Telerehabilitation Effectiveness for Individuals with Temporomandibular Disorders

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"Stay gentle, keep the eyes of a child
Don't harden your heart or your hands
Know to find joy in the darkness is wise
Although they will think you don't understand"
-Brandi Carlile

Dedication:

To Brett, Ella, and Jack:

For your love, support, and laughter
through five years of transition and uncertainty –
for asking about my day,
asking what I'm doing even when you didn't know what it means,
giving me hugs,
always doing your best and inspiring me to do the best I can,
and letting me grow alongside you.
I love you forever.

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For listening, laughing, commiserating, supporting, and distracting;
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For keeping me together;
For caring for me by caring for mine.

ABSTRACT

Background: Temporomandibular joint disorders (TMD) are the second most common musculoskeletal cause of pain and disability. Physical therapy (PT) is an effective treatment, but patients report difficulty accessing high quality care. Telehealth delivery increases access to care, but whether or to what extent telerehabilitation (TR) can effectively deliver care for this population is unknown.

Objectives: 1. Determine PT diagnostic reliability for in-person (IP) and TR diagnosis of TMD; 2. Determine noninferiority of telerehabilitation for individuals with TMD as compared to in-person PT; and 3. Explore telerehabilitation feasibility and long-term outcomes.

Methods: After ethical approval, 207 patients with TMD ages 18-69 chose telehealth (n=113) or in-person (n=94) PT in this open-label prospective cohort noninferiority trial. Telehealth adaptations included guiding patient self-assessment with verbal instructions and visual cues. The PT diagnosis of masticatory myalgia was compared to Orofacial Pain (OFP) specialist clinical diagnoses (reference) to calculate diagnostic agreement in each group using percent agreement and prevalence-adjusted bias-adjusted kappa (PABAK). After 6 weeks of individualized PT treatment, the difference between the proportion of therapy responders in each group was compared to a 10% noninferiority margin. The acceptability, practicability, effectiveness, affordability, side effects/safety, and equity (APEASE) criteria characterized feasibility using data from a post-discharge qualitative questionnaire.

Results: 200 participants completed the PT evaluation (TR=106, IP=94) and 89 participants completed 6-week questionnaires. Both groups had 95% raw agreement and almost perfect diagnostic agreement between PT and reference diagnosis of masticatory myalgia (IP PABAK=0.89[0.76,0.97]; TR PABAK=0.91[0.79,0.97]). The proportion of 6-week therapy responders in each group was TR = 73(62,82)% and IP=62(51,72)% with a small effect size for TR (h=0.30) and the difference between

group proportions was 11(-2,25)%. Intervention evaluation revealed that it satisfied each APEASE criterion for the 11 participants who gave qualitative feedback. **Conclusion**: Telediagnosis of TMD by a PT was reliable, and after 6 weeks TR was effective and noninferior to IP care according to quality-of-life improvement. Patients demonstrated willingness to engage in TR with higher numbers preferring remote care delivery. Clinically these results show that TR is a viable and desirable care option for this population to increase accessibility for patients with TMD.

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List of Abbreviations

APEASE	Acceptability, Practicability, Effectiveness, Affordability, Side Effects/Safety, Equity Criteria
APTA	American Physical Therapy Association
BCW	Behavioral Change Wheel
bDC/TMD	Brief Diagnostic Criteria for Temporomandibular Disorders
CONSORT	Consolidated Standards of Reporting Trials
DC/TMD	Diagnostic Criteria for Temporomandibular Disorders
DDwR	Disc Displacement with Reduction
DDwoR	Disc Displacement without Reduction
DEEP	Developing Effective and Efficient Care Pathways for Patients with Chronic Pain
DJD	Degenerative Joint Disease
EQ-5D-5L	EuroQ0L-5 Dimensions-5 Levels
EMG	Electromyography
GCPS	Graded Chronic Pain Scale
GRS	Global Rating Scale
HCSQ	Health Care Satisfaction Questionnaire
HIPAA	Health Insurance Portability and Accountability Act
H1	Hybrid 1: telerehabilitation to in-person
H2	Hybrid 2: in-person to telerehabilitation
ICC	Intraclass Correlation Coefficient
ICER	Incremental Cost-Effectiveness Ratios
IP	In-Person
ITT	Intention-to-Treat
JFLS-8	Jaw Functional Limitation Scale – 8-item version
K	Cohen's Kappa
MCID	Minimal Clinically Important Difference

MMO	Maximum mouth opening
MRI	Magnetic Resonance Imaging
NIDCR	National Institute of Dental & Craniofacial Research
NPRS	Numeric Pain Rating Scale
NT	No therapy
OA	Osteoarthritis
OFP	Orofacial Pain
OHIP-TMD	Oral Health Impact Profile – Temporomandibular Disorders
OPPERA	Orofacial Pain Prospective Evaluation & Risk Assessment
PHQ-4	Patient Health Questionnaire for Anxiety & Depression
PABAK	Prevalence-Adjusted Bias-Adjusted Kappa
PT	Physical Therapy
QALYs	Quality-adjusted life years
RCT	Randomized Controlled Trial
RDC/TMD	Research Diagnostic Criteria for Temporomandibular Disorders
REDCap	Research Electronic Data Capture
RTUS	Real-Time Ultrasound
TENS	Transcutaneous electrical nerve stimulation
TIDieR	Template for Intervention Description and Replication Checklist
TMD	Temporomandibular Disorders
TMJ	Temporomandibular Joint
TR	Telerehabilitation

Chapter 1: INTRODUCTION

BACKGROUND & SIGNIFICANCE

The group of musculoskeletal conditions known as temporomandibular disorders (TMD) produces a range of orofacial pain symptoms, overlapping with other conditions and presenting management challenges for the health care system.[1] Complex orofacial neuroanatomy includes convergence of the trigeminal and cervical nerve pathways and susceptibility to central sensitization.[2,3] These conditions contribute to chronicity and comorbidity with disorders such as headache, cervicalgia and fibromyalgia,[4] and there is a well-documented connection between TMD and disability.[1,5-8] The National Academies of Science, Engineering and Medicine's consensus report from March 2020 highlighted the societal burden of orofacial pain and recommended conservative multidisciplinary care as first line management.[1] Limited access to specialized providers and poor coordination of care exacerbates the problem of orofacial pain and creates a critical need for more research in this area.

Physical therapy (PT) has been shown to be an effective component of multidisciplinary conservative TMD management.[2,9-17] Physical therapists provide individualized therapy to improve mouth opening, pain, and quality of life for their patients. Because there is limited evidence supporting specific interventions and no validated PT clinical practice guideline, multimodal care is the current standard.[1,18] A recent retrospective review of PT outcomes for patients with all TMD subtypes highlighted the short-term success of multimodal conservative management despite the heterogeneity of care.[12] However, finding PTs with the background and experience to treat TMD is difficult due to varying PT educational requirements[19] and a lack of PT residencies/fellowships for orofacial pain.[20,21] Despite increasing evidence demonstrating success with multimodal PT, limited access to specialized

care in rural areas and poor general knowledge regarding PT for TMD interferes with widespread PT utilization.[1,22]

Telerehabilitation using real-time video PT delivery has the potential to increase access to care for individuals with TMD and prevent development of chronic disabling conditions. Successful utilization in other areas of PT has shown that the lack of in-person contact during telerehabilitation does not restrict its effectiveness.[23-27] However, the unique anatomy and psychosocial considerations for individuals with TMD require a condition-focused investigation. Telerehabilitation studies also reveal heterogeneity due to evolving technology and challenges in adapting in-person treatment interventions, thereby highlighting the need for a standardized approach.[28] Investigating telerehabilitation effectiveness in the TMD population is significant due to the lack of existing evidence for its use in the field of orofacial pain management.

CLINICAL IMPLICATIONS

Study outcomes will quantify telerehabilitation effectiveness and contribute feasibility evidence examining a care delivery method that increases access for individuals with TMD. Regardless of outcome, study results will be significant as they will inform care pathways including underserved populations. These outcomes will thereby align with nationally identified research priorities. This project addresses Objective 3-1 of the National Institute of Dental and Craniofacial Research (NIDCR) 2014-2019 Strategic Plan as “multidisciplinary research to overcome disparities in managing chronic orofacial pain.” The project also meets the National Academies of Science, Engineering and Medicine’s recommendations to “build and sustain collaborative multidisciplinary research” and “improve access to and quality of TMD health care.”[1] Finally, this project aligns with two of the American Physical Therapy Association (APTA) Clinical Research Agenda items: “Determine the PT’s role and impact in contemporary delivery models on prevention of diseases and their

secondary side effects" (item 7) and "Determine effectiveness and efficacy of PT interventions across relevant domains of health" (item 15).[29]

Direct clinical applications of study outcomes include advancing clinical practice by informing PT diagnosis and management of individuals with TMD. Physical therapists use the same diagnostic criteria for TMD assessment as dentists, but these criteria have only been validated for in-person and telehealth use thus far by dental providers.[30-32] Telerehabilitation effectiveness results will reveal whether or to what extent this intervention can be used in place of in-person rehabilitation for individuals with limited ability to find or attend a specialty clinic. Implementation data will inform clinical utilization of telerehabilitation for this population and can be used to create a training plan for therapists to provide this type of care. Results of secondary and future analyses will directly address existing barriers to implementation and progress care for these individuals in a clinically translatable way.

AIMS & HYPOTHESES

Specific Aim 1: Establish TMD PT diagnostic agreement via telerehabilitation.

Aim 1 Hypotheses:

1a) H_A = PT diagnosis will have good diagnostic agreement with an OFP specialist in-person diagnosis as shown by $k_{A(C)} \geq 0.70$. ($k_0 < 0.70$)

1b) H_A = Telerehabilitation PT diagnosis will have good diagnostic agreement with an OFP specialist in-person diagnosis as shown by $k_{A(T)} \geq 0.70$. ($k_0 < 0.70$)

1c) H_A = The kappa values for the two groups will not differ >0.1.

Specific Aim 2: Determine noninferiority of telerehabilitation for individuals with TMD as compared to in-person PT.

Aim 2 Hypothesis:

H_A = Telerehabilitation will be noninferior to in-person rehabilitation after 6 weeks based on a 10% effectiveness margin.

H_A: $P_T - P_C < -0.1$ H_0: $P_T - P_C > -0.1$

P_T = Proportion of positive therapy outcomes in the telerehabilitation group

P_C = Proportion of positive therapy outcomes in the in-person (control) group

-0.1 = pre-specified 10% noninferiority margin for telerehabilitation effectiveness describing a proportional difference with the in-person group as the reference

Specific Aim 3: Explore telerehabilitation feasibility and long-term outcomes.

Aim 3 Hypotheses:

1. Patient satisfaction and cost-effectiveness results will characterize the feasibility of implementing telerehabilitation for individuals with TMD.
2. Long-term rehabilitation outcomes and covariate analysis will identify important predictors of telerehabilitation effectiveness.

Chapter 2: LITERATURE REVIEW

WHAT IS TMD?

Introduction

The group of musculoskeletal conditions known as temporomandibular disorders (TMD) produces a range of orofacial pain symptoms, overlapping with other conditions and presenting management challenges for the health care system.[1] Complex orofacial neuroanatomy includes convergence of cranial and upper cervical nerve pathways and susceptibility to central sensitization.[2,3] These conditions frequently overlap with facial and upper quarter regional disorders and whole-body disorders such as systemic arthritis and fibromyalgia,[4,33] and there is a well-documented connection between TMD and disability.[1,5-7] The financial burden of TMD includes annual health care costs estimated at $4 billion[7] with thousands of out-of-pocket treatment dollars per patient, though the majority (85%) of treatment costs are focused on the small portion of patients with chronic TMD pain and dysfunction.[1,34] The recent National Academies of Science, Engineering and Medicine's consensus report from March 2020 highlighted the societal burden of orofacial pain and recommended conservative multidisciplinary care as first line management.[1] The report also identified individuals with TMD as an underserved population.[1] Limited access to specialized providers and poor coordination of care exacerbates the problem of orofacial pain and creates a critical need for more research in this area. This overview will discuss TMD epidemiology, pathophysiology, comorbidities, diagnosis, and management for clinical applications.

Epidemiology

Temporomandibular disorders comprise ≥30 conditions affecting the muscles and tissues of the temporomandibular joint and are a subset of orofacial pain.[1,33,35] They are usually of musculoskeletal and neuromuscular origin but are frequently

associated with systemic and comorbid effects.[1,4,33] The complexities of pain processing contribute to some individuals with TMD developing chronic pain with psychologic comorbidities involving the autonomic nervous system.[1,33,34] Reported prevalence has traditionally varied, with values ranging from 4.8-15% due to heterogeneous case definitions and the overlap with chronic pain conditions.[1,33-36] For example, a representative sample of individuals in Canada showed 50% reporting at least one symptom without full TMD diagnosis but only 7% overall prevalence.[1] A systematic review and meta-analysis from 2021 recently reported an increased prevalence rate of 31% in the general population.[37] Incidence of TMD is similarly difficult to estimate due to having only a few large-scale longitudinal cohort studies, though an annual incidence rate of 2-3.5% has been reported.[34,38] Most significantly, these conditions are the second most common musculoskeletal cause of pain and disability and one-third of people living to age 70 will experience facial pain.[6] In the Orofacial Pain Prospective Evaluation and Risk Assessment (OPPERA) project from 2005-2012, 49% of patients with incident TMD continued to have pain 6 months after onset[39] demonstrating the potential of these disorders to become chronic if left untreated. A recent systematic review identified some evidence that the presence of myofascial pain and baseline pain intensity was associated with the transition from acute to chronic TMD pain, but overall factors impacting the development of chronicity are unclear.[40]

While no consensus exists regarding etiology, multiple theories have been proposed ranging from mechanical pathology to neuromuscular, muscular and psychopathological sources of TMD.[1,41] The OPPERA study identified risk factors, genetic mechanisms and clinical characteristics of TMDs, contributing significant discoveries regarding TMD etiology.[1,34,38] The two main factors predisposing individuals to development of TMD are psychological distress and a heightened experience of pain known as pain amplification.[34] Additional potential predictors of

TMD onset fall into categories covering clinical, psychological and pain sensitivity factors (Table 1). Controversy exists surrounding occlusal and orthodontic causes of TMD with no strong evidence aside from a weak association with occlusal characteristics.[1,38]

Pathophysiology

Temporomandibular joint (TMJ) anatomy (**Figure 1**) consists of a unique combination of two ginglymoarthrodial joints that function as one unit. As with other synovial joints, the nutrient-rich synovial fluid transports nutrients and waste from the articular surfaces.[33] A capsule surrounds the joint, enclosing the synovial fluid and providing strong lateral support by encompassing the temporomandibular ligament.[42,43] The mandibular condyles fit into the glenoid fossa of the temporal bone, articulating with the eminence anterior to the fossa during mouth opening. Unlike other hyaline cartilage-lined synovial joints, the articular surfaces are lined with fibrocartilage that can repair in response to prolonged loading.[33]

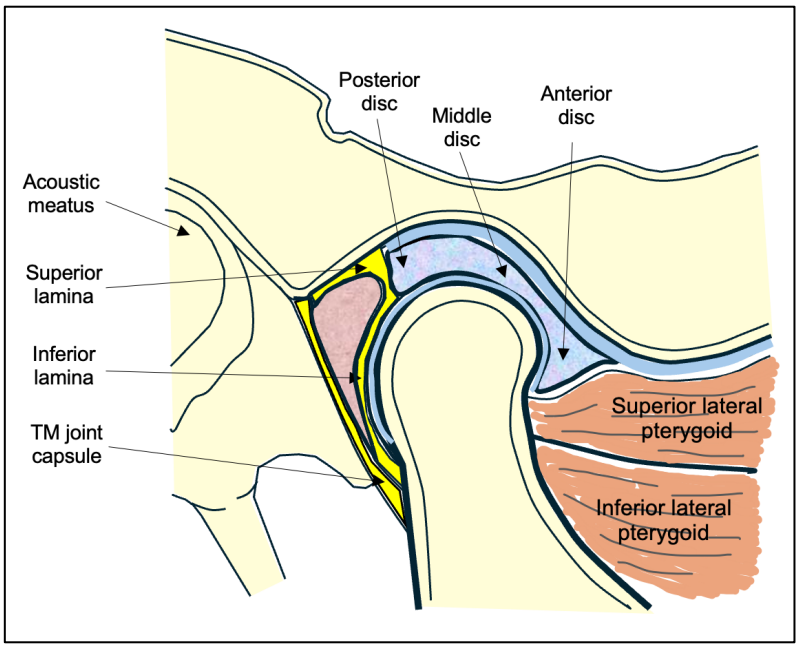


Figure 1. Lateral view of the TMJ (Adapted from Levangie & Norkin, Joint Structure and Function: a Comprehensive Analysis. 5th ed., 2011)

A biconcave, non-innervated articular disc sits atop each condyle to improve joint congruency and provide stability during movement. The disc is made of dense,

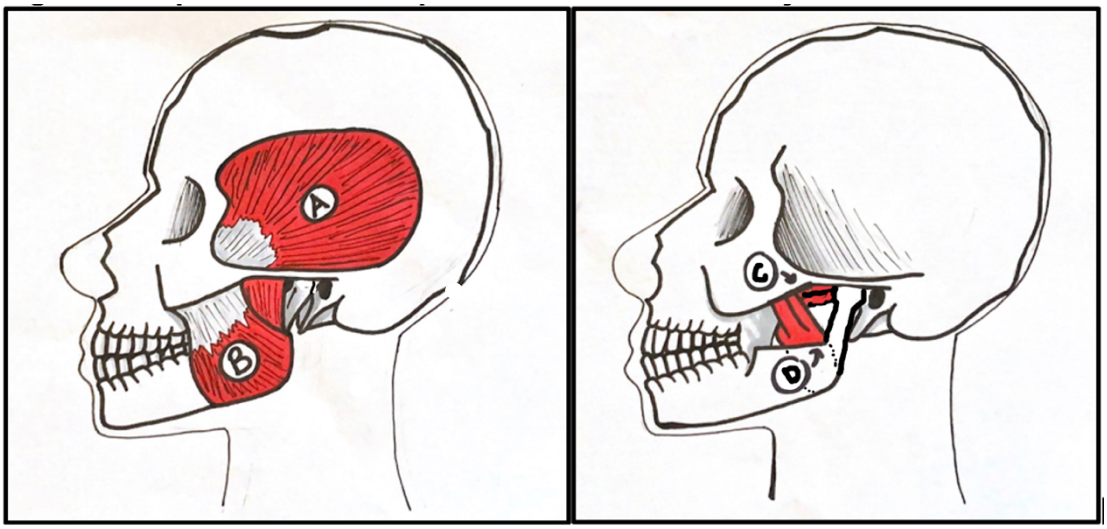
fibrous connective tissue that changes shape in response to force and use, as seen on magnetic resonance imaging (MRI) revealing different disc shapes in open-mouth and closed-mouth positions.[44] The disc's potential to remodel contributes to the development of anterior disc displacement in response to repetitive loading and overuse.[42] Medial and lateral collateral ligaments allow rotational movement between the disc and the condyle, and the posterior ligament attaches to the posterior aspect of the disc to manage disc movement during jaw function.[45,46] The vascularized and innervated ligament contains two bands (or laminae): an elastic superior lamina and a tether-like inferior lamina.[42] The ligament can be a source of pain and inflammation when anterior disc displacement occurs.[46]

Primary TMD

Mechanical TMD conditions develop because of dysfunction related to the articular disc and joint structures. The biomechanics of mouth opening involve a combination of rotation and translation of the TMJ condyle-disc complex. While initially thought to rotate first in isolation, recent biomechanical evidence reveals a coupled relationship of 0.5 mm translation/1° rotation from the opening onset.[47] Jaw rotation accounts for 91% of vertical opening, and translation via lateral pterygoid muscle activity accounts for 99% of protrusion.[47] The digastric muscles and the inferior head of the lateral pterygoid engage at the end range of opening.[45,48] When anterior disc displacement occurs, changes develop in lateral pterygoid muscle balance and function that increase the strain on the disc and can affect the muscle's ability to perform its role of fine motor control with mandibular movements.[48] Jaw catching or locking can occur at this time, wherein the lateral pterygoid cannot fully translate the condyle forward without disc reduction. This condition is associated with jaw clicking and popping along with restricted jaw range of motion, and the disc and

joint surfaces are susceptible to degeneration.[31] While pain can be present with these conditions, the mechanical etiology does not necessarily cause pain.

Patients with painful TMDs comprise the majority of clinical populations.[1,49] Muscle pain is the most common subset of TMD and can result from accumulation of many risk factors.[1] The primary masticatory muscles include the temporalis, masseter, medial and lateral pterygoids (**Figure 2**). Painful myalgia/myofascial pain can occur due to overuse and dysfunction in the masseter, medial pterygoid and temporalis muscles that close the jaw.[45] Along with the medial pterygoids, the lateral pterygoid muscles protrude with bilateral activation and laterally deviate the jaw to the contralateral side with unilateral activation.[45,46] Muscle pain can interfere with talking, eating, yawning, oral hygiene and tolerance of dental treatment. Joint arthralgia describes pain in the TMJ and/or joint capsule and is more localized than muscle pain that can refer to other areas.[31] Inflammation can be involved, but the primary determining factor is whether pain is occurs or changes with joint movement.[31,33]



Superficial: A=Temporalis; B=Masseter Deep (Pterygoids): C=Lateral; D=Medial

Figure 2. Masticatory Muscles: Superficial and Deep views. (Drawings by Ella Kahnert, 2021)

Secondary TMD

Temporomandibular disorders can also occur because of systemic disorders that account for TMJ or masticatory muscle pain, known as secondary TMD. Trigeminal sensory nuclei in the brainstem receive sensory nociceptive information from the face, head, and neck. First-order neurons from various sites including the TMJ, cervical spine and teeth converge in the subnucleus caudalis to excite second-order neurons regardless of their origin. Therefore, headache conditions and dysfunction of the cervical spine or muscles can cause pain in the TMJ, masseter and temporalis through shared nociceptive pathways of afferent cranial and cervical spine nerves.[4,33,34,50] Temporal summation of second-order neurons can activate other subnuclei and synapse with third-order neurons in the thalamus responsible for interpreting pain and programming the appropriate descending motor and pain responses.[4,33] Complexities of pain processing related to the overlap of autonomic, nociceptive, immune, and neuroendocrine systems can increase susceptibility to chronic pain conditions and cause orofacial pain.[51]

Comorbidities

The pain processing outlined above results in comorbidities seen in patients with TMD that can complicate diagnosis and management. Structural changes along nociceptive pathways can trigger central sensitization and amplify pain.[51] Chronic systemic conditions including fibromyalgia, osteoarthritis, rheumatoid arthritis, Sjögren's syndrome, and lupus are therefore common comorbidities causing secondary TMD.[1,34] Chronic fatigue, irritable bowel syndrome, gastroesophageal reflux disorder, migraine and other headaches, and chemical sensitivities frequently occur.[1,4,50] Chronic neck pain is common and a strong association between neck disability and weakness in cervical deep flexor muscles is seen in individuals with TMD.[52,53] Conditions including anxiety, depression and post-traumatic stress disorder

have a bi-directional interaction with pain persistence due to systemic interactions that can amplify orofacial pain.[51] A headache from TMD can occur due to temporalis muscle dysfunction.[31] Finally, non-painful conditions such as respiratory disorders, sleep disorders, vertigo, tinnitus, and Ehlers-Danlos syndrome are comorbidities that complicate traditional orthopedic management strategies.[1] Chronic pain related to comorbidities can affect prognosis,[54,55] which must be considered to develop appropriate strategies for management.

Biopsychosocial Model

In the late 1970's, Charles Engel began to question the traditional biomedical model employed in health care, which only considered pathophysiologic causes of illness.[56] The traditional model viewed psychosocial concerns as unrelated to the body, minimizing undetectable disease as a psychosomatic problem.[57] Engel's solution considered the body as a hierarchy of systems, including biological, psychological and social-environmental factors in the diagnosis and management of illness.[56] This biopsychosocial model of care includes the patient as a member of the care team and relies on multidisciplinary collaboration to address multifactorial causes.[56,57] A multidisciplinary pain team can include any combination of providers such as doctors, dentists, nurses, social workers, rehabilitation therapists and psychologists working together with the patient to break pain cycles and develop management strategies.[58] As previously discussed, the variety of etiologic factors for development of TMD include psychological and social factors that amplify pain.[34,59] Higher levels of chronic pain will decrease the effectiveness of treatment interventions for persistent orofacial pain.[55] Overall, the biopsychosocial model has been found to best represent the complexity of TMD.[1,2,33,51,59-61]

Diagnosis of TMD

The groundbreaking 1992 Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)[36] outlined diagnosis of these disorders and introduced the consideration of psychosocial status into diagnosis and management for individuals with TMD. To complement the physical diagnosis (considered **Axis-I**), the psychosocial status (considered **Axis-II**) is assessed with instruments such as the Graded Chronic Pain Scale (GCPS)[62] and the Patient Health Questionnaire for anxiety and depression (PHQ-4).[31] The 2014 updated Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) simplified and validated the original 1992 criteria with ideal sensitivity and specificity cutoffs of ≥70% and ≥95% respectively[31]. The DC/TMD diagnostic algorithms use history, physical exam, and a variety of imaging techniques to diagnose twelve common TMD conditions. The algorithms presented in the criteria provide an assessment guide to diagnose TMD that can be used by health care providers to determine their plan of care. The algorithms provide specific criteria that must be present in the patient history and patient exam to diagnose myofascial pain conditions, TMJ arthralgia, intra-articular disc disorders, degenerative joint disease, subluxation, and headache attributed to TMD.[31] The full protocol requires completion of 41 Axis-2 items and examination including a 10-section protocol with 12 sets of joint and muscle palpations on both sides of the body.[31,63]

Patient History

When questioning patients about the nature of their pain and functional limitations, the DC/TMD algorithms for pain related TMD diagnoses require pain to be present in specific locations. For myofascial pain conditions and TMJ arthralgia, it must be present in the jaw, temple, ear, or pre-auricular areas. For headache attributed to TMD, the headache must present in one or both temple areas. During

pain questioning, pain of any of these areas should cue the clinician to consider any of the above-mentioned diagnoses for the patient. In addition, one must ask questions regarding activities that will modify the pain. The presence of pain alone does not indicate a TMD diagnosis, as that pain must increase or decrease with jaw use such as opening, closing, biting, chewing, talking, brushing teeth, and/or clenching. For the diagnosis of TMD headache, the headache must be modified with jaw use as well. Answers to these questions will guide palpation and choice of special tests to assess muscle and joint dysfunction.

When evaluating a patient with a potential TMD, additional questions are required beyond the experience of pain. Diagnoses related to disc displacement may not always have pain associated with them, so specific questioning regarding the presence of joint noises with jaw function in the past month is required. The DC/TMD algorithm requires history of joint noise for disc displacement with reduction and degenerative joint disease diagnoses. Joint noises can include clicking, popping, snapping, crunching or other descriptors.[45] Joint crepitus can indicate potential joint degeneration and can lead clinicians to perform joint compression testing during the physical exam. Questioning regarding limited opening, locking, and its relation to joint noise is next necessary to determine whether a potentially displaced disc could be restricting full movement or reducing to allow full movement. According to the DC/TMD algorithm, limited opening that precludes regular jaw function can indicate disc displacement without reduction (DDwoR), and jaw locking in a wide-open position without the ability to close independently can indicate subluxation. Positive findings in these areas will guide the choice of additional objective measures to verify the nature of the symptoms.

Patient Exam

Measuring jaw opening (**Figure 3**), bilateral laterotrusion (**Figure 4),** and protrusion in millimeters (mm) with a ruler provides valuable information to guide TMD diagnosis. If a patient has mentioned limited opening and/or locking in their history, a passive opening <40 mm will implicate disc displacement without reduction with limited opening, and passive opening ≥40 mm will implicate disc displacement without reduction without limited opening according to the DC/TMD.[31] If joint noise was mentioned during the history, palpation for joint noise during patient movement is necessary to confirm its presence and verify its descriptive nature as clicking or crepitus to delineate whether disc displacement or joint degeneration could be causing the symptoms. Confirming the presence of pain with jaw movement is also required for myofascial pain diagnoses in the DC/TMD.[31]

Figure 3. Measuring vertical jaw opening distance with a millimeter (mm) ruler.

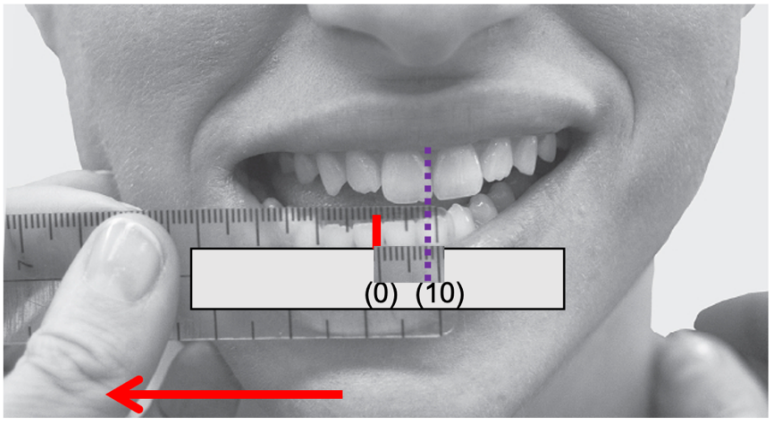


Figure 4. Measurement of Jaw Right Lateral Deviation (Laterotrusion)

Palpation is the final element of the patient exam required for the DC/TMD.[31] The temporalis and masseter muscles are the only two muscles that have demonstrated acceptable sensitivity and specificity, so familiar pain elicited by their palpation is a confirmatory finding for myofascial pain diagnoses. Whether pain spreads beyond the boundary of palpation or not will determine if myofascial pain with referral is present. Familiar pain at palpation of the lateral TMJ condyle will confirm TMJ arthralgia. If palpation in the temporalis reproduces familiar headache, then the TMD headache diagnosis is appropriate.

Imaging

Imaging is required for definitive diagnosis of degenerative joint disease (DJD) and disc conditions due to poor diagnostic accuracy of clinical assessment.[31,64] A diagnosis of DJD without imaging had low sensitivity (0.55) and specificity (0.61) using diagnostic criteria alone.[31] Computed tomography (CT) is considered the gold standard to diagnose TMJ DJD despite having panoramic radiographs commonly available in dentistry.[31,65] Panoramic radiographs and MRI scans showed high sensitivity (0.99-1.00) but low specificity (0.12-0.71) to detect signs of DJD, meaning that a positive DJD sign on either scan indicates its presence but a negative reading could miss a true diagnosis.[64] While the presence/absence of clicking per palpation or patient report is included in the diagnostic criteria for other disc conditions, sensitivity for diagnosing disc displacement with reduction is only 0.34.[31] The only disc condition with sensitivity above the desired threshold of 0.70 without imaging was subluxation at 0.98.[31] Specificity of the diagnostic criteria for all disc conditions was higher than sensitivity, but not higher than the desired 0.95 threshold.[31] Real-time ultrasound (RTUS) has been shown to reliably quantify condylar translation[66] and disc position[65] with potential to provide a cost-effective imaging strategy to

diagnose disc conditions, but there is a lack of widespread training and familiarity with this procedure.[65] The gold standard for diagnosing disc conditions is MRI due to its superior ability to assess soft tissues.[31,44,65]

No imaging gold standard exists to diagnose muscle conditions.[31] The DC/TMD validation project revealed excellent sensitivity (0.90) and specificity (0.99) using diagnostic criteria alone to diagnose myalgia,[31] but the generic nature of this diagnosis complicates its use for treatment planning. The more descriptive diagnosis of myofascial pain with referral has good sensitivity (0.86) and specificity (0.98),[31] but it still does not identify or quantify the limitation for treatment. There is some future potential for the use of RTUS for diagnosis of muscle conditions with its ability to image muscle cross-sectional area, thickness, and fascicle length.[67] Ariji and colleagues demonstrated via RTUS that women with TMD had thicker masseter muscles than healthy controls.[68] However, specific muscle characteristics have not been investigated using RTUS with reference to different diagnoses.[69] Similarly, there is research utility of electromyography (EMG) in this population but no demonstrated clinical or diagnostic application.[70] Using EMG has shown decreased masseter and temporalis activity during clenching in people diagnosed with myofascial pain.[71] Additional EMG studies reveal changes in lateral pterygoid activation related to disc displacement, fatigue and pain.[72,73] However, resting EMG levels are not significantly different between subjects with and without pain, and the diagnostic sensitivity of EMG to diagnose myofascial pain is unacceptable at <0.60.[71]

Additional Testing

While additional tests do exist to assess TMD, they are not necessary for diagnosis according to the DC/TMD.[31] Physical therapists can use additional static and dynamic testing to generally confirm TMD diagnoses.[74] The tests involve therapist-applied isometric (static) or isokinetic (dynamic) resistance to jaw opening,

closing, laterotrusion and protrusion.[74] Pain on static testing indicates muscle involvement, and pain/noise on dynamic testing indicates joint involvement.[74,75] Compared to results of palpation assessment, intraclass correlation coefficients (ICC) were higher for classifying a muscle vs. joint condition using static and dynamic testing.[75] Based on the history and range of motion findings, passive joint accessory testing of distraction and anteromedial glide will assess for joint hypomobility vs. restriction due to muscle tension. If joint degeneration is suspected, joint loading tests including compression or cotton roll testing can further provide information about joint health.[45] While these tests are clinically useful during the exam, they do not delineate arthralgia vs. disc displacement diagnoses and are not included in the official diagnostic criteria.

Lab tests can be used to rule out secondary causes such as rheumatoid conditions or temporal arteritis,[33] but as of yet there are no biological markers that provide diagnostic evidence of pain or TMD.[76] Quantitative sensory and pressure pain threshold testing could identify amplified pain response and possibly central sensitization in this population, but heterogeneous responses and the presence of overlapping conditions limits its utility to diagnose TMD.[76] Neuroradiological markers include white matter changes in the trigeminal nerve and corpus callosum of individuals with TMD, as well as gray matter changes affecting pain intensity and duration.[76] These biomarkers support pain research for TMD[51,76] but the impracticality of MRI brain imaging for clinical diagnosis renders them currently useful for research applications only. Similar conclusions for neurotransmitters and inflammatory mediators indicate that there is future research interest in exploring these markers but no current practical use for clinical diagnosis.[76]

Brief DC/TMD

The algorithms, questionnaires, and documentation required to fully complete the DC/TMD are time-consuming and onerous to use in clinical practice. To

address this concern, the brief DC/TMD (bDC/TMD) was created by a panel of clinicians and researchers, simplifying the Axis-I examination from 10 sections to 4 and decreasing the Axis-II items from 41 to 11.[63] The 23-member panel represented a variety of disciplines treating patients with TMD with the intention of creating a final product clearly defining instruments, examination components, and decision trees (**Figure 5**) to use for diagnosis of TMD that can be implemented outside of Orofacial Pain (OFP) specialty.[63] While data supporting clinical validation of the bDC/TMD has yet to be published, field testing is underway and there is strong potential for this process to be an accessible and effective standardization of TMD diagnosis.

Diagnosis Conclusions

Overall, the diagnostic process for TMD has been well studied for diagnosis by dentists and for research purposes. The DC/TMD provides a validated framework for

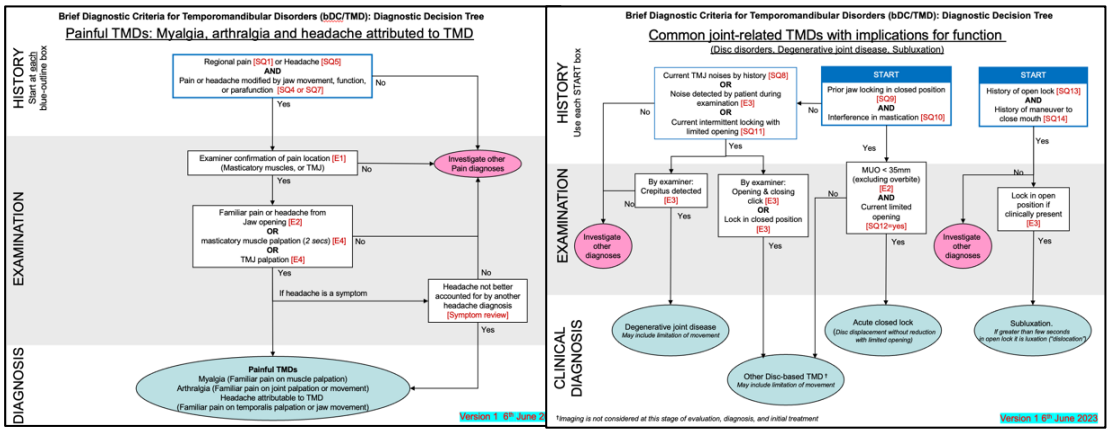


Figure 5. Brief DC/TMD decision trees for evaluation and diagnosis of TMD.

classification and has become the international standard.[31] The criteria have been updated to improve clinical utility,[31,77] but limitations exist due to the time burden required to fully implement the DC/TMD process in the clinic, the reliance on imaging to verify disc conditions, and the lack of an imaging standard to diagnose muscle conditions. The bDC/TMD has been established as a good option for clinical standardization of diagnosis, but the question still remains as to whether these

criteria are valid for use by physical therapists, especially in a virtual context to support telerehabilitation.

TMD Management

As with diagnosis, a biopsychosocial model for treatment is best for TMD management incorporating science from many disciplines including dentistry, health psychology, physical therapy, and other medical providers addressing TMD comorbidities.[1,2,78] Comorbidities must be addressed to provide comprehensive treatment. Multifactorial etiology requires an individual approach to management, using evidence-based interventions to construct a treatment program that involves the patient as an integral part of the management team.[79] As evidence has progressed, TMD management has moved from an intervention-focused field to one that emphasizes conservative, non-invasive management to begin care.[1] No single approach has been identified as the most successful for managing these patients, so they must all be presented and discussed to form the plan of care for each patient.

Self-care is the first consideration as it is easily implemented and enlists the patient as an integral part of the team.[2,80] Education is the first element of self-care, explaining anatomy and the role of contributing factors. Habit and behavior modification is the next component of self-care, helping the patient recognize subconscious parafunctional behaviors that contribute to overuse and microtrauma.[80] Self-care and education can be introduced by a range of health care providers, as it is not specific to any one discipline. Education alone was found to have a successful treatment result in 57% of a group of patients with TMD in a study by Michelotti et al.[81] Self-care alone for 23-26 months resulted in ≥45% resolution of myofascial pain and joint arthralgia symptoms in a group of 69 Italian patients with low pain-related impairments due to TMD.[82] Combining self-care with other interventions is necessary, but the value of this intervention is clear. Physical therapists employ self-care as a key element of rehabilitation which will be discussed further later on.

Dental management of individuals with TMD can include pharmacotherapy and dental appliances. Commonly used medications can include nonsteroidal anti-inflammatory drugs (NSAIDS), corticosteroids, analgesics and muscle relaxants, depending on whether the joint or the muscle is the main focus of treatment.[2,41] Appliances include mouthguards designed to protect the teeth and joints from the effects of bruxism and anterior repositioning devices to treat jaw locking related to disc displacement.[2,80,83] Literature evidence does not support either of these strategies working in isolation,[11,84,85] but they each provide important aspects of management that must be considered for in the overall treatment strategy. Both approaches are considered effective complements to other aspects of multidisciplinary management such as physical therapy based on individual patient needs.[2,41,48,80]

Axis-II instruments used in the DC/TMD (GCPS[82,86] and PHQ-4[54]) have been shown to accurately predict treatment prognosis and therefore identify the need for inclusion of health psychology in TMD management.[87] The bidirectional relationship between autonomic nervous system activation and pain can increase pain amplification and sensitivity in orofacial pain patients.[59] Health psychologist involvement is helpful to develop coping mechanisms and address stress management to decrease orofacial pain.[2,31,45,80] Psychology can modulate contributing factors such as fear of movement, catastrophizing, depression, anxiety, somatization, and stress.[80] Relaxation strategies, biofeedback, and talk therapy are all viable treatments used by health psychologists to complement overall management in this population.[2,80] Cultural and societal stigma can unfortunately interfere with acceptance of this treatment approach, which may negatively affect its implementation.[60] If some patients feel more comfortable selecting physical therapy as their initial intervention, relaxation techniques can be discussed during rehabilitation as an introduction to health psychology. Referral to health psychology

can occur at any time alongside other approaches as barriers to progress become apparent.

Invasive, irreversible interventions such as occlusal adjustments, tooth movement with orthodontics, placement of crowns and restoration, or TMJ surgery are not supported as an initial strategy for TMD management.[1,78] The results of the self-care study of patients in Italy reveal a natural trend toward improvement for individuals with MFP and joint arthralgia.[82] A seminal study supporting conservative care for individuals with DDwoR with limited jaw opening was done by Schiffman and colleagues in 2013, with participants randomized to four different treatment strategies for comparison.[84] Intervention options were medical management alone, rehabilitation alone, or one of two types of surgery: TMJ arthroscopy or TMJ arthroplasty, followed by post-surgical rehabilitation.[84] After 60 months, all subjects improved with no significant difference between groups for jaw range of motion, function or pain.[84] These results showed that there was no difference in outcomes between the least and most invasive interventions, concluding that conservative strategies should be employed first.[84] A systematic review published the following year assessing several interventions for DDwoR came to the same conclusion as the Schiffman study.[84,85] The review included twenty articles with interventions ranging from conservative to highly invasive, and most of them significantly improved symptoms without evidence of superiority for any specific intervention.[85] Another study in 2017 investigated splint therapy, arthrocentesis, pharmacotherapy and low level laser therapy for patients with any disc displacement (with or without reduction) and came to the same conclusion with decreased pain, increased mouth opening and no change in clicking for any groups.[88] Current recommendations align with these conclusions that care pathways should begin with conservative interventions.[1,84]

TMD Management Conclusions

Unfortunately patients sometimes expect that invasive interventions and/or other people are required to fix their conditions, and such expectations can negatively impact the course of care.[89] A comprehensive discussion must precede any treatment decisions wherein the provider presents all treatment options and outlines realistic goals for decreased pain, improved function and independent management.[78] To prevent mismanaged expectations, providers must ensure that patients understand treatment options and the choices they have regarding their care.[78,90] Physical therapy is an effective, goal-based conservative treatment approach that integrates the patient as an active participant in their care.

EFFECTIVENESS

Rehabilitation for TMD

The National Academies of Science, Engineering and Medicine's recommendation to use conservative management as first-line care for individuals with TMD is based on the overwhelming literature evidence that fails to produce superiority of one treatment strategy over others.[1] Physical therapists are frequently included on multidisciplinary care teams for individuals with TMD and their non-invasive treatment approach aligns with the recommendation to begin with conservative management. While Clinical Practice Guidelines exist to guide PTs regarding diagnosis and management of other conditions, there is no official set of recommendations for rehabilitation of patients with TMD.[43] Current PT diagnosis of these conditions is therefore is based on the dentist-created Diagnostic Criteria for Temporomandibular Disorders (DC/TMD), following the same decision-making process as dentists.[31,45] Many studies and systematic reviews have been performed to assess the efficacy and effectiveness of PT for TMD, with no clear superiority of one intervention over others for these conditions.[9,12-14,16-18,49,91-93] As TMD research

progresses, therapists must consider specific evidence-based concepts regarding diagnosis and management of individuals with TMD.

