

# Research Diagnostic Criteria for Burning Mouth Syndrome (RDC/BMS)

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## Introduction

These research diagnostic criteria (RDC) have been developed for use with patients with Burning Mouth Syndrome (BMS) which has been defined as “an intraoral burning or dysaesthetic sensation, recurring daily for more than 2 hours per day over more than 3 months, without evident causative lesions on clinical examination and investigation” by the International Classification of Orofacial Pain (ICOP) 2020<sup>1</sup>. This was previously referred to as primary BMS. These RDC may also be used for patients who have had burning symptoms for less than 3 months, which would then be classified as probable BMS<sup>1</sup>.

The aim of this RDC is therefore to exclude any intraoral burning symptoms which can be attributed to one or more causative lesion(s). An exception to this is a patient who was considered to have a mucosal pain disorder as classified by the ICOP<sup>1</sup>, who following initiation of treatment for the causative lesion(s) continues to report a persistent burning symptom. In this case the patient can then be further classified as having BMS by the RDC<sup>2</sup>.

The RDC has been developed as research diagnostic criteria, which includes all tests which would be included for diagnosis of BMS for research purposes. Once validated, in the future a simplified diagnostic criteria could be produced which would be used for diagnosis of BMS in a purely clinical setting, rather than for research.

The RDC will form four parts: symptom self-report, examination, psychosocial self-report, and aspirational biomarkers. The first three parts support two axes: a physical diagnosis and disease characterization (parts 1 and 2), and psychosocial status of the person (part 3). A 3<sup>rd</sup> axis may be formed from part 4, which includes aspirational biomarkers. The aspirational biomarkers listed in part 4 should be included in the RDC where possible and considered applicable by the clinician, they will be refined and included in the definitive RDC as it is trialled and they are validated for use in BMS.

## Part 1 – Symptom Self Report

### Patient Details

Age:

Gender:

Ethnicity:

Occupation:

### *Section 1A: Primary Symptom*

#### Symptom Description

This question relates to symptoms you may or may not be experiencing **inside** of your mouth. Which of the following are you experiencing? Everyone uses different words so please select as many as required. Please also highlight which you consider to be the worst.

- Burning
- Ache
- Tingling
- Itching
- Roughness
- Sore
- Discomfort
- Other (please specify): \_\_\_\_\_

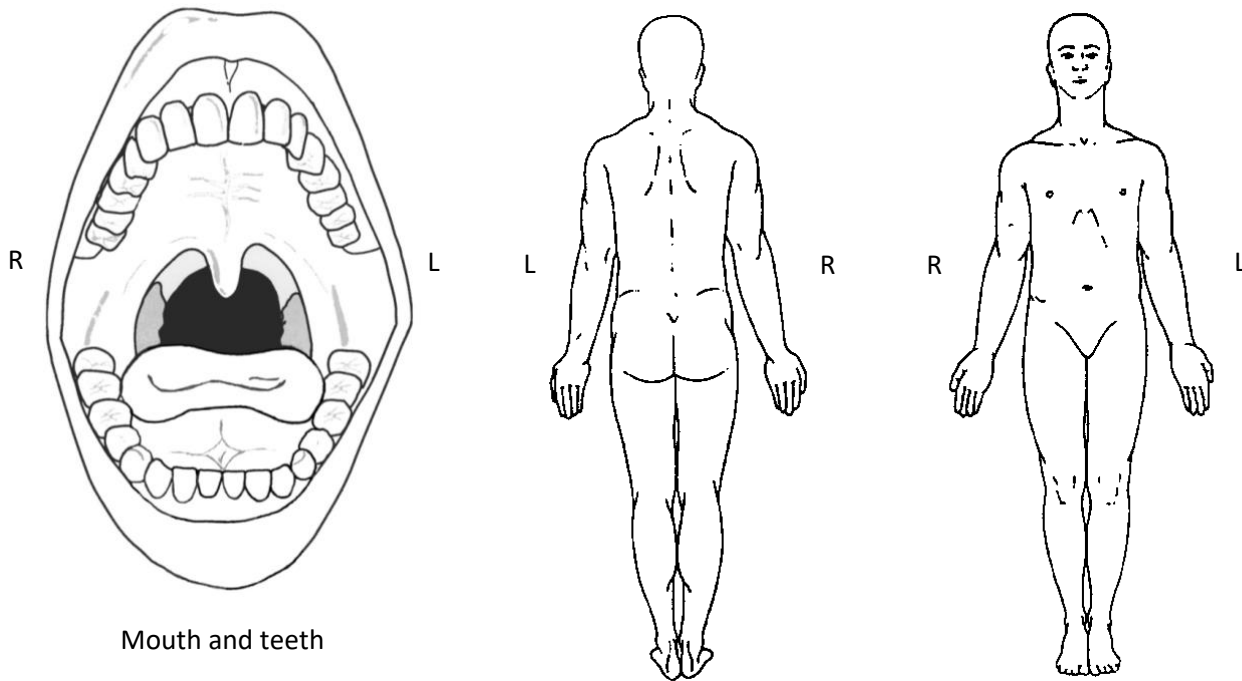
## Short-Form McGill Pain Questionnaire-2 (SF-MPQ-2)

