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# A randomised controlled trial to examine the effectiveness of single-visit Scale and Polish treatment, delivered at different intervals, in maintaining or improving periodontal health of adult patients

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| **Submission date**<br>13/12/2006 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>13/02/2007 | **Overall study status**<br>Completed | |
| **Last Edited**<br>08/10/2013 | **Condition category**<br>Oral Health | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## Study information

**Scientific Title**

## Acronym
S&P TRIAL

## Study objectives
Working hypotheses:
1. Adult patients of General Dental Practitioners (GDPs) who receive one visit scale and polishes at six monthly intervals will have less gingival bleeding around a set of index teeth compared to patients who receive one visit scale and polishes at 12- and 24-month intervals
2. Adult patients of GDPs who receive one-visit scale and polishes at six monthly intervals have less plaque around a set of index teeth compared with patients who receive one visit scale and polishes at 12- and 24-month intervals
3. Adult patients of GDPs who receive one-visit scale and polishes at six monthly intervals will have less calculus around a set of index teeth compared to patients who receive one visit scale and polishes at 12- and 24-month intervals
4. Adult patients of GDPs who receive one-visit scale and polishes at six monthly intervals report higher levels of oral cleanliness compared to patients who receive one visit scale and polishes at 12- and 24-month intervals

Null Hypotheses:
1. There is no difference in the prevalence of gingival bleeding around a set of index teeth in adult patients of GDPs who receive one-visit scale and polishes at six monthly intervals compared to patients who receive one-visit scale and polishes at 12- and 24-month intervals
2. There is no difference in the prevalence of visible plaque around a set of index teeth in adult patients of GDPs who receive one-visit scale and polishes at six monthly intervals, compared to patients who receive one-visit scale and polishes at 12- and 24-month intervals
3. There is no difference in the amount of calculus around a set of index teeth in adult patients of GDPs who receive one-visit scale and polishes at six monthly intervals compared to patients who receive one-visit scale and polishes at 12- and 24-month intervals
4. There is no difference in the mean scores for subjectively assessed oral cleanliness of adult patients of GDPs who receive one visit scale and polishes at six monthly intervals compared to patients who receive one visit scale and polishes at 12- and 24-month intervals

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approval received by Cheshire North and West Ethics Committee on 4th January 2006 (REC Reference: 05/Q1506/100).

## Primary study design
Interventional

## Study design
Randomised, controlled, three-compartment, parallel interventional clinical trial. Assessor and statistician analysing clinical data both blind to allocation of group.

## Study type(s)
Treatment

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

### Interventions
Treatment group:
After a routine dental examination, the test group (group one) will receive a supra-gingival scale and polish of teeth without any adjunctive periodontal therapy such as anti-microbial therapy or root planing. The scale and polish must be completed in one visit by a hygienist working in the practice using an ultrasonic scaler and a slow speed, air motor driven rotary rubber cup with polishing paste. Patients allocated to group one will receive a one-visit scale and polish at baseline, six months, 12 months and 18 months.

Prior to the scale and polish the hygienist will give standardised oral hygiene instruction based on The Scientific Basis of Dental Education. This intervention will be provided four times during the study; at baseline, six months, 12 months and 18 months.

Control groups - there will be two control groups:
Group two: will receive a one visit scale and polish from the hygienist at baseline and 12 months
Group three: will receive a one visit scale and polish at baseline only

Both groups will receive a routine, twice-yearly examination and the same standardised oral hygiene instruction based on The Scientific Basis of Dental Education as group one provided by the practice hygienist at the time of routine examination on a six monthly basis.

All groups will receive an outcome epidemiological examination at 24 months, immediately prior to their routine check up.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
Bleeding: bleeding from gingival margin on light probing measured on a set of index teeth (Ramfjord teeth). This will be according to a dichotomous scale bleeding present\not present.

### Key secondary outcome(s)
1. Plaque: visual presence on a set of index teeth (Ramfjord teeth). This will be according to a dichotomous scale present\not present
2. Calculus: this will involve one measurement, in millimetres using a periodontal probe, taken in the vertical axis of the tooth, on the tooth with the most calculus. The measurements will be confined to the lingual surfaces of the six mandibular incisor and canine teeth
3. Subjective assessment of oral cleanliness will be captured on a five point scale: a single, standardised question will be asked prior to the clinical examination of each participant: How clean does you mouth feel on a scale of one to five, where one is the least clean you can imagine and five is the cleanest you can imagine?

### Completion date
30/06/2008

## Eligibility

## Key inclusion criteria
Participants must:
1. Be male and female adult patients aged between 18 to 60 years of age who are registered at either of the two dental practices on the Wirral and who have had two dental examinations in the last three years and a scale and polish in the last 18 months
2. Have the ability to understand and provide informed consent
3. Be available for the full duration of the study
4. Have a minimum of 20 teeth excluding third molars and not wear a removable prosthetic appliance

## Participant type(s)
Patient

## Healthy volunteers allowed
No

## Age group
Adult

## Lower age limit
18 Years

## Sex
All

## Key exclusion criteria
Patients with the following characteristics will be excluded from the study:
1. Patients who in their GDPs opinion require periodontal treatment other than a one visit scale and polish (this would normally equate to a Basic Periodontal Examination [BPE] score of more than two, i.e. three or four)
2. Patients with acute periodontal disease characterised by the presence of pain, purulent exudate, or severe tooth mobility requiring immediate treatment intervention
3. Patients with a history of rheumatic fever, valvular heart disease or any condition requiring premedication to prevent endocarditis
4. Patients with extensive caries (three or more decayed teeth, requiring more than one visit for restoration)
5. Patients with a removable prosthetic appliance, with the exception of an acrylic splint to prevent nocturnal bruxism
6. Patients with soft or hard tissue tumours of the oral cavity
7. Patients who are pregnant or lactating at the commencement of the trial
8. Patients who are receiving long-term antibiotic, oral steroidal (i.e. except inhalers), or non-steroidal anti-inflammatory drugs
9. Subjects with diabetes, haemophilia or any other medical condition requiring medical support and/or drug therapy that may interfere with the parameters being investigated
10. Involvement in any concurrent study, the nature of which may affect the parameters being investigated in this study
11. Patients who have been formally diagnosed with, and who are receiving treatment for, either Sjogrens syndrome or a dry mouth

## Date of first enrolment
01/02/2006

**Date of final enrolment**
30/06/2008

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**The University of Manchester**
Manchester
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# Sponsor information

**Organisation**
The University of Manchester (UK)

**ROR**
https://ror.org/027m9bs27

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Oral Health Unit of the University of Manchester (UK) - self-funded trial

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 28/12/2011 | | Yes | No |
| Results article | patient perceptions results | 03/10/2013 | | Yes | No |