

Evaluation of tailored electronic reminders on compliance with removable orthodontic retention: a randomised controlled trial.

Parent information sheet
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Chief Investigator: Dr Padhraig Fleming
Senior lecturer/Honorary Consultant in Orthodontics

Researcher: Dr. Dalya Al Moghrabi
PhD student
Barts Health NHS Trust
Phone: 020 7882 8629

We are inviting your child to take part in this research study, which we think may be important. It is essential to read why the research is being done and what it will involve. Please take your time to read the following information carefully. Please ask us anything that is not clear. Take your time to decide whether or not you wish your child to take part in this study.

Retention is a very important part of the overall treatment and is undertaken following the removal of the fixed braces. It is essential to achieve dental stability and to resist the tendency for teeth to move to their start (crooked) position. At present, we do not know how well children are wearing their retainers. Also, we don't know how electronic reminders might influence compliance levels with removable retention regimes among children.

1) What is the purpose of the new study?

The primary aims of this study is to analyse the effect of electronic reminders on compliance of your child with orthodontic retention at 3, 6 and 12 months following removal of the braces.

Further aims are to assess the subjective levels of retainers wear, and to measure the changes in teeth position following removal of the braces. We also aim to explore your child experience with electronic reminders.

2) Why have my child been chosen?

Your child were chosen because they have completed fixed brace treatment in the lower jaw and fit the criteria to get a removable retainer.

3) Does my child have to take part?

No, your child does not have to take part if they do not want to. What happens to your child at this clinic will be the same whether or not he/she takes part in our research.

4) What will happen to my child if they take part?

Now that your child completed his orthodontic treatment, and will get retainers, we will fit a timing device to the retainers, and will be randomly allocated to either receive a reminder or not. All patients will be given codes to avoid using personal data and ensure their anonymity. Your child will be monitored at 3, 6 and 12 months to check that their teeth have not moved from their ideal position and moulds of the teeth will be taken at each visit to help record any dental movement. Also, the readings of the timer will be recorded at each visit.

All the data will be gathered and analysed at the end of the study and you and your child will be informed of the findings if requested.

Some participants will also be asked to partake in a short interview with the researcher to find out more about their experience with the retainers and the electronic reminders. This interview will be audio recorded.

5) What does my child have to do?

Your child will be asked to attend a review clinic at 3, 6 and 12 months to check for any tooth movement and any breakages of their retainers. Moulds of your child's teeth will be taken on those visits, and we will record the readings of the timer.

What happens to your child at this clinic will be the same whether or not your child take part in our research. If you are happy for your child to undertake a one-to-one interview, an appointment will be made to complete the interview in a confidential non-clinical area. This interview will be audio recorded.

6) What are electronic reminders?

Electronic reminders involves using technology to remind you to wear the retainers. This will involve receiving weekly emails, and will continue for a year, to remind your child of wearing their retainers and how important it is in maintaining the position of their teeth.

7) What is the treatment or procedure that is being tested?

We are testing the effectiveness of electronic reminders on patients' compliance in wearing the removable retainers.

8) What are the advantages of the retainers?

Retainers are fitted to help maintain the ideal position of the teeth once they are straightened.

9) What are the possible disadvantages/advantages of taking part?

No additional unpleasant side effects can happen to your child if they take part in this research – there are no extra risks caused by taking part. However, we cannot guarantee your child will gain any benefit for taking part in this study.

10) What if there is a problem?

Queen Mary University of London has agreed that if your child is harmed as a result of your participation in the study, your child will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures your child received during the course of the study. These special compensation arrangements apply where an injury is caused to your child that would not have occurred if your child was not in the trial. These arrangements do not affect your child's right to pursue a claim through legal action.

If you wish to see someone from Patient Advice Liaison Service in person please call 020 3594 2040 or email pals@bartshealth.nhs.uk, where a member of the team will be happy to arrange an appointment for you.

11) Will my child taking part in this study be kept confidential?

The people who will know that your child is taking part in this study are some of the staff at the hospital where your child is being treated and also the research staff who are running this study.

- No-one else will know your child is in the study unless you or your child tell them
- No-one other than the researchers will be shown your records or models.

This research is registered according to the Data Protection Act.

This research is carried out according to government guidance, to help protect the interest of patients. To make sure that these are followed the authorities will have legal access to your child's dental records if your child took part in the study.

The results of the study could be made available to the patients and their parents upon request.

12) What will happen to the results of the research study?

At the end of the study all the information is put together. We won't let anyone else have any information that would let people know who your child is, and their name

will not appear on any of the information we collect about your child - everything is anonymous. We will write a report about the research in an orthodontic journal so that other orthodontists can read about what we have found. We will also tell them about what we have found by presenting our research at orthodontic conferences.

13) Who is organising the research?

The research is being run at the Royal London Dental Hospitals and so the Orthodontic Research Team at the Royal London Dental Hospital are in charge overall. This research was reviewed by Queen Mary University of London and Cambridge Central Research Ethics Committee.

Contact for further information

You can ask Dr Dalya Al Moghrabi (Tel: 020 7882 8629) any questions you may have regarding this study.

Thank you very much for taking the time to read about the research.

If your child take part they can help us to make a difference to others in the future.

You should keep this information sheet. If your child take part in the study, you will also be given a copy of the signed consent sheet to keep.

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