This questionnaire provides you with a list of words that describe some of the different qualities of pain and related symptoms. Please put an **X** through the number that best describes the intensity of each of the pain and related symptoms you have felt during the past 30 days. Use 0 if the word does not describe your pain or related symptoms.

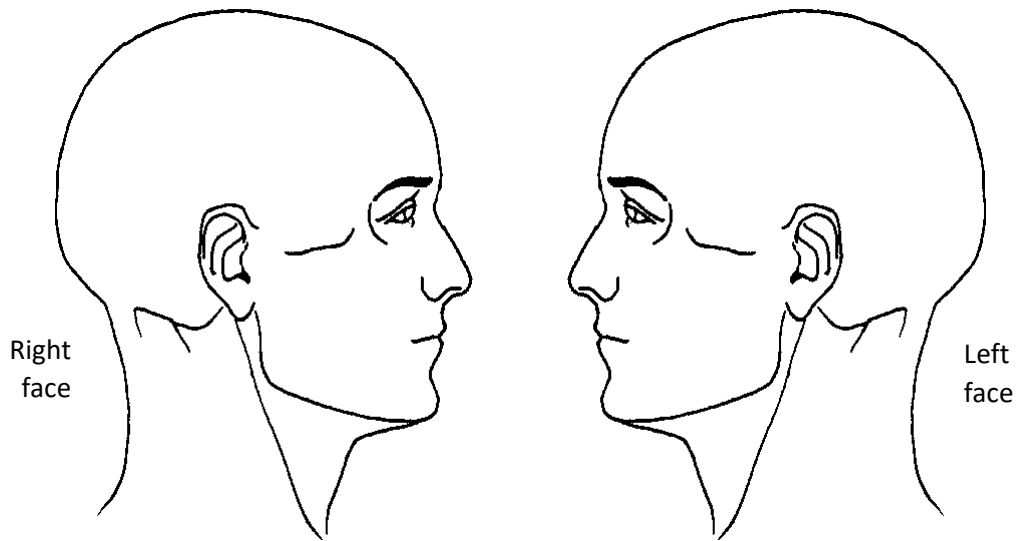
1. Throbbing pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
2. Shooting pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
3. Stabbing pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
4. Sharp pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
5. Cramping pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
6. Gnawing pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
7. Hot-burning pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
8. Aching pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
9. Heavy pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
10. Tender	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
11. Splitting pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
12. Tiring-exhausting	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
13. Sickening	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
14. Fearful	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
15. Punishing-cruel	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
16. Electric-shock pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
17. Cold-freezing pain	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
18. Piercing	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
19. Pain caused by light touch	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
20. Itching	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
21. Tingling or 'pins and needles'	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>
22. Numbness	<i>none</i>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>	<input type="text" value="10"/>	<i>worst possible</i>

