Ohrbach et al., 2008b). Two further studies explored the factor structure of JFLS-20, both describing a three-factor solution (Fetai et al., 2020, Xu et al., 2020). The suggested models were tested in this sample of TMD patients; however, both did not yield a good fit. See figure 3.4 and table 3.6 for details. Considering the lack of abundant literature that describes the factor structure for this scale, exploratory factor analysis (EFA) was deemed appropriate in this case.

Figure 3.4. Structural models applied in confirmatory factor analysis for JFLS-20 in a TMD cohort.




Solution 1. Three-factor model




Solution 2. Three-factor model

Table 3.6. Confirmatory factor analysis fit indices for the models suggested- JFLS-20

| **Solution 1. Three-factor model** (Fetai et al., 2020) | |
|---|---|
| RMSEA (CI) | 0.211(0.198-0.224) |
| RMSEA-SB | 0.176 |
| CFI | 0.677 |
| TLI | 0.634 |
| CFI-SB | 0.692 |
| TLI-SB | 0.651 |
| SRMR | 0.430 |

| **Solution 2. Three-factor model** (Xu et al., 2020). | |
|---|---|
| RMSEA (CI) | 0.167 (0.155-0.179) |
| RMSEA-SB | 0.137 |
| CFI | 0.770 |
| TLI | 0.738 |
| CFI-SB | 0.790 |
| TLI-SB | 0.761 |
| SRMR | 0.135 |

RMSEA: Root mean square of error approximation. CI: 90% Confidence interval. SB: Sattora-Bentler adjustment. CFI: Comparative fit index. TLI: Tucker-Lewis index. SRMR: Standardized root mean squared residual.

Exploratory factor analysis

Since CFA did not yield desirable results in this sample, EFA was conducted to find a suitable factor structure for JFLS-20.

Several steps were involved in executing EFA, starting with evaluating whether the data is suitable for this type of analysis. A pair of tests were used to that end; the Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy and Bartlett's Test of Sphericity. The KMO index ranges from 0 to 1, with values higher than 0.50 considered suitable for factor analysis. The Bartlett's Test of Sphericity should be significant, indicating sufficient intercorrelations for factor analysis. (Hair et al., 1995, Tabachnick and Fidell, 2007). Factor extraction was subsequently carried out using Principal Factor Analysis, to reduce the large number of items into factors. Two rules were utilised; the Kaiser's criteria (eigenvalue > 1 rule) (Kaiser, 1960) and the Scree test (Cattell, 1966). The scree plot is a heuristic graph that plots the eigenvalues against the components. By inspecting the elbow of the plot – the point where the notable decline in factors levels off - the number of retained factors could be estimated (Ledesma et al., 2015).

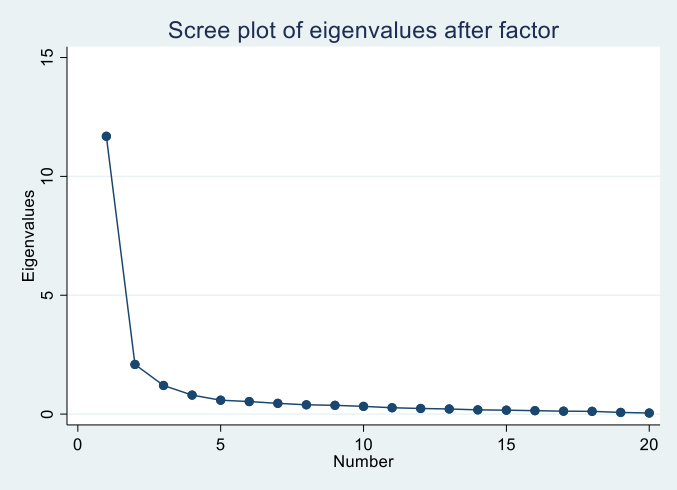
The initially extracted loadings are usually not particularly interpretable because the items may load on multiple factors. Therefore, factor rotation was applied next. It is a mathematical transformation with the aim of obtaining an interpretable factor loading matrix that provides a simple structure solution (Finch, 2020). Factor rotation was done using Promax rotation method with a 0.45 cut-off point for factor loadings. Items were excluded if they had weak loadings on factors (<0.45), or if they cross-loaded on more than one factor.

The Bartlett test of sphericity and the Kaiser-Meyer-Olkin Measure of Sampling Adequacy both gave favourable results; with the former giving a p-value <0.05, and the latter giving a value of 0.914. Next, all the items were inserted in the analysis equation. Promax factor rotation with 0.45 cut-off value was chosen. Three factors were retained as determined by the Kaiser's test (number of eigenvalues >1) and by plotting a scree graph. See figures 3.5 and 3.6 for both, respectively.

Figure 3.5. Eigenvalues of the retained factors during exploratory factor analysis of JFLS-20.

| Factor | Eigenvalue | Difference | Proportion | Cumulative |
|---|---|---|---|---|
| Factor1 | 11.68630 | 9.59733 | 0.5843 | 0.5843 |
| Factor2 | 2.08898 | 0.88396 | 0.1044 | 0.6888 |
| Factor3 | 1.20502 | 0.40466 | 0.0603 | 0.7490 |
| Factor4 | 0.80036 | 0.21559 | 0.0400 | 0.7890 |
| Factor5 | 0.58477 | 0.05678 | 0.0292 | 0.8183 |
| Factor6 | 0.52799 | 0.07543 | 0.0264 | 0.8447 |
| Factor7 | 0.45256 | 0.06055 | 0.0226 | 0.8673 |
| Factor8 | 0.39201 | 0.02219 | 0.0196 | 0.8869 |
| Factor9 | 0.36982 | 0.04481 | 0.0185 | 0.9054 |
| Factor10 | 0.32500 | 0.05671 | 0.0163 | 0.9216 |
| Factor11 | 0.26829 | 0.03099 | 0.0134 | 0.9351 |
| Factor12 | 0.23730 | 0.02174 | 0.0119 | 0.9469 |
| Factor13 | 0.21555 | 0.03685 | 0.0108 | 0.9577 |
| Factor14 | 0.17870 | 0.01227 | 0.0089 | 0.9666 |
| Factor15 | 0.16644 | 0.02198 | 0.0083 | 0.9750 |
| Factor16 | 0.14445 | 0.02090 | 0.0072 | 0.9822 |
| Factor17 | 0.12355 | 0.00747 | 0.0062 | 0.9884 |
| Factor18 | 0.11608 | 0.04542 | 0.0058 | 0.9942 |
| Factor19 | 0.07066 | 0.02450 | 0.0035 | 0.9977 |
| Factor20 | 0.04616 | . | 0.0023 | 1.0000 |

Figure 3.6. Scree plot of retained factors during exploratory factor analysis of JFLS-20.




The first domain contained the items 1-4, 7 and 12, the second domain the items 5,6, 9-11, the third domain the items 13-20. See table 3.7 for the rotated factors containing the corresponding items. No items had weak loadings or cross loaded on more than one factor; therefore, none were deleted.

Table 3.7. Factor loadings of JFLS-20 items during factor analysis using Promax rotation and 0.45 cut off point.

| Variable | Factor1 | Factor2 | Factor3 | Uniqueness |
|---|---|---|---|---|
| jflsq19 | 0.9616 | 0.0307 | -0.1522 | 0.2060 |
| jflsq15 | 0.9296 | 0.0168 | -0.0539 | 0.1785 |
| jflsq20 | 0.7887 | 0.2463 | -0.0912 | 0.1945 |
| jflsq16 | 0.7834 | -0.0940 | 0.2335 | 0.2005 |
| jflsq17 | 0.7328 | -0.1172 | 0.2348 | 0.3054 |
| jflsq13 | 0.7231 | 0.0199 | 0.1933 | 0.2421 |
| jflsq18 | 0.6644 | 0.0122 | 0.1904 | 0.3506 |
| jflsq14 | 0.4664 | 0.2099 | 0.1915 | 0.4338 |
| jflsq1 | -0.0726 | 1.0019 | -0.0486 | 0.1186 |
| jflsq2 | 0.0255 | 0.9441 | -0.0817 | 0.1535 |
| jflsq7 | 0.0597 | 0.9096 | -0.0984 | 0.1933 |
| jflsq8 | 0.1039 | 0.8001 | 0.0239 | 0.2286 |
| jflsq4 | -0.0287 | 0.7427 | 0.2431 | 0.2404 |
| jflsq3 | -0.0816 | 0.6649 | 0.3725 | 0.2649 |
| jflsq12 | 0.4065 | 0.5299 | -0.0772 | 0.3762 |
| jflsq6 | -0.0311 | -0.1225 | 0.9918 | 0.1571 |
| jflsq11 | 0.0246 | -0.0219 | 0.7897 | 0.3689 |
| jflsq5 | -0.0157 | 0.1944 | 0.7528 | 0.2662 |
| jflsq10 | 0.3307 | 0.0064 | 0.6234 | 0.2353 |
| jflsq9 | 0.3246 | 0.1784 | 0.4646 | 0.3052 |

Internal consistency reliability

Cronbach α was computed to assess the internal consistency reliability for the overall scale and for the individual domains. Alpha for the overall score was 0.9605. As for the individual domains, alpha for factor 1 was 0.9421, for factor 2 was 0.8940, and for factor 3 was 0.9422. All values indicated good internal consistency, having fallen over the acceptable value of 0.7 recommended by the COSMIN guidance.

### 3.4.6. Cross sectional analysis of the associations between pain, functional limitation, anxiety, depression and somatisation.

The descriptive analysis of the overall scores showed mean (median) scores of 2.5 (2) for GCPS, 8.1 (7) for GAD-7, 8.95 (8) for PHQ-8, 9.58 (9) for PHQ-15, and 3.1 (3.14) for JFLS-20. None of the participants were Grade 0 on the GCPS as pain related TMD was one of the eligibility criteria for this study. 28.7% were Grade 1, 24.7% were Grade 2, 18.6% were Grade 3 and 27.9% were Grade 4. Just over a third of the participants fell over the 10-point cut-off value of GAD-7 (36.4%) and PHQ-8 (39.5%) indicating clinically relevant anxiety and depression, respectively. Looking at the original classification system for these two PROMs, 35.66% had minimal anxiety, 27.91% had mild anxiety, 18.60% had moderate anxiety and 17.83% had severe anxiety. As for depression, 29.46% had no depression, 18.60% had mild depression, 12.40% had moderate depression, 12.40% had moderately severe depression and 8.53% had severe depression.

The skewness values for all the scores fall within the acceptable -1-1 range, indicating that the values are not heavily skewed. The Shapiro-Wilkes test for normality was also conducted and indicated a significant p-value across all scores apart from GCPS-total. A significant p-value associated with this test indicates a non-normal distribution of the

scores, hence non-parametric tests were conducted for the rest of the analysis. Table 3.8 describes the descriptive statistics for each PROM in detail.

Table 3.8. Descriptive statistics, response distribution, skewness, kurtosis, and normality of distribution for GCPS (CPI, IS), GAD-7, PHQ-8, PHQ-15 and JFLS-20 in a TMD cohort.

| | **N (%)** | **Mean (SD)** | **Median (Range)** | **Skewness** | **Kurtosis** | **S-W (p value)** |
|---|---|---|---|---|---|---|
| **GCPS-total**<br>Grade 1,2<br>Grade 3,4 | 129 (100%)<br>69 (53.5%)<br>60 (46.5%) | 2.5 (1.2) | 2<br>(1-4) | .09 | 1.5 | 0.89 |
| **GCPS-CPI** | 129 (100%) | 56.0 (22.4) | 60<br>(3.3-96.7) | -.44 | 2.3 | 0.002* |
| **GCPS-IS** | 129 (100%) | 36.9 (30.1) | 10 | .46 | 2.2 | 0.005* |
| **GAD-7**<br><10<br>≥10 | 129 (100%)<br>82 (63.6%)<br>47 (36.4%) | 8.1 (6.4) | 7<br>(0-21) | .45 | 2.0 | 0.0001* |
| **PHQ-8**<br><10<br>≥10 | 129 (100%)<br>78 (60.5%)<br>51 (39.5%) | 8.95 (6.6) | 8<br>(0-24) | .48 | 2.3 | 0.0002* |
| **PHQ-15**<br><10<br>≥10 | 129 (100%)<br>74 (57.4%)<br>55 (42.6%) | 9.58 (5.7) | 9<br>(0-24) | .51 | 2.5 | 0.002* |
| **JFLS-20** | 129 (100%) | 3.1 (2.3) | 3.14<br>(0-8.5) | .38 | 2.3 | 0.000* |

* p-value < 0.5 indicating statistical significance. CPI: Characteristic pain intensity. IS: Interference score.

As mentioned in previous sections, the actual scores for the PROMs fell in a range of numerical variables. However, some studies in the literature treated those PROMs as binary variables with a cut-off point of ≥10 in the case of GAD-7, PHQ-15 and PHQ-8 (Pieh et al., 2020, Bierke et al., 2016), and ≥3 in the case of GCPS (Manfredini et al., 2011)(CPI, Interference Score (IS) and JFLS-20 are numerical variables). In other studies, these score were treated as numerical variables (Klotz et al., 2020, Qin et al., 2019). Therefore, the analysis in this chapter was conducted twice, once treating the GCPS, GAD-7, PHQ-15 and PHQ-8 as binary variables (section 1), and another treating them as numerical variables (section 2).

### 3.4.6.I. Section 1

The relationships between the demographic variables and the different scales were studied by running the following tests: Chi square, Fisher's exact test, Kruskal-Wallis test, Mann-Whitney rank sum test and Spearman's correlation as detailed in table 10. Most of the results gave non-significant p-values, apart from the relationship of GCPS (total, CPI and IS), JFLS and PHQ-15 with the smoking status, and CPI scores with gender.

Chi square test revealed a significant difference between the proportions of smoking status categories and GCPS-total (p-value 0.032, $X^2$= 6.891) and PHQ-15 categories (p-value 0.008, $X^2$= 9.6050). A post hoc Dunn test with Bonferroni adjustment was applied to the significant Chi square results of the smoking status categories and GCPS and PHQ-15 while considering the never smokers as the reference group. A significant p-value was obtained when comparing the GCPS scores of the previous and never smokers (p-value=0.04) (never smokers< previous smokers). Additionally, a significant p-value was obtained when comparing the PHQ-15 scores of the current and never smoker (p-value=0.011) (never smokers < current smokers).

Kruskal-Wallis tests also provided strong evidence of a difference between the JFLS-20 (p-value=0.029, $X^2$=7.068), CPI (p-value=0.007, $X^2$=9.966) and interference scores (p-value=0.0007, $X^2$=14.450) of at least one pair of the smoking status groups. Dunn's pairwise post hoc test was also carried out for three groups with Bonferroni adjustment, after considering the never smokers as the reference group. Significant p-value for JFLS-20 was generated when comparing the current smokers to the never smokers (p-value=0.048) (mean rank of never smokers < mean rank of current smokers), for CPI and when comparing the current smokers to the never smokers (p value=0.009) (mean rank of never smokers< mean rank of current smokers) and for

the interference score when comparing both the previous smokers and the current smokers to the never smokers (p-values of 0.0016, 0.017 respectively), mean rank values of never smokers was lower than the other two groups. See table 3.9 for a full description of the statistics.

Table 3.9. Descriptive statistics and p-values resulting from analysis of factors associated with higher levels of graded chronic pain, pain intensity and interference, jaw functional limitation, anxiety, depression, and somatisation in a TMD cohort.

| | N (%) | GCPS-total | CPI | IS | JFLS | GAD-7 | PHQ-8 | PHQ-15 |
|---|---|---|---|---|---|---|---|---|
| **Ethnicity** | | [a]0.34 | [b]0.13 | [b]0.28 | [b]0.21 | [a]0.25 | [a]0.27 | [a]0.36 |
| White | 84 (65.1%) | | | | | | | |
| Asian | 27 (20.9%) | | | | | | | |
| Black | 9 (6.98%) | | | | | | | |
| Mixed | 5 (3.88%) | | | | | | | |
| Other | 4 (3.10%) | | | | | | | |
| | | | | | | | | |
| **Gender** | | [c]0.213 | **[d]0.035*** | [d]0.143 | [d]0.34 | [c]0.51 | [c]0.607 | [c]0.19 |
| Female | 106 (82.2%) | | | | | | | |
| Male | 12 (17.8%) | | | | | | | |
| | | | | | | | | |
| **Smoking status** | | **[c]0.032*** | **[b]0.007*** | **[b]0.0007*** | **[b]0.029*** | [c]0.228 | [c]0.123 | **[c]0.008*** |
| Never† | 84 (65.1%) | | | | | | | |
| Previous | 31 (24%) | **0.04†*** | 0.057† | **0.0016†*** | 0.07† | | | 0.058† |
| Current | 14 (10.9%) | 0.10† | **0.009†*** | **0.017†*** | **0.048†*** | | | **0.011†*** |
| | | | | | | | | |
| **Alcohol** | | [c]0.35 | [d]0.18 | [d]0.16 | [d] 0.22 | [c]0.08 | [c]0.08 | [c]0.998 |
| No | 61 (47.3%) | | | | | | | |
| Yes | 68 (52.7%) | | | | | | | |
| | | | | | | | | |
| **DC-TMD** | | [c]0.32 | [d]0.34 | [d]0.07 | [d]0.064 | [c]0.19 | [c]0.047 | [c]0.88 |
| Myalgia | 62 (48.1%) | | | | | | | |
| Myalgia + IA | 67 (51.9%) | | | | | | | |
| | | | | | | | | |
| **Age** | | [d]0.64 | [e]0.79 | [e]0.76 | [e]0.78 | [d]0.14 | [d]0.40 | [d]0.88 |

a: Fisher's exact test. b: Kruskal-Wallis test. c: Chi square test. d: Mann-Whitney rank sum test. e: Spearman's correlation. *: Significant p-value (<0.05). †: Reference group. †*: significant difference with the reference group after post hoc Dunn test with Bonferroni adjustment.

Chi square test was also conducted to compare the proportions between the binary variables; GCPS-total, GAD-7, PHQ -8 and PHQ-15. P-values were significant for all

the tests, signalling relevant differences between the groups of pain-related disability, clinically relevant anxiety, depression, and somatisation.

Mann-Whitney rank sum test was conducted to assess the difference of distributions of JFLS-20, CPI and interference scores among the previously mentioned binary variables. Again, all the generated p-values were significant, indicating that the distributions of jaw function limitation, pain intensity and interference were significantly different within the binary groups of anxiety, depression, and somatisation in TMD patients. In other words, participants with clinically relevant anxiety, depression and somatisation, had generally higher values of jaw functional limitation, pain intensity and interference.

Spearman's correlation test was conducted to explore the correlations between the different PROMs on a continuous scale; JFLS-20, CPI and interference scores. Jaw functional limitation (JFLS-20) had a significant correlation with pain intensity (p-value 0.001). The correlation coefficient was 0.52 indicating a strong positive correlation (Rafsten et al., 2020). Similarly with jaw functional limitation and interference scores, where the p-value was 0.001, and r=0.59, indicating a strong positive correlation as well. P-values and the tests conducted are shown in table 3.10 in full detail.

Table 3.10. P-values resulting from analysis of the relationships between GCPS (CPI, IS), GAD-7, PHQ-8, PHQ-15, and JFLS-20.

| | GAD-7 | PHQ-8 | PHQ-15 | JFLS-20 |
|---|---|---|---|---|
| GCPS-total | [a]**0.003*** | [a]**0.001*** | [a]**0.008*** | [b]**0.0001*** |
| GCPS-CPI | [b]**0.0269*** | [b]**0.0001*** | [b]**0.0004*** | [c]**0.0001*** (r= 0.52, *CI: 0.381-0.642*) |
| GCPS-IS | [b]**0.0003*** | [b]**0.0007*** | [b]**0.0004*** | [c]**0.0001*** (r= 0.59, *CI: 0.467-0.699*) |
| GAD-7 | - | [a]**0.000*** | [a]**0.001*** | [b]**0.0026*** |
| PHQ-8 | - | - | [a]**0.001*** | [b]**0.0003*** |
| PHQ-15 | - | - | - | [b]**0.0116*** |

a: Chi square test. b: Mann-Whitney rank sum test. c: Spearman's correlation. *: Significant p-value.

### 3.4.6. II. Section 2

For this section, the following PROMs were treated as numerical variables: GCPS, PHQ-15, PHQ-8, and GAD-7. The rest of the PROMs (JFLS-20, CPI and interference scores were treated as numerical in both sections, therefore were not mentioned in this section). The relationships between the demographic variables and the different scales were studied by running the following tests: Mann-Whitney rank sum test and Kruskal-Wallis test.

Most of the results gave non-significant p-values, apart from the relationship between GCPS and smoking status (p-value  0.006, $X^2$= 10.228) and PHQ-15 and the smoking status (p-value 0.019, $X^2$= 7.834) when conducting Kruskal-Wallis. See table 3.11 for the tests conducted and relevant p-values.

Similar to the previous section, a post hoc Dunn test with Bonferroni adjustment was applied to identify the smoking group responsible for the significant p-values. The never smokers' group was assigned the reference group. A significant p-value was obtained when comparing the GCPS scores of the previous and never smokers (p-value=0.008) (never smokers< previous smokers). Additionally, a significant p-value was obtained when comparing the PHQ-15 scores of the previous and never smoker (p-value=0.019) (never smokers < previous smokers).

PHQ-15 scores were also significantly different between males and females (p value= 0.021), and GAD-7 scores correlated significantly but weekly with age (p-value= 0.007, r= 0.23).

Table 3.11. Descriptive statistics and analysis of the factors associated with higher levels of graded chronic pain, pain intensity and interference, jaw functional limitation, anxiety, depression, and somatisation in TMD patients (numerical variables).

| | N (%) | GCPS-total | CPI | IS | JFLS | GAD-7 | PHQ-8 | PHQ-15 |
|---|---|---|---|---|---|---|---|---|
| **Ethnicity** | | [a]0.169 | [a]0.13 | [a]0.28 | [a]0.21 | [a]0.412 | [a]0.330 | [a]0.396 |
| White | 84(65.1%) | | | | | | | |
| Asian | 27(20.9%) | | | | | | | |
| Black | 9(6.98%) | | | | | | | |
| Mixed | 5(3.88%) | | | | | | | |
| Other | 4(3.10%) | | | | | | | |
| | | | | | | | | |
| **Gender** | | [b]0.187 | **[b]0.035*** | [b]0.143 | [b]0.34 | [b]0.82 | [b]0.91 | **[b]0.021*** |
| Female | 106(82.2%) | | | | | | | |
| Male | 12(17.8%) | | | | | | | |
| | | | | | | | | |
| **Smoking status** | | **[a]0.006** | **[a]0.007*** | **[a]0.0007*** | **[a]0.029*** | [a]0.170 | [a]0.232 | **[a]0.019*** |
| Never† | 84(65.1%) | | | | | | | |
| Previous | 31(24%) | **0.008†*** | 0.057† | **0.0016†*** | 0.07† | | | **0.019†*** |
| Current | 14(10.9%) | 0.053† | **0.009†*** | **0.017†*** | **0.048†*** | | | 0.117† |
| | | | | | | | | |
| **Alcohol** | | [b]0.192 | [b]0.18 | [b]0.16 | [b]0.22 | [b]0.188 | [b]0.175 | [b]0.647 |
| No | 61(47.3%) | | | | | | | |
| Yes | 68(52.7%) | | | | | | | |
| | | | | | | | | |
| **DC-TMD** | | [b]0.113 | [b]0.34 | [b]0.07 | [b]0.064 | [b]0.138 | [b]0.099 | [b]0.60 |
| Myalgia | 62(48.1%) | | | | | | | |
| Myalgia + IA | 67(51.9%) | | | | | | | |
| | | | | | | | | |
| **Age** | | [c]0.71 | [c]0.79 | [c]0.76 | [c]0.78 | **[c]0.007* r= -0.23 (*CI: -0.007- -0.06)*** | [c]0.43 | [c]0.91 |

a: Kruskall-Wallis test. b:Mann-Whiteney rank sum test. c: Spearman's correlation. *: Significant p-value (<0.05). †: Reference group. †*: significant difference with the reference group after post hoc Dunn test with Bonferroni adjustment.

Spearman's correlation test was conducted next to explore the correlations between the different PROMs on a continuous scale. Again, all the correlations generated significant p-values, with varying strengths of correlation (r). The strength of correlation was interpreted as small ($r < \pm 0.29$), medium ($r = \pm 0.30$ to $\pm 0.49$) or large ($r = \pm 0.50$ to 1.0) (Rafsten et al., 2020). Table 3.12 describes the results in full.

Large correlations were discovered between PHQ-8 and GAD-7 (r=0.71), PHQ-15 and PHQ-8 (r=0.65), and JFLS-20 and GCPS (r=.57), CPI (r=0.52) and interference score (r=0.59).

Table 3.12. Correlation analysis of the relationships between GCPS (CPI, IS), GAD-7, PHQ-8, PHQ-15 and JFLS-20 P (Spearman's correlation of numerical variables).

| | GAD-7 | PHQ-8 | PHQ-15 | JFLS-20 |
|---|---|---|---|---|
| GCPS-total | **0.0013*** (r=0.28, *CI: 0.108-0.436*) | **0.0001*** (r=0.44, *CI: 0.283-0.572*) | **0.0001*** (r=0.36, *CI: 0.200-0.510*) | **0.0001*** (r=0.57, *CI: 0.442-0.683*) |
| GCPS-CPI | **0.0333*** (r=0.19, *CI: 0.010-0.354*) | **0.0001*** (r=0.41, *CI: 0.249-0.547*) | **0.0001*** (r=0.41, *CI: 0.251-0.548*) | **0.0001*** (r= 0.52, *CI: 0.381-0.642*) |
| GCPS-IS | **0.0002*** (r=0.33, *CI: 0.159-0.478*) | **0.0001*** (r=0.45, *CI: 0.292-0.579*) | **0.0001*** (r=0.41, *CI: 0.250-0.548*) | **0.0001*** (r=0.59, *CI: 0.467-0.699*) |
| GAD-7 | - | **0.0001*** (r= 0.71, CI: 0.612-0.790) | **0.0001*** (r=0.49, *CI: 0.347-0.618*) | **0.0132*** (r=0.22, *CI: 0.041-0.381*) |
| PHQ-8 | - | - | **0.0001*** (r= 0.65. *CI: 0.540-0.746*) | **0.0001*** (r=0.37, *CI: 0.200-0.510*) |
| PHQ-15 | - | - | - | **0.0008*** (r=0.29, *CI: 0.120-0.446*) |

* P-value <0.5 indicating statistical significance.

## 3.5. Discussion

The present study aimed to explore the structural layout and internal consistency of four common scales in a TMD population. GAD-7, PHQ-8 and PHQ-15 have been validated in various samples, such as pregnancy (Soto-Balbuena et al., 2021), atypical chest pain (Lin et al., 2021) and substance use in young people (Bentley et al., 2021). All amounting to abundant literature describing their factor structure. In such a case, confirmatory factor analysis (CFA) was appropriate to apply (Kim and Mueller, 1978). CFA is a method used to compare the measures of construct in a current sample to a hypothesised/suggested model in previous analytical research (Kline, 2011, Sales et al.). Several models were identified for these three scales in our search, and alternative solutions were tested for each. A two-factor model with cognitive and somatic factors was suitable for PHQ-8, with the Cronbach α values of 0.89 and 0.86 for both factors, respectively, affirming good internal consistency as well. Both models

proposed for GAD-7 (one and two-factor models) delivered good results in terms of CFA indices and Cronbach α values. Perhaps with a larger sample size in future research, one model could edge the other in terms of robustness in a TMD population. As for PHQ-15, seven models were tested, with four-factor and bifactor models producing good fit indices. Cronbach α values were the determining factor in this study, as a four-factor solution consisting of GI, pain, cardiopulmonary, and fatigue domains gave the best internal consistency results. Hietaharju et al reported Cronbach α values of 0.85 for PHQ-9, 0.81 for PHQ-15, and 0.91 for GAD-7 in their study comparing the tools of RDC/TMD to the updated version; DC/TMD (Hietaharju et al., 2021). The results of the present study were in keeping with these reported values, indicating that indeed, these three scales have good internal consistency reliability in TMD patients.

JFLS-20 underwent CFA initially in the present study, however, did not generate adequate fit indices. Exploratory factor analysis was deemed appropriate, indicating a suitable three-factor model with very good internal consistency. Studies exploring some psychometric properties of this scale reported Cronbach α values >0.8 (Ohrbach et al., 2008a, Ohrbach et al., 2008b, Fetai et al., 2020, Xu et al., 2020). Again, supporting the results in the present study which demonstrated good internal consistency of the scale. Xu et al, also reported good test-retest reliability as measured by interclass correlation coefficient for the domains of the scale (>0.85), providing additional evidence to support its use in TMD patients.

GAD-7 and PHQ-8/9 are often used together to measure anxiety and depression respectively (Creese et al., 2021, Heindl et al., 2021, Reddy et al., 2021). Previous investigations revealed high levels of psychological disorders in TMD patients ranging from 21.4%-60.1% for moderate-severe depression (Canales et al., 2018) and around 30% for moderate-severe anxiety (Simoen et al., 2020, Bertoli and de Leeuw, 2016).

In the present study over a third of the participants had clinically relevant anxiety and depression (36.4% and 39.5% respectively). Additionally, participants with higher CPI scores, had higher anxiety, depression, and somatisation scores as well.

Somatisation is “the association of medically unexplained somatic symptoms with psychological distress and health-seeking behaviour” (Kirmayer and Robbins, 1991, Kroenke et al., 2002). The triad of anxiety, depression and somatisation seems to constitute the most common psychological problems encountered in primary care (Kroenke et al., 2002). Having reliable measures to recognise somatic symptoms is therefore important. The DC/TMD initiative includes PHQ-15 as a measure of the severity of somatic symptoms, due to the emerging evidence of its importance in the overall symptom reporting in individuals with TMD (Schiffman et al., 2014, Fillingim et al., 2011). Somatic awareness was shown to be elevated among patients with chronic pain and indeed chronic TMD (Manfredini et al., 2010, Macfarlane et al., 2002b). A recent systematic review by Canales et al. (2018) reported prevalence between 28.5%-76.6% for moderate-severe somatisation in TMD patients. Most of the papers in the review, measured somatisation using Symptoms Checklist 90 (SCL-90), an instrument recommended by the original RDC/TMD. Replaced currently by PHQ-15 in the updated criteria (DC/TMD), a shift may occur in future TMD studies to reflect these alterations.

Anxiety, depression, and somatisation are discussed frequently in association with chronic pain. Manfredini et al reported a strong correlation between pain-related disability (GCPS categories) and both depression and somatisation in a multi-centre study of TMD patients (Manfredini et al., 2010). A high correlation coefficient (0.73) was also reported by Yap et al between depression and somatisation, concluding that a considerable section of clinically depressed TMD patients describe frequent non-

specific physical symptoms such as chest pain or GI problems (Yap et al., 2002). While some studies suggested a less significant role for anxiety in chronic myofascial pain (Reiter et al., 2015, Giannakopoulos et al., 2010), others noted a high correlation between anxiety and depression in TMD patients (Simoen et al., 2020) and indicated a statistically significant rise in anxiety when compared to non-TMD patients (Simoen et al., 2020, Resende et al., 2020).

The results of the present study reiterate the relevance of the psychological profile of TMD patients and the importance of such assessment before treatment. The psychological comorbidities are viewed as elements of the biopsychosocial model of pain, which TMD is theorised to fall under (Suvinen et al., 2005, Hampf, 1990). Therefore, it is essential to have reliable and valid instruments able to give trustworthy results, based on which treatments can be planned and support can be arranged.

No gender or ethnic differences were detected in this study in relation to anxiety, depression, and jaw functional limitation. Interestingly, statistically significant results were obtained with PHQ-15, GCPS, and JFLS scores when looking at the smoking status of the participants. While smoking does not offer pain relief, participants in a recent qualitative study exploring chronic pain, described it as a coping strategy (Lee et al., 2021). It serves as a cognitive distraction from the pain, resorting to it to 'calm them down'. Other studies, also report that smokers describe greater pain intensity and greater pain-related functional interference (Lee et al., 2021, Volkman et al., 2015, Weingarten et al., 2009a, Weingarten et al., 2009b), which is in keeping with the results of the present study.

Limitations

All the participants in this study had myofascial TMD with approximately half having intraarticular involvement as well. Taking this into consideration, the results may not

be generalisable to all types of TMD, such as those presenting with functional limitations without pain.

The study was cross-sectional in nature without long term follow ups. Therefore, some psychometric properties could not be explored such as responsiveness and test-retest reliability. It is worthwhile for future research to explore the rest of the psychometric properties of these scales in a larger sample size, to provide further evidence of their suitability in a TMD population.

## 3.6. Conclusion

Previous extensive research highlights the importance of the psychological profile of chronic TMD patients. Having reliable and validated instruments based on which recommendations can be made, is a positive step. The results from this study provide positive psychometric evidence for the use of PHQ-8, GAD-7, PHQ-15 and JFLS-20 in TMD patients. Future research with a larger sample size could also explore other psychometric properties such as test-retest reliability and responsiveness.

# Chapter 4: A meta-synthesis of qualitative data exploring the experience of living with temporomandibular disorders: the patients' voice

## 4.1. Introduction

Temporomandibular disorder (TMD) is a common problem. it represents the most common cause of chronic pain in the orofacial region (Leeson, 2007), and is only behind headache and backache as reason for chronic pain in general (Dworkin, 2011a). Accepting the nature of chronic pain can be difficult for patients, therefore creating challenges to their daily lives (Hoffmann et al., 2011). Simple physical activities could become burdensome, and social interactions with family and friends may become more difficult. This may drive them to become more isolated and consequently result in a heightened experience of pain (Koes et al., 2006, Williams et al., 2012). Chronic pain is also linked with depression, which may go unrecognised and therefore untreated in such patients (McIntosh et al., 2016, Lee et al., 2018). It is likely that the relationship is bidirectional, with chronic pain thought to contribute and also result in poor mental health (Von Korff et al., 1993). Similarly with anxiety and fear of pain, which are both linked to increased likelihood of chronic pain and poorer recovery should it develop (Boersma and Linton, 2006). It is therefore important for clinicians to be aware of the influence of chronic pain on patients and address the modifiable risk factors such as lifestyle and behavior to reduce the impact it has on their lives (Mills et al., 2019).

## 4.2. Aims and objectives

The aim of this review was to synthesise the available qualitative evidence about the experience of living with TMD and the effects it has on daily life.

## 4.3. Materials and methods

Qualitative evidence synthesis offers richer insight than individual primary qualitative studies as it integrates the research findings on this topic in one place (Carroll, 2017). It helps improve our understanding of pain as recounted by the patients themselves, and therefore helps improve the quality of care offered to such patients (Toye et al., 2017b).

A thematic synthesis approach was utilised in this systematic review. Thematic synthesis is one of the range of methods available to synthesise qualitative data. It was chosen as it allows the identification of the prominent themes and organises the identified literature under these themes in a flexible way (Dixon-Woods et al., 2005).

This review was registered on PROSPERO with the following ID: CRD42020171854.

### 4.3.1. Search strategy and locating the literature

The premise of the search strategy was based on the acronym SPICE which represents the following: **S**etting: social setting, **P**erspective: patients, Phenomenon of **I**nterest: temporomandibular disorders, **C**omparison: none, **E**valuation: effect on life. This acronym, developed by Booth (Booth, 2006), is a qualitative counterpart to PICO which is frequently used in quantitative systematic reviews. The key words were first identified by running an initial search in Medline and Embase. The full list of key words could be found in table 4.1. The full search strategy can be found in appendix 5.

Table 4.3. Key words used to build the search strategy

| | |
|---|---|
| Phenomenon of interest | TMD OR TMJD OR temporomandibular disorders OR temporomandibular joint disorders OR temporomandibular joint dysfunction OR internal joint derangement OR disc displacement OR facial myalgia OR masticatory muscles pain, degenerative joint disease OR luxation OR subluxation OR temporomandibular joint osteoarthritis OR masticatory muscle pain OR facial pain OR orofacial pain OR craniofacial pain OR chronic facial pain OR facial arthromyalgia OR TMJ arthralgia |
| Setting | Social |

| | |
|---|---|
| Evaluation | Experience OR satisfaction OR health related quality of life OR coping OR support OR emotional stress OR resilience OR quality of life OR symptom experience OR anxiety OR depression OR personal satisfaction OR emotional support OR physical support OR positive |
| Type of study | Qualitative study OR qualitative research OR interviews OR discussion OR group interviews OR telephone interviews OR Audio recording OR constant comparative analysis OR content analysis OR ethnography OR field notes OR field studies OR focus groups OR grounded theory OR narratives OR observation methods OR participant observation OR thematic analysis OR diary study |

The search strategy aimed to locate all available articles and was constructed for each database in collaboration with a clinical librarian. The data bases used were Medline, Embase, PsycINFO, Web of Science, CINAHL Complete and the Cochrane database. After identifying the eligible articles, the reference lists were hand searched to identify any articles missed from the original search.

### 4.3.2. Inclusion and exclusion criteria

The articles eligible for selection were qualitative studies exploring the experience of adult (>16) patients with TMD and jaw pain. Mixed methods studies were included if the qualitative section was clearly separate from the quantitative section, and only qualitative data was included. Studies with a sample of mixed chronic orofacial pain conditions were included if they contained a sample of TMD patients. The findings and quotes attributed to TMD patients were included, in addition to the data which was not assigned to a particular pain condition. The rationale for this approach, was that these findings applied to the various orofacial pain conditions under investigation in these studies, including TMD. The findings and quotes which were assigned to another pain condition, such as Trigeminal Neuralgia or Oral Dysaesthesia, were not included in the analysis. This method was adopted as focusing solely on papers with a pure sample of TMD might result in missing important findings in studies with a mixed cohort of orofacial pain conditions. Studies were excluded if they were not in the English

language, if they reported on the experience with a certain treatment or intervention or if the full text was unavailable.

### 4.3.3. Study selection and critical appraisal

The studies yielded from the search strategy were reviewed by two reviewers independently. The selection process started with reviewing the title and abstract. The articles which potentially met the inclusion criteria and those which did not contain enough information in the abstract moved to the next step of full article review. The final studies were selected after several discussions among the research team.

The studies included in the review were appraised to assess the transparency of research practice and reporting standards using the Critical Appraisal Skills Programme (CASP) Qualitative Research Checklist. This tool was used as it allows for the appraisal of all types of qualitative studies and is the most used tool for qualitative evidence syntheses in Cochrane and World Health Organisation (WHO) guideline processes (Noyes et al., 2018a). It consists of 10 questions with “Yes”, “No” and “Cannot tell” as possible answers. Two reviewers independently reviewed the studies and discussed the results jointly. Although the appraised studies were given a score according to the CASP instrument, however, cut-off point value for paper exclusion was not set (Noyes et al., 2018a, Robertshaw et al., 2017). Such value is arbitrary and not predetermined by the developers of the instrument. The decision to include or exclude a paper was discussed among the research team and agreed upon mutually.

### 4.3.4. Data extraction and synthesis

The context of each study was extracted by two reviewers. The data included: aims of the study, country, demographics of the participants, criteria for diagnosis of TMD, site of recruitment, method of data collection and method of analysis.

Further data extraction and synthesis followed the thematic synthesis approach. This method was developed by Thomas and Harden (Thomas and Harden, 2008) and involves several steps. First of which was line-by-line coding of the data found under 'findings' or 'results' of the primary studies according to its meaning and content. The codes were examined for similarities and differences and were then organised into 'descriptive themes'. Each descriptive theme contained the codes which were related to each other and feed into that specific theme. Up to this point, the themes reflected the meaning portrayed by the primary studies. Following that, analytical themes were derived. This step was where the analysis 'goes beyond' the content of the original studies, to generate additional concepts and understandings. The findings captured in the descriptive themes were used in this step to infer abstract analytical themes and provide answers to the research question. This step of 'going beyond' the original studies is the defining characteristic of thematic synthesis (Thorne et al., 2004, Britten et al., 2002). The derivation of themes was an inductive and iterative process, where later studies were analysed using concepts generated in earlier studies. However, new concepts were created when necessary.

### 4.3.5. Assessment of the confidence in the review findings

Following data synthesis, the GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research) approach was employed to assess the confidence in the findings. Confidence in the findings of qualitative research is "an assessment of the extent to which a review finding is a reasonable representation of the phenomenon

of interest" (Lewin et al., 2018). This approach was developed to support the use of qualitative research findings in decision-making processes and considers four components: methodological limitations (concerns about the design or conduct of the primary studies), coherence (how clear and cogent the fit is between the data from the primary studies and a review finding), adequacy of data (richness and quantity of data), and relevance (the extent to which the body of data from the primary studies supporting a review finding is applicable to the context -perspective, population, phenomenon of interest or setting- of the review) (Munthe-Kaas et al., 2018, Colvin et al., 2018, Glenton et al., 2018, Noyes et al., 2018b). These components were applied to each finding to give an overall assessment of confidence, ranging from high, moderate, low to very low. For example, if the confidence level in a finding was low, decision makers may decide that this specific finding may not be appropriate to use in policy making and implementation (Lewin et al., 2018). Table 4.3 outlines the evidence profile for each finding using the GRADE-CERQual approach.

### 4.3.6. Reporting of the evidence synthesis

This review was reported according to The Enhancing transparency in reporting the synthesis of qualitative research (ENTREQ) statement (Tong et al., 2012). The statement consists of 21 items grouped into five main domains: introduction, methods and methodology, literature search and selection, appraisal, and synthesis of findings.

## 4.4. Results

### 4.4.1. Description of the studies

The search based on the proposed strategies yielded 3964 articles across all databases. 2983 articles remained after removing the duplicates. After the first step of selection, which involved screening of the titles and abstracts, 140 papers were

included for full text review. Following full text review, 20 studies were finally selected to be included in the qualitative evidence synthesis. See figure 4.1 which is a flowchart of the selection process, table 4.2 for the context of the included studies, and table 4.3 for the CASP quality appraisal. No studies were excluded based on their quality.

Figure 4.1. Flow chart of the selection process.

