



Bwrdd Iechyd Prifysgol
Caerdydd a'r Fro
Cardiff and Vale
University Health Board



BRIGHT

Information for Schools

BRIGHT: Brushing RemInder 4 Good oral HealTh

Why is BRIGHT important?

Tooth decay is very common, affecting nearly one-half of young people aged 12-15 years living in deprived areas. Young people with tooth decay often have toothache, loss of sleep, problems eating and need to take time off school. However, tooth decay can be prevented and one of the most effective ways is regular toothbrushing with fluoride toothpaste.

A study in New Zealand published in the Journal of Public Health Dentistry in 2015 found that sending a text message to mobile phones every week increased how often unemployed young adults brushed their teeth.

In the BRIGHT trial, we would like to use this idea in the UK with young people. We want to investigate whether a lesson in school about dental health followed by a series of text messages reduces tooth decay, increases how often (and how well) young people brush their teeth, and how much this would cost to run.

Why should we take part?

We hope you will agree that this is an important research area, and that information resulting from the research will help young people to look after their teeth better.

Taking part in this research will build a link between your school and your local Dental School and University. Your school will be supported by a local research team throughout the project. We hope that taking part in a large research project will be enjoyable for your students and help to teach them about the importance of research and its impact.

The intervention may reduce tooth decay and therefore reduce the consequences of tooth decay including school absence, which could influence educational outcomes.

Participating schools will receive £1,000 to help cover the administration involved in participating in the trial and members of the local research team will visit the school regularly to support you directly.

What does BRIGHT involve?

BRIGHT will involve approximately 42 Secondary Schools with above average percentage of pupils' eligible for Free School Meals (FSM) across England (South Yorkshire and West Yorkshire), Scotland, and Wales - as we know there are higher levels of tooth decay in deprived areas. From each school we plan to involve around 140 young people aged 11-13 years (Year 7 and Year 8 in English and Welsh schools; S1 and S2 in Scottish schools). These year groups have been chosen to minimise disruption to English and Welsh GCSE and Scottish Qualifications Authority National 5 exam years.

Random allocation is an essential component of the BRIGHT trial as it is the best way of investigating what effect the intervention has on young people. Participating schools will be randomly allocated by a computer program into two groups:

Schools in **GROUP 1** will be asked to deliver a classroom-based session (materials and resources will be provided) to all Year 7 pupils in participating classes, and consenting Year 7 pupils will also receive a series of text messages encouraging them to brush their teeth. Year 8 pupils will NOT receive the classroom-based session or the text messages. In this group Year 7 is the **Intervention** group and Year 8 the **Control** group.

Schools in **GROUP 2** will be asked to deliver a classroom-based session (materials and resources will be provided) to all Year 8 pupils in participating classes, and consenting Year 8 pupils will also receive a series of text messages encouraging them to brush their teeth. Year 7 pupils will NOT receive the classroom-based session or the text messages. In this group Year 8 is the **Intervention** group and Year 7 the **Control** group.

What information will be collected?

For three years we will collect information about tooth decay, how often young people brush their teeth and how much tooth decay affects their lives. This information will be collected as described below:

- Dental professionals will conduct dental examinations on all young people involved at the beginning of the trial and at the end of years 2 and 3 of the trial. Examinations will take place at school and will last approximately 15 minutes per young person. Schools will need to provide a room in which the dental assessments can be conducted. The dental team will need a table for the young person to lie on and two chairs for the dentist and the dental nurse but the local research team will provide everything else.
- Young people in the BRIGHT trial will be asked to complete a questionnaire at the beginning of the trial, six months later, and then once each year for the following three years. A member of the local research team will liaise with the school to find the most suitable time for the questionnaires to be completed and will oversee the delivery, completion and collection. Each questionnaire will take approximately 15 minutes for a young person to complete.
- Parents/carers of participating young people will be asked to complete a questionnaire at the beginning of the trial and once each year for the following three years. These will be sent home with participating pupils at each relevant time point.
- Schools will be asked to provide attendance records for the young people involved at the beginning of the trial and once each year for the following three years.
- The research team may also access routine health and dental records of young people involved.

What will the research team do with the information collected?

Identifiable information, and collected study data, will be stored securely and confidentially at York Trials Unit, University of York. The mobile telephone number and name for text messages of consenting pupils will also be stored at the University of Dundee. Please refer to the Data Sharing Agreement (provided with this document) for more details.

The University of York and the University of Dundee process personal data for research purposes under Article 6 (1) (e) of the GDPR: "Processing is necessary for the performance of a task carried out in the public interest".

And special category data is processed under Article 9 (2) (j) of the GDPR: "Processing is necessary for archiving purposes in the public interest, or in scientific and historical research purposes or statistical purposes."

You can find out more about how we will use the information collected by contacting the research team or by going to <https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/>.