Diagnostic Criteria (DC/TMD)

Physical Therapists evaluating individuals with TMD ask the same patient history questions and perform many of the same manual palpation testing as do TMD dental specialists. The DC/TMD therefore provides an initial framework to determine the appropriate diagnosis for PT management. Physical therapist diagnostic accuracy has been assessed by Kraus & Prodoehl for the TMD subtype of TMJ DDwoR and with limited opening.[91] By comparing the clinical diagnosis of 97 joints to the MRI gold standard, the authors established that the treating PT had 80% overall diagnostic accuracy using established diagnostic criteria in a population referred to PT by dentists. Their analysis revealed 85% diagnostic sensitivity and high positive (82%) and negative (77%) predictive values. Though diagnostic specificity at 73% was lower than the desired 75% threshold, the predictive values indicate that the DC/TMD are acceptable for PTs to use to diagnose this condition.[91]

While the DC/TMD criteria is a helpful guide for PT assessment of TMD, the fact that it was created by dentists creates limitations for physical therapists using it to diagnose all TMD subtypes. Dentists follow a pathoanatomic model of assessment, whereas physical therapists use movement-based impairment models rather than focusing on structural abnormalities. The DC/TMD's pathoanatomical focus conflicts with the process followed for most other joint assessments.[43] Physical therapists treat additional areas such as the cervical spine and perform postural assessment and interventions, which are known to be factors in TMD etiology.[33,43,94] Therefore, clinical and research limitations necessitate assessment and clarification of the DC/TMD for PT use.

Clinical Limitations

Without having a clinical practice guideline for TMD, the DC/TMD is the recommended method for diagnosing TMDs in the PT setting.[45] While it does contain consideration of psychosocial status, it does not contain guidance regarding some important components of the PT exam.[95] The co-morbidity of neck pain, headache pain, and other chronic pain conditions with TMD is well-researched with strong evidence in the literature.[4,50,52,53] Potential sources of pain and disability could go unaddressed in the plan of care without considering the contribution of pain from other areas of the body. A complete clinical PT assessment for an individual with TMD should include evaluation of the cervical spine,[43,45] but there is no mention of this area in the DC/TMD because dentists often do not treat the cervical spine. Palpation of cervical muscles, assessing cervical range of motion and passive intervertebral accessory movement, and special tests including the flexion rotation test and cranio-cervical flexion test must be included.[43] Red flag items such as the vertebral artery test and ligament instability testing[96] are also necessary considerations but are missing from the DC/TMD. As a result, the DC/TMD alone is not sufficient to guide PTs regarding full assessment.[43]

Similar limitations exist concerning TMD patients and chronic pain. Individuals with TMD are susceptible to central sensitization creating hypersensitivity and allodynia, such that systemic pain complaints are frequently co-morbid and extend beyond localized masticatory structures.[33,38] While the DC/TMD includes mention of the Axis II components of psychosocial status as a consideration of diagnosis, it does not include algorithms for diagnosis of chronic pain. As chronic pain has a profound effect on the plan of care and PT outcomes, guidance beyond what is provided in the DC/TMD is essential to provide appropriate patient care.

Research Limitations

The lack of PT assessment guidelines in the DC/TMD creates significant limitations when using it for PT research. Many PT interventions target muscles outside of the temporalis and masseter, such as retraining lateral pterygoid function[48,97] or providing manual therapy to cervical muscles.[98] There is no standard provided for assessing dysfunction in these muscles in the DC/TMD, yet studies in this area are necessary for determining efficacy and effectiveness of PT interventions for individuals with TMD. Until more detail is provided, the problem of inconsistent definitions of dysfunction will likely continue.

Ensuring proper diagnostic assessment is vitally important for patient care, but the inability of the DC/TMD to consider multiple patient diagnoses causes difficulty when considering the design of PT research. Comparison in research works best when diagnoses are similar without the complicating factor of additional conditions, which is how the DC/TMD is designed. However, performing PT research on a representative clinical population becomes difficult when following this model for patient assessment. Many patients have overlapping conditions and there is no protocol in the DC/TMD to determine which diagnosis is primary. A muscle spasm in the inferior head of the lateral pterygoid can create limited opening that fulfills the diagnostic criteria for disc displacement without reduction[46,97], so a study aiming to enroll subjects with the disc diagnosis could in fact get a participant with the muscle disorder instead. Additional diagnostic guidance in this area will help define inclusion/exclusion criteria for studies and will allow for generalization of results to representative clinic populations.

Physical Therapy Management

Successful rehabilitation for people with TMD consists of individualized therapy using multimodal interventions to restore mouth opening, decrease pain, and progress toward functional goals.[12,16] Physical therapy for patients with disc

displacement has been shown to be effective[16] and as effective as TMJ surgery in some cases.[84] Systematic reviews of PT management for all subtypes of TMD consistently show good results with no specific interventions highlighted as being more effective than others.[9,13,14,17,93] Treating the cervical spine and posture is necessary for these patients due to the frequent comorbidity with cervical spine disorders.[45,52,94,99] Manual therapy has demonstrated effectiveness, especially when combined with exercise.[10,18,99] Modalities have some utility in this population with varying results. Many randomized controlled trials (RCT) and systematic reviews have examined interventions for specific diagnoses and in isolation to demonstrate effectiveness for TMD treatments, providing evidence of efficacy with limited generalizability due to the multimodal nature of true clinical care.

Condition-specific Evidence

Disc Displacement Conditions

Without intervention, disc displacements do not tend to spontaneously resolve. After 23-36 months of self-care treatment alone, the proportion of 69 Italian patients with disc displacement conditions stayed the same.[82] A large scale longitudinal study of 789 patients with disc displacement diagnoses and no applied therapy found that after 8 years, 76% of the sample did not change and the remainder was divided between condition progression (14%) and spontaneous improvement (10%).[100] Specific interventions for disc displacement diagnoses include exercises and modalities, with the addition of stretching and joint mobilizations for hypomobility related to DDwoR. A systematic review reported pain reduction after exercise in 80% of subjects and improved range of motion in 75% of subjects with DDwoR compared to no treatment.[101] Low level laser therapy resulted in decreased pain and improved mouth opening in subjects with any disc displacement.[88]

Additional evidence of benefit after PT in a clinical population with DDwoR with limited opening comes from the retrospective, cross-sectional study from Kraus & Prodoehl.[16] This retrospective cross-sectional observational study examined outcomes of individualized PT for patients with this diagnosis.[16] The results revealed significant improvements and large effect sizes in maximum mouth opening (d=1.15) and change in pain (d=2.62).[16] Post-hoc testing demonstrated an association between high patient satisfaction and improvement in mean mouth opening. The cross-sectional design without a control precludes making causal or long-term inferences about the results,[16] but this study informs our choice to use multimodal individualized PT for individuals with this disc condition.

Muscle Conditions

The most common clinical TMD diagnosis is muscle pain described as MFP or myalgia.[1,38,49] Self-care alone resulted in MFP symptom resolution in 45% of patients with low pain-related impairment over 2-3 years,[82] reinforcing the importance of teaching self-care to patients with MFP. Adding a home PT exercise program led to a 20% increase in therapy success rate for individuals with jaw MFP compared to self-care alone.[81] When compared to occlusal splint therapy, PT was found to produce earlier improvement and a shorter duration of care for individuals with myogenous TMD with similar long term effectiveness.[11] A randomized controlled trial of individuals with chronic myogenous TMD found that intraoral manual myofascial therapy significantly decreased pain in the short term compared to education, self-care and exercise alone.[102] The role of specific additional PT interventions has not been well investigated for this category of conditions, despite its prevalence in clinical populations and conclusions of PT efficacy for these individuals.

Individual Physical Therapy Interventions

Education

Patient education includes information about the anatomy of the diagnosed condition, self-care, and relaxation training.[45] Patients are advised to decrease daytime oral habits such as jaw clenching and bruxism using tongue-up, teeth-apart positioning.[103] Relaxation training consists of self-assessment of masseter muscle tension and diaphragmatic breathing to decrease muscle tone.[104] Protecting wide opening with yawning and eating, limiting food to a soft diet, and chewing bilaterally is also advised for patients with limited opening and pain with function. These joint protection interventions have been reported consistently in the literature as important components of any TMD management strategy.[9,103-105 22]

Passive Modalities

Application of heat, ultrasound, and intraoral ice, iontophoresis and/or transcutaneous electrical nerve stimulation (TENS) are commonly used in the clinic to increase circulation, reduce muscle tension and/or inflammation, and disrupt the pain cycle for individuals with TMD.[41,105] Indications for in-clinic modality use include difficulty with exercise performance due to muscle tension, joint inflammation, temporomandibular joint capsular hypomobility, and masticatory muscle spasm. These modalities used to be widely used as PT interventions, but as evidence-based care has progressed there is variable evidence for their effectiveness in this population.[48] A systematic review from 2006 found no literature support for the role of these modalities due to poor methodological quality of most included studies.[105] A study from 2014 by Ucar et al. found that ultrasound significantly decreased pain and improve mouth opening when added to PT treatment for myogenous TMD pain.[106] A high quality 1996 randomized control trial by Schiffman et al. found that iontophoresis significantly improved function but not pain in individuals with TMJ capsulitis and DDwoR.[107] However, there is a lack of much recent evidence investigating modalities in this population.

Manual Therapy

Manual therapy has been more thoroughly studied for treatment of individuals with myogenous and intra-articular TMD. A recent systematic review including all TMD subtypes found that manual therapy significantly decreased pain and improved jaw function in the short term, and that combination with exercise maintained the effectiveness long term.[18] Effective techniques include joint and soft tissue mobilization, intra- and extra-oral trigger point release, and myofascial release for masticatory muscle tension and muscle spasms.[10,41] Cervical muscle trigger point release is helpful to decrease headache pain.[108] Temporomandibular joint mobilization and manual stretching of the jaw and cervical spine effectively treats hypermobility.[9,10,104] Upper cervical spine mobilization helps decrease pain and increase mouth opening and function in patients with TMD.[98,99] Education and instruction regarding self-massage and self-mobilization techniques facilitates home performance of successful interventions.[81]

Exercises/Stretches

Exercises used in PT research for individuals with all subtypes of TMD have not always been clearly defined.[105] The Rocabado 6x6 exercises are a standardized approach for TMD treatment emphasizing diaphragmatic breathing, postural improvement and jaw stabilization, though its literature evidence is limited and warrants further exploration.[103,109] Based on the needs of each patient, exercises for retraining jaw movement patterns include reducing jaw deviation, limiting early protrusion and improving control with opening.[41,103,104] Jaw stretching with tongue depressors and/or fingers treats jaw hypomobility. Cervical stretching and exercises for retraining postural muscles treats forward head posture and/or restricted cervical range of motion, which is frequently present in patients with TMD.[52,104,105,110] Patients with TMD demonstrated decreased cervical flexor and extensor endurance,[52] and deep cervical flexor training contributed to decreased pain and improved mouth opening in this population.[99]

Rehabilitation Effectiveness Conclusions

Literature evidence for individual interventions in general TMD populations does not give guidance regarding treatments for each specific diagnosis; however, studying individual TMD subtypes does not answer questions about management of a true clinical population. Many patients with TMD have both muscle and disc conditions, along with other comorbidities that require attention. For all these reasons, this study will include multiple TMD subtype diagnoses to study PT effectiveness.

Evidence of PT efficacy for individuals with TMD is clear, but all reported evidence relates to standard in-person PT visits. In-clinic modalities and therapist-applied manual therapy relies on in-person contact, and there is no evidence of its use in the telerehabilitation format. Telerehabilitation will require adjustments to deliver these interventions, so a study is clearly required to assess its effectiveness. Existing evidence regarding telerehabilitation must be considered to understand how to best approach this research.

TELEREHABILITATION

Telerehabilitation is the remote delivery of rehabilitation services to patients via electronic technology with many possible methods of delivery. Virtual and digital interventions have great potential to improve convenient, cost-effective access to rehabilitation. Demonstrated success in other areas of PT has minimized concern about the lack of in-person contact during virtual care affecting the efficacy of telehealth.[23-27] However, rapidly evolving technology in this new area of care delivery creates a lack of standardized application and assessment. A 2019 scoping review of real-time telerehabilitation by Horsley et al. noted a need for RCTs and improved definitions of telerehabilitation.[28] Telerehabilitation effectiveness has not been quantified in underserved rural, chronic, and specialized populations.[28] Analyzing the

current evidence will clarify how to translate current knowledge to PT for individuals with TMD and address existing barriers to telerehabilitation implementation.

Evidence for Other Conditions

Post-surgical Rehabilitation

Evidence assessing the effectiveness of telerehabilitation after surgery for orthopedic conditions reveals considerable heterogeneity of interventions and methods. A systematic review from 2017 evaluated fifteen studies for methodological quality and treatment effect, with 80% of the included studies focusing on lower extremity surgery.[27] Over half (53%) of the included studies were poor quality, and only five used synchronous videoconferencing to deliver the intervention.[27] Other intervention methods ranged from telephone calls to video games and interactive systems. While most of the studies reported positive effects of telerehabilitation, taking study quality into consideration limits the strongest evidence for effectiveness to rehabilitation after total hip and knee arthroplasty.[27] Low methodological quality was related to insufficient blinding and lack of a comparison group, leading to clear recommendations to improve standardization in future research.[27]

A subsequent randomized controlled noninferiority trial from Pastoral-Banal and colleagues in 2018 compared telerehabilitation to in-person PT for patients with impingement syndrome after subacromial decompression surgery.[26] The 18 patients included in the analysis all improved after therapy, with the in-person group receiving consultation 5 days per week for 12 weeks to closely mimic the daily email instructions given for home exercises in the telehealth group. Comparing the standardized functional outcome scores between the two groups revealed that telerehabilitation was not inferior to in-person rehabilitation. The potential bias created by the greatly increased therapist time in the in-person group actually strengthens their conclusion that telerehabilitation is as effective as in-person PT,

though it decreases generalizability of results to a traditional clinical setting.[26] This study provides a framework for a randomized controlled trial to examine telerehabilitation for individuals with TMD, though protocol adjustments regarding service delivery and outcome measures need to be considered.

A more recent study from 2020 assessed telerehabilitation noninferiority after total hip replacement using a standard care comparison group and a blinded evaluator to determine outcomes.[111] In this study, neither group received face-to-face consultation; the therapy was provided via iPad-based web application (intervention) or paper protocol instructions, a treatment diary and three in-person PT visits (standard care).[111] Their analysis demonstrated with 80% power that telerehabilitation was noninferior to standard care, and additional linear mixed model analysis revealed both groups had significant improvement over time with no between-group differences after 6 weeks.[111] Their method of analysis is similar to that proposed in this study, though their choice of 80% power level increased the chance of making a type II error in a noninferiority analysis. Overall, this study gives high-quality evidence of telerehabilitation effectiveness after total hip replacement, though the results are not directly generalizable to care for other musculoskeletal conditions.

Musculoskeletal Conditions

Physical therapist diagnostic reliability with virtual assessment has been demonstrated in the literature. Because traditional diagnostic testing relies on direct patient contact for palpation and testing, telerehabilitation requires adjustments for its successful use. Russell et al. examined the diagnostic agreement of lower limb non-articular conditions using adaptations for patients to self-perform testing.[112] Comparison to in-person PT diagnosis established excellent intra- and interrater reliability with kappa=0.81-1.00.[112] While they did not provide the exact kappa

estimates, their choice of kappa adjusts for the effect of chance agreement and their methods support those that will be used in our study of individuals with TMD. A systematic review revealed good diagnostic reliability and validity with objective PT assessments such as pain, swelling, range of motion, muscle strength, and functional assessment of musculoskeletal conditions via telerehabilitation.[113,114] In 2021, Mani et al. demonstrated excellent interrater reliability (interclass correlation coefficients=0.93-1.00) with PT virtual assessment of cervical spine pain, posture, range of motion and disability.[114] Because the cervical spine must be assessed for individuals with TMD, this study provides strong support for our study methods and hypotheses.

Asynchronous telerehabilitation outcomes have been investigated in chronic musculoskeletal conditions. Aily and colleagues demonstrated telerehabilitation feasibility in Brazilian individuals with knee osteoarthritis using quantitative and qualitative methods.[115] The researchers found good adherence to an asynchronous exercise program using telephone follow-up, with 96% of all subjects reporting that they would use telerehabilitation again.[115] While they did not include a control group and were underpowered for functional outcomes analysis, they showed that alternative rehabilitation delivery methods can be accepted and feasible. A study of asynchronous telerehabilitation for chronic low back pain reported improved Oswestry Disability Index scores compared to a clinic-based control group after 4 weeks but after 8 weeks there was no difference between groups.[116] In 2023, Peterson et al. investigated the efficacy of a neck strengthening exercise delivered via internet instructions compared to a control group exercising in the clinic twice per week for patients with chronic whiplash-associated disorders in Sweden.[117] They assessed quality-of-life improvement on the Neck Disability index using noninferiority methods and found that both groups improved, and the internet-based exercise group showed noninferiority of improvement after 3 months and 15 months within the

standardized noninferiority margin.[117] All of these efficacy studies used standardized asynchronous protocols, which was appropriate for the conditions studied but will not be appropriate for an effectiveness study of individuals with TMD. The participants in the Aily study identified qualitatively that they missed having companionship during exercise,[115] which supports the use of synchronous telerehabilitation in our study.

Systematic reviews examining synchronous telerehabilitation for musculoskeletal conditions found similar results regarding effectiveness. The review by Cottrell et al. from 2017 performed meta-analysis of 13 studies, finding moderate to good methodological quality and effectiveness slightly favoring telerehabilitation across all conditions for function.[118] For pain, no difference emerged between rehabilitation methods, and only one study assessed quality of life.[118] The review by Grona et al. from 2018 analyzed 17 studies but did not do a meta-analysis due to heterogeneity of methods and outcomes.[23] The results revealed that patients were generally satisfied with telerehabilitation, and that effectiveness was demonstrated though not all intervention studies included comparison to a control.[23] The review also identified a high risk of bias for many studies and a need for more noninferiority trials assessing telerehabilitation for musculoskeletal conditions.[23]

Evidence for TMD

The COVID-19 pandemic exposed health care gaps related to remote delivery of services, generating research interest investigating telehealth for individuals with TMD. A high-quality systematic review by Abdul et al. from 2023 aiming to compare the use of telemedicine for diagnosis and treatment of TMD only found two studies that met the inclusion criteria, showing potential for utility of telehealth for improvement in jaw function but highlighting a significant knowledge gap in this area.[119] Both studies had a high risk of bias, and neither study specifically assessed telerehabilitation for TMD.

Telediagnosis

A few recent studies have examined remote diagnosis of TMD. A diagnostic agreement study from 2022 by Exposto et al. found excellent agreement between in-person and remote examination of patients with TMD for diagnoses of masseter myalgia (Fleiss' k=0.86), temporalis myalgia (k=1.00), and TMJ arthralgia (k=0.86) with high values of sensitivity and specificity for each.[30] Agreement for diagnosing disc displacement with reduction was only moderate (k=0.52), and along with low sensitivity for this diagnosis they concluded that remote examination can successfully diagnose pain-related TMD while imaging remains the standard for diagnosing disc conditions.[30] This study was underpowered with wide confidence intervals, but generated interest for future analyses. Corelhano et al. investigated the same question and reported similar results in 2024 with a larger sample of 61 patients from an orofacial pain clinic setting, providing detailed information about how they adapted DC/TMD criteria for remote consultation using synchronous video visits.[32] This group also found excellent agreement between in-person and remote examination for diagnosing masticatory myalgia (Cohen's k=0.92), TMJ arthralgia (k=0.86), and substantial agreement for TMD headache (k=0.76).[32] In addition to supporting the efficacy of telediagnosis for painful TMD, this study validated strategies to adapt existing criteria for successful remote examination of individuals with TMD.

As seen with the DC/TMD, the telehealth literature to date has focused primarily on dentist and specialist diagnosis of TMD. To address the question of PT telediagnostic agreement, Hartono et al. investigated the reliability and validity of physical tests used remotely to diagnose TMD by physical therapists.[120] For remotely measuring jaw opening, closing, laterotrusion, and protrusion, they found high inter- (ICC=0.9 to >0.99) and intra-rater reliability (ICC=0.99 to >0.99).[120] Additional tests included direction of patients self-palpating the TMJ, masticatory muscles, joint sounds, and performing isometric tests and accessory joint testing on themselves,

assessed with the Prevalence-Adjusted Bias-Adjusted Kappa (PABAK) statistic. The PABAK statistic accounts for factors that create the kappa paradox wherein high levels of raw agreement end up with low k values using Cohen's k.[121] The PABAK values varied widely, with moderate to good agreement between remote and in-person assessment of TMJ and muscle palpation (PABAK=0.53-0.65), palpation of joint sounds when opening and closing (PABAK=0.53-0.76) and isometric testing (PABAK=0.53-0.88).[120] The variation seen in these results is similar to variation found in other studies assessing in-person performance of these tests. This study reveals that PT utilization of key elements aligning with the DC/TMD is valid and reliable via telediagnosis and highlights the need for noninferiority testing to compare results.

Noninferiority studies

Most research employs a traditional superiority design, using a null hypothesis of no difference between groups for hypothesis testing. But finding no significant difference between groups is not the same as finding the groups to be the same. When there is no evidence of a significant difference, it only fails to prove superiority.[122] There is a chance that there is not adequate power to detect a difference, which increases the chance of making a type II error. It is not feasible to test for the statistical situation of having truly no difference between groups, as an infinite sample size would be required.[123] More specific methods are therefore needed to statistically test for noninferiority or equivalence.[122,123] In response to these challenges, an update to the Consolidated Standards of Reporting Trials (CONSORT) statement was published in 2010 adding recommendations for reporting noninferiority and equivalence trials.[124]

Noninferiority studies seek only to prove that a new treatment is not inferior to a standard treatment approach, requiring a prespecified noninferiority margin to define an acceptable range of difference between groups that can still be considered

effective.[123,124] The margin can either be a clinically-relevant value frequently related to a minimal clinically important difference (MCID) in outcome, or a proportional difference between groups. Setting the margin is understood to be one of the most challenging concepts in statistical design due to the necessary balance between clinical relevance and study feasibility.[123] According to *Fundamentals of Clinical Trials,*[123] the new treatment must retain at least 50% effectiveness as compared to standard care to be considered noninferior. While noninferiority is usually considered a one-sided test, determining two-sided confidence intervals is the CONSORT methodological recommendation to test a noninferiority hypothesis. The lower limit of the 95% confidence interval describing treatment effectiveness or the difference in effectiveness between groups must be within the noninferiority margin to demonstrate noninferiority **(Figure 6)**.[122,123]

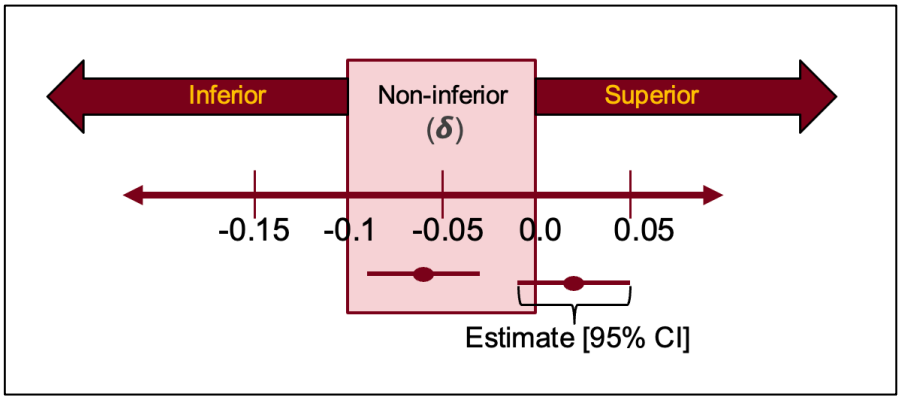


Figure 6. Visualization of noninferiority testing using a 10% non-inferiority margin for difference in effectiveness between groups.

Because telerehabilitation is the application of accepted rehabilitation treatments in a novel delivery format, a noninferiority design is the ideal choice to study its effectiveness. While it is possible that telerehabilitation might be a superior approach in some contexts, it is not reasonable to hypothesize superiority and claim equivalence if no significant difference is found. A systematic review from 2011 of noninferiority studies in telemedicine research found that only 44% of the sixteen included studies performed appropriate statistical testing for noninferiority.[122] Subsequent telerehabilitation research has improved methodological quality and

several studies have investigated telerehabilitation noninferiority. The 2023 study investigating telerehabilitation for patients with chronic whiplash disorder presented a thorough noninferiority analysis of all outcomes with MCID-based noninferiority margins and both intention-to-treat and per-protocol analyses.[117] Studies and study protocols investigating rehabilitation strategies for lower and upper extremities reported use of noninferiority margins between 8-10% depending on each MCID for the functional outcome of interest.[27,111,125-127] Each study demonstrated evidence of telerehabilitation noninferiority or planned to assess for noninferiority within the prespecified margin.

Telerehabilitation Effectiveness Conclusions

The literature reveals effectiveness and noninferiority of telerehabilitation for a variety of musculoskeletal conditions. Physical therapists have shown that assessment and classification is possible in a synchronous digital format for many conditions. Remote diagnosis of TMD is reliable and valid in dentistry, and PTs can reliably perform diagnostic testing of the TMJ and masticatory muscles. Results of management studies reveal that telerehabilitation will provide acceptable care despite the variation in delivery method from standard care. Telerehabilitation could be a way to increase access to care for underserved and rural populations. However, whether or to what extent the demonstrated effectiveness of PT for individuals with TMD will translate to the telerehabilitation format is unknown. The Horsley et al. scoping review specifically identified the need to investigate specific clinical populations, and the Abdul et al. systematic review exposed the lack of intervention studies for individuals with TMD.[28,119] The resulting literature gap will be best served with the proposed telerehabilitation study. Because there are still many unknowns regarding this delivery method, additional data regarding feasibility will be valuable to study as well.

FEASIBILITY

Implementation

Feasibility outcomes differ from health outcomes in that they collect data regarding the healthcare process instead of change in function or pain.[128] In telerehabilitation, process and system outcomes are vitally needed to establish evidence for implementation of this form of healthcare delivery. Despite the clear potential to show decreased costs with telerehabilitation, most studies tend to focus on inherently qualitative health outcomes such as pain, function and patient satisfaction.[28,129] As identified in the Horsley scoping review, gaps emerged concerning telerehabilitation feasibility in underserved rural, chronic, and specialized populations, with specific mention of the need for cost-effectiveness analysis to more fully characterize outcomes of this intervention.[28] The following sections explore the process and system outcomes that will be used in this study as secondary outcomes to characterize the feasibility of telerehabilitation for the specialized population of individuals with TMD.

Patient Satisfaction

Patient satisfaction is a process outcome with multifactorial determinants. Frequently included as an outcome measure in clinical trials, patient satisfaction has been examined through systematic reviews and qualitative studies to identify components of this metric. According to a 2011 systematic review assessing patient satisfaction after musculoskeletal PT, patient satisfaction was generally high and rarely associated with therapy outcome, though only two of the fifteen included studies were RCTs.[130] Themes and predictors of patient satisfaction emerging from the literature include the provider's interpersonal attributes, patient empowerment, and the process of care.[129-133] These concepts can influence the outcomes of clinical trials and guide implementation decisions for clinical care.

The provider-patient relationship is a key component affecting patient satisfaction with care, and rehabilitation is especially susceptible to the subjectivity of the therapist-patient interaction. Interpersonal attributes of health care providers have been identified as especially strong predictors of patient satisfaction.[130,132,133] Determinants of this theme in rehabilitation populations include communication, listening skills, perceived competency, professionalism, and attitude.[115,130,131,134] Therapeutic alliance is the rapport and connection of the provider-patient relationship and has been shown to affect therapy outcomes.[135] A blinded, randomized controlled trial including patients with low back pain demonstrated that emphasizing therapeutic alliance in the therapist interaction significantly improved therapy outcome across all treatment groups with a clear dose-response effect.[135] Therapeutic alliance improved outcomes and patient satisfaction regardless of whether an active treatment was actually performed.[135] Maintaining this relationship throughout telerehabilitation delivery will influence feasibility of its implementation.

Additional components determining patient satisfaction are patient empowerment and the care process. Treatment interventions in rehabilitation that empower patients to self-manage and actively participate in care are positively correlated with high patient satisfaction.[129-131] Involvement in decision-making is another element of empowerment for individuals receiving PT for musculoskeletal conditions.[130] Process of care factors that contribute to high patient satisfaction include the facilities & environment, ease of access, consistency of care, and convenience.[129-133] Telerehabilitation has the potential to provide increased patient empowerment but process barriers with telerehabilitation include technology limitations that could negatively impact patient satisfaction.[132,133] Condition-specific telerehabilitation research is therefore crucial to assess how telerehabilitation trade-offs in these areas affects patient satisfaction.

Patient Preference

Patient beliefs about treatment delivery can affect patient satisfaction. Patient expectations complicate the connection between patient outcomes and patient satisfaction. Zeppeiri et al. demonstrate that in rehabilitation, patient success criteria are different from clinically important outcomes, and that patients don't modify their expectations throughout PT regardless of outcome.[136] A different study examining rehabilitation for patients with low back pain revealed a mismatch between expectations and satisfaction, with some patients changing their outcome expectations after therapy.[131] Any treatment intervention that threatens a participant's beliefs regarding the care process could create a strong preference for one delivery method over another. Randomization to method of care delivery in clinical trials removes patient involvement in that process.[137]

A randomized controlled trial (RCT) is the gold standard in clinical research. The process of randomization is the best available strategy to remove potential bias by dividing covariates equally to create comparable groups for comparison.[123] However, patient preference for treatment modality can impact outcomes of clinical research. When blinding is not possible due to the nature of an intervention such as telerehabilitation vs. in-person care, patient preference can introduce confounding effects.[137] Strong preferences will create systematic differences between participants and can limit trial participation due to refusal of randomization.[137,138] Involvement in decision-making is one of the determinants of empowerment for individuals receiving physical therapy (PT) for musculoskeletal conditions,[130] and randomization to method of care delivery in clinical trials removes patient involvement in that process.[137] Randomizing a patient to a treatment modality which they would not otherwise choose creates ethical questions and could affect patient outcomes including satisfaction with care.[137]

In decision science, treatment choice is based on outcome preferences dependent on patient values and occurrence probabilities regarding each outcome.[137] When these factors are unknown for an outcome, clinical equipoise exists, and a trial is justified. However, patient expectations related to a range of social cognitive variables will still exist to influence expectations and create preference.[137] Placebo studies reveal the effects of patient beliefs on outcomes, where patient outcomes will improve based on belief in care even without true treatment effects. The question as to whether equipoise can truly exist in light of patient expectations and preference creates uncertainty as to whether randomization is truly the only valid way to investigate a treatment.[7]

Preference bias can have a confounding effect on randomization because systematic differences exist between participants with preferences for different interventions. Preference can impact patient satisfaction and other outcomes, leading to treatment difference underestimation even if the number of patients preferring each type of therapy were to be balanced in each group. A potentially smaller treatment effect for patients with a strong preference against the treatment will dilute the treatment effect.[137,139] Even when studies don't show a consistent effect of preference on outcome, they do show that strong preferences between those consenting to randomization exist.[137] Preference trials are an emerging practice where research participants are allowed to choose which intervention group they join. A systematic review by Prady et al. from 2013 examining preference effects in acupuncture trials revealed that 75% of potential participants declined participation if required to be randomized and that randomized participants had higher attrition rates at ≥6 month follow-up timepoints, leading them to conclude that preference trials should be considered if participants were likely to have a strong opinion about the intervention.[140]

Using technology such as real-time telerehabilitation to deliver care is a relatively recent practice with slow implementation, and existing provider and patient beliefs vary widely regarding its effectiveness.[129,141-143] A clinical trial investigating the effectiveness of telerehabilitation will be subject to strong patient preferences regarding this care delivery method, which precludes randomization and impacts patient satisfaction as a treatment outcome. An open-label preference trial is therefore indicated, and including patient satisfaction as a measure of implementation feasibility is necessary to inform clinical translation of research results.

Physical Therapy for TMD

Because TMD diagnostic sub-types have varying anatomical causes of functional impairments and pain, patient satisfaction is an outcome that could be compared across TMD populations. However, this metric has not been well-investigated in populations that have undergone rehabilitation for TMD. The Kraus/Prodoehl study of outcomes after PT for DDwoR found mean satisfaction was 6.8 on a 0-10 Likert scale but did not find a relationship between pain change and patient satisfaction in their population, despite the large effect size of pain change in their results.[16] There is limited additional information about patient satisfaction after PT for TMD symptoms, as most studies have studied the efficacy of individual interventions on functional or quality of life outcomes.

Telerehabilitation Studies

Because of the elements outlined above, many telerehabilitation studies have included patient satisfaction as an outcome of therapy. Unfortunately, studying patient satisfaction suffers from methodological heterogeneity and the lack of a widely used, standardized scale for data collection.[28] Many studies employ their own non-validated Likert-scale questionnaires or qualitative methods to assess

satisfaction. In a 2020 systematic review assessing patient satisfaction with telerehabilitation in rural settings, only four studies met the inclusion criteria of assessing satisfaction as a primary outcome.[133] These studies included PT, occupational therapy, and speech therapy, and studies reported high patient satisfaction (≥92% in two of the studies) after telerehabilitation.[133] A few examples of dissatisfaction were reported, with some mention of difficulty with technology usability.[133] Overall, patient satisfaction is more commonly assessed in the literature as a secondary outcome with generally positive results.

In addition to showing similar patient satisfaction between groups, a study evaluating telerehabilitation after total hip replacement revealed improved adherence and usability in the telerehabilitation group. The study published in 2020 by Nelson et al. used a 14-item satisfaction questionnaire to assess satisfaction and adherence as secondary outcomes.[111] Results showed >85% satisfaction for all questionnaire items across both groups, with 97% overall satisfaction in both groups.[111] They found that 95% of the telerehabilitation group felt their visits were easy to attend as compared to 86% in the control group (p=0.02), and that compliance was better in the telerehabilitation group (86% compared to 74% for control).[111] These results identify the importance of including patient satisfaction as a secondary outcome to examine feasibility in our study of telerehabilitation effectiveness.

Studies using telerehabilitation to treat knee OA have also produced data characterizing determinants of satisfaction and positive reports of patient satisfaction. Aily et al. used a 6-item questionnaire to assess adherence and satisfaction after telerehabilitation in 23 participants, followed by a qualitative interview performed with a cohort of 6.[115] They reported 76% adherence, though 96% of participants stated that they would participate again.[115] Their qualitative results revealed the importance of maintaining therapist interaction,[115] which aligns with the results of a qualitative study by Hinman et al. where patients felt very connected to their therapists during

synchronous telerehabilitation visits.[129] The qualitative Hinman study was unique in that they acquired reactions from patients as well as providers, revealing overall positive responses in both groups despite initial skepticism regarding the utility of telerehabilitation.[129] While therapists reported discomfort without having hands-on contact, no patient responses indicated that they missed that component of care delivery.[129] The data from these studies is valuable, but without a more standardized approach it is difficult to generalize results and compare to other studies.

A validated questionnaire to study patient satisfaction has begun to appear in telerehabilitation research. Some recent studies have used the Health Care Satisfaction Questionnaire (HCSQ), a 23-item questionnaire that covers three dimensions of satisfaction: the relationship with the provider, the service delivery, and the organization of services.[144] The HCSQ also accounts for patient expectations by asking respondents to rate how important each item is an addition to how they perceived their care.[144] The scale has high internal consistency (Cronbach's alpha=0.92) and good test-retest consistency (ICC=0.72).[144] An RCT assessing noninferiority of telerehabilitation after total knee replacement used this scale to assess patient satisfaction and found that the telerehabilitation group had satisfaction scores ranging from 78%-83% in all areas.[145] The in-person group had higher scores (96%-98%) but the difference was not statistically significant.[145] A pilot study of telerehabilitation following proximal humerus fracture found 82% patient satisfaction using the HCSQ,[146] and the authors have published a study protocol for a noninferiority study that will use it as well.[125] Choosing this scale provides a more robust, standardized approach to assess patient satisfaction data in our telerehabilitation study.

Satisfaction Conclusions

The literature presents overwhelming evidence demonstrating patient satisfaction after telerehabilitation. The evidence is limited however by heterogeneity of methods and outcome questionnaires. Patient satisfaction has not been thoroughly examined after rehabilitation for individuals with TMD, as functional outcomes have been the more dominant outcome of interest. Comparing patient satisfaction between telerehabilitation and in-person PT groups using the standardized HCSQ would provide generalizable, clinically significant results to characterize feasibility in the population of individuals with TMD.

Cost-Effectiveness Analysis

An important health system outcome for this study is cost analysis, which analyzes value compared to the cost of investment for a given intervention. Economic evaluations assign relative values to different outcomes, then perform cost comparisons to make decisions about resource allocation.[147] The practice of adding cost analysis to clinical trials allows researchers to assess implementation alongside effectiveness of the intervention.[25,148,149] Cost-effectiveness analysis is the most frequently used form of economic evaluation and considers incremental benefit in the form of quality-adjusted or disability-adjusted life years gained as the result of a given treatment strategy.[147,150] Depending on the viewpoint, time horizon, and population studied for the analysis, the resulting decision model gives insight to characterize feasibility of each intervention.[147] Cost-effectiveness data can inform treatment guidelines and influence international funding decisions.[150] However, there is a noted lack of cost-effectiveness evidence for telerehabilitation studies in the literature.[28,149,151] The following sections will detail the process and the evidence for cost-effectiveness analysis as it applies to the proposed telerehabilitation research.

Procedure

Cost-effectiveness analysis assesses one single clinical/health effect of interest for comparison across interventions.[150] The process of performing cost-effectiveness analysis consists of quantifying costs, effectiveness, and then creating incremental cost-effectiveness ratios (ICERs).[147] These ratios compare the difference in costs for each intervention to the difference in effectiveness. Rehabilitation and telerehabilitation studies have quantified effectiveness in terms of quality-adjusted life years (QALYs) gained,[25,116,148,152,153] using standardized metrics to assign value to different health states. Multiplying each life year by its respective health state value accounts for quality of life, and the total sum describes QALYs gained.[147] This value becomes the denominator in the ICER, and the ratio quotient is the value describing cost-effectiveness as cost per 1 year of QALY gained. If negative, the new treatment is more cost-effective. A treatment could be more effective but more costly, so a maximum threshold of cost-effectiveness gives a metric by which to evaluate the utility of the result. The cost-effectiveness plane gives a helpful visual to understand the process used to analyze this type of data (Figure 5).

Using an appropriate quality of life instrument to generate health state values is a key factor of cost analysis.[147] One such instrument with existing scoring norms for each health state is the EuroQol 5-Dimension, 5-Level (EQ-5D-5L) scale.[154] This instrument is not condition-specific, and it assesses quality of life limitations in 5 areas: mobility, pain/discomfort, self-care, anxiety/depression, and usual activities. Answers are marked on a 5-level ordinal scale, and combining each dimension's 1-5 score creates the final 5-digit health state result ranging from 11111 (no disability) to 55555 (maximum disability).[154] Every possible numeric combination describes a health state with a predetermined value assigned, so scale responses can be mapped for use in QALY determination. A standardized score such as this is required to compare cost-effectiveness analyses across different areas of health care.[147]

There are specific considerations required before undertaking cost-effectiveness analysis.[147,150] First the objectives must be determined within the context of how the decisions will be used. The audience of the evaluation must be considered as they may have specific requirements for the methods and presentation of results. The perspective of the analysis must be predetermined to decide which costs will be considered. The societal perspective is the recommended viewpoint and includes components such as patient costs, the cost of childcare, and lost productivity.[147,150] The health care perspective is another option, which considers payer and provider costs among others.[147,150] The time horizon must be determined, as well as the intervention options of interest. When performed alongside clinical trials, these analyses are frequently underpowered to make definitive conclusions[155] but are valuable for contributing implementation data when assessing intervention effectiveness.

Telerehabilitation Cost-Effectiveness Analysis

There are some literature examples of studies adding cost-effectiveness analysis to trials investigating telerehabilitation. One such study assessed telerehabilitation for nonspecific chronic low back pain in Nigeria, using a McKenzie-based program and comparing to an in-person rehabilitation group.[116] This trial used the Oswestry Disability Index (ODI) to derive QALYs instead of the EQ-5D-5L, as the ODI has preexisting assigned health value states and is an appropriate condition-specific quality of life index. The economic analysis considered patient perspective to determine health care resource use and costs. They found 0.085 QALYs gained in the telerehabilitation group and 0.084 QALYs gained in the control group. Costs were lower in the telerehabilitation group at $61.7 per QALY gained compared to $106 per QALY gained in the control group. After calculating the ICER and bootstrapping to generate a 95% confidence interval, they determined that the telerehabilitation arm of

the study was less costly and more effective. Their small sample size indicates that they were underpowered, but their results are consistent with other studies that show telerehabilitation to be a cost-effective intervention.[116]

Another randomized controlled telerehabilitation trial that added cost-effectiveness analysis compared telerehabilitation to in-person rehabilitation after total knee arthroplasty. Nelson et al. performed a noninferiority trial and considered their analysis from the health service perspective.[148] They used the EQ-5D-5L to derive QALYs and found no significant difference in QALYs gained or health service costs between the two interventions.[148] They did however perform a secondary analysis assessing patient rehabilitation time, and the ICER revealed -4.21 hours per QALY gained favoring the telerehabilitation group.[148] These results align with the study's findings that telerehabilitation was noninferior to in-person care.[111] They also used bootstrapping methods to generate confidence intervals for their ICERs and presented results in the form of a decision tree,[148] which will be methods used in our study. This study is a model upon which we will base much of our cost-effectiveness analysis methodology.

TMD Cost Analysis

There is no condition-specific metric to value different health states for individuals with TMD or orofacial pain. However, the EQ-5D-5L instrument has been investigated for use in individuals with orofacial pain by Durham et al.[156] To validate the scale, a convenience sample of individuals with orofacial pain ≥3 months filled out the EQ-5D-5L along with the Multidimensional Pain Inventory (MPI) scale to assess content validity.[156] Using the United Kingdom scoring norms for the EQ-5D-5L, the researchers assigned values for each state ranging from -0.59 (worse than death) to 1 (perfect health).[156] The researchers found fair to good correlation using Spearman's rho for most pain impact sections of the MPI (pain severity = -0.67; life

interference = -0.49; life control = 0.43; affective distress = -0.50) and poor correlation for one (support = -0.29).[156] The EQ-5D-5L underestimated the impact of pain compared to the MPI, but they concluded overall that the standardized scale could be used for economic analysis in this population and as long as concurrent condition-specific functional scales be included to fully characterize the treatment effect.[156] The Durham study results support using the EQ-5D-5L in this population with awareness of its limitations, and the biopsychosocial components of the scale contribute to its utility in the population of individuals with TMD.

Care costs have been investigated in the orofacial pain population. Durham et al. quantified out-of-pocket and indirect costs of orofacial pain as part of the observational Developing Effective and Efficient Care Pathways for Patients with Chronic Pain (DEEP) study begun in 2012.[156-158] They used the Use of Services and Productivity Questionnaire with an added Time and Travel component to collect information about 6 months of health services use and employment effects, with an added component assessing quality of work performed while in pain.[55,157] The researchers reported that cost discounting was not necessary due to the short six month time frame covered by the questionnaire.[157] Questionnaire data was collected every six months over two years, so during data analysis they adjusted for inflation and pooled costs at each time point to generate mean cost per six months. Out-of-pocket costs consisted of assessment and treatment costs, time and travel and other participant-reported expenditures attributed to orofacial pain; indirect costs included missed work and quality-adjusted work limited by pain.[157] They found that in this population with orofacial pain, higher GCPS level was predictive of higher patient costs.[55,157] As TMD is a subset of orofacial pain, this study provides a costing framework to guide data collection and analysis from the societal perspective for our study.