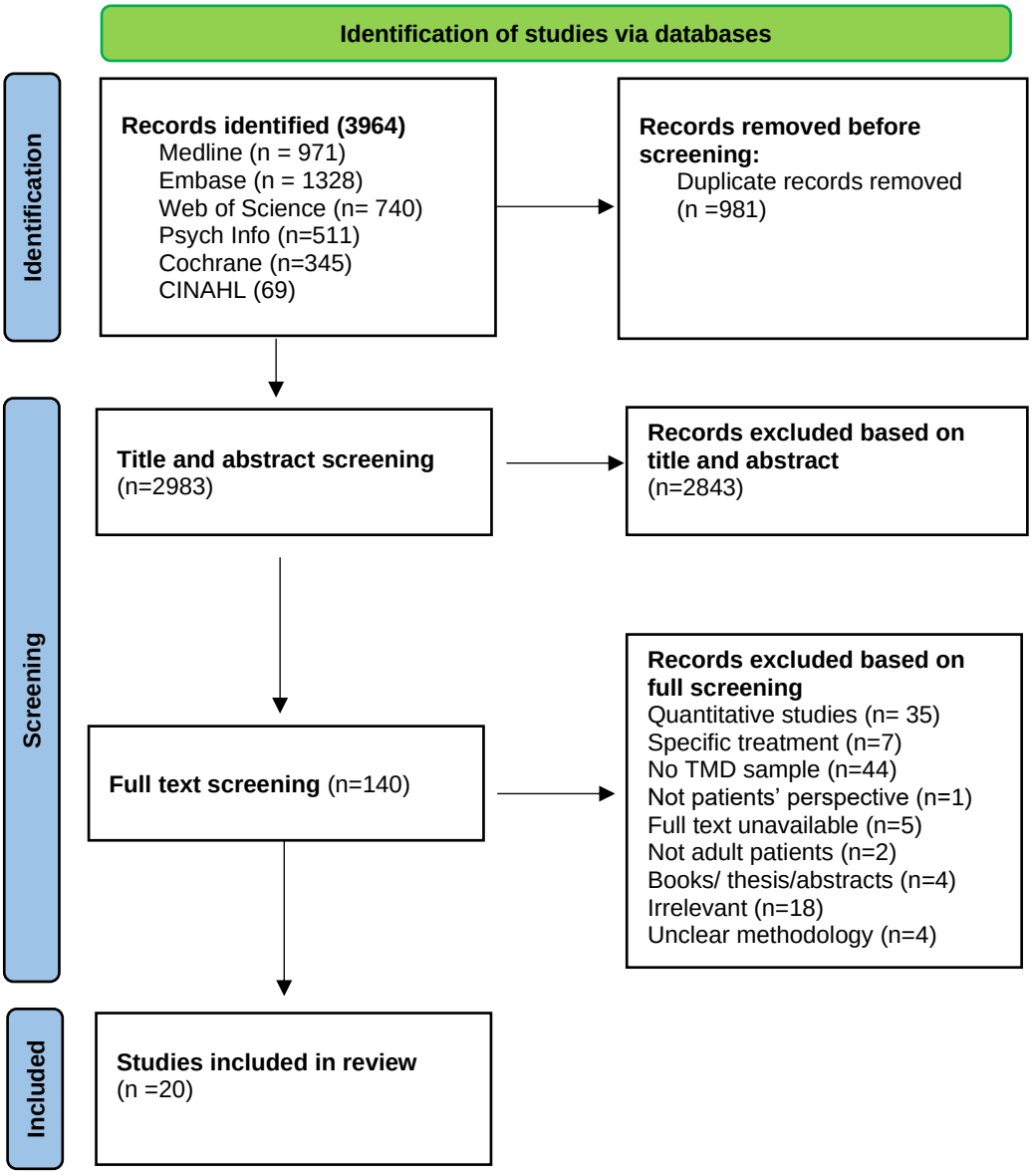


Table 4.2. Context of primary studies

| Author | Country | Aim | Sample size | Age | Gender | Diagnosis | Diagnostic criteria | Recruitment site | Method of data collection | Method of analysis |
|---|---|---|---|---|---|---|---|---|---|---|
| Durham et al (2010) | UK | To describe the difficulties that sufferers of TMDs encounter in obtaining a definitive diagnosis of their condition and to examine critically the impact this has upon them. | 19 | 18-60 | 14F, 5M | TMD (Suffering from pain, i.e., myofascial pain and arthritides, and those suffering from mechanical dysfunction due to disc displacement | RDC/TMD † | Specialist oral and maxillofacial surgery and restorative dentistry clinics. | Semi-structured individual interviews | Constant comparative method (Glasser, 1965). Line-by-line coding inductive and iterative to develop theory. |
| Mienna et al (2014) | Sweden (arctic circle) | To explore thoughts, experiences, and beliefs regarding temporomandibular disorders (TMD) among Sami women with and without TMD in order to gain insights into their health care experiences and to generate a hypothesis regarding factors associated with long-standing TMD | 17 (10 with TMD+7 healthy) | 23-58 | All F | TMD | RDC/TMD | - | Individual interviews | Grounded theory |
| Bonathan et al (2014) | UK | To explore patients' understanding of their orofacial pain | 12 | 26-73 | 9F, 3M | COFP ‡ of non-dental origin (including TMD) | - | Orofacial pain clinic. | Individual semi-structured interviews (face to face and telephone) + narrative letter | Thematic analysis |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Au et al (2014) | Hong Kong | To explore the perceptions and experiences of southern Chinese community dwelling elderly people living in Hong Kong with chronic OFP symptoms and their treatment seeking behaviour. | 25 | 65-83 | 21F, 4M | Non-dental OFP (including TMD) | - | Attendees at daytime social and community centres | Semi-structured individual interview | Thematic Framework Approach that involved a multi-stage thematic analysis |
| Rollman et al (2013) | The Netherlands | To assess possible differences between care seekers and non–care seekers with TMD pain complaints through the use of semi-structured interviews. | 16 | Mean age for non-care seekers 38.9, for care seekers 37.5 | 12F, 4M | TMD | - | The subjects were selected from a larger survey study | Semi-structured individual interviews | Constant comparative analysis and qualitative content analysis. Followed by a Delphi consensus method. |
| Peters et al (2015) | UK | To understand patients', GPs', and dentists' experiences of COFP and identify what barriers may exist to improving psychological management within dental and medical services. | 7 | 17-56 | 5F, 2M | Persistent jaw pain | - | Secondary and tertiary care dental and specialist facial pain clinics | Face-to face individual semi-structured interviews | Constant comparative approach and drawing on the principles of grounded theory. |
| Breckons et al (2017) | UK | The aim of this qualitative study was to critically examine patients' journeys through care, identify their experiences of the care pathway, and use these findings to help explain some of the | 22 (18 for a second interview) | <40 - >70 | 17F, 5M | Persistent OFP of non-dental origin (including TMD) | - | - | Telephone/ face to face semi-structured interviews | Iterative thematic analysis |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | findings in the cost analysis of the care pathways that ran concurrent to this sub study (Durham et al. 2016) | | | | | | | | |
| Hazaveh et al (2018) | Canada | The study aimed to explore this area [the experience of living with COFP and to gain a deeper understanding of the common elements affecting the lives of chronic pain sufferers. | 6 | 27-68 | 1M, 5F | OFP of non-dental origin (Including jaw pain) | - | Pain Clinic | In-depth individual interviews | Phenomenological approach based on the reading approaches (developed by Van Manen) |
| Fjellman-Wiklund et al (2019) | Sweden | To identify predicting factors for perceived treatment need among adult individuals who screened positive to the 3Q/TMD and to explore individuals' thoughts and experiences related to treatment of their TMD complaint | | 20-69 | 201F, 99M | TMD | RDC/TMD | Public Dental Health Service | Written questionnaire | Qualitative content analysis (manifest interpretations) |
| Nilsson et al (2011) | Sweden | To acquire a deeper understanding of adolescents' experience of living with temporomandibular disorders (TMD) pain | 21 | 15-19 (Mean age 17.2) | 19F, 2M | TMD | RDC/TMD | Orofacial pain clinic | Semi-structured individual interviews | Manifest and latent content analysis |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Nilsson et al (2016) | Sweden | To explore adolescents' explanations of their temporomandibular disorder (TMD) pain, their pain management strategies for TMD pain, and their treatment- seeking behaviour. | 21 | 15-19 (Mean age 17.2) | 19F, 2M | TMD | RDC/TMD | Orofacial pain clinic | Semi-structured individual interviews | Qualitative manifest content analysis with an inductive approach. |
| Durham et al (2011) | UK | To develop a robust empirically derived map of TMD sufferers' journey through care | 29 | 18-65 | 23F, 6M | TMD | Diagnosis by criteria derived from the research diagnostic criteria | Dental hospital | Semi-structured individual interviews | Constant comparative method and thematic analysis |
| Eaves et al (2015) | US | Aims not clear. | 95 did baseline interview/ 44 did 4 or 5 interviews (a total of 271 interviews) | 18-69 | - | TMD | RDC/TMD | Community outreach and newspaper advertisements | Semi-structured, open-ended interviews | Not stated – Interviews were transcribed verbatim and coded. Basic code structure consisted of a set of themes. |
| Wolf et al (2006) | Sweden | To use a qualitative research study to analyse the experiences of patients with nonspecific chronic orofacial pain with respect to consultations for their pain condition. | 14 | 21-77 | 11F, 3M | Chronic non-specific OFP (including jaw pain/TMD) | RDC/TMD | Orofacial pain unit | Individual thematic in-depth interviews | Qualitative phenomenological approach |
| Wolf et al (2008) | Sweden | To analyze the nonspecific chronic orofacial pain patient's experience of the pain condition and | 14 | 21-77 | 11F, 3M | Chronic non-specific OFP (including jaw pain/TMD) | RDC/TMD | Orofacial pain unit | Individual thematic in-depth interviews | Qualitative research strategy based on phenomenology. |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | to gain knowledge on the complexity of the problem. | | | | | | | | |
| Garro et al (1994) | US | This article provides, from the perspective of TMJ support group members, a description of this condition and the experiences of these individuals in living with and seeking care for a controversial condition within the context of the American health care system | 32 | 23-69 | 27F, 5M | TMD | Self-reporting of the diagnosis of TMD | "TMJ" support groups | Open ended semi-structured interviews | Not stated – A framework of events and themes was filled out during the interviews. |
| Garro et al (1994) | US | Aims not clear. | 32 | 23-69 | 27F, 5M | TMD | Self-reporting of the diagnosis of TMD | Support group members | Open ended, semi-structured interviews | Not stated – Interviews were taped, transcribed, and content analysed with recurring themes noted. |
| Safour et al (2019) | Canada | To better understand the experiences of individuals who must alter the types of food they eat because of having a chronic temporomandibular joint disorder (TMD) and the digestive issues that these alterations produce | 6 | 24-46 | 4F, 2M | TMD | chronic TMD confirmed by a TMD specialist, and self-reported changes in their dietary habits | Referrals through a university student dental clinic and 2 general hospitals. | Face to face open ended, individual semi structured interviews | Interpretive phenomenology |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Ilgunas et al (2020) | Sweden | To explore the young adult's daily life experiences of GJH*, particularly concerning jaw function and their experiences of medical and dental care providers | 9 | 18-22 | 8F, 1M | GJH and TMD | Beighton score for hypermobility-none for TMD | Department of Clinical Oral Physiology | Semi-structure d individual interviews. | Qualitative content analysis and inductive approach |
| Dinsdale et al (2021) | Australia | To investigate the lived experiences of adults with persistent intra-articular temporomandibular disorders (IA-TMD) by exploring i) the impact of IA-TMD on activity and participation and ii) contextual factors linked with individuals' experiences | 16 | 22-61 | 14F, 2M | Intra-articular TMD. | DC/TMD, Ohrbach et al., 2013 | Privately-owned clinics and social media advertisement | Sem-structures interview framework, using open-ended questions using an online platform (Zoom) | Thematic analysis approach |

†Research Diagnostic Criteria for Temporomandibular Disorders

‡ Chronic oro-facial pain

* General Joint Hypermobility

Table 4.3. CASP quality appraisal

| Paper | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Q9 | Q10 |
|---|---|---|---|---|---|---|---|---|---|---|
| Durham et al (2010) | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Valuable |
| Mienna et al (2014) | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Valuable |
| Bonathan et al (2014) | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Valuable |
| Au et al (2014) | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Valuable |
| Rollman et al (2013) | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Valuable |
| Peters et al (2015) | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Valuable |
| Breckons et al (2017) | Yes | Yes | Yes | Yes | Yes | No | Yes | yes | Yes | Valuable |
| Hazaveh et al (2018) | Yes | Yes | Yes | Yes | Yes | Cannot tell | Yes | Yes | Yes | Valuable |
| Fjellman-Wiklund et al (2019) | Yes | Yes | Cannot tell | Cannot tell | Cannot tell | No | Yes | Yes | Yes | Unclear for qualitative part. |
| Nilsson et al (2011) | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Valuable |
| Nilsson et al (2016) | Yes | Yes | Yes | Yes | Yes | Cannot tell | Yes | Yes | Yes | Valuable |
| Durham et al (2011) | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Valuable |
| Eaves et al (2015) | No | Yes | Cannot tell | Cannot tell | Yes | No | Yes | Cannot tell | Yes | Yes/ somewhat valuable |
| Wolf et al (2006) | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Valuable |
| Wolf et al (2008) | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Valuable |
| Garro et al (1994) | Yes | Yes | Yes | Yes | Yes | No | No | Cannot tell | Yes | Yes/ somewhat valuable |
| Garro et al 1994 | No | Yes | No | Yes | Cannot tell | No | No | Cannot tell | Yes | Yes/ somewhat valuable |
| Safour et al (2019) | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Valuable |
| Ilgunas et al (2020) | Yes | Yes | Yes | Yes | Yes | Cannot tell | Yes | Yes | Yes | Valuable |
| Dinsdale et al (2021) | Yes | Yes | Yes | Yes | Yes | Cannot tell | Yes | Yes | Yes | Valuable |

### 4.4.2. Findings and themes

***TMD causes uncertainty and doubt***

This theme describes the feelings of uncertainty and self-doubt that arose prior to receiving a diagnosis. These feelings arose soon after experiencing the first symptoms and sometimes were further compounded even after seeking professional help (Durham et al., 2010). Worry was due to the mystery of the cause and not having an explanation to the symptoms (Mienna et al., 2014, Bonathan et al., 2014, Durham et al., 2011a). Clinical interactions did not necessarily reduce the uncertainty, as some patients faced scepticism or partial explanations from health care professionals. This fed into the circle of emotional distress and reportedly exacerbated symptoms (Durham et al., 2010, Nilsson and Willman, 2016).

*"I got to the point where because I'd complained about it so much I just stopped complaining because...no-one seems to know what's wrong. So you think oh maybe it's just me, you know, psychosomatic." (Sufferer 3-TMD)* (Durham et al., 2010)

Further uncertainty arose in anticipation of future flare ups, fear of symptoms worsening over time, or of the jaw 'wearing down' causing irreversible damage. (Dinsdale et al., 2021)

*"I'll often think, 'I should chew this the right way', or not use that side of my mouth. That's always in the back of my mind" – 001* (Dinsdale et al., 2021).

<u>Self-constructed explanations to rationalise the symptoms</u>

Constructing explanations to try to understand the pain was also reported (Durham et al., 2010, Bonathan et al., 2014, Au et al., 2014, Nilsson and Willman, 2016). On occasions, these explanations turned into firmly held theories that led to confusion and

rejection of information if they were not in line with their preconceptions.(Bonathan et al., 2014)

*"It preyed on my mind...because I did have a big pain, you know...the girl I worked with she's got a brain tumour ... she's had it about five years now. She had headaches for a long time... You know, it sounds really hard, but you think." (Sufferer 9-TMD) (Durham et al., 2010)*

Desire to make the pain visible

Patients expressed a strong desire to make the pain visible, to provide proof of their symptoms and confirm the reality of their pain (Bonathan et al., 2014). The invisibility of pain undermined the complaints for some patients (Wolf et al., 2008, Hazaveh and Hovey, 2018). Consequently, this drove them to take matters into their own hands by insisting on being taken seriously and demanding specific treatments or referrals (Breckons et al., 2017).

*"Sometimes it's so frustrating . . . so frustrating because people can't see that I'm sick. They look at me and they think that I look fine. I don't like it when people think that I'm pretending to be sick." (Interviewee 5-jaw pain) (Hazaveh and Hovey, 2018)*

*"Now [my] last GP visit that I went to, oh, some months ago, I can't remember when, so obviously I persuaded them to let us take some Voltarol "(Q20, baseline). (Breckons et al., 2017)*

Self-doubt

Lack of diagnostic certainty caused some patients to question the legitimacy of their symptoms (Durham et al., 2010). Doubt creeped in and they started to wonder whether they were imagining the pain (Bonathan et al., 2014, Breckons et al., 2017, Garro et

al., 1994, Garro, 1994). Patients with physical manifestations such as mechanical dysfunction felt that their complaints were legitimate and sought help faster than patients with pain as the only symptom (Durham et al., 2011a).

***TMD has disruptive effects on life***

This theme describes the negative ramifications of having to live with TMD. Patients reported effects on their social lives, professional lives, interpersonal relationships, and their ability to do day-to-day tasks.

Social interactions

A diminished willingness to participate in social activities was reported. Some patients preferred to be alone when in pain, as they could not cope with being around people. Some also restricted their social interaction for fear of jaw locking in public or embarrassment from joint noises (Au et al., 2014, Peters et al., 2015, Hazaveh and Hovey, 2018, Nilsson et al., 2011, Durham et al., 2011a, Eaves et al., 2015, Garro et al., 1994, Dinsdale et al., 2021) . The worry of being perceived unreliable when having to frequently cancel plans was also a factor (Garro et al., 1994, Garro, 1994). Additionally, lack of understanding from family members also discouraged them from engaging in public activities (Durham et al., 2011a). All of which resulted in feeling isolated and unable to participate in social life. (Durham et al., 2010, Au et al., 2014, Peters et al., 2015, Nilsson et al., 2011, Durham et al., 2011a, Wolf et al., 2008). They could also be perceived as unfriendly or hostile, as smiling and talking might be painful for some (Peters et al., 2015, Eaves et al., 2015).

*" I'd be walking down the aisle [at work] and somebody'd say, "Go ahead and smile. It doesn't hurt." And I thought about that later and I thought, you know, it does hurt. It hurts to smile." (Lloyd, 54- TMD) (Eaves et al., 2015)*

*"On the days I'm in pain, I feel that I can't do certain things. I can't cope with being with my friends because I have a headache." (P-12, TMD) (Nilsson et al., 2011)*

Personal relationships

Personal relationships with partners were also in jeopardy of being strained (Hazaveh and Hovey, 2018, Eaves et al., 2015, Durham et al., 2011a, Nilsson et al., 2011). It might be difficult to articulate the suffering, and a lack of understanding or support might be shown (Hazaveh and Hovey, 2018, Eaves et al., 2015). That also had a toll on intimate relations in some cases, as patients expressed a reduced sexual desire and pain during kissing. (Eaves et al., 2015, Dinsdale et al., 2021). Additionally, some might feel guilt over dragging people around them into their pain, and hence, tried to shelter them from perceived risks (Eaves et al., 2015).

*"It [the pain] stresses you out. You don't really realise when it does. But I was getting upset with my husband, I was coming in from work and...I was really narky and my husband would get it in the neck." (Pt 16- Myofascial pain and arthritides group) (Durham et al., 2011a)*

Difficulties were also reported on the partners' behalf, as they could often be unsure of how to deal with their pained spouses (Hazaveh and Hovey, 2018, Eaves et al., 2015). Supportive attitude was definitely shown by some partners. They recommended seeking professional help and suggested treatment strategies (Au et al., 2014, Durham et al., 2011a, Eaves et al., 2015).

Professional life

Declined job performance was a concern on occasions. It felt too taxing and energy consuming to maintain a career. So, pursuing career advancements was abandoned, and seeking less demanding jobs, rejecting career goals or eventually quitting seemed

like the only options (Durham et al., 2010, Breckons et al., 2017, Durham et al., 2011a, Eaves et al., 2015, Garro et al., 1994, Garro, 1994, Hazaveh and Hovey, 2018). They also reported having to take more frequent sick leaves (Hazaveh and Hovey, 2018, Dinsdale et al., 2021).

*"I just turned down a job that I would not have the physical stamina to do. It's changed my world view, in that I think, in that I have to think of my health as a primary consideration where it wasn't before." (Ellen, 38- TMD). (Garro, 1994)*

Financial burden

Financial implications were also revealed. The cost of repeated consultations and alternative treatments caused loss of earnings and in extreme cases, bankruptcy. This, in association with effects on career prospects, could cause extreme hardship to some patients and their families (Peters et al., 2015, Hazaveh and Hovey, 2018).

*"I have had to pay for everything; virtually I am bankrupt trying to get to the bottom of it." (Patient 4) (Peters et al., 2015)*

Daily life

Some patients stated that having TMD did not stop them from doing things most of the time (Hazaveh and Hovey, 2018, Eaves et al., 2015). For others, however, it affected the ability to chew and enjoyment of food. They had to be careful selecting their meals as food is a common trigger for pain, and it could be embarrassing to eat in public due to the clicking noises or the need for a long time to eat (Au et al., 2014, Peters et al., 2015, Hazaveh and Hovey, 2018, Nilsson et al., 2011, Nilsson and Willman, 2016, Safour and Hovey, 2019, Ilgunas et al., 2020, Dinsdale et al., 2021). It also intruded on other important aspects of life, such as sleep quality, carrying out routine activities, ability to talk, yawn, kiss and sing (Au et al., 2014, Peters et al., 2015, Breckons et al.,

2017, Eaves et al., 2015, Wolf et al., 2008, Garro et al., 1994, Garro, 1994, Ilgunas et al., 2020, Dinsdale et al., 2021). They also reported low energy levels, loss of productivity, difficulty concentrating, digestive complications, weight changes and diet modifications (Garro et al., 1994, Wolf et al., 2008, Eaves et al., 2015, Breckons et al., 2017, Nilsson et al., 2011, Hazaveh and Hovey, 2018, Safour and Hovey, 2019, Dinsdale et al., 2021).

*"It affects everything . . . affects me being able to talk . . . eating is exhausting, it takes so long to eat and the pain, it like pulls me down and makes me tired." (Patient 3) (Peters et al., 2015)*

***TMD causes distress***

This theme describes the array of feelings which arose when trying to cope with chronic pain. They ebbed and flowed throughout the clinical journey and interactions with surrounding people.

Patients reported feelings of anxiety, possibly starting as early as the beginning of symptoms due to the bewildering nature of pain (Durham et al., 2011a). They drew on personal experiences in an attempt to rationalise the pain, and often, grim explanations came to mind feeding into the circle of worry and uncertainty (Au et al., 2014, Hazaveh and Hovey, 2018, Durham et al., 2010, Rollman et al., 2013). Patients also reported feelings of discomfort in their own bodies and 'jealousy of normal people'. (Ilgunas et al., 2020)

A part of these sentiments was also directed towards the clinical process they encountered (Mienna et al., 2014, Bonathan et al., 2014, Rollman et al., 2013, Breckons et al., 2017, Hazaveh and Hovey, 2018, Ilgunas et al., 2020). Some experienced lack of diagnosis, lack of empathy from the doctors and absence of

guidance about treatment. The sense of abandonment and being passed around also gave rise to feelings of hopelessness and helplessness (Bonathan et al., 2014, Peters et al., 2015, Hazaveh and Hovey, 2018).

Psychological turmoil continued later as well, with patients expressing feelings of irritation and depression due to ineffective pain control, frustration and anger at the unfairness of life and despair at the prospect of spending the rest of their lives in pain (Durham et al., 2010, Au et al., 2014, Peters et al., 2015, Breckons et al., 2017, Nilsson et al., 2011, Durham et al., 2011a, Wolf et al., 2008, Garro, 1994, Garro et al., 1994). Some completely lost hope which drove them to feel melancholic and hint at suicidal thoughts (Au et al., 2014, Wolf et al., 2008).

*"Sometimes I really want to die...Why do I live so long? I believe that the (jaw) pain could only be solved if I die. I always feel annoyed and depressed...Why is life so tough? I think it's unfair for me to live so long and suffer from the pain!" (Female participant, age 71, with both severe jaw and tongue pain for 3 years). (Au et al., 2014)*

*"I mean this is nothing but a miserable, humiliating, and embarrassing living hell." (Paul, 36-TMD) (Garro, 1994)*

***Understanding TMD- The illness and the causes***

Plausible explanations

Patients expressed their understanding of TMD as a part of a larger complex problem that might be difficult to comprehend (Fjellman-Wiklund et al., 2019, Garro, 1994). They wanted to make sense of it, so they tried to find a physical cause to reconciliate with their symptoms (Peters et al., 2015, Nilsson and Willman, 2016, Garro, 1994, Garro et al., 1994). Once they found an explanation, they tried to reinterpret past events to fit into that explanation (Garro, 1994). Some of the perceived causes for

TMD included: local injury to the facial area, hereditary connection, dental work, parafunctional habits and jaw strain (Garro et al., 1994, Durham et al., 2011a, Nilsson and Willman, 2016, Breckons et al., 2017, Peters et al., 2015, Rollman et al., 2013, Mienna et al., 2014).

*"So you wonder, is it something hereditary, is it something in our genes that caused it, or just what is it?" (Mienna et al., 2014).*

*"I think it might be through having loads of dental treatment from a young age. . .. I have had dental treatment since I was about six." (Patient 2) (Peters et al., 2015)*

Patients had conflicting views on the role of stress and psychological health as a possible contributing factor. Some accepted this model early in their history and pointed it out in their interviews (Mienna et al., 2014, Rollman et al., 2013, Peters et al., 2015, Breckons et al., 2017, Garro, 1994, Garro et al., 1994, Dinsdale et al., 2021), while others refused it completely (Wolf et al., 2006, Garro, 1994, Garro et al., 1994).

*"I believe that it is something I do when I am stressed, so then I address the tension, what caused it, and I do something about it. It manifests itself here [while pointing at jaw]. For someone else this may be the neck. I would first try to figure it out for myself." [interview 13- TMD]. (Breckons et al., 2017)*

*"Have you been under any pressure lately?" As one person explained, "..._ they kind of just turn it on you in a way, by saying it's all stress-related and it's like you're causing it yourself." (TMD patient) (Garro et al., 1994)*

Views on TMD

TMD was perceived negatively by some patients. Even if treatment was effective, concerns over possible future exacerbations cropped up. They described it like "having

a sword hanging over your head" because they did not know when the next episode was going to happen. They also imagined it as a punishment that may occur even if one is assertive of progress (Wolf et al., 2008, Garro, 1994, Garro et al., 1994, Eaves et al., 2015). Additionally, facial pain was described as a class of its own, where it was considered more psychologically distressing than other types of chronic pain (Wolf et al., 2008).

*"You often wonder, when you're pain free, how long are you going to go on this way before it flares up again. You say to yourself, well, this is great, I wish I could be this way. But it's like, you know. when is the next time?" (Carol, 38- TMD) (Garro, 1994)*

Some tried to have a more positive outlook, where they chose to take the pain and interpret it in way that encouraged them to make changes in life. Some even saw it as a "learning experience that made life more rewarding". (Garro, 1994)

*"I can't help but feel like not that there's a purpose to my pain, but that I haven't let it triumph. I've made it into something else. I've made it into a way to make connections to people." (Gail, 37- TMD). (Garro, 1994)*

Stigma

Stigma was associated with TMD in some cases, where they preferred not to mention it to others for fear of being seen in a certain way. They did not want to assume the identity of a chronic pain patient (Garro, 1994, Hazaveh and Hovey, 2018, Eaves et al., 2015). However, that was not always the attitude, and some might perceive no stigma in association with TMD (Eaves et al., 2015).

*"I didn't want them to say we've got a lunatic on our hands here, cause we know what that's about. Some people think it's all in your head, it's mental." (Carol, 38- TMD) (Garro, 1994)*

***Now what? Dealing with TMD***

This theme describes the approach to dealing with TMD. Personal attitudes towards this condition fell between two poles on a spectrum, and this position could shift depending on circumstances, such as the nature and severity of the pain (Breckons et al., 2017)

It is a dominant entity

Pain was sometimes described as an all embracing and dominant entity in life, both physically and psychologically (Hazaveh and Hovey, 2018, Wolf et al., 2008). They put their lives on hold waiting for effective treatment of their symptoms (Garro, 1994, Garro et al., 1994, Nilsson et al., 2011, Dinsdale et al., 2021). They had a need to control their symptoms to be able to move on and live again, and it felt like a full-time job to do so (Eaves et al., 2015, Garro, 1994, Garro et al., 1994).

*Search for an answer is an "ongoing thing that never ends, it's never going to end until I get better" (TMD patient) (Garro, 1994)*

Patients described the overwhelming nature of the pain, where sometimes it was difficult to get up in the morning and find the energy to go through the day (Breckons et al., 2017, Nilsson et al., 2011, Eaves et al., 2015, Wolf et al., 2008). Routine tasks became daunting to do, and some had to rearrange their lives to avoid triggers (Hazaveh and Hovey, 2018, Eaves et al., 2015, Dinsdale et al., 2021, Ilgunas et al., 2020). Pain had an unpredictable nature; therefore, it was hard to plan life. They felt stuck with the pain which consequently caused passivity in life (Bonathan et al., 2014, Mienna et al., 2014, Wolf et al., 2008). Meanwhile, they reminisced about their old lifestyle and were preoccupied with the pain, even if it was absent (Nilsson et al., 2011, Hazaveh and Hovey, 2018, Garro, 1994).

*“Most of my energy is kind of being used up trying to either ignore or fight the pain or something, so there wasn’t much left over to socialize even or anything” (Theresa, 23-TMD). (Nilsson and Willman, 2016)[26]*

Feelings of fear, hopelessness, anxiety, anger, irritation and loss of self-identity were frequent (Hazaveh and Hovey, 2018, Nilsson et al., 2011, Eaves et al., 2015, Garro, 1994, Garro et al., 1994, Ilgunas et al., 2020, Dinsdale et al., 2021). Fear of the symptoms being out of control, hopelessness of any improvement in the future, disappointment due to lack of effective pain control and anxiety that something treatable had been missed. They also felt aggravated and isolated when they had to explain their condition to surrounding people and faced scepticism or disbelief (Hazaveh and Hovey, 2018).

*“That I will go back to where I was, when the pain was out of control and it will never get better and it will just, I will just live in that pain and be just completely like a total prisoner of pain.” (Kay, 37- TMD). (Garro, 1994)*

*“Your mind is always, even when you try to get your mind off it, it’s very quickly brought back to it. You fight with it and you lose, you lose the battle every time, every time” (Debbie, 39, TMD). (Garro, 1994)*

<u>Adapting and moving on</u>

Some patient groups were able to be more accepting of the symptoms. Pain was acknowledged as an” immovable fixture of life” but they learn how to bear it and move on (Garro, 1994, Wolf et al., 2006, Nilsson et al., 2011, Au et al., 2014, Mienna et al., 2014, Hazaveh and Hovey, 2018, Dinsdale et al., 2021).

Some of the useful elements which helped in coping with the symptoms was receiving a diagnosis, getting information about TMD and a reassuring consultation. They were

able to ignore the symptoms by staying connected to surrounding people, engaging in any physical activity to take their mind off it, aiming to live as a healthy person and recognising their own role in healing. Partners, family and friends also helped in handling the symptoms (Bonathan et al., 2014, Au et al., 2014, Breckons et al., 2017, Nilsson et al., 2011, Nilsson and Willman, 2016, Eaves et al., 2015, Wolf et al., 2008, Garro, 1994, Ilgunas et al., 2020, Dinsdale et al., 2021).

*"I could get out there socially and I could count on that, I could be some place and count on being able to. I decide when I'm going to leave, not my body." (Debbie, 39-TMD). (Garro, 1994)*

*"I guess what the appointment has done is drawn a line under it and made me think, well, that's fine, but nothing can be done about it so I just need to get on with things." (participant 5, postconsultation- TMD and chronic idiopathic facial pain) (Bonathan et al., 2014)*

Some preferred silence in dealing with their symptoms, where they hid the pain and dealt with the physical consequences later (Bonathan et al., 2014, Hazaveh and Hovey, 2018, Eaves et al., 2015) .The reason for this behaviour was that they did not want to assume the identity of a chronic pain patient and did not want to burden anyone with it (Hazaveh and Hovey, 2018, Eaves et al., 2015). They tried to 'soldier' through life and maintain a positive outlook (Eaves et al., 2015). Taking it one day at a time helped, as thoughts of the future could be terrifying (Garro, 1994, Eaves et al., 2015, Wolf et al., 2008).

*"No reason to concern anybody else and have anybody else get upset about it. Uh, no, I just put up with it, that's all." (Hank, 65-TMD) (Eaves et al., 2015)*

***Aims and hopes***

This theme describes the aims of the patients, where there was a sense that it was important to gain some control over the pain (Durham et al., 2010, Mienna et al., 2014). Some patients did not have high hopes and realised that the symptoms will not be reversed completely (Hazaveh and Hovey, 2018, Nilsson et al., 2011, Garro et al., 1994). Others, however, wished for complete alleviation of the pain, and restoration of their lifestyle prior to it (Durham et al., 2010, Nilsson et al., 2011, Nilsson and Willman, 2016, Garro, 1994, Garro et al., 1994). They reported getting a "reality check" after diagnosis as to the course of the illness. They also reported feelings of disappointment and disillusionment at the treatment options and their effectiveness (Durham et al., 2010, Fjellman-Wiklund et al., 2019, Garro et al., 1994). Life goals were suspended, and health improvement became the primary concern (Garro, 1994, Garro et al., 1994).

*"You want a magic wand waved over and then it's [the pain's] gone...Then reality kicks in and you think no that's in never never land, that's not the way it works." (Sufferer 13-TMD) (Durham et al., 2010)*

*"I never expect to feel 100% well. If I just get rid of some of it, life will be better." (P-4-TMD) (Nilsson et al., 2011)*

## 4.5. Discussion

The findings of this review suggest that TMD casts largely negative effects over the lives of the patients. Struggles may exist within oneself, but also permeate other facets of life, such as professional aspects and familial relationships. This resonates with quantitative studies on the topic which highlight the negative impact of TMD on several aspects such as: quality of life (Bitiniene et al., 2018) (Dahlstrom and Carlsson, 2010),

sleep quality with pain related TMD (Dreweck et al., 2020), depression, somatisation (Yap et al., 2004), and social impairment (Cioffi et al., 2014). Qualitative reviews on the other hand offer a different angle to look at the evidence. They offer in-depth understanding of the condition as recounted by the patients themselves and rich interpretations relating to the impact of TMD on life. They also offer a valuable insight into the attitudes of patients, their social interactions, and experiences with the healthcare system. Moreover, they give the opportunity to present contradicting views about the same point, gathered from different studies (Flemming et al., 2019).

The findings of the review suggest that TMD pain can be psychologically challenging. Qualitative reviews of other chronic pain conditions present similar data (Toye et al., 2019, Primdahl et al., 2019, Toye et al., 2013b, Toye et al., 2017a, Froud et al., 2014). Feelings of depression, anger, helplessness, anxiety and guilt are described, as these patients try to negotiate their way in a new reality (Toye et al., 2019, Snelgrove and Liossi, 2013, Toye et al., 2013a). Toye et al describe the struggle of a 'new' self, imposed involuntarily as a result of the pain. The patient labours to prevent the erosion of the real self, and looks nostalgically to a past without pain (Toye et al., 2013a). The unpredictability of the future causes fear as well; fear of potential worsening of the symptoms, of reliance on medications, of letting surrounding people down and of stigma (Toye et al., 2013a).

Another theme that is shared in chronic pain is the struggle to be believed. In many cases of chronic pain, there is no tangible evidence of pathology, and consequently, patients battle to validate their pain experience. This may give rise to feelings of doubt that permeates their experiences with family members, work colleagues and health care providers (Toye et al., 2013a). A positive healthcare experience is therefore important to move forward with the pain (Toye et al., 2019, Snelgrove and Liossi,

2013). This experience forms a large part of the life of a chronic pain patient, and it needs to be a pleasant one away from feelings of guilt and blame (Toye et al., 2019). Receiving a concrete diagnosis helps in this aspect, as it promotes feelings of legitimacy and enables them to seek support from family and friends (Toye et al., 2013a). Lachapelle et al report in their study of patients with fibromyalgia, that a delay in diagnosis could lead to the destruction of the social network of the women enduring it (Lachapelle et al., 2008). Feelings of loss of credibility and being socially stigmatised were also reported (Holloway et al., 2007).

Such as with other chronic pain conditions, our findings suggest that TMD imposes financial challenges. It is suggested that chronic pain creates economic impacts not only directly for the patients but also for governments, due to greater need of sick leaves, reduced levels of productivity and the greater risk of leaving the labour market (Phillips, 2009). A US study reported lost productivity amounting to $61 billion per year caused by common pain conditions such as musculoskeletal conditions, back pain and headaches (Stewart et al., 2003). Other reports reviewed the financial impact TMD has on patients in the northeast of England and suggested that the total costs per 6 months range from £321 to £519 per individual (Slade and Durham, 2020). Several direct and indirect costs were implicated, such as specialist consultation costs, employer-related costs due to work loss and presenteeism i.e., 'reduced productivity due to problems with concentration or decision making while at work'. In addition to the challenges imposed on the individual, the group also suggested added pressure on the economy, not only through lost productivity, but also due to the disorganised pathways of the healthcare system in dealing with chronic facial pain patients.

A point of debate currently found in the literature is the need to appraise the quality of qualitative research (Williams et al., 2020). Some qualitative researchers suggest that those studies should not be viewed in the same light as quantitative research. Smith argued that the basic epistemological and ontological assumptions of quantitative and qualitative research do not match, therefore, measures such as validity should not be applied to qualitative studies (Smith, 1984) . Nevertheless, other researchers claim that, indeed, some studies may be more rigorous and well conducted than others. Therefore, should be subject to critical appraisal (Morse et al., 2002). The Cochrane guidance advises that the assessment of methodological limitations for the purpose of systematic reviews and evidence synthesis remains essential, even when studies are not to be excluded on the basis of quality (Noyes J, 2022, Carroll et al., 2013). Given that there are no accepted rules for the exclusion of studies based on quality (Thomas and Harden, 2008), none were excluded on that basis in this review. The methodological rigor of the studies included in this review was generally acceptable, and the research team did not feel the need to exclude any of the articles based on quality as no such cut-off points are yet established. Methodological limitations did however exist. Perhaps most notably is the segment related to the influence of the interviewer on the participant (Item 6 in the CASP checklist). This falls under what is known as ‘reflexivity’ in qualitative research, which means “turning of the researcher lens back onto oneself to recognise and take responsibility for one’s own situatedness within the research and the effect that it may have on the setting and people being studied, questions being asked, data being collected and its interpretation” (Berger, 2015).

The major findings synthesised in this review were supported by multiple primary studies. Furthermore, the CERQual-GRADE assessment showed that the majority of

findings had moderate to high confidence, meaning that it is likely/highly likely that the findings are a reasonable representation of the phenomenon of interest. (Lewin et al., 2018).

Limitations

Six data bases were searched, and articles in the English language only were included. This may have introduced some publication bias, as other relevant studies may have been missed. Grey literature was excluded as well.

Most of the participants recruited in the primary studies, were patients approached in clincial settings (as seen in table 4.2). Hence, the findings of this review may not apply to all patients with TMD, as only a small proportion of people experiencing signs and symptoms of TMD present for treatment (RCSE (2013a)).

Sensitivity analysis was not formally conducted to assess whether the exclusion of the studies with lower CASP scores might have changed the results. However, as shown in the GRADE-CERQual evidence profile, no major findings were supported exclusively by such studies. Hence, omitting these studies was not suspected to have affected the results remarkably.

An argument against qualitative synthesis is that it may take the reader too far away from the primary experience, as it contains interpretations (3rd order constructs) of interpretations (2nd order constructs) of the 1st order constructs as relayed by the patients (Sandelowski and Barroso, 2006). However, this move away beyond the primary studies is identified by some as the key feature of qualitative synthesis (Thorne et al., 2004, Britten et al., 2002). In the words of Margarete Sandelowski, "*metasyntheses are integrations that are more than the sum of parts, in that they offer novel interpretations of findings. These interpretations will not be found in any one*

*research report but, rather, are inferences derived from taking all of the reports in a sample as a whole*" (Thorne et al., 2004). The details of each primary study were presented to preserve the context, and to enable the reader to judge the transferability of the findings to their own setting.

## 4.6. Conclusions

This review aimed to increase our understanding of the experience of living with TMD. It highlighted the profound effects it could have on work, family, financial and social lives, and confirmed the psychological and mental challenges encountered. It is therefore important for healthcare professionals to recognise these effects when dealing with such patients. They may already suffer alterations to their quality of life by the time they present to a clinical setting, and since the clinical journey is a major part of the life of a chronic pain patient, it is important that it is a positive experience.

Table 4.4. GRADE-CERQual Evidence Profile for review findings

| Summary of review finding | Studies contributing to review finding | Methodological limitations | Coherence | Adequacy | Relevance | CERQual overall assessment |
|---|---|---|---|---|---|---|
| 1. Uncertainty and doubt: some patients experienced uncertainty prior to seeing a health care professional. This was later compounded if the clinical visit was unsuccessful in giving a diagnosis. | 6 studies<br><br>(Durham et al., 2010, Mienna et al., 2014, Bonathan et al., 2014, Durham et al., 2011a, Nilsson and Willman, 2016, Dinsdale et al., 2021) | Very minor concerns. | No or very minor concerns | No or minor concerns | Minor concerns<br>(1 study included a TMD sample in addition to other COFP conditions.<br>1 study consisted of Sami women only.<br>1 study consisted of adolescent patients) | High confidence |
| 2. Self-constructed explanations: some patients tried to rationalise the symptoms by constructing their own explanations. These explanations could turn into firmly held theories. | 4 studies<br><br>(Durham et al., 2010, Bonathan et al., 2014, Nilsson and Willman, 2016, Au et al., 2014) | Very minor concerns. | Minor concerns<br>(The pattern of explanations turning into firmly held theories is not explored in detail) | Minor concerns<br>(Explanations turning into firmly held theories is supported in 1 study) | Moderate concerns<br>(2 studies included a TMD sample in addition to other COFP conditions. 1 of which consisted of elderly people.<br>1 study consisted of adolescent patients). | Moderate confidence |
| 3. Desire to make the pain visible: patients expressed a strong desire to make the pain visible in order to confirm the reality of their symptoms. They expressed frustration at the scepticism they faced. | 3 studies<br><br>(Wolf et al., 2008, Bonathan et al., 2014, Hazaveh and Hovey, 2018) | Very minor concerns. | No or very minor concerns | Minor concerns<br>(Not richly explored and supported by 3 studies only) | Minor concerns<br>(All studies include a TMD sample in add ition to other COFP conditions) | High confidence |
| 4. Self-doubt: patients experienced self-doubt when facing diagnostic uncertainty. | 5 studies<br><br>(Durham et al., 2010, Bonathan et al., 2014, Breckons et al., 2017, | Minor concerns<br>(1 of 5 studies has low CASP) | No or very minor concerns | No or very minor concerns | Minor concerns<br>(2 studies include a TMD sample in addition to other COFP conditions) | High confidence |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Garro et al., 1994, Garro, 1994) | | | | | |
| 5. TMD affected social interactions: TMD may cause diminished willingness to participate in social activities. Some patients could not cope with being around people when in pain, which resulted in feeling isolated and unable to participate in social life. On the other hand, staying connected to other people helped some patients cope better. | 10 studies (Durham et al., 2010, Durham et al., 2011a, Dinsdale et al., 2021, Au et al., 2014, Wolf et al., 2008, Hazaveh and Hovey, 2018, Garro et al., 1994, Peters et al., 2015, Nilsson et al., 2011, Eaves et al., 2015) | Minor concerns (1 of 10 studies has low CASP) | No or very minor concerns | No or very minor concerns | Moderate concerns (4 studies included TMD sample in addition to other COFP conditions. 1 of which consisted elderly people. 1 study consisted of adolescent patients) | High confidence |
| 6. TMD affected personal relationships: relationships with partners were sometimes strained due to the difficulty of articulating the suffering and due to a lack of understanding. This had a toll on intimate relations. | 5 studies (Durham et al., 2011a, Dinsdale et al., 2021, Hazaveh and Hovey, 2018, Nilsson et al., 2011, Eaves et al., 2015) | Minor concerns (1 of 5 studies has low CASP) | Minor concerns (Effects on relationship with partners are not explored in depth and may include additional patterns if explored further) | Minor concerns (Patterns of partner support are not richly explored. Effect on sexual interactions is supported by 2 studies only) | Minor concerns (1 study included a TMD sample in addition to other OFP conditions. 1 study consisted of adolescent patients) | Moderate confidence |
| 7. TMD affected professional prospects: maintaining a career was too taxing for some patients. This consequently led to abandonment of jobs on occasions or seeking less demanding ones. | 8 studies (Durham et al., 2010, Durham et al., 2011a, Dinsdale et al., 2021, Hazaveh and Hovey, 2018, Breckons et al., 2017, Garro et al., 1994, Garro, 1994, Eaves et al., 2015) | Minor concerns (2 of 8 studies have low CASP) | No or very minor concerns | No or very minor concerns | Minor concerns (2 studies include a TMD sample in addition to other COFP conditions. | High confidence |

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|---|---|---|---|---|---|---|
| 8. TMD caused financial strain: in addition to the cost of repeated clinical visits and different treatments, loss of employment led to loss of earnings. | 3 studies<br><br>(Hazaveh and Hovey, 2018, Garro et al., 1994, Peters et al., 2015) | Very minor concerns. | Moderate concerns (This finding is largely tied to the insurance cover and the way the healthcare system works in different countries. Hence this finding may not reflect all patterns). | Minor concerns (Finding supported by 3 studies only) | Minor concerns (2 studies included a TMD sample in addition to other COFP conditions) | Moderate confidence |
| 9. TMD affected completing daily activities: having TMD affected a range of daily activities such as: chewing, talking, yawning, and singing. In addition to low sleep quality, energy, and concentration levels. | 13 studies<br><br>(Nilsson and Willman, 2016, Dinsdale et al., 2021, Au et al., 2014, Wolf et al., 2008, Hazaveh and Hovey, 2018, Breckons et al., 2017, Garro et al., 1994, Garro, 1994, Peters et al., 2015, Nilsson et al., 2011, Eaves et al., 2015, Safour and Hovey, 2019, Ilgunas et al., 2020) | Minor concerns (2 of 13 studies have low CASP) | No or very minor concerns | No or very minor concerns | Moderate concerns (5 studies included a TMD sample in addition of other OFP conditions. 1 of which consisted of elderly people. 2 studies consisted with adolescent patients. | High confidence |
| 10. TMD caused psychological distress: negative feelings emerged throughout the journey of dealing with TMD. Starting with anxiety before diagnosis, frustration with the clinical interactions, irritation at the lack of effective pain control and later depression | 14 studies<br><br>(Durham et al., 2010, Mienna et al., 2014, Bonathan et al., 2014, Durham et al., 2011a, Au et al., 2014, Wolf et al., 2008, Hazaveh and Hovey, 2018, Breckons et al., 2017, Garro et al., 1994, Garro, 1994, | Minor concerns (1 of 14 studies have low CASP) | No or very minor concerns | No or very minor concerns. | Minor concerns (3 studies include a TMD sample in addition to other OFP conditions. 1 study is concerned with adolescents). | High confidence |

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| and melancholy at the difficulty of coping with the pain. | Peters et al., 2015, Nilsson et al., 2011, Ilgunas et al., 2020, Rollman et al., 2013) | | | | | |
| 11. Plausible explanations for TMD: Patients expressed their understanding of TMD as a part of a larger complex problem that might be difficult to comprehend. Once they found an explanation, they tried to reinterpret past events to fit into that explanation. Some of the perceived causes were trauma and dental work. | 11 studies<br><br>(Mienna et al., 2014, Durham et al., 2011a, Nilsson and Willman, 2016, Dinsdale et al., 2021, Breckons et al., 2017, Garro et al., 1994, Garro, 1994, Peters et al., 2015, Rollman et al., 2013, Fjellman-Wiklund et al., 2019, Wolf et al., 2006) | Minor concerns<br>(2 of 11 studies have low CASP) | Minor concerns<br>(This pattern is not explored in detail; hence other patterns may emerge if explored further) | Minor concerns<br>(The finding Is complex and could be explored in more detail) | Moderate concerns<br>(3 studies included a TMD sample in addition to other OFP conditions.<br>1 study consisted of Sami women.<br>1 study consisted of adolescent patients) | Moderate confidence |
| 12. Views on TMD: TMD was viewed in a positive or a negative outlook. Positive if they were able to use it to make changes in life, and negative if concerns over the fluctuating nature of the condition persisted even after some pain control. | 4 studies<br><br>(Wolf et al., 2008, Garro, 1994, Garro et al., 1994, Eaves et al., 2015) | Serious concerns<br>(2 of 4 studies have low CASP) | No or very minor concerns | Minor concerns<br>(The finding Is complex and could be explored in more detail) | No or very minor concerns<br>(1 study consisted of a TMD sample in addition to other OFP conditions). | Low confidence |
| 13. Stigma: some patients linked TMD with stigma and preferred not to mention it to other people. Other patients did not perceive stigma in association with TMD. | 3 studies<br><br>(Hazaveh and Hovey, 2018, Garro, 1994, Eaves et al., 2015) | Serious concerns<br>(2 of 3 studies have low CASP) | No or very minor concerns | Minor concerns<br>(Not richly described in the studies) | No or very minor concerns<br>(1 study consisted of a TMD sample in addition to other OFP conditions). | Low confidence |
| 14. Pain is a dominant entity: pain was overwhelming on occasions, both physically and psychologically. Some patients | 11 studies<br><br>(Hazaveh and Hovey, 2018, Garro, 1994, Eaves et al., 2015, Mienna et al., 2014, | Minor concerns<br>(2 of 11 studies have low CASP) | No or very minor concerns | No or very minor concerns | Moderate concerns<br>(4 studies included a sample of TMD in addition to other OFP conditions. 1 | High confidence |

| | | | | | | |
|---|---|---|---|---|---|---|
| found it difficult to plan and progress in life. | Bonathan et al., 2014, Nilsson and Willman, 2016, Dinsdale et al., 2021, Wolf et al., 2008, Breckons et al., 2017, Garro et al., 1994, Nilsson et al., 2011) | | | | Sample consisted of Sami women. 2 studies consisted of adolescent patients). | |
| 15. Adapting and moving on: patients were able to cope better with the pain if they received a diagnosis, a reassuring consultation, support from surrounding people and engaged in physical activity. | 12 studies<br><br>(Hazaveh and Hovey, 2018, Garro, 1994, Eaves et al., 2015, Mienna et al., 2014, Bonathan et al., 2014, Nilsson and Willman, 2016, Dinsdale et al., 2021, Wolf et al., 2008, Breckons et al., 2017, Nilsson et al., 2011, Ilgunas et al., 2020, Au et al., 2014) | Minor concerns (2 of 12 studies have low CASP) | No or very minor concerns | No or very minor concerns | Moderate concerns (5 studies included a sample of TMD in addition to other OFP conditions. 1 study consisted of Sami women. 1 study consisted of elderly people. 2 consisted of adolescent patients). | High confidence |
| 16. Aims and hopes: some patients did not expect complete reversal of symptoms, whereas others wished for total alleviation. | 6 studies<br><br>(Garro, 1994, Mienna et al., 2014, Nilsson and Willman, 2016, Durham et al., 2010, Garro et al., 1994, Nilsson et al., 2011) | Minor concerns (1 of 6 studies have low CASP) | No or very minor concerns | No or very minor concerns | Minor concerns (1 study consisted of Sami women. 2 studies consisted of adolescent patients). | High confidence |

# Chapter 5: A meta synthesis of the experience of temporomandibular disorder patients within the healthcare services.

## 5.1. Introduction

Chronic pain is a significant health problem, affecting approximately 1 in 5 adults worldwide (Breivik et al., 2006, Hardt et al., 2008, Ferreira-Valente et al., 2014). Simple physical activities could become burdensome, and social interactions with family and friends may become more difficult. This may drive the sufferers to become more isolated and consequently result in a heightened experience of pain (Koes et al., 2006, Williams et al., 2012).