Only specified members of the research team and data management team will have access to this information. For data management purposes, identifiable information and coded study data will also be securely stored on password-protected databases in the University of York. Specified members of the data management team will also have access to this identifiable information.

All identifiable information will be archived securely for fourteen years after the end of study (until the youngest person in the study is aged 25), after which it will be destroyed. Identifiable information will not be published or shared. Anonymous study information may be shared with other researchers for research purposes only.

People from regulatory authorities, who check that research is being conducted well, may choose to check this project and will therefore see information collected during BRIGHT.

We will use the information to help us see what reduces tooth decay in young people. We will write reports and tell people about the results of the research, so young people can get the help they need to look after their teeth. No one will be identified in any reports we write.

Contact details for the Co-Data Protection Officers:

Alan Bell
Head of Information Governance and Joint Assistant Director
Culture & Information
University of Dundee
Dundee
DD1 4HN
Email: a.z.bell@dundee.ac.uk

Durham Burt
Information Governance Officer
University of York
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YO10 5DD
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Contact details for the Co-Data Controllers:

University of Dundee
Nethergate
Dundee
Scotland, UK
DD1 4HN

University of York
Heslington
York
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YO10 5DD

What does the BRIGHT intervention itself involve?

Teachers will be asked to deliver the classroom-based session to all pupils in the intervention year group.

Participating schools will receive a lesson plan that will outline learning intentions and success criteria for the lesson, in addition to the appropriate teaching methods and resources to deliver the lesson. The lesson will focus on the short- and long-term impacts of poor oral health and ways to promote good oral health including twice-daily tooth brushing. In addition, it will encourage learners to reflect on how to maintain regular tooth brushing practices.

After the lesson, the pupils will receive twice-daily text messages for the duration of the trial. If the pupils want to stop these text messages, they can do so at any time and at no cost to them.

The intervention has been developed with young people and a team of experts in psychology, dentistry, education and digital technology.

Who is conducting and funding the research?

This project is funded by the National Institute for Health Research Health Technology Assessment programme (project number 15/166/08).

Researchers at the University of Dundee, University of Sheffield, University of Leeds, University of York, Cardiff University, Batley Girls School, Chilypep, and mHabitat will be working on the BRIGHT trial. The York Trials Unit at the University of York is overseeing the organisation of the BRIGHT trial. Should you need to contact the York Trials Unit directly, their details are: BRIGHT Trial Team - York Trials Unit, ARRC Building, University of York, Heslington, York, YO10 5DD, Tel: 01904 3211083, Email: ytu-bright@york.ac.uk.

Ethical approval for the BRIGHT trial has been granted by an NHS Research Ethics Committee.

What do secondary schools need to do?

- Sign the School Agreement to Participate Form and Data Sharing Agreement and return to the research team.
- Ensure the shared understanding and support of all school staff for the project and personnel involved.
- Be a point of contact for parents/carers seeking more information on the project.
- Distribute information to all parents/carers of Year 7 and Year 8 pupils who will be in participating classes in the 2017/2018 academic year about the BRIGHT trial.
- Distribute and manage the collection of any Parent/Carer Opt Out Forms.
- Inform all Year 7 and Year 8 pupils in participating classes in the 2018/2019 academic year about the BRIGHT trial (via information sheets and information events/assemblies - supported by the local research team).
- Facilitate the distribution and collection of Young Person Consent Forms.
- Provide information on the number of pupils whose parent/carer completed an Opt Out Form and the number of pupils who did not consent to take part.
- Facilitate the distribution of Parent/Carer Questionnaires and reminders to parent/carers of pupils who have consented to take part in BRIGHT.
- Provide information on all consenting pupils (excluding any pupils for whom Parent/Carer Opt Out forms have been returned) including full pupil name, gender, date of birth, year group, form group, FSM status, pupil attendance at the beginning of the study for the previous academic year and the current year to-date, and yearly for the remainder of the study.
- Agree to random allocation of the intervention year group and control year group, and commit to implementing the intervention.
- Facilitate the dental assessments and the completion of the Young Person questionnaires at each time point.
- Consider talking to the local research team further and facilitating a visit from researchers to the school to talk to staff members and pupils about the BRIGHT intervention - you would be contacted separately about this.

Please see the BRIGHT School Responsibilities and Timescales document for more detailed information.

A member of the local research team will support the school throughout the study. They will liaise with, and visit the school, to oversee all data collection activities.

What happens next?

If you have any further questions about the BRIGHT trial, please do get in touch with us:

BRIGHT Trial Team – Dr Peter Day
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Faculty of Medicine and Health
University of Leeds
LEEDS LS2 9LU
Tel: 0113 343 6139
Email: p.f.day@leeds.ac.uk

If you decide you would like your school to take part in BRIGHT, please complete and return the accompanying Agreement to Participate Form and Data Sharing Agreement at the information meeting or afterwards by post to the above address.

Thank you for reading this information