## Pain Drawing

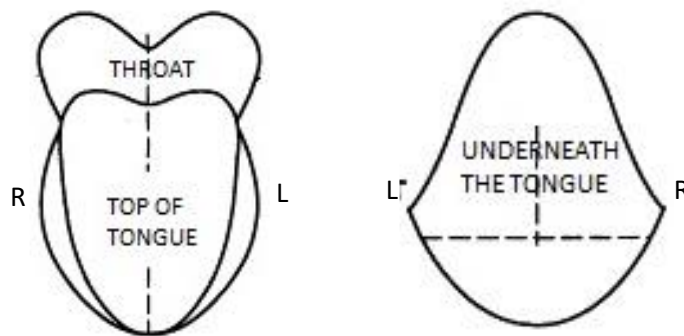
Indicate the location of ALL of your different pains by shading in the area, using the diagrams that are most relevant. If there is an exact spot where the pain is located, indicate with a solid dot (●). If your pain moves from one location to another, use arrows to show the path.



Mouth and teeth



Tongue



### Onset

Did your symptoms start spontaneously? Yes/No

How long ago were the onset of your symptoms? \_\_\_\_ Days/Weeks/Months (Delete as appropriate)

At the time your symptoms started had any of the following happened in the same period of time? If yes please give details:

- Started taking new medications (including mouthwashes, toothpaste)
- Had dental treatment
- Had any illnesses (mental and/or physical)
- Change in diet

If yes to above, please give details below:

At the time of onset of your symptoms, or within the most recent year, have you had any significant or stressful life events? Yes/No

### Current Symptoms

During the past 3 months, how many days per month did you usually experience your symptoms? \_\_\_\_ Days

During the past 3 months, how much time per day in total did you usually experience your symptoms? (Please tick):

- Less than 5 minutes
- 5 minutes to less than 30 minutes
- 30 minutes to less than 1 hour
- 1 hour to less than 2 hours
- 2 hours to less than 4 hours
- 4 hours to less than 6 hours
- 6 hours to less than 12 hours
- 12 hours or longer

Do your symptoms vary over the course of 24-hour period? Yes/No. If yes, please describe below.

Do your symptoms wake you up from sleep? Yes/No.

Do you wake up with symptoms? Yes/No.

Exacerbating and Relieving Factors

Please give a list of anything which makes your pain worse, e.g. specific types of food, stress, tiredness, mood, speech.

Is there anything which makes the pain better? E.g. sipping water or chewing gum or candy, relaxation or distraction.

Have you had any previous treatment for your symptoms? If yes, what and did it help?





*Section 1B: Associated Features*

Do you have any of the following problems in addition to those mentioned above? (Please tick all that apply):

**Taste:**

- Changed taste of foods, specifically:
  - Sour
  - Salty
  - Sweet
  - Bitter
- Metallic taste
- Other change in taste, please describe \_\_\_\_\_
- If you have ticked any of the above is this:
  - A persistent spontaneous taste experienced throughout the day
  - Only associated with food

**Dryness:**

- Dry mouth
- Dry eyes

Do any of the following make the symptoms in your mouth worse?

- Chilli or spicy foods
- Citrus flavours (e.g. citrus, lemon)
- Hot drinks
- Cold drinks
- Toothpastes, if yes do they contain:
  - Sodium lauryl sulphate
  - Fluoride
- Mint flavours
- Talking
- Wearing dentures

Do any of the following make the symptoms in your mouth better?

- Meals
- Sipping water
- Milk products
- Chewing gum or candy
- Hot drinks
- Cold drinks
- Talking
- Wearing dentures
- Rest or sleep

*Section 1C: Illness and Medications*

Please complete the following questions, if you are unsure about any of the medications or illnesses then please ask your clinician when you see them. It would be helpful to bring a full list of your medications with you to your appointment.

