ISRCTN54471768 https://doi.org/10.1186/ISRCTN54471768

Validation of a new dental scoring system to assess the junction in the mouth where the gums meet the teeth

Submission date	Recruitment status	[_] Prospectively registered
06/03/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/03/2019	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
24/10/2022	Oral Health	

Plain English summary of protocol

Background and study aims
This research study has been designed to validate a new clinical scoring system (index) for dentists, which is focused at the junction where the gums meet the teeth. The index has been designed to look specifically for worn surfaces of the teeth and receding gums in this area as this is an increasing problem in the population and can often cause problems, such as sensitive teeth. The researchers are developing the index to act as a guide for dentists on how to manage problems in this area, such as receding gums from toothbrushing too vigorously and sensitivity from exposed dentine near the gum. It is hoped that once this index has been developed, the information can be given to dentists equipping them with better knowledge to advise and treat their patients.

Who can participate?
Healthy adults (over 18), with a minimum of 10 teeth

What does the study involve?
Participants attend one appointment which lasts about 30 minutes. The study visit consists of a short oral examination, which is repeated by three different research dentists to ensure they are scoring the same as each other. Each tooth is given two scores (one for the outside surface of the tooth near the cheek and one for the inside surface near the tongue/roof of the mouth) for any areas that show tooth wear and gum recession.

What are the possible benefits and risks of participating?
There are no direct, immediate benefits from taking part in the study. There are no risks of participating as all procedures and assessments are carried out by experienced and qualified dentists using standard dental instruments.

Where is the study run from?
Bristol Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2018 to July 2019

Who is funding the study?
University of Bristol (UK)

Who is the main contact?
Dr Barbara Warnes
barbara.warnes@bristol.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Barbara Warnes

Contact details
Bristol Dental School
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY
+44 (0)1173426937
barbara.warnes@bristol.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
225373

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 225373

Study information

Scientific Title
Cervical Localisation Code - Validation of a new code

Acronym
Cervical

Study objectives
The four cervical localisation codes proposed (0-3) represent clinically distinguishable scenarios which can be scored reproducibly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/09/2018 by London - Queen Square Research Ethics Committee, HRA NRES Centre Manchester, Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, Tel: +44 (0)207 104 8225, 0207 104 8019, Email: nrescommittee.london-queensquare@nhs.net, REC ref: 18/LO /1418

Study design
Single-site cross-sectional observational epidemiological validation study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Healthy dentate adult volunteers aged 18 or over

Interventions
This is an observational study. The clinical examination will involve capturing scores for the cervical localisation code on all eligible tooth surfaces, 7-7 both arches (buccal and palatal /lingual). Certain dental exclusions will apply: missing teeth, teeth with gross caries, any tooth surface with crown or bridgework, any tooth surface with a fixed orthodontic appliance and any tooth surface with a large restoration in the proximity of the cementoenamel junction.

Participants will be randomised by study staff equally to 3 treatment sequence groups using a block randomisation scheme. The 3 investigator dentists are to be labelled A, B and C. Thirteen of the 39 participants will be scored by the 3 dentists in the sequence A-B-C-A, another 3 will be scored by the 3 dentists in the sequence B-C-A-B. The remaining 13 will be scored by the 3 dentists in the sequence C-A-B-C.

Intervention Type
Other

Primary outcome(s)
Inter- and Intra-examiner agreement of the proposed clinical classification (as assessed by the cervical localisation score) of the cervical region using three independent dentists assessing the same participants, in a randomised treatment sequence, at a single timepoint

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
14/07/2019

Eligibility

Key inclusion criteria
1. Healthy participants of either gender
2. Aged 18 or over
3. Understand and are willing, able and likely to comply with all study procedures and restrictions
4. Accept the form of the study and signs a declaration of informed consent
5. Have a minimum of 10 teeth not including implants or teeth with crowns and bridges

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
39

Key exclusion criteria
1. An employee and/or family relative of the investigator dentist
2. Anyone who the investigator's opinion is not suitable to take part in the study

Date of first enrolment
06/03/2019

Date of final enrolment
24/06/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Dental School
University of Bristol

Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data will be stored in the University of Bristol Data Repository. The weblink to the repository is: data.bris.ac.uk/data but the researchers do not have a unique link to the data for this study yet. The data will be stored in an 'open' format so anyone can access it. Data will be available after the results have been published in a scientific journal (July 2020, 12 months from the last data collection point). The consent form contains the following statement: 'I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers'. The clinical trials unit will allocate each participant a unique study ID number. On the CRF only date of birth, gender and participant ID are recorded. The only data stored electronically will identify the scoring numbers by study ID.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	05/08/2020	Yes	No
Dataset		12/04/2021	19/10/2022	No	No

HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 2.0	11/11/2025	11/11/2025	No	Yes
Protocol file		14/11/2018	24/10/2022	No	No