Patients with chronic pain conditions are also reported to use healthcare services more frequently than other patient groups (White et al., 2001) (Campbell and Guy, 2007). It has been suggested that although clinicians adhere to guidelines in their management of pain, they may not always consider patients views on management strategies (Bergman et al., 2013).This may result in unmet patients' expectations and promote excessive use of health services to help cope with the pain.

This qualitative evidence synthesis was undertaken as a first step to develop a patient reported experience measure (PREM) for patients with TMD to assess their experience within the healthcare services. A rigorous development process involves input from the target population, experts in the field and from the relevant literature (FDA, 2009). To establish data triangulation and ensure that all the important aspects of care were captured in the new instrument, a systematic review of the literature was conducted, with a view to incorporate the findings in the new tool.

## 5.2. Aims and objectives

1. To explore and synthesise the available qualitative evidence regarding the experiences of TMD patients within healthcare and explore the difficulties they encounter.
2. To aid in the development of a topic guide that can be used in the next phase of the PREM development (focus groups to obtain patient input).

## 5.3. Materials and methods

The review was registered on PROSPERO with the registration ID: CRD42020176820.

### 5.3.1. Search strategy

The key words for the search were based on the SPICE acronym. The concepts of the framework were as follows; **Setting**: clinical setting, **Perspective**: patients, **Phenomenon of Interest**: temporomandibular disorders, **Comparison:** none, **Evaluation**: patient experience/satisfaction.

The search strategy aimed to locate all available articles and involved three steps. Firstly, an initial search was run using Medline and Embase to identify MeSH terms and key words describing our search. The following MeSH terms and keywords were used:

(Temporomandibular Joint Disorders or Temporomandibular Joint Dysfunction Syndrome or Facial Pain or fac* myalgia or masticat* muscle pain*) AND (Personal Satisfaction or Attitude or experience* or satisfaction* or healthcare service* or health care service* or perspective* or concern* or opinion*) AND (Qualitative research or Interview or Focus groups or qualitative stud* discussion* or audio recording*)

Secondly, the published articles were identified by running the search strategy in the following databases: Medline, Embase, PsycINFO, Web of Science, CINAHL Complete and the Cochrane database. Finally, hand searching of the references lists of the included articles was performed for additional studies that may have been missed form the previous search. The full search strategy can be found in appendix 5.

### 5.3.2. Inclusion and exclusion criteria

The studies eligible for inclusion were qualitative studies that report on aspects of TMD patients' experience within the healthcare services. Mixed method studies were included if they contained a qualitative component that was clearly separate from the quantitative component. Studies with a sample of patients with a mix of chronic orofacial pain (COFP) conditions were also included if they contained a sample of TMD patients. The findings and quotes attributed to TMD patients were extracted, in addition to the data which was not assigned to a particular pain condition. The rationale for this approach, was that these findings applied to the various orofacial pain conditions under investigation in the studies, including TMD. The findings and quotes which were assigned to another pain condition, such as Trigeminal Neuralgia or Oral Dysaesthesia, were not included in the analysis. This method was adopted as focusing solely on papers with a pure sample of TMD might result in missing important findings in studies with a mixed cohort. The eligible studies also reported on patients over the age of 16 (16 was used as it is the age when children transition into the adult healthcare services in the UK) and were written in the English language. Studies were excluded if they focused on the experiences with a specific treatment or intervention, were focused on the views of healthcare professionals only, if the full text was unavailable, and grey literature.

### 5.3.3. Study selection and critical appraisal

The review process and critical appraisal was similar to the process reported in chapter 4. See section 4.3.3. for the full description of the process.

### 5.3.4. Data extraction and synthesis

The context of the studies was extracted by two reviewers. The data extracted included objectives, demographics of the participants, criteria for diagnosis of TMD, site of recruitment, method of data collection and method of analysis. Further data extraction and synthesis followed the thematic synthesis approach developed by Thomas and Harden in 2008 (Thomas and Harden, 2008). A full description of this process can be found in chapter 4 section 4.3.4.

### 5.3.5. Assessment of the confidence in the review findings

GRADE-CERQual approach was used to assess the confidence in the review findings. See chapter 4 section 4.3.5. for a detailed description of this process.

### 5.3.6. Reporting of the evidence synthesis

This review was also reported according to the ENTREQ statement, which was described in detail in chapter 4 section 4.3.6.

## 5.4. Results

### 5.4.1. Description of studies

The search based on the proposed strategies yielded 3964 articles across all databases. 2983 articles remained after removing the duplicates. After the first step of selection, which involved screening of the titles and abstracts, 140 papers were included for full text review. Following full text review, 17 studies were finally selected to be included in this qualitative evidence synthesis. No studies were excluded based on quality. The flow chart of the selection process, context of the included studies and

their quality appraisal can be found in the previous chapter under the results section (section 4.4.1.). This review consisted of 17 of the 20 papers included in the review reported in chapter 4. Three papers were not incorporated in this review as they did not contain information regarding the clinical experience of the patients and were focused on the effect TMD has on day-to-day life (Dinsdale et al., 2021, Safour and Hovey, 2019, Nilsson et al., 2011).

### 5.4.2. Findings and themes

***Care seeking attitudes***

This theme describes the factors which drove TMD patients to seek medical help and the concerns they had regarding healthcare services.

<u>The need for information</u>

Patients looked for information online, from friends, textbooks and magazines (Bonathan et al., 2014, Au et al., 2014, Rollman et al., 2013, Ilgunas et al., 2020). However, the information received from health care professionals was deemed most trustworthy by some patients (Bonathan et al., 2014, Au et al., 2014). They sought information to gain understanding about their condition, to help them cope with the pain, and to give guidance about where to seek care (Bonathan et al., 2014, Fjellman-Wiklund et al., 2019).

<u>Validation of the pain experience</u>

The pain experience was hard to articulate, and some patients were anxious of people believing they were exaggerating the symptoms (Bonathan et al., 2014, Hazaveh and Hovey, 2018, Durham et al., 2011a). Therefore, they turned to the health care professionals to seek validation and legitimisation of their symptoms, as it entitled

them to seek support and lessened their anxiety (Fjellman-Wiklund et al., 2019, Garro, 1994).

*"I feel I have a legitimate complaint, that it's something that's not in my head. I know there is a physical reason for it" (Brenda, 37). (Garro, 1994)*

*"I had such vague complaints; I did not have the idea that this could have to do with my jaws. But when I came into the waiting room, I saw another guy rubbing his temples. Then I thought: I am not the only one; I'm not some kind of nutcase. I am at the right place." [interview 15]. (Rollman et al., 2013)*

Patient characteristics

Some patients were more insistent than others on professional help. Personal traits may dictate that, such as catastrophising. Some patients found the pain very alarming and a top priority to address. Others were more confident in their own ability to self-manage, thought that seeking professional health was an exaggeration, or simply lost confidence in the health care providers. (Rollman et al., 2013)

*"To check if my complaint is something serious, I use the Internet, talk to friends, but I do not go to my general practitioner. I wish I could, but there is a lack of empathy." (Rollman et al., 2013)*

*"I went to see my general practitioner. I thought, maybe I have a brain tumour, maybe something is wrong." [Interview 2]. (Rollman et al., 2013)*

Surrounding family and friends may influence the decision to seek professional help as well (Nilsson and Willman, 2016, Durham et al., 2011a). This originated from an area of concern, but also due to being annoyed by some of the manifestations, such as repeated clicking sounds (Nilsson and Willman, 2016).

Pain characteristic

Persistent or increasing pain drove patients to seek medical help. Additionally, ineffective pain control prompted some to come back seeking other treatment options, or alternatively caused disengagement from healthcare services (Rollman et al., 2013, Breckons et al., 2017).

*" I am very close to actually going back now [to name of primary care practitioner], because it's [the pain] starting [to increase again]. . . . I am going to [through] a few bits at the moment with stress and it's [the pain] coming back how it was, and it's really bad. I can feel it coming back. It [the jaw] clicks out of joint and then it hurts, but it's [the pain] nowhere near as bad as it has been, but it's only getting worse." (Q18, 12 mo). (Breckons et al., 2017)*

Concerns seeking health care

Some of the concerns that patients expressed which deterred them from seeking professional help were the cost and time associated with dental visits. Cost was a significant concern, and some expressed frustration over the lack of insurance to cover TMD in some countries (Garro et al., 1994). And the more clinicians they saw, the more concerned they were about the cost (Au et al., 2014, Eaves et al., 2015, Garro et al., 1994, Garro, 1994). Additionally, they faced the difficulty of finding the right caregiver, as some were uncertain who to seek for help (Nilsson and Willman, 2016)

*"It was my mom who said I should come here. I had no idea where I should go". (P 1) (Nilsson and Willman, 2016)*

*"Taking time off is too much hassle." [interview 7] (Rollman et al., 2013)*

The attitude of the clinician had an effect on the willingness to return for follow up visits (Au et al., 2014, Rollman et al., 2013, Ilgunas et al., 2020) . Some reported distrust, lack of empathy on part of the clinical team, and expressed fear of the clinician suggesting psychological reasons for their pain (Hazaveh and Hovey, 2018, Garro et al., 1994, Garro, 1994, Ilgunas et al., 2020) . They also felt blamed when treatment was ineffective and chose to disengage from healthcare services. Therefore, losing confidence in the clinician and the treatment provided (Au et al., 2014, Garro et al., 1994, Ilgunas et al., 2020) .

***Expectations and health care experience***

This theme describes the general experience of TMD patients with healthcare, where they reported both positive and negative elements.

Some patients came to the clinical appointment with a set of expectations, such as finding a cure, resolving the pain, receiving the long-sought information and diagnosis, undergoing scans and tests and being involved in the decision-making process (Durham et al., 2010, Bonathan et al., 2014, Breckons et al., 2017, Hazaveh and Hovey, 2018, Fjellman-Wiklund et al., 2019, Nilsson and Willman, 2016). The interaction with the services could help the patients move forwards with the pain and adjust their views and expectations, or it could leave them feeling frustrated and more concerned than before.

Some patients described their encounter in healthcare services as ambiguous, felt being passed around and unsupported especially in primary care (Peters et al., 2015, Hazaveh and Hovey, 2018, Durham et al., 2011a, Wolf, 2006). They also reported inadequate clinical discussions about their condition, difficulties in access to care, long waiting times in clinics, refusal of further appointments and seemingly inconsistent

referral patterns (Breckons et al., 2017, Hazaveh and Hovey, 2018, Durham et al., 2010, Nilsson and Willman, 2016, Eaves et al., 2015, Durham et al., 2011a, Rollman et al., 2013, Wolf, 2006, Ilgunas et al., 2020). Patients reported referral to a range of specialities such as ENT, oral surgery, psychology and referral back and forth between primary and secondary care (Breckons et al., 2017, Garro, 1994). They sometimes had to insist on a referral and were declined to be referred because the practitioner was not convinced of their symptoms and refused to take the pain seriously (Durham et al., 2010, Hazaveh and Hovey, 2018). The long waiting times to get an appointment or a referral reportedly worsened their symptoms and exacerbated their concerns (Durham et al., 2011a, Durham et al., 2010).

*"Well, I felt terrible, especially when my GP [general medical practitioner] refused to refer me anywhere and told me I was a timewaster who was just imagining it. And, you know, not to bother him anymore." (Sufferer 8) (Durham et al., 2010)*

*" And so I was in some intense pain . . . and it was so funny because as soon as I got to the doctors they tell me I should go to the dentist, and then as soon as I go to the dentist they tell me they can't do anything for me, I have to go back to the doctors. And so it's a lot of shifting back and forth, and I didn't have a lot of time as a student and working full time and so . . . I've just kind of dealt with the pain". (Lisa, 30). (Eaves et al., 2015)*

*"An adequate interview was missing, no good questions." [interview 11]. (Rollman et al., 2013)*

Other patients however were content with their experience in healthcare. They reported that their clinical visit helped reduce their worry, had a positive impact on the relationship with the pain, helped put their mind to rest after ruminating endlessly about

the symptoms and enabled them to abandon their pursuit for answers and invasive treatments. (Bonathan et al., 2014, Wolf, 2006).

*“Even though I haven’t come away with a cure, I feel in a better position to cope with my symptoms.” (participant 4, postconsultation) (Bonathan et al., 2014)*

*“I guess what the appointment has done is drawn a line under it and made me think, well, that’s fine, but nothing can be done about it so I just need to get on with things.” (participant 5, postconsultation). (Bonathan et al., 2014)*

Patients’ characteristics and preconceptions were also factors that influenced the outcome of the clinical visit, as some came in with very specific hopes and expectations. Conflict with their pre-understandings sometimes led to rejection of information. (Bonathan et al., 2014, Rollman et al., 2013)

*“ . . . you don’t necessarily always want to tell them that they are in the wrong because they are the ones who are the doctors.” (participant 3, preconsultation) (Bonathan et al., 2014)*

Another subtheme that emerged was the repeated clinical attendance for patients with TMD (Durham et al., 2010, Rollman et al., 2013, Durham et al., 2011a, Garro et al., 1994, Garro, 1994). Possible reasons included: lack of diagnosis, lack of information, difficulty accepting the diagnosis, desire to be referred, lack of concordance between expectations and explanations of TMD, unresolved pain, dissatisfaction with the clinical visit, and the low self-efficacy of some patients and their need for ongoing care. This phenomenon emerged before and after receiving a diagnosis.

*“I think for me the frustration initially was a lot of appointments [with varying primary care practitioners] but I wasn’t really getting anything from them because nobody was really—well I didn’t feel like they [the health care professionals consulted in primary*

*care] were taking the whole situation very seriously". (Q22, baseline) (Breckons et al., 2017)*

***The patient-clinician interaction***

This theme describes the impact the healthcare professionals may have on the healthcare experience. Some patients reported lack of diagnostic certainty on the part of the clinician in terms of determining the cause of the pain, especially in primary care. They described receiving partial explanations which amplified their worry. (Durham et al., 2010, Mienna et al., 2014, Breckons et al., 2017, Garro, 1994)

*"What kind of a doctor could there be who would understand this? I've looked high and low." (Mienna et al., 2014)*

*"I've been to see them all [dental and medical professionals]. The GPs don't seem to know what to do. I just don't know where to go next. I go to GPs and they just give me more tablets and that's it" (Q12, 12 mo). (Breckons et al., 2017)*

Many faced a negative experience with their clinician. They faced scepticism about the authenticity and severity of the complaints, disinterest, the implication that they were imagining their pain or were simply seeking attention. They also reported limited time given discussing the problem and refusal to refer (Durham et al., 2010, Mienna et al., 2014, Au et al., 2014, Rollman et al., 2013, Peters et al., 2015, Breckons et al., 2017, Hazaveh and Hovey, 2018, Wolf, 2006, Garro et al., 1994, Durham et al., 2011a, Ilgunas et al., 2020). This attitude caused them to feel dismissed and therefore affected their willingness to accept the information offered by the care provider. It also discouraged them from seeking further treatment with them (Bonathan et al., 2014, Au et al., 2014, Ilgunas et al., 2020). Interestingly, this was also reported by some patients with symptoms of hypermobility, locking and clicking of the jaw. (Ilgunas et al., 2020)

*“I was badly treated at the clinic. The dentists who work there thought I was a “psych” case and that I needed something. They said: ”There is nothing wrong with you, it is all in your head. Just calm down and get some psychiatric help instead.” It isn’t fun to hear such things”. (Wolf, 2006)*

*“I feel as if the dentist is only concerned about making money. He plows through each patient, me in any case, in 15 minutes”. (Wolf, 2006)*

*“The dentist also thought it was nice to include my private life in his analysis. He said: “You have such personal problems. You must understand that you are under pressure.” Such statements make me crazy. Don’t sit there and tell me what problems I have! I’ll take care of that best myself!” (Wolf, 2006)*

On the other hand, some patients reported a very pleasant experience with their clinicians. They felt understood, listened to, and appreciated being given a thorough examination. This consequently made them trust the information and diagnosis offered even if they were expecting scans and tests. They trusted the treatment offered and felt more able to self-manage (Bonathan et al., 2014, Breckons et al., 2017, Durham et al., 2011a).

*“I felt the professor listened to me more than the other health care professionals I have seen and took into account the effects the pain was having on my life in general, rather than just treating me as a diagnosis.” (participant 4, postconsultation) (Bonathan et al., 2014)*

*“I have faith in them [the GPs] and, and they’re good in that they listen and they act on what you say in that they’ve never kind of gone oh you’re talking rubbish about anything” (Q13, baseline) (Breckons et al., 2017)*

*"I'm told by the professional, no it's not that serious... he [dental consultant] filled us with confidence and he, like, I felt as if he knew exactly what he was doing, what he was [doing], you know, and gives us confidence" (Pt 23) (Durham et al., 2011a)*

***Diagnosis as a stepping-stone for improvement***

This theme describes the importance of receiving a diagnosis for patients with TMD. A delay or even lack of diagnosis was a common theme among the examined studies. Patients reported seeing many practitioners before getting it and mentioned receiving multiple diagnoses as well. This delay was frustrating and evoked anxiety and fear that the pain was signalling something sinister (Durham et al., 2010, Bonathan et al., 2014, Nilsson and Willman, 2016, Peters et al., 2015). Furthermore, if unclear explanations were given, it resulted in additional clinical visits to get to the bottom of it (Breckons et al., 2017). The lack of diagnosis caused uncertainty, self-doubt about the legitimacy of the complaint, failure to progress, and opened the door for constructing their own explanations to the pain (Breckons et al., 2017, Hazaveh and Hovey, 2018, Nilsson and Willman, 2016, Durham et al., 2011a, Garro et al., 1994, Garro, 1994, Peters et al., 2015). In some instances, they were more concerned with the diagnosis than the treatment options. (Durham et al., 2011a)

*"Why a diagnosis would help me is because my mind, since 1987, has been, shall we say, in a bit of turmoil. I think, "What is happening inside my head? Have I got a tumour?" etc., etc." (Breckons et al., 2017)*

*"I got panic-stricken. I didn't know what was going on." (P-2) (Nilsson and Willman, 2016)*

*"I wasn't necessarily thinking of the cure, more of knowing what was wrong with the jaw. That was, I think, the primary thought in my mind was I wanted to know what this was. And then I think the cure was second" (Pt 15) (Durham et al., 2011a)*

Receiving a diagnosis was emphatically mentioned by many of the patients as a very important step in their pain journey. They felt elated and reassured as it gave legitimacy to the complaints, acknowledged their illness, and confirmed they were not alone. It also empowered them to ask questions and look for information about the condition. They mentioned the importance of diagnosis in ceasing the exhausting search for answers, initiating self-coping strategies, and giving entitlement to seek support once the pain experience has been validated. (Durham et al., 2011a, Peters et al., 2015, Durham et al., 2010, Bonathan et al., 2014, Garro, 1994, Garro et al., 1994).

*"I mean you had a name for it and you knew you weren't alone with it so it eased your mind totally really knowing that it wasn't anything too serious." (Sufferer 7) (Durham et al., 2010)*

It also meant receiving the right information about the condition and they can then begin discussing the treatment options. Hence, it helped manage the expectations and the long-term prognosis (Durham et al., 2010, Eaves et al., 2015).

*"You want a magic wand waved over and then it's [the pain's] gone...Then reality kicks in and you think no that's in never never land, that's not the way it works." (Sufferer 13) (Durham et al., 2010)*

***Management***

This theme describes the different management strategies offered to the patients. Treatment in general was not sought if the symptoms were mild, or if they did not interfere much with life (Fjellman-Wiklund et al., 2019). In other cases, however,

patients were persistent in finding the treatment, and this search intensified with increasing pain and intrusion on daily life (Garro, 1994).

Management was reported to be inconsistent and inappropriate at times resulting in ineffective pain control and even making things worse in some cases (Garro, 1994, Fjellman-Wiklund et al., 2019, Breckons et al., 2017, Durham et al., 2010). A lot of teeth related management approaches were offered (Durham et al., 2010). Furthermore, treatment was sometimes offered without reaching a firm diagnosis first, and mainly included pain killers (Durham et al., 2010, Mienna et al., 2014, Breckons et al., 2017, Hazaveh and Hovey, 2018).

*"I think it [the pain and problems] got worse in a sense. And I was probably becoming more distressed because I thought that once the tooth was taken out, and that was a big step to have something like that removed, that it would be okay [the pain and problems would be resolved]." (Sufferer 3) (Durham et al., 2010)*

On occasions, treatment plans consisted of multiple attempts until the effective modality was found (Breckons et al., 2017). A range of management approaches were offered to treat TMD with varying degrees of success including: oral splints, physiotherapy, acupuncture, biofeedback, dental work, orthodontic treatment and surgery (Mienna et al., 2014, Breckons et al., 2017, Hazaveh and Hovey, 2018, Nilsson and Willman, 2016, Eaves et al., 2015, Garro, 1994, Garro et al., 1994). Some expressed difficulties in making treatment decisions, as different explanations were offered with different treatments (Garro et al., 1994). Medications were also offered but many patients voiced concerns over the frequent use of analgesics. They were concerned about the side effects and drug interactions with other medications; hence some did not use them unless in severe pain. Additionally, they expressed concerns

over the effectiveness, as they reported them not to be useful or with declining effectiveness over time (Eaves et al., 2015, Au et al., 2014, Hazaveh and Hovey, 2018, Nilsson and Willman, 2016).

*"I mean the jaw pain if you take strong painkillers it gets under control but I can't just do that all the time. Painkillers make me slow. It's so nerve-wracking and stressful, especially when I have an exam coming up". (Hazaveh and Hovey, 2018)*

*"I've had oral splints. I've tried several of them, but I don't know that I've gotten any better." (Mienna et al., 2014)*

Self-management strategies were also reported, such as: physical activities, jaw stretching exercises, meditation, yoga, distraction techniques, hot or cold compresses, and making lifestyle changes (Au et al., 2014, Rollman et al., 2013, Peters et al., 2015, Breckons et al., 2017, Hazaveh and Hovey, 2018, Nilsson and Willman, 2016, Eaves et al., 2015). Some expressed that the ability to self-manage was associated with their knowledge about the illness, the triggers, its fluctuating course, confidence in the clinician, and reduction in pain and dysfunction levels that they were able to manage on their own. They also reported getting better at self-management over time (Durham et al., 2011a, Breckons et al., 2017).

*"I've got to the point now where I think I've got to do it because I can only help myself now, it's not a case of...I could come here for the next 12 months but unless I continue to help myself it's not going to get any better as well" (Pt 16) (Durham et al., 2011a)*

Lack of education on the proper methods to self-manage sometimes resulted in patients undertaking harmful practices to relieve the pain. It led to uncertainty on the part of the patients about which strategies were useful (Bonathan et al., 2014, Peters et al., 2015, Hazaveh and Hovey, 2018).

*"I found . . . a video of exercises you could do, pushing your jaw in and out, and I did try that for a week. My jaw's initial reaction was a lot of pain, but then it did seem to get a little bit better. I thought: I don't know if this is right or not for me; I'm not sure if I should be doing this . . . am I making it worse?" (Bonathan et al., 2014)*

***Seeking support***

This theme describes the patients' attitudes toward the social support needed from the surrounding people.

"I'm not the only one" - Social networks (Mienna et al., 2014, Bonathan et al., 2014, Rollman et al., 2013, Durham et al., 2011a, Wolf, 2006, Ilgunas et al., 2020)

Social networks were reportedly important for patients with TMD. They welcomed being informed of support groups as it confirmed that they were not alone. They appreciated the knowledge shared and helped them set realistic expectations. (Ilgunas et al., 2020). They may not join regularly however, as it could be energy consuming to do so.

*"Maybe then [if I had a diagnosis] there are things I can do, like support groups. I don't even know if I would want to go to one, but knowing that they are there, that there is an option, some sort of community spirit thing." (participant 4, preconsultation) (Bonathan et al., 2014)*

Family and friends

As for the support sought from family and friends, patients had contradictory attitudes. Some sought that support and reported that it helped them cope better with the pain and was important for survival (Nilsson and Willman, 2016, Au et al., 2014, Ilgunas et al., 2020). Whereas others preferred to suffer in silence and kept the pain to themselves. They revealed that they did not want to burden their loved ones with their

pain, or they thought they would not understand and hence there was no point in talking about the pain with them. Additionally, they did not want to come across as "whiney" and take the identity of a chronic pain patient (Au et al., 2014, Hazaveh and Hovey, 2018, Nilsson and Willman, 2016, Eaves et al., 2015).

*"If I had not had animals, family, and a boyfriend, I wouldn't have survived." (P-4) (Nilsson and Willman, 2016)*

*"I don't really talk to them [friends] about my pain. I don't really like to explain about the pain. I guess I'm scared that they wouldn't understand". (Interviewee 2) (Hazaveh and Hovey, 2018)*

*"No reason to concern anybody else and have anybody else get upset about it. Uh, no, I just put up with it, that's all". (Eaves et al., 2015)*

## 5.5. Discussion

To our knowledge, this was the first qualitative systematic review focussing on the experience of TMD patients within the healthcare services. In the appraisal of the quality of the included studies using the CASP checklist, none of the studies were excluded based on quality. Interestingly, most of the papers did not discuss the influence of the interviewer on the research (item 6 of CASP checklist) or what is known as reflexivity in qualitative research. This transparency in describing the intersecting relationships between the researcher and the participants increases the credibility of the findings and enables a deeper understanding of the work (Dodgson, 2019).

Similar reviews were found elsewhere in the literature for chronic pain conditions, such as rheumatoid arthritis (Toye et al., 2019, Primdahl et al., 2019), chronic non-malignant

musculoskeletal pain (Toye et al., 2013b, Toye et al., 2013a) and low back pain (Froud et al., 2014). Strong similarities in findings were identified, which suggests that despite the localised nature of TMD, it may interfere with the daily lives of patients as significantly as systemic chronic pain conditions.

A growing body of evidence highlights the importance of a pleasant clinical experience to patients. It is not only expected, but also humane (Doyle et al., 2013). Previous reviews of chronic pain conditions have revealed an element of dissatisfaction with the healthcare services (Toye et al., 2013b, Toye et al., 2017a, Toye et al., 2014, Fu et al., 2016). Patients may struggle to negotiate the system and often feel like a "shuttlecock" due to the constant referrals back and forth between different components of the healthcare system (Toye et al., 2013b). TMD patients seem to share this problem too. They mentioned repeated clinical attendance due to various reasons, such as lack of diagnosis, lack of information and dissatisfaction with the clinical visit. Some general medical and dental practitioners report being conscious of their uncertainty in making a diagnosis of TMD or giving the appropriate treatment advice once the diagnosis has been made. This is likely due to insufficient exposure to TMD problems in their undergraduate studies, or lack of the set of skills to manage patients with TMD during subsequent postgraduate training (Peters et al., 2015). Regardless of the cause of the hesitation in the diagnosis and management of patients with TMD in primary care, this can lead to onward referral to more than one specialist service and hence the 'shuttlecock' experience for patients.

The importance of receiving a diagnosis was highlighted strongly in this review. It was described previously by Toye et al as a "quest for the holy grail", where patients need it in order to validate their pain experience and begin the quest for pain control (Toye et al., 2017a). It is highly valued and integral to a sense of credibility. Without a firm

label to the pain, doubt permeates familial and social relationships and creates powerful emotions such as fear, agitation and guilt (Toye et al., 2013b). Patient education and reassurance are important in the context of chronic pain as well. They form a ‘cornerstone’ of back pain management according to the International Association for the Study of Pain (IASP), and are the first-line management approach for musculoskeletal pain (Ernstzen et al., 2021). Some misconceptions are commonly associated with chronic pain, such as the necessity of imaging to diagnose pain conditions, and that activities should be avoided when in pain (O’Keeffe et al., 2019, Sharma et al., 2020). Therefore, discussion about the patients’ expectations, fears and beliefs is encouraged as it may work to empower patients, alleviate their concerns, allow them to develop the essential skills to manage their pain and decrease dependency of healthcare professionals (Ernstzen et al., 2021). Different modes can be utilised to deliver education, such as verbal discussions, written material (leaflets and pamphlets) and audio-visual aids. Several benefits were also reported in association with group management strategies (Linton et al., 2005, Jones et al., 2013), where the patients found these sessions helpful in learning new information, skills, coping techniques, and knowing they were not alone (Jones et al., 2013).

Health professionals may play an important role in coping with the pain. Chronic pain patients have expressed the need to be believed, listened to and treated with dignity (Toye et al., 2017a). These features forge a trusting relationship with the patients and are integral to their ability to self-manage (Fu et al., 2016). In this review, TMD patients felt strongly about the importance of being looked after by an understanding and empathic clinician. It might make them more receptive of the information, and more able to cope with their symptoms. This has also been proposed by Doyle et al where the authors reported in their quantitative systematic review a positive association

between patient clinical experience and self-reported outcomes. They attributed this to better adherence to treatment instructions and medications, and better use of preventive care (Doyle et al., 2013).

Durham et al have suggested a clinical journey map for patients with TMD. A potential application of this map was to identify the time points in clinical care where introducing intervention would be most useful. This suggests that the life effects of TMD could be reduced if standardised conservative therapy is introduced early in primary care alongside early diagnosis. This helps in establishing a perceived control over the condition and could also aid in decreasing the burden on secondary care in terms of managing these patients (Durham et al., 2011a).

Multiple quantitative studies have explored the barriers to healthcare in different countries (Kullgren et al., 2012, Douthit et al., 2015, Reuter et al., 2014, Garcia-Subirats et al., 2014). Some of the factors revealed, paralleled our results such as: unfavourable evaluation of medical care, some personality traits, in addition to the traditional barriers, such as access, time and cost of care. These shared barriers confirm that such healthcare problems are not exclusive to COFP patients but span different fields and different countries. However, it is still unclear whether these delays could influence the outcome of TMD management. Our results suggest that long waiting times to get an appointment or a referral may inflame the patients' anxiety, worsen their symptoms, and possibly make them more prone to self-constructed explanations to the pain. And once some preconceptions take hold, it may be difficult to persuade some patients otherwise.

The role of qualitative evidence is increasingly recognised within a range of decision-making processes, such as guideline development and policy making (Lewin et al.,

2018, Glenton et al., 2016). Qualitative evidence presents a unique way to deliver the experiences of a wide range of stakeholders, and the examination of such views promotes participative democracy and public accountability (Lewin et al., 2018). GRADE-CERQual assessment, hence, plays an important role in the process by providing an evidence profile, based on which confidence in the findings of qualitative research can be judged. As reported in table 5.1, the confidence in the findings of this review all ranged from moderate to high. Meaning that it is likely/highly likely that the review findings are a reasonable representation of the phenomenon of interest (Lewin et al., 2018).

Limitations

Although the literature search was conducted systematically and rigorously, the review focussed on articles published in the English language in the six aforementioned databases. Grey literature was also not included, which may have introduced some publication bias.

Sensitivity analysis was not formally conducted to assess whether the exclusion of the studies with lower CASP scores might have changed the results. However, as shown in the GRADE-CERQual evidence profile displayed in table 5.1, no major findings were supported exclusively by such studies. Hence, we do not suspect that omitting these studies would have affected the results remarkably.

Qualitative evidence synthesis by default requires researchers to interpret concepts. However, the concept of ‘going beyond’ the original studies has been identified by some as the hallmark of this type of synthesis, so it does need to be a limitation per se (Thomas and Harden, 2008). Additionally, we ensured that individual interpretations remained grounded within the experience of the original studies (Toye et al., 2013b). Some may also argue against qualitative systematic reviews on the grounds that they

de-contextualise the findings of the primary studies (Sandelowski and Barroso, 2006, Thomas and Harden, 2008). The context was preserved in this review by presenting a summary of each primary study, so the readers can judge the transferability of the findings to their own setting.

## 5.6. Conclusions

The effects of TMD on the patients' lives range from minimal to debilitating. In consequence, patients may become anxious, depressed, and melancholic. This makes them a challenging group of patients to deal with. Thus, when this is combined with the problems within healthcare – especially primary care- an unpleasant encounter could arise for both parties. Ongoing research have already identified some problems within the pathway of healthcare for COFP patients and suggest that the current pathway does not meet the patients' needs. Further research is needed to determine the parts of healthcare experience which potentially have the most effect on patient reported outcomes, and to quantify these effects in order to maximise the effectiveness of financial resources in correcting these problems.

Table 5.1 GRADE CERQual evidence profile for review findings

| Summary of review finding | Studies contributing to finding | Methodological limitations | Coherence | Adequacy | Relevance | CERQual overall assessment |
|---|---|---|---|---|---|---|
| 1. The need for information: Patients sought information from different sources. They needed information to understand their condition and be able to cope better with the pain. | 5 studies (Bonathan et al., 2014, Au et al., 2014, Rollman et al., 2013, Ilgunas et al., 2020, Fjellman-Wiklund et al., 2019) | Minor concerns (1 of the 5 studies has low CASP) | No or very minor concerns | No or very minor concerns. | Minor concerns (2 studies have a sample of TMD in addition to other COFP conditions, 1 of which consisted of elderly patients). | High confidence |
| 2. Validation of the pain experience: it entitled patients to seek support and lessened their anxiety, especially if surrounding people believed they are exaggerating the symptoms. | 5 studies (Durham et al., 2011a, Bonathan et al., 2014, Fjellman-Wiklund et al., 2019, Hazaveh and Hovey, 2018, Garro, 1994) | Moderate concerns (2 of the 5 studies have low CASP) | No or very minor concerns | Minor concerns (the finding Is complex and could be explored in more detail) | Minor concerns (2 study had a TMD sample in addition to other COFP conditions). | Moderate confidence |
| 3. Patient characteristics: some personal traits may influence the choice to seek professional help such as catastrophizing. | 1 study (Rollman et al., 2013) | Very minor concerns | No or very minor concerns | Moderate concerns (supported by 1 study only) | No or very minor concerns | High confidence |
| 4. Pain characteristics: Persistent or increasing pain drove patients to seek medical help. | 2 studies (Breckons et al., 2017, Rollman et al., 2013) | Very minor concerns | No or very minor concerns | Moderate concerns (supported by 2 studies only) | No or very minor concerns (1 study had a TMD sample in addition to other COFP conditions). | High confidence |
| 5. Concerns seeking professional help include cost, time, finding the right | 7 studies | Minor concerns | No or very minor concerns | No or very minor concerns | Minor concerns (1 study had a sample of TMD in addition to | High confidence |

| | | | | | | |
|---|---|---|---|---|---|---|
| caregiver, and the attitude of the clinician. | (Rollman et al., 2013, Au et al., 2014, Ilgunas et al., 2020, Garro, 1994, Nilsson and Willman, 2016, Eaves et al., 2015, Garro et al., 1994) | (2 of the 7 studies have low CASP) | | | other COFP conditions and consisted mainly of elderly patients. 1 study consisted of adolescent patients). | |
| 6. Patients were unhappy with the healthcare services if they felt unsupported, passed around, were not given enough time and waited long for appointments. | 10 studies<br><br>(Breckons et al., 2017, Durham et al., 2011a, Rollman et al., 2013, Ilgunas et al., 2020, Hazaveh and Hovey, 2018, Nilsson and Willman, 2016, Eaves et al., 2015, Durham et al., 2010, Peters et al., 2015, Wolf et al., 2006) | Minor concerns (1 of the 10 studies has low CASP) | No or very minor concerns | No or very minor concerns | Minor concerns (3 studies have a TMD sample in addition to other COFP conditions. 1 study consisted of adolescent patients). | High confidence |
| 7. Patients who were content with the clinical visit reported reduced anxiety, better relationship with the pain and abandoned their search for information and invasive treatments. | 2 studies<br><br>(Bonathan et al., 2014, Wolf et al., 2006) | Very minor concerns. | Moderate concerns (This finding is complex and if explored further, contradictory patterns may emerge) | Moderate concerns (The finding is complex and further exploration is needed) | Minor concerns (Both studies have a TMD sample in addition to other COFP conditions). | Moderate confidence |
| 8. Repeated engagement in healthcare services, due to lack of diagnosis, unresolved pain and dissatisfaction with the clinical visit. | 5 studies<br><br>(Durham et al., 2011a, Rollman et al., 2013, Garro, 1994, Durham et al., | Minor concerns (1 of the 5 studies have low CASP) | No or minor concerns. | No or very minor concerns. | No or very minor concerns. | High confidence |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 2010, Garro et al., 1994) | | | | | |
| 9. The patient-clinician interaction: lack of diagnostic certainty amplified worry. Negative clinician attitude was widely reported, and it affected their willingness to accept information, induced anger and discouraged them from seeking further treatment with these clinicians. | 13 studies<br><br>(Breckons et al., 2017, Durham et al., 2011a, Bonathan et al., 2014, Au et al., 2014, Rollman et al., 2013, Ilgunas et al., 2020, Hazaveh and Hovey, 2018, Garro, 1994, Durham et al., 2010, Peters et al., 2015, Wolf et al., 2006, Mienna et al., 2014, Garro et al., 1994) | Minor concerns (1 of the 13 studies have low CASP) | No or minor concerns. | No or very minor concerns. | Moderate concerns (5 studies have a TMD sample but also other OFP conditions. 1 of which consisted of elderly patients. 1 study consisted of Sami women). | High confidence |
| 10. The patient-clinician interaction: understanding and empathic clinicians induced trust in the information and treatment given. It also helped with the ability to self-manage. | 3 studies<br><br>(Breckons et al., 2017, Durham et al., 2011a, Bonathan et al., 2014) | Very minor concerns | Minor concerns (Additional patterns may emerge if explored further) | Minor concerns (effects of a positive clinician attitude needs to be more thoroughly explored) | Minor (2 studies have a TMD sample in addition to other COFP conditions). | Moderate confidence |
| 11. Diagnosis was important for improvement: diagnosis validated the pain experience, helped in abandoning the search for answers, helped in initiating self-coping strategies and gave entitlement to seek support. | 7 studies<br><br>(Durham et al., 2011a, Bonathan et al., 2014, Garro, 1994, Durham et al., 2010, Peters et al., 2015, Garro et al., 1994, Eaves et al., 2015) | Minor concerns (2 of the 7 studies have low CASP) | No or very minor concerns | No or very minor concerns | No or very minor concerns (1 study has a TMD sample in addition to other COFP conditions). | High confidence |

| | | | | | | |
|---|---|---|---|---|---|---|
| 12. Management: a range of treatment options were offered with varying degrees of success. They were inconsistent or inappropriate at times which led to ineffective or worse pain control. | 9 studies<br><br>(Breckons et al., 2017, Hazaveh and Hovey, 2018, Garro, 1994, Durham et al., 2010, Mienna et al., 2014, Garro et al., 1994, Fjellman-Wiklund et al., 2019, Nilsson and Willman, 2016, Eaves et al., 2015) | Minor concerns (3 of 9 studies have low CASP) | No or very minor concerns | No or very minor concerns | Moderate concerns (2 studies have a TMD sample in addition to other COFP conditions. 1 study consisted of Sami women. 1 study is consisted of adolescent patients). | High confidence |
| 13. Seeking support: patients appreciated being told about support groups. | 2 studies<br><br>(Bonathan et al., 2014, Ilgunas et al., 2020) | Very minor concerns | No or very minor concerns | Moderate concerns (supported by 2 studies only) | No or very minor concerns (1 study has a TMD sample in addition to other COFP conditions. | High confidence |
| 14. Family and friends: while some patients relied heavily on family and friends' support to cope with the pain, others preferred to deal with the pain on their own. They did not want to burden them with their pain or thought they would not understand. | 5 studies<br><br>(Au et al., 2014, Ilgunas et al., 2020, Hazaveh and Hovey, 2018, Nilsson and Willman, 2016, Eaves et al., 2015) | Minor concerns (1 of 5 studies has low CASP) | No or very minor concerns | No or very minor concerns | Moderate concerns (2 studies have a TMD sample in addition to other COFP conditions. 1 of which consisted of elderly patients. 1 study consisted of adolescent patients). | High confidence |

# Chapter 6: Development of a Patient-Reported Experience Measure for patients with TMD (PREM-TMD). Phase 1: A series of online focus groups.