Are you taking, or have you taken, any of the following medications whilst experiencing these symptoms in your mouth (details of the type of medications you are taking can normally be found on the patient information sheet inside the medication box):

- Antibiotics (e.g. amoxicillin)
- ACE inhibitors (e.g. lisinopril)
- Angiotensin receptor blockers (e.g. losartan)
- Antiretrovirals (e.g. drugs used in the management of HIV)
- Anticholinergic (e.g. ipratropium)
- Clonazepam, or any other benzodiazepine drug
- Drugs which list a dry mouth a common side effect on their information leaflet
  - If yes, please state drug name(s): \_\_\_\_\_
- Thiazide diuretics (e.g. Bendroflumethiazide)
- Antihistamines (e.g. loratadine)
- Other drugs which list taste disturbance as a common side effect on their information sheet:
  - If yes, please state drug name(s): \_\_\_\_\_
- Corsodyl (chlorhexidine) and alcohol mouthwash
- Cinnamon Aldehyde toothpaste
- Hormone replacement therapy

Do you have any of the following illnesses or medical symptoms?

- Diabetes
- Hyper or Hypo thyroidism
- Menopause/Peri – menopause
- Multiple sclerosis
- Scleroderma
- Anaemia
- Viral infection
- Sjogrens
- Ear infection – including around the time of onset of your burning mouth symptoms
- Heartburn/GORD
- Other pain conditions
- Dry eyes/mouth
- Radiotherapy
- Chemotherapy
- Upper respiratory tract infection – including around the time of onset of your burning mouth symptoms
- Lichen Planus
- Lupus or other connective tissue disorders
- Vulvodynia

Do you have any silver or grey fillings in your mouth which contain mercury (amalgam fillings)? Yes/No

If yes, approximately how long have you had the fillings? \_\_\_\_\_

Do you drink alcohol? If yes please give details below on how often and how much.

Do you smoke? If yes please give details below on how often, the type of tobacco and how long you have smoked for.





## Part 2 – Examination

Aim to exclude the following: salivary disorders, mucosal disease (VB, Infective, Autoimmune (Lupus, Lichen Planus), Idiopathic (erythema migrans), trauma (chemical, thermal, radiation, mechanical), anaemia signs on the tongue, metal allergy.

### *Section 2A: Extra Oral Examination*

- TMJ
- Muscles
- Lymph nodes
- Salivary Glands
- Cranial Nerve Exam (NB drop some for DC)
- Skin inspection
- Goitre

### *Section 2B: Intra Oral Examination*

- Soft tissue screen
- Wetness of mucosa? Frothing, dry thick saliva or dryness (mirror stick to buccal mucosa)
- Salivary glands:
  - Ducts
  - Objective dryness (froth, mirror stick)
- Specific tongue:
  - Appearance
    - Shiny
    - Bold
    - Deep grooves/fissures
    - White coated
  - Colour
  - Papilla
- Basic periodontal exam (whatever the local protocol is, e.g. BPE, DPSI)
- Teeth:
  - Sharp edges
  - Rough restorations
  - Tooth wear (gross): erosion, attrition, (abrasion?)
  - Caries
  - Association with amalgam restorations/metallic crowns?
- Dentures and appliances:
  - Clasps
  - Tongue space
  - Trauma
  - Hygiene of denture
  - Age of denture
  - Denture in good repair

### *Section 2C: Investigations*

The following list of investigations are at baseline related only to the primary symptom of burning, these are therefore the standard set for all patients. However, others may be added in depending on the outcome of the above examination based on clinical judgement (e.g salivary flow rate).

Haematological:

- CBC/FBC (Hb, MCV, MCH, WCC)
- B12, Fe, Folate (Vitamin B1, 2, 6, 12)
- Serum Ferrum, Ferritin, Total Iron Binding Capacity (TIBC)
- Magnesium
- Zinc
- HbA<sub>1</sub>C
- TFT (T3, T4, TSH)
- LFT (ALT, AST, GGT, ALK Phos, Albumin)
- ESR **or** CRP
- Autoantibodies:
  - Anti Ro and Anti La
  - ANA
  - ENA
- Serum homocysteine level

Patch test: adjunctive for clinical suspicion

Candida:

- Mandatory: swab or smear for gram-staining
- Aspirational: saliva sample for testing of presence and load of candida infection

QST:

A full QST is aspirational, however where available this should be carried out as per the protocol below (table 1<sup>3</sup>). If full QST is not possible then carry out a QualST instead as follows<sup>4</sup>:

Evaluate sensitivity to touch, cold and pin prick stimuli first on a non-painful site followed by the painful site. For touch stimuli apply with a cotton swab in a single stroke over 1-2cm of oral mucosa. For cold stimuli apply with a stainless steel dental spatula which has been kept cool in ice water for 1-2 seconds. For pin prick stimuli apply a moderate force (a force that would be painful but would not penetrate the mucosal surface) for 1 second.