A cost utilization study investigated costs specifically in a population of individuals with TMD. White et al. described costs from the patient perspective, defining participants as any patient seen in Oregon for a TMD-related diagnosis from the source population of any member of the Kaiser Permanente Northwest Division Health Management Organization 1/1/1990-12/31/1995.[159] The study did not provide any effectiveness data, but only aimed to describe costs and compare them to a group of case-matched controls. They determined utilization as numbers of TMD clinic visits, non-TMD clinic visits, dental visits, outpatient & inpatient services, radiologic procedures, outside claims and referrals, and amounts of medications.[159] They determined costs from billing records, fees for procedure codes, an HMO costing analysis, and from pharmacy pricing, and they adjusted costs to 1995 rates.[159] Results showed that individuals with TMD used more health care services of any kind than did control participants, including a higher mean number of urgent care visits.[159] TMD cases had a significantly more medication utilization with 2.6 times the amount of antidepressant dispensation and 2.4 times the amount of narcotic analgesics.[159] Total costs for TMD cases were 1.6 times that of control cases over the 6 year time period.[159] The results highlight the need for cost-effectiveness analysis alongside a trial for individuals with TMD.

Cost-Effectiveness Analysis Conclusions

Adding cost-effectiveness analysis to trials provides essential information that contributes to health system outcome implementation support for an intervention. The slow process of clinical translation will be augmented by such data, which is needed for the study of telerehabilitation. Evidence from telerehabilitation studies reveals that the intervention is generally cost-effective, depending on which perspective is used for the analysis. Studies considering the societal or patient perspective of healthcare use are of greater interest in the field of telerehabilitation, as utilization and cost differences have been demonstrated here for individuals with

TMD.[159] The work done to validate the EQ-5D-5L for individuals with orofacial pain[156] and to describe societal perspective costs for individuals with orofacial pain[157] provides support for questionnaires and methods that will be used in our study. The cost analysis presented alongside the noninferiority study by Nelson et al.[111,148] provides methodological design guidance for our study investigating telerehabilitation for individuals with TMD.

Barriers to Implementation

The rapidly evolving health care landscape has recently acknowledged the utility of virtual care delivery during the contact restrictions imposed during the COVID-19 pandemic.[142,160-164] However, the shift to telemedicine use during the pandemic has highlighted implementation barriers that have thus far limited its widespread adoption. The heterogeneity and lack of standardization is an overarching problem, with over 100 definitions of telemedicine presented in peer-reviewed literature.[160] Despite consistent literature evidence highlighting TR effectiveness for orthopedic and musculoskeletal conditions,[26,27,113,118,122,129,131,165] barriers persist and must be overcome to progress healthcare alongside the technology evolution present in the rest of society. Provider- and patient-level barriers to adoption include reimbursement, access, privacy & security, convenience & fit, and values & beliefs.

Reimbursement

Before the pandemic onset in March 2020, physical therapy (PT) provision via telerehabilitation was significantly restricted by private insurance, state, and Medicare reimbursement regulations prohibiting its use for new patient evaluations and limiting its utility for follow-up visits.[142,166-168] Many of these restrictions have been relaxed during the pandemic but there is no information regarding whether the updated policies and billing procedures will ensure proper reimbursement for telerehabilitation

services after the pandemic emergency order ends. While physicians are allowed in some cases to provide telemedicine services across state lines, PT licensures still mostly prevent this practice from occurring.[167,168] Clarity from insurance and healthcare providers regarding telerehabilitation reimbursement will be required for providers and patients to fully accept this form of healthcare delivery.

Access

Issues of access are consistently identified in telerehabilitation research as key components of successful delivery and adoption.[167,169-172] In their 2016 narrative review on the state of telehealth, Dorsey and Topol assert that the fundamental aim of telehealth is "to increase access to care."[167] However, technology use requires available equipment, reliable internet, and skill. The same review identifies that at that time, only 58% of adults over the age of 65 used the internet causing a "digital divide" to be a significant limitation for telehealth implementation.[167] While technology access has improved due to stronger bandwidth, widespread device usage and new platforms for videoconferencing, many patients continue to struggle with access and scheduling, especially in rural and underserved areas.[116,168] Given that rural and underserved populations stand to benefit the most from telerehabilitation,[28,173] this barrier will limit visit quality and de-incentivize patients to participate.[169] Many older patients and providers have limited comfort and skill with technology use, biasing them against telerehabilitation use.[173] The cost of updating technology has also been highlighted as a barrier to provider implementation, and the lack of cost analysis evidence in telerehabilitation leaves this barrier unaddressed.[28,172,173]

Privacy & Security

Health information privacy and security concerns continue to impact telerehabilitation acceptance. Privacy breach is a real consideration with online videoconferencing platforms, causing patients to be concerned about engaging in

virtual consults involving sensitive health information.[171,172,174] A scoping review by Horsley et al. revealed that 67% of telerehabilitation studies did not identify whether they used secure platforms for care delivery or not.[28] Patients have also expressed occasional discomfort with the visibility of their condition in their home environment as a privacy concern.[171] A 2019 review by Galea identified that health care providers are uneducated About ways to protect health information during telehealth sessions.[175] The recent relaxation of consequences for HIPAA violations by "good faith provision of telehealth services during the COVID-19 nationwide public health emergency"[163] has attempted to reduce the provider-level barrier, but does not improve patient confidence in the privacy and security of telemedicine visits. Providers will need to improve their knowledge base regarding protection of health information when the emergency order ends, supporting the need for telerehabilitation standardization and training to facilitate implementation.

Convenience & Fit

Daily routine fit and convenience is a key factor in telerehabilitation success and implementation. While are many ways that telerehabilitation improves patient convenience, significant barriers persist for certain populations. Children must have adults assist them with accessing visits and maintaining attention, and the visits must fit into parents' schedules to be feasible.[162,164] Patients with significant mobility limitations after surgery or requiring assistance with transfers will require the presence of a family member or caregiver during the visit, as remote providers are unable to provide the usual safety oversight that is a given during in-person visits.[168] Patients may also be inconvenienced by the lack of access to machines and equipment that would typically be provided during in-person PT visits, and providers need to adapt exercises to fit within the patient's home environment.[142]

Clinical issues with telerehabilitation are also convenience barriers for providers. The significant heterogeneity and lack of standardization seen in TR research has left a void regarding PT evaluation and care provision guidelines and best practices.[118,167,169,175] Physical therapists need information regarding dosage and duration of therapy to develop the plan of care and set expectations.[165,173] Evidence does not yet exist for all joints and conditions treated by PTs, and existing research on musculoskeletal conditions cannot be simply generalized.[118] Electronic health records necessitate an additional device for point-of-care documentation during telerehabilitation sessions. Training and guidance are needed to prevent PT workflow disruption and to facilitate convenience and fit of telerehabilitation into daily clinic schedules.[141,172]

Values & Beliefs

The final area of limitation to telerehabilitation implementation is patient and provider values and beliefs. Even with reports of positive experiences and high satisfaction with telemedicine, many patients continue to express a preference for face-to-face care.[170] Qualitative research reveals patient and provider views that telerehabilitation would work best as an adjunct supplement to traditional in-person care, not as a stand-alone delivery method.[116,143,170] The variety of available delivery methods range from emailed exercises to synchronous videoconferencing, and the heterogeneity of methods yields a variety of patient responses.[169,176] Aligning patient values with delivery method is vital for success, which requires flexibility and facility from providers. Many PTs are not comfortable with their ability to adapt existing skills for telerehabilitation use and are not motivated to implement this form of care delivery.[129,141,169] Developing a comprehensive online training plan such as the one used in the study by Jones et al. for training PTs to provide telerehabilitation for knee OA[141] will facilitate successful implementation. Studies like the one described in this

proposal are necessary to develop telerehabilitation training programs for individuals with TMD.

E-health for TMD

A recent qualitative study has been completed assessing provider and patient beliefs regarding the usability of electronic interventions for individuals with TMD.[143] Eleven Dutch physical therapists and nine Dutch patients with TMD were interviewed to gain perspective about their views of the idea of using “e-Health” (electronic care delivery) in any form for this purpose. The study explored their views to identify potential usability and barriers to future telerehabilitation use in this population. The therapists identified some benefits that they saw as complementary to their traditional in-person work, but did not feel that electronic care delivery could replace in-person assessment.[143] Improved convenience and compliance facilitation were key themes identified as benefits, and variable comfort with technology was identified as a barrier.[177]

Patients and PTs were generally positive about the idea of telerehabilitation, but only as a complement to in-person care. These findings reveal that existing beliefs are a barrier to telerehabilitation adoption as the primary care delivery method. A full RCT comparing telerehabilitation delivery to standard in-person care in this population may not yet be possible as potential participants may not be willing to be randomized to full telerehabilitation. Results of an open-label non-inferiority study will provide effectiveness and feasibility data to explore these barriers further and generate support for a future RCT.

Implementation Barriers: Conclusions

As health care embraces new technology supporting synchronous telerehabilitation visits, the need to standardize and improve the quality of evidence for this intervention has become apparent. Heterogenous and poor study

methodology limits the generalizability of telerehabilitation results that could work toward breaking down barriers. Current evidence clearly supports the need for high quality clinical trials assessing health outcomes and cost of real-time telerehabilitation in the specialized TMD population. Using validated outcome questionnaires and methods that allow for reproducibility and generalizability of evidence is the only way to address barriers, facilitate translation of results and implement telerehabilitation.

APEASE Criteria

Using a standardized theoretical framework for behavior change allows researchers to evaluate the feasibility of implementing an intervention. One such framework is the APEASE criteria; an intervention must be assessed and evaluated for Acceptability, Practicability, Effectiveness, Affordability, Side-Effects, and Equity in order to be successfully implemented.[178] These criteria examine the socioeconomic and cultural factors that create barriers to implementation, making them useful for thorough and methodical evaluation of telehealth research.[179,180] Considering telerehabilitation for individuals with TMD as the intervention, the parameters outlined by Michie et al.[178] will address feasibility of implementation in the following ways:

- Acceptability – assesses appropriateness of telehealth according to relevant stakeholders such as patients and providers (barriers addressed: **values & beliefs, convenience & fit**)
- Practicability – evaluates whether telehealth can provide routine clinical care without needing highly specialized or trained personnel (barriers addressed: **values & beliefs, convenience & fit**)
- Effectiveness/Cost-Effectiveness – determines the effect size of telehealth in a real-world context and factors into cost-effectiveness when used in the ratio

to cost (barriers addressed: **knowledge gaps for an underserved population, reimbursement, values & beliefs**)

- Affordability – the extent to which telehealth can be accessed and used by all within a reasonable budget (barriers addressed: **reimbursement, access**)
- Side-Effects – unintended or negative consequences of telehealth such as breaches of confidentiality, lack of compliance, or the possibility of less effective care (barriers: **privacy & security, values & beliefs**)
- Equity – accessibility for patients of all socioeconomic and educational levels, cultural backgrounds, and in various locations to utilize telehealth for care delivery (barriers addressed: **reimbursement, access**)

Using the APEASE framework to inform exploratory analyses of this clinical trial examining telerehabilitation for individuals with TMD will provide a standardized methodology to examine feasibility of the intervention.

CONCLUSION

The existing body of evidence demonstrates good diagnostic accuracy and efficacy with in-person PT and telerehabilitation effectiveness in other PT populations. There is also evidence of patient satisfaction cost-effectiveness with telerehabilitation. Several literature gaps are identified, including a need for more evidence concerning PT effectiveness in TMD clinical populations, a lack of telerehabilitation research regarding cost-effectiveness and effectiveness for individuals with TMD, a lack of standardization for collecting patient satisfaction data, and barriers to be addressed regarding implementation of telerehabilitation for individuals with TMD. The overall question emerges: is PT diagnostic accuracy and patient outcomes with telerehabilitation as good as in-patient rehabilitation in a clinical TMD population? To answer this question, a trial comparing telerehabilitation for individuals with all TMD subtypes assessing feasibility as secondary outcome measures is clearly needed. Because participant and PT blinding is not possible and

because patients with TMD have expressed concern that full telerehabilitation is less desirable than traditional in-person PT,[143] an open-label trial is the most appropriate design for this study.

The National Academies of Science, Engineering & Medicine has called for more research focused on care for the underserved, specialized population of individuals with TMD.[1] If TMD care is to continue progressing alongside care for other joints, telerehabilitation must be investigated in this specific population. Regardless of outcome, study results will enhance care for this population by characterizing the utility of this intervention which is already being used without evidence since the onset of the COVID-19 pandemic.

Chapter 3: STUDY METHODS

STUDY SUMMARY

The long-term objective of this project was to compare telerehabilitation versus in-person delivery of Physical Therapy (PT) services for individuals with Temporomandibular Disorders (TMD). Based on previous literature and survey data from our multidisciplinary clinic, the central hypothesis of this project was that telerehabilitation will have similar outcomes as compared to in-person PT. To test this hypothesis, an open-label controlled noninferiority preference trial compared telerehabilitation and in-person PT for individuals with TMD. A convenience sample of patients referred to PT was allocated to telerehabilitation or standard in-person care for diagnosis and PT management according to patient preference. The diagnosis made by the physical therapist was compared to a criterion standard diagnosis from the referring orofacial pain (OFP) specialist to establish diagnostic agreement for each group (Aim 1). To compare therapy outcomes, the change in quality-of-life (QoL) summary score of ≥ minimal clinically important difference (MCID = 6.9 units) after 6 weeks established therapy effectiveness as a binary positive or negative response. The proportion of positive therapy response in each group was compared and a difference of ≤10% between groups defined telerehabilitation noninferiority (Aim 2). Exploratory secondary analyses determined preliminary implementation science data (Aim 3). The study is ongoing and future analyses will explore telerehabilitation long-term effectiveness, economic analysis, and implementation science data through discharge and follow-up 6 months post-discharge for this population. The results of this study quantify how telerehabilitation can help overcome the barriers to multidisciplinary TMD treatment. Clinically these results will inform how PTs can utilize telerehabilitation to improve care for individuals with TMD.

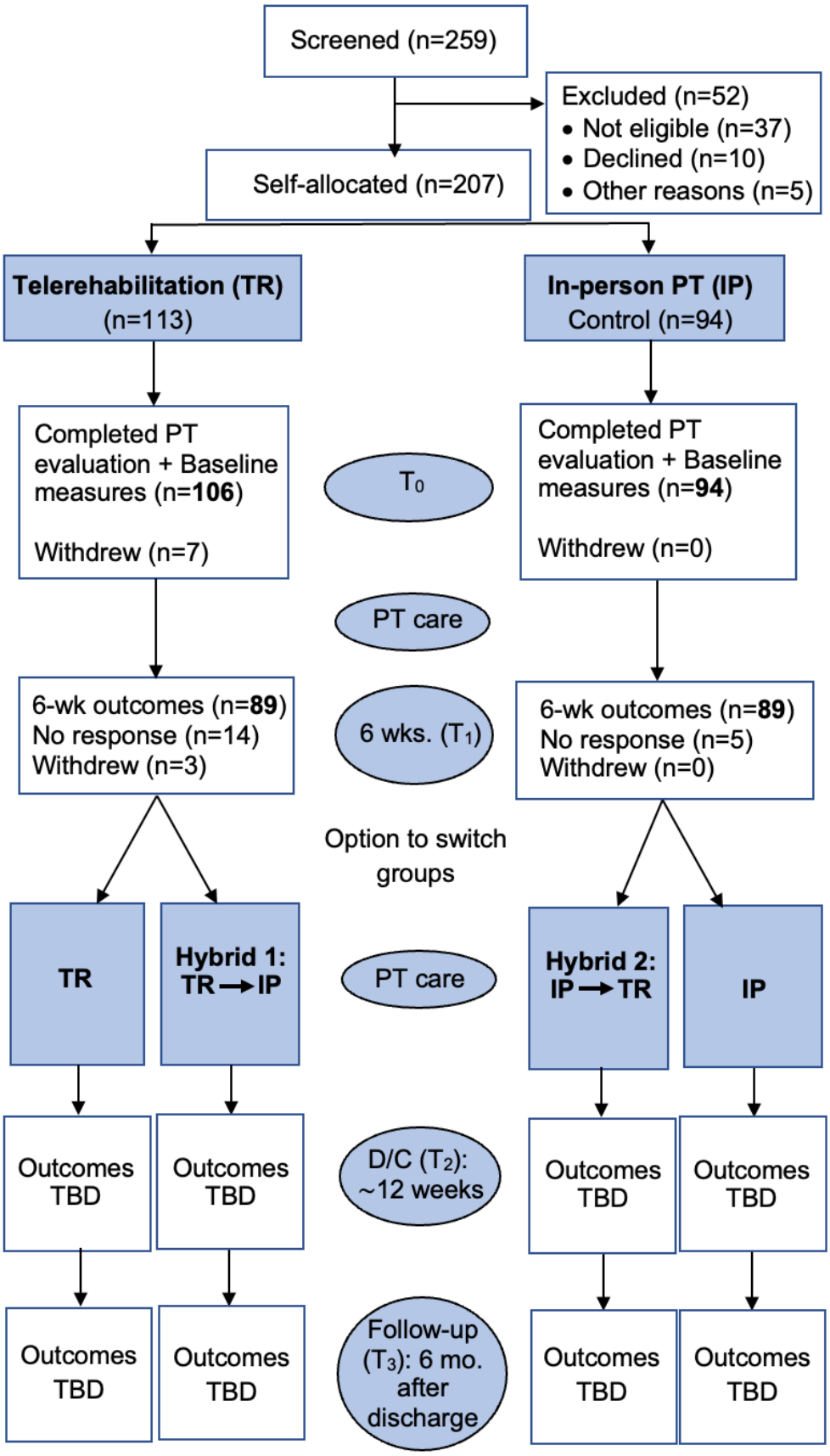


Figure 7. Study Flow from screening to final follow-up

DESIGN

This project was an effectiveness study examining telerehabilitation with a prospective cohort noninferiority trial. It was an open label preference clinical trial wherein participants chose their rehabilitation format with a 1:1 ratio of telerehabilitation to control group participation. Aim 1 analysis was an embedded cross-sectional study on data collected after allocation but before interventions occurred. Aim 2 noninferiority analysis on the prospective cohort was done after 6 weeks. Aim 3 exploratory analyses have considered 6-week outcomes and qualitative feedback from some patients 6 months after discharge as of the time of writing to assess secondary outcomes of the noninferiority preference trial. Participants and providers were not able to be fully blinded due to the nature of this trial, indicating its appropriateness for the preference clinical trial design. **Figure 7** shows a complete visualization of study flow.

PARTICIPANTS

Inclusion/Exclusion Criteria

Subject inclusion/exclusion criteria defined a clinical population of individuals with TMD able to participate in telerehabilitation and likely to benefit from PT. Much of the criteria aligned with the inclusion/exclusion criteria used to create the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD),[31] which was the basis for the diagnostic approach used in this study. These criteria captured the desired population and minimized loss to follow-up while ensuring legal compliance with Minnesota (MN) telerehabilitation legislation. These criteria also defined the same population that was used to validate the OHIP-TMDs self-reported quality of life instrument[181] which was used to determine the primary treatment outcome in this study.

Inclusion

1. 18-69 years old;

   By limiting this study to individuals aged 18-69, participation was not contingent on a patient representative giving consent or facilitating visit compliance. This was the age range used to validate the RDC/TMD[77] and was therefore the most appropriate group in which to use the DC/TMD[31] for diagnosis.

2. Diagnosed with ≥1 TMD subtype by the OFP specialist and referred to PT;

   The twelve common TMD subtypes with DC/TMD diagnostic algorithms are arthralgia, four types of myalgia/myofascial pain, four types of disc displacement disorders, degenerative joint disease, subluxation, and TMD headache.[31] This criterion ensured that the study population includes individuals with TMD who have been identified as likely to benefit from the rehabilitation intervention.

3. No previous PT knowledge of the participant diagnosis;

   The DC/TMD diagnostic algorithms relied on manual contact for palpation to fulfill much of the criteria,[31] but the virtual telerehabilitation format allowed only verbal cues and communication to guide clinical decision-making. To minimize bias and improve reproducibility and generalizability in the study of PT diagnosis via telerehabilitation, the assessing PT could not have prior knowledge of the referring TMD specialist's diagnosis.

4. Email access

   Self-reported outcome questionnaires for data collection were filled out remotely in REDCap, and links to these questionnaires were sent via email at each timepoint. The telerehabilitation group participants also needed email access to receive links for each visit.

5. Possession of a device that can be positioned for hands-free telerehabilitation visits (telerehabilitation group);

This study used secure software (Zoom Video Communications; San Jose, CA, version 5.7.8) provided through the University of Minnesota (UMN) for telerehabilitation. Any device with internet access and a camera can be used for synchronous telerehabilitation with a free version universally available. Instructions will be given regarding how to download and access Zoom. Instructions were given regarding camera positioning for visits.

6. Willingness and ability to comply with all study requirements and PT program
7. Ability to provide informed consent;

This study used a convenience sample of patients already engaged in TMD specialty care at the UMN TMD, Orofacial Pain & Dental Sleep Medicine clinic. Participants were eligible to receive PT regardless of their inclusion in this study, and their ability to understand and consent to participation was required for ethical research performance.

Exclusion

1. Non-English speakers
2. No location available to do telerehabilitation visits in of the state of MN;

Many patients travel to the UMN TMD clinic for care due to the widespread lack of available TMD specialists in other states. While the United States government has increased Medicare reimbursement for telehealth services since the COVID-19 public health emergency, legal restrictions regarding provision of telerehabilitation to patients residing in different states still exist.[166,168] At the time of this study, the state of MN did not participate in therapy compacts that would have allowed a PT with MN licensure to treat a patient who is outside of the state.

3. Women in the last trimester of pregnancy;

Pregnancy is not a contraindication for PT in individuals with TMD, but the time requirements of physical therapy lasting up to 12 weeks could have

overlapped with delivery which and disrupted care, precluded compliance with study requirements, or contributed to attrition.

4. Referred for post-surgical rehabilitation;

    Telerehabilitation for post-surgical rehabilitation has been shown to be effective in other joints[27,145,182] but has not yet been studied in individuals with TMD. This population is of interest but will be better studied in future research once more evidence is known regarding telerehabilitation efficacy for individuals with TMD.

5. Severe chronic pain as identified by level 4 classification on the Graded Chronic Pain Scale (GCPS);

    Patients with chronic pain can successfully respond to physical therapy, but severe chronic pain can interfere with the body's ability to make changes. Level 4 classification on the GCPS is strongly associated with severe depression and somatization,[86] which is associated with poor treatment prognosis in individuals with TMD.[183] Excluding these individuals intended to capture the population of individuals likely to benefit from PT.

6. Current diagnosis or existence of the following conditions:

a. Neuropathic pain;
b. Fibromyalgia and/or generalized widespread pain as defined by pain on both sides of the body in ≥3 areas above and below the waist;
c. Rheumatoid arthritis or juvenile idiopathic arthritis;
d. Dystonia or other movement disorder;
e. Fractures and/or recent jaw or facial trauma;
f. Malignancies;
g. Current substance abuse;

Many of these conditions contribute to orofacial pain but this study aimed to define a clinical population with TMD, so they were excluded from the study. Individualized PT

requires variation of treatment interventions and therapy duration based on the patient diagnosis, functional goals, and response to therapy. Restricting the population to individuals with common TMD diagnoses reduced population heterogeneity and variance while preserving generalizability. These criteria aligned with those used in the research establishing diagnostic criteria[31,36,77] for these TMD diagnoses.

Sample size

Sample size for this non-inferiority study was calculated to have 90% power to draw conclusions due to the increased potential of making a type II error in non-inferiority studies. Significance level was set to 0.05 to minimize type I error.

Aim 1: The *a priori* power analysis for the diagnostic agreement analysis was based on two raters diagnosing the presence/absence of masticatory myalgia as the primary diagnosis. Since masticatory myalgia is the most common diagnosis seen in clinical populations,[33,49] there was a high probability that both raters would record a positive diagnosis given our inclusion/exclusion criteria defining a population with TMD. For this reason, a positive response rate of 80% was used in the sample size calculation for both raters. As the one-way null hypothesis states that $k_0<0.7$, any value <0.7 is considered a valid choice. If $k_0=0.35$, 76 participants in each group would be required to detect a kappa value (k_A) of ≥0.7; if $k_0=0.4$, 101 participants in each group would be required to detect k_A ≥0.7 (Appendix I). Aim 1 and 2 analyses were done on the same individuals, so with 89 participants in each group there would be 90% power to detect k≥0.70 for aim 1 assuming fair or less diagnostic agreement under the null.

Aim 2: The sample size calculation method for aim 2 assumed a noninferiority study that will compare the difference between group treatment success rates to a pre-set noninferiority margin to assess telerehabilitation effectiveness.[15, 16] For this

study, rehabilitation effectiveness was described as a binary positive or negative result based on the OHIP-TMDs score change after 6 weeks. The % positive result quantified therapy success rate in each treatment group for comparison.

Anticipating that telerehabilitation would be less preferred, the *a priori* power analysis used a 2:3 ratio of telerehabilitation to in-person (standard care) participants. Using a 10% noninferiority margin and therapy success rates of 75% (standard care) and 65% (telerehabilitation), 76 telerehabilitation participants and 113 in-person participants were determined to be needed to test for noninferiority of telerehabilitation (Appendix). Once the study began, telerehabilitation emerged as the preferred group with enrollment occurring twice as fast. Adjusting to 1:1 group allocation required 89 participants in each group (Appendix), which was feasible given the recruitment rate, so a study modification was made after 1 year. Parameter choices for the sample size analysis were made based on literature evidence, clinical significance and study feasibility with sensitivity analysis revealing how different choices affected sample size requirements (Appendix).

Noninferiority margin: A pre-set noninferiority margin of 10% was chosen in accordance with clinical significance and other noninferiority studies in rehabilitation and telerehabilitation. Noninferiority margins in other studies ranged from 8-15% based on the MCID of the outcome measure.[125,145,182,184-186] The MCID for the OHIP-TMDs is 6.9,[181] which is a 9% change on the scale. Setting the margin at 10% improves study feasibility while closely approximating the OHIP-TMDs MCID and aligning with previous research.

Therapy success rates: The OHIP-TMDs validation study reported a 70% treatment success rate, but the rehabilitation provided in the study consisted primarily of unsupervised exercise and advice with only 11% of the participants receiving actual PT as their treatment intervention.[181] Expert PT care consists of individualized interventions given to address specific functional limitations and contributing factors

to progress toward patient-specific goals.[89] Given that this proposed study provided a supervised treatment intervention delivered by an expert PT and that PT effectiveness for TMD is well established in the literature,[10,12,18,41,48,85,93,102,187,188] increasing the anticipated response rate to 75% in the standard care group is reasonable. As no data yet exists assessing success rate of telerehabilitation for individuals with TMD and the PT will not be able to provide the interventions in-person as described in existing literature, the anticipated success rate for this group was set lower at 65%.

Aim 3: The study was not powered for the exploratory analyses that will be included to complete this aim. When cost-effectiveness analysis is performed alongside clinical trials, these analyses are usually underpowered.[155] For patient satisfaction, telerehabilitation literature has shown non-inferiority of satisfaction in telerehabilitation samples.[111] Sample size calculation for a non-inferiority analysis considering a 1:1 allocation ratio and a high proportion of success in both groups yielded 32 participants and 51 participants required in the telerehabilitation and control groups to have 90% power at 5% significance (Appendix I). To assess co-variates and predictors, sample size analysis comparing two independent groups revealed that 60 subjects in each group will be required to find a general effect size of 0.6 at 90% power and alpha level of 5% significance (Appendix I). Given that ≥89 subjects were recruited in each group for the primary analyses, there could be sufficient power for some of the secondary analyses depending on the final numbers in each group.

Ethical Approval

All participants in this study received and signed an informed consent for trial participation and for delivery of clinical care. All work was carried out with approval by

the University of Minnesota Institutional Review Board (IRB ID: STUDY00015476) and the trial was registered on clinicaltrials.gov (NCT05318313).

Funding Support

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Recruitment

Participants were recruited from the TMD, Orofacial Pain & Dental Sleep Medicine Clinic patient population at the University of Minnesota School of Dentistry. Patients diagnosed with one of the twelve common TMDs according to the DC/TMD[31] by any of the five OFP specialist dentists and 7 OFP resident dentists and referred to PT were identified at the time of their initial clinic visit. Postings in the treatment rooms and handouts describing the study provided additional information, and participants either contacted the PI or consented to being contacted for additional details regarding study participation. The recruitment process aligned with the pre-existing PT referral and scheduling process, facilitated by the clinic faculty and staff. Participants were reimbursed with $100 gift cards upon completion of outcome questionnaires at 6 weeks, discharge, and 6 months after discharge, and in-person visit parking costs were covered by study funding.

Screening

Potential participants completed screening questionnaires to determine eligibility. To ensure that the treating PT remained blinded to the referring diagnosis, participants completed the screening questionnaire through Research Electronic Data Capture (REDCap) software[189] (Appendix) which used scoring algorithms to

determine study eligibility. The PI and potential participant met either via Zoom or in-person to discuss study details and the consent form. If a patient did not qualify for the study, the REDCap algorithm thanked them for their time and directed them to schedule PT as a traditional patient.

Allocation

Potential participants were given the option to schedule their PT evaluation to be done either via telerehabilitation using synchronous video visits or via in-person visits. Their preference was recorded in the screening questionnaires, and they scheduled accordingly once consent was recorded. The treating PT verified participant understanding of group assignment before sending them baseline questionnaires. Recruitment continued until 89 participants in each group have submitted their 6-week questionnaires.

Blinding

The nature of this study precluded blinding of participants or the providers to group assignment. However, the PT was blinded to the referring diagnosis to allow for the PT evaluation process alone to guide the PT diagnostic decision-making. A blinded evaluator completed the bDC/TMD verification according to the orofacial pain (OFP) specialist clinical assessment documentation to determine the reference diagnoses. The blinded evaluator also verified questionnaire completeness to maintain PT outcome blinding while minimizing missing data.

Retention

If a patient did not appear for their initial visit or follow-up visits or did not complete outcome questionnaires at 6 weeks, the PI and treating PT contacted them via email and then by phone if they did not respond. Up to 10 attempts to contact were made. To incentivize patients to fill out all REDCap questionnaires for follow-up,

the Clincards were not distributed and/or reloaded until the questionnaires were completed at each time point. The study assistant verified questionnaire completion and contacted the participant when needed to fill in any missing data and ensure receipt of reimbursement. The Clincard and the first $25 was distributed when participants completed the OHIP-TMD at 6-weeks, the second $25 loaded onto the existing card at discharge, and the third $50 distribution was loaded when patients completed outcome questionnaires 6 months after the 12-week timepoint (9 months after starting PT) to minimize missing data for the long-term follow-up data.

DATA COLLECTION

Outcome Variable Definitions

Demographic variables included age, sex, gender identification, race, income level, education level, GCPS level, anxiety/depression level, and TMD criterion standard subtype diagnosis. Baseline variables included maximal mouth opening in millimeters (mm), numeric pain rating scale (NPRS) pain level, Global rating scale (GRS) function level 0-100, and OHIP-TMD summary score for quality of life. All dependent variables are defined below:

Aim 1

The dependent variable for Aim 1 was PT diagnosis, and the primary outcome variable for Aim 1 was the **diagnostic presence of masticatory myalgia** as compared to a criterion reference standard. Paired observations consisted of two providers evaluating the same participant at different times. The referring OFP specialist (criterion reference) evaluated first in-person, followed by the PI at the PT evaluation (blinded to the specialist diagnosis) occurring anywhere from later the same day to 1-2 weeks later. Standardized patient diagnoses based on the bDC/TMD diagnostic algorithms[31] could have included masticatory myalgia, TMJ

arthralgia, disc displacement conditions, degenerative joint disease, TMD headache, and “other” diagnoses. This outcome was used to quantify groupwise diagnostic agreement with the referring specialist. Secondary outcome variables for Aim 1 included the presence of the remaining bDC/TMD diagnoses to be used in secondary analyses further quantifying diagnostic agreement.

Aim 2

The dependent and primary outcome variable for Aim 2 was **patient quality of life improvement after 6 weeks of PT for TMD** as quantified by the change in OHIP-TMD summary score[181] from the pre-therapy to the 6-week timepoint. If the change score was ≥6.9 units, therapy was classified as a success. The binary outcome of therapy success (yes/no) was quantified as a proportion for use in the noninferiority analysis.

Additional dependent variables for Aim 2 secondary analyses included commonly used markers and potential predictors of clinical rehabilitation outcomes. They were collected and analyzed after 6 weeks of care to assess covariate effects and perform prespecified subgroup analyses.

1. **Total number of PT visits**;

   Individualized therapy dictates that the number of visits will vary for participants, rather than following a set protocol. Recording the number of visits for each participant allowed for the assessment of whether the number of therapy visits differed between groups and/or was associated with functional outcomes.

2. **Change in mouth opening (mm)** from the first to final PT visits;

   This objective measurement was the only quantitatively measured jaw range of motion outcome used for the DC/TMD[31] and is commonly measured in jaw rehabilitation studies. While not all patients with TMD have limited jaw opening,

this measure is usually taken on all patients and is an efficient way to quantify mobility. This data was taken from the medical record.

3. Change in pain as measured by the **Numeric Pain Rating Scale (NPRS);** This 11-point scale asks participants to rate pain from 0-10 (no pain-worst pain) and has been shown to have moderate reliability in individuals with neck pain without radiculopathy.[190] This pain rating scale is universally used by PTs and other health care providers but has not been expressly evaluated in a population with TMD. This data was taken from the medical record and from additional outcome questions (Appendix II).
4. Functional improvement as measured by the **Global Rating Scale (GRS);** This scale asks participants to rate their function from 0-100% with 100% aligning with normal pre-injury function. This scale has been correlated with commonly used functional outcome measures in a population after knee anterior cruciate ligament (ACL) repair, showing responsiveness to change.[191] This scale is quick and easy to use in the clinic but has also not been evaluated in a population with TMD. This data was taken from the medical record and from additional outcome questions (Appendix II).

Aim 3

While the study was not powered for analysis of the following dependent variables, exploratory analysis gives information to further characterize telerehabilitation effectiveness in individuals with TMD and assesses feasibility of implementing telerehabilitation for this population. These analyses also provide preliminary evidence for future research priorities in this area. Future exploratory assessment of long-term telerehabilitation effectiveness will include the same dependent variables as the Aim 2 secondary analyses using data collected at discharge and 6-months after discharge.

Patient satisfaction is an important contributor to therapy success and could be affected by varying the care delivery method. Provider attributes and the process of care delivery are key elements of this outcome, and the interaction between patient expectations and experience determines satisfaction. The multidimensional **HCSQ score**[144] accounts for patient expectations in the outcome to quantify patient satisfaction with telerehabilitation, and mean scores in each group were compared to assess for differences. **Qualitative assessment of patient satisfaction** occurred for patients at 6-months post-discharge who opted to fill out a brief final study feedback questionnaire containing questions aligned with the APEASE criteria.

Quality Adjusted Life Year (QALY)[147] is a measure of health outcome that combines qualitative and quantitative health gains into a single metric. It uses quality weights based on health preferences that are then assigned to different health states. The duration of a certain health state (in years) multiplied by the corresponding quality weight for that state yields the QALYs gained. In this study, health states were determined using the EuroQoL-5 Dimension-5 Level (EQ-5D-5L) scale. For treatment groups, the baseline health state duration is approximately 3 months (0.25) and the post-PT health state is 9 months (0.75) to collectively make up the 1-year time horizon. The difference between QALYs gained on average in each therapy group is used as the denominator for the incremental cost-effectiveness ratio (ICER) in cost-effectiveness analysis.[147] Baseline health status data will be used to describe a hypothetical “no treatment” group.

Therapy costs were considered as two dependent variables for future cost-effectiveness analysis. The first was the overall societal costs associated with TMD for participants assessed over the 1-year time horizon for cost-effectiveness analysis. Societal costs include health system costs for all consultations, medication and treatments, productivity losses for the patient due to their TMD symptoms, childcare expenses, productivity losses for companions and childcare providers, and time and

travel expenses for PT visits. The second dependent variable was the time and travel costs of PT for each group during the intervention. Costs will be collected using the Telerehabilitation TMD Study Cost Questionnaire at baseline, discharge, and 6 months after discharge. For each cost variable, the difference between costs on average in each therapy group will be used as the numerator for the ICER calculation.[147] Baseline cost data will be extrapolated for the hypothetical "no treatment" group for comparison.

Outcome Questionnaires

Screening

The long form of the TMD Pain Screener[192] is a validated 3-question screening instrument designed to provide an efficient, cost-effective tool to identify individuals with pain-related TMD for clinical and research settings (Appendix II).[193] Scoring assigns 0-2 points based on multiple choice a, b or c responses for each question and the threshold value for a positive score identifying the presence of TMD is 3.[193] The scale was validated in individuals with painful TMD, demonstrating 99% sensitivity and 97% specificity to identify the true presence or absence of TMD.[193] In this study, the pain screener provides additional data to verify the inclusion criterion of a participant with a TMD diagnosis. While the scale has low specificity to exclude individuals with odontogenic pain,[194] the role of the expert TMD specialist initially diagnosing and identifying potential participants will exclude those individuals from the sample.

The GCPS is a graded classification of chronic pain severity initially developed in 1992 and validated in a number of pain populations, including 392 individuals with TMD.[62,192] This study used the most recent validated version, considering symptom assessment within the past 30-days.[195] There are six items asking participants to rank pain intensity and amount of interference due to pain on a

0-10 scale, and one item asking for the number of disability days due to facial pain (Appendix II). Scoring combines mean pain intensity with disability points ranging 0-3 for on the number of disability days and amount of interference caused by pain.[192] The five resulting grades of chronic pain severity are: 0 (no disability), 1 (low disability-low pain intensity), 2 (low disability-high pain intensity), 3 (high disability-moderate limitation), 4 (high disability-severe limitation).[62,86,192] The prognostic value of the scale has been well-established,[62] and a multicenter center study has demonstrated a strong correlation between severe somatization and depression and high pain-related disability for GCPS level 4.[86] In this study, this scale identified participants likely to benefit from PT for study inclusion and provided chronic pain categorization for covariate and subgroup analysis.

Baseline

The OHIP-TMD is a 22-item patient-reported outcome instrument used to assess quality of life for individuals with TMD. It was adapted from the previous non-condition-specific Oral Health Impact Profile (OHIP) using a mixed methods approach for clinical and research use in populations with TMD.[181,196] The original OHIP questionnaire showed 90.9% association between TMD symptom prevalence and Axis-II questionnaires assessing psychosocial factors,[87] supporting its use for condition-specific adaptation. Scoring uses a 0-4 Likert scale with a maximum of 4 points for each answer, and a lower score indicates better quality of life. The scale has good test-retest ability (ICC=0.805), content validity (mean index score = 0.73).[181] The validation study performed by Yule et al. demonstrated responsiveness to change with an MCID (6.9) and standard deviation (15.9) for use in sample size calculation for TMD research.[181] Yap et al. demonstrated that the OHIP-TMD was able to discriminate between patients with and without TMD, showing perfect extent-prevalence correlations (Spearman's rho (rs) = 1.00) in a population of young adults

in Singapore.[197] There are only a few validated outcome questionnaires for TMD clinical and research use, and of those available the OHIP-TMD is the only condition-specific instrument with established responsiveness to change.[198,199] The questions capture the biopsychosocial effects of TMDs to quantify the full impact of TMDs on quality of life, supporting its use to collect therapy primary outcome data for this study.

The 8-item Jaw Functional Limitation Scale (JFLS-8) is the short form of the longer 20-item JFLS-20.[200,201] The validated 20-item version covers three different constructs including chewing, opening mobility, and expression. Scoring for each item asks participants to rate their limitation on a 0-10 scale, culminating in a summary score that quantifies limitation due to jaw dysfunction. Validation revealed high item reliability (0.99) but low construct validity due to poor correlation with other scales assessing depression (correlation=0.02), somatization (0.2) and pain-related disability (0.26).[201] Validation of the shorter JFLS-8 in a subset of individuals with TMD according to RDC/TMD criteria demonstrated 0.94 correlation with the JFLS-20.[200] The JFLS-8 global score demonstrated good correlation with three subscales assessing limitation in mastication, mobility, and verbal/emotional expression (correlation=0.84-0.86) demonstrating its ability to identify functional limitation in this population, making it a useful clinical tool.[200] However, the JFLS does not fully capture the negative impact of TMD on quality of life and responsiveness to change was only investigated in a pilot study demonstrating a nonsignificant trend toward score improvement after therapy for symptoms of TMD ($p=0.05$).[201] Therefore, it was not selected as the primary outcome tool in this study. It was included because the data will be used in a future exploratory analysis to address the existing evidence gap regarding responsiveness to change for this useful clinical tool.

The Patient Health Questionnaire for anxiety and depression (PHQ-4)[202] is a short four-question scale that combines two questions each assessing anxiety and

depression. This scale is suggested as one of the instruments used to collect Axis-II data for consideration of psychosocial status with the DC/TMD.[31] Factorial validity for each scale item ranged 0.82-0.90, and good reliability was demonstrated by Chronbach's alpha=0.85.[202] Overall, this tool has been shown to be useful for screening anxiety and depression and its brevity makes it ideal for clinical settings. It was used in this study to inform consideration of biopsychosocial status with diagnosis, to provide baseline demographic data for the study population, and for covariate and subgroup analyses.

The EuroQoL-5 Dimension-5 Level (EQ-5D-5L) scale[154] is a generic pre-scored system of health classification that is commonly used in health care economic analysis. The European EuroQoL Group developed the scale with 5 levels (no problems, slight problems, moderate problems, severe problems, unable/extreme) for each of 5 dimensions: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression.[147] Each possible 5-digit response combination defines a health state with a value score ranging from 0 (dead) to 1 (perfect health), providing health state valuations based on population norms.[147,156] It also includes a visual analog scale (VAS) for rating health 0-100 to quantify health based on the participant's judgment.[154] Changes on this scale define QALYs that quantify effectiveness in economic analysis. Durham et. al validated the EQ-5D-5L for use in orofacial pain populations, establishing good convergent validity (correlations of 0.67 for pain severity and 0.49 for pain interference) with a scale commonly used to measure pain-related disability in orofacial pain.[156] The study was done on a heterogeneous orofacial pain population with more diagnostic variability than what will exist in participants with TMD for this study, though they did use the same TMD Pain-Screener for inclusion. They concluded that the EQ-5D-5L will underestimate the impact of orofacial pain, but that its ability to identify QALYs in the population of individuals with orofacial pain creates utility for comparison across conditions.[156]

Health states are identified by the level (1-5) for each dimension as a list of all responses (eg. 11353, 21123, etc.). Health state valuations have been calculated based on preferences and presented for use in United States economic research in the 2019 study by Pickard et al. with a scoring algorithm provided for research use.[203] Score calculation details are described in the Statistical Analysis section of this proposal. Baseline health state data allowed for quantification of health state improvement after PT in each group when compared against discharge health state data. The baseline data will also be used to quantify health status of a hypothetical "no treatment" group for additional comparison.