## 6.1. Introduction

Chronic pain is one of leading causes of disability in the world (Vos et al., 2012). It is estimated that 100 million adults in the USA (Simon, 2012), and 28 million in the UK suffer from chronic pain (Fayaz et al., 2016). The clinical journey is a major part of the life of chronic pain patients. Hence, it is important to them that it is a pleasant one (Toye et al., 2019). In fact, the patients' feedback on the experience they encounter in healthcare services was established internationally as a marker of quality and a good source of information for improvement schemes (Raleigh et al., 2015). It seems however, that chronic pain patients frequently experience unsatisfactory clinical encounters (Toye et al., 2013b, Toye et al., 2017a, Toye et al., 2014, Fu et al., 2016). Similarly with patients with chronic orofacial pain, where it was previously reported that the current care pathways in the UK are still disorganised, resulting in delayed diagnosis and effective treatment for this cluster of patients (Breckons et al., 2017).

Patient Reported Experience Measures are validated tools which gather the patients' views of their experience while they are receiving care (Kingsley and Patel, 2017). The data gathered from such questionnaires help not only in improving patient-centred care but also grant vital feedback to care providers about patients' impressions, and provide a reliable tool for clinical research, audits, and quality improvement schemes (Kingsley and Patel, 2017). An experience questionnaire that is patient centred should encompass the values and aspects as prioritised by the target population (Paterson, 2004) .Therefore, their involvement in the development process is necessary (Wiering et al., 2017b, Wiering et al., 2017a, Meadows, 2011). Qualitative research is

appropriate in this case, as it involves asking patients about their experiences with certain conditions and settings. It is a means which enables researchers to gain access into well-grounded and rich descriptions of the world as experienced by others (Austin and Sutton, 2014)

## 6.2. Aims and objectives

This study aimed to discover the healthcare priorities for patients with TMD and to explore their journey within the National Health Service (NHS) in England, starting from primary care all the way to a tertiary clinical centre. The findings generated form this study, were used to generate the items of the proposed questionnaire.

## 6.3. Materials and methods

A qualitative methodology was chosen as it gave the participants the freedom to describe their journey in-depth and enabled them to offer valuable input regarding the important aspects of healthcare to them. The study received ethical approval from the Southeast Scotland Research Ethics Committee 1 prior to data collection (REC reference:19/SS/0130).

To ensure the safety of the participants and the research team, the group discussions took part using an online platform (Zoom) in response to the SARS-CoV-2 outbreak in the UK at the time of conducting the study.

### 6.3.1. Participants

There are no uniform recommendations regarding the ideal number of participants in focus groups. Streiner and Norman proposed that each focus group should contain 6 to 12 patients (Streiner et al., 2016), while Tausch et al recommended focus groups with 4-6 participants (Tausch and Menold, 2016). Therefore, five patients with TMD were recruited for each focus group in this study. The number of focus groups

depended on the point where data saturation was reached. Data saturation is achieved when no new themes or information are emerging (Gill et al., 2008).

The participants in this series were TMD patients with associated pain, diagnosed by facial pain specialists in a tertiary medical centre in central London with a facial pain unit. The diagnosis was later confirmed by the research team and the participants were classified according to the Diagnostic Criteria for TMD (DC/TMD). Purposive consecutive sampling was used to select patients who were over the age of 18, had a good command of the English language, and were able to give informed consent. Eligible participants were approached after their routine clinical visit and were informed about the study verbally and provided with a patient information sheet. If they were willing to participate, they were booked into a group discussion and signed a consent form. The consent was done remotely in line with the guidance of the Health Research Authority (HRA).

### 6.3.2. Data collection

The discussions were conducted by two moderators, and were audio recorded. Both interviewers introduced themselves as researchers and were not involved in the clinical care of any of the participants out of concern that they would hesitate to discuss any negative experiences. At the interview, they took care to avoid allowing their notions and expectations to influence the participants' answers. Both interviewers were clinicians and were trained in qualitative research.

Semi-structured interviews were used to elicit data from the participants as this method allows patients the freedom to describe their experience, but within the scope of pre-determined questions. The interviews were directed using a topic guide that covered a range of subjects, such as initial visits in primary care, referrals to secondary and

tertiary care centres, experience using NHS services and effect on symptoms along the way. Follow up and probing questions were also used. The guide was inspired by the previous qualitative evidence synthesis carried out in preparation for this study and was adjusted as the interviews progressed to elicit the data most suited to the aims of the research. The topic guide can be found in appendix 6. The participants were also asked to comment on the NHS patient experience framework at the end of each discussion and make suggestions on how to make it more suited to the experience of TMD patients, as it was used as a basis for the PREM in later stages (NHS, 2011, Bosworth et al., 2015). See Figure 6.1 for the NHS patient experience framework.

Data collection followed the constant comparative method, where the data gathered from each focus group was coded before holding the next one. Subsequently, these codes were constantly revisited, and interpretations were reviewed in light of the new gathered data, until it was clear that no new themes were emerging (Hewitt-Taylor, 2001). This approach allowed for examining each interview and comparing it to previously collected material, before any further data collection took place (Mathison, 2005), hence helping in guiding subsequent interviews.

Figure 6.1. NHS patient experience framework

NHS

# NHS Patient Experience Framework

In October 2011 the **NHS National Quality Board (NQB)** agreed on a working definition of patient experience to guide the measurement of patient experience across the NHS. This framework outlines those elements which are critical to the patients' experience of NHS Services.

- **Respect for patient-centred values, preferences, and expressed needs,** including: cultural issues; the dignity, privacy and independence of patients and service users; an awareness of quality-of-life issues; and shared decision making;
- **Coordination and integration of care** across the health and social care system;
- **Information, communication, and education** on clinical status, progress, prognosis, and processes of care in order to facilitate autonomy, self-care and health promotion;
- **Physical comfort** including pain management, help with activities of daily living, and clean and comfortable surroundings;
- **Emotional support** and alleviation of fear and anxiety about such issues as clinical status, prognosis, and the impact of illness on patients, their families and their finances;
- **Welcoming the involvement of family and friends,** on whom patients and service users rely, in decision-making and demonstrating awareness and accommodation of their needs as care-givers;
- **Transition and continuity** as regards information that will help patients care for themselves away from a clinical setting, and coordination, planning, and support to ease transitions;
- **Access to care** with attention for example, to time spent waiting for admission or time between admission and placement in a room in an in-patient setting, and waiting time for an appointment or visit in the out-patient, primary care or social care setting.

This framework is based on a modified version of the Picker Institute Principles of Patient-Centred Care, an evidence based definition of a good patient experience. When using this framework the NHS is required under the Equality Act 2010 to take account of its Public Sector Equality Duty including eliminating discrimination, harassment and victimisation, promoting equality and fostering good relations between people.

DH Department of Health

Gateway reference number 17273

### 6.3.3. Data analysis

Framework analysis was used for the purposes of this study. It is a part of a broad family of methods known as thematic analysis or qualitative content analysis. The method was developed by Jane Ritchie and Liz Spencer, from the Qualitative Research Unit at the National Centre for Social Research in the United Kingdom in the late 1980s (Ritchie and Lewis, 2003). Its defining feature is the matrix which is used to reduce the data and produce highly structured output (Gale et al., 2013). Framework analysis can be adapted to allow for inductive, deductive or a combined analysis approach, which was used in this study. There were specific issues to explore; the NHS patient experience framework gave a starting point to the aspects which were most important to patients generally. However, the analysis also left space for other unexpected aspects which might be specifically important to TMD patients. Therefore, the framework was set aside initially, and the analysis was data-driven so as not to overlook any important aspects.

Framework analysis consists of seven steps: transcription, familiarisation with the interviews, coding of the data, developing a working analytical framework, applying the analytical framework, charting data into the framework matrix, and finally interpreting the data (Gale et al., 2013).

The focus groups were transcribed verbatim first. The student researcher then became familiar with the data by listening to the audio recording and reading the transcripts simultaneously and writing reflective notes and initial impressions about the data. Next, the raw data was coded ‘openly’ meaning that the codes were generated based on the content of the transcripts and were not predefined before the analysis began. This was to adopt a more inductive approach and avoid missing any important data. The transcripts were coded line-by-line, and the similar codes were aggregated in a

common category. The natural categories which emerged, interestingly matched to a great extent the domains of the NHS framework. So, the emerging themes were then matched under the overarching themes (domains) of the NHS framework, which was modified slightly to better represent the experience of TMD patients. A combination of a priori aspects and emergent issues were used to develop the categories which best fit the data we had and answered the research question.

The initial framework which arose from this step was reapplied to the transcripts by indexing them using the existing categories to ensure that the data and codes were easily accessible. A spreadsheet was then generated to help in charting the data into the matrix (framework). Charting involved summarising and reducing the data to manageable levels. It was important to have a balance between trying to reduce the data, but at the same time to preserve as much context or 'feel' of the data so as to correctly interpret the finding in the later stages. Therefore, a brief description of the context of each code was added into the spreadsheet in addition to direct quotes from the participants to support the findings. Finally, the findings were interpreted in keeping with the context of the codes. Data interpretation involved moving beyond the data to try to make sense of it by exploring the themes and writing an analytical description with the help of the reflective notes, impressions, and context of the codes (Gale et al., 2013).

## 6.4. Results

### 6.4.1. Participants

Approximately 22 participants were invited (19 females, 3 males). However, five patients declined due to scheduling conflicts and two due to unwillingness to engage through an online platform. Eventually, 15 participants were able to take part (14

females, 1 male) with an age range of 19-79 years. The details of the participants are listed in table 6.1.

Data saturation was reached after holding three group discussions as no new themes emerged in the third interview. Each interview lasted approximately 80 minutes each.

Table 6.1. Participants details.

| Number | Sex | Age | Diagnosis | Group number | Consultations in a specialist pain unit. |
|---|---|---|---|---|---|
| 1 | F | 70 | Myalgia and DDwR. | 1 | Several consultations |
| 2 | F | 79 | Myalgia and arthralgia | 1 | Several consultations |
| 3 | F | 39 | Myalgia and headache attributed to TMD. | 1 | Several consultations |
| 4 | M | 55 | Myalgia and DDwR. | 1 | 1 consultation |
| 5 | F | 57 | Arthralgia and DDwR. | 1 | 1 consultation |
| 6 | F | 22 | Myalgia. | 2 | 2 consultations |
| 7 | F | 50 | Myalgia, DDwR with intermittent locking. | 2 | Several consultations |
| 8 | F | 19 | Myalgia. | 2 | 2 consultations |
| 9 | F | 28 | Myalgia, DDwR with intermittent locking. | 2 | 2 consultations including a telephone consultation. |
| 10 | F | 25 | Myalgia. | 2 | 2 consultations including a telephone consultation. |
| 11 | F | 27 | Myalgia and arthralgia. | 3 | Several consultations |
| 12 | F | 50 | Myalgia and Headache attributed to TMD. | 3 | Several consultations |
| 13 | F | 71 | Myalgia | 3 | Several consultations |
| 14 | F | 43 | Myalgia | 3 | 2 consultations |
| 15 | F | 79 | Myalgia | 3 | Several consultations |

### 6.4.2. Findings and themes

***Domain 1: Respect for patient-centred values, preferences, and expressed needs.***

Being believed and taken seriously

This element of care was among the most important for TMD patients. Several had negative experiences with this aspect, especially in primary care, where they encountered clinicians who were sceptical of their symptoms and the effect they had on their quality of life.

*“No [I wasn’t believed]. Especially when I said to him the pain had moved and he said 'no, no, it's all in your mind'. (Participant 14)*

*“And you know, just knowing that somebody actually is treating it seriously helps to cope.” (Participant 1)*

Decision making

Patients expressed the importance of being involved in the decision-making process and treatment planning. They were left frustrated when this was not the case, as they might have been expecting certain treatment options, and were left wondering why those options were not offered. This led to an unsatisfactory consultation, and feelings of being told what to do rather than discussing all available avenues.

*“So yeah, I think probably in summary it seems like the process you go through is rather rigid, rightly, or wrongly, I don’t know if that’s the case but that’s what it seemed to me. So I’ve had to go through these various hoops before I can get to this suggestion that my dentist made of a more rigid gum guard which they thought would help me”. (Participant 4)*

Expectations

Many patients came to their consultations with a set of expectations. Some of these expectations were realistic, while others were more attached to prior preconceptions. Patients expressed their wish for pain relief, reassurance about the nature of the condition and the possibility of effective treatment. Other patients also expected scans, x-rays, and certain treatment options.

Scans and tests when offered, were viewed as a positive step forward. It offered reassurance and showed that practical steps were being taken to address the problem.

*“I suppose I expected a confirmation of my diagnosis which probably meant that more tests had to be done (Participant 3)*

*“Obviously, I wanted pain relief, but I wanted reassurance that this is going to be something that I’m going to able to manage”. (Participant 7)*

***Domain 2: Coordination and integration of care***

Experience in primary care

Experiences in primary care varied. Some participants recounted negative encounters where they faced disbelief and scepticism regarding their symptoms. Partial explanations were given, and psychological distress was implied as the main cause of the symptoms. Some patients found this explanation unpleasant, adding to their distress, and in some cases making them feel helpless and desperate for some help.

*“So, after that, I kind of gave up and just thought oh if even the GP, the dentist, even the hospital tells me it's nothing, nothing abnormal” (Participant 11)*

*“I went home crying because I thought it's really in my head, no one's going to know anything or be able to give me any information whatsoever about the pain that I was feeling because it got to the point that I couldn't even eat” (Participant 11)*

The treatment approaches offered mainly consisted of medications such as antibiotics and pain killers, and bite guards. The lack of effective treatment coupled with lack of diagnostic certainty and reassurance was frustrating and stressful.

*“And then they tried to knock me out, put me under, and they tried to realign my jaw thinking it had been dislocated and it was the worst experience, I felt like my jaw was just going to snap because they were putting so much force” (Participant 11)*

*“For probably several years I’d been having tooth ache on and off and not realising, thinking I’d got a minor infection or something like that and getting antibiotics which obviously was of no help.” (Participant 4)*

Repeated clinical attendance to reach the right caregiver

The participants mentioned having to see several clinicians before reaching the right caregiver. They visited multiple general practitioners (GPs), general dental practitioners (GDPs), physiotherapists, and private clinicians. Reasons responsible were the lack of diagnosis, GPs and GDPs considering the condition not their area of expertise and referring to each other, and in some cases not knowing where to refer in secondary care, consequently leading to multiple referrals at the same time.

This struggle to reach the right caregiver made the participants feel frustrated and irrelevant, as often they were passed around with no real help. Once the right caregiver was reached, however, the clinical experience became much more positive.

*"I'd seen two GPs, two dentists and two admittances to A&E and no one had any idea, like no idea whatsoever" (Participant 11)*

*"I had the exact same thing of the dentist passed me to the GP, and then the GP passed me back to the dentist. I think that went on for me for at least a year, where it was just like, oh, I think you have TMD, but you should go to the GP because we don't know how to treat that, and whatnot, and it was a bit confusing" (Participant 10)*

*"So, much more positive and in terms of knowledge, understanding and actually working together as well, so yes, it was a much more positive experience when I had the right people" (Participant 12)*

Road to secondary and tertiary care

The road to specialist units consisted of both positive and negative experiences. Positive accounts described a smooth referral process and short waiting times to get an appointment. While negative accounts outlined a stressful process of long waiting periods to get an initial appointment stretching up to a year and a half. Referral letters were also sometimes 'lost in the mix' and caught in a lot of red tape.

This lengthy period of waiting for consultations with people of expertise sometimes had a negative impact on the symptoms. Patients explained that it was mainly the natural progression of the condition without effective management, in addition to the stress of waiting for a confirmation of an upcoming appointment. On the other hand, some patients' symptoms were better during the waiting period, and they felt 'silly' coming into their appointment as there was nothing much to report.

*"Probably worse because all the stress didn't help because, like I said, they kept telling me they had sent it. But, whenever I spoke to [the hospital], they hadn't received any information regarding me from the dentist" (Participant 11)*

*"My symptoms continued to get worse. .... They were just getting worse on a daily basis. I don't think it was because I was anxious having an appointment or getting to my appointment. I think it's just naturally I was just getting more pain". (Participant 9)*

Coordination of care

Once under the care of a specialised unit, the patients emphasised the importance of the coordination of care from an administrative point of view and also between clinicians, departments, and other hospitals as well.

Timely and coordinated referrals were important, and patients were left frustrated when they took a long time to come through or were cancelled without notice. Again, this delay caused agitation, and worsening of symptoms on occasions. Patients also described the importance of a clear pathway of care.

*"[The referral] that wasn't done right in my case, so I had to chase. But I felt I was very much the person that had to be on it and if I didn't instigate and if I didn't push things would have not happened so…" (Participant 3)*

Some specialised hospitals, being NHS-run teaching hospitals, allow for different clinicians to care for the same patient during follow up appointments. Good coordination between these clinicians was highlighted. The participants encountered

clinicians offering different input to their regular doctors, who were occasionally uninterested, or discharged them from the service. This caused stress and disappointment as they had to fight their way back into the system.

*"When I keep coming in, you know, I would be seeing different people, and that was really stressing me out, and the stress does make my situation a lot worse". (Participant 7)*

*"On one occasion I was really, really upset, and this is what I meant by when I saw a different doctor. I don't think she went through my notes very well". (Participant 7)*

*"I'd come in and I wouldn't be seeing my regular doctor, and I had to keep explaining myself, and on one occasion I was actually discharged from the hospital because the doctor that I normally see wasn't there" (Participant 7)*

Organised care

Organised care was expectedly brought up as an important aspect of care, especially in reference to the cancellation and confirmation of appointments. Short notice changes or cancellations of appointments were reported occasionally and were frustrating to the patients especially during episodes of flare up where they need to see their caregiver.

*"Well, I live in the northeast and I think it was on the Friday and I said I can't possibly, it's such short notice and he said well, you've missed a lot of appointments. I said well, I've never had any letters" (Participant 15)*

***Domain 3: Information, communication, and education***

Diagnosis

Early on during their journey with TMD, most participants seemed to struggle with receiving a diagnosis. An official diagnosis was given early in some cases, but more often than not, the symptoms were brushed over as 'just grinding' or stress related. Patients expressed relief to finally get a label, as it meant that their symptoms were

not ‘nothing’ and they were not imagining their pain. Diagnosis offered reassurance and relief that things will take off and treatment can therefore commence after struggling to validate their pain for a long time.

*“For probably several years I’d been having tooth ache on and off and not realising, thinking I’d got a minor infection or something like that and getting antibiotics which obviously was of no help” (participant 4)*

*“So it was really a relief for me to find out that at least now they can give me treatment for my problem” (participant 2)*

Information and education

Receiving adequate information about TMD was equally important to patients. They appreciated dealing with a knowledgeable and informative clinician, and welcomed the extra material given at the end of the clinical visits in the form of leaflets. These handouts helped them understand their condition better especially as not all the oral information sink in at the time during the consultation.

Other sources of information which would be appreciated were links to trusted websites to read further about TMD, links to private avenues for treatments not funded by the NHS, and information about up-and-coming research regarding TMD.

*“Well, I think the doctor that I saw gave me a handout which I find really good because when you're at the appointment you don't always take everything in. And so, when you get home, you can read about it”. (Participant 12)*

*“It felt nice to talk to someone who obviously knew what they were talking about. I felt like I got a little bit of clarity”. (Participant 10)*

Communication

Communication, or lack thereof, was unsurprisingly upsetting to patients. On occasions, appointments were cancelled without prior notice, treatment options were

cancelled due to funding withdrawal, patients were discharged without their knowledge, or had to chase up their referrals as no confirmation was given for extended periods of time. When encountered, this lack of communication was unpleasant, and left the patients feeling ill prepared for their next appointments. They also emphasised the importance of good communication with their GP or GDP, especially in terms of medications and treatment options.

Suggestions for better communication included: an efficient point of contact with the service, a text reminder of appointments beforehand rather than voicemails or phone calls, and reference codes allocated for each patient that details the information of upcoming clinical visits.

*"They didn't tell me until I got there and when I got there, to be told that sorry we can no longer offer this service to you, I broke down a little bit because I had nothing else." (Participant 11)*

***Domain 4: Physical comfort***

Pain control and treatment plan

Most patients appreciated having a clear 'action plan' to control the pain where different treatment options were offered and discussed. This was reassuring and encouraging as it signalled that 'something can be done', and if one thing does not help, there is an alternative. They also welcomed the holistic approach of management and a clear long-term strategy.

The patients also emphasised the importance of prompt and timely management. They believed that if they received the right treatment earlier, they would not be in this level of pain now.

*"Yes, and also the willingness to try something else when it comes along. Not to say well, pop in in six months and we'll check and then you're just doing the same thing over and over" (participant 1)*

*"I think they relieved my stress a little bit, because now I can try all these different options, and if they don't work then I can just come back, and we can try something else" (Participant 10)*

Comfortable clinical environment

As any other group of patients, being surrounded in a comfortable and inviting clinical environment was welcome. That includes a clean, aesthetically pleasant, and easy to navigate building.

*"I was very welcomed; it was very clean and inviting so that was all good" (Participant 4)*

***Domain 5: Emotional support***

Understanding and recognition of suffering

One of the themes that emerged strongly in the three groups was the need to be believed, listened to, and taken seriously by healthcare professionals. They expressed a need to be understood and for their symptoms not to be downplayed or dismissed. For some participants, the effects of TMD were profound on their lives. However, several encountered negative experiences where they were turned away and were told the symptom were in 'their mind'. They felt frustrated trying to explain the pain and encountered primary healthcare providers who became annoyed with them and suggested dealing with the symptoms on their own.

One participant recounted an extreme case in primary healthcare where she was told she 'was lying' about her symptoms because her jaw was working normally. She became desperate and helpless that no one was ever going to help.

*"The hospital, he told me I was point blank lying because it couldn't be my jaw because I could talk, so it wasn't anything to do with my jaw, it was all in my head basically". (Participant 11)*

Being believed, listened to, and understood, sometimes invoked an emotional reaction in some patients. They felt relieved and reassured to have a care provider who appreciated the effect the pain was having on their lives. They also felt they were better able to cope once they were taken seriously.

*"I think just the fact that it is recognised that actually this condition is very uncomfortable, painful and it's not just a nothing because sometimes it's very disturbing" (Participant 1)*

*"I just got used to the pain, I guess, because it felt like no-one was really taking it seriously, and they didn't understand the symptoms, and didn't understand the impact it could have on your life" (Participant 9)*

<u>Interaction with the clinician</u>

Unsurprisingly, the clinician played a big role in the clinical experience. They felt reassured when the clinician offered enough time for each patient and ensured the information was understood. These qualities made them feel supported, made the hospital experience very positive and helped them cope better with the pain.

On the other hand, clinical interactions could be a source of stress. Such as when trying to convince the clinical team of the sincerity and impact of the symptoms, when no reassurance and diagnosis were offered after several visits, or when treatment was delivered in a slow and rigid manner.

*'The first time I felt I wasn't being listened to, and I think with this kind of condition it's very important that the patient feels that they are being listened to'. (Participant 7)*

*'And to know that you're under the care of people that know what they're doing, what's going on with your condition. I think that's quite reassuring'. (Participant 7)*

Group sessions/forums

The benefit of supervised group meetings was highlighted. Such discussions reassured the patients of the validity of their complaints and addressed some fears about the expected course of the condition. Even after a satisfying clinical encounter with a clear diagnosis, the whole picture may still be incomplete. So, these groups offered the opportunity to obtain more information and try new things.

*'But it was probably one of the most positive experiences I had right at the beginning when I didn't really understand what was going on'. (Participant 12)*

***Domain 6: Transition and continuity***

The participants were aware that TMD is a chronic pain condition, and that self-management is key. However, they pointed out the importance of regular reviews with their doctors, as it helps them stay motivated and keeps the management plan under review. They reported that despite the advice and recommendations from doctors, they may still go through episodes of severe pain during which they need support form professionals.

*"Yeah, and also continuity. I think it's really important that people see familiar faces. I know it's not always possible, but I think, for me, that's very important" (Participant 7)*

***Domain 7: Access to care***

The participants highlighted different stages of access to care, starting with getting the actual appointment in a specialist unit and waiting for that, access and navigation of the relevant building, and waiting times in clinic. In some cases, waiting for the initial appointment with a specialist centre was a long process, stretching up to 18 months.

This extended period of waiting could worsen the symptoms and add to their stress and frustration.

Another aspect of access highlighted was in cases of emergency. TMD patients might experience sudden locking of the jaw or episodes of intense pain. They were aware of the long-term nature of care, but also would appreciate prompt access in cases where they need extra support or help urgently.

*'So, there was no emergency place, which I found really, that's what I needed, and it wasn't there'. (Participant 6)*

The patients also highlighted the importance of helpful and efficient reception area, along with a smooth check-in process in making their experience more pleasant.

*"Well, it was delayed, I waited probably 2.5 hours to be seen anyway because things were so chaotic." (Participant 5)*

***Domain 8: Welcoming the involvement of family and friends***

Interestingly, the involvement of family and friends in care was not crucial to this group of participants. They mentioned that they may turn to them for support, but they would not necessarily involve them in their care, as most of them attend to their appointments alone anyway. They did acknowledge, however, that it may be crucial for other patients who need support, so were careful not to dismiss this area as an important part of the clinical experience.

***Domain 9: Accountability***

An extra theme that emerged was the need for accountability. Patients felt the need for a point of contact, through which they could give comments and feedback about their care. This outlet would also act on behalf of the patients in following up on appointments and referrals.

*"I think you always need someone who is accountable that you can go back to if things start to go wrong or you have questions." (Participant 4)*

***Domain 10: Transparency***

Transparency in dealing with the service users was also underlined. Patients prefer to hear accurate information even if it was unpleasant. For example, they prefer to know that the waiting lists for certain procedures were long, rather than being left wondering when they might hear back. This promotes understanding and manages expectations rather than evoke annoyance and frustration.

*"Yes, because I think if you're told you've got to wait six months it's probably an unpalatable thing to say to someone but at least they know." (Participant 4)*

## 6.5. Discussion

Qualitative research provides valuable insight into the patients' experiences and could be used to inform clinical decision making and patient care (Tong et al., 2016). One of the difficulties which may be encountered in a clinician-patient relationship, is the discrepancy between 'the objective body and body as lived'. This gap in experiences may create a difference in the approach to illness, leading in turn to a lack of shared assumptions about moving forward. Qualitative research is therefore an excellent tool to portray the reality of the area under investigation and enhance understanding of the situation (Hewitt-Taylor, 2001).

Qualitative research is also contextual, meaning that the setting of the research matters. Hence, it is important to report on this aspect clearly, to enable the reader to determine the relevance and applicability of the research findings. This piece of research consisted of group discussions which took place online with TMD patients, recruited from facial pain clinics at an NHS tertiary care centre in London. Some of the findings reported here may well apply to other settings, for example primary care, or

even a different country all together. However, this may not always be the case, such as with findings pertaining to referrals and access to care. These may differ from one country to another, or even from one centre to another in the same city. Additionally, the qualitative researcher may also influence the findings. In fact it is sometimes said that 'the researcher is the research instrument' (Dodgson, 2019). Therefore, it is also important to describe who is doing the research and their positionality in relation to what is being studied. This concept refers to what is known as 'reflexivity' in qualitative research, or " awareness of the influence the researcher has on the people or topic being studied, while simultaneously recognising how the research experience is affecting the researcher" (Gilgun, 2008). The researchers involved in data collection were both clinicians. However, they were not involved in the clinical care of any of the patients, to avoid influencing their accounts in case they had negative experiences with their caregivers at the hospital. Data analysis was likewise conducted by an 'outsider' (the student researcher), who did not meet the patients prior to the relevant research activities. Moreover, the analysis process was documented, where a track was kept of the decisions made, in case these choices were to be revisited. Having said that, reflexive analysis remains challenging, where in the words of Finlay "It is all too easy to fall into an infinite regress of excessive self-analysis at the expense of focusing on the research participants" (Finlay, 2002).

Focus groups are a popular method in health research to gain perspective and understanding, whether it is patients', clinicians' or other groups (Côté-Arsenault and Morrison-Beedy, 2005, Tausch and Menold, 2016). They are a useful method in topic exploration, questionnaire development and phenomenon descriptors (Côté-Arsenault and Morrison-Beedy, 2005). When done well, a great deal of information could be obtained from a small group of patients, and with guidance, participants can go back

and forth in the discussion and produce a rich blend of perspectives (Côté-Arsenault and Morrison-Beedy, 2005) . Additionally, they might generate more ideas and give a wider coverage of a specific problem than individual interviews (Tausch and Menold, 2016). One of the main disadvantages of focus groups, on the other hand, is the extensive effort and time required to organise them. Moreover, the discussion involving multiple people could easily drift off-track and moderators may find it difficult to bring it back on-course. They could also suffer from over or under dominance of certain individuals. These problems, however, can be solved by intervening verbally or by having experienced moderators (Wiering et al., 2017b). Another aspect to consider when planning focus groups is the number of participants. The number should be large enough to gain enough understanding of the different opinions and perspectives, while small enough to allow everyone sufficient time to participate fully. Too few participants may add some pressure on some of them to constantly speak, while too many may interfere with the flow of the discussion and hinder the participation of some (Côté-Arsenault and Morrison-Beedy, 2005). Hence, five participants were selected for each group in this study.

This series of focus groups aimed to increase our understanding of the aspects of healthcare that were important to patients with TMD. The participants gave accounts of the difficulties encountered in healthcare in general, but also specific to TMD patients. As with other chronic pain conditions, they struggled in several aspects, notably the struggle to be believed and taken seriously. In many cases of TMD, there may not be tangible evidence of pathology, and the clinician relies mainly on the story of the patient. Some participants have recounted not only disbelief and scepticism, but also harmful practices to address the pain, such as ‘jaw realigning’ procedures and teeth extractions. This disbelief was not only encountered in a clinical setting but also

extended to affect social and familial relationships (Durham et al., 2010, Hazaveh and Hovey, 2018). Patients struggled to articulate the pain they were going through to family members, and ultimately gave up trying to explain. A confirmed label to the condition may therefore help TMD patients to a great effect. A diagnosis, along with a satisfying clinical encounter, a reassuring clinician and receiving enough information about the condition were important factors in the ability to cope and move forward with the pain. It offered reassurance of the legitimacy of their complaints and meant that things can take off in terms of management.

Frequent clinical engagement seems to be a genuine issue for patients with chronic orofacial pain (COFP). Breckons et al studied the clinical pathways of patients with COFP in the UK, and suggested that the current pathways do not meet the patients' needs (Breckons et al., 2017). A major problem identified was the lengthy periods to obtain a diagnosis and adequate treatment from first presenting with the complaints. Patients also reported repeated clinical attendance in primary and secondary care in search of effective pain control. The participants in this series of focus groups reported that they were bounced back and forth between dentists and GPs as each considered facial pain a part of the others' expertise. Primary care clinicians also referred to several specialities at one time, due to uncertainty about which centres or specialities deal with these kinds of complaints. This may have added unnecessary burden to the NHS and delayed access to effective treatment.

These results are also mirrored in the chronic pain literature as well. For example lack of interest shown by healthcare professional, and long waiting times in secondary care (Hadi et al., 2017). Hadi et al also highlight the lack of GPs' specialised knowledge in pain management, short consultation times, and the lack of a multidisciplinary approach (Hadi et al., 2017).

The reported benefits from group sessions should be taken into consideration. This brings to the discussion the possibility of creating a regular supervised platform for these patients. The financial and logistical implications may well prevent such a regular exercise in most care facilities. However, with the increasing evidence of the benefit of these platforms (Subramaniam et al., 1999, Farr et al., 2021), it may prove to be cost effective in the long term in managing the mental and psychological wellbeing of these patients.

The participants confirmed the suitability of the NHS framework to their experiences in healthcare. Interestingly, however, some participants suggested two additional domains, accountability, and transparency. They were mentioned in the sense of preferring an effective point of contact with the service, to receive feedback and act on behalf of the patients in managing appointments and referrals should problems arise.

Limitations

The limitations to this piece of research included the inherent limitations associated with online focus groups. Such limitations include technical difficulties and the disruption to the flow of the discussion in the case of loss of connection. Additionally, probing may prove a more difficult task, as the moderator may not be able to pick up on non-verbal cues and body language (Fox et al., 2007). The participants however were comfortable using the chosen online platform and faced no technical issues during the recorded sessions. Data security was maintained by having passwords to protect the meeting. Therefore, no one without an invitation from the host was able to gain access to the meeting room.

Additional limitations were related to the sample used. The research team attempted to recruit a representative sample of TMD patients as much as possible, by including

participants of both genders, with positive and negative experiences, and new and follow up patients with a wide age range and diverse ethnic backgrounds. However, it was difficult to recruit more male participants due to scheduling conflicts and willingness to engage in online discussions. This may have affected the generalisability of the results. It is worth noting however, that females are more likely to develop persistent TMD (Slade et al., 2013a, Palmer and Durham, 2021), with a female: male ratio reported between 4-8:1 in a clinical setting (Leeson, 2007, Drangsholt et al., 1999, Bush et al., 1993, Maixner et al., 2011). This may have skewed the sample in favour of female patients attending clinical appointments for treatment of TMD.

Some participants may have held back on their negative accounts out of concern that their feedback could reach their caregivers. However, they were thoroughly assured prior to taking part that the answers will remain anonymous and none of their clinical team members were directly involved in moderating the groups so as not to affect their willingness to share their views.

## 6.6. Conclusions

Unsurprisingly, many of the aspects of care which are important to TMD patients are shared with other patient groups as well, such as fast access to care, coordinated referrals, and good communication with the clinical team (Nguyen et al., 2011, Foley et al., 2016, Chipidza et al., 2015). The findings suggest that delays in delivering appointments with people of expertise may have caused worsening of symptoms. On occasions due to the stress of chasing up a referral which did not materialise, or on other occasions due to the natural progression of the condition without any effective treatment. It may be worthwhile for future research to explore the effect of the different facets of healthcare on the perceived outcomes and measure the most influential

aspects so as to prioritise them if attempts were made to correct the care pathways of COFP patients. Research could also investigate the possibility of promoting the NHS health centres which deal with COFP among primary care clinicians. This may result in faster referrals and help avoid unnecessary referrals to centres which do not offer treatment for chronic pain.

The next step involved the second phase of developing the PREM for patients with pain related TMD. The findings from this qualitative study, in addition to the previous qualitative evidence synthesis, ensured data triangulation by collecting data from different sources and were used next to generate the items of the questionnaire. Later stages also tested the validity and reliability of the questionnaire using a quantitative design.

# Chapter 7: Development of a Patient-Reported Experience Measure for patients with TMD (PREM-TMD). Phase 2: Item formulation, expert opinion, and cognitive testing.

## 7.1. Introduction

The use of patient reported measures has recently increased, in recognition that patient input is important to evaluate the status of health, quality of life and other outcomes of treatment (Rothrock et al., 2011, Willke et al., 2004). For some constructs of health, patient reported measures are the only way to gauge changes, such as pain levels, distress, and satisfaction with care (Rothrock et al., 2011). In many cases, several instruments exist for the same construct or outcome, thereby making the development of a new instrument unnecessary. Where the development of a new instrument is needed, one of the initial stages is to define the construct to be measured and develop a conceptual framework. This is done by describing the components of that framework and the possible linkages among them (Rothrock et al., 2011, Earp and Ennett, 1991). The assistance of domain experts and patients can serve this purpose, by providing qualitative data which can help in framework creation and enhancing the content validity (Brod et al., 2009). Patients can describe the components of the construct most important and relevant, and experts can provide insight into the components most relevant clinically and commonly shared among the patients (Rothrock et al., 2011).

A new instrument can be developed rigorously by acquiring input from previous literature, the target population and from experts in the field (FDA, 2009). A review of the literature can reveal the way a concept had been described in previous works, explore related items form existing measures, and inform response options and recall periods (DeWalt et al., 2007). Patient input can be obtained through various stages of

development, starting from concept elicitation through focus groups or interviews, and cognitive testing to assess the suitability and readability of the proposed instrument.

Patient reported instruments are broadly developed by applying several steps, starting with item generation, item reduction and improvement, formatting the questionnaire and psychometric analysis (Tadakamadla et al., 2017, Hepworth et al., 2019, Gondivkar et al., 2018). Item generation is facilitated by interviewing the patients.

In the previous chapter, patient input was procured to identify the important aspects of healthcare to TMD patients. The findings from these group discussions, in addition to the previous qualitative evidence synthesis, were used to generate the items of the questionnaire. Subsequently, cognitive testing was planned to test the suitability, relevance, and acceptability of the new tool.

## 7.2. Aims and objectives

1. To generate a candidate list of questions to be included in the new instrument.

2. To obtain input from domain experts, where they assess the suitability of the items.

3. To obtain further input form the target population through a series of cognitive interviews, where they assess the relevance, comprehensibility, and comprehensiveness of the newly developed PREM.

## 7.3. Materials and methods

### 7.3.1. Design

A qualitative study design was adopted in the initial stages of PREM development, in the form of focus groups for concept elicitation and subsequently individual interviews for cognitive testing.

The NHS patient experience framework was used as a basis of the PREM as it consists of a comprehensive list of domains which are important to patients (NHS, 2011, Bosworth et al., 2015). The domains are respects for patient centred values, coordination and integration of care, information, communication and education, physical comfort, emotional support, welcoming the involvement of family and friends, transition and continuity and finally access to care. These domains were inspired by the Picker's Institute principles for patient-centred care (Paparella, 2016) and were used as a basis of other PREMs such as the patient-reported experience measure for patients with Rheumatoid Arthritis and other rheumatic conditions (Bosworth et al., 2015). Patient experience has several definitions such as 'what the process of receiving care feels like for the patient, their family and carers' (2013), or the 'feedback from patients on what actually happened in the course of receiving care or treatment, both the objective facts and their subjective views of it' (2012c). This was the construct intended for this instrument.

The study received ethical approval from the Southeast Scotland Research Committee 1 and the Health Research Authority (HRA) prior to data collection. (REC reference:19/SS/0130).

### 7.3.2. Participants

The target population were patients over the age of 18 with TMD with associated pain, diagnosed by specialists in a facial pain unit at the Eastman Dental Hospital. The patients were later classified according to the Diagnostic Criteria for TMD (DC/TMD) by the research team. They were competent in the English language, able to give informed cosent and had at least one clinical visit to the specialist facial pain unit. Following the recommendations of the COnsensus-based Standards for the selection

of health Measurement Instruments (COSMIN), seven participants were enrolled for cognitive testing.

Participants for the interviews were first screened and approached during their routine clinical visits where they were given written information about the study. Informed consent was obtained remotely, while adhering to the guidance of the HRA for e-consents. Once written consent was obtained, the interviews were scheduled.

### 7.3.3. Item generation

The findings from the previous series of focus groups, in addition to the findings of the qualitative evidence synthesis, were used to generate the priority items for the new PREM. Multiple questions were generated for each domain to address the patients' concerns and to capture the important aspects of care for this group of patients. The questions covered a range of topics relevant for new patients as well as follow up patients.

The items were checked for clarity, and negative wording. The proposed response options ranged from 1-5 representing the following: (5) "Strongly agree", (4) "Agree", (3) "Neutral", (2) "Disagree", (1) "Strongly disagree", in addition to one extra option of "Not applicable" if the item does not apply to them.

### 7.3.4. Item reduction and improvement

#### 7.3.4.I. Experts' input

The list of candidate questions was circulated to six healthcare professionals who manage TMD patients regularly for comments about the suitability, relevance, comprehensiveness of the items, and the general format of the questionnaire. Several discussions were held where suggestions were made to the length of the questionnaire and the wording of some items.

### 7.3.4. II. Cognitive interviews

The aim of cognitive debriefing was to ensure that the candidate list of questions was relevant, comprehensive, and comprehensible and to ensure that they were readable and worded appropriately. It did not involve a wider inquiry into the experiences and concerns of the patients, as it aimed to keep to the conditions as close to those of questionnaire completion in reality, with the added feature of verbalising their thoughts (Paterson, 2004, Jobe and Mingay, 1989, Subar et al., 1995).

Seven participants were enrolled at this stage to give feedback regarding the readability, relevance, comprehensiveness, and comprehensibility of the questionnaire. In each interview, the participants were asked to read the questionnaire, and think aloud (Charters, 2010). The purpose of this exercise was to ensure that participants interpret the questions similarly and as intended by the research team. In addition, they were invited to assess the acceptability and readability of the questions and suggest any missing items. The participants were also asked to mark the importance of each question on a five-point likert scale ranging from ‘very important’ to ‘not important at all’ (Baró et al., 2009). The purpose of this exercise was to identify the most important questions, in order to be able to reduce the number of items.

Bristowe et al reported in their study to develop a PROM which reflects the breadth of concern for patients with HIV, that participants with HIV preferred questionnaires no longer than two pages (up to four sides) or no longer than 25 questions long (Bristowe et al., 2020). Therefore, the questions with the highest mean importance score were selected for inclusion with a view of keeping the list close to 25 questions without compromising important questions.

After selecting the items and implementing the participants' comments, one participant was shown the modified version of the PREM to ensure that the changes were acceptable and important items were not removed.

Further refinement and item reduction was expected at the later stages of development, such as during the statistical validation and reliability testing.

## 7.4. Results

### 7.4.1. Participants

Seven participants were enrolled to take part in cognitive interviewing (6 females and 1 male), with an age range of 39-79.

They were recruited from different facial pain and oral surgery clinics in order to get a comprehensive view regardless of the way the clinician operates. Five of the participants took part in the previous focus groups and were interested to take part in the subsequent interview. Table 7.1 describes the details of the participants.

Table 7.1. Participants details.

| Participant number | Gender | Age | DC/TMD classification | Participation |
|---|---|---|---|---|
| 1 (#1 in FGs‡) | F | 70 | Myalgia, DDwR† | Focus group + cognitive interview |
| 2 (#2 in FGs‡) | F | 79 | Myalgia, arthralgia | Focus group + cognitive interview |
| 3 (#3 in FGs‡) | F | 39 | Myalgia, headache attributed to TMD. | Focus group + cognitive interview |
| 4 (#12 in FGs‡) | F | 50 | Myalgia and Headache attributed to TMD. | Focus group + cognitive interview |
| 5 (#13 in FGs‡) | F | 71 | Myalgia | Focus group + cognitive interview |
| 6 | M | 68 | Myalgia, DDwR† | Cognitive interview |
| 7 | F | 62 | Myalgia | Cognitive interview |

†: Disc displacement with reduction. ‡: focus groups.

### 7.4.2. Item generation

The PREM was designed as a series of questions that came under each domain of the NHS patient experience framework, with response options ranging from ‘Strongly agree’ to ‘Strongly disagree’. The questionnaire contained nine domains, as opposed to the seven domains suggested in the original framework. Two extra domains (accountability and transparency) were suggested by the participants of the focus groups and were added to allow for comprehensiveness at this stage.

The preliminary list of candidate questions was 52 questions long. The questions were developed while taking into consideration the different ways the clinics operate at the hospital, whether it is the first clinical visit or a follow up visit, and whether the patient was discharged or referred following their visit. The respondents were also offered the opportunity to add any additional remarks in a comments box at the end of the questionnaire. The candidate list of questions is shown in table 7.2 which also details the source of the question and a supporting quote. The items highlighted in bold were questions inspired from the qualitative evidence synthesis.