Table 1: Taken from Devine et al. (2018)<sup>3</sup>.

Test	Description	Equipment
Cool detection threshold	A small thermode applied to the affected nerve distribution is set at a baseline temperature and cools at a defined rate until the patient indicates when they first feel cold sensation. Test is repeated 3 times and an average value recorded.	Thermal QST apparatus
Warm detection threshold	A small thermode applied to the affected nerve distribution is set at a baseline temperature and warms at a defined rate until the patient	Thermal QST apparatus

	<p>indicates when they first feel warm sensation.</p> <p>Test is repeated 3 times and an average value recorded.</p>	
Thermal sensory limen	The difference threshold for alternating cool and warm stimuli	Thermal QST apparatus
Cold pain threshold	<p>A small thermode applied to the affected nerve distribution is set at a baseline temperature and cools at a defined rate until the patient indicates when they first feel pain caused by cold sensation.</p> <p>Test is repeated 3 times and an average value recorded.</p>	Thermal QST apparatus
Heat pain threshold	<p>A small thermode applied to the affected nerve distribution is set at a baseline temperature and warms at a defined rate until the patient indicates when he or she first feels pain caused by heat sensation.</p> <p>Test is repeated 3 times and an average value recorded.</p>	Thermal QST apparatus
Mechanical detection threshold	<p>Semmes Weinstein monofilaments are placed perpendicular to the skin in the affected nerve distribution and force is applied until the filament deforms. At this point, a known reproducible force is applied. An ascending and descending series of monofilaments applying different amounts of force is used to measure the contact detection threshold.</p> <p>This is repeated 5 times and a mean value taken.</p>	Semmes Weinstein monofilaments
Mechanical pain threshold	<p>A custom-made weighted pinprick is applied to the affected nerve distribution. An ascending and descending series of pinpricks is used to measure the MPT.</p> <p>This is repeated 5 times and a mean value taken.</p>	Weighted pinprick

<p>Mechanical pain sensitivity and dynamic mechanical allodynia</p>	<p>MPS: Seven weighted pinprick stimuli of different intensities are applied in a random order and repeated five times for each test site. DMA involves moving innocuous stimuli such as a Q-tip, cotton wisp and soft toothbrush across the test site in between pinprick stimuli. The patient gives a numerical pain rating for each stimulus. A total of 50 stimuli (pinprick and tactile) should be given at each test site.</p>	<p>Weighted pinprick Q-tip Cotton wisp Soft toothbrush</p>
<p>Temporal summation of pain as wind up ration</p>	<p>10 pinprick stimuli of equal intensity are given at an interstimulus interval of 1 Hz. The patient is asked to give a numerical pain rating for this stimulus which is compared to the pain rating for a single stimulus. Each series of 10 stimuli is repeated 5 times in the affected nerve distribution and an average value is taken.</p>	<p>Weighted pinprick</p>
<p>Vibration detection threshold</p>	<p>Vibrating tuning forks are placed over a bony prominence in the affected nerve distribution. The patient indicates if they can feel vibration or not and three series of descending stimulus intensities are used to determine the VDT.</p>	<p>Vibrating tuning forks</p>
<p>Pressure pain detection threshold</p>	<p>A pressure algometer or pressure gauge device is applied to the affected nerve distribution. Three series of slowly ascending stimulus intensities are applied and the patient indicates when pain is felt. An average value of the 3 readings is taken.</p>	<p>Pressure algometer or pressure gauge</p>



## Part 3 – Psychosocial

### Short version:

- PHQ-4
- Ultra brief catastrophising scale
- Also refer to GCPS V2 and pain diagram included in part 1

### Long version:

- PHQ-9
- GAD-7
- PHQ-15
- Ultra brief catastrophising scale
- OBC
- PROMIS Short Form v1.0 – Sleep Disturbance 8a
- Also refer to GCPS V2 and pain diagram included in part 1

Section 3A: PHQ-4

Over the last 2 weeks, how often have you been bothered by the following problems? Please place a check mark in the box to indicate your answer.