The Telerehabilitation TMD Study Cost Questionnaire is a collection of questions designed to assess the overall cost of orofacial pain and the PT treatment that will occur during this study. It was adapted from two questionnaires used in the DEEP study assessing the cost of orofacial pain, the Use of Healthcare Services and Productivity Questionnaire and the Time and Travel Questionnaire.[55,157] Adaptations included changing wording for United States use, streamlining questions to reduce response burden, and focusing the time and travel section questions on the PT intervention for this study. Questions focus on the societal perspective of the patient and the community considering costs incurred over the previous six months to collect data for demographic comparison. Sections include Consultations (1), Medications and Treatments (2), Productivity Losses (3), Additional Information (4), and Time & Travel (5). At baseline, the time and travel section will not be included as the intervention will not have yet occurred. Baseline costs described the societal costs of TMD for the 6 months prior to study onset and will be used in future cost-effectiveness analysis for demographic comparison, covariate analysis, and extrapolation to describe societal costs for the hypothetical "no treatment" group

Follow-up

Therapy outcome data was collected three times after the onset of PT. Data collection 6 weeks after the onset of PT included the OHIP-TMD for Aim 2 primary outcome analysis and the following questionnaires for secondary analysis: JFLS-8, EQ-5D-5L, and a patient satisfaction questionnaire. The same questionnaires with the Cost Questionnaire added were collected at discharge and again 6 months after discharge to assess long term therapy outcomes. The Cost Questionnaire had the following wording changes at follow-up:

- **Discharge**: Wording was changed to ask about costs over the three months preceding data collection instead of six months to capture costs during the intervention period. It also had a Time & Travel component (Section 5) added to capture costs directly related to the intervention.
- **6 months after discharge**: Wording was changed back to six months preceding data collection and did not have Section 5 included.

The Health Care Satisfaction Questionnaire (HCSQ) is a 23-item instrument that was designed to assess the inherently qualitative concept of patient satisfaction with health care. The instrument was developed in a population of elder adults using a combination of qualitative and quantitative methods and classifies satisfaction by three factors: provider relationship, service delivery, and service organization.[144] The scale is reliable with internal consistency measured by Cronbach's alpha=0.92 and good correlation of ICC=0.72 between the three factors.[144] Each question involves two responses using 4-point Likert Scales (1-4 points); one assessing perceived importance (P) and the other assessing whether the experience met their expectations I. Each item is scored by using the equation E(2P-E) to account for patient expectations in assessing their experiences.[144] Instrument scoring involves summing the result for each question. While the population used to create and validate the scale is

different from the one that was used in this study, this scale has been used recently in telerehabilitation research on populations of varying ages and conditions.[125,145] The scale has therefore demonstrated its ability to quantify patient satisfaction with studies comparing telerehabilitation to standard in-person rehabilitation.

Clinical Exam

Diagnostic Criteria

The Diagnostic Criteria for Temporomandibular Disorders (DC/TMD)[31] is a set of recommendations that provided updates to the original Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)[36] from 1992. The groundbreaking classification system is notable for introducing the consideration of psychosocial status (Axis II) into diagnosis and management considerations for individuals with TMD via Axis II instruments such as the GCPS. The DC/TMD simplified and validated physical (Axis I) diagnostic algorithms for using history, physical exam, and a variety of imaging techniques for twelve common TMDs with ideal sensitivity and specificity cutoffs of ≥70% and ≥95% respectively.[31] The algorithms presented in the criteria[204] provide an assessment guide to determine TMD diagnosis but is still lengthy and burdensome to complete in a clinical setting and have been simplified further with the Brief DC/TMD (bDC/TMD) decision trees.[63] In this study, the blinded evaluator retrospectively applied data from the OFP specialist clinic notes to decision trees informed by preliminary unpublished drafts of the bDC/TMD[63] algorithms (**Figure 8**) to determine the criterion reference standard for comparison in the diagnostic agreement analysis (Aim 1).

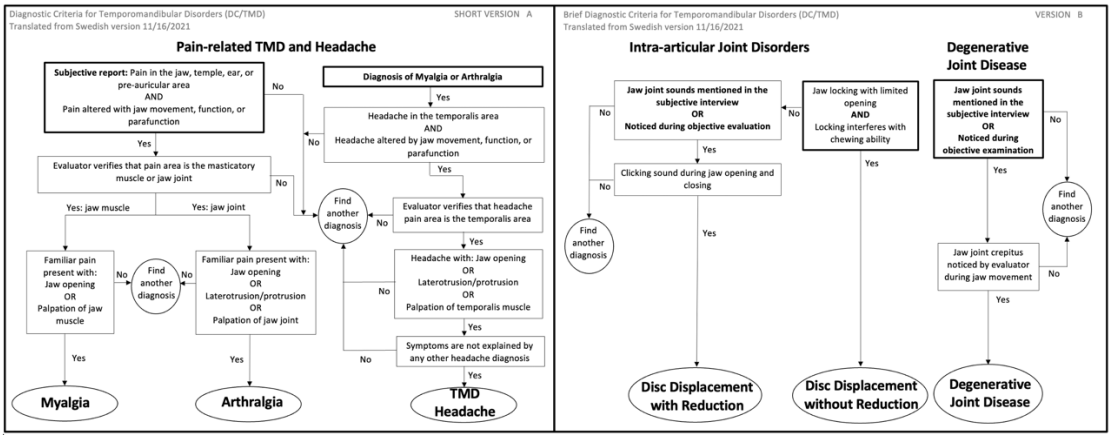

Figure 8. Decision trees informed by preliminary drafts of the brief diagnostic criteria for TMD developed by Durham et al.[63]

The five clinic referring providers (DN, SK, CH, GA, EMF) were experienced specialized OFP dentists who have completed advanced training in TMD and orofacial pain with many years of specialty practice in this population. Before the beginning of the study, the PI met with clinic staff, the five referring OFP specialists and the OFP residents to explain the study objectives and procedures. Study procedures were introduced during a 1-hour training to clarify inclusion/exclusion criteria, recruitment process and diagnostic procedures, and were reviewed during daily clinic team meetings as needed to standardize assessment approaches across all assessing providers and OFP residents. The training was repeated with every set of new residents, and again as needed if the fidelity checks indicated that the process was not being followed.

Physical Therapy Evaluation

The treating PT (EK) had sixteen years of experience exclusively treating OFP and TMD, and an existing collaborative relationship with the referring OFP specialists. The PT evaluation began with a thorough patient interview informed by bDC/TMD symptom questionnaire patient history questions[63] to determine symptom location, onset, intensity, duration, aggravating and alleviating factors, and functional limitations. Questions about oral parafunctional habits, sleep habits, stress level, occupation and hobbies, previous treatment, medical history, trauma history, and

comorbidities delineated contributing factors. The OHIP-TMD and JFLS-8 responses combined with each patients' goals and expectations for treatment informed functional goals to guide therapy interventions and discharge planning.

Objective tests and measures recommended by the original DC/TMD are a part of the PT objective examination and produce objective information used in bDC/TMD diagnosis. Standard procedure for in-person objective assessment included using a vertical stainless-steel millimeter (mm) ruler to measure incisor overlap, pain-free and maximum unassisted and assisted jaw opening (**Figure 4**), bilateral laterotrusion (**Figure 5**) and protrusion. Whether masticatory muscle (masseter and temporalis – illustrated in **Figure 2**) and TMJ palpation reproduced familiar pain and detected joint noises contributed to diagnostic consideration. Palpation of other areas including intraoral lateral and medial pterygoids (**Figure 2**), posterior and sub-mandibular regions, and cervical musculature yielded information to further identify the presence or absence of a myalgia diagnosis and directed individualized PT interventions. Additional evaluation components included static (isometric) and dynamic (resisted movement) tests of jaw movements to delineate muscle vs. joint involvement,[74] passive accessory motion testing of the TMJ to assess hypomobility, postural and cervical spine assessment.

An impairment-based classification system combined with the bDC/TMD classification method guided determination of the PT diagnosis (**Figure 9**). No current rehabilitation clinical practice guideline exists yet for diagnosis and management of TMD. A decision tree formulated from the DC/TMD, recommendations for PT application by Harrison et al.,[45] and modeled after the impairment-based PT practice guideline for neck pain[205] classified patients by mobility vs. motor coordination deficits based on objective testing results. From there joint vs. muscle deficit and other additional findings determined the bDC/TMD diagnosis. While not a part of the decision tree, grading irritability was also necessary

for treatment planning.

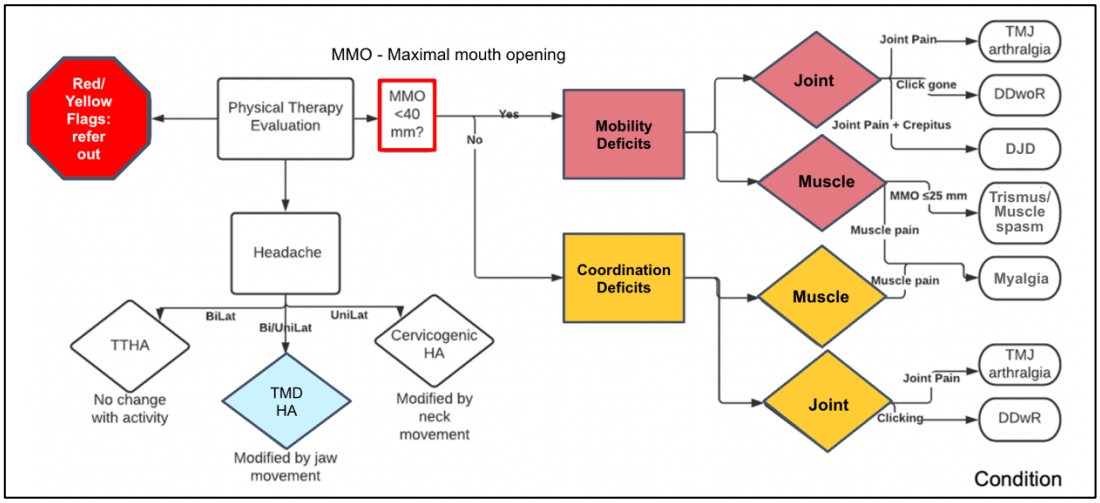

Figure 9. Decision tree combining PT evaluation and classification approaches with the DC/TMD to diagnose TMD subtypes

In-person PT diagnosis: Patients came to the UMN School of Dentistry TMD, Orofacial Pain & Dental Sleep Medicine Clinic for a 1-hour in-person evaluation. The diagnostic information was collected via traditional in-person testing and documented in the health record. The primary diagnosis designation was also input into REDCap for data collection.

Telerehabilitation PT diagnosis*:* The PT evaluation and follow-up visits were performed via Zoom software (Zoom Video Communications; San Jose, CA, version 5.7.8) using password protection to ensure confidentiality during patient visits.[206] This software has been successfully used in qualitative research[48] and has become commonly used due to the COVID-19 pandemic.[161] The therapist emailed a Zoom link the morning of each scheduled visit.

Adaptations for telerehabilitation: To perform the objective assessment in the telerehabilitation group, the manual contact used for in-person testing was replaced by verbal cues directing the patient to perform the tests on themselves. The PT showed pictures of the anatomical structures and demonstrated self-testing (**Figure 10**).

Figure 10. Synchronous PT examination via Zoom software showing the use of visual aids to guide palpation and therapist demonstration of measuring mouth opening

- **Range of motion**: Each patient in this group received a cardboard Therabite Range of Motion scale upon randomization (**Figure 11**).[207] These scales are reliable for self-measurement with an intraclass correlation coefficient of 0.92 (95% CI: 0.88, 0.95) compared to a gold standard clinician measurement.[208] During the telerehabilitation visit, the patient positioned themselves perpendicular to the camera to measure jaw opening and protrusion measurements and facing the camera for laterotrusion to ensure visualization of the Therabite scale numbers. If the patient did not have the scale, stacked fingertips were used to screen for hypomobility as outlined in the methods reported by Corelhano et al.[32] and the mm measurement for baseline PT data collection was then taken from the medical record value as measured by the OFP specialist.

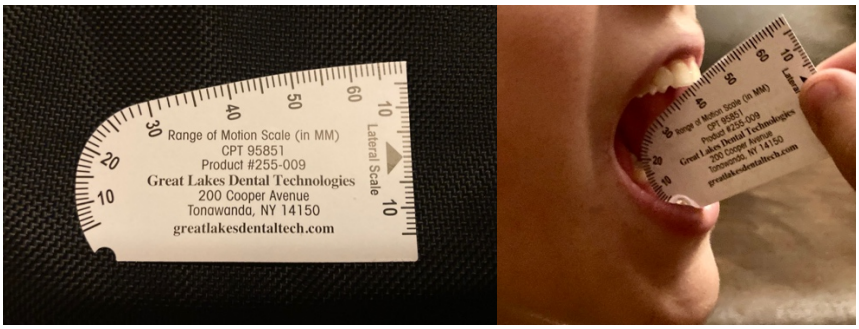

Figure 11. Cardboard Therabite Range of Motion Scale: Handheld scale to be given to telerehabilitation participants for self-use when measuring jaw range of motion during PT sessions.

- **Palpation:** The therapist gave direction regarding location and amount of pressure for palpation of the TMJ and all muscles to be assessed looking for reproduction of familiar pain. To standardize palpation pressure, participants were directed to use 1 finger applying 2-3 kg of pressure (enough pressure to achieve nail bed blanching) for 3 seconds.
- **Static and dynamic testing:** The therapist demonstrated and verbally cued self-performance of these tests.
- **Postural and cervical spine assessment:** The therapist observed posture and cervical range of motion with cues for the patient to self-perform overpressure. Self-palpation of cervical musculature occurred with the same cues as for masticatory musculature. Isometric resisted cranio-cervical flexion with verbal cues for patient performance gave a gross assessment of deep cervical flexor muscle activation and endurance.

As with the in-person PT evaluation, diagnostic results were entered into the health record and the primary diagnosis designation was input into REDCap for data collection.

Physical Therapy Intervention

Physical Therapy for individuals with TMD has been shown to be generally successful for decreasing pain and improving maximum mouth opening with no specific recommendations beyond multimodal combinations of non-invasive interventions such as exercise, manual therapy, relaxation, stretching, and biofeedback.[10,12,18,41,48,85,93,102,187,188] Because each diagnosis has unique rehabilitation considerations and twelve common subtypes of TMD will be included, it was not possible to standardize PT interventions. The Template for Intervention Description and Replication (TIDieR) Checklist[179] (**Appendix III**) was followed for reporting the PT intervention details.

In this effectiveness study, an individualized plan of care was constructed after the PT evaluation based on each patient's reference standard diagnosis and modified as needed based on their response to therapy. The same therapist performed every evaluation and follow-up visit to standardize care delivery. Once diagnostic data was entered into REDCap, the therapist reviewed the reference standard diagnosis for plan of care determination if diagnostic differences existed. All participants received education and self-care training at each visit. All participants also received evidence-based PT interventions from the same experienced PT that performed the evaluation. These interventions were targeted to decrease muscle tension pain, restore mobility and/or joint stability, develop muscle balance and control, improve function, and meet rehabilitation goals. See Appendix III for treatment planning specifics and a list of intervention options.

Thirty-minute follow-up visit frequency and time to discharge varied between patients based on diagnosis, condition irritability and feasibility. Conditions causing hypomobility and higher irritability as indicated by constant pain and mouth opening ≤25 mm were generally scheduled 1x/week for 4-6 weeks. Participants with instability/poor coordination, with lower irritability, and/or individuals with difficulty scheduling more frequently were generally scheduled 1x/2 weeks for 6 weeks with more education facilitating home management and self-progression. After 6 weeks, treatment was adjusted and/or tapered based on mid-therapy assessment.

Mid-therapy assessment occurred 6 weeks after PT evaluation. Therapy effectiveness was measured for later analysis using the OHIP-TMD, JFLS-8, EQ-5D-5L, and patient satisfaction questionnaires. Patients had the opportunity at this point to either stay in their initial group or switch to the opposite group. Therapy group switching created four unbalanced treatment groups for secondary analysis at PT discharge and at 6 months after therapy (**Figure 7**): 1. Telerehabilitation (TR); 2. In-

person (IP: control); 3. Hybrid 1 (H1: Telerehabilitation to in-person); 4. Hybrid 2 (H2: In-person to telerehabilitation).

Treatment was progressed based on therapy response and functional goal progress was monitored throughout rehabilitation. When patients reported difficulty with compliance, adaptations to home program performance were prescribed with patient input to increase adherence. When patients canceled or failed PT visits, they were contacted via phone call or email by clinic staff to reschedule and if the patients did not respond they were again contacted by the treating PT. Developing independent management for continued self-care after discharge was a primary focus of treatment, and ≥90% independence with self-care as determined by the global rating scale was the primary discharge criteria. Individualized functional goal attainment also factored into the discharge decision. If patients reported unwillingness to continue with PT or did not respond after 5 contact attempts, patients were discharged from PT.

In-person Rehabilitation

The in-person rehabilitation group was considered standard care, and therefore was the control in this study. Manual interventions such as masticatory and cervical muscle soft tissue mobilization, jaw, and cervical spine joint mobilizations, and intra- and extraoral trigger point release were applied in person to improve mobility and decrease masticatory and cervical muscle tension and pain. Exercises and stretches were explained and demonstrated to participants, and during participant demonstration feedback consisted of verbal, visual and manual cues to ensure proper performance. Modalities such as ultrasound, intraoral electrogalvanic stimulation, and heat/cold packs were occasionally used to facilitate muscle tension release.

Telerehabilitation

Treatment planning, frequency, and progression for the telerehabilitation group occurred the same way as for the in-person therapy group but with virtual delivery of care. The morning of each session, the PT sent a Zoom link that participants used to join a password-protected video session at the scheduled treatment time. Because the therapist could not manually contact the participant during the sessions, verbal cues and demonstration allowed participants to self-perform necessary assessment and therapy interventions in response to directions. Participants used the cardboard Therabite range of motion scale (**Figure 10**; provided at the time of randomization and initial PT scheduling) for self-measurement of jaw movement at all visits. Specific verbal cues regarding location, hand positioning, amount of pressure, and desired feedback guided palpation and resisted testing. The therapist explained and demonstrated jaw and cervical spine exercises, stretches, and manual techniques for participant self-performance, looking for appropriate demonstration of each activity in response. Directions were given regarding proper use of home heat and ice in conjunction with the PT visit as needed.

Endpoints

Data Collection

The primary data collection endpoint occurred once data was collected for the noninferiority analysis (Aim 2) because the endpoint for Aim 1 analysis occurred after all PT evaluations were completed. The primary endpoint occurred 6 weeks after beginning PT once the OHIP-TMD questionnaire is completed for each participant. This timepoint was chosen because PT for TMD can average up to 12 weeks, and if participants have not achieved a minimal clinically important change on the OHIP-TMD[181] by the midpoint then therapy is not likely to be successful and a change must occur. Performing analysis with 6-week data maintained two treatment groups for an

adequately powered non-inferiority analysis at a clinically relevant time. Group switching based on patient preference after 6-weeks of care aligned with true clinical telerehabilitation use but resulted in unbalanced groups that cannot be used for non-inferiority analysis.

Clinical Care

Discharge from PT to independent home management occurred when patients met the primary long-term goal of patient-reported ≥90% independence with self-care according to the Global Rating Scale or when patients stopped attending therapy visits or responding to contact attempts. Functional limitations as identified by the patient history and the jaw functional limitation scale (JFLS-8) guided additional individualized short- and long-term goals as patients worked toward independent management. The nature of individualized PT means that visit numbers varied between individuals, which is consistent with usual PT care and increases generalizability of results to a true clinical population. In a 2021 retrospective study of 100 patients receiving PT for common TMDs, they averaged 9.39 visits with no significant correlation between number of visits and change in maximum mouth opening.[12] A 2019 cross-sectional study of 97 patients who received PT for disc displacement without reduction reported visit numbers ranging from 1-27 and an average of 5.5 visits with the majority (38%) at 4-6 total visits.[16]

Secondary Endpoint

The entire study ended after data collection for outcomes to be used in secondary analysis occurred. This happened 6 months after discharge, approximately 9 months after the PT evaluation assuming an average of 12 weeks for therapy duration.

Operational Procedures

Study Risks

This study involved non-invasive delivery of routine clinical care in both treatment arms. Therefore, study risks were minimal and aligned with risks associated with clinical care. These risks included possible discomfort during or after manual therapy interventions for the standard care group (in-person PT), managed by setting expectations and maintaining communication throughout therapy sessions. Other risks included possible contraindications to modality use such as ultrasound and electrical stimulation for in-person participants, managed by thorough chart and medical history review along with clear communication during modality use to minimize risks.

There were some potential risks involved with telerehabilitation delivery and digital data management. Delivering care via telerehabilitation prevented the provider from monitoring patient vital signs, directly supervising transfers or perceiving the actual amount of pressure that a patient is applying to their own muscles, risking the provider missing key signs of adverse reaction to guided therapy interventions. Zoom software security breaches during the telehealth visits could possibly occur, violating privacy and confidentiality as set forth by the Health Insurance Portability and Accountability Act (HIPAA). Using the UMN Zoom platform with password encryption and the waiting room feature[206] minimized the chance of unintended participants viewing the telerehabilitation sessions. While using REDCap for data collection and consent is HIPAA compliant due to password protection and Duo authentication requirements, a systemwide cybersecurity data breach would compromise confidentiality.

Adverse Event Reporting

Adverse events could include negative reactions to therapy and/or data security breaches as outlined above. There were no incidents involving loss of consciousness or lasting harm because of an intervention. At the time of writing, there were also no reports of data security breaches. Any such incidents would have

been reported to the senior mentor (Dr. Don Nixdorf) and the Institutional Review Board (IRB). There were also no unintended problems related to symptoms and care delivery methods, and participants were asked about such problems at each follow-up visit. Any unintended problems would have been reported to clinic supervisors with IRB reporting occurring at their discretion.

Data and Safety Monitoring Plan

Once 50% of participants needed for the Aim 2 analysis were enrolled and completed the 6-week data collection, the primary analyses for Aim 1 & 2 occurred to ensure that the processes were working properly and to assess power for conclusions at that time. Enrollment for the telerehabilitation group ended 6 weeks before it ended for the in-person group due to achieving the necessary number of Aim 2 respondents early.

Clinical site monitoring was conducted to ensure that the rights of human subjects were protected, that the study was implemented in accordance with the protocol and/or other operating procedures, and that the quality and integrity of study data and data collection methods was maintained. The PI, supervising mentor Dr. Donald Nixdorf, clinic faculty, and staff closely monitored the participants as they progressed through the study; no outside clinical site monitoring was employed for this study. Mentor meetings with Dr. Nixdorf monitored and evaluated study processes bi-monthly. Therapy documentation was based on the Standards of Practice for Physical Therapy as determined by the American Physical Therapy Association (APTA).

Data Management and Statistical Program

The PI was primarily responsible for data management in REDCap except for the input of data needed to determine therapy outcomes that require blinding. The data requiring blinding was managed by the study assistant including all digital diagnostic algorithm responses and OHIP-TMDs responses (pre-therapy and at

follow-up timepoints). Copies of signed consent forms and study information were emailed to participants. Participant data was de-identified in REDCap for analysis and only the PI and study assistant had access to identifying information for clinical care and participant reimbursement purposes. Data analysis was stored in the password-protected, HIPAA compliant UMN REDCap and Box systems. The statistical program used for analysis was R running in RStudio, version 2024.04.2+764.[209]

STATISTICAL ANALYSIS

Primary analyses followed the intention-to-treat (ITT) principle. Because ITT analyses can bias the results toward no difference, per-protocol analyses eliminating participants who never returned for follow-up but who did fill out 6-week questionnaires were performed to further evaluate the treatment effect and assess the strength of study conclusions.

Descriptive statistics compared baseline patient demographics between groups to evaluate the success of randomization by revealing group similarities and differences. Demographics included the following: age, sex, gender, race, income level, education level, baseline OHIP-TMD score, GCPS level, PHQ4 score, baseline average pain (NPRS), baseline function (GRS). Baseline mouth opening (mm), and proportion of each TMD subtype diagnosis.

Aim 1: Establish TMD PT diagnostic agreement via telerehabilitation.

Primary analysis

The presence or absence of a masticatory myalgia diagnosis was considered positive or negative accordingly, and a study assistant blinded to participant identity assigned the appropriate designation in response to the bDC/TMD algorithm-generated diagnoses. Percent (%) agreement between the OFP specialist myalgia

diagnosis (criterion reference standard) and the PT myalgia diagnosis was calculated for each participant yielding mean % agreement for diagnosis of myalgia in each group.

Prevalence was assessed to determine whether Cohen's kappa (k) or the prevalence-adjusted bias-adjusted kappa (PABAK) statistic should be used, since k is subject to the kappa paradox based on very high or low diagnostic prevalence.[121] The kappa estimate and two-tailed confidence intervals at 5% significance determined PT diagnostic reliability as compared to the criterion reference standard in each group after correcting for chance (hypotheses 1a & 1b). The lower limit difference between the telerehabilitation and in-person group confidence intervals was assessed to determine noninferiority of telerehabilitation diagnostic agreement (hypothesis 1c; difference <0.1).

Secondary analyses

Diagnostic agreement for other diagnoses**:** Assessing groupwise diagnostic agreement for all other subtype diagnoses using k and PABAK further quantified the effectiveness of telediagnosis. Considering the criterion reference diagnosis as a gold standard, calculating sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios for all subtype diagnoses explored diagnostic accuracy.

Aim 2: Determine noninferiority of telerehabilitation for individuals with TMD as compared to in-person PT.

Primary analysis

Intention-to-treat analysis was used for all participants. Therapy effectiveness was described for each participant as a binary positive/negative success outcome after 6 weeks. A successful therapy result was defined as a change in OHIP-TMD self-reported quality of life raw score ≥ 6.9 units. This value was chosen because it is

the minimum clinically important difference on the OHIP-TMD scale as reported by Yule et al.[181] The proportion of therapy success in the telerehabilitation group (P_T) minus the proportion of therapy success in the in-person control group (P_C) yielded the proportional success difference between groups to be compared against a pre-set 10% noninferiority margin ($P_T - P_C \leq -0.1$). While noninferiority tests are one-sided, the approach recommended by the CONSORT statement for reporting noninferiority trials is to perform a two-sided test to generate two-sided confidence intervals.[124] Normality was assessed by visualized using histograms and Q-Q plots. A t-test comparing group proportions established a point estimate and 95% confidence interval for the difference between groups for noninferiority analysis, with in-person care as the reference. The lower limit of the confidence interval must be between 0 and -0.1, to have evidence to reject the null inferiority hypothesis. A per-protocol analysis consisting only of participants who attended ≥2 PT visits was performed to assess the sensitivity of the noninferiority results.

Additional assumptions for running a noninferiority test include constancy and assay sensitivity. The constancy principle is that the control or standard care treatment effect remains the same over time. Constancy cannot be tested but must be discussed as a possible study limitation. Assay sensitivity is the consistent ability to demonstrate a difference between active treatment and no treatment over time. Assay sensitivity of the OHIP-TMDs scale has not yet been demonstrated in the literature as most studies using this scale are cross-sectional in design.[198,199] However, there is no other region-specific functional scale that has been validated or assessed for responsiveness to change in this population.[198] This fact is another reason that secondary analyses will contribute data of interest for future research, and the assay sensitivity assumption will be discussed as a study limitation.

Secondary analyses

Secondary outcomes assessed included number of visits, patient satisfaction, and mean change from baseline in OHIP-TMD scores, MMO, average NPRS level, GRS, and EQ-5D-5L. The variables were assessed for normality using histograms and Q-Q plots and means and standard deviations were calculated in each group. For the mean change scores, within-group clinical significance was assessed for change from baseline by comparing to the MCID for each variable and Cohen's d effect sizes ($CI_{95\%}$) quantified effectiveness. Between-group differences were assessed using t-tests or Mann-Whitney tests depending on the results of normality testing. For the mean change scores, Cohen's d standardized effect sizes and the $CI_{95\%}$ were calculated comparing TR to IP care after 6 weeks for each outcome. Cohen's d effect sizes were categorized as 0.2=small, 0.5=moderate, and 0.8=large.

Additional noninferiority assessment**:** Each effect size $CI_{95\%}$ lower limit was compared to a standardized noninferiority margin created by dividing the relevant MCID by the pooled standard deviation. The MCID for each variable was taken from the relevant literature and were identified as follows: OHIP-TMD change = 6.9[181], MMO = 2.54 mm[92], moderate change in NPRS = 0.60[92], GRS change = 2.9%[191], EQ-5D-5L change = 0.04.[210] As the study was only powered for the primary analysis, power for these analyses was assessed to further quantify the conclusions.

Covariate effects**:** The study was also not powered to assess for the effect of covariates. However, whether potential covariates are influencing the outcomes data was of interest as a secondary analysis. To do this, Omnibus univariate correlation testing of potential covariates using ANOVA Type III Sums of Squares was performed using $p<0.05$ as the cutoff for inclusion. Potential covariates included age, gender, number of visits, GCPS classification, PHQ4 level, baseline OHIP-TMDs score, baseline mouth opening, baseline GRS rating, baseline NPRS average pain rating, and TMD subtype diagnosis. Stepwise model selection using AIC as criteria

produced a full linear model for noninferiority analysis using logistic regression adjusting for the covariates that significantly influenced the outcome data. The estimated odds ratio for each variable included in the model quantified the odds of therapy success for the presence of each binary variable or for an increase of 1 for each continuous variable, and p-values quantified significance.

Aim 3: Explore telerehabilitation feasibility and long-term outcomes.

Intervention Mapping

Intervention mapping followed a three-stage approach informed by the Behavior Change Wheel and the Theoretical Domains Framework.[178,211]

Stage 1: Understand the Behavior

A literature review was done to examine and define the problem of TR acceptability in the population of patients with TMD. This review identified barriers to implementation that were considered during intervention development and guided the who, what, where, and when decision-making regarding adaptations to existing in-person PT protocols for this population. These barriers were used to define components of the Capability, Opportunity, Motivation (COM-B) model[212] for further consideration in future stages of mapping.

Stage 2: Intervention Content

The next step of intervention mapping involved determining which of the 9 Intervention Functions as defined by Michie et al. applied for each component of the COM-B model.[212] The functions describe different processes that influence behavior change and contribute to a more complete assessment of intervention feasibility. The final step of this stage was to consider how different policy categories surrounding TR delivery would support or impair successful behavior change.[212]

Stage 3: Intervention Delivery

Implementation strategy was assessed according to the behavior change

techniques employed and the mode of intervention delivery. Details describing techniques and delivery were taken from TR visit documentation in clinic records for the 11 participants in this feasibility study. The final map provided a comprehensive view of the TR intervention and its capacity to influence behavior change for this population.

Intervention Evaluation

The APEASE criteria was used to provide a framework for thorough assessment of telerehabilitation feasibility. Each criterion was assessed using quantitative and qualitative study data as follows:

- **Acceptability:** Responses to the final study feedback questionnaire
- **Practicability:** Responses to the final study feedback questionnaire
- **Effectiveness:** Results of noninferiority analysis and secondary analyses of functional outcomes; patient satisfaction results
- **Affordability:** Cost questionnaire data, responses to the final study feedback questionnaire
- **Side Effects:** Assessment of any adverse events, results of noninferiority analysis
- **Equity**: Subgroup analysis results assessing outcomes for different demographic groups

Long-term outcomes of telerehabilitation: future analyses

The study is ongoing for participants that have not yet been discharged from PT or who have not yet reached 6 months post-discharge. The following analyses will occur once the final study endpoints have been reached for all remaining participants.

Group interaction: To assess whether there is a group interaction that could bias the noninferiority outcome, a mixed method ANOVA will consider the within-

subjects effect of time (baseline, discharge, 6 months post-discharge) and the between-subjects (interaction) effect of group. The final model adjusted for significant covariates as described in the Aim 2 analysis section will be used as the full linear model for mixed ANOVA analysis. This analysis will occur when the 6-month post-discharge timepoint data has been collected to assess long-term effectiveness.

Assumptions for a mixed ANOVA include having a representative sample, normal distribution of residuals, homogeneity of variance for the between-subjects condition, and equal variance within-subjects (sphericity). Because the within-subjects factor violates the independent observation assumption with traditional two-way ANOVA, the mixed ANOVA must be used as it mathematically accounts for the violation. Testing for sphericity verifies whether the variation within-individuals assumption is met and must be checked as variation within individuals is more problematic than variation between individuals. Sphericity will be assessed using Mauchly's test for sphericity, and if it is statistically significant then the Greenhouse-Geisser correction will be used.

Analysis for interaction will consist of first running a type III sums of squares ANOVA on the full linear model with the interaction term specified. If the interaction term is significant, then it means that the change in functional summary score over time does differ by group. Tukey's adjustment for post-hoc analysis is included in the R code, and statistics for group means and differences between group means can be obtained from the analysis. If the interaction term is not significant, then the interaction is left out of the model and a main effects model is run instead to obtain group means for comparison. The two main effects are the effect on the dependent variable over time, and the effect on the dependent variable of group. While this noninferiority study is not powered to make conclusions about the interaction, the results of this analysis will be compared against the noninferiority analysis to further characterize the treatment effect of telerehabilitation in this population.

Cost-Effectiveness Analysis: Costs considering the societal viewpoint over a 1-year time horizon will be assessed at baseline, discharge, and 6 months after discharge for use in cost-effectiveness analysis. Cost questionnaire answers from the identified sections will quantify the following for each participant for the 6 months after the PT intervention:

Cost of managing TMD considering the following components (Sections 1-5):

- Health system costs of any care for TMD;
- Productivity losses for patients, companions during sessions, and childcare providers
- Costs of childcare and travel for the intervention provided in this study.

Sensitivity analysis considering time and transportation for each group

For each variable, the average will be calculated for each therapy group.

Effectiveness will be established as previously described based on the baseline and 12-week follow-up responses from the EQ-5D-5L questionnaire. Briefly, the response for each of the 5 questions will determine the health state and valuation will be calculated according to the 2019 United States value state data determined by Pickard et al.[203] Table 2 in the publication lists the health state valuations, and for any needed calculations the following process will be followed: "…an index-based summary score is obtained by subtracting parameter estimates for each dimension level of the health state from 1. For example, for the health state 21 354, the utility would be 1 – (0.096 + 0 + 0.101 + 0.414 + 0.299) = 0.090."[203] The difference between health state value at baseline and 12-week follow-up will be calculated for each participant to quantify change in health state, and multiplying by 0.5 will generate the QALYs gained as a result of PT for 6 months after PT. The average QALYs gained will be calculated for each therapy group.

Cost-effectiveness analysis is performed by calculating ICERs. To do this, an ICER will be calculated for each of the two cost variables. The numerator will consist

of subtracting the average costs in the IP control group from the average costs in the telerehabilitation groups. Telerehabilitation groups include TR, H1, and H2 (**Figure 7**). The hypothetical "no treatment" group (NT) will be used as an additional comparator. The denominator will consist of similarly subtracting the average QALYs gained in each group with the in-person or no therapy groups used as the reference.

$$\text{ICER} = \frac{\text{Cost}_{TR} - \text{Cost}_{IP}}{\text{QALY}_{TR} - \text{QALY}_{IP}}$$

By performing the calculation for each of the two cost variables, the resulting ICERs will quantify: 1. The general cost-effectiveness of telerehabilitation in each format; 2. The specific cost-effectiveness of telerehabilitation delivery in each format. The results will be presented in a table and visualized on the cost-effectiveness plane (**Figure 12**).

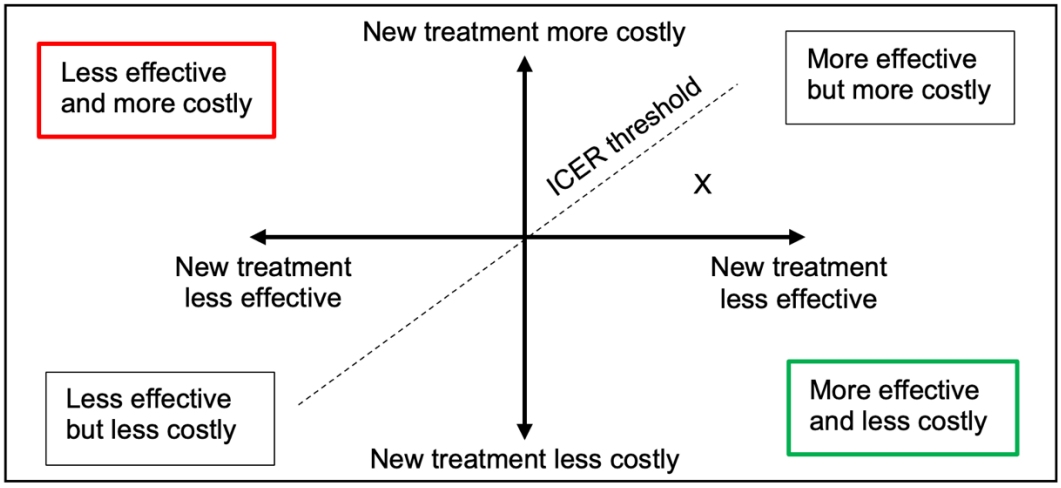

Figure 12. Cost-Effectiveness Plane Visualizing Cost-Effectiveness Analysis
----- = Maximum acceptable incremental cost-effectiveness ratio (ICER) threshold
X = ICER point estimate describing a more costly but more effective intervention above the threshold that would be recommended for adoption

Subgroup Analyses: Future analyses once the 6-month follow-up data is attained will include subgroup analyses to further explore how outcomes of telerehabilitation vary in each group. Pre-specified subgroups for exploratory analysis include sex, diagnostic subtype (muscle vs. joint primary diagnosis, disc displacement with reduction vs. disc displacement without reduction), PHQ-4 level

(low vs. high), GCPS level (0-1 vs. 2-3). A mixed ANOVA for groups at the four data collection timepoints will assess for interaction and main effects (group & time) for:

a) Therapy Duration
    i) Number of visits
    ii) Length of care
b) Functional Improvement
    i) Change in mouth opening
    ii) Pain as quantified by the NPRS
    iii) Function as quantified by the GRS
c) Patient Satisfaction
d) Costs of TMD care during the intervention time as quantified by the discharge cost questionnaire data

Chapter 4: Diagnostic agreement of telehealth and in-person physical therapy diagnosis of temporomandibular disorders (Aim 1)

Effective rehabilitation clinical care requires an accurate assessment and diagnosis upon which the treatment plan is based. An understanding of how well a telehealth evaluation aligns with the in-person standard of care is required to fully examine the effectiveness of telerehabilitation. As the outcome of a clinical evaluation is clinical diagnosis, comparing diagnostic agreement between PT and an in-person standard will answer this question. However, the control condition must be established in order to compare the telerehabilitation results. Therefore, the first aim of this thesis is to establish PT diagnostic agreement for the in-person group and also for the telerehabilitation group followed by noninferiority comparison of the results.

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ABSTRACT

Background: Temporomandibular joint disorders (TMD) are the second most common musculoskeletal cause of pain and disability in the general population, and access to care is limited. Telehealth delivery of physical therapy (PT) could increase access to care, but the reliability of telediagnosis of TMD by PT is unknown.

Purpose: The purpose of this cross-sectional reliability study was to establish in-person (IP) and telerehabilitation (TR) PT diagnostic reliability for myalgic TMD as compared to reference diagnoses provided by Orofacial Pain (OFP) specialists, and to assess noninferiority of telediagnosis by PT within a 10% margin.

Methods: Orofacial pain (OFP) specialists determined reference standard clinical diagnoses and referred participants to PT. After ethical approval, 200 patients with TMD ages 18-69 chose telehealth (n=106) or in-person (n=94) PT according to their preference. Diagnoses were based on the brief diagnostic criteria for TMD; virtual assessment guided patient self-testing with verbal cues. Primary outcomes considered diagnosis of masticatory myalgia and assessed diagnostic agreement between disciplines using percent agreement and prevalence-adjusted bias-adjusted kappa (PABAK). Ninety-five percent confidence intervals ($CI_{95\%}$) assessed significance, and a lower limit difference <10% described noninferiority of telediagnosis. Secondary outcomes were diagnostic accuracy, agreement, and noninferiority comparison for other TMD subtypes.

Results: Both groups had 95% raw agreement and almost perfect diagnostic agreement between PT and reference diagnosis of masticatory myalgia. For the IP group, myalgia was 93% prevalent and PABAK=0.89[0.76,0.97]. For the TR group, myalgia was 94% prevalent and PABAK=0.91[0.79,0.97]. The $CI_{95\%}$ lower limit difference was 0.03. Each subtype diagnosis had moderate to high values of agreement, with values of diagnostic accuracy that were similar across groups.

Conclusion: For the most common TMD diagnoses seen in clinical populations, telediagnosis by a PT was reliable and noninferior to IP diagnosis. Clinically these results indicate that remote assessment of TMD by PT is reliable and can help expand care access for this underserved population.

INTRODUCTION

Temporomandibular joint disorders (TMD) are underrecognized musculoskeletal conditions with complex etiology that place strain on the health care system. Frequently co-morbid with conditions such as headache and cervicalgia, TMD is the second most common musculoskeletal cause of pain and disability after low back pain, and one-third of people living to age 70 will experience facial pain.[4,6] The financial burden of TMD includes annual health care costs estimated at $4 billion including thousands of patient out-of-pocket dollars.[1,7] The need to improve TMD research has gained national attention, and multiple agencies have identified the urgent need to study high quality conservative care for individuals with TMD.[1,213]

Physical therapy (PT) provides effective, evidence-based treatment that can help individuals with TMD and aligns with the recommendation to start with conservative care for these conditions.[1,16,214] However, no clinical practice guideline exists yet to standardize PT diagnosis and management of TMD and patients report difficulty finding PT providers with experience treating TMD.[1] Delivering PT remotely via real-time synchronous video visits, or telerehabilitation (TR), has potential to expand access for patients with TMD but there is little to no current evidence examining the effectiveness of telerehabilitation for this population. As effective care first requires an appropriate diagnosis, the question of in-person (IP) and TR diagnostic reliability must be assessed.

In-person clinical diagnosis of TMD by dentists and PT is informed by established Diagnostic Criteria for TMD (DC/TMD), but has only been validated by dental orofacial pain (OFP) specialists.[31,45] A 2017 retrospective study by Kraus & Prodoehl demonstrated 80% overall PT diagnostic accuracy for TMJ disc displacement without reduction (DDwoR) using an MRI gold standard in a population referred to PT by dentists.[91] A masticatory myalgia diagnosis is the most common TMD subtype and has 0.90 diagnostic sensitivity among dental specialists using the

DC/TMD but has not yet been studied in PT.[1,31,38] Physical therapist assessment of musculoskeletal conditions frequently follows a movement-based framework rather than the pathoanatomic paradigm seen in orthopedic practice and dentistry, creating uncertainty regarding best practices for combining the DC/TMD with PT clinical reasoning for diagnosis of individuals with TMD.[215] Establishing a process and control data for DC/TMD diagnosis in IP PT is necessary to compare whether TR diagnosis is acceptable.

A few recent studies have examined remote diagnosis of TMD by dentists. A diagnostic agreement study from 2022 by Exposto et al. found excellent agreement between in-person and remote examination of patients with TMD for diagnoses of masticatory myalgia and TMJ arthralgia, and moderate agreement for diagnosing disc displacement with reduction (DDwR).[30] Corelhano et al. investigated the same question and found similar results using Cohen's kappa (k) in 2024 with a larger sample of patients from an OFP clinic setting while providing detailed descriptions of adjustments made for remote assessment.[32] In addition to supporting the efficacy of telediagnosis for painful TMD, these studies validated strategies to adapt existing criteria for successful remote examination of individuals with TMD.

To address the question of PT telediagnostic agreement, Hartono et al. investigated the reliability and validity of physical tests used remotely by PTs compared to IP PT diagnosis to satisfy the DC/TMD and diagnose TMD.[120] They found high inter- and intra-rater reliability for measuring jaw movement, and moderate to good agreement between remote and in-person assessment of palpation and isometric testing using Prevalence-Adjusted Bias-Adjusted Kappa (PABAK = 0.53-0.88).[120] This study reveals that PT performance of tests for TMD is valid and reliable via telehealth, though the reliability of their diagnostic outcomes remains unknown.