Table 7.2. List of preliminary items

| Items | Quotes (Focus groups and **systematic review**) to support item |
|---|---|
| Domain 1: Respect for patient-centred values, preferences, and expressed needs. | |
| **Being believed and taken seriously**<br>1. I was treated respectfully as an individual<br>2. I felt believed and was taken seriously<br>3. The clinical staff showed interest in my condition<br>4. The clinician appreciated the effect the pain has on my life | *No [I wasn't believed]. Especially when I said to him the pain had moved and he said 'no, no, it's all in your mind'.*<br><br>*The hospital, he told me I was point blank lying because it couldn't be my jaw because I could talk, so it wasn't anything to do with my jaw, it was all in my head basically.*<br><br>*And you know, just knowing that somebody actually is treating it seriously helps to cope.*<br><br>*she wasn't really interested in my situation with my jaw, and it just, kind of, upset me.*<br><br>*I just got used to the pain, I guess, because it felt like no-one was really taking it seriously, and they didn't understand the symptoms, and didn't understand the impact it could have on your life.* |
| **Decision making**<br>5. I had a discussion with the clinician about the treatment options<br>6. I was involved in the decisions about treatments and care strategies | *So yeah, I think probably in summary it seems like the process you go through is rather rigid, rightly or wrongly, I don't know if that's the case but that's what it seemed to me.*<br><br>*Maybe you can have some kind of feedback into that as opposed to just saying right, we're going to do this, this and this. I don't know. In some cases maybe there are options and they can be discussed with you which probably happens anyway but it would be nice to see that in there maybe.* |
| **Expectations**<br>7. The care strategy matched my expectations<br>8. **The clinical visit helped manage my expectations** | *I was hoping for a bit more, to be honest because I've still got a problem and the exercises I was doing weren't helping at all really and actually irritated it sometimes, it actually made it more sore.* |

| | |
|---|---|
| | ***"You want a magic wand waved over and then it's [the pain's] gone...Then reality kicks in and you think no that's in never never land, that's not the way it works."*** |
| Domain 2: Coordination and integration of care | |
| **Repeated clinical attendance to reach the right caregiver**<br>9. I feel I have reached the right caregiver for my condition | *I had the exact same thing of the dentist passed me to the GP, and then the GP passed me back to the dentist. I think that went on for me for at least a year, where it was just like, oh, I think you have TMD, but you should go to the GP because we don't know how to treat that, and whatnot, and it was a bit confusing* |
| **Referral to the Eastman**<br>10. I waited a long time to get an appointment here<br>11. The referral process to this hospital was a smooth one<br>12. My symptoms did not get worse whilst waiting for my appointment here | *I had to wait about a year and a half to get any form of an appointment at the Eastman, and then once I did then I had a really good experience. It was just the administrative side, which was really slow, for myself anyway.*<br><br>*I had to pay my dentist to even give me a new letter that I then had to take up to Eastman's myself because she told me twice it had been sent and a year later, I still had not heard anything from them.*<br><br>*My symptoms continued to get worse. . I think it's just naturally I was just getting more pain. My jaws were getting worse. The clicking was getting worse. The locking was getting worse as part of my condition.* |
| **Coordination of care**<br>13. I am made aware of the different teams that will/are looking after me<br>14. The pathway of care is clear to me<br>15. The onward referrals were timely and coordinated (if you had any yet).<br>16. There is good coordination between the different clinicians who look after me<br>17. The health team is fully up to date with my situation | *I don't know what's happening, I hadn't heard anything either. I was being referred back I think to my original one [ENT] but I've not heard anything.*<br><br>*Not at all because I had an ear problem at the same time and they've kind of crossed over and I've kind of got lost in the mix of it all. So I don't really know where I'm going with it now even because there isn't a clear pathway.* |

| | |
|---|---|
| | *[The referral] that wasn't done right in my case so I had to chase. But I felt I was very much the person that had to be on it and if I didn't instigate and if I didn't push things would have not happened so… When I keep coming in, you know, I would be seeing different people, and that was really stressing me out, and the stress does make my situation a lot worse.*<br><br>*But also not take up the appointment time just having to re-explain yourself. Rather spend it on perspectives, on solutions, and not having to explain yourself.* |
| **Organised care**<br>18. My appointments are well organised<br>19. I did not experience unexpectedly cancelled or delayed appointments<br>20. I receive reminders of my appointments an acceptable period beforehand | *But, since it's been the new building, they've never stuck to one appointment, they always give you one then cancel it, change it, they might not send you a letter or they might forget to call you or to remind you of which appointment is still standing.*<br><br>*Well, I live in the north east and I think it was on the Friday and I said I can't possibly, it's such short notice and he said well, you've missed a lot of appointments. I said well, I've never had any letters.* |
| Domain 3: Information, communication, and education | |
| **Diagnosis**<br>21. **I received a diagnosis for my condition during my initial visits here** | ***"I mean you had a name for it and you knew you weren't alone with it so it eased your mind totally really knowing that it wasn't anything too serious."*** |
| **Information and education**<br>22. I received enough information about my condition<br>23. I was given extra material to read about my condition<br>24. I feel adequately educated about my condition?<br>25. I was given enough time to ask any questions | *Well, I think the doctor that I saw gave me a handout which I find really good because when you're at the appointment you don't always take everything in. And so, when you get home you can read about it. (3)*<br><br>*I thought it never felt rushed. There was always time to ask questions and ensure that I'd understood the information that I'd been given, so that was always very nice.* |
| **Communication**<br>26. There is good communication with the hospital<br>27. I am made aware of a means of communication with my clinical team | *And then you get other departments that are completely dysfunctional, communication is pretty bad and you're constantly trying to chase up stuff that should be happening.* |

| | |
|---|---|
| | *So it would be nice to have some sort of PA or person that you speak to because as I said, I waited months on end to find out that it was not done in the first place.* |
| Domain 4: Physical comfort | |
| **Pain control and treatment plan**<br>28. I am satisfied with the treatment plan decided<br>29. The long-term care strategy is clear to me<br>30. The treatment options were delivered in a timely manner<br>31. **Pain control is adequate enough to let me get on with daily life activities** | *Yes, and also the willingness to try something else when it comes along. Not to say well, pop in in six months and we'll check and then you're just doing the same thing over and over.*<br><br>*So, I still don't know what there is for me to do for the future. I have no idea because I haven't got any idea of what's going to happen next.*<br><br>*So from being referred back in September, I haven't had any sort of what's the word for it…actual hands-on treatment in any form at the moment, which is a bit frustrating, I guess.* |
| **Comfortable clinical environment**<br>32. The surrounding physical environment was comfortable | *I was very welcomed, it was very clean and inviting so that was all good.* |
| Domain 5: Emotional support | |
| **Understanding and recognition of suffering**<br>33. I was listened to and understood during the visit<br>34. I felt emotionally supported by the clinical staff<br>35. The visit alleviated any concerns I had | *I mean, there have been occasions when I felt that I haven't been understood, and it's been related to other issues, and that's been quite upsetting.*<br><br>*I felt that, okay, someone is starting to understand me. I felt like I had to offload quite a bit of my emotions purely to get the doctor to understand because of the experiences leading up to the telephone conversation*<br><br>*Obviously, I wanted pain relief, but I wanted reassurance that this is going to be something that I'm going to able to manage.* |
| **Clinician interaction**<br>36. My clinician was reassuring and supportive<br>37. My clinician was knowledgeable and informative | *to know that you're under the care of people that know what they're doing, what's going on with your condition. I think that's quite reassuring.* |

| | |
|---|---|
| 38. **have confidence in my clinical team** | *It felt nice to talk to someone who obviously knew what they were talking about. I felt like I got a little bit of clarity, because I'd been passed around for so many years with no real, kind of, help.*<br><br>***"I have faith in them [the GPs] and, and they're good in that they listen and they act on what you say in that they've never kind of gone oh you're talking rubbish about anything"*** |
| **Group sessions/forums**<br>39. I was made aware of group sessions/ forums | *Also, the group sessions they had with other TMD patients had helped immensely in alleviating some concerns.*<br><br>*We all sat there and just spoke about what sets it off and getting more information and that was a big relief to know there was something and it wasn't literally just me being a bit crazy.* |
| Domain 6: Transition and continuity | |
| 40. **I feel better able to cope with my pain**<br>41. **I was given adequate advice to self-manage**<br>42. **I feel less dependent on professional help**<br>43. I feel I am able to check in with my clinician if I needed to | ***"Even though I haven't come away with a cure, I feel in a better position to cope with my symptoms."***<br><br>***I've got to the point now where I think I've got to do it because I can only help myself now, it's not a case of...I could come here for the next 12 months but unless I continue to help myself it's not going to get any better as well.***<br><br>*I was really pleased, because they gave me regular appointments to see them until it did calm down.* |
| Domain 7: Access to care | |
| 44. Access to the clinic location was smooth<br>45. Navigating the building was straightforward<br>46. The reception staff were helpful<br>47. The check-in process was smooth<br>48. I waited a reasonable amount of time before being seen<br>49. I feel able to get an urgent appointment in cases of severe flare-ups | *I got sent to all four floors before they put me in the right department.*<br><br>*So, navigating around the hospital was completely fine. That was completely stress free. They were very sharp about where I needed to go.* |

| | |
|---|---|
| | *So, I felt initially I was, the receptionist, sort of, passed the buck and said, I'll speak to her instead when she was sitting there, and she could have addressed it herself*<br><br>*It's just an observation that I made, because you don't want to be stressed out with thinking about, oh, am I in the right department. I was told to come to this floor. Why is this lady telling me that she can't find me in the system? I think things like that make a difference*<br><br>*And also, waiting times. When I come in, if my appointment is at 11 and I'm not seen until about half twelve, that has upset me in the past.*<br><br>*So, there was no emergency place, which I found really, that's what I needed, and it wasn't there.* |
| Domain 8: Involvement of family and friends | |
| 50. I feel able to take members of my family/friends to my appointments | |
| Domain 9: Accountability | |
| 51. I feel I am able to give feedback to the hospital about my visit? | *I think you always need someone who is accountable that you can go back to if things start to go wrong or you have questions.* |
| Domain 10: Transparency | |
| 52. I feel the clinical staff were transparent and forthright | *Yes, because I think if you're told you've got to wait six months it's probably an unpalatable thing to say to someone but at least they know.* |

### 7.4.3. Item reduction and improvement

#### 7.4.3.I. Experts' input

The candidate list of questions was presented to six expert healthcare professionals who deal regularly with patients with TMD. They suggested some amendments to the wording of some items to make them clearer and easier to read. Additionally, they recommended the omission of 10 items, as they were deemed too similar to other questions. The amendments suggested at this stage are detailed in table 7.3.

Table 7.3. Amendments suggested by domain experts.

| | Item | Comments by healthcare professionals | Amendment |
|---|---|---|---|
| 1 | I was treated respectfully as an individual | | Removed |
| 2 | I felt believed and was taken seriously | | |
| 3 | The clinician showed interest in my condition | | |
| 4 | The clinician appreciated the effect the pain had on my life | | Rephrased to 'The clinician acknowledged the impact of pain on my life' |
| 5 | I had a discussion with the clinician about the treatment options | | Rephrased to 'The clinician explained the treatment options adequately' |
| 6 | I was involved in the decisions about treatments and care strategies | Jargon | Rephrased to 'I was involved in the decisions about my care' |
| 7 | The care strategy matched my expectations | Jargon | Rephrased to 'The clinical visit matched my expectations' |
| 8 | The clinical visit helped manage my expectations | | |
| 9 | I felt I have reached the right caregiver for my condition | TMD patients are usually under the care of more than one clinician | Rephrased to clinical team |
| 10 | I waited a reasonable time to get a referral here | Ambiguous | Rephrased to' I waited a reasonable amount of time from when I was referred until I was seen in the facial pain clinic |
| 11 | The referral process to the hospital was a smooth one | | Rephrased to: straightforward |

| | | | |
|---|---|---|---|
| 12 | I was made aware of the different teams that will/are looking after me | | Removed |
| 13 | The pathway of care was clear to me | Slightly jargon language | |
| 14 | The onward referrals were timely and coordinated. | | |
| 15 | There was good coordination between the different clinicians who look after me | | |
| 16 | The health team was fully up to date with my situation | | Removed |
| 17 | My appointments were well organised | Redundant | Removed |
| 18 | I did not experience unexpectedly cancelled or delayed appointments | | Rephrased to 'I did not experience unexpected appointment cancellations or delays in receiving appointments' |
| 19 | I received reminders of my appointments an acceptable period beforehand | | |
| 20 | I received a diagnosis for my condition during my first visit here | | |
| 21 | I received enough information about my condition | | Rephrased to 'I received information about my condition to a satisfactory level' |
| 22 | I was given extra material to read about my condition | | "leaflets" was added |
| 23 | I felt adequately educated about my condition | Redundant | Removed |
| 24 | I was given enough time to ask any questions | | |
| 25 | There is good communication with the hospital | | |
| 26 | I was made aware of a means of communication with my clinical team | | Rephrased to ' I was given information on how to contact my clinical team should I need to' |
| 27 | I was satisfied with the treatment plan decided | | |
| 28 | The long-term care strategy was clear to me | Jargon + redundant (similar to 27) | Removed |
| 29 | The treatment options were delivered in a timely manner | | |
| 30 | Pain control is adequate enough to let me get on with daily life activities | This question is not measuring the hospital experience per se | Removed |
| 31 | The surrounding clinical environment was comfortable | | |

| | | | |
|---|---|---|---|
| 32 | I was listened to and understood during the visit | | |
| 33 | I felt emotionally supported by the clinical staff | Redundant | Removed |
| 34 | The visit alleviated any concerns I had | | Rephrased to: My concerns were addressed by the clinical staff |
| 35 | My clinician was reassuring and supportive | | |
| 36 | My clinician was knowledgeable and informative | | |
| 37 | I have confidence in my clinical team | | |
| 38 | I was made aware of group sessions/ forums | | |
| 39 | I feel better able to cope with my pain | | |
| 40 | I was given adequate advice to self-manage | | |
| 41 | I feel less dependent on professional help | | |
| 42 | I feel I am able to check in with my clinician if I needed to | | Removed |
| 43 | Access to the clinic location was smooth | | |
| 44 | Navigating the building was straightforward | Redundant | Removed |
| 45 | The reception staff were helpful | | |
| 46 | The check-in process was smooth | | |
| 47 | I waited a reasonable amount of time before being seen | | “In clinic” was added |
| 48 | I was able to get an urgent appointment in cases of severe flare-ups | | |
| 49 | I felt able to take members of my family/friends to my appointments | | |
| 50 | I felt able to give feedback to the hospital about my visit | | |
| 51 | The clinical staff were transparent and forthright | | |
| 52 | Overall, I am satisfied with my experience | | |

### 6.4.3. II. Cognitive interviews

The participants were invited to join through an online platform at a pre-arranged time. They received some material prior to the interview time, including the questionnaire and a sheet to mark the importance score for each item. The list at this stage contained

42 questions, after the omission of 10 items on the recommendations of the domain experts.

The remote interviews ranged from 30-60 minutes each. The participants found most of the questions clear and understandable. None of the questions were found to be offensive or uncomfortable to answer. The mean importance score was calculated for each item to determine the most important questions. The questions with the highest importance score were selected for inclusion with a view of keeping the list close to 25 questions without compromising important questions.

The list was further refined by taking into account the comments and suggestions of the participants, for example vague wording or repetitive items (Parslow et al., 2019). For instance, the question ‘The clinician showed interest in my condition” was deemed too similar to the question “I was listened to and understood during the visit”. Although both had a high importance score, only the second one was included. One item was also removed as it was too vague for a few participants and required further explanation (The pathway of care was clear to me).

Five items with low importance scores were also selected from the original list because they were strongly emphasised in the literature and in the focus groups. For example, the question ‘I received a diagnosis during my first visit here’. Some participants did not expect to receive a diagnosis on the very first visit and thought it might be unrealistic at times. So, this question was changed to ‘I received a timely diagnosis at this clinic’. Another item which was kept was the question about the involvement of family and friends. These items could be deleted at a later stage, but if they were deleted at this stage, it would be difficult to restore them later (Broder et al., 2007).

The modified version of the PREM was shown to an additional participant. Minor changes were suggested to the wording of some items, and no additional items were suggested. The final list of questions consisted of 28 questions, with six response options (strongly agree, agree, neutral, disagree, strongly disagree, and not applicable), in addition to one question assessing the satisfaction with the experience as a whole. Table 7.4 describes the comments made during the interviews and the amendments implemented.

Table 7.4. Patients' comments and following amendments

| | Items | Impact score | Proposed changes | Reason for exclusion |
|---|---|---|---|---|
| 1 | I felt believed and was taken seriously | 4.25 | I felt respected and understood | |
| 2 | The clinician showed interest in my condition | 4.25 | | Redundant |
| 3 | The clinician acknowledged the impact of pain on my life | 4 | | |
| 4 | The clinician explained the treatment options adequately | 4.5 | | |
| 5 | I was involved in the decisions about my care | 4.5 | | |
| 6 | The clinical visit matched my expectations | 4 | | |
| 7 | The clinical visit helped manage my expectations | 3.75 | | Low impact score |
| 8 | I felt I had the right clinical team for my condition | 4.5 | | |
| 9 | I waited a reasonable time from when I was referred until I was seen in this clinic | 3.5 | | Low score but included as it was emphasised strongly in previous literature and focus groups |
| 10 | The referral process to the hospital was straightforward | 4.5 | | |
| 11 | The care pathway was clear to me | 4 | | Vague wording- needed further clarification |
| 12 | The onward referrals were timely and coordinated. | 4.5 | | |
| 13 | There was good coordination between the different clinicians who look after me | 3.75 | There was good coordination between the different clinicians who looked after my facial pain | Low score but included as it was emphasised strongly in previous literature and focus groups |
| 14 | I did not experience unexpected appointment cancellations or delays in receiving appointments | 4.5 | | |
| 15 | I received reminders of my appointments in advance | 4.25 | | |

| | | | | |
|---|---|---|---|---|
| 16 | I received a diagnosis on my first appointment | 3 | I received a timely diagnosis at this clinic | Low score but included as it was emphasised strongly in previous literature and focus groups |
| 17 | I received enough information about my condition | 4.5 | I received information about my condition to a satisfactory level (expert suggestion) | |
| 18 | I was given written material to read about my condition (leaflets) | 3.75 | | Low impact score |
| 19 | I was given enough time to ask any questions | 4.5 | | |
| 20 | I was given information on how to contact my clinical team should I need it | 4.25 | | There is good communication with the hospital. |
| 21 | There is good communication with the hospital. | 4.25 | | |
| 22 | I was satisfied with the treatment plan decided | 4.25 | | |
| 23 | The treatment options were delivered in a timely manner | 3.25 | | Low score but included as it was emphasised strongly in previous literature and focus groups |
| 24 | The clinical environment was comfortable | 2.75 | | Low impact score |
| 25 | I was listened to and understood during the visit | 4.75 | I was listened to and believed during the visit | |
| 26 | My concerns were addressed by the clinical team | 3 | | Low impact score |
| 27 | My clinician was reassuring and supportive | 4.5 | | |
| 28 | My clinician was knowledgeable and informative | 3.5 | | Low impact score |
| 29 | I have confidence in my clinical team | 4 | | |
| 30 | I was made aware of group sessions/ forums | 3.5 | | Low impact score |
| 31 | I feel better able to cope with my symptoms | 4 | | |

| | | | | |
|---|---|---|---|---|
| 32 | I was given adequate advice to self-manage | 4.25 | | |
| 33 | I feel less dependent on professional help | 2.25 | | Low impact score |
| 34 | Access to the clinic location was easy | 2.5 | | Low impact score |
| 35 | The reception staff were helpful | 3.5 | | Low impact score |
| 36 | The check-in process was straightforward | 3.5 | | Low impact score |
| 37 | I waited a reasonable amount of time before being seen in clinic | 4 | I waited a reasonable amount of time in the waiting area before being seen in clinic | |
| 38 | I was able to get an urgent appointment in cases of severe flare-ups | 4 | I was able to get urgent appointments when I needed them. | |
| 39 | I felt able to take members of my family/friends to my appointments | 3.75 | | Low score but included as it was emphasised strongly in previous literature and focus groups |
| 40 | I felt able to give feedback to the hospital about my visit | 4 | | |
| 41 | The clinical staff were transparent and forthright | 3.25 | | Low impact score |
| 42 | Overall, I am satisfied with my experience | 4.5 | | |

## 7.5. Discussion

Findings from this qualitative study, both focus groups and cognitive interviews, provided valuable information about the important aspects of care for patients with temporomandibular disorders. These findings, in addition to input form the literature, were used to develop a new tool for the routine assessment of the clinical experience of these patients. Measuring the hospital experience and obtaining feedback offers meaningful insight into what matters most to patients. Over the past few decades, hospital experience has increasingly become crucial to clinical quality (D.O.H, 2008a). The delivery of a clinically effective intervention may no longer be viewed as a successful clinical experience for patients if it was not delivered in a timely manner, in poor clinical conditions or from uncompassionate clinicians (2012c). Therefore, healthcare services in England are now required to review patient experience as part of quality assessments, and funding to some services is tied to improvements to patient experience (2012d).

The assessment of patients' feedback could also be used meaningfully to understand the problems faced when delivering care to patients, to compare organisations for performance assessment and to inform referring clinicians about the quality of services. Furthermore, there seems to be some evidence linking a positive experience to better patient outcomes due to better adherence to treatment instructions and better use of preventive services (Doyle et al., 2013).

The experience of chronic pain patients with healthcare services seems to be of particular importance. Several qualitative systematic reviews of chronic pain conditions have mentioned in one way or another its significance as a major part of their lives (Toye et al., 2019, Toye et al., 2013b, Ghai et al., 2021, Primdahl et al., 2019). Therefore, if a questionnaire was developed to capture this experience, patient

involvement would be prudent (Fitzpatrick et al., 1998, Paterson, 2004, Wiering et al., 2017b). It gives important insight into the relevance of the questions and ensures that the questionnaire is easy to complete by the target population (Wiering et al., 2017b, Haywood, 2007). Lack of patient input may compromise the validity, sensitivity, and response of a questionnaire (Meadows, 2011, Fossey and Harvey, 2001, Wiering et al., 2017b). A major drawback to patient involvement is the logistics behind it; it adds to the cost, time, and complexity of the research (Wiering et al., 2017b). These challenges might discourage developers form involving patients. However, this might not be the case for much longer, as patient involvement is increasingly required by official organisations such as the American Food and Drug Administration (FDA, 2009).

According to the COSMIN guidance, the content validity is the degree to which the content of an instrument is an adequate reflection of the construct to be measured (Mokkink et al., 2010b). It is assessed by asking the patients and professionals about the relevance, comprehensiveness, and comprehensibility of the items and the suitability of the response options (Terwee et al., 2018). Content validity is often considered one of the most important measurement properties of a patient reported measure, and lack thereof, could affect most of them negatively (Terwee et al., 2018). Irrelevant questions may decrease the internal validity and interpretability of the patient reported measure. Moreover, it could lead to low response rates if patients feel that they are bring asked irrelevant questions or frustrated because important questions are being missed (Terwee et al., 2018, 2008). This series of cognitive interviews therefore provided the opportunity to check the relevance, acceptability, content and face validity of the questionnaire.

Patient input ideally reflects the different manifestations of the construct. This study included participants with negative aspects to their experience as well as participants with a positive experience. A purposive sample of participants was also chosen to best represent participants in different stages of care at the tertiary care centre, duration of symptoms, a wide age range and with different ethnic backgrounds. The Eastman Dental Hospital is a tertiary centre for facial pain cases, with referrals coming in from all over England. In many cases, English is not the first language for many patients. In order to make sure that the phrasing of the items is appropriate for all patient backgrounds, two participants were invited to take part with non-English first languages. They both confirmed the understandability and readability.

Strengths and limitations

Major strengths for the study were the involvement of patients in developing the PREM, which ensured the relevance of the questions to this cluster of patients, and the methodological rigor with which the study was conducted. Data triangulation was also ensured by having input from the literature as well as from patients. A qualitative evidence synthesis was carried out in preparation for this study, to complement the data gathered from the focus groups and make sure that all important aspects of care were noted.

The limitations to this piece of research included the inherent limitations associated with online focus groups and interviews. The research design had to be amended in response to the SARS-CoV-2 outbreak in the UK at the time of conducting this study to ensure the safety of the participants and the research team. These limitations included a change in the dynamic of the group discussion when compared to that of a traditional face to face meeting (Woodyatt et al., 2016). Additionally, the study required internet access with users who were adept at online technology. This may have

discouraged some patients from taking part. It is worth noting however, that several participants in this piece of research were of advanced age. All the participants were comfortable navigating the online platform, as such platforms may have risen in popularity during the coronavirus pandemic (Koeze and Popper, 2020).

The overall sample size used in the cognitive interviews consisted of 6 females and 1 male. This may have affected the generalisability of the results as males were underrepresented. It is worth noting however, that with TMD patients, female patients present to a clinical setting more frequently than male patients, with a reported ratio between 4-8:1 (Drangsholt et al., 1999, Bush et al., 1993, Maixner et al., 2011). This may have skewed the sample in favour of female patients.

## 7.6. Conclusions

The patient reported experience measure for patients with TMD is a brief questionnaire which aims to provide healthcare services with a means to evaluate their performance and measure the impact of implemented changes to the care of TMD patients. The following step for validation of the new tool was a quantitative pilot study which took place at a specialist facial pain unit to evaluate its psychometric properties. Further refinement of the questions was expected at this stage. Consideration was also given to undetected problems which arose after the questionnaire was applied to a larger sample size.

# Chapter 8: Development of a Patient-Reported Experience Measure for patients with TMD (PREM-TMD) Phase 3: structural validation and reliability testing.

## 8.1. Introduction

Patient Reported Experience Measures or PREMs are validated questionnaires used to gather information on patients' experiences while receiving care, and typically measure the aspects of care that are important to patients (Graham and Woods, 2013). They do not look at the outcome of care specifically, but at the process of care and the impact it had on their experience, whether positively or negatively. The data gathered could have useful applications, such as quality improvement strategies, research, and audits (Kingsley and Patel, 2017, Weldring and Smith, 2013).

As the most important stakeholders in the healthcare system (Carman et al., 2013) patients can play a crucial role in the development and validation of such measures. After all, it is their views the system is seeking. The construction of a reliable and valid patient reported measure requires a defined psychometric development process (Barnett et al., 2013, Kingsley and Patel, 2017), generally starting with concept elicitation and item generation, formulating a pilot questionnaire, testing and revising it (Kingsley and Patel, 2017, Comins et al., 2021, Sundaresan et al., 2016). The adequacy of an instrument, whether newly developed or existing, depends on whether its psychometric properties are satisfactory (FDA, 2009). Therefore, the testing of such properties offers valuable evidence to support its use in clinical and research settings.

As with Patient-Reported Outcome Measures (PROMs), PREMs can be developed for a specific condition or disease, to ensure that the questions asked are relevant to that specific cohort and guarantee that important questions are not missed. In fact, numerous PREMs have been developed for multiple conditions and settings thus far,

such as mental health (Bjertnaes et al., 2015), palliative care (Claessen et al., 2012), maternity care (Scheerhagen et al., 2015), trauma (Bobrovitz et al., 2012), postoperative care (Stubbe et al., 2007) and many others. A literature search was conducted to locate a similar instrument for patients with temporomandibular disorders. However, no such measure was identified. Therefore, a multi-phase study was designed to develop and validate a PREM for TMD patients. A systematic review was conducted in preparation to acquire input form the literature regarding the recorded experiences of TMD patients in a clinical setting. The following phase ensured patient involvement by running a series of focus groups and cognitive interviews to generate, revise and shortlist a number of candidate questions to be included in the final PREM. The third phase outlined in this chapter involved running a pilot study to establish some of its psychometric properties.

## 8.2. Aims and objectives

1. To explore some psychometric properties of the newly developed PREM-TMD, including structural validity, internal consistency, and test-retest reliability in a TMD population.

2. To explore the associations between PREM-TMD, demographic characteristics and psychological co-morbidities.

## 8.3. Materials and methods

### 8.3.1. Design

This was a cross sectional quantitative study, which was reviewed and given a favourable ethical opinion by the Southeast Scotland Research Ethics Committee 1. (REC reference:19/SS/0130).

### 8.3.2. Participants

Eligible participants were invited to take part in the study after their routine clinical visits to the oral surgery and facial pain units at the Eastman Dental Hospital. The participants were informed about the study verbally and were given a patient information sheet. Interested participants were invited to sign two copies of the consent form, one of which was for the patients' own records.

### 8.2.2. Inclusion and exclusion criteria

Eligible patients satisfied the following inclusion criteria: over the age of 18, having a diagnosis of TMD with associated pain according to the DC/TMD criteria, with pain being the main complaint for attendance to clinic. Patients having at least one of the following diagnoses were eligible: myalgia (local myalgia, myofascial pain, myofascial pain with referral), arthralgia and headache attributed to TMD. Additionally, good command of the English language and the ability to give informed consent were required.

Patients were excluded if they had a diagnosis of intra-articular TMD with no pain symptoms, recent history of trauma or surgery to the head and neck area, poor command of the English language, inability to give informed consent and if they were under the age of 18.

### 8.3.3. Sample size calculation

The sample size was estimated based on the number of items in the preliminary draft of the questionnaire – 28 items. In line with the The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidance, an adequate sample when performing factor analysis would be 4-6 participants per item and at least

100 in total (Mokkink et al., 2018b, Terwee et al., 2018, Prinsen et al., 2018). Therefore, the estimated sample was 140 participants at this stage.

### 8.3.4. Procedure and outcome measures

The study activities took part after concluding the routine clinical visit with the patients. A comprehensive oral examination was conducted, and the participants were classified according to the DC/TMD classification criteria.

The participants were then asked to complete a set of questionnaires which included the following:

1. PREM-TMD: An experience questionnaire developed in collaboration with TMD patients to assess their healthcare experience. At this point, the PREM contained 28 questions.

2. Demographics form which included: age, sex, ethnicity, smoking status, alcohol consumption, systemic co-morbidities, employment status, education level, current treatment, and global improvement and satisfaction with treatment on a seven-point likert scale.

3. DC/TMD symptom questionnaire: This form is used to assess TMD pain and identify factors that are important to the diagnosis of myalgia, arthralgia and headaches. Items from this questionnaire are used in the diagnostic algorithms for each disorder within the DC/TMD criteria (Schiffman et al., 2014).

4. DC/TMD questionnaires: These questionnaires aim to obtain a comprehensive evaluation of psychological functioning and are in line with the recommendations of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) which suggest measuring the following domains in clinical trials assessing

pain: intensity, emotional functioning, general and disease specific physical functioning (Dworkin et al., 2005).

a. Graded Chronic Pain Scale Version 2.0 (GCPS): This instrument consists of two subscales: Characteristic Pain Intensity (CPI), and pain-related interference. A final grade is computed to produce a Chronic Pain Grade with the following classification: Grade 0: none, Grade 1: low intensity pain, without disability, Grade 2: high intensity pain without disability, Grade 3: moderately limiting, Grade 4: severely limiting (Von Korff et al., 1992). GCPS scores were split into 2 categories in this study: high pain-related impairment (grades 3 and 4) and low disability or no disability at all (grades 0,1, and 2). (Manfredini et al., 2011, Manfredini et al., 2010)

b. Jaw Functional Limitation Scale-20 (JFLS-20): This instrument is a 20-item scale for overall functional limitation of the masticatory system. It consists of three subscales: Mastication, mobility, and verbal and non-verbal communication. Norms have not yet been established for this instrument. However, it can be used to identify jaw-related functional limitations and then can be used to document changes over time (Ohrbach et al., 2008a, Ohrbach et al., 2008b).

c. General Anxiety Disorder-7 (GAD-7): A measurement of anxiety. It consists of the seven core symptoms of generalised anxiety disorder. Response options range from ‘0’: not at all to ‘3’: nearly every day. Scores range from 0-21, and values of 5, 10, and 15 represent cut-off points for mild, moderate, and severe anxiety. (Spitzer et al., 2006). A 10-point cut off score was used in this study to indicate clinically relevant anxiety, hence categorising the scores into a binary variable (Pieh et al., 2020, Feingold et al., 2017).

d. Patient Health Questionnaire-8 (PHQ-8): This instrument measures the severity of depressive disorders. it consists of eight of the nine criteria on which the DSM-IV diagnosis of depressive disorders is based (American Psychiatric Association, 1980). Response options range from '0': not at all to '3': nearly every day. The scores range from 0-24, with values of 5, 10, 15, and 20 representing cut-off points for mild, moderate, moderately severe, and severe depression, respectively (Kroenke et al., 2009). A 10-point cut off score was also used in this study to indicate clinically relevant depression, hence categorising the scores into a binary variable (<10 and ≥10) (Pieh et al., 2020, Feingold et al., 2017)

e. Patient Health Questionnaire-15 (PHQ-15): An instrument to assess the non-specific physical symptoms. Each symptom is scored from '0': not bothered at all to '2': bothered a lot. Scores of 5, 10, 15, represented cut-off points for low, medium, and high somatic symptom severity. (Kroenke et al., 2002). Similar to the previous two scales, a 10-point cut-off score was applied to establish patients with somatisation disorder (Bierke et al., 2016, North et al., 2019).

### 8.3.5. Statistical analysis

Statistical analysis was carried out using Stata version 17 (StataCorp, College Station, TX, U.S.A.). Descriptive analysis was first conducted to summarise the demographics and outcome scores of the sample. The skewness and kurtosis of the data were also tested, as well as the normality of distribution using the Shapiro-Wilkes test.

#### 8.3.5.I. Overall score calculation

PREM-TMD at this stage consisted of 28 questions and one extra question assessing the overall experience. The response options were as follows: strongly agree, agree, neutral, disagree, strongly disagree and not applicable (N/A). In order to avoid having

the total score lowered in case of having N/A chosen, the total score was not a simple sum of the items but was in the form of a percentage of the total sum to the total maximum possible points.

Choosing N/A does not necessarily mean that the experience was worse. For example, in answering the question 'There was good coordination between the different clinicians who looked after my facial pain', a "N/A" answer in this case may simply mean that this was the patient's first visit, or that they happened to see the same clinician in subsequent visits. Therefore, in order to account for the N/A answers, the following scoring formula was adopted:

$$\text{Total score} = \frac{\sum items}{(\text{final numer of items x } 5) - (\text{number of NA answers x } 5)} \text{ x } 100\%$$

### 8.3.5. II. Exploratory factor analysis (EFA)

Factor analysis is perhaps one of the most commonly used statistical techniques in social sciences (Finch, 2020). Its models lie on a continuum, at one end is exploratory analysis and on the other is confirmatory analysis (CFA). From a conceptual standpoint, EFA is more appropriately used when little is known about the structure underlying a set of observed variables (e.g., items of a new questionnaire), therefore urging the researcher to engage in exploratory investigation of the factor structure (Finch, 2020). Factor analysis is a common tool to investigate the validity of questionnaires and is a useful tool to reduce the number of items into latent factors based on commonalities within the data (Atkinson et al., 2011). The COSMIN guidance suggests its use to evaluate the structural validity of patient reported outcome measures (Mokkink et al., 2018a, Mokkink et al., 2018b, Terwee et al., 2018).

Several steps were involved in executing factor analysis, starting with evaluating whether the data is suitable for this type of analysis. A pair of tests were used to that

end; the Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy and Bartlett's Test of Sphericity. The KMO index ranges from 0 to 1, with values higher than 0.50 considered suitable for factor analysis. The Bartlett's Test of Sphericity should be significant, indicating sufficient intercorrelations for factor analysis (Hair et al., 1995, Tabachnick and Fidell, 2007). Factor extraction was subsequently carried out using Principal Factor Analysis, to reduce the large number of items into factors. Two rules were utilised; the Kaiser's criteria (eigenvalue > 1 rule) (Kaiser, 1960) and the Scree test (Cattell, 1966). The scree plot is a heuristic graph that plots the eigenvalues against the components. By inspecting the elbow of the plot – the point where the notable decline in factors levels off - the number of retained factors could be estimated (Ledesma et al., 2015).

The initially extracted loadings are usually not particularly interpretable because the items may load on multiple factors. Therefore, factor rotation was applied next. It is a mathematical transformation with the aim of obtaining an interpretable factor loading matrix that provides a simple structure solution (Finch, 2020). Factor rotation was done using Olbimin (0) oblique rotation method, with a 0.45 cut-off point for factor loadings (John et al., 2014). Items were excluded if they had weak loadings on factors (<0.45), or if they cross-loaded on more than one factor. Step wise removal of items was performed to avoid needless item removal and therefore compromising the content validity of the questionnaire.

#### 8.3.5.III. Internal consistency reliability

Internal consistency is the degree of the interrelatedness among the items based on values between 0 (no agreement) and 1 (perfect agreement). The COSMIN guidance recommends using Cronbach α with a minimum cut-off point of 0.7 as an acceptable value (Terwee et al., 2007, Mokkink et al., 2010b). George and Malley propose the

following criteria as well: values >0.9 are excellent, >0.8 are good, >0.7 are acceptable, >0.6 are questionable, >0.5 are poor and <0.5 are unacceptable (George and Malley.). Cronbach's alpha coefficients were computed to assess the internal consistency of the overall score and of the individual factors.

### 8.3.5. IV. Test-retest reliability

It is the reliability of the instrument selected over time (Mokkink et al., 2018a). In general, instruments are administered at two points in time. Streiner and Norman recommend a period of 12-14 days as an acceptable retest period (Streiner et al., 2016) and similar recommendations were also made by the American FDA guidance (2009). Interclass correlation coefficients (ICC) were calculated for the continuous variables; total PREM scores and the scores of the individual factors. Weighted kappa was used for the individual items which are ordinal variables.

ICC values >0.75 are considered excellent, values between 0.40-0.75 are considered fair to good, and <0.40 are poor (Fleiss, 1986, Drenth et al., 2018). The COSMIN guidance also recommends a cut-off point of 0.7 (Terwee et al., 2007).

The majority of the participants were invited to complete the questionnaire two weeks after the baseline visit, with the aim of getting at least 50 respondents to constitute a good sample size to assess test-retest reliability (Terwee et al., 2012). They were given the choice of a paper copy to be sent back to the research team via a pre-paid envelop or complete it electronically via email.

### 8.3.5. IV. Associations between PREM-TMD, demographic variables and other psychological comorbidities.

Data distribution was first tested for the outcomes (PREM-TMD, GCPS, GAD-7, PHQ-8, PHQ-15 and JFLS-20) using the Shapiro-Wilk test for normality. As all data were

not normally distributed, non-parametric tests were used to explore the associations between the variables. Bivariable analysis was performed using Mann-Whitney rank sum test, Kruskal-Wallis test and Spearman's correlation for continuous variables, and chi-square and Fisher's exact tests for categorical variables. All tests were two-tailed and p-values < 0.05 were considered statistically significant.

#### 8.3.5.V. Missing data

The missing data for JFLS-20, PHQ-8, GAD-7 and PHQ-15 were handled according to the DC/TMD scoring manual. Single imputation by the mean of the remaining items is suggested.

- JFLS-20: Computation of a score with missing items is adjusted by dividing by number of items present. Scores can be calculated when no more than two items are missing from the mastication domain, one item from mobility and two from communication.

- PHQ-8: The total scores can still be valid with up to three items missing. The total score is calculated by dividing the total sum by the number of items present and multiplying by 8 (as though all eight items are present).

- GAD-7: Up to two missing items can be allowed to calculate a valid score. Computation is similar to PHQ-8.

- PHQ-15: Up to five items can be missing. Computation is similar to PHQ-8.

## 8.4. Results

### 8.4.1. Participants

139 participants completed PREM-TMD and a demographics form after their routine clinical visits to the oral surgery and facial pain units at the Eastman Dental Institute. 59.71% (83) of the patients who completed the study questionnaires were on their first visit to the Eastman, while 40.29% (56) were follow up patients. The majority of the participants were female (81.29 %) with a female: male ratio of 4.3:1. The mean age of the participants was 41.4 years (±15.0 SD) with a range of 18-79 and median of 40. Table 8.1 describes the participants' characteristics in detail. The mean number of co-morbidities and other chronic pain conditions was 0.8 (±1.1 SD) and 1.5 (±1.4 SD) respectively. The mean number of clinicians consulted before the first visit to the Eastman was 2.1 (±2.3 SD), with a range of 1-17 clinicians, including general practitioners (GPs) and general dental practitioners (GDPs).

Table 8.1. Descriptive statistics of the demographic variables of the study participants.

| **Variable** | N (%) |
|---|---|
| **Visit status** | |
| First visit | 83 (59.71%) |
| Follow up visit | 56 (40.29%) |
| **Ethnicity** | |
| White | 89 (64.03%) |
| Asian | 28 (20.14%) |
| Black | 12 (8.63%) |
| Mixed | 6 (4.32%) |
| Other | 4 (2.88%) |
| **Sex** | |
| Female | 113 (81.29%) |
| Male | 26 (18.71%) |
| **Marital status** | |
| Single | 67 (48.20%) |
| Married | 47 (33.81%) |
| Living with partner | 13 (9.35%) |
| Divorced | 8 (5.76%) |
| Widowed | 4 (2.88 %) |
| **Employment** | |
| Employed | 96 (69.06%) |
| Unemployed | 13 (9.35%) |
| Retired | 13 (9.35%) |
| Homemaker | 9 (6.47%) |
| Student | 8 (5.76%) |

| | |
|---|---|
| **Smoking status** | |
| Never smoked | 90 (64.75%) |
| Previous smoker | 33 (23.74%) |
| Current smoker | 16 (11.51%) |
| **Alcohol consumption** | |
| Non-drinker | 69 (49.64%) |
| Drinker | 70 (50.36%) |
| **Schooling** | |
| School | 48 (34.53%) |
| Some university | 14 (10.07%) |
| University | 43 (30.94%) |
| Post graduate degree | 34 (24.46%) |
| **DC-TMD classification** | |
| Myalgia | 68 (48.92%) |
| Myalgia + IA involvement | 71 (51.08%) |

### 8.4.2. Psychometric properties of PREM-TMD

PREM-TMD at this stage consisted of 28 questions plus one question about the general experience. Table 8.2 outlines the questions included in the pilot study and the response distribution for each option. The following items were of note:

- Items 9 and 10 (The onward referrals from this clinic were timely and coordinated) and (There was good coordination between the different clinicians who looked after my facial pain). These items were largely applicable to follow up patients hence the high percentage of N/A answers. It was additionally noted that a large number of **1st visit** patients were answering these questions incorrectly, i.e., choosing a certain rating when in fact they should be choosing N/A. To correct this, the following note was subsequently attached to these items: 'Choose N/A if this is your first visit'. It was observed that 1st visit patients were answering the question correctly after this addition, i.e., choosing N/A.
- Items 26 and 27 (I was able to get urgent appointments when I needed them) and (I felt able to take members of my family/friends to my appointments). Both items had a high percentage of N/A answers (57% and 61% respectively). In this case, N/A indicates low relevance to the patients, therefore, both items were excluded

from further analysis. In relation to item 27, it was taken into consideration that during the SARS-CoV-2 outbreak - with several associated restrictions at the time - the patients may have been asked by the hospital to attend their appointments alone, making this percentage misleading. However, as mentioned in the previous chapter, the importance score for this item was low (3.75) and the participants in the focus groups did not highlight it strongly as an important aspect of the hospital experience. Therefore, after 3 rounds of patients' input, no sufficient justification was found to keep this question in the final version of PREM-TMD.

- Item 28 (I felt able to give feedback to the hospital about my visits). Several participants mentioned that they felt this question was unnecessary as by default when completing the entire PREM, they are providing feedback. This was also confirmed by one of the TMD experts consulted during the process of developing the PREM (RNR). Therefore, this item was removed from further analysis.

#### 8.4.2.I. Missing values

Regarding PREM-TMD, only seven values were missing in the entire sample for seven participants, making a percentage of 0.17% of the entire dataset. These values were replaced by the integer value of the mean of the rest of the items.

The missing values for the rest of the scales is mentioned in detail in chapter 3 section 3.3.4.