---

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

---

TOTAL SCORE =

---

If you checked off <u>any</u> problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?			
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 3B: Ultra Brief Pain Catastrophising Scale

1. In the **PAST THREE MONTHS**, when you felt pain, how much did you feel you couldn't stand it any more? (Circle number)

0      1      2      3      4      5      6      7      8      9      10

Not at all

All the time

2. In the **PAST THREE MONTHS**, when you felt pain, how much did you worry all the time about whether it will end? (Circle number)

0      1      2      3      4      5      6      7      8      9      10

Not at all

All the time

3. In the **PAST THREE MONTHS**, when you felt pain, how much did you keep thinking about how much it hurts? (Circle number)

1      1      2      3      4      5      6      7      8      9      10

Not at all

All the time

Section 3C: PHQ-9

Over the last 2 weeks, how often have you been bothered by the following problems? Please place a check mark in the box to indicate your answer.

	Not at all	Several days	More than half the days	Nearly every day
	0	1	2	3
1. Little interest or pleasure in doing things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Feeling down, depressed, or hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Trouble falling or staying asleep, or sleeping too much	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Feeling tired or having little energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Poor appetite or overeating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Trouble concentrating on things, such as reading the newspaper or watching television	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Thinking that you would be better off dead or of hurting yourself in some way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

TOTAL SCORE =

If you checked off <u>any</u> problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?			
Not difficult at all	Somewhat difficult	Very Difficult	Extremely difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 3D: GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems? Place a check mark in the box to indicate your answer.

	Not at all	Several days	More than half the days	Nearly every day
	0	1	2	3
1. Feeling nervous, anxious or on edge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Not being able to stop or control worrying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Worrying too much about different things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Trouble relaxing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Being so restless that it is hard to sit still	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Becoming easily annoyed or irritable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Feeling afraid as if something awful might happen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

TOTAL SCORE =

If you checked off <u>any</u> problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?			
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 3E: PHQ-15

During the last 30 days, how much have you been bothered by any of the following problems?  
Please place a check mark in the box to indicate your answer.

	Not bothered 0	Bothered a little 1	Bothered a lot 2
1. Stomach pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Back pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Pain in your arms, legs, or joints (knees, hips, etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Menstrual cramps or other problems with your periods [women only]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Headaches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Chest pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Dizziness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Fainting spells	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Feeling your own heart pound or race	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Shortness of breath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Pain or problems during sexual intercourse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Constipation, loose bowels, or diarrhea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Nausea, gas, or indigestion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Feeling tired or having low energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Trouble sleeping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

TOTAL SCORE =

**PLEASE COMPLETE THE ADDITIONAL QUESTION ON THE NEXT PAGE**

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If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult  
at all

Somewhat  
difficult

Very  
difficult

Extremely  
difficult

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Section 3F: OBC

How often do you do each of the following activities, based on **the last 30 days**? If the frequency of the activity varies, choose the higher option. Please place a (v) response for each item and do not skip any items.

Activities During Sleep		None of the time	< 1 Night /Month	1-3 Nights /Month	1-3 Nights /Week	4-7 Nights/ Week
1	Clench or grind teeth <b>when asleep</b> , based on any information you may have	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Sleep in a position that puts pressure on the jaw (for example, on stomach, on the side)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Activities During Waking Hours		None of the time	A little of the time	Some of the time	Most of the time	All of the time
3	Grind teeth together <b>during waking hours</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Clench teeth together <b>during waking hours</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Press, touch, or hold teeth together other than while eating (that is, contact between upper and lower teeth)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Hold, tighten, or tense muscles without clenching or bringing teeth together	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Hold or jut jaw forward or to the side	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Press tongue forcibly against teeth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Place tongue between teeth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Bite, chew, or play with your tongue, cheeks or lips	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Hold jaw in rigid or tense position, such as to brace or protect the jaw	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Hold between the teeth or bite objects such as hair, pipe, pencil, pens, fingers, fingernails, etc	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	Use chewing gum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	Play musical instrument that involves use of mouth or jaw (for example, woodwind, brass, string instruments)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	Lean with your hand on the jaw, such as cupping or resting the chin in the hand	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	Chew food on one side only	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	Eating between meals (that is, food that requires chewing)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18	Sustained talking (for example, teaching, sales, customer service)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	Singing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



