

# Protocol for Fluoride delivery RCT

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## Investigators

Dr Jayne Harrison	Consultant Orthodontist, Liverpool University Dental Hospital
Dr Norah Flannigan	Senior Clinical Lecturer University of Liverpool / Hon Consultant Orthodontist, Liverpool University Dental Hospital
Prof Susan Higham	Professor in Oral Biology, University of Liverpool

### **Aims**

This RCT aims to determine the most effective way of delivering fluoride to orthodontic patients to prevent demineralisation

### **Population**

Patients aged 11-16 years inclusive undergoing orthodontic treatment with fixed appliances

### **Interventions**

- 1 - Twice daily brushing with standard fluoride toothpaste (1450ppm) plus application of fluoride varnish (e.g. Duraphat 22,600ppm) every 3 months,
- 2 - Twice daily brushing with standard fluoride (1450ppm) plus application of Tooth Mousse Plus (with Fluoride) applied daily
- 3 - Twice daily brushing with high strength (2800ppm) fluoride toothpaste.

### **Comparison**

Standard regime: twice daily brushing with standard fluoride toothpaste (1450ppm) plus plus daily use of fluoride mouthwash (0.05%; 225ppm).

### **Outcomes**

- Primary - The presence of new demineralisation developing on the anterior teeth during fixed orthodontic treatment assessed using white light images and images taken using a QLF-D bi-illuminator.
- Secondary - The degree ( $\Delta F$ ) and extent ( $\Delta Q$ ) of enamel demineralisation on the surfaces of teeth.
- The plaque score ( $\Delta R$ ) on the surfaces of teeth.
  - Malocclusion impact questionnaire
  - Patients' perception of WSLs

**Implications of results:** The results from this study will help inform national and international orthodontic practice to establish the most effective method of preventing demineralisation during orthodontic treatment.