The advantages of using manual contact during patient assessment include a trained provider directly feeling tissue properties and delivering a standardized amount of pressure with palpation and testing, ensuring that IP care remains the standard for diagnosis. However, the convenience and availability of telerehabilitation could greatly expand access to care for individuals with TMD. Therefore, to explore one aspect of telerehabilitation effectiveness for this population, the objective of this cross-sectional study was to establish IP and TR PT diagnostic reliability as compared to reference diagnoses provided by Orofacial Pain (OFP) specialists with the following hypotheses:

1. In-person PT diagnosis will have good diagnostic agreement with an OFP specialist as defined by $k_{(IP)} \geq 0.70$.
2. Telerehabilitation PT diagnosis will have good diagnostic agreement with an OFP specialist in-person diagnosis as defined by $k_{(TR)} \geq 0.70$.
3. A TR PT diagnosis will be noninferior to IP PT diagnosis within a 10% margin.

METHODS

Participants

This cross-sectional reliability study was embedded within an open-label prospective cohort trial at the University of Minnesota TMD, Orofacial Pain & Dental Sleep Medicine Clinic in Minneapolis, MN. Patients were allocated to groups based on their preference for PT care delivery format, making it an open-label preference trial. All work was carried out with approval by the University of Minnesota Institutional Review Board (IRB ID: STUDY00015476) and the trial was registered on clinicaltrials.gov (NCT05318313).

A convenience sample of patients ages 18-69 diagnosed with TMD and referred to PT by an OFP specialist was recruited and enrolled between June 2022-June 2024. Study inclusion/exclusion criteria (**Table 1**) were aligned with those used

to validate the original DC/TMD[31] and intended to capture a population of patients likely to benefit from PT while ensuring legal compliance with MN telerehabilitation legislation. All participants in this study received and signed an informed consent for trial participation and for delivery of PT clinical care. After enrollment, participants were allowed to choose whether they wanted to have their PT evaluation done IP or via TR. Participants then completed baseline questionnaires and the 4-item Patient Health Questionnaire for Anxiety and Depression (PHQ-4) for additional demographic and Axis-II assessment.

Diagnostic Procedures

Paired observations consisted of two providers independently evaluating the same patient at different times. The referring OFP specialist (criterion reference) evaluated first in the standard IP format before enrollment, followed by the PT (blinded to the specialist diagnosis) after enrollment. The PT evaluation occurred at the patient's convenience within standard clinic hours, anytime from later the same day to 3 weeks later in either the IP or TR format chosen by the patient (**Figure 13**). Standardized patient diagnoses could have included masticatory myalgia, TMJ arthralgia, DDwR, DDwoR, degenerative joint disease (DJD), and TMD headache (TMD HA). The primary outcome variable was the diagnostic presence of masticatory myalgia as compared to the criterion reference standard diagnosis. The secondary outcome variable for Aim 1 was the diagnostic presence of the remaining TMD subtypes to be used in secondary analyses further quantifying diagnostic agreement.

Criterion reference diagnosis

The five OFP specialists who referred participants to PT in this study (DRN, SK, CH, GA, EMF) had previously completed advanced training in DC/TMD-informed diagnosis and treatment of TMD and OFP with many years of specialty practice in this population. The setting was an academic teaching clinic, and OFP residents also

participated in evaluating and referring patients to PT. As the full DC/TMD evaluation process is time-consuming and difficult to employ in the clinic, a shortened version titled the Brief DC/TMD (bDC/TMD) was used to standardize diagnosis.[63] A blinded evaluator retrospectively filtered the OFP specialist clinical assessment data through a decision tree informed by an unpublished preliminary draft of the bDC/TMD (**Figure 8**) to determine the reference standard diagnosis for comparison in the diagnostic agreement analysis. Before the beginning of the study, the PI met with clinic staff, OFP specialists, and resident trainees to explain the study objectives and procedures during a 1-hour training to clarify inclusion/exclusion criteria, recruitment process and diagnostic procedures, and were reviewed during daily clinic team meetings as needed to standardize assessment.

Physical Therapy diagnosis

The evaluating PT (EK) had sixteen years of experience exclusively treating OFP and TMD at multidisciplinary clinics alongside dental OFP specialists. The PT evaluation began with a thorough patient interview informed by bDC/TMD patient history questions to determine symptom location, onset, intensity, duration, aggravating and alleviating factors, and functional limitations. Questions about oral parafunctional habits, sleep habits, stress level, occupation and hobbies, previous treatment, medical history, trauma history, and comorbidities delineated contributing factors.

Objective PT examination included tests and measures used in bDC/TMD diagnosis. In-person evaluation used a vertical stainless-steel millimeter (mm) ruler to measure maximum mouth opening (MMO; **Figure 3),** bilateral laterotrusion (**Figure 4**) and protrusion. Palpation of masseter and temporalis muscles (**Figure 2**) and the TMJ assesses for presence of familiar pain and/or joint noises. Palpation of other areas including intraoral lateral and medial pterygoids (**Figure 2**), posterior and sub-

mandibular regions, and cervical musculature yielded information to further identify the presence or absence of other diagnoses and direct individualized PT interventions. Additional evaluation components included static (isometric) and dynamic (resisted movement) tests of jaw movements to delineate muscle vs. joint involvement,[74] passive accessory motion testing of the TMJ to assess hypomobility, and assessment of posture and the cervical spine.

In this study, an impairment-based classification system combined with the bDC/TMD classification method guided determination of the PT diagnosis. A PT decision tree (**Figure 9**) formulated from recommendations for PT application of the DC/TMD by Harrison et al.,[45] and modeled after the impairment-based PT practice guideline for neck pain[205] classified patients by mobility vs. motor coordination deficits based on objective testing results. From there joint vs. muscle deficit classifications and additional findings were filtered through the bDC/TMD-informed decision trees (**Figure 8)** to guide PT diagnosis.

In-person PT diagnosis: Patients came to the UMN TMD, Orofacial Pain & Dental Sleep Medicine clinic for a 1-hour in-person evaluation.

Telerehabilitation PT diagnosis*:* Each 1-hour PT evaluation was performed via Zoom software (Zoom Video Communications; San Jose, CA, version 5.7.8) using password protection to ensure confidentiality during patient visits.[206] To perform the objective assessment in the telerehabilitation group, the PT used verbal cues, pictures and demonstration to guide patient self-testing (**Figure 10**).

- **Range of motion**: Each patient in this group received a cardboard TheraBite Range of Motion scale[216] upon enrollment (**Figure 11**). These scales are reliable for self-measurement with an intraclass correlation coefficient of 0.92 (95% CI: 0.88, 0.95) compared to a gold standard clinician measurement.[208] During the telerehabilitation visit, the patient positioned themselves perpendicular to the camera to assess jaw opening

and protrusion measurements and facing the camera for laterotrusion to ensure visualization of the TheraBite scale numbers. If the patient did not have the scale, stacked fingertips were used to screen for hypomobility as outlined in the methods reported by Corelhano et al.[32]

- **Palpation:** The therapist gave direction regarding location and amount of pressure for palpation of the TMJ and all muscles to be assessed looking for reproduction of familiar pain. To standardize palpation pressure, participants were directed to use 1 finger applying 2-3 kg of pressure (enough pressure to achieve nail bed blanching) for 3 seconds.
- **Additional testing:** The therapist observed posture and demonstrated and verbally cued self-performance of static, dynamic, and accessory joint tests.

Statistical Analysis

All analyses were performed in R running in RStudio, version 2024.04.2+764.[209] The GRRAS 2011 guidelines for reporting reliability and agreement studies were used in preparation of this manuscript.[217]

Study Power

The sample size for this cross-sectional study was based on the *a priori* power analysis for the prospective clinical trial requiring 89 participants in each group after 6 weeks of care. Anticipating 15% attrition for the prospective cohort, enrollment targets were set at 105 participants in each group and ended when 89 participants completed 6-week outcomes. As the one-way alternative hypothesis states that $k_A \geq 0.7$, the null hypothesis can be any value $k_0 < 0.7$. The *a priori* power analysis assuming an 80% positive rate of myalgia diagnosis by both raters at 5% significance revealed that for ≥90 participants, there will be 90% power to determine $k \geq 0.70$ assuming $k < 0.38$ under the null.

Primary analyses: diagnostic agreement for masticatory myalgia

Percent (%) agreement between the reference standard and the PT diagnosis regarding presence or absence of myalgia was calculated for each participant yielding mean % agreement for PT diagnosis of myalgia in each group. Prevalence and bias were assessed and the prevalence-adjusted bias-adjusted kappa (PABAK) statistic was calculated in addition to Cohen's kappa (k), since k is subject to the kappa paradox based on very high or low diagnostic prevalence.[121] The kappa estimate and two-tailed 95% confidence intervals ($CI_{95\%}$) at 5% significance determined PT diagnostic reliability as compared to the criterion reference standard in each group after correcting for chance (hypotheses 1 & 2). The lower limit difference between the PABAK telerehabilitation and in-person group confidence intervals was assessed to determine noninferiority of telerehabilitation diagnostic agreement (hypothesis 3; the absolute value of the $CI_{95\%}$ lower limit difference must be ≤0.1 to show noninferiority). The strength of agreement was interpreted as ≤0.2=poor, 0.21-0.4=fair, 0.41-0.6=moderate, 0.61-0.8=substantial, and 0.81-1=almost perfect.[218]

Secondary analyses: diagnostic agreement and accuracy for all diagnoses

Groupwise diagnostic agreement for all other subtype diagnoses was calculated using % Agreement, k, and PABAK to further quantify the effectiveness of telediagnosis. Confidence intervals assessed significance, and noninferiority was assessed by comparing the lower limits of the PABAK intervals across groups for each subtype diagnosis. Considering the criterion reference diagnosis as a gold standard, additional measures of diagnostic accuracy were calculated for all subtype diagnoses in each group: sensitivity (true positives/(true positives + false negatives)), specificity (true negatives/(true negatives + false positives)), positive predictive values (true positives/(true positives + false positives)), negative predictive values

(true negatives/(true negatives + false negatives)), positive likelihood ratios (sensitivity/(1- specificity)), and negative likelihood ratios ((1- sensitivity)/specificity), with a $CI_{95\%}$ for each.

RESULTS

A sample of 200 patients who had criterion reference evaluations with one of the four experienced OFP specialists enrolled in the study and completed the evaluation, with 94 participants choosing the IP group and 106 choosing TR. There were no adverse events reported for any patients during or after any evaluations. Demographics analysis of the preference-allocated groups revealed that the only significant difference was age, with a difference of 4 years between groups. See **Table 2** for the full report of group demographics.

The distribution of diagnoses in each group was similar. Masticatory myalgia was the most prevalent diagnosis with no statistically significant difference in prevalence rate between groups. Most subtypes were either highly or minimally present in each group, with no significant difference of subtypes between groups as shown in **Figure 14**. Six participants had only 1 diagnosis (4 TR participants, 2 IP participants). All other participants had ≥2 subtype diagnoses, including masticatory myalgia for 82 TR participants and 75 IP participants. The average time lapse from reference diagnosis to PT diagnosis was 18 days for the IP group and 22 days for the TR group, with no statistical difference between groups (p=0.23).

Diagnostic Agreement

For the primary outcome of diagnosing masticatory myalgia, both TR and IP control had high raw agreement and substantial diagnostic agreement with the in-person reference standard according to kappa (PABAK) coefficients and $CI_{95\%}$ lower limits well above the hypothesized threshold of k≥0.70, thereby supporting hypotheses 1 and 2. Noninferiority analysis of the difference between masticatory

myalgia PABAK $CI_{95\%}$ lower limits yields 0.03, which is within the predetermined 10% noninferiority margin and supports hypothesis 3 (**Table 3**). Values of Cohen's kappa and raw agreement are presented alongside PABAK in **Table 3**, and contingency tables showing all agreement and disagreement data are in **Table 4**.

The secondary analysis of agreement for all other subtypes considering PABAK revealed substantial agreement for DDwoR and DJD in both groups, and moderate agreement for diagnosing TMJ arthralgia, DDwR, and TMD HA. Because TMD HA was only moderately prevalent, the PABAK correction did not improve the estimate for this diagnosis. Each evaluation group had a range of moderate to almost perfect PABAK coefficients, from 0.47-0.91 in the TR group and 0.51-0.89 in the IP group. TR diagnosis of DDWoR and DJD along with IP DJD diagnosis all met the $k \geq 0.70$ hypothesis. Noninferiority comparison revealed that TR diagnosis was noninferior to IP for all subtypes except for TMJ arthralgia. See **Table 3** for results of all diagnostic agreement analyses.

Diagnostic Accuracy

High sensitivities and modest specificities were evident in both groups for diagnoses of masticatory myalgia, TMJ arthralgia, DDwR, and TMD HA. The remaining diagnoses of DDwoR and DJD showed the reverse with high specificities and low to modest sensitivities. Comparative analysis of sensitivity and specificity is presented for each diagnosis across groups in **Figure 15**. Values of sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios are reported in **Table 5** along with $CI_{95\%}$ for each.

DISCUSSION

This study examined the reliability of TMD diagnosis by a PT at a multidisciplinary clinic and established agreement in the IP control group and the experimental TR group. Comparison between these conditions assessed the

effectiveness of PT diagnosis via telehealth. The primary outcome of interest was diagnosis of masticatory myalgia because it is the most common singular diagnosis of painful TMD in clinical populations yet has no specific mechanism underlying the condition, creating diagnostic uncertainty.[1]

The sample captured in this study reflects the characteristics of populations with TMD and there are similar demographics between groups despite the lack of randomization. Both groups were predominantly female and white, which aligns with the socio-demographics reported by the National Academies of Science, Engineering and Medicine from the NHIS 2017-2018 dataset.[1] There were lower numbers of ethnically and racially diverse participants and higher numbers of participants in each group with college and post-professional degrees than seen in the NHIS 2017-2018 dataset[1] likely due to the academic clinic setting for the study. The most prevalent diagnosis was masticatory myalgia followed by TMJ arthralgia, highlighting that patients with pain are more likely to seek care. The IP group was on average younger than the TR group, which was likely related to many being students that were already on campus for educational purposes, thus choosing IP care due to the convenience of the on-campus clinic. The groups were not significantly different regarding pain levels, mouth opening, chronic pain and anxiety/depression levels, and distribution of diagnoses. Overall, any effect of preference bias in group selection did not create other systematic differences that would affect the strength of study conclusions.

Diagnostic agreement

The lack of having a gold standard for all TMD diagnoses leaves diagnostic agreement as the best option for investigating this research question, however kappa values can be difficult to interpret and assess for significance.[121] Kappa values are subject to the kappa paradox when there is too much agreement, so the very high prevalence of a condition like masticatory myalgia will result in a low k coefficient

requiring the PABAK adjustment. Yet PABAK assesses a hypothetical situation that is uninformative on its own, and traditional hypothesis testing for significance only provides information about whether the true value is different from the selected null value. Presenting all results including raw agreement, Cohen's k and PABAK with corresponding $CI_{95\%}$ gives a complete reflection of reliability and the factors that influence it.

The high prevalence of masticatory myalgia in both groups necessitated analysis using PABAK which yielded almost perfect diagnostic agreement in both PT evaluation groups with narrow confidence intervals and clear noninferiority of a TR diagnosis. These significant results validate the use of the bDC/TMD by PT to diagnose masticatory myalgia in either format. These results are consistent with the initial DC/TMD validation results and previous studies of telediagnosis by dental providers[30-32] and support TR as a feasible clinical option for PT assessment of the most common painful TMD condition. Noninferiority of diagnosing myalgia via TR evaluation compared to standard IP assessment is compelling evidence supporting telehealth use to improve care access for this population.

For pain-related disorders of TMJ arthralgia and TMD HA, agreement was moderate and lower than found in previous studies.[30-32] Clinic procedures did not always allow for the reference and PT evaluations to occur on the same day, leading to a time lapse during which patients would sometimes implement self-care or other specialist recommendations before starting PT. Inter-observer reliability of TMJ lateral pole palpation is already known to be poor[75] so the evaluation time delay could have influenced evaluation results to further decrease diagnostic agreement for TMJ arthralgia in both groups. Combined with the subjectivity of patient self-assessment for identifying pain in the small area of the TMJ lateral condyle, these factors explain the low agreement and inferiority of a TR diagnosis of TMJ arthralgia. However, the presence or absence of these conditions likely will not change the PT

care already being considered for any concurrent diagnoses of movement disorders and muscle pain.

For disc disorders and DJD, agreement was moderate to substantial and similar between groups. These results align with DC/TMD validation results for IP diagnosis of disc disorders and previous studies for remote diagnosis of disc disorders.[30-32] The presence of jaw clicking is an imperfect criterion to diagnose a reducing disc, so the DC/TMD and bDC/TMD use clicking as the clinical indicator of DDwR and recommend imaging as the gold standard for diagnosis.[31,63] In this study the PT was blinded to pre-existing diagnostic information which could explain the moderate agreement seen for PT diagnosis of DDwR in this study. There was still substantial agreement for diagnosing DDwoR and DJD, and a TR diagnosis of each met the hypothesis for agreement. Obtaining imaging for each patient is unnecessary and unrealistic, which supports PT use of the bDC/TMD criteria in both IP and TR formats for these diagnoses even without imaging information available.[63]

Diagnostic accuracy

There is no available gold standard for every TMD subtype. Given this, we considered the OFP specialist diagnosis as a reference standard for analysis of TR diagnostic accuracy. Overall, each diagnosis had similar values of sensitivity and specificity across groups, indicating no major groupwise systematic differences in accuracy level and supporting the conclusion of TR noninferiority. With conservative, noninvasive interventions like those used in PT, the implications of a false positive or negative are less concerning as all interventions are reviewed and adjusted at each visit depending on patient response.

Painful TMD subtypes

The high sensitivity values for masticatory myalgia, TMJ arthralgia, and TMD HA show that the diagnostic criteria consistently identify the conditions when they

were present. While the low specificity values for myalgia and TMJ arthralgia reveal a tendency toward false negatives, this inverse relationship is common, and their high positive predictive values still indicate strong clinical utility. Positive likelihood ratios for these diagnoses mean that a positive diagnosis will slightly improve the likelihood of actually having TMJ arthralgia, and that it will increase the likelihood of having myalgia and TMD HA by almost two- and three-fold. Overall, PT diagnostic accuracy analysis reveals that using the bDC/TMD will correctly identify painful TMD conditions, and the same considerations exist regarding false negatives regardless of evaluation format.

Intra-articular TMD subtypes

Diagnostic accuracy for these subtypes varied along with prevalence. The less prevalent diagnoses of DDwoR and DJD had low sensitivities and high specificities, indicating a greater chance of having false positives but a negative diagnosis is likely a true negative. High positive likelihood ratios indicate that a positive diagnosis considerably increases the likelihood of having DDwoR or DJD, especially with IP diagnosis, but very wide confidence intervals temper the significance of this finding. The more prevalent diagnosis of DDwR had high sensitivities and moderate specificities along with high positive predictive values, indicating good clinical utility of a positive diagnosis despite its lower values of diagnostic agreement. Given that an imaging gold standard does exist for diagnosis of these conditions and that conservative care minimizes the consequences of a false positive, this evidence supports PT use of the bDC/TMD to adequately diagnose intra-articular TMD conditions in either format as long as consideration is given to the possibility of identifying false positive diagnoses.

Limitations

One clear limitation of telediagnosis is the need to rely on patient self-assessment which is subject to response bias and variability due to the subjective nature of verbally guiding self-testing. Fear or uncertainty may have influenced response to palpation or patients being afraid to self-palpate or resist movement with appropriate pressure or confidence. For these reasons, patient education and establishing trust and therapeutic alliance is vitally important during a TR PT evaluation. Having only one PT evaluator in this study standardized delivery of patient education and evaluation performance across groups, but future research using multiple trained and calibrated PT providers is needed for evidence of generalizability.

Physical therapists are autonomous, skilled healthcare providers who provide evidence-based care for musculoskeletal conditions and are independently capable of diagnosis. The choice made in this study to use the OFP specialist as the reference diagnosis could imply that PT diagnosis is inferior to that of a dental specialist in multidisciplinary care. However, in this case the choice was made because there is not yet a PT clinical practice guideline for TMD diagnosis and the only available diagnostic criteria has only been validated by dental specialists. These results are needed to guide PT application of these criteria and to support widespread standardization of the role of PT in multidisciplinary care for individuals with TMD.

The time lapse to PT diagnosis must be considered as a limitation and a possible confounding factor. Diagnostic agreement results are more meaningful when the assessments are done on the exact same participant, so the time delay of up to 3 weeks between the reference and PT evaluations could have introduced variability in symptom presentation that may increase the chance of disagreement. However, previous research has demonstrated that variability exists even when

testing patients on the same day. The initial RDC/TMD Axis I validation revealed Fleiss kappa coefficients ranging from k=0.55-0.63 for the common TMD diagnoses and lower values at k=0.13-0.43 for the less common diagnoses when patients were assessed by multiple examiners within the same day, leading to the validation project that updated and created the current DC/TMD guidelines.[219] In a different study, multiple examiners performing intraoral quantitative sensory testing exhibited variability as shown by intra-examiner intraclass correlation coefficients ranging from 0.10-0.62.[220] In this study, the time delay did not seem to be a confounding factor for the primary outcome of diagnosing masticatory myalgia. The natural variation inherent with testing people and restrictions of self-testing may be more responsible for disagreement than time delay.

Finally, there were study limitations created by performing an effectiveness study in a true clinical population of patients with TMD. By including participants with multiple TMD diagnoses and overlapping co-morbidities beyond those identified in the exclusion criteria, there were possible confounding factors that could have impacted diagnosis and assessment results. However, restricting the study population to individuals with a single diagnosis would not have been feasible or realistic in this effectiveness study given that only 6 participants had a single diagnosis. It was also important to see how well the DC/TMD works to classify patients with co-morbidities since there is no criteria addressing overlapping pain from cervical or other structures in the guidelines. Assessing diagnostic agreement within this real-life context is necessary for translation of results to actual clinical care.

CONCLUSION

This study contributes to the body of research exploring telehealth feasibility and progressing toward the standardization TMD diagnosis by a PT. At the time of

writing, this was the first study to examine the use of the bDC/TMD by PTs and to examine the utility of TR in a clinical setting for PT diagnosis of individuals with TMD. With the rapid adoption of virtual services seen since the onset of the COVID-19 pandemic, these results are clinically significant in that they clearly support the use of bDC/TMD criteria by PTs via TR as a viable option to diagnose masticatory myalgia, the most common form of painful TMD, in a critically underserved population. These results align with previous research while investigating the specific condition of PT diagnosis as compared to an OFP specialist reference diagnosis, which was previously unknown in this context and is important for collaboration in multidisciplinary care. Future investigation of standardized protocols for IP and TR TMD assessments combining the bDC/TMD and the PT movement system paradigm is warranted, especially with multicenter designs, to investigate generalizability.

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Table 1. Study Inclusion & Exclusion Criteria

Inclusion Criteria	Exclusion Criteria	
18-70 years old	No location in MN for visits	<u>Facial/Jaw pain secondary to:</u> Neuropathic Pain Fibromyalgia Rheumatoid Arthritis Dystonia/movement disorder Fractures/trauma Malignancies
≥1 TMD subtype diagnosis	3rd trimester of pregnancy	
Email & device for telehealth	Post-surgical patient	
Access to transportation	GCPS: Level 4	
Can provide informed consent	Current substance abuse	

TMD = Temporomandibular Disorder; GCPS = Graded Chronic Pain Scale

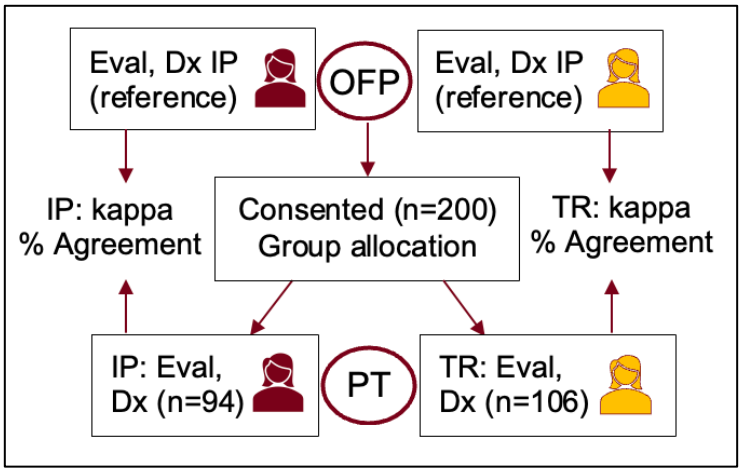

Figure 13. Study flow for diagnostic agreement and accuracy assessment. Dx=Diagnosis; IP=In-Person; TR=Telerehabilitation; OFP = Orofacial Pain specialist; PT=Physical Therapist

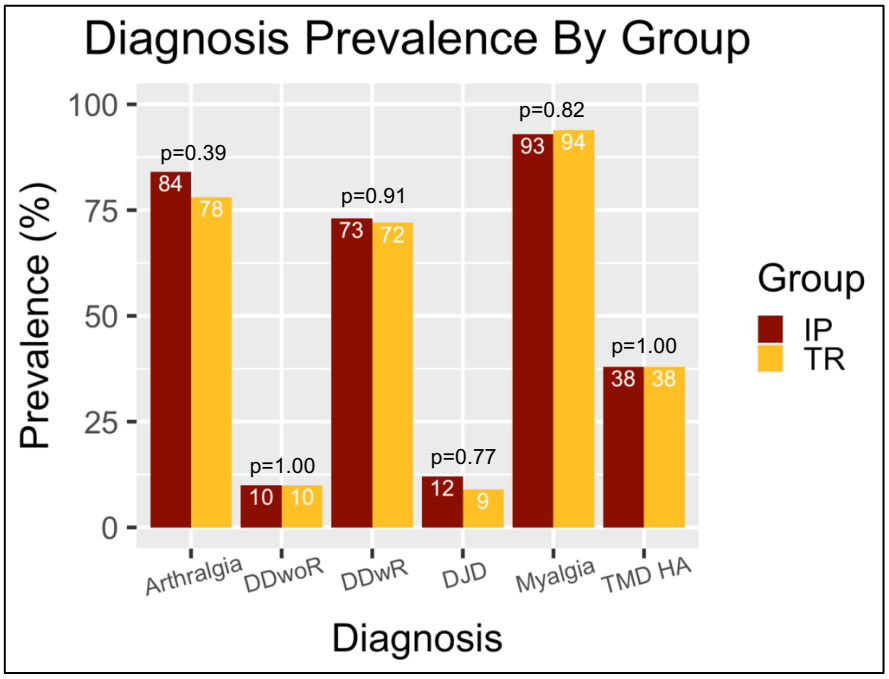

Figure 14. Diagnostic prevalence of each TMD subtype across physical therapy evaluation groups. IP = In-Person; TR = Telerehabilitation; DDwoR = Disc displacement without reduction; DDwR = Disc displacement with reduction; DJD = Degenerative Joint Disease; TMD HA

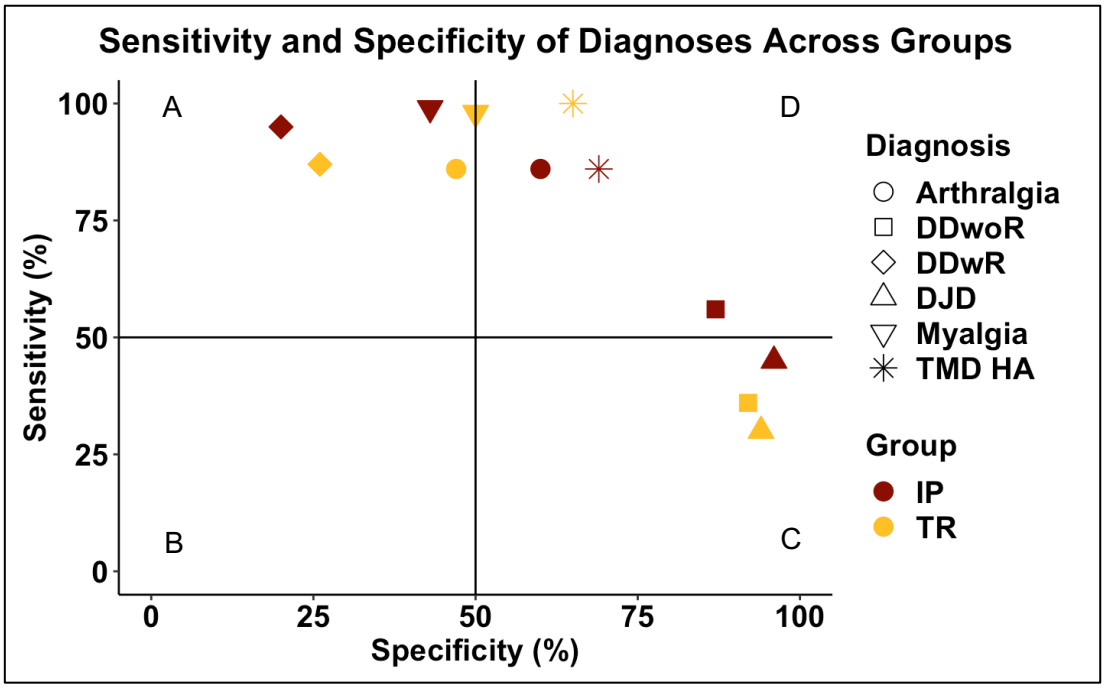

Figure 15. Each quadrant is labeled at the area representing its level of accuracy for interpreting results: A = True positive, False negative; B = False positive, False negative; C = False positive, True negative; D = True Positive, True negative. DDwoR=Disc displacement without reduction; DDwR=Disc displacement with reduction; DJD=Degenerative Joint Disease; TMD HA=Headache due to TMD; IP=In-person; TR=Telerehabilitation

Table 2. Demographics of each physical therapy evaluation group and p-values for group comparison

		Telerehabilitation group (n=106)	In-Person group (n=94)	p-value
Age in years; mean(range)		36.9 (19-69)	32.5 (18-69)	0.02*
Gender n(%)	Male	15 (14%)	10 (11%)	0.59
	Female	86 (81%)	80 (85%)	0.58
	Non-Binary	5 (5%)	4 (4%)	1.00
Ethnicity n(%)	Hispanic/Latino	1 (1%)	3 (3%)	0.53
	Not Hispanic/Latino	103 (97%)	89 (95%)	0.59
	Unknown	2 (2%)	2 (2%)	1.00
Race n(%)	American Indian	2 (2%)	1 (1%)	1.00
	Asian	11 (10%)	13 (14%)	0.59
	Black/African American	8 (8%)	1 (1%)	0.06
	Prefer no answer	3 (3%)	1 (1%)	0.70
	White	82 (77%)	78 (83%)	0.42
Education n(%)	High school	8 (7%)	4 (4%)	0.50
	Some college	23 (22%)	20 (21%)	1.00
	College grad	41 (39%)	32 (34%)	0.59
	Graduate/post-professional	34 (32%)	38 (41%)	0.28
Income n(%)	Low	18 (17%)	17 (18%)	0.99
	Middle	43 (41%)	31 (33%)	0.34
	Upper	32 (30%)	39 (42%)	0.13
	Prefer no answer	13 (12%)	7 (7%)	0.37
Functional Measures mean(SD)	MMO (mm)	45.8 (6.8)	44.6 (7.6)	0.27
	Average Pain (1-10)	3.0 (2.0)	3.1 (1.8)	0.76
	Highest Pain (1-10)	5.6 (2.1)	5.5 (2.0)	0.80
	GRS (0-100)	79.5 (23.1)	84.2 (17.0)	0.10
Axis-II Measures mean(SD)	GCPS (0-3)	0.78 (1.1)	0.69 (1.1)	0.57
	PHQ-4 (0-12)	3.0 (2.7)	3.2 (2.9)	0.72

*Significant at $p<0.05$; MMO = Maximal mouth opening; GRS = Global rating scale
GCPS = Graded Chronic Pain Scale; PHQ-4 = Patient Health Questionnaire for Anxiety & Depression

Table 3. Telerehabilitation and in-person physical therapy analysis of diagnostic agreement with an in-person reference diagnosis for all TMD subtypes with noninferiority analysis comparing lower limits of PABAK 95% confidence intervals

Diagnosis	Telerehabilitation group n=106			In-Person group n=94			Non-inferiority
	% Agree	k [$CI_{95\%}$]	PABAK [$CI_{95\%}$]	% Agree	k [$CI_{95\%}$]	PABAK [$CI_{95\%}$]	
Myalgia	95%	**0.52** [0.15,0.89]	**0.91** [0.79,0.97]	95%	**0.52** [0.15,0.88]	**0.89** [0.76,0.97]	**0.03***
TMJ Arthralgia	74%	**0.14** [-0.07,0.35]	**0.47** [0.28,0.63]	83%	**0.19** [-0.06,0.44]	**0.66** [0.48,0.80]	**0.20**
DDwR	75%	**0.34** [0.14,0.54]	**0.49** [0.30,0.65]	79%	**0.46** [0.25,0.66]	**0.57** [0.38,0.73]	**0.08***
DDwoR	86%	**0.27** [0.00,0.54]	**0.72** [0.55,0.84]	84%	**0.32** [0.06,0.58]	**0.68** [0.50,0.82]	**0.05***
DJD	88%	**0.25** [-0.04,0.54]	**0.75** [0.60,0.87]	90%	**0.47** [0.18,0.77]	**0.82** [0.65,0.92]	**0.05***
TMD HA	78%	**0.59** [0.45,0.72]	**0.57** [0.38,0.71]	76%	**0.52** [0.35,0.68]	**0.51** [0.31,0.68]	**0.07***

k = Cohen's kappa; PABAK = Prevalence-Adjusted Bias-Adjusted Kappa; % Agree = % Agreement; $CI_{95\%}$ = 95% Confidence Interval; TMJ = Temporomandibular Joint; DDwR = Disc displacement with reduction; DDwoR = Disc displacement without reduction; DJD = Degenerative Joint Disease; TMD HA = Headache due to TMD
*Noninferiority as defined by $|TR_{LL}\text{-}IP_{LL}<0.1|$

Table 4. Contingency table presenting agreement data as numbers of patients with positive vs. negative diagnoses for each subtype by rater, comparing PT diagnosis to Orofacial Pain specialist reference diagnosis in each PT evaluation group

		Telerehabilitation group			In-person group		
		In-person Criterion Reference diagnosis (n)			In-person Criterion Reference diagnosis (n)		
	PT diagnosis (n)	+	-	Total	+	-	Total
Masticatory myalgia	+	98	3	101	86	4	90
	-	2	3	5	1	3	4
	Total	100	6	106	87	7	94
TMJ Arthralgia	+	72	17	89	75	12	87
	-	11	6	17	4	3	7
	Total	83	23	106	79	15	94
DDwR	+	65	16	81	59	10	69
	-	11	14	25	10	15	25
	Total	76	30	106	69	25	94
DDwoR	+	4	8	12	5	11	16
	-	7	87	94	4	74	78
	Total	11	95	106	9	85	94
DJD	+	3	6	9	5	3	8
	-	7	90	97	6	80	86
	Total	10	96	106	11	83	94
TMD HA	+	40	23	63	31	18	49
	-	0	43	43	5	40	45
	Total	40	66	106	36	58	94

+ = Diagnosis present; - = Diagnosis absent

DDwR = Disc displacement with reduction; DDwoR = Disc displacement without reduction; DJD = Degenerative Joint Disease; TMD HA = Headache attributed to TMD

Table 5. Physical therapy diagnostic sensitivity and specificity, predictive values and likelihood ratios for each TMD subtype diagnosis in each evaluation group.

Diagnosis		Sensitivity % [$CI_{95\%}$]	Specificity % [$CI_{95\%}$]	Positive Predictive Value %[$CI_{95\%}$]	Negative Predictive Value %[$CI_{95\%}$]	Positive Likelihood Ratio [$CI_{95\%}$]	Negative Likelihood Ratio [$CI_{95\%}$]
Myalgia	TR	**98** [93,100]	**50** [12,88]	**97** [92,99]	**60** [15,95]	**1.96** [0.88,4.36]	**0.04** [0.01,0.20]
	IP	**99** [94,100]	**43** [10,82]	**96** [89,99]	**75** [19,99]	**1.73** [0.91,3.29]	**0.03** [0.00,0.23]
TMJ Arthralgia	TR	**87** [78,93]	**26** [10,48]	**81** [71,88]	**35** [14,62]	**1.17** [0.91,1.52]	**0.51** [0.21,1.23]
	IP	**95** [88,99]	**20** [4,48]	**86** [77,93]	**43** [10,82]	**1.19** [0.92,1.54]	**0.25** [0.06,1.02]
DDwR	TR	**86** [76,93]	**47** [28,66]	**80** [70,88]	**56** [35,76]	**1.60** [1.13,2.27]	**0.31** [0.16,0.60]
	IP	**86** [75,93]	**60** [39,79]	**86** [75,93]	**60** [39,79]	**2.14** [1.31,3.49]	**0.24** [0.13,0.47]
DDwoR	TR	**36** [11,69]	**92** [84,96]	**33** [10,65]	**93** [85,97]	**4.32** [1.55,12.0]	**0.69** [0.44,1.09]
	IP	**56** [21,86]	**87** [78,93]	**31** [11,59]	**95** [87,99]	**4.29** [1.92.9.59]	**0.51** [0.24,1.06]
DJD	TR	**30** [7,65]	**94** [87,98]	**33** [7,70]	**93** [86,97]	**4.80** [1.41,16.3]	**0.75** [0.50,1.12]
	IP	**45** [17,77]	**96** [90,99]	**62** [24,91]	**93** [85,97]	**12.6** [3.48,45.5]	**0.57** [0.33,0.97]
TMD HA	TR	**100** [91,100]	**65** [52,76]	**63** [50,75]	**100** [92,100]	**2.87** [2.06,3.99]	**0** [0,NA]
	IP	**86** [71,95]	**69** [55,80]	**63** [48,77]	**89** [76,96]	**2.77** [1.85,4.16]	**0.20** [0.09,0.46]

$CI_{95\%}$ = 95% Confidence Interval; TR = Telerehabilitation; IP = In-person; TMJ = Temporomandibular Joint; DDwR = Disc displacement with reduction; DDwoR = Disc displacement without reduction; DJD = Degenerative Joint Disease; TMD HA = Headache due to TMD

Chapter 5: Telerehabilitation effectiveness for individuals with TMD: A noninferiority study (Aim 2)

Physical therapy is an effective intervention to treat individuals with TMD, but many patients with these disorders report having difficulty finding providers to help them. Delivering PT vis synchronous video visits, or telerehabilitation, (TR) would help improve access to care for this population, but whether or to what extent TR can be expected to produce outcomes similar to in-person (IP) care remains unknown. Therefore, the second aim of this thesis is to establish the effectiveness of PT for individuals with TMD after 6 weeks of care as compared to IP PT in preference-allocated groups, and to assess noninferiority of the results against a 10% margin.

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ABSTRACT

Background: Temporomandibular joint disorders (TMD) cause pain and disability and can become chronic if left untreated. Telehealth delivery of physical therapy (PT) could increase access to care, but whether or to what extent telerehabilitation (TR) can deliver care similar to the in-person (IP) standard is unknown.

Purpose: The purpose of this study was to determine TR effectiveness as compared to IP PT after 6 weeks of individualized care for patients with TMD using a 10% margin of noninferiority for comparison.

Methods: After ethical approval, 207 patients with TMD ages 18-69 chose telehealth (n=113) or in-person (n=94) PT according to their preference in this open-label prospective cohort noninferiority trial. The primary outcome after 6-weeks of care was the proportion of therapy responders in each group as determined by improvement ≥6.9 units on the Oral Health Impact Profile for TMD (OHIP-TMD) scale. The lower limit for the 95% confidence interval for the difference between proportion was compared to a 10% margin to determine noninferiority. Secondary outcomes included patient satisfaction, number of visits, change in pain, change in function, and change in mouth opening. Additional analyses included calculating effect sizes, noninferiority comparisons using standardized margins, and covariate assessment.

Results: After 6 weeks, 89 participants completed outcome questionnaires in each group. The proportion of responders in each group was TR = 73(62,82)% and IP=62(51,72)% with a small effect size for TR (h=0.30) and the difference between group proportions was 11(-2,25)%. Improvements in OHIP-TMD scores were clinically significant in both groups and TR improvement was non-inferior to IP. Additional analyses revealed non-inferiority of other functional outcomes, high patient satisfaction (TR=93.8(8.4)%, IP=93.8(8.1)%), an average of 3 visits per group at 6 weeks, and co-variate testing revealed that low chronic pain level, higher baseline OHIP-TMD score, and higher number of visits increased the odds of success.

Conclusion: After 6 weeks of PT, TR was effective and non-inferior according to quality-of-life improvement. In the short-term, the OHIP-TMD scale best represented changes with therapy, and TR was noninferior to IP care for other functional outcomes as well. Patient satisfaction was high with the same average number of visits between groups. Clinically these results show that TR is a viable care option to increase accessibility for patients with TMD.

INTRODUCTION

Temporomandibular disorders (TMD) are a group of musculoskeletal conditions with a range of orofacial pain symptoms creating management challenges for the health care system. As identified by the National Academies of Science, Engineering and Medicine (NASEM) in 2020, these conditions are underrecognized yet overtreated with invasive irreversible procedures.[1] Comorbidity with disorders such as headache, cervicalgia and fibromyalgia create a strong connection between TMD and disability. [1,4-8] The prevalence of TMD has been estimated at 31% in the adult general population and if left untreated the pain and disability created by these conditions are known to become chronic.[1,37,40]

Management of TMD begins with diagnosis according to the Diagnostic Criteria for TMD (DC/TMD) streamlined recently by the brief DC/TMD.[31,63] The criteria combine questionnaires with physical temporomandibular joint (TMJ) and muscle assessments to determine painful and intra-articular subtype diagnoses alongside psychosocial factors that influence response to care. Given the lack of demonstrated effectiveness for invasive orthodontic or surgical interventions, the first-line recommendation for care is biopsychosocial conservative management including combinations of counseling, medication, self-care, oral appliances, and physical therapy (PT).[1]

Multidisciplinary management for patients with TMD frequently includes collaboration between dentistry and PT with no single intervention demonstrating superior effectiveness.[221] Systematic reviews report favorable outcomes after PT for all TMD diagnostic subtypes.[9,10,17,187,222] Kraus and Prodoehl found large effect sizes for improvement in maximum mouth opening (d=1.15) and change in pain (d=2.62) after individualized PT for nonreducing disc displacement.[16] A retrospective review of PT for all TMD subtypes found similar short-term results for improvement in mouth opening and pain.[12] Individualized PT allows the therapist to develop a plan of care

specific to the diagnoses, functional limitations, and therapy goals for each patient. This approach allows providers to account for psychosocial considerations and collaborate with other disciplines to maximize outcomes and effectiveness of interventions.

One of the challenges reported by patients with TMD is difficulty finding specialty providers to direct their care, resulting in heavy health care utilization with thousands of out-of-pocket dollars spent and an average of 4 providers seen for these conditions.[1,223] Work is in progress on a PT Clinical Practice Guideline for treating patients with TMD, but there is currently no standardization of TMD educational content in accredited PT programs and fellowships in the United States. Survey data reported by Prodoehl et al. in 2019 revealed extreme variation in the number of specific TMD curricular hours ranging from 1.5-50 across the 84 entry-level Doctor of PT program responses.[19] Students in these programs rarely had the opportunity to observe or work with patients experiencing TMD, and many PTs end up avoiding these patients due to feeling uncomfortable with their skills.[19,20]

The rapid adoption of telehealth during the COVID-19 pandemic demonstrated the utility of internet-based care delivery for increasing access and overcoming barriers.[119,160] Using telerehabilitation (TR) for other musculoskeletal complaints such as low back, knee and shoulder conditions has shown effectiveness, though heterogeneity and high risk of bias has existed in much of the early TR research.[23] TR has become more standardized as technology and public comfort with telehealth has improved, and rehabilitation scientists have begun using noninferiority methods to assess and demonstrate effectiveness.[111,127,182] The convenience and cost savings of telehealth have generated interest in its use for individuals with chronic conditions and underserved populations.[28,119]

Delivering PT via real-time video visits through TR could address existing barriers and increase access to care for patients with orofacial pain including TMD,

but whether or to what extent it can produce beneficial outcomes is unknown. The ability of noninferiority analysis to determine the effectiveness of a new treatment as compared to an existing standard makes it an ideal method to investigate this question. The purpose of this study was to determine TR effectiveness as compared to IP PT after 6 weeks of individualized care for patients with TMD. The hypothesis was that TR therapy response after 6 weeks would be noninferior within a 10% margin.

