

# Effectiveness of a clinical guideline to improve the dental health in orthodontic patients with fixed appliances: study protocol for a cluster randomized trial

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Other
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24400

### Source

NTR

### Brief title

Guideline effectiveness orthodontics

### Health condition

Enamel carious lesions, white spot, prevention, guideline, effectiveness, orthodontic treatment.

Ontkalkingen, richtlijn, effectiviteit, preventie, orthodontische behandeling.

## Sponsors and support

**Primary sponsor:** Radboud University Medical Center

**Source(s) of monetary or material Support:** Nederlandse Vereniging van Orthodontisten

## Intervention

## Outcome measures

### Primary outcome

## Primary outcome

The primary outcome measure is the incidence of WSLs after 6 to 9 months of treatment with fixed appliances and at the end of treatment using the CPG for prevention of WSLs compared to usual preventive measures in patients treated with full fixed orthodontic appliances.

## Secondary outcome

### Secondary outcomes

Secondary outcome is adoption of the CPG in routine clinical orthodontic practice. This will be measured in terms of :

- Professionals attitude toward working with the CPG for prevention of WSLs, measured by means of a questionnaire.
- Professionals compliance with key recommendations in the CPG for prevention of WSLs, measured by auditing the EPF.
- Patients views on the preventive care provided, measured by means of an questionnaire .

## Study description

### Study objective

The aim of this study is twofold:

- 1) To assess the effectiveness of a CPG converted into a CDSS, in actually preventing the development of WSLs during orthodontic treatment with fixed appliances compared to usual preventive measures.
- 2) To evaluate the effect of a multifaceted implementation strategy of a CPG based CDSS into routine clinical practice.

### Study design

T0(before treatment), T1 (6-9 months into treatment with fixed appliances) and T2 (end of treatment with fixed appliances)

### Intervention

the implementation of a CPG for prevention of WSLs prior and during orthodontic treatment with fixed appliances

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

All patients between 12 and 18 years of age, with fully erupted permanent dentition, who are scheduled for treatment with full fixed appliances, are eligible to participate in this study.

### **Exclusion criteria**

-Patients younger than 12 years of age because they do not have a fully erupted dentition, patients older than 18 years of age because after this age the risk of development of WSLs is reduced.

-Patient diagnosed with astma bronchiale because the use of Durphat is contra-indicated.

-Patients with physical or mental problems incapable of practicing proper oral hygiene.

-Patients who refuse to use prescribed preventive products or are allergic to these products.

-Patients with missing incisors, canines and/or premolars because these are the teeth being scored.

-Patients with cleft lip and palate and craniofacial anomalies because for these patients different preventive strategies are needed.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Other
Enrollment:	840
Type:	Unknown

## Ethics review

Not applicable	
Application type:	Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

### Register

NTR-new

NTR-old

Other

### ID

NL4766

NTR5012

Oosterkamp : BCM

## Study results