



BRIGHT



Information for Parents/Carers

BRIGHT: Brushing RemInder 4 Good oral HealTh

What is BRIGHT?

BRIGHT is a research project, which is being carried out by researchers at Sheffield Teaching Hospitals NHS Foundation Trust, Tayside Health Board and the universities of Dundee, Sheffield, Cardiff, Leeds and York (York Trials Unit). We want to find out if a lesson at school about dental health and caring for teeth, and then sending young people text messages, can help them look after their teeth. Tooth decay is very common and affects many young people. It causes them pain, embarrassment and time off school. We want to find a way to help young people have less tooth decay.

Some classes at your child's school will get a lesson about dental health and the pupils in those classes will receive text messages if they want to. Some classes will not receive the dental health lesson or the text messages. A computer will decide this at random (like a lottery).

We will look to see if the lesson and text messages make any difference in levels of tooth decay in young people's teeth. We will collect information over 3 years about: tooth decay, how often young people brush their teeth and how much tooth decay affects their lives.

What does taking part mean for my child?

- Your child will find out about BRIGHT at school. If they want to take part, they will need to complete a consent form. We have included the information they will get, and a copy of the consent form they will complete, with this leaflet for your information.
- We need to know your child's mobile phone number. The number will only be used to send text messages about tooth brushing to some young people in the project. The number will be stored securely and not shared with anyone outside of the research team.
- Your child will be asked to answer some questions about their health and their teeth. We will send a paper booklet with the questions in to your child at school, 6 or 8 times over 3 years. The questions will not be difficult to answer.
- A dentist and dental nurse will visit your child's school and will check your child's teeth. They may also ask your child to brush their teeth during the visit. This will take about 10 minutes and will be done at school during the school day. This will happen 3 times over 3 years. Some children may be asked if they would be happy for a dentist to look at their teeth twice on the same day or in the same week (this is to check the information the dentists are collecting). They will only check your child's teeth. **Your child will need to continue seeing their usual dentist.**
- Your child's school will tell us about the number of days off school your child has, so we can see if the lesson and text messages help to reduce missed school days.
- We may look at information about your child's education that their school holds about them. We may also look at information about your child's dental health that is collected by the NHS (such as NHS Digital and NHS National Administrative Health Data). We might do this for up to 5 years after the end of BRIGHT. To help us do this, we may ask your school for your child's home postcode.

BRIGHT has been funded by the NIHR HTA. For more information please visit:

<https://www.journalslibrary.nihr.ac.uk/programmes/hta/1516608/#/>

BRIGHT Parent Carer Information Sheet V3.1 20180828 IRAS ID 223377

- If your child completes the questionnaires and dental assessment at the beginning of the study, they will be given a £10 shopping voucher.
- If your child completes the questionnaires and dental assessment at the end of the study, they will be given a £5 shopping voucher to say thank you.
- We may ask your child to talk to a researcher at school about what it was like taking part in this project. We will send you further information about this at the time and separate agreement from your child will be sought for this.

Will I receive feedback on my child's dental health?

No, **your child needs to continue seeing their usual dentist**. If, however, the project dentist thinks there might be a serious condition, the research team will get in touch with you through your child's school and, with your agreement, will make arrangements for your child to be seen by their doctor. This is very unlikely to happen.

Does my child have to take part?

No, you can decide if you want to let your child take part.

If you decide to let your child take part, they will find out more about BRIGHT at school and, if they want to take part, they will be asked to sign a consent form and provide their mobile telephone number. If they want to stop getting the text messages, they can text back STOP for free to the phone number the text comes from. If they want to stop taking part in BRIGHT altogether, they (or you) can contact the research team (contact details are at the end of this sheet) at any time and they do not need to give a reason.

If you are happy to let your child take part in BRIGHT, you do not need to do anything. Your child will be included in the study if they decide to take part and complete the consent form at school.

If you DO NOT want your child to take part in BRIGHT, please let your child's school know by returning the enclosed Parent/Carer Opt Out Form to your child's school within the next 2 weeks. This will not change things at school or their usual dental care and you do not have to give us a reason.

What does taking part mean for me?

We want to find out about your child's dental health, so we are asking parents/carers if they would be willing to answer some questions too. If your child decides to take part in BRIGHT, we will be in touch with you again through your child's school to ask you to complete some questionnaires, up to 4 times over 3 years. The questions will be about your child's teeth and any visits your child makes to the dentist - they will not be difficult to answer.

If you decide to complete the questionnaires, you can always change your mind later on by contacting the research team (contact details are at the end of this sheet). If you decide not to complete the questionnaires, it won't change your child's involvement in BRIGHT.

Each year that we send out parent/carers questionnaires, all parents/carers who complete the questionnaires will be entered into a prize draw with the chance of winning £300 in vouchers.

If I have more than one child, which child/children are being asked to take part?

Children in participating classes in Year 7 and Year 8 at participating schools are being invited to take part in BRIGHT. If you have children at other schools, those schools may not be taking part. If you are unsure which children are being invited to take part please contact your child's school.

Why should we take part?

We hope you will agree that it is important to find out how to help young people to look after their teeth better. We also hope that taking part in a large research project will be fun for your child and help to teach them about the importance of research.

Who is responsible for the information collected in BRIGHT?