Table 8.2. Candidate list of questions included in the pilot study and response distribution for each item.

| Items | SA (5) | A (4) | N (3) | D (2) | SD (1) | N/A |
|---|---|---|---|---|---|---|
| Domain 1: Respect for patient-centred values, preferences, and expressed needs | | | | | | |
| 1. I felt respected and understood | 83% | 15% | 2% | 0% | 0% | 0% |
| 2. The clinician acknowledged the impact of pain on my life | 81% | 15% | 3% | 1% | 0% | 0% |
| 3. The clinician explained the treatment options adequately | 82% | 15% | 2% | 0% | 0% | 1% |
| 4. I was involved in the decisions about my care | 76% | 17% | 6% | 0% | 1% | 0% |
| 5. The clinical visit matched my expectations | 65% | 20% | 11% | 3% | 0% | 1% |
| Domain 2: Coordination and integration of care | | | | | | |
| 6. I felt I had the right clinical team for my condition | 75% | 17% | 6% | 2% | 0% | 0% |
| 7. I waited a reasonable amount of time from when I was referred until I was seen in this clinic | 34% | 20% | 20% | 15% | 9% | 2% |
| 8. The referral process to the hospital was straightforward | 42% | 25% | 13% | 9% | 8% | 3% |
| 9. The onward referrals from this clinic were timely and coordinated. | 19% | 15% | 3% | 1% | 0% | 62% |
| 10. There was good coordination between the different clinicians who looked after my facial pain | 22% | 10% | 3% | 2% | 1% | 62% |
| 11. I did not experience unexpected appointment cancellations or delays in receiving appointments | 55% | 15% | 11% | 9% | 8% | 2% |
| 12. I received reminders of my appointments in advance | 73% | 17% | 1% | 3% | 2% | 4% |
| Domain 3: Information, communication, and education | | | | | | |
| 13. I received a timely diagnosis at this clinic | 68% | 24% | 5% | 2% | 0% | 1% |
| 14. I received information about my condition to a satisfactory level | 74% | 18% | 7% | 1% | 0% | 0% |
| 15. I was given enough time to ask any questions | 87% | 12% | 0% | 0% | 0% | 1% |
| 16. I was given information on how to contact my clinical team should I need to | 58% | 23% | 13% | 4% | 1% | 1% |
| 17. There is good communication with the hospital | 51% | 24% | 14% | 4% | 1% | 6% |
| Domain 4: Physical comfort | | | | | | |
| 18. I was satisfied with the treatment plan decided | 62% | 24% | 9% | 4% | 0% | 1% |
| 19. The treatment options were delivered in a timely manner | 62% | 19% | 7% | 1% | 1% | 10% |
| Domain 5: Emotional support | | | | | | |
| 20. I was listened to and believed during the visit | 82% | 14% | 3% | 1% | 0% | 0% |

| | | | | | | |
|---|---|---|---|---|---|---|
| 21. My clinician was reassuring and supportive | 85% | 10% | 4% | 1% | 0% | 0% |
| 22. I have confidence in my clinical team | 81% | 13% | 6% | 0% | 0% | 0% |
| Domain 6: Transition and continuity | | | | | | |
| 23. I was given adequate advice to self-manage | 68% | 24% | 7% | 0% | 0% | 1% |
| 24. I feel better able to cope with my symptoms | 40% | 30% | 22% | 4% | 2% | 2% |
| Domain 7: Access to care | | | | | | |
| 25. I waited a reasonable amount of time in the waiting area before being seen in clinic | 65% | 22% | 7% | 5% | 1% | 0% |
| 26. I was able to get urgent appointments when I needed them | 12% | 7% | 13% | 6% | 5% | 57% |
| Domain 8: Involvement of family and friends | | | | | | |
| 27. I felt able to take members of my family/friends to my appointments | 17% | 7% | 10% | 1% | 4% | 61% |
| Domain 9: Accountability | | | | | | |
| 28. I felt able to give feedback to the hospital about my visits | 54% | 19% | 10% | 2% | 0% | 15% |
| 29. Overall, I am satisfied with my experience in this clinic | 71% | 23% | 6% | 0% | 0% | 0% |

SA: Strongly agree. A: Agree. N: Neutral. D: Disagree. SA: Strongly disagree. N/A: Not applicable

### 8.4.2. II. Exploratory factor analysis

After amending the questionnaire according to the previous comments, 25 questions comprised the PREM at this stage and were used in conducting exploratory factor analysis.

The value for the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.843, and the p-value for the Bartlett test of sphericity was 0.001. Both results confirmed the suitability of the items undergoing EFA, as the former fell over the 0.5 cut off point, and the latter resulted in a p-value <0.05, indicating statistical significance. Six factors were retained after running the analysis with eigenvalues >1. See figure 8.1.

Figure 8.1. The number of retained factors after running exploratory factor analysis for PREM-TMD

Factor analysis/correlation — Number of obs = 139
Method: principal-component factors — Retained factors = 6
Rotation: (unrotated) — Number of params = 135

| Factor | Eigenvalue | Difference | Proportion | Cumulative |
|---|---|---|---|---|
| Factor1 | 8.17498 | 5.92320 | 0.3270 | 0.3270 |
| Factor2 | 2.25178 | 0.36036 | 0.0901 | 0.4171 |
| Factor3 | 1.89141 | 0.31350 | 0.0757 | 0.4927 |
| Factor4 | 1.57791 | 0.27715 | 0.0631 | 0.5558 |
| Factor5 | 1.30076 | 0.21727 | 0.0520 | 0.6079 |
| Factor6 | 1.08348 | 0.09882 | 0.0433 | 0.6512 |
| Factor7 | 0.98466 | 0.06325 | 0.0394 | 0.6906 |
| Factor8 | 0.92142 | 0.04791 | 0.0369 | 0.7275 |
| Factor9 | 0.87351 | 0.13332 | 0.0349 | 0.7624 |
| Factor10 | 0.74019 | 0.06186 | 0.0296 | 0.7920 |
| Factor11 | 0.67833 | 0.03731 | 0.0271 | 0.8191 |
| Factor12 | 0.64102 | 0.06045 | 0.0256 | 0.8448 |
| Factor13 | 0.58057 | 0.07956 | 0.0232 | 0.8680 |
| Factor14 | 0.50102 | 0.02581 | 0.0200 | 0.8880 |
| Factor15 | 0.47521 | 0.02079 | 0.0190 | 0.9070 |
| Factor16 | 0.45442 | 0.10772 | 0.0182 | 0.9252 |
| Factor17 | 0.34670 | 0.01347 | 0.0139 | 0.9391 |
| Factor18 | 0.33323 | 0.04663 | 0.0133 | 0.9524 |
| Factor19 | 0.28661 | 0.04382 | 0.0115 | 0.9639 |
| Factor20 | 0.24279 | 0.03997 | 0.0097 | 0.9736 |
| Factor21 | 0.20282 | 0.05747 | 0.0081 | 0.9817 |
| Factor22 | 0.14534 | 0.01547 | 0.0058 | 0.9875 |
| Factor23 | 0.12987 | 0.02820 | 0.0052 | 0.9927 |
| Factor24 | 0.10167 | 0.02137 | 0.0041 | 0.9968 |
| Factor25 | 0.08030 | . | 0.0032 | 1.0000 |

LR test: independent vs. saturated: chi2(300) = 1945.05 Prob>chi2 = 0.0000

Next, factor rotation was applied to give an interpretable factor loading matrix that provides a simple structure solution. Oblimin (0) rotation method with a 0.45 as cut-off point was applied. Figure 8.2 outline the factor loadings for each item. The following observations were noted:

- Items 5, 23,19 have weak loading on their factors.
- Item 1 is cross loading on factor 1 and factor 3.
- Item 12 is the only item in factor 6.

Figure 8.2. Factor loadings for the items of PREM-TMD using EFA with Oblimin rotation method.

| Variable | Factor1 | Factor2 | Factor3 | Factor4 | Factor5 | Factor6 | Uniqueness |
|---|---|---|---|---|---|---|---|
| premq21 | 0.9614 | -0.0200 | -0.0613 | 0.0158 | 0.0147 | 0.0428 | 0.1227 |
| premq20 | 0.8887 | 0.0105 | 0.0455 | -0.0339 | -0.0205 | 0.0415 | 0.1889 |
| premq22 | 0.7833 | 0.1450 | 0.1178 | 0.0049 | 0.0083 | -0.0681 | 0.1853 |
| premq2 | 0.7181 | -0.0234 | 0.2499 | -0.0850 | -0.0023 | 0.0576 | 0.3490 |
| premq14 | 0.5010 | 0.3869 | 0.1035 | 0.1720 | 0.0756 | -0.0308 | 0.2815 |
| premq6 | 0.4461 | 0.3874 | -0.0493 | 0.0654 | 0.0137 | -0.2871 | 0.4206 |
| premq16 | 0.1026 | 0.7094 | -0.4098 | 0.0413 | 0.0181 | -0.0338 | 0.4550 |
| premq17 | -0.1217 | 0.6801 | 0.0225 | -0.1141 | 0.0803 | 0.2641 | 0.4980 |
| premq24 | -0.0281 | 0.6339 | 0.2936 | -0.0375 | -0.0662 | 0.0553 | 0.4285 |
| premq18 | 0.1774 | 0.6293 | 0.2184 | 0.0514 | -0.0176 | 0.0267 | 0.3122 |
| premq13 | 0.0864 | 0.5369 | 0.3225 | 0.1588 | -0.0391 | -0.1227 | 0.3386 |
| premq5 | 0.2537 | 0.4010 | 0.1295 | 0.1952 | 0.0895 | -0.2054 | 0.4654 |
| premq3 | 0.1516 | 0.1449 | 0.7179 | 0.0735 | -0.0118 | -0.1038 | 0.2442 |
| premq4 | 0.1571 | 0.1694 | 0.6592 | 0.1670 | 0.0131 | -0.1447 | 0.2423 |
| premq1 | 0.4786 | -0.1213 | 0.6070 | -0.0087 | -0.0050 | 0.0564 | 0.2986 |
| premq23 | 0.1592 | 0.3529 | 0.4144 | 0.0494 | -0.1179 | 0.0650 | 0.4796 |
| premq19 | -0.0302 | 0.3084 | 0.3353 | 0.1419 | 0.1092 | 0.1715 | 0.6396 |
| premq8 | -0.1244 | 0.0249 | 0.1198 | 0.7384 | 0.0765 | -0.0234 | 0.4200 |
| premq7 | -0.2939 | 0.0376 | 0.2244 | 0.6802 | 0.0392 | -0.0224 | 0.4503 |
| premq11 | 0.0396 | 0.0474 | 0.0714 | 0.6466 | 0.0204 | 0.4184 | 0.3719 |
| premq15 | 0.3447 | -0.0780 | -0.2282 | 0.5890 | 0.0034 | -0.0409 | 0.5210 |
| premq25 | 0.1923 | -0.0671 | -0.2434 | 0.5884 | -0.2139 | -0.1370 | 0.5291 |
| premq10 | 0.0670 | -0.0396 | 0.0443 | -0.0722 | 0.9504 | -0.0394 | 0.0973 |
| premq9 | -0.0358 | 0.0202 | -0.0686 | 0.0812 | 0.9440 | 0.0202 | 0.0904 |
| premq12 | 0.1070 | 0.0704 | -0.0827 | 0.0361 | -0.0231 | 0.8365 | 0.2898 |

● Items grouped into factors. ● Items with weak loadings (below the 0.45 cut-off point). ● Items cross loading on two factors. ● A single item in one factor.

Stepwise removal of items 5, 19, 12 and 23 was undertaken. After which, a good solution was achieved with **five factors and 21 questions**. The results were also confirmed by examining the accompanying scree plot. Figure 8.3 outlines the factor loadings after excluding items (5,19,12,23), figures 8.4 and 8.5 are the accompanying

scree plot and the final correlation matrix of the remaining items, and table 8.3 outlines the final version of PREM-TMD.

Figure 8.3. Factor loadings after stepwise exclusion of 4 items of PREM-TMD using EFA with Oblimin rotation.

| Variable | Factor1 | Factor2 | Factor3 | Factor4 | Factor5 | Uniqueness |
|---|---|---|---|---|---|---|
| premq21 | 0.9552 | -0.0453 | -0.0252 | 0.0094 | 0.0156 | 0.1281 |
| premq20 | 0.8744 | 0.0658 | 0.0054 | -0.0426 | -0.0214 | 0.1952 |
| premq22 | 0.7950 | 0.1632 | 0.0917 | -0.0002 | 0.0045 | 0.1871 |
| premq2 | 0.6663 | 0.2664 | 0.0046 | -0.0991 | 0.0019 | 0.3730 |
| premq14 | 0.5372 | 0.1585 | 0.3237 | 0.1864 | 0.0805 | 0.2781 |
| premq6 | 0.5255 | 0.0641 | 0.2439 | 0.0834 | 0.0092 | 0.5208 |
| premq3 | 0.0934 | 0.8273 | 0.0828 | 0.0472 | -0.0187 | 0.1800 |
| premq4 | 0.1407 | 0.7476 | 0.0712 | 0.1450 | 0.0068 | 0.2342 |
| premq1 | 0.3765 | 0.6470 | -0.0837 | -0.0379 | 0.0024 | 0.3164 |
| premq17 | -0.1384 | 0.0443 | 0.7450 | -0.0948 | 0.0619 | 0.4733 |
| premq16 | 0.1933 | -0.3825 | 0.7118 | 0.0800 | -0.0059 | 0.4251 |
| premq24 | 0.0014 | 0.2885 | 0.6219 | -0.0093 | -0.0526 | 0.4266 |
| premq18 | 0.2093 | 0.2718 | 0.5652 | 0.0675 | -0.0195 | 0.3299 |
| premq13 | 0.1397 | 0.3886 | 0.4407 | 0.1729 | -0.0421 | 0.3667 |
| premq8 | -0.1320 | 0.1517 | 0.0431 | 0.7314 | 0.0776 | 0.4082 |
| premq7 | -0.2962 | 0.2548 | 0.0370 | 0.6622 | 0.0230 | 0.4574 |
| premq11 | -0.0052 | 0.0058 | 0.1373 | 0.6488 | 0.0477 | 0.5190 |
| premq15 | 0.3708 | -0.1905 | -0.1095 | 0.5951 | 0.0168 | 0.5175 |
| premq25 | 0.2385 | -0.1553 | -0.1636 | 0.5905 | 0.2126 | 0.5507 |
| premq10 | 0.0611 | 0.0503 | -0.0448 | -0.0714 | 0.9541 | 0.0903 |
| premq9 | -0.0286 | -0.0734 | 0.0255 | 0.0873 | 0.9463 | 0.0862 |

Figure 8.4. Scree plot of the retained factors of the final version of PREM-TMD

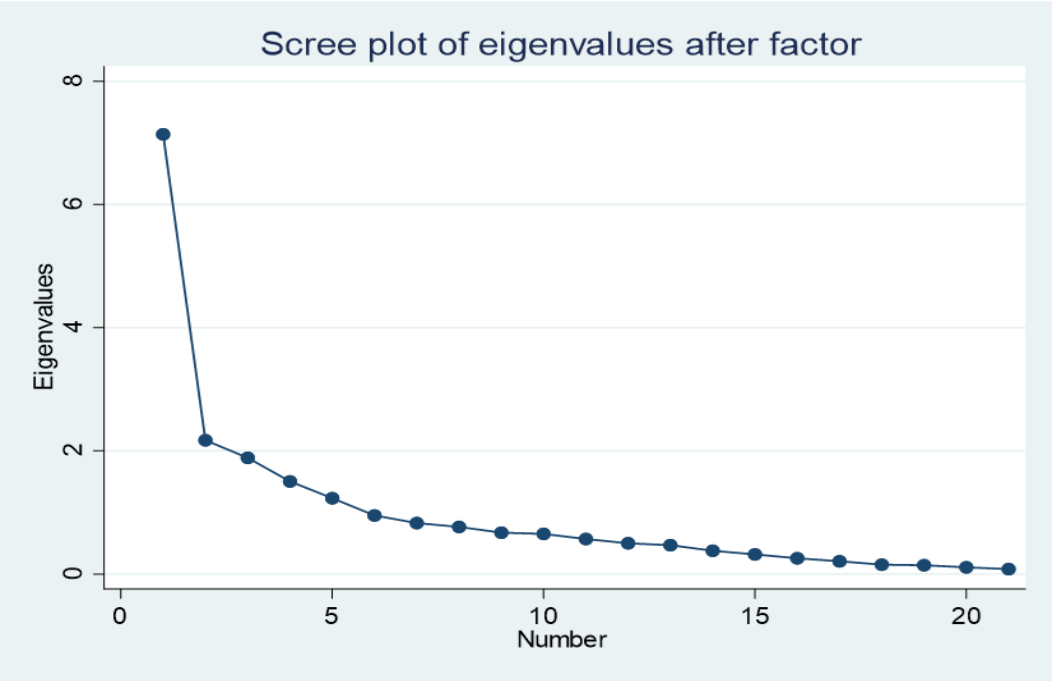


Figure 8.5. Correlation matrix of the remaining items of PREM-TMD.

| | premq1 | premq2 | premq3 | premq4 | premq6 | premq7 | premq8 | premq9 | premq10 | premq11 | premq13 | premq14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| premq1 | 1.0000 | | | | | | | | | | | |
| premq2 | 0.6480 | 1.0000 | | | | | | | | | | |
| premq3 | 0.6344 | 0.4744 | 1.0000 | | | | | | | | | |
| premq4 | 0.5859 | 0.4609 | 0.8186 | 1.0000 | | | | | | | | |
| premq6 | 0.3058 | 0.3998 | 0.4003 | 0.4737 | 1.0000 | | | | | | | |
| premq7 | 0.0905 | -0.0099 | 0.1791 | 0.2149 | 0.0584 | 1.0000 | | | | | | |
| premq8 | 0.1222 | 0.0873 | 0.2066 | 0.2788 | 0.1121 | 0.4914 | 1.0000 | | | | | |
| premq9 | -0.0546 | -0.1102 | -0.0168 | -0.0145 | -0.0155 | 0.0353 | 0.1123 | 1.0000 | | | | |
| premq10 | 0.0317 | 0.0597 | 0.0246 | 0.0673 | 0.0521 | 0.0396 | 0.0267 | 0.8241 | 1.0000 | | | |
| premq11 | 0.1866 | 0.1150 | 0.1609 | 0.1870 | 0.1252 | 0.3456 | 0.4174 | 0.1080 | -0.0219 | 1.0000 | | |
| premq13 | 0.4323 | 0.2954 | 0.6198 | 0.5776 | 0.4708 | 0.2075 | 0.2761 | 0.0378 | -0.0124 | 0.2540 | 1.0000 | |
| premq14 | 0.4948 | 0.5181 | 0.4958 | 0.5026 | 0.5922 | 0.1788 | 0.2334 | 0.0653 | 0.1160 | 0.2972 | 0.6784 | 1.0000 |
| premq15 | 0.1340 | 0.1882 | 0.1687 | 0.2276 | 0.2593 | 0.1398 | 0.2670 | 0.0737 | -0.0745 | 0.3298 | 0.1662 | 0.2557 |
| premq16 | 0.0963 | 0.2616 | 0.1004 | 0.1575 | 0.2408 | 0.0968 | 0.1607 | 0.0631 | 0.0196 | 0.1417 | 0.3321 | 0.2916 |
| premq17 | 0.1496 | 0.1160 | 0.2812 | 0.2333 | 0.1544 | 0.0793 | 0.1158 | 0.1118 | 0.0875 | 0.1289 | 0.2742 | 0.2778 |
| premq18 | 0.4015 | 0.4314 | 0.5215 | 0.5287 | 0.5064 | 0.1950 | 0.1845 | 0.0186 | 0.0419 | 0.2607 | 0.5588 | 0.6172 |
| premq20 | 0.5296 | 0.6219 | 0.4108 | 0.3906 | 0.4468 | 0.0040 | 0.0902 | -0.0865 | -0.0154 | 0.1055 | 0.4216 | 0.6134 |
| premq21 | 0.5151 | 0.6599 | 0.3365 | 0.3689 | 0.5034 | -0.0188 | 0.1150 | -0.0614 | 0.0096 | 0.1619 | 0.3580 | 0.6122 |
| premq22 | 0.5364 | 0.6020 | 0.5108 | 0.5444 | 0.5654 | 0.0410 | 0.1063 | -0.0547 | 0.0316 | 0.1696 | 0.4879 | 0.6710 |
| premq24 | 0.3669 | 0.3222 | 0.3822 | 0.3875 | 0.3104 | 0.1460 | 0.1843 | 0.0112 | 0.0309 | 0.2503 | 0.5000 | 0.4764 |
| premq25 | 0.0460 | 0.0417 | 0.0745 | 0.1388 | 0.1724 | 0.1958 | 0.2223 | -0.1263 | -0.1473 | 0.1726 | 0.1506 | 0.2457 |

| | premq15 | premq16 | premq17 | premq18 | premq20 | premq21 | premq22 | premq24 | premq25 |
|---|---|---|---|---|---|---|---|---|---|
| premq15 | 1.0000 | | | | | | | | |
| premq16 | 0.1406 | 1.0000 | | | | | | | |
| premq17 | 0.0378 | 0.3047 | 1.0000 | | | | | | |
| premq18 | 0.2107 | 0.3071 | 0.3760 | 1.0000 | | | | | |
| premq20 | 0.2128 | 0.1767 | 0.1427 | 0.4293 | 1.0000 | | | | |
| premq21 | 0.2484 | 0.2416 | 0.0853 | 0.3971 | 0.8905 | 1.0000 | | | |
| premq22 | 0.2417 | 0.2137 | 0.1903 | 0.5295 | 0.8163 | 0.8310 | 1.0000 | | |
| premq24 | 0.0173 | 0.2531 | 0.3349 | 0.6172 | 0.2995 | 0.2431 | 0.3845 | 1.0000 | |
| premq25 | 0.3118 | 0.0517 | -0.0719 | 0.0714 | 0.1262 | 0.1500 | 0.1558 | 0.0395 | 1.0000 |

Table 8.3. The final version of PREM-TMD.

| | **Factor 1 (Emotional support)** |
|---|---|
| 1 (21) | My clinician was reassuring and supportive |
| 2 (2) | The clinician acknowledged the impact of pain on my life |
| 3 (20) | I was listened to and believed during the visit |
| 4 (22) | I have confidence in my clinical team |
| 5 (6) | I felt I had the right clinical team for my condition |
| 6 (14) | I received information about my condition to a satisfactory level |
| | **Factor 2 (Respect for patient-centred values, preference and needs)** |
| 7 (1) | I felt respected and understood |
| 8 (4) | I was involved in the decisions about my care |
| 9 (3) | The clinician explained the treatment options adequately |
| | **Factor 3 (Information, communication, and education)** |
| 10 (13) | I received a timely diagnosis at this clinic |
| 11 (16) | I was given information on how to contact my clinical team should I need to |
| 12 (17) | There is good communication with the hospital |
| 13 (18) | I was satisfied with the treatment plan decided |
| 14 (24) | I feel better able to cope with my symptoms |
| | **Factor 4 (Access to care)** |
| 15 (7) | I waited a reasonable amount of time from when I was referred until I was seen in this clinic |
| 16 (8) | The referral process to the hospital was straightforward |
| 17 (11) | I did not experience unexpected appointment cancellations or delays in receiving appointments |

| | |
|---|---|
| 18 (25) | I waited a reasonable amount of time in the waiting area before being seen in clinic |
| 19 (15) | I was given enough time to ask any questions |
| | **Factor 5 (Coordination of care)** |
| 20 (9) | The onward referrals from this clinic were timely and coordinated. |
| 21 (10) | There was good coordination between the different clinicians who looked after my facial pain |

| | |
|---|---|
| | 29. Overall, I am satisfied with my experience in this clinic |

After amending the PREM according to the previous comments, the final questionnaire contained 21 questions with a maximum point score of 105, making the total score calculation formula as follows:

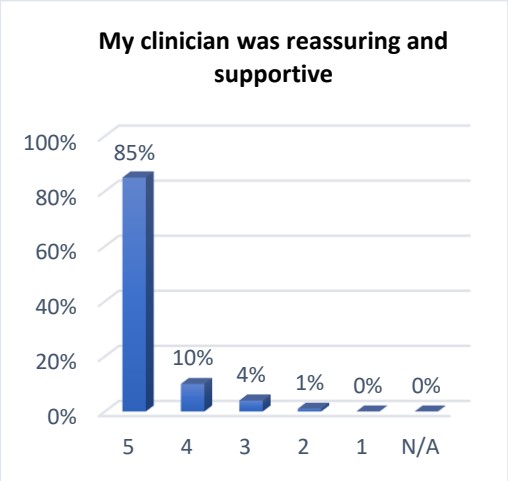
$$\text{Total score} = \frac{\sum items\ 1{-}21}{105{-}(\text{number of NA answers x } 5)}\ \text{x } 100\%$$

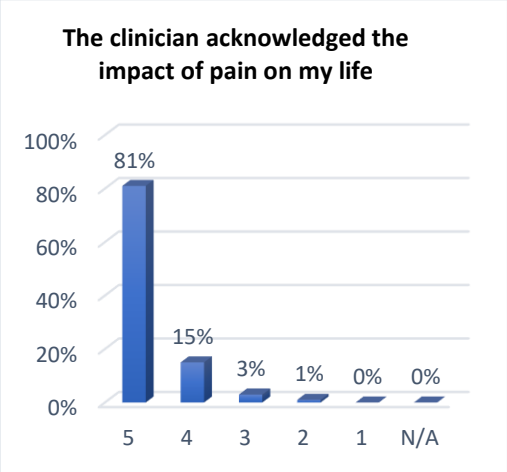
This formula shall be included as a footnote with the PREM to guide and facilitate total score calculation in future use of the PREM. Appendix 7 shows the final version of PREM-TMD.

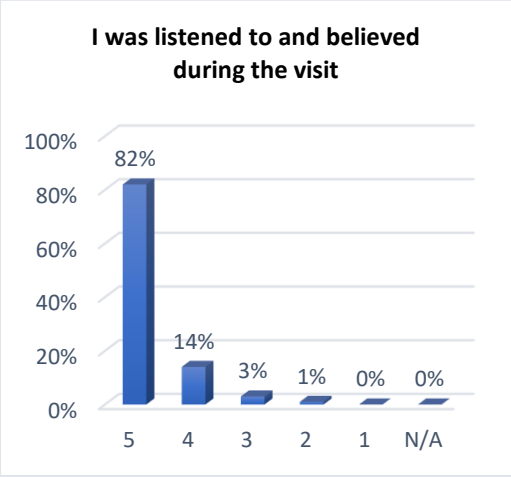
After applying the formula to the current sample, the mean experience score was 89.6% (±9.1% SD), with the scores ranging from 53.3% to 100% positive experience. Additionally, a statistically significant and strong Spearman's correlation was observed between the total computed score and item 29 (Overall, I am satisfied with my experience in this clinic) (r= 0.66, p value .0001). This feeds into supporting the convergent validity of PREM-TMD. Figure 8.6. shows the response distribution for each item of the final version of PREM-TMD.

Figure 8.6. The response distribution for each item in the final version PREM-TMD

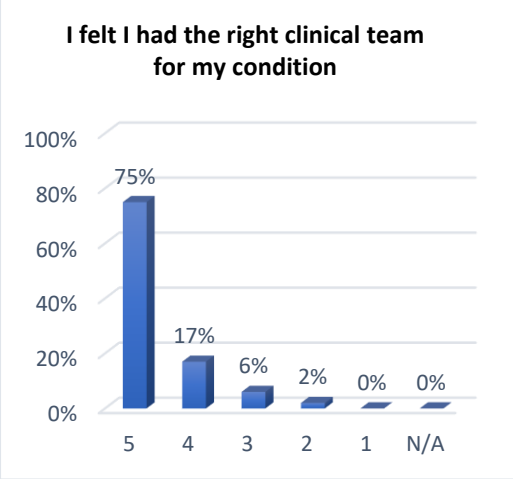
***Domain 1: Emotional support***

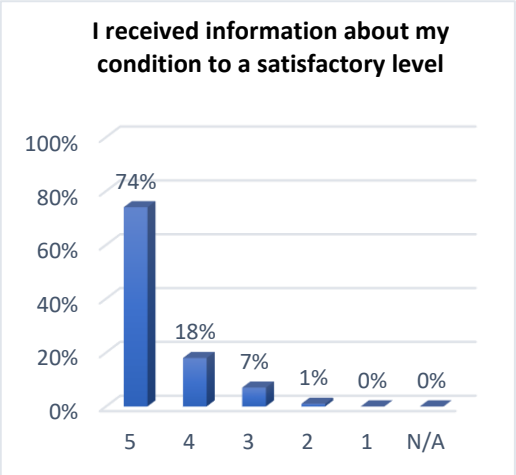


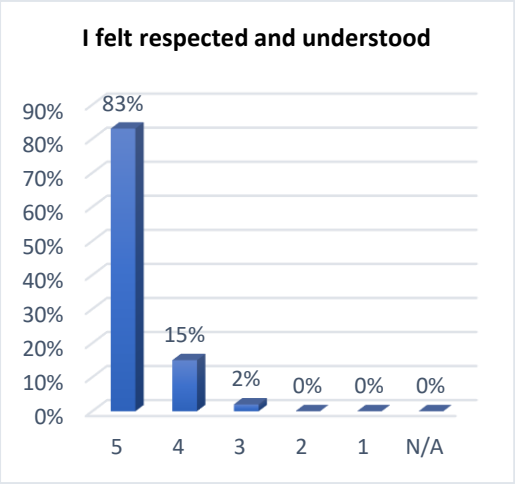



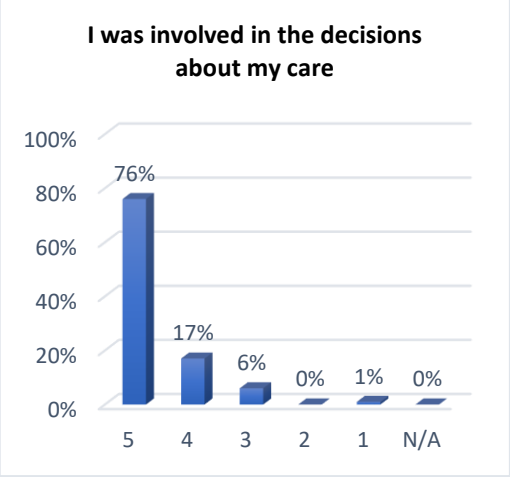


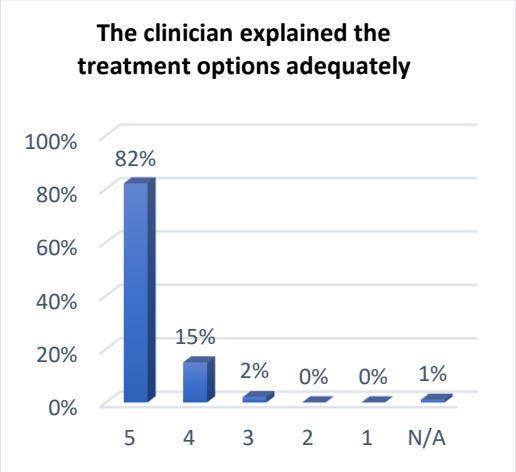


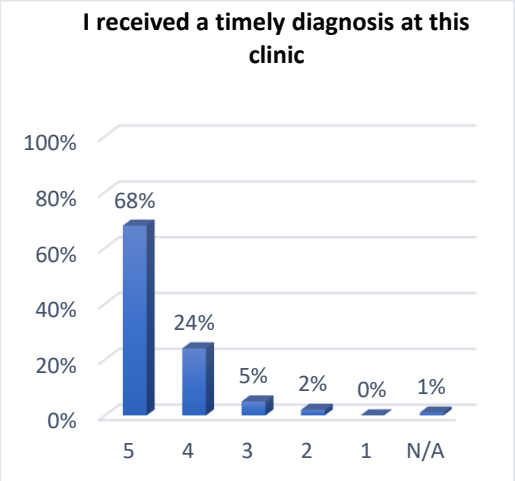
## ***Domain 2 (Respect for patient-centred values, preference and needs)***

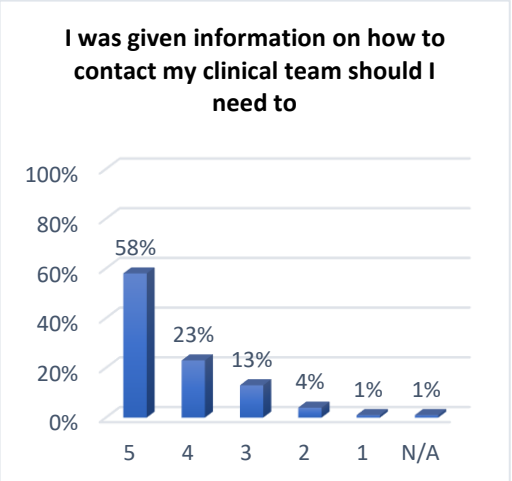


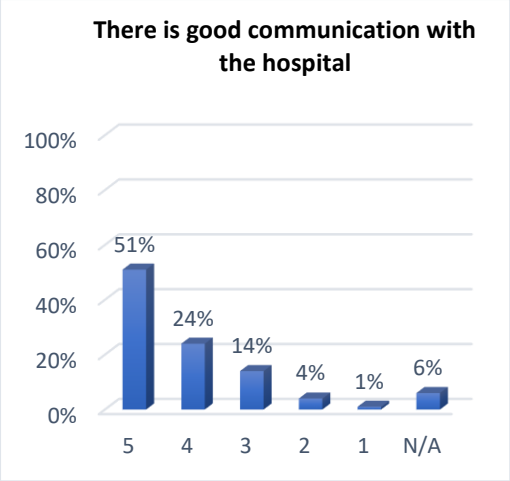



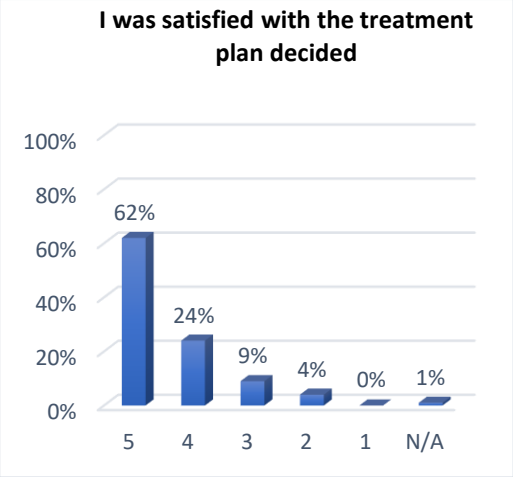



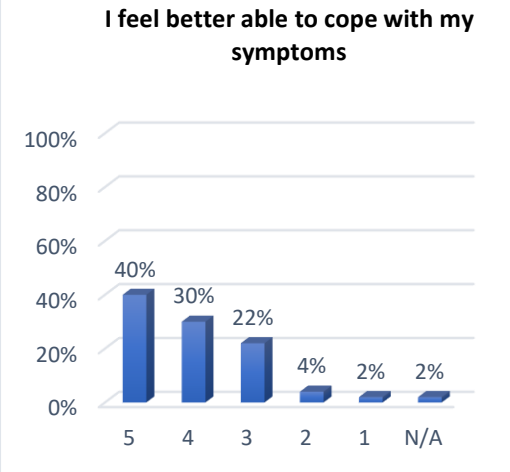

## ***Domain 3 (Information, communication, and education)***



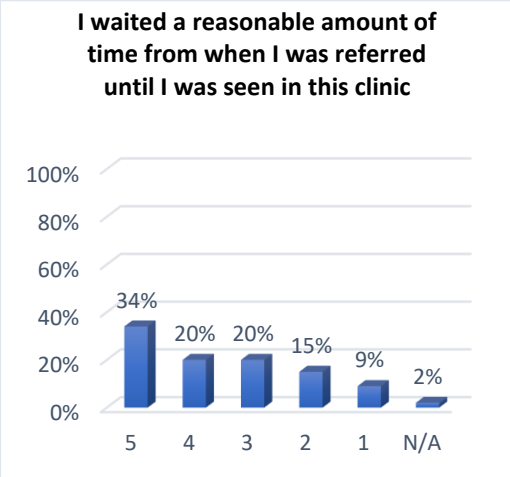



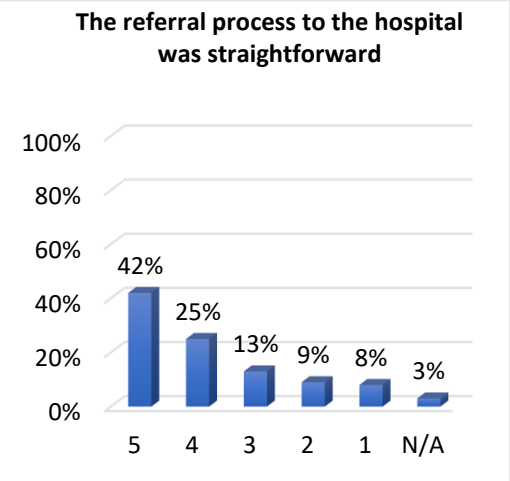


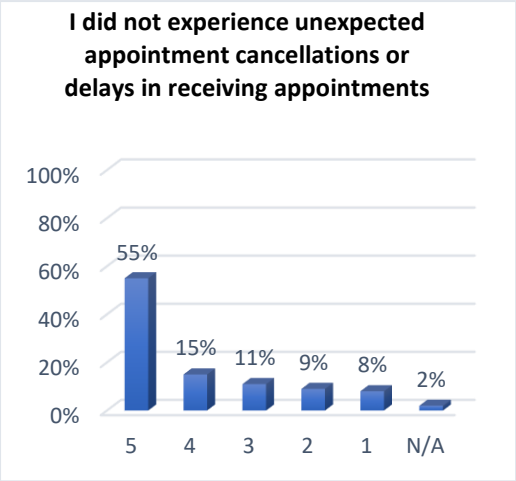



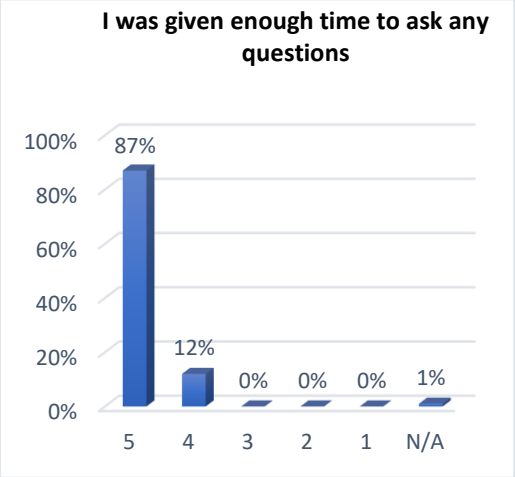

## ***Domain 4 (Access to care)***



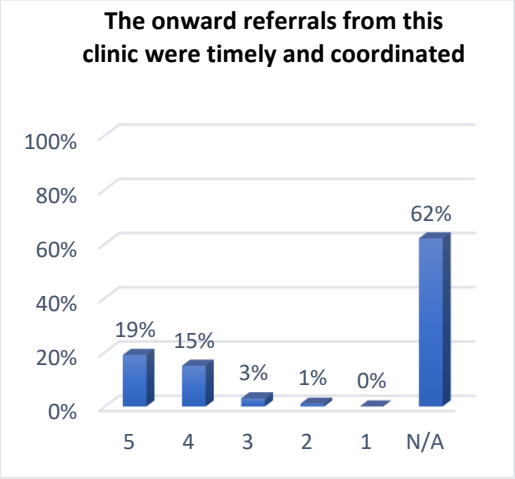



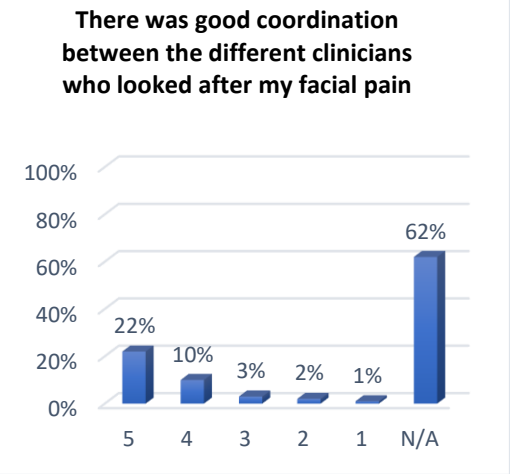







## ***Domain 5 (Coordination of care)***




### 8.4.2.III. Internal consistency reliability

Cronbach α was calculated to evaluate the internal consistency of the overall questionnaire, and the individual factors as well. Overall Cronbach α was 0.7285. Cronbach α for factor 1 (Emotional support) was 0.9020, factor 2 (Respect for patient-centred values, preference and needs) was 0.8590, factor 3 (Information, communication, and education) was 0.736, factor 4 (Access to care) was 0.6600, and factor 5 (Coordination of care) was 0.9036. All the values fell above the 0.7 cut-off point for acceptable Cronbach α values, except for factor 4 with a 'questionable' value of 0.66.

### 8.4.2. IV. Test-retest reliability

50 participants returned the questionnaires to evaluate test-retest reliability (9M, 41F). All the participants preferred to be sent the questionnaire via email. The email was sent two weeks after the participants' in-hospital visit, and a reminder was sent the following week for the non-responders. None of the patients attended any additional

clinical visits during this period; therefore, the measured construct (hospital experience in this case) is assumed to be stable between the two time points.

The agreement between both questionnaires, at baseline and two weeks later, was computed using ICC for the total score and scores for the individual factors. Two-way random effects model was used as systematic differences are considered part of the measurement error (McGraw and Wong, 1996, Terwee et al., 2007). Weighted kappa using quadratic weights was calculated for the individual items.

ICC for the total score of PREM-TMD was 0.732. ICC for the individual factors were 0.734, 0.479, 0.758, 0.754 and 0.799 for factors 1,2,3,4 and 5 respectively. All the values fall above the 0.70 cut off point, expect for factor 2, with a fair ICC of 0.479.

Table 8.4 outlines the Cronbach α and ICC for the overall PREM and individual factors and weighted kappa values for each item individually.

Table 8.4. Cronbach α, ICC and weighted kappa associated with PREM-TMD.

| Items | Cronbach α | ICC (95% CI) | Weighted kappa (95% CI) |
|---|---|---|---|
| **All items (overall)** | **0.7285** | **0.732*** (*0.27-0.88*) | |
| **Factor 1 (Emotional support)** | **0.9020** | **0.734*** (*0.28-0.88*) | |
| 1. My clinician was reassuring and supportive | | | **0.36*** (*0.026-0.684*) |
| 2. The clinician acknowledged the impact of pain on my life | | | **0.62*** (*0.360-0.880*) |
| 3. I was listened to and believed during the visit | | | **0.62*** (*0.372-0.860*) |
| 4. I have confidence in my clinical team | | | **0.53*** (*0.318-0.744*) |
| 5. I felt I had the right clinical team for my condition | | | **0.55*** (*0.300-0.790*) |
| 6. I received information about my condition to a satisfactory level | | | **0.53*** (*0.350-0.707*) |
| **Factor 2 (Respect for patient-centred values, preference and needs)** | **0.8590** | **0.479*** *(0.10-0.70)* | |
| 7. I felt respected and understood | | | **0.42*** (*0.063-0.774*) |
| 8. I was involved in the decisions about my care | | | **0.11** (*-0.098-0.311*) |
| 9. The clinician explained the treatment options adequately | | | **0.18** (*-0.044-0.396*) |
| **Factor 3 (Information, communication, and education)** | **0.736** | **0.758*** *(0.38-0.89)* | |
| 10. I received a timely diagnosis at this clinic | | | **0.27*** (*0.048-0.497*) |
| 11. I was given information on how to contact my clinical team should I need to | | | **0.47*** (*0.198-0.732*) |
| 12. There is good communication with the hospital | | | **0.39*** (*0.107-0.680*) |
| 13. I was satisfied with the treatment plan decided | | | **0.37*** (*0.088-0.649*) |
| 14. I feel better able to cope with my symptoms | | | **0.41*** (*0.211-0.602*) |
| **Factor 4 (Access to care)** | **0.66** | **0.754*** *(0.56-0.86)* | |
| 15. I waited a reasonable amount of time from when I was referred until I was seen in this clinic | | | **0.38*** (*0.052-0.706*) |
| 16. The referral process to the hospital was straightforward | | | **0.63*** (*0.362-0.898*) |
| 17. I did not experience unexpected appointment cancellations or delays in receiving appointments | | | **0.55*** (*0.244-0.860*) |
| 18. I waited a reasonable amount of time in the waiting area before being seen in clinic | | | **0.66*** (*0.406-0.907*) |
| 19. I was given enough time to ask any questions | | | **0.36*** *(0.104-0.622*) |
| **Factor 5 (Coordination of care)** | **0.9036** | **0.799*** *(0.65-0.89)* | |
| 20.The onward referrals from this clinic were timely and coordinated. | | | **0.70*** (*0.490-0.900*) |
| 21. There was good coordination between the different clinicians who looked after my facial pain | | | **0.54*** (*0.276-0.803*) |
| Overall, I am satisfied with my experience in this clinic | | | **0.33*** (*0.066-0.597*) |

* Associated p value <0.05

### 8.4.3. Associations between PREM-TMD, demographic variables and psychological comorbidities.

129 participants completed the entire set of questionnaires at this stage. Shapiro-Wilkes was conducted to evaluate normality in the data. All the variables did not have a normal distribution, therefore non-parametric tests were used in this instance. The skewness (the degree of deviation from the median or the extent to which a variable's distribution is symmetrical) (Scott and Mazhindu, 2005) and kurtosis (a measure of whether the distribution is too peaked) (Hair et al., 1995) were also tested. All the variables had acceptable values with none outside the range of -1-1 for kurtosis and skewness. Values falling outside these cut off points indicate distributions that are too flat or too peaked, or with a substantially skewed distribution. Table 8.5 describes the mean, median, kurtosis and skewness values of the variables.