METHODS

Design

This prospective cohort noninferiority trial was carried out at the University of Minnesota TMD, Orofacial Pain & Dental Sleep Medicine Clinic in Minneapolis, MN. Patients were allocated to groups based on their preference for PT care delivery format to align with usual clinical care, making it an open-label effectiveness preference trial. All work was carried out with approval by the University of Minnesota Institutional Review Board (IRB ID: STUDY00015476) and the trial was registered on clinicaltrials.gov (NCT05318313). The CONSORT statement for reporting noninferiority and equivalence trials was followed when preparing this manuscript.[124]

Participants

A convenience sample of patients ages 18-69 diagnosed with TMD and referred to PT by an OFP specialist was recruited and enrolled in a 1:1 ratio of telerehabilitation (TR) to in-person (IP) control group participation between June 2022-June 2024. Study inclusion/exclusion criteria (**Table 1**) were informed by those used to validate the original diagnostic criteria for TMD and intended to capture a population of patients likely to benefit from PT while ensuring legal compliance with MN telerehabilitation legislation.[31,181] All participants in this study received and signed an informed consent for trial participation and for delivery of PT clinical care. After

enrollment, participants were allowed to choose whether they wanted to do their PT evaluation and ensuing care IP or via TR. Participants then completed the Oral Health Impact Profile for TMD (OHIP-TMD) scale, rated average pain and highest pain 0-10 on the numeric pain rating scale (NPRS), and reported current function 0-100% on the Global Rating Scale (GRS). Additional baseline questionnaires included the Graded Chronic Pain Scale (GCPS), the Euroquol-5 Dimensions-5 Levels (EQ-5D-5L) scale to capture current health state values, and the 4-item Patient Health Questionnaire for Anxiety and Depression (PHQ-4) for demographics and Axis-II assessment. Participants also completed outcome questionnaires at 6-weeks, adding a patient satisfaction questionnaire. See **Figure 7** for study flow.

Intervention

In this effectiveness study, an individualized plan of care was constructed after the PT evaluation based on each patient's reference standard diagnosis and functional goals and modified as needed based on their response to therapy. Because each diagnosis has unique rehabilitation considerations and no TMD diagnoses were excluded, PT interventions were generally standardized according to the treatment planning guidelines listed in **Table 6.** A licensed PT (EK) with 16 years of specialized experience treating patients with OFP in multidisciplinary clinics performed every evaluation and follow-up visit to standardize care delivery. At each visit, all participants received education and self-care training along with evidence-based PT interventions tailored to their diagnoses and symptoms. These interventions were targeted to decrease muscle tension pain, restore mobility and/or joint stability, develop muscle balance and control, improve function, and meet rehabilitation goals. See **Table 7** for definitions of intervention options.

Thirty-minute follow-up visit frequency and time to discharge varied between patients based on diagnosis, condition irritability and feasibility. Visit frequency

occurred as closely as possible to metrics related to the diagnoses and functional limitations:

1. If the primary diagnosis was a condition causing hypomobility and higher irritability as indicated by constant pain and mouth opening ≤25 mm, patients were scheduled 1x/week for up to 6 weeks as patient schedules allowed, tapering to 1x/2 weeks once mouth opening increased to ≥35mm.
2. If the primary complaint and diagnosis was a condition related to instability/poor coordination, with lower irritability, and/or individuals with difficulty scheduling more frequently were scheduled 1x/2 weeks for 6 weeks with increased education facilitating home management and self-progression.

   Treatment was progressed based on therapy response and functional goal progress was monitored throughout rehabilitation. When patients reported difficulty with compliance, adaptations to home program performance were prescribed with patient input to increase adherence. When patients canceled or failed PT visits, they were contacted via phone call or email by clinic staff to reschedule and if the patients did not respond they were contacted again by the treating PT. If patients reported unwillingness to continue with PT or did not respond after 5 contact attempts, patients were discharged from PT.

Mid-therapy assessment occurred 6 weeks after PT evaluation with self-reported outcomes questionnaires and objective TMJ ROM measurements. While PT continued until discharge, this manuscript analyzed outcomes after 6 weeks of PT to assess short-term TR effectiveness. Developing independent management for continued self-care after discharge was a primary focus of treatment, and ≥90% independence with self-care as determined by the global rating scale was the primary discharge criteria for all patients. The TIDieR Checklist (**Appendix III**) was used for reporting PT intervention details when preparing this manuscript.[179]

In-person Rehabilitation

The IP rehabilitation group was considered standard care in this study. Manual interventions such as masticatory and cervical muscle soft tissue mobilization, jaw, and cervical spine joint mobilizations, and intra- and extraoral trigger point release were applied in person to improve mobility and decrease masticatory and cervical muscle tension and pain. Exercises and stretches were explained and demonstrated to participants, and during participant demonstration feedback consisted of verbal, visual and manual cues to ensure proper performance. Modalities such as ultrasound, intraoral electrogalvanic stimulation, and heat/cold packs were occasionally used to facilitate muscle tension release.

Telerehabilitation

Treatment planning, frequency, and progression for the TR group occurred the same way as for the in-person therapy group but with virtual delivery of care. The morning of each session, the PT sent a Zoom link that participants used to join a password-protected video session at the scheduled treatment time. Because the therapist could not manually contact the participant during the sessions, verbal cues and demonstration allowed participants to self-perform necessary assessment and therapy interventions in response to directions. Participants used a cardboard Therabite range of motion scale (**Figure 10**; provided at the time of randomization and initial PT scheduling) for self-measurement of jaw movement at all visits.[207] Specific verbal cues regarding location, hand positioning, amount of pressure, and desired feedback guided palpation and resisted testing. The therapist explained and demonstrated jaw and cervical spine exercises, stretches, and manual techniques for participant self-performance, looking for appropriate demonstration of each activity in response. Directions were given regarding proper use of home heat and ice in conjunction with the PT visit as needed.

Outcome Measures

Therapy effectiveness was measured using the self-reported OHIP-TMD scale, a 22-item patient-reported outcome instrument that captures the biopsychosocial effects of TMD.[181,198] The 0-4 Likert scale scoring for the 22-item questionnaire yields a maximum score of 88 indicating worst possible quality of life.[181] Additional functional outcomes were measured by GRS rating, EQ-5D-5L health state level, MMO, average and high pain levels, and the Health Care Patient Satisfaction Questionnaire (HCSQ).

The primary outcome for effectiveness in this study was the proportion of responders in each group reporting significant quality of life improvement on the OHIP-TMD scale after 6 weeks. A participant was classified as a responder if the OHIP TMD change score from baseline improved by at least the minimal clinically important difference (MCID) of 6.9 units.[181] The proportion of responders was chosen for noninferiority comparison to account for the variation created by including participants with different diagnoses and individualized treatment programs in this effectiveness study.

Secondary outcomes exploring TR effectiveness at 6 weeks consisted of functional outcomes including change in OHIP-TMD score, MMO in mm, average pain and highest pain 0-10, GRS, and EQ-5D-5L rating. Additional outcomes included average number of visits at 6-weeks, and patient satisfaction via HCSQ score (0-100%).

Statistical Analysis

All analyses were performed in R running in RStudio, version 2024.04.2+764.[209] Primary analyses followed the intention-to-treat (ITT) principle. Because ITT analyses can bias the results toward no difference, per-protocol (PP) analyses were performed to further evaluate the treatment effect and assess the

strength of study conclusions. The PP analyses eliminated participants who never returned for follow-up in the 6 weeks after their PT evaluation.

Power and sample size

Sample size calculations using a 10% noninferiority margin yielded 89 participants per group to compare the difference between the proportion of responders having a significant improvement in OHIP-TMD score after 6 weeks. Power was set at 90% with 0.05 significance due to the increased potential of making a type II error in non-inferiority studies.[124] As there is no data yet regarding PT response rate to individualized PT in this population, parameter choices for the sample size analysis were based on the OHIP-TMD validation study results showing 70% improvement after treatment with self-care and dentist-guided conservative management; this study assumed a standard IP PT response rate of 75% and a TR response rate of 65%. The 10% noninferiority margin was chosen based on previous TR noninferiority studies for musculoskeletal conditions showing on average ≤10% difference between responder rates in each group.[117] To account for the possibility of 15% attrition, target enrollment was 105 patients per group.

Demographic analysis

Descriptive statistics compared baseline patient demographics between groups to evaluate the success of preference allocation by revealing group similarities and differences. Demographics included the following: willingness to be randomized, age, sex, gender, race, income level, education level, baseline OHIP-TMD score, GCPS level, PHQ4 score, NPRS level, GRS function, MMO, average and high pain levels, and prevalence of each TMD diagnosis.

Primary analysis

Rehabilitation responders were described as a binary positive or negative result based on whether their OHIP-TMDs score change after 6 weeks was ≥6.9 units. The % positive result quantified the proportion of responders in each treatment group to determine Cohen's h effect size and for noninferiority comparison. The proportion in the TR group (P_T) minus the proportion in the IP control group (P_C) yielded the difference between groups to be compared against the pre-set 10% noninferiority margin ($P_T - P_C \leq -0.1$). While noninferiority tests are one-sided, the approach recommended by the CONSORT statement for reporting noninferiority trials is to perform a two-sided test to generate two-sided confidence intervals.[124] A t-test comparing group proportions established a point estimate and 95% confidence interval for the difference between groups for noninferiority analysis, with IP care as the reference. The lower limit of the confidence interval needed to be between 0 and -0.1 to have evidence of TR noninferiority.

Secondary analyses

Secondary outcomes assessed included number of visits, patient satisfaction, and mean change from baseline in OHIP-TMD scores, MMO, average NPRS level, GRS, and EQ-5D-5L. The variables were assessed for normality using histograms and Q-Q plots and means and standard deviations were calculated in each group. For the mean change scores, within-group clinical significance was assessed for change from baseline by comparing to the MCID for each variable and Cohen's d effect sizes ($CI_{95\%}$) quantified effectiveness. Between-group differences were assessed using t-tests or Mann-Whitney tests depending on the results of normality testing. For the mean change scores, Cohen's d standardized effect sizes and the $CI_{95\%}$ were calculated comparing TR to IP care after 6 weeks for each outcome. Cohen's d effect sizes were categorized as 0.2=small, 0.5=moderate, and 0.8=large.

Additional noninferiority assessments: Each effect size $CI_{95\%}$ lower limit was compared to a standardized noninferiority margin created by dividing the relevant MCID by the pooled standard deviation. The MCID for each variable was taken from the relevant literature and were identified as follows: OHIP-TMD change = 6.9[181], MMO = 2.54 mm[92], moderate change in NPRS = 0.60[92], GRS change = 2.9%[191], EQ-5D-5L change = 0.04.[210] As the study was only powered for the primary analysis, power for these analyses was assessed to further quantify the conclusions.

Covariate effects: Omnibus univariate correlation testing of potential covariates using ANOVA Type III Sums of Squares was performed using $p<0.05$ as the cutoff for inclusion. Potential covariates included age, gender, number of visits, GCPS classification, PHQ4 level, baseline OHIP-TMDs score, baseline mouth opening, baseline GRS rating, baseline NPRS average pain rating, and TMD subtype diagnosis. Stepwise model selection using AIC as criteria produced a full linear model for noninferiority analysis using logistic regression adjusting for the covariates that significantly influenced the outcome data. The estimated odds ratio for each variable included in the model quantified the odds of therapy success for the presence of each binary variable or for an increase of 1 for each continuous variable, and p-values quantified significance.

RESULTS

Participants

A sample of 207 University of Minnesota TMD clinic patients from the Minneapolis-Saint Paul metropolitan and greater Minnesota areas were recruited and enrolled between June 16, 2022, and June 10, 2024. Participants were allocated according to their preference to either the TR (n=113) or IP (n=94) group, with a higher number of participants expressing a preference for TR. In the TR group, 106 (94%) completed the PT evaluation and baseline questionnaires, and 89 (79%)

completed the 6-week questionnaires. In the IP group, 94 (100%) completed the PT evaluation and baseline questionnaires, and 89 (95%) completed the 6-week questionnaires (**Figure 7**). There were no adverse events reported for any patients during or after any PT sessions.

Demographics analysis of the preference-allocated groups revealed that a large proportion of participants in each group (TR: 80%, IP: 86%) were female and there were significant group differences for randomization preference and age. The TR group had a majority (56%) report that they would not have been willing to be randomized vs 22% in the IP group. The mean age of the TR group was 5 years higher than the IP group. All IP participants and all but 4 TR participants had multiple TMD subtype diagnoses with no significant differences in diagnostic prevalence between groups. OHIP-TMD scale score, or function at baseline between groups. See **Table 8** for the full report of group demographics.

Primary analysis: Response to rehabilitation

The proportion of therapy responders was higher in the TR group (65/89, P = 0.73, $CI_{95\%}$: 0.62,0.82) than in the IP group (55/89, P = 0.62, $CI_{95\%}$: 0.51,0.72) and the two confidence intervals overlapped. There was a small effect size for TR at h=0.30. The $CI_{95\%}$ lower limit for the difference between group proportions was within the 10% noninferiority margin at -2% and gives evidence that TR was noninferior to IP care (**Figure 17**). Per-protocol analysis restricted to participants with ≥2 visits before the 6-week timepoint did not change the noninferiority conclusion with a 1% decrease in the difference between proportions, a smaller TR effect size of h=0.22, and a $CI_{95\%}$ lower limit of -5% for the difference between group proportions. See **Figure 16** for therapy responder results. Post-hoc power analysis revealed >90% power for the ITT conclusion and 88% power for the PP conclusion.

Secondary analyses

Results for number of visits in each group and patient satisfaction after 6 weeks were not normally distributed. The IP group averaged 3.3(1.4) visits and TR averaged 3.2(1.3) visits with no significant difference between them (p=0.50). Patient satisfaction also showed no significant difference at 93.8(8.1)% in the IP group and 93.8(8.4)% for TR (p=0.70).

For the outcomes assessing mean change from baseline, clinically significant changes were evident for OHIP-TMD score improvement and decrease in maximum pain with moderate to large effect sizes in both groups. Decrease in average pain was clinically significant in both groups with a small effect size for TR and moderate for IP. For increase in GRS, the TR group showed a clinically significant increase but a small effect size, and the IP effect was negligent. Mean MMO changed <0.5 mm in both groups and effect sizes were small for EQ-5D-5L value state increase in both groups. These variables were all normally distributed, and testing revealed no significant differences between groups in mean values for each. See **Table 9** for within-group mean changes and effect sizes, and p-values for between-group comparisons.

Noninferiority analyses: The TR noninferiority analysis of the variables assessing mean change from baseline is shown in **Figure 17**. The lower limit of each effect size $CI_{95\%}$ was within the lower limit of the standardized margin except for decrease in average and highest pain, which had estimates and $CI_{95\%}$ that crossed the entire margin for both variables.

Covariate analysis: Stepwise variable selection produced a prediction model for odds of therapy success shown in **Table 10**. The odds of success were estimated to be 48% and 11% higher when visit number and baseline OHIP-TMD scores each increased by 1, respectively. The odds of therapy success for patients with moderate GCPS level were estimated to be 86% lower than those with low GCPS level. These

differences were all statistically significant. The odds of success for patients in the TR group were estimated to be 21% higher than those in the IP group, though this result was not statistically significant. Presence of the TMD subtype diagnoses of DDwoR and DJD were also in the model as decreasing the odds of success, though their effects were also not statistically significant.

DISCUSSION

This study evaluated the effectiveness of TR for individuals with TMD by comparing quality-of-life improvement after 6-weeks to the control condition of IP PT care. Both groups demonstrated short-term improvement from baseline, and the proportion of TR therapy responders with a significant improvement on the OHIP-TMD scale was noninferior which supported the hypothesis that TR is noninferior to IP PT care. This trial was the first effectiveness study to investigate telehealth use for rehabilitation in this chronically underserved population.

At baseline, the groups were mostly similar regarding demographic distributions and functional measures of TMD despite the fact that patients were allowed to self-select treatment group according to their preference. The higher enrollment numbers for the TR group demonstrated that patients in this population were very accepting of telehealth as an option for care. One baseline demographic difference between groups was that a majority of TR participants reported unwillingness to be randomized, which aligns with observations made by Walter et. al. (2017) and Kowalski & Mrdjenovich (2013) that strong preferences regarding treatment and randomization could decrease trial participation and supports our preference trial design choice to study this intervention.[137,138]

Preference effects were clear in the greater number of participants who enrolled in the TR group, yet attrition was also higher in this group. A lower proportion completed the PT evaluation and there was 21% attrition at 6 weeks, vs.

5% attrition in the IP group. The TR attrition rate was larger than the 15% expected, indicating that while many of the participants felt strongly about doing PT remotely there was also a less engaged portion of this group. Preference allocation contributes to clinical translation of study results because rehabilitation clinic patients are typically allowed to choose how they receive care. These results reveal that for those that stayed in the study TR was noninferior, yet there is also potential for TR participants to become less engaged in care.

The IP therapy group was on average significantly younger than the TR group, and ethnic and racial diversity was lower than in the general population, both of which likely reflect the study setting at an academic clinic on campus at a large midwestern university. Undergraduate and graduate students tended to prefer IP participation due to the convenience of having therapy close to their residence or classes, which could have brought down the average age. The age range for each group was nearly the same, spanning the entire allowed age for study participation and only differing by 1 year on the lower end between groups. Age was included as a potential covariate in the logistic regression prediction model analysis, but model selection did not identify age as a significant covariate.

Another important baseline demographic finding is that the sample enrolled in this study is generally representative of the population of patients with TMD. The majority of patients with TMD tend to be female and white, and the most common diagnoses are masticatory myalgia and TMJ arthralgia; the population in this study reflects those same characteristics.[1] The mean score for TMD patients in the OHIP-TMD validation study was 33.4 (17.0)[181] which is close to both group baseline mean OHIP-TMD scores and variation in this study, indicating that the sample in this study did have impaired quality-of-life at baseline sufficient to be assessed for improvement with the OHIP-TMD scale. The baseline mean MMO values in each group were >40 mm and not significantly different from each other, showing that this sample did not

have severe limitation of mouth opening. This finding is unsurprising given the low prevalence of diagnoses related to mechanical restriction in each group (DDwoR and DJD) and is the same as the findings reported by Calixtre et al. in the 2020 study that determined MCIDs for moderate improvement in current pain and MMO for patients with TMD.[92]

Primary outcome

The proportion of therapy responders for the sample size estimation was set at 75% for the standard condition and 65% for the experimental condition, but the proportions seen in the data were actually reversed and lower than expected at 62% for the standard condition and 73% for the experimental. While different from assumed, the proportion of success after standard IP PT care for patients with TMD has not been reliably quantified in the literature according to the OHIP-TMD or another comprehensive condition-specific instrument. The 70% proportion used for sample size estimation was taken from a population with TMD that had care supervised by dentists with minimal exercise supervision and follow-up that occurred at 12 weeks.[181] Follow-up in this study was twice as soon at 6 weeks with an average of 3 visits in that time period for both groups. The average length and number of visits for an entire episode of TMD care is variable, but the retrospective review by Fisch et al. reported an average of 8-10 visits without any quantification of time length.[12] In this context, 62% improvement at 1/3 of the average total visits is a reasonable finding for the IP group. The increased proportion of success in the TR group at 73% could be biased by the fact that there was 21% attrition at this time point. Assuming that the patients lost to follow-up did not find success with PT and/or pursued other care options, their absence likely inflated the proportion of success in the remaining participants. Therefore, these results should be interpreted with caution and still considered evidence of noninferiority, rather than assuming that TR was more successful than IP care. Despite these success proportions presenting

differently from what was expected, there was still ≥88% power for the noninferiority conclusions from both ITT and per-protocol analyses.

Secondary outcomes

Number of visits and patient satisfaction: Measures of therapy engagement are more qualitative in nature but contribute important data to guide clinicians and patients regarding expectations for TR in this population. The average number of visits was nearly the same in each group at about 3, indicating that for the TR patients who stayed in the study they engaged at a similar rate as the IP participants after 6 weeks. This visit rate corresponds with every other week PT frequency, which is the usual rate of visit frequency at this clinic for patients with motor coordination deficits as their movement classification. There were not enough participants with hypomobility in each group to look more closely at differences in visit frequency based on this metric, and outcomes at discharge and long-term follow-up will more clearly demonstrate any differences if they exist.

Other studies examining patient satisfaction with TR have demonstrated levels of satisfaction noninferior to IP care.[111,115,133,145] In this study, results aligned with previous literature as patient satisfaction was >93% in each group indicating high levels of satisfaction with care on average even when participants did not demonstrate success at 6 weeks according to the OHIP-TMD MCID. Clinically, these results indicate that TR is acceptable to patients who prefer this option and that they can be expected to engage and feel successful at rates similar to those for the existing IP standard of care. Future analysis including satisfaction at discharge and using noninferiority methods for non-normally distributed variables will further examine patient satisfaction.

Additional noninferiority analyses: These analyses improve the sensitivity of noninferiority analysis by keeping the outcome continuous rather than categorical but were not feasible as primary outcomes due to the increased sample size required to

maintain adequate power with this method. While the study was not powered for these specific analyses as evidenced by the wide $CI_{95\%}$ for all, the results provide an additional evaluation of the noninferiority result to more fully characterize the effectiveness of TR for individuals with TMD. Group comparison revealed TR group noninferiority of all secondary outcomes except for change in average and highest pain levels.

Patient outcomes in TMD research suffer from the lack of consistent outcomes use across studies. The biopsychosocial nature of TMD creates difficulty with selection of a representative outcome measure. As a result, individual measurements of MMO, pain, or strength do not adequately capture disability or improvement over time and a variety of additional instruments are used with varying utility and psychometric properties.[198,224] The OHIP-TMD scale has been shown to best capture the psychosocial effects of TMD and has been increasingly used in this population to assess quality of life.[198] In this study, the highest within-group effects and most clinically significant short-term improvement after 6 weeks was seen for OHIP-TMD quality of life scale score for both groups. There is evidence that both groups improved from baseline for this metric, though the effect size confidence intervals were quite wide.

Results for individual functional outcomes highlighted the variation reflected in the literature for patients with TMD. The next strongest effects were for change in average and highest pain levels, which seemed clinically significant and were not significantly different between groups. However, the very small MCID for pain change required much higher participant numbers to adequately assess for noninferiority and resulted in underpowered analyses. Average MMO in this study did not change much at 6 weeks in either group, which is clinically appropriate given that baseline measurements did not reveal hypomobility as a characteristic of this sample. The IP group slightly increased and the TR group slightly decreased jaw opening. A

decrease in opening is not unusual with treatment, as seen in the retrospective review by Fisch et al. where the average MMO decreased in females from baseline at 41.0(8.2) to 37.1(6.5) at discharge.[20] The GRS and EQ-5D-5L values also did not reflect significant improvement from baseline, likely because 6 weeks is too short for systemic measures of function to capture change when treatment is focused on one joint area. While underpowered, the general trend toward noninferiority of TR for all measures but pain change lent secondary support to the noninferiority hypothesis. These results also reinforce the utility of a condition-specific scale like the OHIP-TMD to assess short-term improvement for TMD care, and future analysis including long-term outcomes from discharge and 6-months post-discharge will further assess these individual functional measures.

Covariate analysis: Telehealth for patients with TMD has been adopted relatively quickly in recent years without much literature evidence assessing its effects.[28,119] To account for additional factors that could influence patient response to therapy and increase or decrease its effectiveness, covariate analysis was undertaken to further explore this question. The final multivariate model, formed by adding variables and controlling for their effect, improved the prediction of odds of success compared to using just the group variable. In this sample, the model showed that increasing the number of visits predicted an increase in the odds of success, demonstrating that even if TR were inferior to IP care it is better than no care at all. The results also identified that higher baseline OHIP-TMD score yet lower chronic pain level increased the odds of success, meaning that TR can help patients with all levels of disability, but the odds of success are better with lower levels of chronic pain. There was no clear influence of age or TMD subtype diagnosis, indicating that while the IP group was younger, the difference was likely not clinically significant, and that TR success is not likely to vary according to any specific diagnoses.

Limitations

There are two assumptions for running a noninferiority test that were unable to be tested in this study: constancy and assay sensitivity. The constancy principle is that the standard care treatment effect remains the same over time. Assay sensitivity is the consistent ability to demonstrate a difference between active treatment and no treatment over time. Assay sensitivity of the OHIP-TMDs scale has not yet been demonstrated in the literature as most studies using this scale have been cross-sectional in design and intervention studies rarely include a no treatment group.[198,199] As research in these areas continues to develop, more data regarding these assumptions will emerge to strengthen our conclusions. The long-term follow-up and planned future analyses from this study will assess treatment effects lasting 6-months after discharge and will therefore address the constancy principle, and extrapolating baseline data as a hypothetical no treatment group for future cost analysis will give information addressing assay sensitivity.

The lack of randomization and volunteer sample in this preference trial were limitations of this study. While most of the baseline comparisons revealed no systematic differences between groups, the two differences that did emerge concerned strong beliefs about how patients received their PT in the TR group and led to a younger group enrolling for IP care. These findings limit the generalizability of study results to the greater population, though they are important to consider in the context of clinical applications of TR. Patients clearly want the option to have TR because of factors like living farther away from the clinic and having less flexibility for time off at jobs compared to the schedule flexibility available for college students. Physical therapists must consider the social determinants of health when developing a care plan and setting expectations for success, and while these design choices were limitations the preference effects were distributed equally across groups and should not diminish the strength of the TR noninferiority conclusion. These results

also demonstrate that a future randomized controlled trial investigating TR noninferiority is possible but will need to account for difficulty enrolling participants.

Another study limitation was the inclusion of many TMD subtype diagnoses and the resulting need to adjust individualized care. This fact highlights the ongoing conflict between employing standardization to minimize bias in clinical research vs. studying interventions the way they are actually used in clinical care. The approach used in this study outlined in **Table 5** aimed to minimize clinical reasoning differences in an attempt to balance the conflict mentioned above. However, these results are also reflective of one PT and until a standardized Clinical Practice Guideline is published there will continue to exist variation in treatment approaches for patients with TMD. Future research in this area including multiple PTs following a standardized care plan for TR as well as PT in general will create more evidence regarding outcomes of PT for patients with TMD.

CONCLUSION

This study was the first to examine TR effectiveness in a true clinical population of patients with TMD at a multidisciplinary orofacial pain clinic. After 6 weeks, TR was noninferior to standard IP care according to the proportion of therapy responders on the OHIP-TMD quality of life scale. The odds of TR therapy success were increased in patients with lower levels of chronic pain who were compliant with therapy visits, especially if they started with a worse OHIP-TMD score at baseline. Out of all outcome measures assessed, the OHIP-TMD best captured the short-term response to therapy in this sample. Future research considering long-term outcomes of this study, employing randomization, and using multiple PT providers will address study limitations and further explore these conclusions.

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Table 6. TMD Impairment-based Treatment Guidelines[94]

Mobility deficits	**Motor Coordination deficits**
Prioritize joint vs. muscle	
Reduce irritability: • Pain Neuroscience Education • Mindfulness • Relaxation training	
Joint protection: relax muscles to allow stretching and improve range of motion	Joint protection: avoid overuse and progression of disc displacement
Restore straight, functional jaw opening: • Controlled rotation • Stretching, mobilization to increase range of motion • Restore laterotrusion	Restore straight, functional opening: • Controlled rotation • Limit maximum opening • Isometric training in all directions
Assess & treat cervical deficits and/or muscle pain	

Standardization of Physical Therapy treatment decision-making individualized to patient impairments and diagnoses

Table 7. Definitions of Physical Therapy Interventions for TMD management[94]

Intervention		**Temporomandibular joint**	**Cervical spine/Whole body**
Self-Care/Education		Tongue up/teeth apart Avoid clenching & bruxism <u>Joint protection:</u> Avoid gum Bilateral chewing Soft diet Limit max opening	Sleep position adjustment Ergonomic training Postural Education Limit caffeine & nicotine Avoid leaning on the chin
Exercise	Muscle Retraining	Controlled rotation Mirror-assisted movement Rhythmic Stabilization	Occipito-atlanto nodding Axial Extension Scapular Retraction
	Strengthening	Isometric training Isokinetic training	Deep cervical flexors Scapular retraction Abdominal strength
Stretching		Passive: Fingers/Knuckles, Tongue Depressors Active: Opening wide Assisted: Scissors stretch	Cervical Sidebending Cervical Flexion Scalenes, Suboccipitals, Sternocleidomastoid Axial extension
Manual Therapy	Joint mobilization	Distraction Anteromedial Glide Lateral Glide	Upper cervical spine Thoracic spine
	Trigger point release	Intraoral & extraoral masticatory muscles	Cervical muscles
	Soft tissue mobilization	Intraoral & extraoral masticatory muscles	Cervical muscles
Passive Modalities		Heat/ice, Transcutaneous electrical nerve stimulation (TENS), Intraoral electrogalvanic stimulation (EGS)*, Ultrasound*	

*In-clinic only

Table 8. Baseline Demographics of preference-allocated PT groups and p-values for group comparison.

Group Demographic		Telerehabilitation group (n=89)	In-Person group (n=89)	p-value
Unwilling to be randomized; n(%)		50 (56%)	20 (22%)	<0.001*
Age in years; mean (range)		37.4 (19-69)	32.6 (18-69)	0.02*
Gender n(%)	Male	13 (15%)	9 (10%)	0.49
	Female	71 (80%)	76 (85%)	0.43
	Non-Binary	5 (5%)	4 (5%)	1.00
Ethnicity n(%)	Hispanic/Latino	1(1%)	3 (3%)	0.61
	Not Hispanic/Latino	86 (97%)	84 (95%)	0.72
	Unknown	2 (2%)	2 (2%)	1.00
Race n(%)	American Indian	2 (2%)	1 (1%)	1.00
	Asian	11 (13%)	12 (14%)	1.00
	Black/African American	5 (6%)	1 (1%)	0.21
	Prefer no answer	3 (3%)	1 (1%)	0.61
	White	68 (76%)	74 (83%)	0.35
Education n(%)	High school	6 (7%)	4 (5%)	0.74
	Some college	19 (21%)	19 (21%)	1.00
	College graduate	33 (37%)	29 (32%)	0.64
	Graduate/post-professional	31 (35%)	37 (42%)	0.44
Income n(%)	Low	15 (17%)	15 (17%)	1.00
	Middle	33 (37%)	30 (34%)	0.75
	Upper	29 (33%)	37 (42%)	0.28
	Prefer no answer	12 (13%)	7 (7%)	0.33
Functional Measures mean(SD)	OHIP-TMD score (0-88)	36.9 (15.1)	32.3 (17.1)	0.06
	JFLS-8 score (0-80)	16.3 (11.0)	14.1 (10.8)	0.18
	MMO (mm)	46.0 (6.3)	44.4 (7.7)	0.15
	Average Pain (1-10)	2.9 (2.0)	3.1 (1.8)	0.50
	Highest Pain (1-10)	5.5 (2.1)	5.5 (2.1)	0.91
	GRS (0-100%)	80.8 (21.2)	84.8 (16.6)	0.17
	EQ-5D-5L (0-1)	0.81(0.15)	0.81(0.14)	0.82
Axis-II Measures mean(SD)	GCPS (0-3)	0.76 (1.2)	0.71 (1.1)	0.74
	PHQ-4 (0-12)	2.9 (2.7)	3.1 (2.9)	0.68
Diagnosis Prevalence n(%)	Myalgia	84 (94%)	84 (94%)	1.00
	TMJ Arthralgia	70 (79%)	75 (84%)	0.44
	DDwR	60 (67%)	65 (73%)	0.51
	DDwoR	11 (12%)	9 (10%)	0.81
	DJD	9 (10%)	10 (11%)	1.00
	TMD HA	31 (35%)	36 (40%)	0.54

*Significant at p<0.05; OHIP-TMD = Oral Health Impact Profile for TMD; MMO = Maximal mouth opening; EQ-5D-5L = EuroQuol-5 Dimensions-5 Levels Quality of Life scale; l GRS = Global rating scale; GCPS = Graded Chronic Pain Scale; PHQ-4 = Patient Health Questionnaire for Anxiety & Depression; DDwR = Disc Displacement with reduction; DDwoR = Disc displacement without reduction; DJD = Degenerative Joint Disease; TMD HA = Headache attributed to TMD

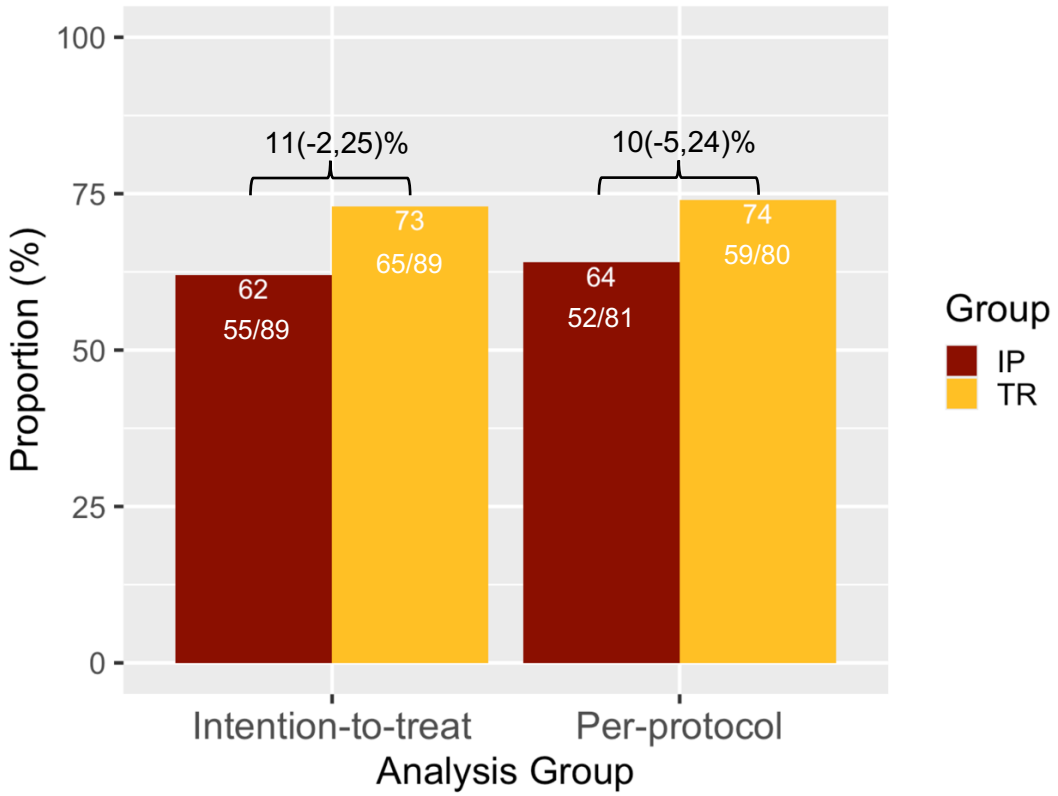

Figure 16. Intention-to-treat and per-protocol proportions of therapy responders in each group with >6.9 score improvement on the Oral Health Impact Profile for TMD at 6 weeks. Data labels above the bars show the estimate and 95% confidence interval for each difference between proportions. Intention-to-treat included all participants, n=178; Per-protocol included only participants with ≥2 visits at 6 weeks, n=161. IP = In-person; TR = Telerehabilitation.

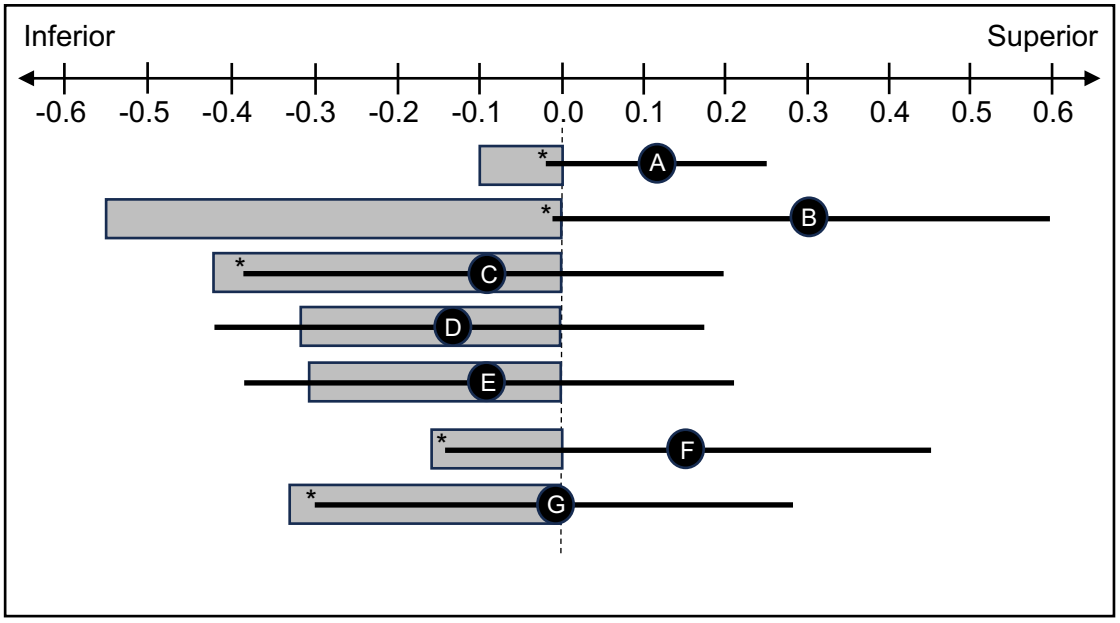

Figure 17. Telerehabilitation noninferiority results for estimates and 95% confidence intervals describing difference in effectiveness from in-person care at 6 weeks. Gray shaded bars indicate noninferiority margins: 10% for the primary outcome and standardized for secondary outcomes by dividing the minimum clinically important difference by the pooled standardized deviation for each variable.
*Noninferior within noninferiority margins
Primary: A = Difference in proportion of therapy responders; 0.11[-0.02,0.25]
Secondary: effect size [$CI_{95\%}$] | lower limit of standardized margin
B = Oral Health Impact Profile for TMD improvement; 0.30[-0.01,0.60] | -0.55
C = Maximal mouth opening change; -0.09[-0.39,0.20] | -0.42
D = Average pain decrease; -0.13[-0.42,0.17] | -0.32
E = Highest pain decrease; -0.09[-0.38,0.21] | -0.31
F = Global rating scale increase; 0.15[-0.14,0.45] | -0.16
G = EQ-5D-5L health state value increase; -0.01[-0.30,0.28] | -0.33

Table 9. Table of within-group improvement and between-group comparisons for Telerehabilitation effectiveness after 6 weeks and p-values for groupwise differences.

Secondary outcome measure – change from baseline		6-week Improvement Mean(SD)	Within-Group Effect Size[$CI_{95\%}$]	MCID	Pooled Standard Deviation	p-value
OHIP-TMD score (0-88)	IP	10.7(11.7)	0.63[0.33,0.93]	6.9	12.5	0.05
	TR	14.4(13.4)	0.95[0.64,1.26]			
JFLS-8 score (0-80)	IP	3.38(8.98)	0.31[0.01,0.61]	N/A	8.52	0.99
	TR	3.36(8.04)	0.31[0.01,0.61]			
Maximum mouth opening (mm)	IP	0.24(6.38)	0.03[-0.26,0.32]	2.54	6.10	0.54
	TR	-0.33(5.81)	-0.05[-0.34,0.24]			
Average pain (0-10)	IP	1.11(1.96)	0.62[0.32,0.92]	0.60	1.88	0.40
	TR	0.88(1.80)	0.44[0.14,0.74]			
Highest pain (0-10)	IP	1.01(1.96)	0.48[0.18,0.77]	0.60	1.95	0.56
	TR	0.84(1.94)	0.40[0.10,0.70]			
Global Rating Scale (0-100%)	IP	1.91(16.2)	0.11[-0.20,0.40]	2.9	17.6	0.30
	TR	4.63(18.9)	0.22[-0.07,0.51]			
EQ-5D-5L health state value (0-1)	IP	0.03(0.12)	0.25[-0.05,0.55]	0.04	0.11	0.94
	TR	0.03(0.11)	0.20[-0.10,0.50]			

IP = In-person; TR = Telerehabilitation; $CI_{95\%}$ = 95% Confidence Interval; MCID = Minimal Clinically Important Difference; OHIP-TMD = Oral Health Impact Profile for TMD; JFLS-8 = Jaw Functional Limitation Score – 8 item; EQ-5D-5L = Euroquol 5-Dimensions 5-Levels quality of life scale

Table 10. Final logistic regression prediction model for odds of therapy success using stepwise selection with AIC criteria.

	Estimated OR	$CI_{95\%}$ of OR	p-value
Telerehabilitation group	1.21	(0.55, 2.64)	0.636
Number of visits	1.48	(1.08, 2.01)	0.013*
Moderate GCPS level	0.14	(0.03, 0.69)	0.016*
Baseline OHIP-TMD score	1.11	(1.07, 1.15)	<0.001*
DDwoR: yes	0.49	(0.2, 1.19)	0.114
DJD: yes	0.4	(0.12, 1.39)	0.150

*Statistically significant at $p<0.05$

OR = Odds Ratio; $CI_{95\%}$ = 95% Confidence Interval; GCPS = Graded Chronic Pain Scale; OHIP-TMD = Oral Health Impact Profile for TMD; DDwoR = Disc Displacement without Reduction; DJD = Degenerative Joint Disease

Chapter 6: Feasibility of Telerehabilitation for individuals with TMD (Aim 3)

There is literature evidence that patients with TMD were not comfortable with exclusively using telerehabilitation (TR) to address their conditions prior to the COVID-19 pandemic.[143] Telehealth interventions on the whole have since been rapidly adopted as a way to maintain and increase access to care, but a lack of standardization or usability knowledge has resulted in heterogeneity regarding their development and application.[28,166] Feasibility research examines health process outcomes rather than clinical outcomes to support and guide implementation of interventions. The third aim of this thesis is to assess the feasibility of telerehabilitation (TR) for individuals with TMD using standardized theoretical frameworks to bridge the gap between knowledge to practice.

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ABSTRACT

Background: Remotely delivered interventions were necessary during the COVID-19 pandemic and have the potential to increase access to high-quality care for patients with TMD. However, there is some question as to whether telerehabilitation (TR) is acceptable and feasible for this population.

Purpose: The purpose of this analysis was to determine the feasibility of TR for individuals with TMD informed by the Behavior Change Wheel (BCW) and Acceptability, Practicability, Effectiveness, Affordability, Side Effects/Safety, and Equity (APEASE) criteria examining usability.

Methods: After ethical approval, patients with TMD ages 18-69 from a larger prospective clinical trial who had chosen TR for their care were given the option to complete a qualitative questionnaire after discharge from therapy. The intervention was mapped according to the BCW to determine how it addressed implementation barriers. Intervention evaluation was informed by the APEASE criteria using the demographics, qualitative questionnaire answers, and therapy results for the participants who completed the questionnaire.