20	Yawning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21	Hold telephone between your head and shoulders	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Section 3G: PROMIS Short Form v1.0 – Sleep Disturbance 8a

Please respond to each question or statement by marking one box per row.

In the past 7 days...		Very poor	Poor	Fair	Good	Very good
Sleep109	My sleep quality was.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
In the past 7 days...						
		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep116	My sleep was refreshing.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep20	I had a problem with my sleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep 44	I had difficulty falling asleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep108	My sleep was restless.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep72	I tried hard to get to sleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep67	I worried about not being able to fall asleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep115	I was satisfied with my sleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

## Part 4 – Biomarkers (Aspirational)

The below are a list of aspirational biomarkers which may or may not be able to be included depending on what is available at each centre.

- Biopsy<sup>5-9</sup>: this would be to consider epithelial fibre number and penetration, Substance P, TRPV<sub>1</sub>, Sodium channels and menthol receptors.
- Salivary tests<sup>10</sup>: these may include salivary flow rate, GRP, saliva proteomic, saliva composition and salivary genetics (e.g. COMT).
- Saliva and or blood samples to include<sup>11,12</sup>: microbes, dopamine, progesterone, oestrogen, serotonin, glutamate, GABA, proinflammatory markers, Mφ Activity, tryptinase, artemin, H pylori, menopausal index.
- Imaging (functional)<sup>13-20</sup>: options include arterial spin labelling MRI, MR Neurography, PET combined MRI, MR spectroscopy.
- QST<sup>21-26</sup>: to include electrical stimulation for differential testing of the somatic sensory V3 and special sensory chorda tympani, blink reflex differences, and hypo function of chorda tympani using electrical taste or tingling detection threshold ration in thermal or mechanical QST for investigation of thermal or mechanical threshold differences and chemical QST for assessment of respond to capsaicin, cinnamon, menthol and local anaesthetic.
- Other adjunctive or aspirational psychosocial investigations<sup>27-29</sup>: sleep as a predictor or impact of sleep (PROMIS questionnaire set), previous or current abuse considering the best methodology for investigation (questionnaire vs structured interview), self-efficacy, somatosensory amplification, perceived stress scale.

## Part 5 – Scoring Instructions

### *Section 1A: Primary Symptom Short Form McGill Questionnaire Scoring Instructions*

The Short Form McGill Questionnaire version 2<sup>30</sup> comprises 22 questions scored 0-10. The following pain scores can be calculated:

- Total pain: average of all ratings
- Continuous pain: average of questions 1, 5, 6, 8, 9, 10
- Intermittent pain: average of questions 2, 3, 4, 11, 16, 18
- Neuropathic pain: average of questions 7, 17, 19, 20, 21, 22
- Affective pain: average of questions 12, 13, 14, 15

### *Section 1A: Primary Symptom Graded Chronic Pain Scale Scoring Instructions*

The graded chronic pain scale<sup>31,32</sup> gives three initial scores:

**Characteristic Pain Intensity (CPI)** compute mean of items 2-4 (pain right now, worst pain, average pain), and multiply by 10.

**Interference Score:** compute mean of items 6-8 (daily activities, social activities, work activities), and multiply by 10.

**Disability points for number of days with interference:** assign points based on below table

**Disability points for the interference score:** assign points based on the below table

<b>Points for Disability Days (0-30 Days)</b>		<b>Points for Pain-related Interference Score</b>	
0-1 Days	0 Points	0-29	0 Points
2 Days	1 Point	30-49	1 Point
3-4 Days	2 Points	50-69	2 Points
5+ Days	3 Points	70+	3 Points

The total Disability Points = Points for Disability Days + Points for Interference Score.