Table 8.5. Mean, median, skewness and kurtosis values of the study variables.

| Variable | Mean (SD) | Median | Skewness | Kurtosis |
|---|---|---|---|---|
| Premq1 | 4.80 (0.46) | 5.0 | 0.0000 | 0.0000 |
| Premq2 | 4.74 (0.59) | 5.0 | 0.0000 | 0.0000 |
| Premq3 | 4.77 (0.62) | 5.0 | 0.0000 | 0.0000 |
| Premq4 | 4.68 (0.65) | 5.0 | 0.0000 | 0.0000 |
| Premq6 | 4.67 (0.67) | 5.0 | 0.0000 | 0.0000 |
| Premq7 | 3.50 (1.43) | 4.0 | 0.0082 | 0.0191 |
| Premq8 | 3.78 (1.43) | 4.0 | 0.0000 | 0.6322 |
| Premq9 | 1.61 (2.15) | 0.0 | 0.0036 | 0.0000 |
| Premq10 | 1.58 (2.15) | 0.0 | 0.0013 | 0.0000 |
| Premq11 | 3.91 (1.45) | 5.0 | 0.0000 | 0.7753 |
| Premq13 | 4.58 (0.78) | 5.0 | 0.0000 | 0.0000 |
| Premq14 | 4.66 (0.64) | 5.0 | 0.0000 | 0.0004 |
| Premq15 | 4.83 (0.56) | 5.0 | 0.0000 | 0.0000 |
| Premq16 | 4.28 (1.05) | 5.0 | 0.0000 | 0.0001 |
| Premq17 | 3.98 (1.41) | 4.0 | 0.0000 | 0.0025 |
| Premq18 | 4.43 (0.87) | 5.0 | 0.0000 | 0.0000 |
| Premq20 | 4.78 (0.53) | 5.0 | 0.0000 | 0.0000 |
| Premq21 | 4.80 (0.54) | 5.0 | 0.0000 | 0.0000 |
| Premq22 | 4.74 (0.59) | 5.0 | 0.0000 | 0.0000 |
| Premq24 | 3.93 (1.15) | 4.0 | 0.0000 | 0.0049 |
| Premq25 | 4.43 (0.96) | 5.0 | 0.0000 | 0.0008 |
| Premq29 | 4.64 (0.60) | 5.0 | 0.0000 | 0.0522 |
| Total score | 0.90 (0.09) | 0.92 | 0.0000 | 0.0235 |
| GCPS | 2.46 (1.18) | 2.0 | 0.6684 | 0.0000 |

| | | | | |
|---|---|---|---|---|
| CPI | 56.02 (22.40) | 60.0 | 0.0409 | 0.0205 |
| PHQ8 | 8.96 (6.60) | 8.0 | 0.0255 | 0.0159 |
| GAD7 | 8.14 (6.41) | 7.0 | 0.0353 | 0.0001 |
| PHQ15 | 9.58 (5.68) | 8.5 | 0.0182 | 0.1974 |
| JFLS20 | 3.11 (2.26) | 3.14 | 0.0693 | 0.0354 |
| Age | 39.90 (14.28) | 37.0 | 0.0209 | 0.1400 |
| Comorbidities | 0.79 (1.12) | 0.0 | 0.0000 | 0.0000 |
| Other CP | 1.50 (1.45) | 1.0 | 0.0011 | 0.6322 |
| Onset | 7.49 (7.99) | 4.0 | 0.0000 | 0.0002 |
| GIS | 1.22 (1.68) | 0.0 | 0.0002 | 0.0001 |

Premq: PREM-TMD question. CP: chronic pain conditions. CPI: characteristic pain intensity. GIS: Global improvement and satisfaction with treatment.

The mean age of the participants was 39.9 years (±14.28 SD), with a median of 37. The majority of them were female patients (82.17%) and just under two thirds were first visit patients (59.7%) as opposed to follow up visits (40.3%). Around a third had no depression and minimal anxiety (29.46% and 35.66% respectively), with the remaining participants ranging from mild to severe anxiety and depression. The mean number of co-morbidities and other chronic pain conditions in this cohort was 0.79 (±1.1 SD) and 1.49 (±1.5 SD) respectively. The majority of the patients were using a combination of treatments at the time (62.02%), while 15.50% were not receiving active treatment. 20.94% of the participants reported improvement in their symptoms in comparison to their previous visits, and only 1.55% reported minimal worsening of their symptoms. Table 8.6 describes the demographic distribution of the participants in detail.

In order to identify any associations with the final PREM-TMD score, bivariable analysis was conducted with the demographic characteristics and the total scores of other scales. The results show very few significant associations between PREM-TMD total score and the rest of the variables. Those with a significant p-value were the Spearman's correlations between PREM-TMD and CPI (p-value=0.0199, r= -0.20), and PREM-TMD and JFLS (p-value=0.0235, r=-0.19). Spearman's correlations were negative, signifying reduced PREM-TMD score with higher values of these variables.

Despite the significant p-value, the strength of correlation appears to be weak. Additionally, a statistically significant difference was detected between PREM-TMD scores of the first visit and follow up patients as shown by the Mann-Whitney rank test (p-value=0.0380). First visit patients were found to have higher scores than follow up patients. Tables 8.6 and 8.7 show the tests conducted and the results in detail.

Table 8.6. Analysis of the associations between PREM-TMD, demographic data, pain, anxiety, depression, and somatisation levels (categorical variables)

| Study variable | N (%) | P value |
|---|---|---|
| [a] **Visit status** | | **0.0380*** |
| - First visit | 77 (59.7%) | |
| - Follow up | 52 (40.3%) | |
| [b] **Ethnicity** | | 0.7362 |
| - White | 84 (65.12%) | |
| - Asian | 27 (20.93%) | |
| - Black | 9 (6.98%) | |
| - Mixed | 5 (3.88%) | |
| - Other | 4 (3.10) | |
| [a] **Sex** | | 0.5518 |
| - Male | 23 (17.83%) | |
| - Female | 106 (82.17%) | |
| [b] **Marital status** | | 0.5738 |
| - Single | 64 (49.61%) | |
| - Married | 43 (33.33%) | |
| - Living with partner | 13 (10.08%) | |
| - Divorced | 6 (4.65%) | |
| - Widowed | 3 (2.33%) | |
| [b] **Employment** | | 0.1815 |
| - Employed | 93 (72.09%) | |
| - Unemployed | 12 (9.30%) | |
| - Retired | 7 (5.43%) | |
| - Homemaker | 9 (6.98%) | |
| - Student | 8 (6.20%) | |
| [b] **Smoking status** | | 0.1530 |
| - Never smoked | 84 (65.12%) | |
| - Previous smoker | 31 (24.03%) | |
| - Current smoker | 14 (10.85%) | |
| [a] **Alcohol consumption** | | 0.4883 |
| - Non-drinker | 61 (47.29%) | |
| - Drinker | 68 (52.71%) | |
| [b] **Schooling** | | 0.2211 |
| - School | 42 (32.56%) | |
| - Some university | 13 (10.08%) | |
| - University | 40 (31.01%) | |
| - Post graduate | 34 (26.36%) | |
| [a] **DC-TMD classification** | | 0.5960 |
| - Myalgia | 62 (48.06%) | |

| | | |
|---|---|---|
| - Myalgia+ IA involvement | 67 (51.94%) | |
| [b] **GIS** | | 0.1191 |
| - First visit | 77 (59.69%) | |
| - Very much improved | 9 (6.98%) | |
| - Much improved | 7 (5.43%) | |
| - Minimally improved | 11 (8.53%) | |
| - No change | 23 (17.83%) | |
| - Minimally worse | 2 (1.55%) | |
| - Much worse | 0 (0%) | |
| - Very much worse | 0 (0%) | |
| [b] **GCPS** | | 0.1516 |
| - Grade 1 | 37 (28.68%) | |
| - Grade 2 | 32 (24.81%) | |
| - Grade 3 | 24 (18.60%) | |
| - Grade 4 | 36 (27.91%) | |
| [a] **GCPS (binary)** | | 0.1511 |
| -Grade 1,2 | 69 (53.5%) | |
| -Grade 3,4 | 60 (46.5%) | |
| [b] **PHQ-8 levels** | | 0.9581 |
| - No depression | 38 (29.46%) | |
| - Mild | 40 (31.01%) | |
| - Moderate | 24 (18.60%) | |
| - Moderately severe | 16 (12.40%) | |
| - Severe | 11 (8.53%) | |
| [a] **PHQ-8 (10 cut-off point)** | | 0.8355 |
| -<10 | 78 (60.47%) | |
| -≥10 | 51 (39.53%) | |
| [b] **GAD-7 levels** | | 0.2535 |
| - Minimal anxiety | 46 (35.66%) | |
| - Mild | 36 (27.91%) | |
| - Moderate | 24 (18.60%) | |
| - Severe | 23 (17.83%) | |
| [a] **GAD-7 (10-cut off point)** | | 0.0476 |
| -<10 | 82 (63.57%) | |
| -≥10 | 47 (36.43%) | |
| [b] **PHQ-15 levels** | | 0.0795 |
| - Minimal | 23 (17.83%) | |
| - Low | 51 (39.53%) | |
| - Medium | 30 (23.26%) | |
| - High | 25 (19.38%) | |
| [a] **PHQ-15 (10 cut-off point)** | | 0.7262 |
| -<10 | 74 (57.36%) | |
| -≥10 | 55 (42.64%) | |
| [b] **Treatment strategies** | | 0.5242 |
| - No active treatment | 20 (15.50%) | |
| - Physiotherapy | 21 (16.28%) | |
| - Acupuncture | 2 (1.55%) | |
| - Splint | 2 (1.55%) | |
| - Medications | 4 (3.105) | |
| - CBT | 0(0%) | |
| - Mix | 80 (62.02%) | |

a: Mann-Whitney rank sum test. b: Kruskal-Wallis equality of proportions rank test. * p-value <0.05 indicating statistical significance.

Table 8.7. Analysis of the associations between PREM-TMD, demographic data, pain, anxiety, depression, and somatisation levels (continuous variables).

| Study variable | Mean (SD) | Median | Range | P value | Spearman's rho *(95% CI)* |
|---|---|---|---|---|---|
| [c] Age | 39.9 (14.3) | 37 | 18-74 | 0.5196 | r= 0.057 *(-0.122-0.233)* |
| [c] GCPS | 2.5 (1.2) | 2.0 | 1-4 | **0.0412*** | **r= -0.18** *(-0.347- -0.002)* |
| [c] CPI | 56.0 (22.4) | 60.0 | 3.33-96.67 | **0.0199*** | **r= -0.205** *(-0.369- -0.028)* |
| [c] JFLS | 3.1 (2.3) | 3.14 | 0-8.47 | **0.0235*** | **r=-0.19** *(-0.364- -0.022)* |
| [c]PHQ-8 | 8.96 (6.6) | 8.0 | 0-24 | 0.9693 | r= -0.003 *(-0.181-0.175)* |
| [c]GAD-7 | 8.1 (6.4) | 7.0 | 0-21 | 0.1425 | r= 0.130 *(-0.049-0.301)* |
| [c] PHQ-15 | 9.58 (5.7) | 8.5 | 0-24 | 0.2479 | r= -0.102 *(-0.275-0.077)* |
| [c] Co-morbidities | 0.79 (1.1) | 0 | 0-6 | 0.1457 | r= 0.129 *(-0.050-0.300)* |
| [c] Other CP† | 1.49 (1.5) | 1.0 | 0-6 | 0.8410 | r= 0.018 *(-0.161-0.195)* |
| [c] Time of onset | 7.5 (7.9) | 4.0 | 0.05-38 | 0.6866 | r= 0.036 *(-0.143-0.212)* |

c: Spearman's correlation. †: chronic pain conditions. *: p-value <0.05 indicating statistical significance. r: Spearman's rho.

## 8.5. Discussion

The present chapter described the development and initial validation of a Patient Reported Experience Measure for patients with Temporomandibular Disorders (PREM-TMD), a brief measure to evaluate the experience of adult patients with pain related TMD within the healthcare services. This instrument was developed for use in service evaluation, audits, and clinical research. The structural validity, internal consistency and test-retest reliability were explored in this chapter, all generating satisfactory results according to the COSMIN initiative guidance.

The domains of the instrument captured the experience in terms of emotional support, respect for patient centred values, adequacy of information provided, prompt access to care and coordination of care. It initially covered 9 domains containing 52 questions, however, with patient and experts' input, and subsequent statistical validation, five

domains with 21 questions were deemed suitable to cover the patient experience within the healthcare services. This framework differed slightly than the one suggested by the NHS, where involvement of family and friends and physical comfort were not of paramount importance to TMD patients. The former domain was debated extensively with the patients in the focus groups and cognitive interviews, and the general consensus was that most of the patients attend their clinical appointments alone anyway. Similarly for the other domain, where the physical surroundings were of lesser importance to receiving enough information or a satisfactory treatment plan, for example. Nevertheless, both domains were kept in later stages to avoid premature elimination. However, after another round of patient input in the form of a pilot study to explore the psychometric properties, the former domain was omitted, and the questions of the later domain were best suited under different factors. It is worth noting that a comments box was attached to the bottom of instrument as well, providing the patients with the opportunity to elaborate on certain points if they wish.

The scoring method chosen generated a percentage, with scores closer to 100% representing better experiences. In addition to accounting for the possible “not applicable” responses, a score in the form of a percentage may be more intuitive than the simple sum of items in judging the positiveness of the experience. The mean experience score in this study was 89.6%, indicating a largely very positive experience at the Eastman Dental Hospital. High scores were marked especially in association with the items addressing the interaction with the clinicians, such as items about the doctors being supportive, understanding and interested. The percentages associated with the response options “Strongly disagree” and “Disagree” were generally low, ranging from 0%-24% in total for both options together. The upper value of this range is associated with the item regarding waiting times since being referred to getting an

appointment at the hospital. When answering this particular question, many patients acknowledged the circumstances surrounding the NHS in terms of dealing with the aftermath of SARS-CoV-2 outbreak at the time of the study. However, it might be an area of interest to investigate in the future with the aim of improving this aspect of care for the patients.

The underlying structural layout was identified by exploratory factor analysis (EFA), where five factors were suggested. EFA is deemed suitable when the researcher has little or no prior information regarding the expected latent structure underlying a set of questions (Finch, 2020). Although some information was available regarding the expected number of factors, as defined by the NHS experience framework and the associated PREMs which used it as a basis (Bosworth et al., 2015), the items of this questionnaire were however new, and the relationships between them were unexplored. Therefore, EFA was applied in this case. The stability of this solution could be confirmed in future research using confirmatory factor analysis.

Two aspects of reliability were also studied in the present chapter, internal consistency, and test-retest. The overall Cronbach α and interclass correlation coefficient were 0.07285 and 0.732, both confirming good reliability of the instrument. The patients were asked to complete the questionnaire two weeks after the baseline visit. None of the participants were expected to have another clinical visit within this time period, therefore, the corresponding answers represented the proceedings of the clinical visit in question and the stability of the construct (the hospital experience) could be assumed.

The content validity was assessed in previous phases of this research. Considering that the other measurement properties could be negatively affected by the lack of

content validity, the FDA and COSMIN initiatives recommend its evaluation early on (Terwee et al., 2018). Patients and professionals in this study were asked about the relevance, comprehensibility, and comprehensiveness of the questions during the previous qualitative component, thereby ensuring good content and face validity of the instrument.

One of the strengths associated with PREMs, was the objective manner in which they measure the experience as compared to satisfaction surveys (Kingsley and Patel, 2017). In the present study, demographic variables such as age, ethnicity, gender, schooling level, and psychological co-morbidities such as anxiety, depression and somatisation had no influence on the final experience scores. The factors which were found to have an association were the visit status, characteristic pain intensity (CPI) and JFLS-20 scores. Some of the patients who attended follow up appointments have been under the care of the hospital for extended periods of time. Expectedly, they may have been exposed to wider facets of care, such as onward referrals and seeing different clinicians during follow up appointments. Therefore, it was more likely that they faced more problems while under the care of the same service in comparison to patients attending their first appointments, thereby affecting their experience scores. Additionally, chronic pain patients usually seek professional help when the pain intensifies, and interference in life urges them to seek treatment (Majedi et al., 2020). As such, the patients in this study may have attended their clinical visits with a sense of frustration at the effect the pain was having on their lives, which in turn may have influenced their perception of a positive clinical experience.

There were a number of limitations associated with the present study. The psychometric properties investigated so far appear to be sound. However, it still requires additional psychometric testing to establish other aspects such as

interpretability of the score, and responsiveness. Other limitations were related to the sample size used. Exploratory factor analysis in general is a technique for large samples (Kyriazos, 2018). The definition of a large and sufficient sample is still however debatable. The sample used in the present study was adequate according to the recommendations of the COSMIN initiative. However, in future research, it may be worthwhile to use a larger sample size to confirm the suitability of the suggested factor solution and establish a comprehensive profile of the associated psychometric properties. Finally, the participants for this study were recruited from a tertiary care centre in the UK which operates within the structure of the NHS, and the newly developed PREM was a reflection of their views and experiences. Therefore, if the instrument is applied in other contexts, caution should be exercised in interpreting the results.

## 8.6. Conclusions

PREM-TMD is a brief and easy to complete instrument used to assess the hospital experience of patients with pain related TMD. It can be useful in service evaluation schemes, audits, and clinical research. Although more psychometric testing is required, the structural validity, internal consistency and test-retest reliability are satisfactory, and the instrument shows promise in assisting facial pain services in examining their performance.

The present study was an initial step in the validation of PREM-TMD. Further research is recommended to establish the other psychometric properties, and to determine the feasibility of implementing this instrument in routine clinical practice.

# Chapter 9. General discussion and future work

## 9.1. Summary

The field of patient reported experience measures (PREMs) has been continuously evolving over the last few decades. They have gained international recognition as an indicator of quality due to several attributes such as the ability to obtain a comprehensive view of healthcare as perceived by the users. This patient-level information could drive service improvement strategies and be used as a measure for public reporting and benchmarking of health institutions (Bull et al., 2019). The measured patient experience provides factual and reliable data that can be used to stimulate quality enhancing actions, measure patient centredness, determine positive modifications, and evaluate new services (De Rosis et al., 2020).

Numerous PREMs have been established in multiple settings and contexts. However, none were found to evaluate the experience of patients with temporomandibular disorders, or indeed facial pain within the context of clinical care. Hence this piece of research aimed to create and validate a Patient Reported Experience Measure for patients with Temporomandibular disorders (PREM-TMD). The project was planned to include both qualitative and quantitative components in a mixed methods design. The qualitative part offered several elements, starting with a qualitative evidence synthesis which analysed the recorded experiences of TMD patients in the literature. The results of the systematic reviews outlined in chapters 4 and 5, pooled data from 20 qualitative studies exploring the effects TMD could have on patients' lives and their encounters within healthcare. In line with the reports of other chronic pain patients, the clinical experience is important to this group as well, and some aspects seem to affect their ability to cope with the symptoms such as receiving a diagnosis and being

understood and listened to by healthcare professionals. The information gathered from this review served multiple purposes. Firstly, it helped develop the topic guide used in subsequent stages of the research. Secondly, it complemented the data gathered from the focus groups later on, thus ensuring data triangulation and collection from multiple sources. And finally, it helped meet an important element in the development of patient reported measures, which is input from the relevant literature. Input form the target population and domain experts was collected later on.

The subsequent qualitative study reported in chapter 6 explored the experiences of the patients with the NHS in England when seeking treatment for their symptoms. A series of three focus groups was held remotely with 15 patients who described their clinical journey and highlighted the aspects of care which were important to them. Guided by the NHS patient experience framework, the items of the new PREM were generated. This framework was adopted as it included the elements regarded as essential for all patients within the NHS. It was based upon the principles of patient centred care as suggested by the Picker's Institute, and was used as basis for other PREMs, such as the one for patients with rheumatoid arthritis (RA) and other rheumatic conditions (Bosworth et al., 2015). The questions of the new instrument were generated from the data gathered in the focus groups and the preceding systematic review. The candidate list of questions was circulated to six healthcare professionals who deal with TMD patients regularly and were invited to comment on the list of questions for suitability and relevance. The alterations made according to these comments are detailed in chapter 7 which also reported the results of the subsequent cognitive testing in collaboration with the patients. The contribution from these three sources – previous literature, target population and domain experts-established good content and face validity. It also ensured that the questions were

relevant and suitable for the target population, and important questions were not being missed.

Chapter 8 described the qualitative component of the research, where a questionnaire-based study was designed to explore some psychometric properties associated with the new PREM; structural validity, internal consistency, and test-retest reliability. All the properties gave satisfactory results, thereby providing positive evidence to support the suitability of the new instrument in measuring the experience of TMD patients within healthcare. This chapter also explored the relationships between the measured experience and other variables, such as demographic data, pain levels and psychological co-morbidities. Very few associations were discovered, which in turn supported the initial suggestion that PREMs measure the experience in an objective and focused manner.

The Patient Reported Outcome Measures (PROMs) used in this project to measure pain, functional limitation, and psychological distress were common PROMs recommended by the DC/TMD initiative to gain a comprehensive assessment of the physical and psychological functioning of TMD patients. While this classification criterion is closest to a gold standard and is very popular among researchers (as outlined in chapter 2), some of the PROMs suggested needed additional evidence of psychometric testing in a TMD population. Chapter 3 described a cross sectional study to explore the structural validity and internal consistency reliability of four common PROMs in a TMD population: Patient Health Questionnaire 8 and 15 (PHQ 8,15), General Anxiety Disorder-7 (GAD-7) and Jaw Functional Limitation Scale 20 (JFLS-20). The results were satisfactory, and positive evidence was obtained for their use in a TMD population. Hence, they were used with confidence in the subsequent phases.

The strengths of this piece of research included patient involvement in multiple steps during the development of the new PREM. While developers might opt out of involving patients due to the added cost, time and complexity to the research, it is however strongly recommended in several guidelines, such as the American Food and Drug Administration (FDA, 2009), and the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) (Mokkink et al., 2018a, Terwee et al., 2018). In this study patients were involved in item generation, item reduction and improvement, and during psychometric testing. Another strength was the use of validated PROMs. Where PROMs did not have sufficient evidence of validity in a TMD population, additional testing was conducted for the purposes of this study. This new evidence could be a welcome addition to the current literature and useful for other researchers to make more informed choices when selecting PROMs for their own research. This project also provided a qualitative evidence synthesis exploring the experiences of TMD patients, which to the best of our knowledge, was the first to do so.

Careful consideration should also be given to the limitations associated. The PREM was designed in collaboration with patients recruited form the oral surgery and facial pain units at the Eastman Dental Hospital, which is a tertiary care centre operating within the structure of the NHS. Expectedly, the newly developed PREM reflected the experiences and views of these patients. Therefore, careful consideration should be given to the results obtained if the PREM was used in other contexts.

This pilot study presents positive results regarding the structural validity, internal consistency, and test-retest reliability of the new PREM and showcases it as a promising and simple tool that can be used to assess the experience of TMD patients within healthcare. The full psychometric profile, however, is still not established, and

further research is needed to determine the responsiveness, measurement error and construct validity of this new tool.

We also reflect on the sample size used in the quantitative component of this project. Factor analysis in general is a large sample analysis, although the definition of 'large' is still debatable. And although the sample size in this study satisfies the requirements of the COSMIN initiative, if might be worthwhile to confirm the results using a larger sample size in the future.

## 9.2. Lessons learnt from existing patient-centred strategies

Monitoring the quality of healthcare services in collaboration with the patients could give valuable insight into what works and what needs improving (Coulter, 2006, De Rosis et al., 2020). Furthermore, the dissemination of organisation performance data publicly can potentially prompt positive changes and influence the culture and behaviours of healthcare professionals (Murante et al., 2014, De Rosis et al., 2020). PREMs can be powerful tools to orientate these efforts. However, further research is needed which explores the role of PREMs specifically in driving quality improvement schemes. So far, limited evidence shows that the collection of patient experience data could lead to sustained improvements in patient satisfaction (Davies and Cleary, 2005, Gleeson et al., 2016). In order for this type of data to be used meaningfully in driving change, careful consideration should be given to the organisational factors which act as barriers or facilitators. Gleeson et al reviewed the approaches to using patient experience data for quality improvement (QI) in healthcare settings (Gleeson et al., 2016). The group could not identify studies that used formal quality QI methods of data collection, analysis or reporting. Furthermore, the commonly targeted areas in the studies were administrative practices (e.g., appointment management) and patient education (e.g., producing discharge materials, medication guides). Overall, the most

success based on the use of PREM data involved small, incremental changes that did not require changes in clinician behaviour.

The routine collection of questionnaires is not a new concept to the NHS. Some established programmes include the Friends and Family test (FFT), the NHS national survey programme, and the national PROMs programme. Lessons could be learnt from such examples. In England, the Healthcare Commission is now responsible for the NHS patient experience survey programme which covers inpatients, emergency departments, outpatients and young patients. In each eligible trust, 850 patients are sampled, and the survey is conducted by the trust or by an approved external contractor using standard protocols (Reeves and Seccombe, 2008). Additionally, since 2009, patients undergoing varicose vein, groin hernia and hip and knee replacement surgery within the NHS, routinely complete a set of PROMs before and after surgery (Kyte et al., 2016). The Health & Social Care Information Centre collects and publishes the arising data in quarterly and annual reports. The aim of the national PROMs programme is to provide patient-level information regarding the outcome of care within the NHS, encouraging poorer performing organisations to improve while focusing on patient benefit (Kyte et al., 2016, NHS). Predominately, the questionnaires are collected in paper form, and the annual cost of the programme is estimated around £825,000 (NHS, 2016, Kyte et al., 2016). Some problems may have constricted its full potential in influencing service change so far, such as lack of feedback and routine discussions with clinicians/ providers regarding the results, and possibly the scepticism of the clinicians regarding the effectiveness of PROMs in informing service change and patient care (Kyte et al., 2016). Such problems may well impact the routine collection of PREMs as well. Hence the importance of examining and addressing the barriers up to an organisational level when planning similar initiatives.

The Picker's institute investigated the implementation of PREM questionnaires into the national COPD audit programme (Skipper, 2014). Some preferences were reported by the patients such as favouring paper self-completed questionnaires, ideally sent home with the option to send back by post or given to complete within each setting. If completed in-situ, they preferred that the person administering the questionnaire not be involved in their care. Postal surveys may be favourable from an administrative point of view as they were less of a burden at practice level, plus they had higher response rates across multiple settings (secondary care and pulmonary rehabilitation settings). Response rates for online surveys were exceedingly low (less than 5%), and hence were not recommended at the time.

Another useful example is presented in a report by De Rosis et al, investigating PREMs collection, reporting and use by 21 hospitals of two Italian regions (De Rosis et al., 2020). The results indicated that response rates tended to increase over time, reaching around 30% after becoming stable and up to 80% in some inpatient settings. The importance given to such questionnaires by the management was reported as key in being perceived as a positive initiative, leading in consequence to healthcare workers being proactive in seeking patient feedback. Real time access and sharing of the results also enhanced the contribution of practitioners in such initiatives. The approach to viewing PREMs as tools to identify 'what went right' alongside 'what went wrong' could also increase the willingness to engage, and eventually lead to positive behavioural changes. Open ended questions for example, provided room for narrative feedback by the patients. Such comments, especially when positive, were valued by the practitioners and allowed them to monitor their contributions to the patient experience. It was recognised as an effective means of support to the involved

personnel and could potentially be used as a lever to encourage and motivate health workers who may feel the need of being better valued (De Rosis et al., 2020).

## 9.3. Future work

Further work is recommended following the present study. First and foremost is investigating the remainder of the psychometric properties of PREM-TMD. This piece of research successfully demonstrated that it has sound structural validity, internal consistency and test-retest reliability. Additional evidence is needed which explores hypothesis testing for construct validity, responsiveness, and measurement error of the instrument.

As no 'gold standard' exists in this case, criterion validity can not be tested. An example of criterion validity testing is when a shorter version of an already exiting instrument is being developed (Mokkink et al., 2010a). Another aspect to investigate is 'hypothesis testing for construct validity' where hypotheses are tested about expected relationships with other outcomes measures of good quality (Mokkink et al., 2010a). For example, testing the relationship between PREM-TMD and other questionnaires of experience such as the Care Quality Commission's outpatient survey (CQC, 2011). The aim in this case being strong correlations between the two instruments in the same direction. Responsiveness is another aspect to explore, which indicates longitudinal validity when scores might change (Mokkink et al., 2019). Likewise for the instrument's cut off points of the scores which constitute good or bad experiences.

The new instrument is designed for patients with chronic TMD. However, it may prove useful in other chronic facial pain conditions as well, such as oral dysesthesia or persistent idiopathic facial pain. Rather than starting from scratch, some PROMs may

be modified and validated for use in populations other than the one intended for the original instrument. For example, Patient Health Questionnaire-9, a measure of depression, was originally tested in patients from primary care and obstetrics-gynaecology clinics (Kroenke et al., 2001) . Later, this measure was tested in several populations such as palliative care (Chilcot et al., 2013), and spinal cord injury patients (Krause et al., 2011). Another example is the OHIP-14, which was modified and validated in TMD patients to produce OHIP-TMD (Yule et al., 2015). Future psychometric validation of PREM-TMD in various orofacial pain populations, may generate satisfactory results, potentially removing the need for PREM development projects especially designed for these populations. In such case, alterations to the wording or the structure of the questionnaire can be expected.

Having reliable and valid measures could facilitate future research investigating the improvements in patient outcomes based on the clinical experience. For example, a longitudinal study could explore whether an overall positive hospital experience has any effect on perceived health outcomes such as pain levels or psychological distress. Similarly, the influence of the individual components of care could also be investigated. For instance, the impact of fast access to care or good communication on the patients' ability to cope, or pain levels during subsequent clinical visits.

And finally, a feasibility study is recommended to investigate the most suited strategy to use the PREM in locations such as the Eastman Dental Hospital. Points of interest could be method of collection, staff involved in administration, analysis, interpretation of the results, and the associated budgeting requirements. Patient and public involvement activities have always been a valuable element to research, and patient input in this case could be extremely helpful. For example, focus groups could be conducted to explore patients' preferences in terms of method and time of collection.

This information, alongside input from healthcare professionals, clinical staff and managers could provide a robust strategy to incorporate the questionnaire into routine clinical care, and to effectively use the resulting data in identifying areas of concern. Subsequently, quality improvement initiatives can be tailored and applied to these areas.

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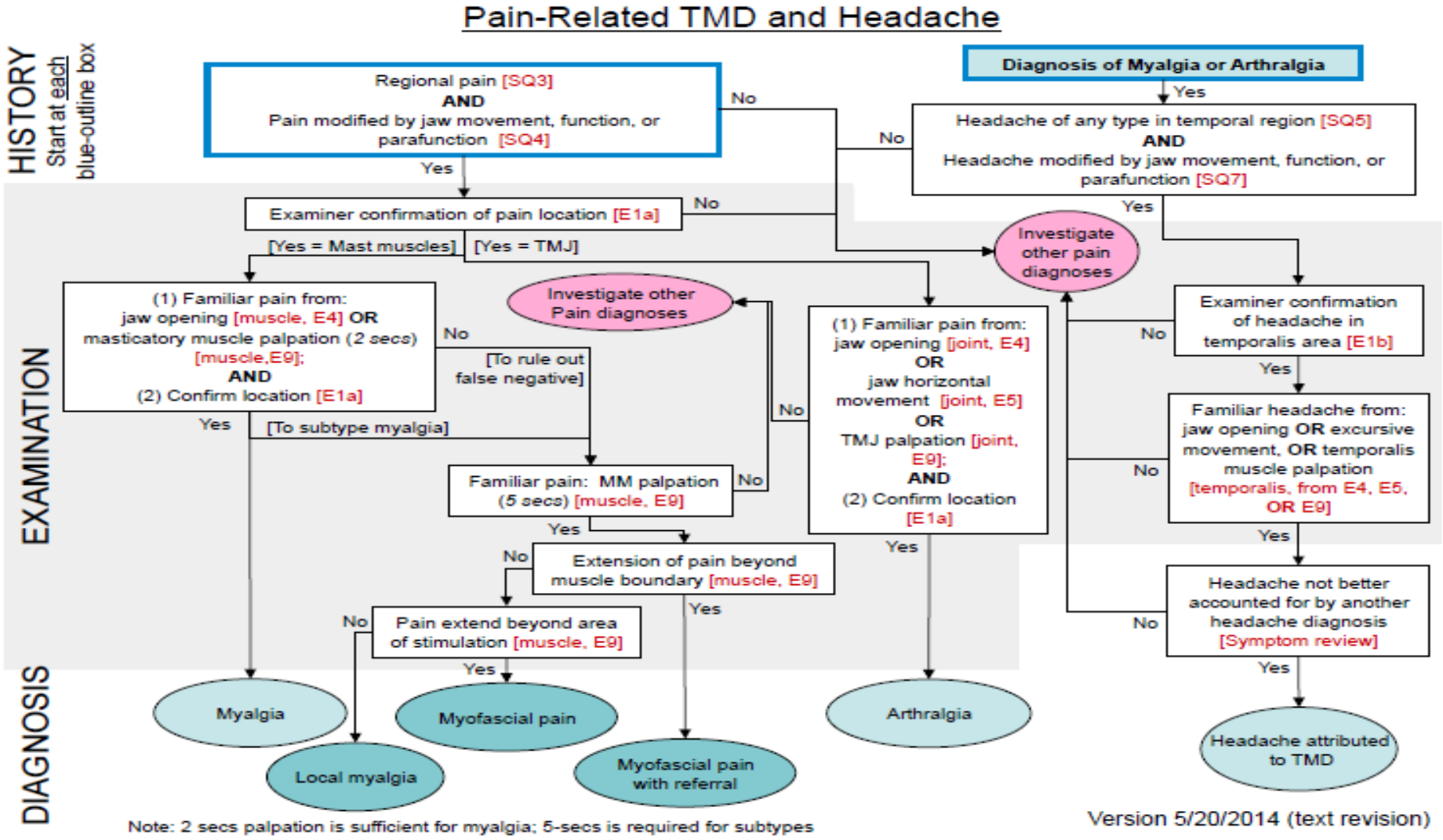
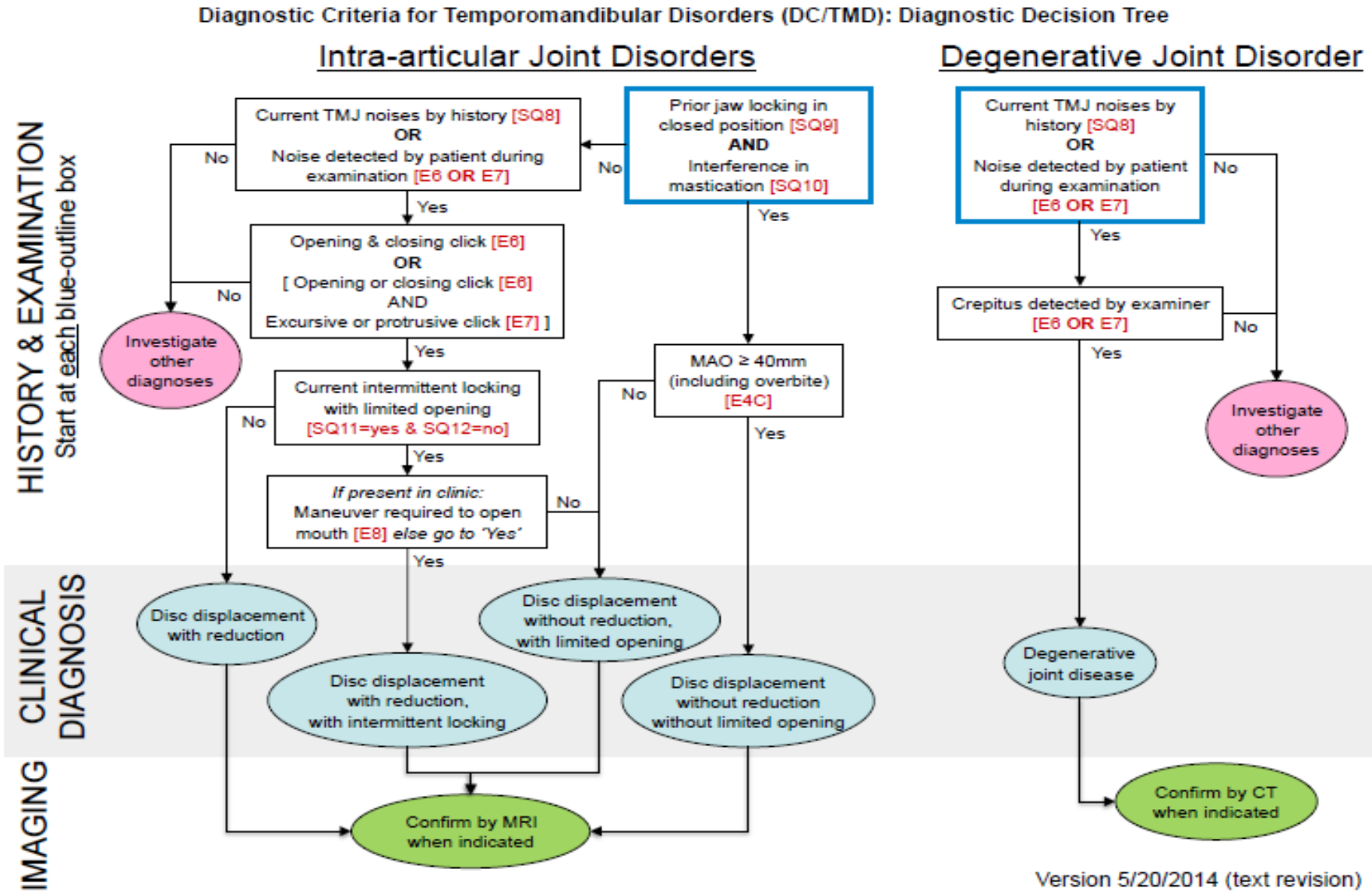
# Appendices

## Appendix 1: DC/TMD diagnosis decision tree




Diagnostic Criteria for Temporomandibular Disorders (DC/TMD): Diagnostic Decision Tree
Intra-articular Joint Disorders
Degenerative Joint Disorder
HISTORY & EXAMINATION
Start at each blue-outline box
CLINICAL DIAGNOSIS
IMAGING
Current TMJ noises by history [SQ8] OR Noise detected by patient during examination [E6 OR E7]
Prior jaw locking in closed position [SQ9] AND Interference in mastication [SQ10]
Opening & closing click [E6] OR [ Opening or closing click [E6] AND Excursive or protrusive click [E7] ]
Current intermittent locking with limited opening [SQ11=yes & SQ12=no]
If present in clinic: Maneuver required to open mouth [E8] else go to 'Yes'
MAO ≥ 40mm (including overbite) [E4C]
Investigate other diagnoses
Disc displacement with reduction
Disc displacement with reduction, with intermittent locking
Disc displacement without reduction, with limited opening
Disc displacement without reduction without limited opening
Confirm by MRI when indicated
Current TMJ noises by history [SQ8] OR Noise detected by patient during examination [E6 OR E7]
Crepitus detected by examiner [E6 OR E7]
Investigate other diagnoses
Degenerative joint disease
Confirm by CT when indicated
Yes
No
Version 5/20/2014 (text revision)

# Appendix 2: Ethical approvals

## REC approval

Lothian NHS Board

**South East Scotland Research Ethics Committee 01**

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG

**www.nhslothian.scot.nhs.uk**

Date: 20 December 2019

[redacted]

20 December 2019

Dr Rachel Leeson
UCL Eastman Dental Institute, Oral Surgery Unit
256 Gray's Inn Road
London, UK
WC1X 8LD

Dear Dr Leeson

| | |
|---|---|
| **Study title:** | **Development and validation of a patient reported experience measure for temporomandibular disorders patients.** |
| **REC reference:** | **19/SS/0130** |
| **IRAS project ID:** | **268196** |

Thank you for your letter of 20 December 2019, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Conditions of the favourable opinion**

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

- The Chair noted that there appears to have been some confusion between the text that the HRA suggested in their response of 16 December 2019 with the section title "Who has

approved the study" The Chair appreciates that this is not your fault but would be grateful if you would please amend this heading to "Who has *reviewed* the study" as the REC does not "approve" a study; they review and provide an ethical opinon.

**You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.**

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee ( see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**After ethical review: Reporting requirements**

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

**Ethical review of research sites**

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

**Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

| *Document* | *Version* | *Date* |
|---|---|---|
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance confirmation] | 1.0 | 03 July 2019 |
| GP/consultant information sheets or letters [GP letter Phase 1] | 1.0 | 03 July 2019 |
| GP/consultant information sheets or letters [GP letter Phase 2] | 1.0 | 03 July 2019 |
| Interview schedules or topic guides for participants [Interview Schedule and Topic Guide] | 1.0 | 03 July 2019 |
| IRAS Application Form [IRAS_Form_12112019] | | 12 November 2019 |
| Letter from funder [Funding letter] | 1.0 | 03 July 2019 |
| Other [Academic supervisor CV- Prof Stefano Fedele] | 1.0 | 03 July 2019 |
| Other [Academic supervisor CV- Dr Richeal Ni Riordain] | 1.0 | 03 July 2019 |
| Other [Response table ] | 2.0 | 16 December 2019 |
| Participant consent form [CF phase 1] | 2.0 | 16 December 2019 |

| | | |
|---|---|---|
| Participant consent form [CF phase 2] | 2.0 | 16 December 2019 |
| Participant information sheet (PIS) [PIS phase 1] | 2.0 | 16 December 2019 |
| Participant information sheet (PIS) [PIS phase 2] | 2.0 | 16 December 2019 |
| Referee's report or other scientific critique report [Evidence of peer review] | 1.0 | 03 July 2019 |
| Research protocol or project proposal [Protocol ] | 2.0 | 16 December 2019 |
| Summary CV for Chief Investigator (CI) [Chief Investigator CV] | 1.0 | 03 July 2019 |
| Summary CV for student [Student CV] | 1.0 | 03 July 2019 |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [Protocol summary] | 1.0 | 03 July 2019 |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [lay summary] | 2.0 | 16 December 2019 |
| Validated questionnaire [Questionnaires] | 1.0 | 03 July 2019 |

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

**HRA Learning**

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

**19/SS/0130** **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

Dr [redacted]
Chair

Email: [redacted]othian.scot.nhs.uk

*Enclosures:* "After ethical review – guidance for researchers"

HRA approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Rachel Leeson
UCL Eastman Dental Institute, Oral Surgery Unit
256 Gray's Inn Road
London, UK
WC1X 8LD

Email: hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

07 January 2020

Dear Dr Leeson

**HRA and Health and Care Research Wales (HCRW) Approval Letter**

| | |
|---|---|
| **Study title:** | **Development and validation of a patient reported experience measure for temporomandibular disorders patients.** |
| **IRAS project ID:** | **268196** |
| **REC reference:** | **19/SS/0130** |
| **Sponsor** | **University College London** |

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

**How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?**
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

**How should I work with participating non-NHS organisations?**
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

**What are my notification responsibilities during the study?**

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

**Who should I contact for further information?**
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **268196**. Please quote this on all correspondence.

Yours sincerely,

[redacted]
Approvals Specialist

Email: hra.approval@nhs.net

Copy to: M[redacted], University College London

# Appendix 3: Consent forms and patient information sheets.


**Informed consent form (Phase 1)**

Title of the project: Development and validation of a **P**atient **R**eported **E**xperience **M**easure for patients with **T**emporo**M**andibular **D**isorders in a clinical setting (PREM-TMD).

