

# Trismus RfPB trial: TheraBite® versus wooden spatula in the amelioration of trismus in head and neck cancer patients

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<b>Registration date</b> 26/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-wooden-spatulas-therabite-device-head-neck-cancer-patients-mouth-opening-problems-trismus-trial>

## Contact information

### Type(s)

Scientific

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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT01733797

### Protocol serial number

13415

# Study information

## Scientific Title

Trismus RfPB trial: A randomised pilot study of TheraBite® use versus wooden spatula in the amelioration of trismus in head and neck cancer patients

## Study objectives

Trismus is a tightening of jaw opening. The negative impact of trismus on the quality of life of head and neck cancer patients is well established. It affects eating, drinking, speaking and social function and is often as debilitating as any disfigurement resulting from treatment. The use of jaw exercises using a TheraBite® appliance following treatment has been shown to reduce the level of trismus in small studies. Many UK centres, however, use stacked wooden spatulas inserted between the incisors as a means of passive exercise. There is anecdotal evidence that suggests the use of exercises prior to treatment may help reduce the severity of the trismus experienced by the patient.

This study will enroll 112 head and neck cancer patients allocated by chance to use either the TheraBite® or wooden spatula, and patients will be asked to perform mouth exercises with either the Therabite or wooden spatula prior to and throughout their treatment. A review of the literature has suggested that use of passive mouth exercises could improve maximum mouth opening and hence QOL for these patients. Mouth opening will be the key outcome for the study measured over the time of treatments.

There is a need to evaluate both the effectiveness and cost-effectiveness of TheraBite® as opposed to wooden spatulas to evaluate whether they should be adopted as standard care in head and neck cancer patients. In this pilot trial, we will look at how well various questionnaires help us measure benefits of the TheraBite® to patients, as compared to usual care with wooden spatulas.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

NRES Committee North West - Greater Manchester North, First MREC approval date 01/06/2012, ref: 12/NW/0414

## Study design

Randomised controlled study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Trismus in head and neck cancer patients

## Interventions

TheraBite® is intended for use in individuals who are restricted in their ability to open their jaws (trismus or jaw hypomobility)

Wooden spatula, Wooden lollipop shaped sticks

Follow Up Length: 6 month(s)

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Maximum mouth opening recorded daily

### **Key secondary outcome(s)**

1. Patient compliance and tolerability measured at 3 and 6 months
2. Quality of Life and Health Economic outcome at baseline, 3 and 6 months

### **Completion date**

25/06/2014

## **Eligibility**

### **Key inclusion criteria**

1. Provision of signed, written informed consent
2. Aged 18 years and older
3. Able to read and write English sufficiently to be able to complete questionnaires
4. Stage 3/4 oral and oropharyngeal cancer patients undergoing primary chemoradiotherapy or surgical free flap plus post operative radiotherapy or post operative chemoradiotherapy
5. All patients will receive 60-70 Gy in 30-35 fractions over 6 to 7 weeks to the region of the pterygoid muscles
6. All patients will have at least some trismus as indicated by subjective tightening in the jaw

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

**Total final enrolment**

71

**Key exclusion criteria**

1. <12mm mouth opening (cannot use TheraBite®)
2. Anatomically unable to use Therabite for example patients who may only be partially dentate and to use the Therabite would place extreme stress on the existing teeth
3. Cognitive impairment as judged by the clinicians
4. International patients treated who will not have routine UK follow up
5. Previous surgery or radiotherapy (RT) to the head and neck prior to this diagnosis
6. Any patient who has no subjective tightening of the jaw

**Date of first enrolment**

23/11/2012

**Date of final enrolment**

25/06/2014

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Christie Hospital**  
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**Sponsor information****Organisation**

Christie Hospital NHS Foundation Trust (UK)

**ROR**

<https://ror.org/03v9efr22>

**Funder(s)**

**Funder type**

Government

## Funder Name

NIHR (UK) - Central Commissioning Facility (CCF)

## Results and Publications

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2018	10/04/2019	Yes	No
<a href="#">Protocol article</a>	protocol	30/03/2018	10/04/2019	Yes	No
<a href="#">Plain English results</a>			26/10/2022	No	Yes