This gives the following classification:

<b>Grade 0</b>	No pain in the prior 30 days
<b>Grade 1</b>	CPI < 50 < 3 Disability Points
<b>Grade 2</b>	CPI ≥ 50 < 3 Disability Points
<b>Grade 3</b>	3 to 4 Disability Points (Regardless of CPI)
<b>Grade 4</b>	5 to 6 Disability Points (Regardless of CPI)

### *Section 3A: PHQ-4 Scoring Instructions*

The total score is calculated by adding together the scores of each of the 4 items listed. These are rated as<sup>33</sup>:

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

### *Section 3B: Ultra Brief Pain Catastrophising Scale Scoring Instructions*

This score is calculated by taking the average of the 3 scores. Higher scores equal higher catastrophisation<sup>34,35</sup>.

### *Section 3C: PHQ-9 Scoring Instructions*

The total score is calculated by adding together the scores for each of the 9 items listed. These are rated as<sup>36-39</sup>:

- 0-4: Normal
- 5-9: Mild
- 10-14: Moderate
- 15-29: Moderately severe
- 20-27: Severe

### *Section 3D: GAD-7 Scoring Instructions*

The total score is calculated by adding together the scores for each of the items listed. These are rated as<sup>40</sup>:

- 0-4: Normal
- 5-9: Mild anxiety
- 10-14: Moderate anxiety
- 15-21: Severe anxiety

### *Section 3E: PHQ-15 Scoring Instructions*

The total score is calculated by adding together the scores for each of the 15 items listed. These are rated as<sup>41-42</sup>:

- 0-4: Normal
- 5-9: Mild
- 10-14: Moderate
- 15-30: Severe

### *Section 3F: OBC Scoring Instructions*

The total score is calculated by adding together the number of items with a non-zero response or as a weighted sum. Norms for the OBC in BMS have not yet been established, however as a guide in chronic TMD patients the following scores are used<sup>43</sup>:

- 0-16: Normal

- 17-24: Seen twice as often in those with TMD
- 25-62: Seen 17 times more in those with TMD and therefore considered a risk factor contributing to TMD onset

*Section 3G: PROMIS Short Form v1.0 – Sleep Disturbance 8a Scoring Instructions*

The score can be calculated using the PROMIS software available at [https://www.assessmentcenter.net/ac\\_scoringervice](https://www.assessmentcenter.net/ac_scoringervice). Alternatively the score can be calculated by calculating the raw score by adding together the scores for each of the 8 items listed, the lowest raw score being 8 and the highest 40. Then use the table below to convert the raw score to a T-Score. The T-Score rescales the raw score into a standardised score with a mean of 50 (standard deviation of 10), and a score of 50 is the average for the US general population. Therefore as an example, a patient with a T-Score of 40 is one standard deviation below the mean (and therefore one standard deviation better than average) and a patient with a T-Score of 60 is one standard deviation above the mean (and therefore one standard deviation worse than average).<sup>43</sup>

Raw Score	T-Score	SE*
8	28.9	4.8
9	33.1	3.7
10	35.9	3.3
11	38.0	3.0
12	39.8	2.9
13	41.4	2.8
14	42.9	2.7
15	44.2	2.7
16	45.5	2.6
17	46.7	2.6
18	47.9	2.6
19	49.0	2.6
20	50.1	2.5
21	51.2	2.5
22	52.2	2.5
23	53.3	2.5
24	54.3	2.5
25	55.3	2.5
26	56.3	2.5
27	57.3	2.5
28	58.3	2.5
29	59.4	2.5
30	60.4	2.5
31	61.5	2.5
32	62.6	2.5
33	63.7	2.6
34	64.8	2.6
35	66.1	2.7
36	67.5	2.8
37	69.0	3.0
38	70.8	3.2
39	73.0	3.5
40	76.5	4.4.

\*SE=Standard error on T-score metric

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