Results: After discharge from TR, 11 participants completed the qualitative questionnaire. There were a range of patient races, education levels, and geographic locations represented in the sample. Mapping revealed that the intervention addressed barriers using the intervention functions of Education, Modeling, Training, and Enablement. Intervention evaluation revealed that all APEASE criteria were met. All 11 participants reported a good experience with TR and 91% reported that they strongly agreed that it was high quality care. Average patient satisfaction at was 93.1(6.6)% at 6 weeks and 96.6(3.7)% at discharge. Secondary effectiveness results revealed quality-of-life improvement 4x the minimal clinically important difference on the Oral Health Impact for TMD scale at discharge.

Conclusion: The TR intervention was acceptable, usable, and feasible for the participants with TMD in this sample. Patients improved after therapy with high levels of patient satisfaction. Results of this analysis support wider application of TR methods and create a foundation for future economic analysis.

INTRODUCTION

Temporomandibular Disorders (TMD) are a group of conditions affecting the jaw, face and head that become chronic and cause disability if not addressed.[8] They are the second most common musculoskeletal cause of pain and disability in the general population, yet patients with these conditions are overlooked and underserved due to overlap with comorbidities including fibromyalgia, headaches, cervicalgia, anxiety, and depression.[1,4,6] Physical therapy (PT) is an effective intervention to treat patients with TMD[9,10,17,187,222], but patients report difficulty accessing high quality care.[1]

The COVID-19 pandemic revealed the utility of digital interventions to maintain and improve access to healthcare, including telerehabilitation (TR) to deliver PT. The pre-pandemic state of TR suffered from a lack of standardized delivery with research revealing considerable heterogeneity in methods, outcome measures, and barriers to implementation.[23,28,170,175,225] Many studies investigating TR effectiveness have revealed good results and noninferiority of digital care delivery[111,117,126,184,186], but real-life utility also depends on whether or not clinicians and patients will engage in care. With the gradual return to in-person care there has been an increased focus on telehealth feasibility and implementation research to improve strategies for sustainable incorporation of telehealth beyond emergency use.[142,226,227]

Using a standardized framework to systematically evaluate an intervention supports decision-making to bridge the gap from knowledge to clinical practice. Two frameworks commonly used in feasibility research are the Behavior Change Wheel (BCW) and the Acceptability, Practicability, Effectiveness, Affordability, Side effects/safety, Equity (APEASE) critera.[180,211,212] The BCW visualizes the core concepts of capability, opportunity, and motivation surrounded by intervention functions aligned with validated theoretical domains from psychological research and rimmed by policy categories supporting intervention delivery (**Supplemental Figure**

1).[212] Evaluating an intervention according to the BCW visualizes its potential to influence behavior change, and using the APEASE criteria for assessment allows for full systematic analysis of feasibility.[180,228,229]

Feasibility research focuses on tracking health process outcomes rather than change in pain or other functional outcomes. There is minimal evidence of feasibility regarding telehealth for patients with TMD, and a pre-pandemic study assessing patient views of TR for TMD revealed that patients did not feel that it was acceptable as more than a complement to the standard of in-person care.[119,143] Providing PT via TR would significantly increase access to care, but a truly feasible TR intervention for individuals with TMD must identify and address the determinants of behavior to ensure patient acceptance of TR for these conditions. The purpose of this analysis was to determine the feasibility of TR for individuals with TMD informed by the BCW and APEASE criteria examining acceptability and usability.

METHODS

This feasibility analysis was performed on a subset of participants who had completed TR care in an open-label prospective cohort noninferiority clinical trial that compared TR to in-person PT for individuals with TMD at the University of Minnesota TMD, Orofacial Pain & Dental Sleep Medicine Clinic in Minneapolis, MN between June 2022-June 2024. All work was carried out with approval by the University of Minnesota Institutional Review Board (IRB ID: STUDY00015476) and the trial was registered on clinicaltrials.gov (NCT05318313). The Template for Intervention Description and Replication (TIDieR) Checklist (**Appendix III**) was used for reporting TR intervention details in this manuscript. Feasibility assessment included intervention mapping and evaluation informed by the Behavioral Change Wheel and Applicability, Practicability, Effectiveness, Affordability, Side Effects/Safety, and Equity (APEASE) theoretical frameworks.[178,180,211]

Intervention Description

A convenience sample of patients ages 18-69 diagnosed with TMD and referred to PT by an orofacial pain specialist was recruited and enrolled according to study inclusion/exclusion criteria (**Table 1**). These criteria were intended to capture a population of patients likely to benefit from PT while ensuring legal compliance with MN telerehabilitation legislation. All participants received and signed an informed consent for trial participation and for delivery of PT clinical care. Telerehabilitation participants were allocated based on their preference for telehealth care delivery, and the 11 participants in this qualitative analysis signed an additional consent form to complete an additional questionnaire after their discharge from PT. According to Davids et al., qualitative feasibility research recommends at least ten participants to capture 80% of the problems with an e-learning intervention.[230]

To adapt care for remote delivery, synchronous PT visits were done via Zoom software (Zoom Video Communications; San Jose, CA, version 5.7.8) using password protection to ensure confidentiality during patient visits.[206] The initial study screening and consent discussion occurred via Zoom to check and problem-solve connectivity issues or questions before beginning PT. Participants were emailed and mailed study details including instructions and suggestions for using Zoom along with a hand-held Therabite scale[216] for home measurement of jaw movement (**Figure 11**).

The same PT (EK) performed all remote evaluations and delivered care at each follow-up visit. Participants had a 60-minute initial PT evaluation with adaptations for remote assessment including self-palpation and self-testing guided by visual aids and demonstration (**Figure 10**). Classification and diagnosis occurred based on measurements and palpation responses according to a decision tree for PT assessment of TMD[215] (**Figure 9**) that was informed by the brief diagnostic criteria for TMD.[63] Follow-up visits were 30-minutes long, scheduled according to patient classification and availability following these metrics as able:

1. Weekly for mobility deficit conditions
2. Every other week for coordination deficits with mobility >40 mm

Care at each visit was individualized to participant symptoms, functional limitations, and functional goals. Each participant received education about TMJ anatomy and their diagnosis, self-care and joint protection instructions, and pain neuroscience education. Self-care activities included relaxation, sleep position and ergonomic adjustments, habit awareness and reversal, and self-massage with imagery for muscle tension release. Exercises included movement retraining, muscle stabilization, and stretching as needed for each participant. Home modalities included heat or ice. If patients cancelled or no-showed appointments, the clinic staff contacted them for rescheduling and the PT contacted them up to 5 times if they did not respond. Discharge for the 11 participants in this study occurred when patients met their functional goals.

Participants completed study questionnaires at baseline, 6-weeks, discharge, and qualitative feedback was collected 6 months post-discharge. Functional assessment for effectiveness at baseline, 6-weeks and discharge included the condition-specific Oral Health Impact for TMD (OHIP-TMD) quality-of-life scale[181] and the Euroquol-5 Dimensions-5 level (EQ-5D-5L), a generic quality-of-life scale used to quantify health state valuation for cost-effectiveness analysis.[203] The Health Care Satisfaction Questionnaire (HCSQ) was completed at 6-weeks and discharge which quantified patient satisfaction with care 0-100% accounting for patient expectations alongside experience with care.[144] The qualitative final study questionnaire included three open-ended questions and three questions assessing their experience with TR using a 5-item Likert-scale (**Supplemental Figure 2**). Patients received $25 compensation at both of the 6-week and discharge timepoints to incentivize questionnaire completion.

Intervention Mapping

Intervention mapping followed a three-stage approach informed by the BCW and the Theoretical Domains Framework.[178,211]

Stage 1: Understand the Behavior

A literature review was done to examine and define the problem of TR acceptability in the population of patients with TMD. This review identified barriers to implementation that were considered during intervention development and guided the who, what, where, and when decision-making regarding adaptations to existing in-person PT protocols for this population. These barriers were used to define components of the Capability, Opportunity, Motivation (COM-B) model[212] for further consideration in future stages of mapping.

Stage 2: Intervention Content

The next step of intervention mapping involved determining which of the 9 Intervention Functions as defined by Michie et al. applied for each component of the COM-B model.[212] The functions describe different processes that influence behavior change and contribute to a more complete assessment of intervention feasibility. The final step of this stage was to consider how different policy categories surrounding TR delivery would support or impair successful behavior change.[212]

Stage 3: Intervention Delivery

Implementation strategy was assessed according to the behavior change techniques employed and the mode of intervention delivery. Details describing techniques and delivery were taken from TR visit documentation in clinic records for the 11 participants in this feasibility study. The final map provided a comprehensive view of the TR intervention and its capacity to influence behavior change for this population.

Intervention Evaluation

The APEASE criteria[180] were retrospectively used to inform acceptability and

usability analysis for the 11 participants after completing TR for their TMD conditions. The analysis considered the following outcomes for each criterion:

Acceptability: Average HCSQ patient satisfaction 0-100% at 6-weeks and discharge; questionnaire responses regarding experience with TR and quality of care; willingness to be randomized to another form of care delivery.

Practicability: Average number of visits, questionnaire responses regarding similarity of care to in-person PT; answers to open-ended questions regarding TR choice and experience post-discharge.

Effectiveness: Secondary outcomes quantifying functional improvement on the OHIP-TMD and EQ-5D-5L scales at 6-weeks and discharge for the 11 participants in this analysis; future cost-effectiveness analysis will further quantify this criterion using EQ-5D-5L results and cost data from the entire noninferiority trial cohort.

Affordability: Insurance reimbursement outcomes retrospectively collected from clinic records; responses to open-ended questions regarding TR choice and experience.

Side Effects/Safety: Data regarding safety measures taken and adverse events; number of visits and therapy compliance for the 11 participants in this analysis, retrospectively collected from clinic records.

Equity: Responses to open-ended questions regarding TR choice; demographics outcomes regarding gender, race, educational level, income, and TMD diagnoses.

RESULTS

The 11 participants who completed the qualitative questionnaire represented a range of TMD diagnosis combinations, races, and educational backgrounds. The majority of the sample was female (73%) and white (64%). Full demographic analysis is reported in **Table 11**. The number of study visits ranged from 1-4 at 6 weeks with a median of 4, and from 3-10 at discharge with a median of 5. The intervention timeline is shown in **Figure 18**.

Intervention Mapping

Barriers to behavior change identified by the literature review included issues related to reimbursement, access, and values/beliefs. Variation and uncertainty regarding insurance coverage for telehealth services existed before the COVID-19 pandemic[167,168], and while restrictions have been relaxed during the pandemic, legislation to make TR reimbursement permanent is uncertain. At the time of writing, Medicare had only provisionally approved reimbursement for TR through December 31, 2024.[231] Patients reported concerns about limited access due to poor technology skills.[143,173] Finally, despite identifying the convenience of TR as a facilitator for behavior change, patients with musculoskeletal conditions including TMD stated that in-person care was still a better option and that TR was only of interest as a complement to traditional care.[143,170] These barriers indicated that the intervention needed the physical therapist to employ strategies before the visits occurred to address concerns, and to maintain face-to-face goal-driven care with a personal, individualized approach during visits.

The strategies identified to respond to each barrier addressed each component in the COM-B model. The most common intervention functions used to support these strategies were Education, Modeling, Training, and Enablement. The policy categories that supported TR delivery included Environmental/Social planning, Communication, and Service provision. Implementation included internet delivery of services with email communication to deliver exercise pictures and description as well as to answer questions and problem-solve between visits. Specific techniques employed to change behavior are listed along with other results in the final BCW-informed COM-B model (**Table 12**).

Intervention Evaluation

Feasibility evaluation revealed the following APEASE criteria results: Acceptability: Patients were enrolled in TR based on their preference, and at

baseline, 64% of the participants reported that they would not have participated if allocation had been done by randomization instead of preference. Average patient satisfaction at was 93.1(6.6)% at 6 weeks and 96.6(3.7)% at discharge. All participants answered “strongly agree” when asked if they had a good experience with TR, and a majority (91%) answered “strongly agree” when asked if they felt the care they received was high quality. See **Figure 19** for final study feedback Likert-scale question responses.

Practicability: The mean(SD) and median number of visits at discharge were 5.7(2.0) and 5 respectively. All participants either strongly or somewhat agreed that TR visit quality was similar to in-person (**Figure 19**), and open-ended question answers mentioned ease of TR use and convenience (**Table 13**).

Effectiveness: Future cost-effectiveness analysis results will quantify this criterion from a health process standpoint, but in this report secondary functional outcomes demonstrated TR effectiveness. With only 11 participants the analysis was underpowered to conclude statistically significant improvements from baseline, but the average changes on the OHIP-TMD scale and the EQ-5D-5L health state values were greater or equal to minimal clinically important differences (MCIDs) at 6 weeks and discharge. Results for these secondary outcomes are reported in **Table 14.**

Affordability: Open-ended questionnaire answers mentioned saving time and money (**Table 13**). Affordability was also demonstrated by clinic staff completing insurance verifications and by screening visit discussions about insurance coverage to ensure that prior authorizations and referrals were acquired if needed. There were no issues with care coverage for the participants in this sample.

Side effects/Safety: There were no adverse events, safety issues or side effects including problems with compliance or access reported for any participants.

Equity: Demographic results showed a variety of patient educational levels, races, and diagnoses served by TR delivery in this sample (**Table 11**). Open-ended

question answers showed patients choosing TR due to living a long distance away from the clinic (**Table 13**).

DISCUSSION

These results provide evidence of acceptability and usability of TR for individuals with TMD. They generally align with other studies assessing health process barriers and satisfaction outcomes after TR interventions for musculoskeletal conditions. A mixed methods study by Hinman et al. reported high levels of patient satisfaction after Skype delivery of TR for knee osteoarthritis, finding that face-to-face digital delivery of care actually felt individualized and personal.[129] Moffet et al. found noninferiority of patient satisfaction according to the HCSQ scale after TR following total knee arthroplasty.[145] A study with methods similar to our analysis by Ponzano et al. used the BCW to develop a TR intervention for patient self-management of vertebral fractures using education, training, and goal-setting that successfully satisfied the APEASE criteria and resulted in high levels of compliance and patient satisfaction.[228] At the time of writing the Ponzano study was only other example assessing TR at this level of systematic analysis, demonstrating the clinical importance of our analysis for individuals with TMD.

Addressing the barriers identified in the study by van der Meer et al. was a key component of intervention design.[143] Maintaining face-to-face personal interactions was a component designed to preserve social interaction and facilitated real-time two-way feedback necessary to guide self-performance of testing and exercises. The high proportion of strong agreement with statements regarding having a good experience with TR and receiving high quality care likely relate to this aspect of intervention delivery method. Concerns about technology use were thoroughly addressed at the pre-therapy study screening visit, demonstrating the value of communication and training to influence behavior. Reimbursement concerns were minimal since the provisional extension of Medicare coverage of TR through

December 31, 2024, reduced uncertainty in this area.[231]

APEASE Criteria

Acceptability: The participants who reported unwillingness to be randomized demonstrated acceptability such that those patients accepted TR care as better than no care at all regardless of therapy outcomes. Average patient satisfaction was >90% at both time points, indicating that patients accepted TR throughout the process, not just at the end when final outcomes were achieved.

Practicability: The average number of visits for an episode of in-person TMD care was 9.4(5.3) in a retrospective study be Fisch et al.[12], so practicability was shown in this study with an average visit number of 5.7(2.0) meaning that patients required less visits than the in-person average to meet their goals. Additional support for this criterion came from participants agreeing that TR was similar to in-person care and mentioning TR convenience and ease of use, revealing that this intervention can be used without need for significant adaptations or additional resources.

Effectiveness: The lower number of patients needed for feasibility research precludes drawing statistically significant conclusions regarding functional outcomes, but comparing improvement to MCIDs allows consideration in the context of clinical significance. Considering the 6.9-unit MCID on the condition-specific OHIP-TMD scale[181], this sample demonstrated two-fold improvement at 6-weeks and four-fold improvement at discharge. A MCID for improvement in EQ-5D-5L health state valuation has not yet been assessed for the population of patients with TMD, but 0.04 has been reported in a population with allergic rhinitis that was validated against a quality-of-life scale similar to the OHIP-TMD.[210] According to this value, improvement on this scale was most visible at discharge. However, long-term EQ-5D-5L results considering a 1-year time horizon from baseline will be used to calculate quality-adjusted life-years for cost-effectiveness analysis on a larger sample and will contribute additional feasibility data for this intervention.

Affordability: Qualitative questionnaire results mentioned saving time and money due to the lack of transportation costs and ease of scheduling around work. Minimizing the need to take time off and/or find childcare likely factored into this criterion and will be more fully quantified in the future with cost analysis. Changing the policy areas of Legislation and Regulation would have further addressed the barrier of reimbursement concern, but those areas were outside the scope of this intervention. Results of this feasibility analysis will contribute valuable data toward higher level policy changes to work toward ensuring permanent coverage and access to TR.

Safety/Side Effects: While there were no adverse effects for patients in this study, other possible side effects included poor response to care or lower visit compliance. While the average visit numbers were lower than the in-person average reported by Fisch et al.[12], the improvement on the functional scales indicated that this did not negatively impact the response to care.

Equity: The sample of 11 participants who provided qualitative feedback represented a variety of demographics. In addition to demonstrating the accessibility of TR to patients of varying races and educational backgrounds, multiple questionnaire comments mentioning living far away from the clinic showed that TR increased equity for patients living in different geographic locations. The fact that insurance coverage for TR was available during this study also ensured equity and demonstrates that future legislation to make access permanent is required in this respect.

LIMITATIONS

This study was primarily limited by the fact that the qualitative feedback questionnaire was completed voluntarily 6 months post-discharge, and study setup was such that patients who did not complete discharge questionnaires did not automatically become eligible to submit feedback. The APEASE assessment was limited to the first 11 participants who responded by the time of writing. The large

clinical trial was still ongoing, and other participants had either dropped out between 6 weeks and discharge, were still in the period between discharge and 6-month follow-up or were lost to follow-up. None of the patients who dropped out between 6 weeks and discharge responded when contacted about filling out the optional feedback questionnaire. Demographic analysis of these participants revealed There were 3 participants who completed discharge questionnaires who declined to complete the qualitative questionnaire, and upon further analysis they all had clinically significant improvement on the OHIP-TMD scale, 90-100% HCSQ ratings, and no other demographic differences that would explain why they did not complete the questionnaire. For this reason, cost-effectiveness analysis considering all trial participants will add important feasibility data to the discussion.

Another limitation is that while the intervention was successful due to the maximization of communication strategies, it also depended heavily on good communication to achieve this success. Significant flexibility was required if connections were poor, ranging from using phones for audio to rescheduling appointments. The study was limited to English speakers and adults and therefore results were unable to fully assess the equity criterion for patients who require interpreters or who are younger and unable to respond reliably to cues or instruction.

Finally, allowing patients to choose TR according to their preference and providing monetary compensation likely created some bias that amplified the success of TR. These benefits were available to all participants in the study, so the bias was applied equally, but must still be considered when assessing feasibility results for this intervention. These feasibility conclusions apply only when patients are allowed to choose TR for their care. Preference allocation does contribute to the clinical significance and generalizability of results because patients are usually allowed to choose how they receive their care in the clinic.

CONCLUSION

This analysis used the BCW and APEASE criteria to determine whether a TR intervention for individuals with TMD sufficiently addressed implementation barriers. Results contribute important data regarding health process outcomes that support TR feasibility for this population. Overall, TR intervention mapping revealed good potential to influence patient acceptance and successful satisfaction of all APEASE criteria after TR guidance of TMD symptom management. Viewing the intervention through the APEASE lens clearly demonstrated its acceptability and usability and future cost-effectiveness analysis will further inform the analysis on a larger scale.

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Dissertation Fellowship from the University of Minnesota Graduate School.

Table 11. Baseline Demographics of Telerehabilitation Study Participants

Group Demographic		Study Participants (n=11)
Unwilling to be randomized; n (%)		7 (64%)
Age in years; mean (range)		39.6 (24-59)
Gender n (%)	Male	3 (37%)
	Female	8 (73%)
	Non-Binary	0 (0%)
Ethnicity n (%)	Hispanic/Latino	0 (0%)
	Not Hispanic/Latino	11 (100%)
Race n (%)	American Indian	1 (9%)
	Asian	2 (18%)
	Black/African American	1 (9%)
	White	7 (64%)
Education n (%)	High school	1 (9%)
	Some college	2 (18%)
	College graduate	5 (46%)
	Graduate/post-professional	3 (27%)
Income n (%)	Low	0 (0%)
	Middle	6 (55%)
	Upper	4 (36%)
	Prefer no answer	1 (9%)
Temporomandibular Diagnoses n (%)	Myalgia + TMJ Arthralgia	1 (9%)
	Myalgia + DJD	1 (9%)
	Myalgia + DDwR	2 (18%)
	Myalgia + DDwR + Arthralgia	3 (27%)
	Myalgia + DDwoR + Arthralgia	3 (27%)
	Myalgia + DDwR + DJD + Arthralgia	1 (9%)

OHIP-TMD = Oral Health Impact Profile for TMD; EQ-5D-5L = EuroQuol-5 Dimensions-5 Levels Quality of Life scale; TMJ = Temporomandibular Joint; DJD = Degenerative Joint Disease; DDwR = Disc Displacement with reduction; DDwoR = Disc displacement without reduction

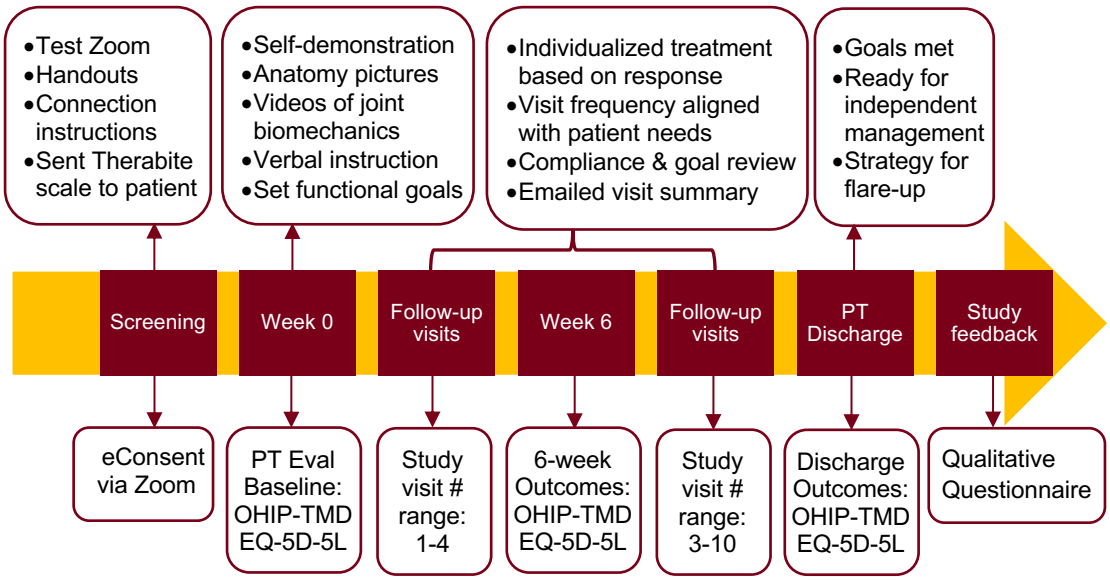


Figure 18. Intervention timeline and details for Telerehabilitation participants. PT = Physical Therapy; OHIP-TMD = Oral Health Impact Profile for TMD scale; EQ-5D-5L = EuroQuol-5 dimensions-5 levels functional scale

Table 12. Intervention Capability-Opportunity-Motivation Model.

Component			Intervention Functions	Intervention-specific Behavior change Techniques
Capability	**Physical**	Gain skills	• Training • Modeling	Demonstrate exercise or movement, give instructions Give performance feedback Request responses from patient self-assessments Educate regarding anatomy, joint biomechanics, pain neuroscience Show pictures, videos Plan to align exercises with daily activities
	Psychological	Gain knowledge	• Education • Enablement	
Opportunity	**Physical**	Technology assistance	• Training • Environmental Restructuring	Send instructions for Zoom use, test during screening Give information for checking insurance coverage Real-time video visits in patient's home environment Practice exercises in their real-life setting while maintaining provider contact
	Social	Face-to-face interaction	• Modeling • Enablement	
Motivation	**Reflective**	Awareness	• Education • Persuasion	Motivational interviewing Positive language & imagery Set and track functional goals Facilitate problem-solving and long-term independent management Give resources for home use
	Automatic	Goal setting & monitoring	• Enablement	

Final model from intervention mapping illustrating targeted behaviors, intervention functions, and specific techniques used to facilitate behavior change

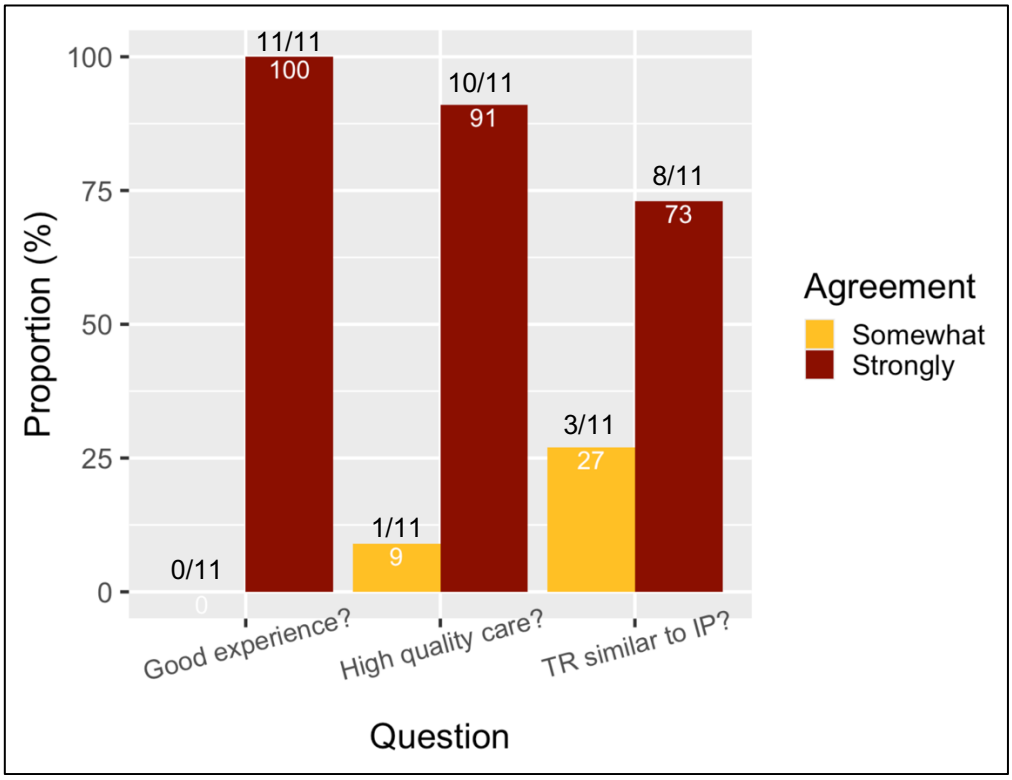


Figure 19. Proportion of agreement level in responses with questions qualitatively assessing feelings about telerehabilitation care. Ratios above each bar describe the number of participants choosing that response. TR = Telerehabilitation; IP = In-person

Table 13. Qualitative open-ended responses to final study feedback questionnaire categorized by the number of responses that mentioned each theme and quotes given as examples.

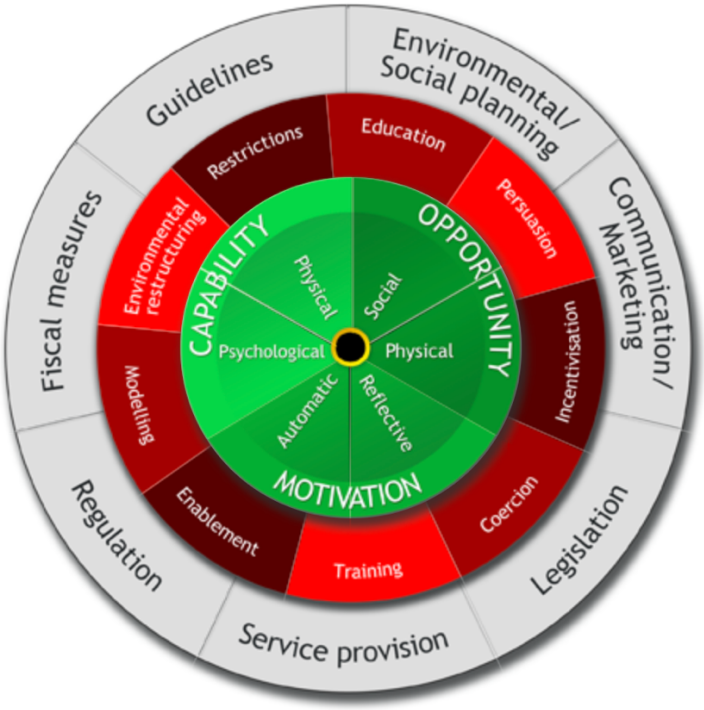
Theme	Responses (n)	Quotes
Ease of use	3	"It was great to have the virtual physical therapy option. It allowed me to save time and more easily schedule sessions."
Availability	2	"Easier for job and schedule"
Convenience	3	"I preferred this method. I saved time and money and received quality care from a quality provider."
No commute	5	"It was nice to save time by not commuting." "I live six hours away from the U of M."

Questions asked included "Why did you choose telerehabilitation for your care?"; "Is there anything you would like to tell us about your experience in this study?"; and "Any additional feedback you wish to share:"

Table 14. Secondary outcomes demonstrating condition-specific and general functional improvement from baseline after 6 weeks and discharge from PT.

Outcome Measure	Baseline Score mean(SD)	Improvement at 6 weeks mean(SD)	Improvement at discharge mean(SD)	Discharge Score mean(SD)	MCID
OHIP-TMD (0-88)*	35.9(13.6)	17.8(12.4)	30.7(14.4)	5.2(4.0)	6.9
EQ-5D-5L (0-1)**	0.84(0.1)	0.04(0.1)	0.09(0.1)	0.93(0.1)	0.04

*Higher score means worse quality of life; **Higher score means a better health state
PT = Physical Therapy; MCID = Minimal Clinically Important Difference; OHIP-TMD = Oral Health Impact Profile for TMD scale; EQ-5D-5L = EuroQuol-5 dimensions-5 levels functional scale



Supplemental Figure 1. The Behavior Change Wheel as described by Michie et al. (2011): The hub is the capability, opportunity, motivation model. Intervention Functions are the middle and policy categories are around the rim.[212]
https://creativecommons.org/licenses/by/2.0/

1. Why did you choose Telerehabilitation for your care?

   Please rate the following in terms of how much you agree or disagree with each statement.

2. The care I received was high-quality.
   Strongly agree , somewhat agree, neither agree/disagree, somewhat disagree, strongly disagree

3. Telerehabilitation visits were similar to in-person visits.
   Strongly agree, somewhat agree, neither agree/disagree, somewhat disagree, strongly disagree

4. I had a good experience with telerehabilitation.
   Strongly agree, somewhat agree, neither agree/disagree, somewhat disagree, strongly disagree

5. Is there anything you would like to tell us about your experience in this study?

6. Any additional feedback you would like to share:

Supplemental Figure 2. Final telerehabilitation study feedback questionnaire providing qualitative feedback regarding experience with care.

Chapter 7: Conclusion

This thesis assessed the effectiveness of TR for individuals with TMD, considering elements spanning the entire episode of care from initial diagnosis through health process outcomes after discharge. Study outcomes describe a clinically effective and feasible method of care delivery that would increase care access for individuals with TMD. Results indicate that: 1. Physical therapists can reliably diagnose masticatory myalgia via TR; 2. Telerehabilitation is noninferior to IP care for meaningful quality-of-life improvement after 6 weeks of care for individuals with TMD; 3. Telerehabilitation is a feasible mode of care delivery for patients with TMD. Conclusions from this comprehensive analysis fill knowledge gaps regarding a service that has been rapidly adopted without evidence since the onset of the COVID-19 pandemic in 2020. The work reported in this thesis will contribute even more data once future economic analysis and secondary outcome analyses using data from long-term follow-up are complete.

Diagnostic agreement of telehealth and in-person physical therapy diagnosis of temporomandibular disorders (Aim 1)

Telediagnosis of masticatory myalgia by a PT had almost perfect diagnostic agreement with an IP OFP specialist criterion reference diagnosis (PABAK = 0.91[0.79,0.97]) after adapting standard evaluation techniques using verbal cues to guide patient self-examination. The level of agreement was noninferior to agreement found for IP diagnosis control between PT and OFP specialist (PABAK = 0.89[0.76,0.97]). PT diagnostic agreement for other TMD subtypes assessed via telehealth revealed moderate to substantial agreement (PABAK = 0.47-0.91) and noninferiority with IP PT assessment for all subtypes except TMJ arthralgia. This

study was the first to investigate telediagnosis of TMD in a true clinical population and these results provide novel evidence toward standardizing PT diagnosis of TMD.

All three hypotheses were supported in this analysis for some of the secondary outcomes in addition to the primary outcome of masticatory myalgia. Diagnosis of DJD in both groups met the k≥0.70 hypothesis ($PABAK_{TR}$ = 0.75[0.60,0.87]; $PABAK_{IP}$ = 0.82[0.65,0.92]) within a 10% margin of difference. While only diagnosis of DDwoR in the TR group met the hypothesis (PABAK = 0.72[0.55,0.84]), noninferiority of PABAK estimates for all other subtypes except TMJ arthralgia reveal that even when agreement with the OFP specialist was not as high as expected, these results were distributed similarly between the two PT evaluation formats.

Assessment of TMD was well-suited for telehealth adaptation because the cameras in devices used for video calls are positioned to visualize the face. Sending participants a ruler designed for oral measurement use allowed quantification of jaw opening that was easy for patients to use and was not subject to projection angle errors. Previous studies of OFP specialists found similar success with telediagnosis[30,32] and this study applies evidence that PTs can reliably perform TMJ testing via telehealth[120] in a clinical context to render diagnoses. Directing patients in self-palpation and appropriate pressure application allowed for decision-making that combined PT movement-based assessment with the bDC/TMD.[63] Successful diagnosis is required to develop a treatment plan, so this evidence supports the use of TR for an entire episode of clinical care. Patients facing transportation restrictions or barriers will benefit from having TR as an option for treating their TMD symptoms.

Study limitations related to aligning this study with usual clinical care are likely the explanation for the lower levels of agreement seen with diagnosing TMJ arthralgia, DDwR, and TMD HA. It is standard clinical practice for OFP specialists to introduce joint protection and self-care strategies at their evaluation. The time lapse

between the OFP reference diagnosis and the PT evaluation was on average >18 days in the IP group and >21 days in the TR group, and while this is not unusual in a clinical setting it likely functioned as a confounder in this study. The existence of multiple subtype diagnoses in one patient is also common but makes it difficult to describe these results for each single diagnosis since in reality symptoms may present differently when multiple factors are involved. At the same time, it is still important to investigate the question of diagnostic reliability in a true clinical context since that is how clinicians will be applying the evidence contributed from this study.

Another limitation was having only 1 PT rater using patient self-reported outcomes of guided self-assessment to synthesize findings and determine diagnoses. Information bias likely occurred especially if patients were hesitant to palpate areas that were already painful or if they didn't find the exact area of the joint or muscle to palpate correctly. Having 1 PT did standardize the process, but also limits generalizability of results. Future analysis using multiple providers following the methods outlined in this study will provide further evidence quantifying the utility of these methods to adapt standard practices for telehealth delivery.

Despite these limitations, study findings provide valuable demographics description of a clinical population with TMD and insight regarding how PT evaluation functions compared to OFP specialists for this population. Multidisciplinary care is the gold standard for management of individuals with TMD[1], and it is vital that PTs and dentists each understand how the other discipline approaches assessment and diagnosis. Masticatory myalgia is the most common painful TMD subtype seen in this population, and these results demonstrate that a telehealth PT evaluation can reliably diagnose it. These results provide a solid foundation upon which the other aims of this thesis can build a clear picture of how TR care can develop and be implemented in this underserved population.

Telerehabilitation effectiveness for individuals with TMD: A noninferiority study (Aim 2)

After using TR to deliver individualized care for individuals with TMD for 6 weeks, the proportion of patients with a meaningful improvement on the OHIP-TMD functional scale (73%) was noninferior compared to the proportion for standard care (62%) within a 10% margin. These patients were self-allocated to TR, indicating that they preferred this type of care. While the estimate for the proportion of improvement was itself larger than the margin, the lower limit of the $CI_{95\%}$ describing the difference (11[-0.02,0.25]%) was within the -10% range and therefore demonstrates noninferiority rather than superiority of TR. Secondary analysis revealed that both groups improved from baseline beyond the 6.9-unit MCID for the OHIP-TMD scale. Both groups averaged approximately 3 visits in 6 weeks with high patient satisfaction ratings at 9.38% (TR = 93.8(8.14)5, IP = 93.8(8.37)%). The most relevant predictors increasing the odds of success after TR were visit compliance, having a low level of chronic pain classified by the GCPS, and a higher baseline OHIP-TMD score.

The noninferiority hypothesis was supported for the primary outcome of therapy success, and using a standardized noninferiority margin specific to each normally distributed secondary outcome revealed that the noninferiority hypothesis was also supported for the measures of change in jaw opening and functional improvement on the EQ-5D-5L and GRS scales. The analyses for change in average and highest pain levels were underpowered to assess noninferiority in the short term but future analyses through discharge and 6 months post-discharge will give additional information regarding how TR affected these measures. The most significant overall conclusion to emerge from the secondary noninferiority analyses was that the OHIP-TMD measure provided the most comprehensive assessment of

overall improvement for patients with TMD compared to other measures of pain or function.

This report is the first study to examine this question in a true multidisciplinary clinical population of patients with TMD. Clinically these results provide evidence that patients can improve with TR even in the short term after 3 visits in 6 weeks. This information is significant because it aligns with how PTs make decisions about progression of a patient's individualized plan of care. The results can influence goal setting and expectations, such that a time frame of 4-6 weeks is reasonable to expect to see these patients meet short term goals for OHIP-TMD improvement with high levels of patient satisfaction. For patients who live far away from the clinic or who struggle to attend regular PT visits, this evidence supports the fact that TR is effective regardless of TMD subtype diagnosis. This information is especially useful for OFP specialists to support their recommendations for including TR in multidisciplinary care planning for patients.

Providing individualized care according to each patient's diagnosis, symptom progression, and schedule is the norm in clinical care but creates a limitation in research because care delivery is not standardized for all participants. Literature evidence supports the delivery of individualized care for individuals with TMD[16,232], but there is currently no clinical practice guideline to provide evidence supporting interventions and treatment planning for PT care for this population. These study results therefore demonstrate that following a general process for standardizing care as described in the methods and can be used as a starting point for future research in this area using multiple PT practitioners.

Another key limitation of this study was the open label preference allocation of the participants, in that it could have introduced bias inflating the treatment effect of TR. This bias was distributed equally across groups, as every participant had the opportunity to join their preferred group, and aside from finding that the IP group was

on average younger there were no other systematic differences in demographics between groups. However, the results showing greater average improvement in OHIP-TMD scores and a higher proportion of improvement for the TR group may have been related to the preference effect. The TR group demonstrated a greater proportion of individuals at baseline with a strong preference for not being randomized to care, which could indicate that this group was more committed to finding success with their treatment. However, this group also had a higher level of attrition than the IP group, so while there may have been a stronger tendency for them to want to improve, that effect did not extend to preventing dropout. Ultimately these findings reflect the importance of allowing patients to have a voice regarding care delivery, and they counter the general belief that patients do not accept TR as an option for PT care delivery.

When considered alongside the findings from the Aim 1 diagnostic agreement analysis, these conclusions support the use of TR for clinical diagnosis and short-term management for patients with TMD. The odds of success are greater when patients are compliant and have a lower level of chronic pain, and the OHIP-TMD is an acceptable measure to track quality-of-life improvements. Future analyses will clarify whether these results extend to long-term outcomes and subgroup categories for diagnosis, and using randomization and multiple providers would expand generalizability of results. Combining these conclusions with feasibility results will fully capture the effectiveness of TR for individuals with TMD.

Feasibility of Telerehabilitation for individuals with TMD (Aim 3)

Results of feasibility analysis considering health process outcomes for a subset of 11 participants in this study revealed that TR delivery was acceptable and usable in this population. BCW mapping revealed that important aspects of delivery impacting behavior change were the use of face-to-face real-time video visits and

using communication strategies to train and enable participants to self-assess and monitor their own progress. The intervention met each APEASE criterion according to patient satisfaction metrics and qualitative responses identifying a good experience with TR that was convenient, easy to use, and similar to IP care. This study was the first to assess TR implementation in a true clinical population of individuals with TMD and contributes important data for use in future cost-effectiveness analysis.

Study results supported the aim 3 hypothesis that patient satisfaction would describe feasibility of TR with high patient ratings of 93.1(6.6)% at 6 weeks and 96.6(3.7)% at discharge. Combined with qualitative responses from patients including open-ended answers and ratings for Likert-scale questions, these results give a more comprehensive assessment of the satisfaction metric. Secondary outcomes assessing effectiveness for these participants revealed clinically significant improvements at 6-weeks and discharge. The average short-term change in OHIP-TMD score was over twice the value of the 6.9-unit MCID (17.8(12.4)) and at discharge it was even higher (30.7(14.4)). Overall functional improvement according to the EQ-5D-5L was greatest at discharge (0.09(0.1)) and larger than the MCID of 0.04. Future analysis is required to assess the other components of aim 3 hypotheses concerning cost-effectiveness analysis and long-term outcomes once data has been collected for all study participants. This thesis primarily considered outcomes after 6-weeks, rendering future analyses outside of scope.

Key study limitations included the volunteer nature of the preference-allocated sample, creating bias also seen in the aim 2 analysis. The qualitative responses primarily came from participants who were very happy with their care, which likely inflated the treatment effect. Regardless, results from this effectiveness study align with conditions of true clinical care and can be considered valid to assess feasibility as seen by results from the BCW mapping and APEASE analysis.

Implementation data is a vitally important component of assessment that is not commonly aligned with clinical research evaluating effectiveness. This study was able to satisfy criteria for both kinds of research, employing preference allocation, noninferiority methods, and qualitative analysis to answer research questions. Overall, results for all three aims demonstrate how TR can be used to improve access to PT care for individuals with TMD.

SUMMARY

Patients with TMD are currently underserved and overlooked, but these conditions have the potential to become chronic and contribute to disability if left unaddressed. Access to high quality care is limited, and this analysis demonstrates that adapting standard PT assessment and intervention strategies using verbal cues during real-time video sessions is an effective care delivery method to fill this access gap. Patients not only engaged in care but indicated that they would not have participated in the study if not allowed to have care via TR. Systematic feasibility assessment revealed that TR is acceptable and usable by this population. Clinically these results indicate that when allowed to choose their care delivery method, patients with TMD can be expected to engage and gain quality-of-life improvements after 6-weeks of care that are not worse than those seen with standard IP PT. Future research is required to complete economic analysis and subgroup analyses, and to increase the scale using multiple PTs in a multicenter trial employing randomization to more stringently control for systematic differences and assess noninferiority.