The University of Dundee and Tayside Health Board are the co-sponsors for this study based in the United Kingdom. The University of Dundee and York Trials Unit (University of York) will act as the data controllers for this study, which means that each organisation is responsible for looking after information collected during the study and using it properly.

What will happen to the information collected in BRIGHT if we take part?

Information collected during the study will be processed and stored in accordance with the General Data Protection Regulation (GDPR; introduced on 25th May 2018). The legal basis for processing information we collect about you and your child during the study is as a task carried out in the public interest and for scientific and research purposes.

On behalf of the co-sponsors, researchers at Sheffield Teaching Hospitals NHS Foundation Trust, Tayside Health Board and the universities of Dundee, Sheffield, Cardiff, Leeds and York (York Trials Unit) will collect and use information from your child, your child's school, yourself, and potentially from your child's dental records, in order to undertake this study. This information will include your child's name, contact details, and home postcode, and potentially your child's NHS number (or CHI number in Scotland) and health information relating to your child, which is regarded as a special category of information. All information will be collected using agreed procedures.

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. Personal information that identifies you or your child will not be published in any reports.

Personal information collected during the study that identifies you or your child will be stored securely and confidentially at York Trials Unit, University of York, in paper form and on password-protected databases. Your child's mobile telephone number and name for text messages will also be stored at the University of Dundee. Only some members of the research team and data management team will have access to this information. Personal information that identifies you or your child will be kept 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.

The people who analyse the information will not be able to identify you or your child. Information collected by the research team may be shared with other researchers for research purposes only, but they will not be given your name or your child's name.

Researchers from Sheffield Teaching Hospitals NHS Foundation Trust, Tayside Health Board and the universities of Dundee, Sheffield, Cardiff, Leeds and York (York Trials Unit) may use your child's name and contact details to contact them about the study, make sure that relevant information about the study is recorded for their care, and oversee the quality of the study. People from the University of Dundee, Tayside Health Board, and regulatory organizations may look at the information we collect about you or your child to check the research is being done well.

Your rights to access, change, or move your information or your child's information are limited, as we need to manage the information in specific ways in order for the research to be reliable and accurate. If you withdraw your child from the study, we will keep the information about you and your child that we have already obtained. To safeguard the rights of you and your child, we will use the minimum personally-identifiable information possible.

To help keep your child safe, we may need to let you and your child's school know if a response that your child provides raises concern.

You can find out more about how we will use your child's information by contacting the research team or by going to: <https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/>. If you have any questions or concerns in relation to the project and/or how your child's personal data will be used, please contact the research team. You can also contact the University of York's Data Protection Officer at dataprotection@york.ac.uk. For further information see: <https://www.york.ac.uk/records-management/dp/>

Who is conducting and funding the research?

BRIGHT is funded by the National Institute for Health Research Health Technology Assessment Programme (project number 15/166/08). The study is being co-sponsored by the University of Dundee and Tayside Health Board and is led

by Professor Nicola Innes at the Dundee Dental School. Ethical approval for BRIGHT has been granted by an NHS Research Ethics Committee.

What if something goes wrong?

If anything out of the ordinary happens to your child as a result of taking part in BRIGHT, you can contact the research team on the contact details at the end of this sheet.

If you have any concerns about your participation or your child's participation in BRIGHT, you have the right to raise your concern with a researcher involved in conducting the study (please see contact details below).

If you have a complaint about your participation in BRIGHT, you have the right to raise a formal complaint. In the first instance, you should make a complaint to the researcher leading the study: Professor Nicola Innes (tel: 01382 381631, email: n.p.innes@dundee.ac.uk). Alternatively, you can complain to the Information Commissioner's Office at: <https://ico.org.uk/concerns/>

In the event that you think you or your child have suffered harm as a result of your participation in BRIGHT, there are no automatic financial compensation arrangements. However, you may have the right to make a claim for compensation. Where you wish to make a claim, you should consider seeking independent legal advice but you may have to pay for your legal costs.

Insurance

The University of Dundee and Tayside Health Board are co-sponsoring the study. The University of Dundee maintain a policy of public liability insurance which provides legal liability cover in respect of damages, costs and expenses arising out of claims. The other partners in the study, the NHS and other institutions will also maintain insurance to cover their liability in relation to their conduct of the study.

What happens next?

- If you decide you are happy for your child to take part in BRIGHT, you do not need to do anything. Your child will find out more about the study at the school and will be asked to complete a Young Person Consent Form if they want to take part.
- If you decide that you DO NOT want your child to take part in BRIGHT, then please complete the Parent/Carer Opt Out Form and return it to your child's school within the next 2 weeks.
- If you do not return the Parent/Carer Opt Out Form by the date listed on the school cover letter, we will assume that you are happy for your child to take part in BRIGHT if they would like to.

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

BRIGHT Trial Team - York Trials Unit ARRC Building University of York Heslington YORK YO10 5DD Tel: 01904 321083 Email: ytu-bright@york.ac.uk	BRIGHT Trial Team - Professor Zoe Marshman University of Sheffield School of Clinical Dentistry Claremont Crescent SHEFFIELD S10 2TA Tel: 0114 215 9398 Email: z.marshman@sheffield.ac.uk
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If you would like some independent advice about BRIGHT, you can talk to Professor Helen Rodd (email: h.d.rodd@sheffield.ac.uk).

Thank you for reading this information