Investigators: Dr Rachel Leeson, Professor Stefano Fedele, Dr Richeal Ni Riordain, Dina Taimeh (PhD student)

Please sign your **initials** here

1. I confirm that I have read and understood the information sheet dated 1/4/2020 version 4.0 for the above study. I have had the opportunity to consider information, ask questions, and had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that the information which I have already provided will still be used for the purposes of this research project if I withdraw from the study. However, I understand that this is optional, and I do not have to agree to this. (Please leave this box blank if you do not agree to this) ☐
4. I agree that sections of my medical notes may be looked at by researchers, responsible individuals from regulatory authorities where it is relevant to my taking part in research, the sponsor University College London (UCL), and University College London Hospitals (UCLH) NHS Trust. I give permission for these individuals to have access to my records. ☐
5. I understand that the information which I have already provided will still be used for the purposes of the study if I lose capacity to participate and confirm ongoing consent. However, I understand that this is optional, and I do not have to agree to this. (Please leave this box blank if you do not agree to this) ☐
6. I agree to be contacted by letter/phone/email by the researchers who may need to clarify information I have provided for the study. ☐
7. I agree to be audio/video recorded during the group discussions (or personal interview) and for anonymous quotes to be used in possible study publications. ☐
8. I agree that I might be asked to complete a set of questionnaires related to my oral and general health as specified in the patient information sheet. I understand that my information will remain anonymous. ☐
9. I agree to my GP being informed of my involvement in this study. (Please leave this box blank if you do not wish us to inform your GP) ☐

10. I agree to take part in the above study ☐

| | |
|---|---|
| Name of participant (PRINT): | |
| Date: | |

| | |
|---|---|
| Name of researcher obtaining consent: | |
| Date: | |

***When completed:***

***1 For participant, 1 (original) for researcher file, 1 to be kept in medical notes***

# Participant information sheet (Phase 1)

Title of the project: Development and validation of a Patient Reported Experience Measure for patients with TemporoMandibular Disorders in a clinical setting (PREM-TMD).

Please read this sheet carefully. Please ask if you do not understand or would like more information

## 1. Invitation to participate

We would like to invite you to participate in our research study, which is part of a PhD project. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you may have. You may discuss this with family members or friends.

## 2. What is the purpose of this study?

- Many international and national organisations, including the NHS, have highlighted the importance of a pleasant experience for patients during their visits to healthcare centres to receive treatment. Previous research has shown that a good hospital experience has positive impacts on safety, clinical effectiveness and correlates positively with patient reported scores such as treatment adherence. However, determining what is important to achieve a positive experience during hospital visits could be difficult without direct input from the ones experiencing it- the patients.

- Several ways to capture the patient experience during hospital visits have already been established. These include: satisfaction surveys and patient reported experience measures, which we aim to create in this study.

- Patient reported experience measures have already been developed in many fields, such as cancer care, mental health and rheumatoid arthritis. However, so far, there remains no valid tool to capture the hospital experience of patients with temporomandibular disorders (TMD). In this study, we aim to create the first patient reported experience measure for the particular use of this population of patients.

## 3. Why have I been invited?

You have been identified as a potential participant because you have been diagnosed with temporomandibular disorder.

- 10 of the participants will be asked to complete a set of questionnaires that will help us estimate the duration of time required for their completion. These questionnaires will be used in the second phase of our study. We estimate that it might take up to 45 minutes to complete them. We will send you the questionnaires by post, or if you prefer, via email.

**7. Expenses and payment**

We will cover your travel expenses to and from the location of the discussion, up to a maximum of £60 in case of a face to face discussions.

**8. Will my normal care be affected?**

Your treatment will not be altered in anyway by your participation in this study. Also, we would like to inform your general practitioner if you decide to participate.

**9. What are the possible risks of taking part?**

We do not foresee any risks in participating in this research.

**10. What are the possible benefits?**

We hope that by learning the important aspects of healthcare experience, we are able to create a questionnaire dedicated purposefully for TMD patients. This questionnaire will be used in future research, audits and clinical performance evaluation, quality improvement schemes and to improve patient-centred care.

**11. What happens when the research study stops?**

After we have performed our analysis we can provide you with the results and explain what it means. The results of this study might also be published in scientific conferences and medical journals.

**12. What if there is a problem?**

- Any complaint about the way you have been dealt with during the study will be addressed. The detailed information concerning this is given in the next part of this information sheet. If you have any concerns or complaints you should contact your study doctor in the first instance.

- University College London (UCL) holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

- If you are concerned about any aspect of this study, please speak to the researchers who will do their best to answer your questions. Please contact Dr Rachel Leeson [redacted] Professor Stefano Fedele [redacted] Dr Richeal Ni Riordain ([redacted] or Dina Taimeh ([redacted].uk). If you remain unhappy, you can make a formal complaint through the National Health Service (NHS) complaints procedure. Details can be obtained through the University College London Hospitals (UCLH) Patient Advice and Liaison Service (PALS) on 0207 3447 3041, email: PALS@uclh.nhs.uk, address: PALS, Ground Floor Atrium, University College Hospital, 235 Euston Road, London, NW1 2BU.

13. Confidentiality

- The typing of the group discussion will be anonymised and transcribed by a member of the research team. We will store the transcript in a locked filing cabinet in a secure magnetic card accessed building. Only researchers associated with the study will have access to the transcript.

- You will not be identifiable through any of the data and information released from this study. Your anonymity will also be preserved in any published material from this study.

- All patient information will be treated in the strictest confidence, in accordance with the UK Data Protection Act 2018, and the General Data Protection Regulation (GDPR) applied from 25 May 2018. UCL is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCL will keep identifiable information about you for 5 years after the study has finished.

- Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained unless you request otherwise. To safeguard your rights, we will use the minimum personally-identifiable information possible.

- UCLH Eastman Dental Hospital will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from UCL and regulatory organizations may look at your medical and research records to check the accuracy of the research study. UCLH Eastman Dental Hospital will pass these details to UCL along with the information collected from you. The only people in UCL who will have access to information that identifies you will be people who need to contact you to provide details of the group discussion or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

- There might be some inherent risk of confidentiality breach associated with focus groups, as we cannot control what other participants might say after the focus groups about what

has been shared. However, we will encourage all participants to refrain from revealing any identifiable information about other participants.

**14. What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available. If this happens, we shall tell you about it and discuss whether you want to continue in the study. If you decide to continue you will be asked to sign an updated consent form.

**15. What happens if I decide to withdraw from the study?**

You can withdraw from the study at any time. This will not affect your medical care in any way. We would still like to use the information you have already provided for the purposes of the study. If you do not wish us to do so, please indicate that in the consent form by leaving that option blank.

**16. What if I lose capacity to give consent during the study?**

In the case a participant loses capacity to participate and confirm ongoing consent, we will not ask him/her for further information and it will mark the end of his/her participation in the study. However, we would still like to use the information already provided in our analysis. If you do not wish us to so, please indicate that in the consent form by leaving that option blank.

**17. Will my GP be informed?**

With your consent we would like to inform your GP of your participation in this study by sending a letter. If you would rather we do not inform your GP, you can indicate so by leaving that option blank in the consent form.

**18. What will happen to the study results?**

The results will be used in future medical research, and the results might be disseminated in scientific conferences and as publication in medical/scientific journals. We hope that this will help in the management of temporomandibular disorders. No details that specifically identify you will be included. We can provide you with details of any publication and a lay summary of the results of the study, at your request. These can be sent to you with one of your clinical appointment letters. Please use the contact details at the back of this document to reach us.

**19. Who is organising and funding the research?**

This study has been designed and organised by senior staff members of the Eastman Dental Institute. The research costs for the study will be supported by a PhD Scholarship from The University of Jordan, Amman, Jordan. NHS treatment costs [standard and excess] will be supported by UCLH and Service Support Costs via the NIHR Clinical Research Network North Thames.

**20. Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable ethical opinion by the South East Scotland Research Ethics Committee 1.

**21. Further information and contact details**

You are encouraged to ask any questions you wish, before, during or after your participation in this study.

Name: Dr Rachel Leeson

[redacted]et

Eastman Dental Institute, London, WC1E 6DE

Name: Professor Stefano Fedele

[redacted]

Address: 21 University Street

Eastman Dental Institute, London, WC1E 6DE

Name: Dr Richeal Ni Riordain

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Name: Dina Taimeh

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Thank you for taking the time to read this information sheet and to consider this study.

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## Informed consent form (Phase 2)

Title of the project: Development and validation of a **P**atient **R**eported **E**xperience **M**easure for patients with **T**emporo**M**andibular **D**isorders in a clinical setting (PREM-TMD).

Investigators: Dr Rachel Leeson, Professor Stefano Fedele, Dr Richeal Ni Riordain, Dina Taimeh (PhD student)

Please sign your initials here

1. I confirm that I have read and understood the information sheet dated 14/12/2020 version 4.0 for the above study. I have had the opportunity to consider information, ask questions, and had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that the information which I have already provided will still be used for the purposes of this research project if I withdrew from the study. However, I understand that this is optional, and I do not have to agree to this. (Please leave this box blank if you do not agree to this). ☐

4. I agree that sections of my medical notes may be looked at and will be included in data analysis by researchers, responsible individuals from regulatory authorities where it is relevant to my taking part in research, the sponsor University College London (UCL), and University College London Hospitals (UCLH) NHS Trust. I give permission for these individuals to have access to my records. ☐

5. I understand that the information which I have already provided will still be used for the purposes of the study if I lose capacity to participate and confirm ongoing consent. However, I understand that this is optional, and I do not have to agree to this. (Please leave this box blank if you do not agree to this) ☐

6. I agree to be contacted by letter/phone/email by the researchers who may need to clarify information I have provided for the study. ☐

7. I agree that I will be completing a set of questionnaires related to my oral and general health as specified in the patient information sheet. I understand that I may be completing these questionnaires on 3 different occasions. ☐

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8. I agree to have an oral examination performed by an investigator to collect clinical data. I understand that my information will remain anonymous ☐

9. I agree to my GP being informed of my involvement in this study. (Please leave this box blank if you do not wish us to inform your GP) ☐

10. I agree to take part in the above study ☐

| | |
|---|---|
| Name of participant (PRINT): | |
| Date: | |

| | |
|---|---|
| Name of researcher obtaining consent: | |
| Date: | |

***When completed:***

***1 For participant, 1 (original) for researcher file, 1 to be kept in medical notes***

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# Participant information sheet (Phase 2)

Title of the project: Development and validation of a **P**atient **R**eported **E**xperience **M**easure for patients with **T**emporo**M**andibular **D**isorders in a clinical setting (PREM-TMD)

## 1. Invitation to participate

We would like to invite you to participate in our research study, which is part of a PhD project. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have.

You have been identified as a potential participant because you have been diagnosed with the condition that we are studying. The following information is provided so that you can make an informed decision regarding your willingness to participate. We encourage you to discuss the study with family and friends and ask us if there is anything which is not clear or if you would like more information.

## 2. What is the purpose of this study?

- Many international and national organisations, including the NHS, have highlighted the importance of a pleasant experience for patients during their visits to healthcare centres to receive treatment. Previous research has shown that a good hospital experience has positive impacts on safety, clinical effectiveness and correlates positively with patient reported scores such as treatment adherence. However, determining what is important to achieve a positive experience during hospital visits could be difficult without direct input from the ones experiencing it- the patients.
- Several ways to capture the patient experience during hospital visits have already been established. These include: satisfaction surveys and patient reported experience measures, which we aim to create in this study.
- Patient reported experience measures have already been developed in many fields, such as cancer care, mental health and rheumatoid arthritis. However, so far, there remains no valid tool to capture the hospital experience of patients with temporomandibular disorders (TMD). In this study, we aim to create the first patient reported experience measure for the particular use of this population of patients.

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**3. Why have I been invited?**

You have been identified as a potential participant because you have been diagnosed with temporomandibular disorder.

**4. Do I have to take part?**

It is up to you to decide whether you want to join the study or not. If you are interested in joining, one of the study team will go through this information sheet with you, explain the study in more detail and answer any questions you may have. You can take as much time as you need to decide if you want to participate, and you are free to take this information sheet with you and consider the matter further at home. If you decide to participate in this study. You are free to withdraw at any time and without giving a reason. This would not affect the standard of care you receive. Participation in this study will in no way affect your legal rights.

**5. How do I take part in the study?**

If you decide to take part in this study, you will first be asked to sign a consent form. Then we will ask you to do the following:

**Visit 1**

- During your routine visit to the Eastman Dental Hospital, we will ask you to complete a set of questionnaires. This might take up to 45 minutes to complete. We will then conduct a brief clinical assessment including history taking and oral examination. There will be no notable changes to you regular clinical visits, although it might add an extra 60 minutes to your routine visit. We will also provide you with one questionnaire for you to take home and we would ask that you would complete this questionnaire in **14 days' time**. A stamped addressed envelope will be provided for you to return the second questionnaire to the hospital.
- If you had your consultation by telephone, we will send the questionnaires by email or by post for you to complete remotely. If you chose to have the questionnaires sent to you by post, we will provide you with a stamped addressed envelope to return the questionnaires to the research team. We will also rely on your clinical notes to confirm your diagnosis instead of performing a clinical examination.

- After your visit, and with your consent, we will also use the questionnaires you provided during your routine visit. No personal information will be extracted from these questionnaires except your initials and date of birth. The information obtained will not trace back to you.

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**Visit 2** (your routine follow up visit)

- During this visit, we will ask you to complete another set of questionnaires that are similar to the questionnaires you completed during the first visit. We will also conduct a brief clinical assessment similar to the one undertaken in Visit 1. If your consultation was conducted by telephone, we will send you the questionnaires by post or email. If you chose the post, we will provide you with a stamped and addressed envelop to return the questionnaires to the research team.

- We may also use information from the questionnaires you routinely complete during your visit. This step is undertaken to make comparisons with the scores you provided in your previous visit and observe any changes in the severity of your symptoms.

- If you are discharged from the care of your clinician at visit 1, the second visit will take place at the Eastman Clinical Investigation Centre at a time convenient for you.

- This visit will be the end of your participation in this study.

## 6. What will I have to do?

You will be asked to sign the consent forms, attend the Eastman Dental Hospital for two visits (including the present visit) and complete a set of questionnaires. If you had your clinical consultation by telephone, you will be asked to sign a consent form and complete a set of questionnaires. All the documents will be sent to you by email or by post if you prefer.

## 7. Will my normal care be affected?

Your treatment will not be altered in anyway by your participation in this study. Also, we would like to inform your general practitioner if you decide to participate.

## 8. What are the possible risks of taking part?

We do not foresee any risks in participating in this research. Although, your hospital visits might last 60 minutes longer.

## 9. What are the possible benefits?

This is the second phase of creating a patient reported experience measure dedicated purposefully for TMD patients. This questionnaire might be used in future research, audits and clinical performance evaluation, quality improvement schemes and to improve patient-centred care.

## 10. What happens when the research study stops?

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After we have performed our analysis, we can provide you with the results and explain what it means. The results of this study might also be published in scientific conferences and medical journals.

**11. What if there is a problem?**

• Any complaint about the way you have been dealt with during the study will be addressed. The detailed information concerning this is given in the next part of this information sheet. If you have any concerns or complaints, you should contact your study doctor in the first instance.

• University College London (UCL) holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

• If you are concerned about any aspect of this study, please speak to the researchers who will do their best to answer your questions. Please contact Dr Rachel Leeson [redacted], Professor Stefano Fedele ([redacted]Richeal Ni Riordain [redacted] or Dina Taimeh ([redacted]k). If you remain unhappy, you can make a formal complaint through the National Health Service (NHS) complaints procedure. Details can be obtained through the University College London Hospitals (UCLH) Patient Advice and Liaison Service (PALS) on 0207 3447 3041, email: PALS@uclh.nhs.uk, address: PALS, Ground Floor Atrium, University College Hospital, and 235 Euston Road, London, NW1 2BU

**12. Confidentiality**

- You will be given a unique personal identification code on both copies of the questionnaire. We will store the questionnaire and the code sheet in a locked filing cabinet in a secure magnetic card accessed building. Only researchers associated with the study will have access to completed questionnaires and your code. You will not be able to be identified through any of the data and information released from this study.
- All patient information will be treated in the strictest confidence, in accordance with the UK Data Protection Act 2018, and the General Data Protection Regulation (GDPR) applied from 25 May 2018. UCL is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCL will keep identifiable information about you for 5 years after the study has finished.

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- UCLH Eastman Dental Hospital will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from UCL and regulatory organizations may look at your medical and research records to check the accuracy of the research study. UCLH Eastman Dental Hospital will pass these details to UCL along with the information collected from you. The only people in UCL who will have access to information that identifies you will be people who need to contact you to provide details about the questionnaire or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

**13. What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available. If this happens, we shall tell you about it and discuss whether you want to continue in the study. If you decide to continue you will be asked to sign an updated consent form.

**14. What happens if I decide to withdraw from the study?**

You can withdraw from the study at any time. This will not affect your medical care in any way. We would still like to use the information you have already provided for the purposes of the study. If you do not wish us to do so, please indicate that in the consent form by leaving that option blank.

**15. What if I lose capacity to give consent during the study?**

In the case a participant loses capacity to participate and confirm ongoing consent, we will not ask him/her for further information and it will mark the end of his/her participation in the study. However, we would still like to use the information already provided in our analysis. If you do not wish us to so, please indicate that in the consent form by leaving that option blank.

**16. Will my GP be informed?**

With your consent we would like to inform your GP of your participation in this study by sending a letter. If you would rather we do not inform your GP, you can indicate so by leaving that option blank in the consent form.

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**17. What will happen to the study results?**

The results will be used in future medical research, and the results might be published in scientific conferences and as publication in medical/scientific journals. We hope that this will help in the management of temporomandibular disorders. No details that specifically identify you will be included. We can provide you with details of any publication and a lay summary of the results of the study, at your request. These can be sent to you with one of your clinical appointment letters. Please use the contact details at the back of this document to reach us.

**18. Who is organising and funding the research**

This study has been designed and organised by senior staff members of the Eastman Dental Institute. The research costs for the study will be supported by a PhD Scholarship from The University of Jordan, Amman, Jordan. NHS treatment costs [standard and excess] will be supported by UCLH and Service Support Costs via the NIHR Clinical Research Network North Thames.

**19. Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable ethical opinion by the Southeast Scotland Research Ethics Committee 1.

**20. Further information and contact details**

You are encouraged to ask any questions you wish, before, during or after your participation in this study.

Name: Dr Rachel Leeson
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Eastman Dental Institute, London, WC1E 6DE

Name: Professor Stefano Fedele
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Name: Dr Richeal Ni Riordain

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Name: Dina Taimeh

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Thank you for taking the time to read this information sheet and to consider this study.

## Appendix 4: Study questionnaires

**Initials:** **Date of birth:**

**Ethnicity**

**White**

☐ Welsh / English / Scottish / Northern Irish / British ☐ Gypsy or Irish Traveller

☐ Irish ☐ Any other white background:

**Mixed**

☐ White and black Caribbean ☐ White and black African

☐ White and Asian ☐ Any other mixed background:

**Asian or Asian British**

☐ Indian ☐ Pakistani

☐ Bangladeshi ☐ Chinese

☐ Any other Asian background

**Black or Black british**

☐ Caribbean ☐ African

☐ Any other Black background:

**Other Ethnic group:**

**Gender**

☐ Male ☐ Female ☐ Other

**Marital status**

☐ Married ☐ Living with a partner ☐ Divorced

☐ Widowed ☐ Single

**Employment**

☐ Employed: ☐ Part time ☐ Full time

☐ Looking after the family or home as a homemaker

☐ Unemployed and actively seeking work

☐ Retired

**Smoking status**

☐ Current smoker ☐ Previous smoker ☐ Never smoked

Number/ sessions per day:

**Alcohol consumption**

In an average week, how many times do you drink?.....

How many units do you drink at a time?

☐ 0 units ☐ 1-2 units ☐ 3-6

☐ 7-9 ☐ >9

- Single small shot of spirits: 1 unit
- Pint of lower-strength lager/beer/cider: 2 units
- Standard glass of red/white/rosé wine: 2 units

**What is the highest level of schooling that you have completed?**

☐ Completed school ☐ Some university

☐ University graduate ☐ Professional or post-graduate level

## Medical history

Do you have any of the following?

☐ Heart problems .....

☐ Breathing problems.....

☐ Liver disease.....

☐ Kidney disease.....

☐ Joint problems.....

☐ Skin disease.....

☐ Diabetes

☐ High blood pressure

☐ Bleeding problems.....

☐ Fits.....

☐ Regular fainting attacks.....

☐ Allergies. Please specify:

☐ Other chronic pain conditions: ☐ Lower back pain

☐ Upper back pain ☐ Neck pain

☐ Fibromyalgia ☐ Irritable bowel syndrome

☐ Other facial pain conditions (example: migraine, tension headache, burning mouth syndrome ...etc). Please specify:

☐ Other conditions:

## PAIN

1. Have you ever had pain in your jaw, temple, in the ear, or in front of the ear on either side? — No ☐ Yes ☐

**If you answered NO, then skip to Question 5.**

2. How many years or months ago did your pain in the jaw, temple, in the ear, or in front of the ear first begin? _____years _____months

3. In the last 30 days, which of the following best describes any pain in your jaw, temple, in the ear, or in front of the ear on either side?

Select ONE response.

- ☐ No pain
- ☐ Pain comes and goes
- ☐ Pain is always present

**If you answered NO to Question 3, then skip to Question 5.**

4. In the last 30 days, did the following activities change any pain (that is, make it better or make it worse) in your jaw, temple, in the ear, or in front of the ear on either side?

| | | No | Yes |
|---|---|---|---|
| A. | Chewing hard or tough food | ☐ | ☐ |
| B. | Opening your mouth, or moving your jaw forward or to the side | ☐ | ☐ |
| C. | Jaw habits such as holding teeth together, clenching/grinding teeth, or chewing gum | ☐ | ☐ |
| D. | Other jaw activities such as talking, kissing, or yawning | ☐ | ☐ |

## HEADACHE

5. In the last 30 days, have you had any headaches that included the temple areas of your head? — No ☐ Yes ☐

**If you answered NO to Question 5, then skip to Question 8.**

6. How many years or months ago did your temple headache first begin? _____years _____months

7. In the last 30 days, did the following activities change any headache (that is, make it better or make it worse) in your temple area on either side?

| | | No | Yes |
|---|---|---|---|
| A. | Chewing hard or tough food | ☐ | ☐ |
| B. | Opening your mouth, or moving your jaw forward or to the side | ☐ | ☐ |
| C. | Jaw habits such as holding teeth together, clenching/grinding, or chewing gum | ☐ | ☐ |
| D. | Other jaw activities such as talking, kissing, or yawning | ☐ | ☐ |

| JAW JOINT NOISES | | | | Office use | | |
|---|---|---|---|---|---|---|
| 8. | In the last 30 days, have you had any jaw joint noise(s) when you moved or used your jaw? | **No** ☐ | **Yes** ☐ | **R** ☐ | **L** ☐ | **DNK** ☐ |
| **CLOSED LOCKING OF THE JAW** | | | | | | |
| 9. | Have you ever had your jaw lock or catch, even for a moment, so that it would not open ALL THE WAY?<br>**If you answered NO to Question 9 then skip to Question 13.** | ☐ | ☐ | ☐ | ☐ | ☐ |
| 10. | Was your jaw lock or catch severe enough to limit your jaw opening and interfere with your ability to eat? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 11. | In the last 30 days, did your jaw lock so you could not open ALL THE WAY, even for a moment, and then unlock so you could open ALL THE WAY?<br>**If you answered NO to Question 11 then skip to Question 13.** | ☐ | ☐ | ☐ | ☐ | ☐ |
| 12. | Is your jaw currently locked or limited so that your jaw will not open ALL THE WAY? | ☐ | ☐ | ☐ | ☐ | ☐ |
| **OPEN LOCKING OF THE JAW** | | | | | | |
| 13. | In the last 30 days, when you opened your mouth wide, did your jaw lock or catch even for a moment such that you could not close it from this wide open position?<br>**If you answered NO to Question 13 then you are finished.** | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14. | In the last 30 days, when you jaw locked or caught wide open, did you have to do something to get it to close including resting, moving, pushing, or maneuvering it? | ☐ | ☐ | ☐ | ☐ | ☐ |

## GCPS

1. On how many days in the **last 6 months** have you had facial pain? _____ Days

2. How would you rate your facial pain **RIGHT NOW?** Use a scale from 0 to 10, where 0 is "no pain" and 10 is "pain as bad as could be".

No pain — Pain as bad as could be

0 1 2 3 4 5 6 7 8 9 10

3. In the LAST 30 DAYS, how would you rate your **WORST** facial pain? Use the same scale, where 0 is "no pain" and 10 is "pain as bad as could be".

No pain — Pain as bad as could be

0 1 2 3 4 5 6 7 8 9 10

4. In the LAST 30 DAYS, **ON AVERAGE**, how would you rate your facial pain? Use the same scale, where 0 is "no pain" and 10 is "pain as bad as could be". [That is, *your usual pain* at times you were in pain.]

No pain — Pain as bad as could be

0 1 2 3 4 5 6 7 8 9 10

5. In the LAST 30 DAYS, how many days did your facial pain keep you from doing your **USUAL ACTIVITIES** like work, school, or housework? (every day = 30 days)

_____ Days

6. In the LAST 30 DAYS, how much has facial pain interfered with your **DAILY ACTIVITIES**? Use a 0-10 scale, where 0 is "no interference: and 10 is "unable to carry on any activities".

No interference — Unable to carry on any activities

0 1 2 3 4 5 6 7 8 9 10

7. In the LAST 30 DAYS, how much has facial pain interfered with your **RECREATIONAL, SOCIAL AND FAMILY ACTIVITIES**? Use the same scale, where 0 is "no interference: and 10 is "unable to carry on any activities".

No interference — Unable to carry on any activities

0 1 2 3 4 5 6 7 8 9 10

8. In the LAST 30 DAYS, how much has facial pain interfered with your **ABILITY TO WORK**, including housework? Use the same scale, where 0 is "no interference: and 10 is "unable to carry on any activities".

No interference — Unable to carry on any activities

0 1 2 3 4 5 6 7 8 9 10

## JFLS-20

For each of the items below, please indicate the level of limitation **during the last month**. If the activity has been completely avoided because it is too difficult, then circle '10'. If you avoid an activity for reasons other than pain or difficulty, leave the item blank.

| | | No limitation | | | | | | | | | | Severe limitation |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. | Chew tough food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 2. | Chew hard bread | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 3. | Chew chicken (e,g,, prepared in oven) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 4. | Chew crackers | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 5. | Chew soft food (e,g,, macaroni, canned or soft fruits, cooked vegetables, fish) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 6. | Eat soft food requiring no chewing (e.g., mashed potatoes, apple sauce, pudding, pureed food) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 7. | Open wide enough to bite from a whole apple | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 8. | Open wide enough to bite into a sandwich | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 9. | Open wide enough to talk | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 10. | Open wide enough to drink from a cup | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11. | Swallow | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 12. | Yawn | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 13. | Talk | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 14. | Sing | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 15. | Putting on a happy face | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 16. | Putting on an angry face | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 17. | Frown | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 18. | Kiss | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 19. | Smile | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 20. | Laugh | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

## GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems? Place a check mark in the box to indicate your answer.

| | Not at all | Several days | More than half the days | Nearly every day |
|---|---|---|---|---|
| | 0 | 1 | 2 | 3 |
| 1. Feeling nervous, anxious or on edge | ☐ | ☐ | ☐ | ☐ |
| 2. Not being able to stop or control worrying | ☐ | ☐ | ☐ | ☐ |
| 3. Worrying too much about different things | ☐ | ☐ | ☐ | ☐ |
| 4. Trouble relaxing | ☐ | ☐ | ☐ | ☐ |
| 5. Being so restless that it is hard to sit still | ☐ | ☐ | ☐ | ☐ |
| 6. Becoming easily annoyed or irritable | ☐ | ☐ | ☐ | ☐ |
| 7. Feeling afraid as if something awful might happen | ☐ | ☐ | ☐ | ☐ |
| TOTAL SCORE = | | | | |

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

| Not difficult at all | Somewhat difficult | Very difficult | Extremely difficult |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

PHQ-8

Over the last 2 weeks, how often have you been bothered by the following problems? Please place a check mark in the box to indicate your answer.

| | Not at all<br>0 | Several days<br>1 | More than half the days<br>2 | Nearly everyday<br>3 |
|---|---|---|---|---|
| 1. Little interest or pleasure in doing things | ☐ | ☐ | ☐ | ☐ |
| 2. Feeling down, depressed, or hopeless | ☐ | ☐ | ☐ | ☐ |
| 3. Trouble falling or staying asleep, or sleeping too much | ☐ | ☐ | ☐ | ☐ |
| 4. Feeling tired or having little energy | ☐ | ☐ | ☐ | ☐ |
| 5. Poor appetite or overeating | ☐ | ☐ | ☐ | ☐ |
| 6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down | ☐ | ☐ | ☐ | ☐ |
| 7. Trouble concentrating on things, such as reading the newspaper or watching television | ☐ | ☐ | ☐ | ☐ |
| 8. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual | ☐ | ☐ | ☐ | ☐ |
| Total score = | | | | |

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

| Not difficult at all | Somewhat difficult | Very difficult | Extremely difficult |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

## PHQ-15

During the last 4 weeks, how much have you have been bothered by any of the following problems? Please place a check mark in the box to indicate your answer.

| | Not bothered | Bothered a little | Bothered a lot |
|---|---|---|---|
| | 0 | 1 | 2 |
| 1. Stomach pain | ☐ | ☐ | ☐ |
| 2. Back pain | ☐ | ☐ | ☐ |
| 3. Pain in your arms, legs, or joints (knees, hips, etc) | ☐ | ☐ | ☐ |
| 4. Menstrual cramps or other problems with your periods [women only] | ☐ | ☐ | ☐ |
| 5. Headaches | ☐ | ☐ | ☐ |
| 6. Chest pain | ☐ | ☐ | ☐ |
| 7. Dizziness | ☐ | ☐ | ☐ |
| 8. Fainting spells | ☐ | ☐ | ☐ |
| 9. Feeling your heart pound or race | ☐ | ☐ | ☐ |
| 10. Shortness of breath | ☐ | ☐ | ☐ |
| 11. Pain or problems during sexual intercourse | ☐ | ☐ | ☐ |
| 12. Constipation, loose bowels, or diarrhea | ☐ | ☐ | ☐ |
| 13. Nausea, gas, or indigestion | ☐ | ☐ | ☐ |
| 14. Feeling tired or having low energy | ☐ | ☐ | ☐ |
| 15. Trouble sleeping | ☐ | ☐ | ☐ |
| TOTAL SCORE = | | | |

## Visual analogue scale for pain intensity

1. How would you rate your facial pain RIGHT NOW? Please mark your answer (x) on the following scale where 0 is "no pain" and 100 is "pain as bad as could be"

0 _____ 100

2. In the last 30 days, how would you rate your WORST facial pain? Use the same scale where 0 is "no pain" and 100 is "pain as bad as could be"

0 _____ 100

3. In the last 30 days, ON AVERAGE, how would you rate your facial pain? Use the same scale where 0 is "no pain" and 100 is "pain as bad as could be"

0 _____ 100

**Global improvement and satisfaction with treatment (GIS)**

Compared to your last visit, how satisfied are you with your improvement and treatment?

| |
|---|
| ☐ This is my first visit |
| ☐ Very much improved |
| ☐ Much improved |
| ☐ Minimally improved |
| ☐ No change |
| ☐ Minimally worse |
| ☐ Much worse |
| ☐ Very much worse |

What is the current management for your jaw symptoms? You can choose more than one.

| | | | |
|---|---|---|---|
| ☐ Jaw exercises | ☐ Warm/cool compresses | ☐ Bite guard | ☐ Medication (Ibuprofen, amitriptyline. Etc) |
| ☐ Acupuncture | ☐ Cognitive behavioural therapy | ☐ No active management | ☐ Other (please specify): |

## Appendix 5: Search strategy for the qualitative evidence synthesis.

**Search strategy (Medline, Embase, PsychInfo):**

1. Temporomandibular Joint Disorders/

2. Temporomandibular Joint Dysfunction Syndrome/

3. Facial Pain/

4. Temporomandibular Joint/

5. Temporomandibular Joint Disc/

6. Masticatory Muscles/

7. Myalgia/

8. Arthralgia/

9. 6 and 7

10. 4 and 8

11. (TMD or TMJD or Temporomandibular disorder* or Temporomandibular joint dysfunction* or internal joint derangement* or Disc displacement or Fac* myalgia or masticat* muscle pain* or Degenerative joint disease or luxation* or orofac* pain* or Cranio* pain* or Fac* arthromyalgia or fac* pain).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

12. Personal Satisfaction/

13. "Quality of Life"/

14. Social Support/

15. Depression/

16. Anxiety/

17. Attitude/

18. (Experience* or Satisfaction* or Cop* or Support* or Stress* or resilience or quality of life or healthcare service* or health care service* or perspective* or concern* or opinion*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

19. Qualitative Research/

20. Focus Groups/

21. Interview/

22. Grounded Theory/

23. (qualitative stud* or qualitative research or interview* or discussion* or audio recording* or constant comparative analysis or content analysis or ethnograph* or field note* or field stud* or focus group* or grounded theor* or narrative* or observation or them* analysis or diary study).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

24. 12 or 13 or 14 or 15 or 16 or 17 or 18

25. 19 or 20 or 21 or 22 or 23

26. 1 or 2 or 3 or 4 or 5 or 9 or 10 or 11

27. 24 and 25 and 26

28. limit 27 to (human and english language)

**Search strategy (Cochrane database)**

ID Search Hits

#1 MeSH descriptor: [Temporomandibular Joint Disorders] explode all trees

#2 MeSH descriptor: [Temporomandibular Joint Dysfunction Syndrome] explode all trees

#3 MeSH descriptor: [Facial Pain] explode all trees

#4 MeSH descriptor: [Temporomandibular Joint] explode all trees

#5 MeSH descriptor: [Masticatory Muscles] this term only

#6 MeSH descriptor: [Myalgia] explode all trees

#7 MeSH descriptor: [Arthralgia] this term only

#8 #4 and #7

#9 #5 and #6

#10 TMD or TMJD or "Temporomandibular disorder*" or "Temporomandibular joint dysfunction*" or "internal joint derangement*" or "Disc displacement" or "Fac* myalgia" or "masticat* muscle pain*" or "Degenerative joint disease" or luxation* or "orofac* pain*" or "Cranio* pain*" or "Fac* arthromyalgia" or "fac* pain"

#11 #1 or #2 or #3 or #8 or #9 or #10

#12 MeSH descriptor: [Quality of Life] explode all trees

#13 MeSH descriptor: [Social Support] explode all trees

#14 MeSH descriptor: [Depression] explode all trees

#15 MeSH descriptor: [Anxiety] explode all trees

#16 MeSH descriptor: [Attitude] this term only

#17 Experience* or Satisfaction* or Cop* or Support* or Stress* or resilience or "quality of life" or "healthcare service*" or "health care service*" or perspective* or concern* or opinion*

#18 #12 or #13 or #14 or #15 or #16 or #17

#19 MeSH descriptor: [Qualitative Research] explode all trees

#20 MeSH descriptor: [Focus Groups] explode all trees

#21 MeSH descriptor: [Interview] explode all trees

#22 MeSH descriptor: [Grounded Theory] explode all trees

#23 "qualitative stud*" or "qualitative research" or interview* or discussion* or "audio recording*" or "constant comparative analysis" or "content analysis" or ethnograph* or "field note*" or "field stud*" or "focus group*" or "grounded theor*" or narrative* or observation or "them* analysis" or "diary stud*"

#24 #19 or #20 or #21 or #22 or #23

#25 #11 and #18 and #24

**Search strategy CINAHL Plus**

S48 S34 AND S40 AND S47 ( Limiters - English Language; Exclude MEDLINE records)

S47 S41 OR S42 OR S43 OR S44 OR S45 OR S46

S46 "qualitative stud*" or "qualitative research" or interview* or discussion* or "audio recording*" or "constant comparative analysis" or "content analysis" or ethnograph* or "field note*" or "field stud*" or "focus group*" or "grounded theor*" or narrative* or observation or "them* analysis" or "diary stud*"

S45 (MH "Thematic Analysis")

S44 (MH "Grounded Theory")

S43 (MH "Semi-Structured Interview") OR (MH "Unstructured Interview") OR (MH "Structured Interview") OR (MH "Interviews")

S42 (MH "Focus Groups")

S41 (MH "Qualitative Studies")

S40 S35 OR S36 OR S37 OR S38 OR S39

S39 Experience* or Satisfaction* or Cop* or Support* or Stress* or resilience or "quality of life" or "healthcare service*" or "health care service*" or perspective* or concern* or opinion* or "attitude*"

S38 (MH "Anxiety")

S37 (MH "Depression")

S36 (MH "Quality of Life")

S35 (MH "Personal Satisfaction")

S34 S25 OR S26 OR S29 OR S32 OR S33

S33 TMD or TMJD or "Temporomandibular disorder*" or "Temporomandibular joint dysfunction*" or "internal joint derangement*" or "Disc displacement" or "Fac* myalgia" or "masticat* muscle pain*" or "Degenerative joint disease" or luxation* or "orofac* pain*" or "Cranio* pain*" or "Fac* arthromyalgia" or "fac* pain"

S32 S30 AND S31

S31 (MH "Arthralgia")

S30 (MH "Temporomandibular Joint")

S29 S27 AND S28

S28 (MH "Muscle Pain")

S27 (MH "Masticatory Muscles")

S26 (MH "Facial Pain")

S25 (MH "Temporomandibular Joint Diseases") OR (MH "Temporomandibular Joint Syndrome")

**Search strategy: Web of Science**

# 4

(#3 AND #2 AND #1) AND LANGUAGE: (English)

# 3

TS= (Experience* or Satisfaction* or Cop* or Support* or Stress* or resilience or "quality of life" or "healthcare service*" or "health care service*" or perspective* or concern* or opinion* or depress* or anxi*)

# 2

TS= ("qualitative stud*" or "qualitative research" or interview* or discussion* or "audio recording*" or "constant comparative analysis" or "content analysis" or ethnograph* or "field note*" or "field stud*" or "focus group*" or "grounded theor*" or narrative* or observation or "them* analysis" or "diary stud*")

# 1

TS= ("Temporomandibular Joint Disorders" or "Temporomandibular Joint Dysfunction Syndrome" or TMD or TMJD or "Temporomandibular disorder*" or "Temporomandibular joint dysfunction*" or "internal joint derangement*" or "Disc displacement" or "Fac* myalgia" or "masticat* muscle pain*" or "Degenerative joint disease" or luxation* or "orofac* pain*" or "Cranio* pain*" or "Fac* arthromyalgia" or "fac* pain")

## Appendix 6: Topic guide for focus groups

**Introduction**

- Name, role, brief description of your research (aims and objectives)
- Set the scene for the interview (time, recording).

**Opening questions**

Generally, how would you describe a pleasant clinical experience (keeping in mind the symptoms of TMD)?

**Core questions**

**Pre-visit to the Eastman**

1. How was that visit in primary care?
   - Respect/ believed/ diagnosis?
2. Did you have any expectations going there?
   - Interaction
   - Treatment offered
   - Referral to other specialists
   - Imaging or tests
3. How was your journey from primary care to here? Was it a smooth referral process or were there some difficulties along the way?
4. How long did you wait before you got an appointment at the Eastman? Was that reasonable?
5. How did you feel during that waiting period/ referral process? (did your symptoms get worse/better?)

**Eastman visit**

1. How would you describe your visits to the Eastman? Why?
2. Did you have any expectations coming here? Were they met?
3. Do you recall receiving a diagnosis on your first visit?
4. Were you concerned or worried before your visit? Did the visit alleviate your concern?
5. What were the most important aspects of that interaction that you think made a difference to your symptoms?
   - Diagnosis/ Information
   - Welcoming environment/ family and friends
   - Waiting time- what do you think is a reasonable waiting time?
   - Interaction with the clinician

- Access
- Emotional support
- Treatment

6. How about the interaction with the clinician and the staff?
7. Did your symptoms improve after the visit? What helped?
8. Do you think you were given enough time during your visits? Was that important to you?
9. Were you made aware of any support groups? Do you think they are important?
10. If you would change some of aspects of the visit here, what would you change? Why? / What were the negative aspects of your visit?
11. What were the positive aspects of your visit?

**After Eastman visit**

1. Were you referred to another specialist? Who suggested the referral?
2. Do you think the care was coordinated?

**The NHS patient experience framework**

The NHS have suggested the following elements as important aspects for a pleasant hospital experience. Do you agree with them as a patient with TMD?

Would you change any of them?

Would you add anything else?

If you were asked to put them in order according to importance, how would you order them?

## Appendix 7: Final version of PREM-TMD

Please score the following statements by choosing the option which best describes your experience with **THIS CLINIC**. Choose N/A if the statement does not apply to your situation.

| Item | Strongly agree | Agree | Neutral | Disagree | Strongly disagree | Not applicable |
|---|---|---|---|---|---|---|
| **Domain 1: Emotional support** | | | | | | |
| 1. My clinician was reassuring and supportive | 5 | 4 | 3 | 2 | 1 | N/A |
| 2. The clinician acknowledged the impact of pain on my life | 5 | 4 | 3 | 2 | 1 | N/A |
| 3. I was listened to and believed during the visit | 5 | 4 | 3 | 2 | 1 | N/A |
| 4. I have confidence in my clinical team | 5 | 4 | 3 | 2 | 1 | N/A |
| 5. I felt I had the right clinical team for my condition | 5 | 4 | 3 | 2 | 1 | N/A |
| 6. I received information about my condition to a satisfactory level | 5 | 4 | 3 | 2 | 1 | N/A |
| **Domain 2 (Respect for patient-centred values, preference and needs)** | | | | | | |
| 7. I felt respected and understood | 5 | 4 | 3 | 2 | 1 | N/A |
| 8. I was involved in the decisions about my care | 5 | 4 | 3 | 2 | 1 | N/A |
| 9. The clinician explained the treatment options adequately | 5 | 4 | 3 | 2 | 1 | N/A |
| **Domain 3 (Information, communication, and education)** | | | | | | |
| 10. I received a timely diagnosis at this clinic | 5 | 4 | 3 | 2 | 1 | N/A |
| 11. I was given information on how to contact my clinical team should I need to | 5 | 4 | 3 | 2 | 1 | N/A |
| 12. There is good communication with the hospital | 5 | 4 | 3 | 2 | 1 | N/A |
| 13. I was satisfied with the treatment plan decided | 5 | 4 | 3 | 2 | 1 | N/A |

| | | | | | | |
|---|---|---|---|---|---|---|
| 14. I feel better able to cope with my symptoms | 5 | 4 | 3 | 2 | 1 | N/A |
| **Domain 4 (Access to care)** | | | | | | |
| 15. I waited a reasonable amount of time from when I was referred until I was seen in this clinic.<br>* Can you specify how long this was? _____ weeks/months | 5 | 4 | 3 | 2 | 1 | N/A |
| 16. The referral process to the hospital was straightforward | 5 | 4 | 3 | 2 | 1 | N/A |
| 17. I did not experience unexpected appointment cancellations or delays in receiving appointments | 5 | 4 | 3 | 2 | 1 | N/A |
| 18. I waited a reasonable amount of time in the waiting area before being seen in clinic.<br>*Can you specify how long this was? _____minutes | 5 | 4 | 3 | 2 | 1 | N/A |
| 19. I was given enough time to ask any questions | 5 | 4 | 3 | 2 | 1 | N/A |
| **Domain 5 (Coordination of care)**<br>**Choose N/A if this is your first visit.** | | | | | | |
| 20. The onward referrals from this clinic were timely and coordinated. | 5 | 4 | 3 | 2 | 1 | N/A |
| 21. There was good coordination between the different clinicians who looked after my facial pain | 5 | 4 | 3 | 2 | 1 | N/A |
| 22. Overall, I am satisfied with my experience in this clinic | 5 | 4 | 3 | 2 | 1 | N/A |

Would you like to add any additional comments?

Admin use: Total score = $\frac{\sum items\ 1-21}{105-(\text{number of NA answers x } 5)}$ x 100%

## Appendix 8: Publications from the present thesis

### Articles accepted in peer-reviewed journals

Taimeh D, Leeson R, Fedele S, Ni Riordain R. A meta-synthesis of qualitative data exploring the experience of living with temporomandibular disorders: the patients' voice. Oral Surgery.

### Abstracts presented in peer-reviewed conferences

D. Taimeh, S. Fedele, R. NiRiordain and R. Leeson. Patient Reported Outcome Measures (PROMs) used in temporomandibular disorders (TMD). A review of the literature. European Association of Oral Medicine. 2021.

D. Taimeh, R. NiRiordain, S. Fedele and R. Leeson. Healthcare priorities in patients with chronic facial pain of temporomandibular disorders: A series of online focus groups. 12th Congress of the European Pain Federation, Pain in Europe XII. Dublin, Ireland 2022.