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APPENDICES

APPENDIX I: R CODE

Power and Sample Size

Diagnostic agreement (Aim 1)

R code for sample size determination assuming each rater will diagnose myofascial pain when it is present 80% of the time, k≥7.0 for desired true kappa, and varying values of the null hypothesis

```
> library(irr)
> N.cohen.kappa(0.80, 0.80, 0.7, 0.65, alpha=0.05, power=0.90, twosided=FALSE)
[1] 3001
> N.cohen.kappa(0.80, 0.80, 0.7, 0.4, alpha=0.05, power=0.90, twosided=FALSE)
[1] 101
> N.cohen.kappa(0.80, 0.80, 0.7, 0.35, alpha=0.05, power=0.90, twosided=FALSE)
[1] 76
> N.cohen.kappa(0.80, 0.80, 0.7, 0.2, alpha=0.05, power=0.90, twosided=FALSE)
[1] 37
> N.cohen.kappa(0.80, 0.80, 0.7, 0.0, alpha=0.05, power=0.90, twosided=FALSE)
[1] 17
```

Noninferiority Analysis of Telerehabilitation Effectiveness (Aim 2)

R code for sample size calculation comparing group proportions where 3L=noninferiority trial, p1=success rate in the telerehabilitation group, p2=success rate in the control group, delta=noninferiority margin.

```
> library(SampleSize4ClinicalTrials)
```

> ssc_propcomp(design = 3L, ratio = 0.67, alpha = .05, power = 0.90, p1=0.75, p2=0.85, delta = 0.1) *#2:3 ratio of treatment to control assuming 85% success in the control group*

Treatment Control

1 58.96 88

> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.90, p1=0.65, p2=0.75, delta = 0.1) *#1:1 ratio of treatment to control*

Treatment Control

1 89 89

> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.90, p1=0.65, p2=0.75, delta = 0.1) *#1:1 ratio of treatment to control assuming a higher percentage (75%) of success in the treatment group*

Treatment Control

1 89 89

> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.90, p1=0.70, p2=0.80, delta = 0.1) *#1:1 ratio of treatment to control with a higher proportion of success in the control group*

Treatment Control

1 80 80

Aim 2 sensitivity analysis of sample size required if unbalanced groups

> ssc_propcomp(design = 3L, ratio = 0.33, alpha = .05, power = 0.90, p1=0.65, p2=0.75, delta = 0.1) *#1:3 ratio of telerehabilitation to control at 75% success in control group*

Treatment Control

1 62.04 188

> ssc_propcomp(design = 3L, ratio = 0.67, alpha = .05, power = 0.90, p1=0.65, p2=0.75, delta = 0.1) *#2:3 ratio of telerehabilitation to control at 75% success in control group*

Treatment Control

1 75.71 113

> ssc_propcomp(design = 3L, ratio = 0.43, alpha = .05, power = 0.90, p1=0.65, p2=0.75, delta = 0.1) *#3:7 ratio of telerehabilitation to control at 75% success in control group*

	Treatment	Control
1	66.22	154

> ssc_propcomp(design = 3L, ratio = 0.43, alpha = .05, power = 0.90, p1=0.70, p2=0.80, delta = 0.1) *#3:7 ratio of telerehabilitation to control at 80% success in control group*

	Treatment	Control
1	59.77	139

> ssc_propcomp(design = 3L, ratio = 0.67, alpha = .05, power = 0.90, p1=0.70, p2=0.80, delta = 0.1) *#2:3 ratio of telerehabilitation to control at 75% success in control group*

	Treatment	Control
1	68.34	102

> ssc_propcomp(design = 3L, ratio = 0.67, alpha = .05, power = 0.90, p1=0.80, p2=0.90, delta = 0.1) *#2:3 ratio of telerehabilitation to control at 80% success in control group*

	Treatment	Control
1	47.57	71

> ssc_propcomp(design = 3L, ratio = 0.43, alpha = .05, power = 0.90, p1=0.80, p2=0.90, delta = 0.1) *#3:7 ratio of telerehabilitation to control at 90% success in control group*

	Treatment	Control
1	42.57	99

Aim 2 sensitivity analysis of sample size required for different noninferiority margin and success rates

> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.90, p1=0.66, p2=0.75, delta = 0.09)

	Treatment	Control
1	109	109

> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.90, p1=0.70, p2=0.75, delta = 0.09)

Treatment Control

1 174 174

> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.90, p1=0.75, p2=0.75, delta = 0.1)

Treatment Control

1 322 322

> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.80, p1=0.75, p2=0.75, delta = 0.1)

Treatment Control

1 232 232

> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.90, p1=0.70, p2=0.70, delta = 0.1)

Treatment Control

1 360 360

> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.90, p1=0.60, p2=0.70, delta = 0.1)

Treatment Control

1 97 97

Exploratory secondary analyses (Aim 3)

Patient Satisfaction:

Non-inferiority comparison of 2:3 allocation ratio at high proportions of satisfied patients in each group.

> ssc_propcomp(design = 3L, ratio = 0.67, alpha = .05, power = 0.90, p1=0.85, p2=0.95, delta = 0.1)

Treatment Control

1 34.17 51

Non-inferiority comparison of 1:1 allocation ratio at high proportions of satisfied patients in each group.

```
> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.90, p1=0.85, p2=0.95, delta = 0.1)

  Treatment Control

1        38      38
```

Non-inferiority comparison of 1:1 allocation ratio at lower proportions of satisfied patients in each group.

```
> ssc_propcomp(design = 3L, ratio = 1, alpha = .05, power = 0.90, p1=0.65, p2=0.75, delta = 0.1)

  Treatment Control

1        89      89
```

Sample size required to find a moderate effect size for two sample group comparisons with any secondary analysis.

```
> pwr.t.test(d=0.6, sig.level = 0.05, power = 0.90, type = "two.sample")


     Two-sample t test power calculation


              n = 59.35155

              d = 0.6

      sig.level = 0.05

          power = 0.9

    alternative = two.sided


NOTE: n is number in *each* group
```

APPENDIX II: FORMS

SCREENING INSTRUMENTS

TMD-Pain Screener

1. In the last 30 days, which of the following best describes any pain in your jaw or temple area on either side?

    a. No pain

    b. Pain comes and goes

    c. Pain is always present

2. In the last 30 days, have you had pain or stiffness in your jaw on awakening?

    a. No

    b. Yes

3. In the last 30 days, did the following activities change any pain (that is, make it better or make it worse) in your jaw or temple area on either side?

    A. Chewing hard or tough food

        a. No

        b. Yes

    B. Opening your mouth or moving your jaw forward or to the side

        a. No

        b. Yes

    C. Jaw habits such as holding teeth together, clenching/grinding, or chewing gum

        a. No

        b. Yes

    D. Other jaw activities such as talking, kissing, or yawning

        a. No

        b. Yes

Graded Chronic Pain Scale (GCPS)

1. 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".

										Pain as bad
No pain										as could be
0	1	2	3	4	5	6	7	8	9	10

2. 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".

										Pain as bad
No pain										as could be
0	1	2	3	4	5	6	7	8	9	10

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 10 is "pain as bad as could be". [That is, *your usual pain* at times you were in pain.]

										Pain as bad
No pain										as could be
0	1	2	3	4	5	6	7	8	9	10

4. 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

5. 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”.

										Unable to carry on
No interference										any activities
0	1	2	3	4	5	6	7	8	9	10

6. 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

7. 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

Additional screening questions:

1. Age: ____

2. In this study, participants will receive their physical therapy (PT) care either using telerehabilitation over Zoom or in-person at the TMD clinic (parking for PT sessions will be reimbursed). Are you willing to be randomly assigned to a method of PT delivery?

   ☐ Yes (Move to question 3)

   ☐ No (Move to question 2a)

3. If you are not willing to be randomly assigned, what is your preferred method of PT delivery?

☐ Telerehabilitation using Zoom

☐ In-person PT at the U of MN TMD clinic

3. Do you have email access to receive Zoom links for virtual PT visits?

☐ Yes

☐ No

4. Do you have access to a device to use for virtual Zoom PT visits?

☐ Yes

☐ No

5. Do you have access to reliable transportation to the University of Minnesota TMD clinic for PT sessions?

   ☐ Yes

   ☐ No

6. Is your permanent residence and/or your location for Zoom PT visits in the state of Minnesota?

   ☐ Yes

   ☐ N

7. Are you currently pregnant, could you be pregnant, or are you planning to get pregnant in the next six months?

   ☐ Yes

   ☐ No

8. Do you currently experience any of the following?

	Yes	No
a. Neuropathic (nerve) pain	☐	☐
b. Fibromyalgia	☐	☐
c. Pain on both sides of the body in ≥3 areas above and below the waist	☐	☐
d. Rheumatoid arthritis	☐	☐
e. Juvenile idiopathic arthritis	☐	☐
f. Dystonia or other movement disorder	☐	☐
g. Jaw fractures and/or recent jaw or facial trauma	☐	☐
h. Any malignant tumors	☐	☐
i. Substance abuse	☐	☐

E-CONSENT

Your PT or dental specialist should have talked through this form with you, answered questions, and checked for your understanding. If you are interested in participating in this study, please proceed with signing the form as directed by your provider.

Thank you!

Title of Research Study: Telerehabilitation Effectiveness for Individuals with ***Temporomandibular Disorders (TMD): A Non-inferiority Study***

Investigator Team Contact Information: Emily Kahnert, DPT, CCTT
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Emily Kahnert, DPT, CCTT Investigator Departmental Affiliation: Division of TMD & Orofacial Pain Phone Number: 612-626-0140 Email Address: kahnert@umn.edu	Study Staff: Loren "Tom" Keeler Phone Number: 218-208-7045 Email Address: keele075@umn.edu

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Your physical therapist, who is also responsible for this research study, [is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by the University of Minnesota Division of Rehabilitation Science, Medical School, and by the Division of TMD and Orofacial Pain, School of Dentistry.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because We are asking you to take part in this research study because you have a diagnosis of a temporomandibular disorder (TMD; problems with your jaw joints and/or jaw muscles that cause you pain) and your TMD specialist has recommended that you start physical therapy (PT) at our clinic.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

During the pandemic, more people began doing PT virtually using real-time video calls known as telerehabilitation. There are potential benefits to using telerehabilitation such as improved convenience, decreased cost, and improved safety during a public health emergency. Telerehabilitation has been helpful for other conditions such as headaches and low back pain. Physical therapy for people with TMD is known to be helpful, but we don't know if telerehabilitation is as effective as traditional in-person PT for people with these conditions. What we learn from this study could help improve access to expert TMD PT for many people.

How long will the research last?

We expect that you will be in this research study for the length of your PT, with long term follow-up questionnaires to fill out once after you have finished PT. Physical therapy for people with TMD lasts on average up to 12 weeks and digital questionnaires will be filled out before PT starts, 6 weeks after starting PT, and at PT discharge. The long-term follow-up questionnaires will be sent over email 6 months after you have finished PT. If you request more time to finish the at-home surveys, you may get up to 1 week to finish these portions of the study.

What will I need to do to participate?

You will be asked to schedule a PT evaluation at the TMD clinic, and you will be asked to complete online questionnaires about your health and jaw function. You will be asked to attend PT visits either virtually using Zoom (telerehabilitation) or in-person at the TMD clinic. The number of follow up appointments and how often you will have follow up visits will be decided during your PT evaluation and over the course of your physical therapy.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

Any health risks from being in this study are the same risks that apply to standard PT clinical care. With regular patient care, you may feel muscle soreness or a flare in your symptoms after evaluation and/or exercise performance. You will be given recommendations to decrease any discomfort that may occur, and care delivery will be adjusted to prevent continued discomfort.

Some of the health questionnaires in this study are personal in nature. You might feel worn out from completing these questionnaires. You can skip any questions you do not want to answer.

There is a chance that information collected about you in this study could accidentally be seen by someone who is not part of the study team. We store your data securely to try to prevent this. We also use security measures with Zoom software to make sure that telerehabilitation visits are confidential.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research aside from receiving recommended clinical PT care for your TMD. If you choose to be in the telehealth group, you may find more flexibility with how and where you have PT. We cannot promise any benefits to others from your taking part in this research.

What happens if I do not want to be in this research?
There are no known alternatives, other than deciding not to participate in this research study. You will be able to schedule PT at the TMD clinic or Zoom telehealth visits if you do not want to be in this research.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?
We expect about 218 people from the TMD clinic will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?
If you decide you want to be part of this study, you will be screened and scheduled for a physical therapy (PT) appointment with Dr. Emily Kahnert, DPT, a specialized TMD physical therapist at the University of Minnesota's TMD & Orofacial Pain Clinic. You may choose to either attend your PT appointment using Zoom as telerehabilitation or in-person at the TMD clinic. You may choose to switch your appointment type (in-person or Zoom telerehabilitation) after your first 6 weeks. Once you are scheduled, you will complete online questionnaires to assess your health and jaw function before your PT begins.

If you attend your PT visits using Zoom telerehabilitation:

- You will receive instructions on how to download the Zoom software needed to attend your PT visits. (There is no fee to download or use Zoom).
- A Zoom link will be sent to you from Dr. Emily Kahnert's email 24-hours before your scheduled visits. You will click the link from the email on your device and the PT will allow you access to the PT Zoom visit.
- Before your first appointment, you will receive a small handheld ruler. You will be instructed on how to use the ruler for jaw measurement during your Zoom telerehabilitation appointment.
- During your visits, you will be instructed on how to measure your jaw movements with the provided ruler.
- Dr. Kahnert will instruct you on how to perform certain tests to assess your joints and muscles and will give you feedback while you are performing these tests.
- You will be given instructions on how to perform self-massage if you experience pain after your Zoom telerehabilitation visit.

If you attend your PT visits in-person:

- Your PT visits will take place at the University of Minnesota TMD & Orofacial Pain Clinic.
- Dr. Kahnert will perform certain tests to assess your joints and muscles.

For both the Zoom telerehabilitation visits and the in-person visits:

- Your first visit will be a 60-minute PT evaluation where you will be asked to answer questions about your symptoms and your health
- You will undergo an assessment to determine what your condition requires for successful rehabilitation.
- You will be given self-care suggestions to perform at home to decrease pain and improve jaw function.
- Dr. Kahnert will speak with you regarding the timing of your follow up visits. This will be determined by the course of treatment. The number of follow up visits can range from 3 to 12 visits for up to 12 weeks, with each visit lasting approximately 30 minutes.
- Your progress will be assessed at each follow up visit, and your treatment may change based on each assessment.
- You will be asked to do at-home exercises and other activities on your own, in order to decrease pain and improve jaw function.
- At each 30-minute follow-up visit, your care may be adjusted and progressed based on your symptom response to the activities you have been performing at home.
- At 6 weeks into your physical therapy, and again at discharge, you will be asked to complete an online survey about your health and jaw function. Once the survey is completed, you will receive payment for this portion of your participation in this study.
- 6 months after you have completed therapy, you will again be asked to complete an online survey. Once the survey is complete, you will receive payment for this portion of your participation in the study.
- At the end of the study, you will be asked to consider completing an additional, final questionnaire where you can give us feedback about your experience participating in this study. This questionnaire will take approximately 5 to 10 minutes to complete, depending on the level of detail you choose to share. This survey is voluntary and is anonymous, so no one will know who completed the questionnaire.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for: a study screening appointment and attending 12 physical therapy visits, either in person or using Zoom.

You will be asked to do after visit care, such as pain management techniques and exercises.

You will be asked to complete an online questionnaire at the end of your first 6 visits, and again 6 months after your last appointment.

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Can I be removed from the research?

It's possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed. This does not mean that you will have to stop your physical therapy. You will keep any compensation that has been distributed to you already, but no future compensation will be given.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any additional costs to you outside of the costs of regular clinical care. Physical therapy costs will be billed to your insurance company and clinic co-pays will be assessed as they would with standard physical therapy visits, like all other such care in the TMD & Orofacial Pain Clinic.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Your participation in this research will involve the collection and processing of your personal data, as described above and in any HIPAA Authorization Form we have provided to you. Please indicate whether you consent to the collection and processing of your personal data by placing your initials underneath the appropriate selection.

◯ Yes, I consent to the collection and processing of my personal data.
◯ No, I do not consent to the collection and processing of personal data.

Enter your initials here to verify that you selected the correct option above.

_____

(Your consent is entirely voluntary, but declining to provide it may materially impede your ability to participate in this research and receive any treatment.)

To the extent your personal data are protected by the GDPR, you have the right to—

- Know what data we are collecting, where they will be processed, and how they will be used;
- View and correct your personal data;
- Obtain and transfer your personal data to another organization;
- Have certain personal data destroyed (except when data retention is otherwise required or authorized under the GDPR or other controlling legal authority);
- Withdraw your consent to the continued collection of your personal data; and
- Certain other actions described in Chapter III of the GDPR.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☐ My genetic testing records _____ (initial)

☐ My mental health diagnosis/treatment records ____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

· The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

· Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

· The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

· Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

· Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

Greenphire ClinCard and Mastercard

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic, or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data and specimens when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to $100 for your time and effort. You will receive $25 after completing online questionnaires at 6-weeks, $25 after completing online questionnaires at discharge, and $50 after completing online questionnaires 6 months after your last appointment. You will receive a voucher to cover your parking for the in-person study visits you attend.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.
You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive a cardholder agreement. Be sure to read all of this information for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, and MasterCard, will be given your name, date of birth, address and social security number. They will use this information as part of the payment process. Greenphire will only need your social security number if the payment exceeds $599. Greenphire and MasterCard will not receive any information about your health status or the study in which you are participating.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of participant:

_____
(Please click the green "add signature" button, sign, and save)

Typed Name of Participant	_____ (First Last)
Date:	_____
Signature Block for Person Obtaining Consent:	
Signature of Person Obtaining Consent	_____ (Please click the green "add signature" button, sign, and save)
Typed Name of Person Obtaining Consent	_____ (First Last)
Date	_____ (Click on Now)

Consent Form Addendum

Signing this additional consent form gives us permission to send you a final post-study questionnaire which is optional and any answers you give will remain anonymous. If you do not wish to complete a final post-study questionnaire, no action is needed and you do not need to sign; simply close the window and ignore the invitation.

Title of Research Study: Telerehabilitation Effectiveness for Individuals with Temporomandibular Disorders: A Non-Inferiority Study

Investigator Team Contact Information:
For questions about research appointments, the research study, research results, or other concerns, contact the study team at:

Investigator Name: Emily Kahnert, DPT, CCTT Investigator Departmental Affiliation: Division of TMD & Orofacial Pain Phone Number: 612-626-0140 Email Address: kahnert@umn.edu	Study Staff: Loren "Tom" Keeler Phone Number: 218-208-7045 Email Address: keele075@umn.edu

Please read this consent addendum carefully and take your time making your decision. As the researcher or study staff discusses this addendum with you, please ask them to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to sign this consent addendum.

Participation in research is voluntary. Your decision whether or not to participate will not affect your clinical care. If you choose to participate, you are free to withdraw at any time without affecting the relationship with your clinical care provider.

Except for the change described in this addendum, the terms of your original consent form remain in full effect

Update to the Study:
Once you complete the last of the 6-month questionnaires, you will be asked to consider completing an additional, final questionnaire where you can give us feedback about your experience on this study. This questionnaire will take approximately 5 to 10 minutes to complete, depending on the level of detail you choose to share. This survey is voluntary and is anonymous, so no one will know who completed the questionnaire.

Whom do I contact if I have questions, concerns or feedback about my experience?
This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

SIGNATURES:

The purpose of this consent addendum has been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research or this addendum, or to obtain information or offer input about the research. I have read this addendum and agree to the choices I have indicated above, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this addendum. Your signature documents your permission to take part in this research.

Signature of participant:

_____
(Please click the green "add signature" button, sign, and save)

Typed Name of Participant

_____
(First Last)

Date

_____
(Click on Now)

DATA COLLECTION INSTRUMENTS

Patient Health Questionnaire for Anxiety and Depression (PHQ-4)

Over the last two weeks, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Feeling down, depressed or hopeless	0	1	2	3
4. Little interest or pleasure in doing things	0	1	2	3
TOTALS	_____	_____	_____	_____

TOTAL SCORE (sum) = _____

Scoring:
0-2 = Normal
3-5 = Mild
6-8 = Moderate
9-12 = Severe

Subscores:
If scores for Q 1+2 ≥ 3; Anxiety suggested
If scores for Q 3+4 ≥ 3, Depression suggested

Oral Health Impact Profile – TMDs (OHIP-TMD)

All questions phrased as “Over the last month…” with responses possible:

Never	Hardly ever	Occasionally	Fairly often	Very often
(0)	(1)	(2)	(3)	(4)
☐	☐	☐	☐	☐

1. Have you had difficulty chewing any foods because of problems with your jaws, teeth, or mouth?
2. Have you had difficulties opening or closing your mouth?
3. Have you had painful aching in your mouth, face, or ear?
4. Have you had a sore jaw?
5. Have you had headaches because of problems with your jaws, teeth, or mouth?
6. Have you found it uncomfortable to eat any foods because of problems with your jaws, teeth, or mouth?
7. Have you felt that talking was painful because of problems with your jaws, teeth or mouth?
8. Have you been worried by jaw or dental problems?
9. Have you been self-conscious because of your jaws, teeth, or mouth?
10. Have jaw or dental problems made you miserable?
11. Have you felt tense because of problems with your jaws, teeth, or mouth?
12. Have you had to avoid eating some foods because of problems with your jaws, teeth, or mouth?
13. Have you had to interrupt meals because of problems with your jaws, teeth, or mouth?
14. Has your sleep been interrupted because of problems with your jaws, teeth, or mouth?
15. Have you been upset because of problems with your jaws, teeth, or mouth?
16. Have you found it difficult to relax because of problems with your jaws, teeth or mouth?
17. Have you felt depressed because of problems with your jaws, teeth, or mouth?

18. Has your concentration been affected because of problems with your jaws, teeth, or mouth?
19. Have you been a bit irritable with other people because of problems with your jaws, teeth, or mouth?
20. Have you had difficulty doing your usual jobs because of problems with your jaws, teeth, or mouth?
21. Have you felt that life in general was less satisfying because of problems with your jaws, teeth, or mouth?
22. Have you been unable to work to your full capacity because of problems with your jaws, teeth, or mouth?

Jaw Functional Limitation Scale-8 item (JFLS-8)

For each of the items below, indicate the level of limitation during the past month. If the activity was completely avoided because it is too difficult, indicate '10.' If you avoid an activity for reasons other than pain or difficulty, then leave the item blank.

1. Chew tough food

No Limitation										Severe Limitation
0	1	2	3	4	5	6	7	8	9	10

2. Chew chicken (eg, prepared in oven)

No Limitation										Severe Limitation
0	1	2	3	4	5	6	7	8	9	10

3. Eat soft food requiring no chewing (eg, mashed potatoes, apple sauce, pudding, pureed food)

No Limitation										Severe Limitation
0	1	2	3	4	5	6	7	8	9	10

4. Open wide enough to drink from a cup

No Limitation										Severe Limitation
0	1	2	3	4	5	6	7	8	9	10

5. Swallow

No Limitation										Severe Limitation
0	1	2	3	4	5	6	7	8	9	10

6. Yawn

No Limitation										Severe Limitation
0	1	2	3	4	5	6	7	8	9	10

7. Talk

No Limitation										Severe Limitation
0	1	2	3	4	5	6	7	8	9	10

8. Smile

No Limitation										Severe Limitation
0	1	2	3	4	5	6	7	8	9	1

Additional outcome questions:

Numeric Pain Rating Scale:

On a scale from 0 (no pain) to 10 (worst possible pain), where is your pain level today? ___

On a daily basis, what is your pain on average at its best? ___

On a daily basis, what is your pain on average at its worst? ___

Global Rating Scale:

On a scale from 0-100% with 100% indicating full independent management (ideal function), what is your function today compared to before PT treatment? ___

EuroQoL-5 Dimension-5 Level (EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ☐

I have slight problems in walking about ☐

I have moderate problems in walking about ☐

I have severe problems in walking about ☐

I am unable to walk about ☐

SELF-CARE

I have no problems washing or dressing myself ☐

I have slight problems washing or dressing myself ☐

I have moderate problems washing or dressing myself ☐

I have severe problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

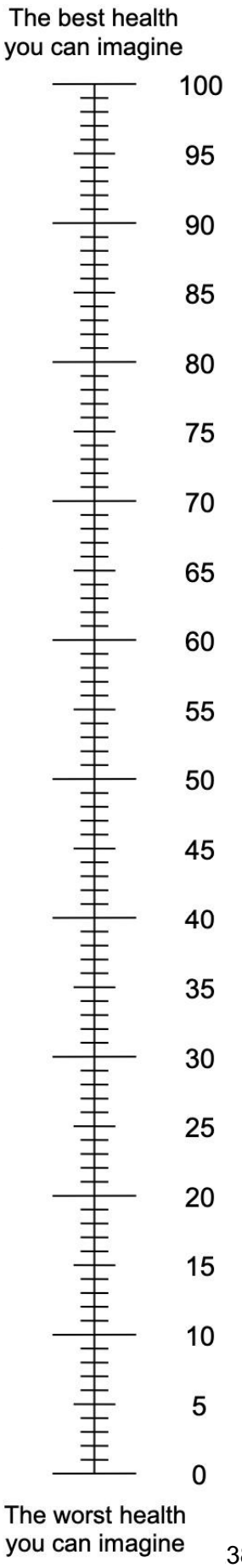
I have no problems doing my usual activities ☐

I have slight problems doing my usual activities ☐

I have moderate problems doing my usual activities ☐

I have severe problems doing my usual activities ☐

I am unable to do my usual activities ☐



PAIN/DISCOMFORT

I have no pain or discomfort ☐

I have slight pain or discomfort ☐

I have moderate pain or discomfort ☐

I have severe pain or discomfort ☐

I have extreme pain or discomfort ☐

ANXIETY/DEPRESSION

I am not anxious or depressed ☐

I am slightly anxious or depressed ☐

I am moderately anxious or depressed ☐

I am severely anxious or depressed ☐

I am extremely anxious or depressed ☐

We would like to know how good or bad your health is TODAY.

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Please mark an X on the scale to indicate how your health is TODAY.
- Now, write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

Telerehabilitation TMD Study Cost Questionnaire

We would like to find out what money and time you and your family had to spend to manage the pain in your mouth and or face over the last six* months. Your answers will give those who make decisions about patient treatment a clearer understanding of the burden on you and your family caused by the pain.

The information that you provide will be completely confidential. Your answers will be combined with the answers provided by other people involved in the study and reported in such a way that it will not identify you or influence your treatment.

Although this questionnaire appears large, several subsections may not be relevant to your situation and the questions are organized to move you past questions that are not relevant to you. Please answer every question that you think is relevant to you. If you are not sure or cannot remember the exact details, please give the best answer you can. In each case chose the answer that is most accurate. There are no right or wrong answers. Please complete all questions until you reach "Thank you this is the last page of the questionnaire."

Please type within the boxes like this: 1 8 ☐☐ or X ☐

**For the 12-week data collection, "six months" will be replaced with "three months"*

SECTION 1: CONSULTATIONS IN LAST 6 MONTHS

Over the last four months how many times have you visited the practitioners listed below and have you had to pay for the visits? Please give the total out of pocket amount you had to pay for the consultation(s). Please do not include any prescription charges.

Question 1.1: Visits to a General Medical Practitioner

Have you seen a general medical practitioner?

Yes ☐ No (move to question 1.2) ☐

If yes, how many times have you seen a general practitioner? ☐☐☐

If you had to pay anything for your appointments, how much have you paid in total over the last six months? $☐☐☐.☐☐

Question 1.2: Visits to a General Dental Practitioner

Have you seen a general dentist? Yes ☐ No (move to question 1.3) ☐

If yes, did you see them as an insurance patient? Yes ☐ No ☐

How many times did you see the dentist? ☐☐☐

If you had to pay anything for your dental appointments, how much have you paid in total over the last six months? $☐☐☐.☐☐

Question 1.3: Visits to a Physical Therapist

Have you seen a physical therapist? Yes ☐ No (move to question 1.6)☐

If yes, did you see them as an insurance patient? Yes ☐ No ☐

How many times did you see the physical therapist? ☐☐☐

If you had to pay anything for your physical therapist appointments, how much have you paid in total over the last six months? $☐☐☐.☐☐

Question 1.4: Visits to a Psychologist

Have you seen a psychologist? Yes ☐ No (move to question 1.7) ☐

If yes, did you see them as an insurance patient? Yes ☐ No ☐

How many times did you see the psychologist? ☐☐☐

If you had to pay anything for your psychology appointments, how much have you paid in total over the last six months? $☐☐☐.☐☐

Question 1.5: Other healthcare professional visits

Have you had other visits to healthcare professionals?

Yes ☐ No (move to section 2) ☐

If yes, please specify what type of practitioner(s) and which specialty:

……

……

If yes, did you see them as an insurance patient? Yes ☐ No ☐

How many times did you see them? ☐☐☐

If you had to pay anything for your appointments, how much have you paid in total over the last six months? $☐☐☐.☐☐

SECTION 2: MEDICATION AND TREATMENT

The following section asks about any medications that you have used, or treatments you have received, during the last six months for your pain

Question 2.1: In the last four months, which of the following medications have been prescribed by your doctor/dentist (including tablets, capsules, injections, and creams) to be used to manage your pain in your mouth and or face?

Choose all that apply. Please give details of the medication's total daily dose (the total amount in milligrams of the tablets you take per day) and whether you have used this medication regularly or only when needed. If you are not using any of the medications listed below, please check this box ☐ and go to question 2.4.

Anti-inflammatory painkillers ☐

For example: Naproxen, Diclofenac (also known as Voltarol)
Please give name(s) of drug(s):
Please indicate total daily dose ☐☐☐☐ milligrams (mg)
Used regularly ☐ or as needed ☐

Opiate (opioid) painkillers ☐

For example: Tramadol, MST Continus (Morphine), OraMorph (Morphine), Fentanyl
Please give name(s) of drug(s):
Please indicate total daily dose ☐☐☐☐ milligrams (mg)
Used regularly ☐ or as needed ☐

Tricyclic antidepressants ☐

For example: Amitriptyline Hydrochloride (also known as Triptafen, Elavil), Nortriptyline (also known as Pamelor, Aventyl), Dosulepin Hydrochloride (also known as Dothiepin Hydrochloride), Clomipramine hydrochloride

Please give name(s) of drug(s):
Please indicate total daily dose ☐☐☐☐ milligrams (mg)

Antiepileptics ☐

For example: Gabapentin (also known as Neurontin), Pregabalin (also known as Lyrica), Carbamezapine (also known as Tegratol)

Please give name(s) of drug(s):
Please indicate total daily dose ☐☐☐☐ milligrams (mg)

Other medications that are not listed ☐.

Please give name(s) of drug(s):
Please indicate total daily dose ☐☐☐☐ milligrams (mg)
Used regularly ☐ or as needed ☐

Question 2.2: Over the last six months have you paid for your prescriptions?

Yes (please continue with question 2.3) ☐ No (go to question 2.4) ☐

Question 2.3: Over the last six months how much, in total, have you paid for your prescriptions? Please specify the amount in the box below.

Total amount spent on prescriptions $☐☐☐.☐☐

Question 2.4: In the last six months, have you used any over-the-counter measures to help manage your pain, for example painkillers bought from the pharmacy, hot or cold packs bought from a shop?

No ☐ (go to question 2.5) Yes ☐ (continue to complete the table below)

If you have used over-the-counter measures to help control your pain, please indicate their name, how often you have used each medication in the last four months, and their approximate cost in the table below.

Name	How often have you used this item over the last four months?	Amount spent on medication
		$
		$
		$

Question 2.5: Over the last six months have you had any of the following treatments or devices/appliances for treatment of your pain? Please check all that apply and provide the total **out of pocket** costs of the treatment provided.
If you have not received any of these, please check this box ☐ and go to section 3.

Treatment or device	Received by you in order to try and manage your pain	Out of Pocket Cost
a) Dental fillings	Yes ☐ No ☐	Total cost $☐☐☐☐☐.☐☐
b) Dental Extractions	Yes ☐ No ☐	Total cost $☐☐☐☐☐.☐☐
c) Dental crowns (caps) or bridges	Yes ☐ No ☐	Total cost $☐☐☐☐☐.☐☐
d) Dental implants	Yes ☐ No ☐	Total cost $☐☐☐☐☐.☐☐
e) Dentures	Yes ☐ No ☐	Total cost $☐☐☐☐☐.☐☐
f) Soft splint (mouth guard)	Yes ☐ No ☐	Total cost $☐☐☐☐☐.☐☐
g) Hard splint	Yes ☐ No ☐	Total cost $☐☐☐☐☐.☐☐
h) TENS machine	Yes ☐ No ☐	Total cost $☐☐☐☐☐.☐☐
i) Surgical procedure	Yes ☐ No ☐ Procedure:	Total cost $☐☐☐☐☐.☐☐
j) Medical procedure	Yes ☐ No ☐ Procedure:	Total cost $☐☐☐☐☐.☐☐
k) Other	Please specify:	Total cost $☐☐☐☐☐.☐☐

SECTION 3: PRODUCTIVITY LOSSES

This section of the questionnaire asks about how the pain in your face and or mouth has affected both your paid work and your unpaid work. By unpaid work we mean activities such as household chores, shopping, caring for children and voluntary work, non-leisure activities that involve your time but for which you do not get paid.

Question 3.1: Please indicate the date your pain started. If you cannot remember a specific date then please indicate the year it started.

Day ..... Month.....Year.....

Please write in today's date. Day ..... Month.....Year.....

Question 3.2: Are you currently in paid work or self-employed?

Yes ☐ (occupation…….. working ☐☐☐ hours per week) No ☐

Question 3.3: Before your pain started, were you in paid work or were you self-employed?

Yes ☐ (occupation…….. worked ☐☐☐ hours per week)

No ☐ (go to question 3.8)

Question 3.4: Since your pain started have you been absent from work?

Yes ☐ (please continue with question 3.5) No ☐ (go to question 3.7)

Question 3.5: In the last six months how much time have you been absent from your work due to the pain in your mouth and or face?

Number of ☐☐weeks ☐☐days

If you have been absent from paid work because of your pain, have you now returned to paid work?

Yes ☐ (continue with question 3.6) No ☐ (go to question 3.8)

Question 3.6: When you first returned to paid work or self-employment did you work fewer hours than before your pain started?

Yes ☐ (total number of hours worked per week: ☐☐☐ hours) No ☐

Question 3.7 parts a, b, c and d

a) How many hours per day and days per week would you normally work?

Normal number of hours worked per day ☐☐☐hours

Normal number of days worked per week ☐☐☐days

b**) In the last four months approximately how many days did you go to your paid work with pain in your mouth and or face?**

Number of days worked with pain in last six months ☐☐☐days

c) Please indicate for each statement that is mentioned how often it applied to you in the past four months: I did go to work but as a result of health problems...

	Never	Sometimes	Often	Always
...I had trouble concentrating	☐	☐	☐	☐
...I had to work at a slower pace	☐	☐	☐	☐
...I had to isolate myself	☐	☐	☐	☐
...I found decision-making more difficult	☐	☐	☐	☐
...I had to put off some of my work	☐	☐	☐	☐
...others had to take over some of my work	☐	☐	☐	☐

...I had other problems (please share): ……

d) When at work suffering from pain in your mouth and or face, how much work do you actually perform during regular hours on the scale below? (Circle number)

1	2	3	4	5	6	7	8	9	10
Practically nothing									Normal quantity

When at work suffering from pain in your mouth and or face, what is the quality of the work you perform on the scale below? (Circle number)

1	2	3	4	5	6	7	8	9	10
Poor quality									Normal quality

Question 3.8: Before your pain started, how many hours a week, on average, did you spend on unpaid work (household chores, shopping, childcare or voluntary work)?

Number of hours worked, on average, per week: ☐☐☐hours

Question 3.9: In the last six months have you undertaken any unpaid work?

Yes ☐ (Total number of hours worked on average, per week: ☐☐☐hours) No ☐

SECTION 4: ADDITIONAL INFORMATION

The next section of the questionnaire asks whether there are any other costs not covered previously in this questionnaire.

Question 4.1: Have you incurred any other costs because of your pain?

Yes ☐ No ☐

If yes, what were they for and how much did you spend? In the table below please write the purpose of other costs and the amount of money spent.

Purpose	Amount spent
	$☐☐☐☐.☐☐
	$☐☐☐☐.☐☐
	$☐☐☐☐.☐☐
	$☐☐☐☐.☐☐
	$☐☐☐☐.☐☐

Do you have any further comments or any information you would like to add about costs you have incurred because of your pain in or therapy the last six months?
.....
.....
.....

Question 4.2: Please write down any other costs you have had to pay for related to the pain in your mouth and or face in addition to the things we have already asked about in this questionnaire. For example, telephone calls, extra laundry, clothing or heating, or additional travel expenses such as having to use taxis rather than car or public transport.
.....
.....
.....

SECTION 5: TIME & TRAVEL

Mode of therapy delivery: Telerehabilitation ☐ In-person ☐
Number of PT visits: ☐

Attendance at physical therapy
Please answer these questions regardless of which therapy group you were in. If you were in the telerehabilitation group, please answer as if you would have been coming in person.

Question 5.1: What was/would have been your normal form of transportation?
Car/motorcycle ☐ How many miles was a one way trip? ☐☐☐
Walk/bicycle ☐
Public transport (bus, train) ☐ Cost of one way trip $☐☐.☐☐
Taxi/Rideshare (Lyft, Uber) ☐ Cost of one way trip $☐☐.☐☐

Question 5.2: What was/would be your normal traveling time?
Travelling time ☐☐ hrs:☐☐ mins

Question 5.3: Did someone usually go with you to your appointment?

No ☐ Yes ☐ (If Yes, please indicate who **usually** went with you)

You may check more than one box if appropriate:
Partner/spouse ☐
Child/children under 16 years ☐
Other relative ☐
Paid caregiver ☐
Other (please **specify)** ☐
Details:……..

If yes, did this person pay one-way fares? No ☐ Yes ☐ (Cost $☐☐.☐☐)
What would your companion **normally** have been doing as their **main** activity if they had not gone with you to the
practitioner?.....

Question 5.4: Did you have to arrange childcare or care for other dependents?
No ☐ Yes ☐ N/A ☐ (no children or dependents)

If yes, how many long did the person caring for your child/children/dependent(s) spend looking after your child/children/dependents during PT? ☐☐ hrs:☐☐ mins

Did you pay this person? No ☐ Yes ☐ Amount paid for care: $☐☐.☐☐

If you **did not** pay this person, what they would have been doing if they were not caring for your
children/dependents?.....

Question 5.5: Did/would telerehabilitation visits change your childcare situation?
No ☐ Yes ☐ N/A ☐ (no children or dependents)
If yes,
how?.....

Is there anything else that you would like to tell us about your pain condition or this questionnaire?

Thank you. This is the last page of the questionnaire.

Healthcare Satisfaction Questionnaire (HCSQ)

Perceived performance response scale: "Do you feel that…"
1=not at all; 2=somewhat; 3=very much; 4=extremely

Expectation response scale: "How important is it that…"
1=not important at all; 2=slightly important; 3=very important; 4=extremely important

Answer each question twice, once for each scale:

1) You can trust the professionals	P:___ E:___
2) The professionals are courteous	P:___ E:___
3) The professionals respect your privacy	P:___ E:___
4) The professionals you met seem competent	P:___ E:___
5) The professionals treat your information confidentially	P:___ E:___
6) You receive honest answers to your questions	P:___ E:___
7) The same professional looks after you each time	P:___ E:___
8) The professionals treat you with respect	P:___ E:___
9) The professionals show a sense of responsibility toward you	P:___ E:___
10) The professionals really understand your needs	P:___ E:___
11) The professionals you met take your problem seriously	P:___ E:___
12) The professionals talk to you in words you can understand	P:___ E:___
13) The professionals encourage you to get support from your family & friends	P:___ E:___
14) The professionals tell you about the different choices you have	P:___ E:___
15) The professionals give you advice regarding how to prevent the problem from recurring	P:___ E:___
16) The professionals give you all the information you need about where to go, what to do, and what not to do	P:___ E:___
17) The professionals inform you about the available services	P:___ E:___
18) The professionals take your lifestyle into account	P:___ E:___
19) The appointments you make with the professionals are obtained quickly	P:___ E:___
20) You don't have to go through too many steps when you want to contact a professional	P:___ E:___
21) You didn't have go through too many steps when you wanted to get help	P:___ E:___
22) The professionals take the necessary time to take care of you	P:___ E:___
23) The professionals are accessible at times that are convenient for you	P:___ E:___

APPENDIX III: REPORTING GUIDELINES

Guidelines for reporting Reliability and Agreement Studies (GRRAS)

GRRAS checklist for reporting of studies of reliability and agreement
Version based on Table I in: Kottner J, Audigé L, Brorson S, Donner A, Gajeweski BJ, Hróbjartsson A, Robersts C, Shoukri M, Streiner DL. Guidelines for reporting reliability and agreement studies (GRRAS) were proposed. J Clin Epidemiol. 2011;64(1):96-106

Section	Item #	Checklist item	Reported on page #
Title/Abstract	1	Identify in title or abstract that interrater/intrarater reliability or agreement was investigated.	
Introduction	2	Name and describe the diagnostic or measurement device of interest explicitly.	
	3	Specify the subject population of interest.	
	4	Specify the rater population of interest (if applicable).	
	5	Describe what is already known about reliability and agreement and provide a rationale for the study (if applicable).	
Methods	6	Explain how the sample size was chosen. State the determined number of raters, subjects/objects, and replicate observations.	
	7	Describe the sampling method.	
	8	Describe the measurement/rating process (e.g. time interval between repeated measurements, availability of clinical information, blinding).	
	9	State whether measurements/ratings were conducted independently.	
	10	Describe the statistical analysis.	
Results	11	State the actual number of raters and subjects/objects which were included and the number of replicate observations which were conducted.	
	12	Describe the sample characteristics of raters and subjects (e.g. training, experience).	
	13	Report estimates of reliability and agreement including measures of statistical uncertainty.	
Discussion	14	Discuss the practical relevance of results.	
Auxiliary material	15	Provide detailed results if possible (e.g. online).	

CONSORT Statement 2006 - Checklist for Non-inferiority and Equivalence Trials: Items to include when reporting a non-inferiority or equivalence randomized trial

PAPER SECTION **And topic**	Item	**Descriptor**	**Reported on Page #**
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned") specifying that the trial is a non-inferiority or equivalence trial.	
INTRODUCTION Background	2	Scientific background and explanation of rationale, *including the rationale for using a non-inferiority or equivalence design.*	
METHODS Participants	3	Eligibility criteria for participants *(detailing whether participants in the non-inferiority or equivalence trial are similar to those in any trial(s) that established efficacy of the reference treatment)* and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group *detailing whether the reference treatment in the non-inferiority or equivalence trial is identical (or very similar) to that in any trial(s) that established efficacy,* and how and when they were actually administered.	
Objectives	5	Specific objectives and hypotheses, *including the hypothesis concerning non-inferiority or equivalence*.	
Outcomes	6	Clearly defined primary and secondary outcome measures *detailing whether the outcomes in the non-inferiority or equivalence trial are identical (or very similar) to those in any trial(s) that established efficacy of the reference treatment* and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	
Sample size	7	How sample size was determined *detailing whether it was calculated using a non-inferiority or equivalence criterion and specifying the margin of equivalence with the rationale for its choice*. When applicable, explanation of any interim analyses and stopping rules (*and whether related to a non-inferiority or equivalence hypothesis*).	
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	

Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s), *specifying whether a one or two-sided confidence interval approach was used*. Methods for additional analyses, such as subgroup analyses and adjusted analyses.	
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group.	
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was *"intention-to-treat" and/or alternative analyses were conducted*. State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval). *For the outcome(s) for which non-inferiority or equivalence is hypothesized, a figure showing confidence intervals and margins of equivalence may be useful*.	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	
Adverse events	19	All important adverse events or side effects in each intervention group.	
DISCUSSION Interpretation	20	Interpretation of the results, taking into account the *non-inferiority or equivalence hypothesis and any other* study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

TIDier CHECKLIST

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.		
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.		
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).		
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.		
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.		
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.		
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.		
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.		
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.		
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).		
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.		
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.		

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protoc or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, th TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist