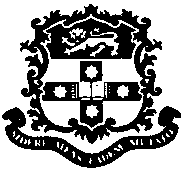
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**Study comparing three different expansion devices**

**INFORMATION FOR Children (10-12 YEARS)**

**What is the Study about?**

This is a hand out that has been put together to help you decide if you would like to take part in our research study about using an expander plate. This study is to find if one type of expander plate is better at widening your upper jaw. This expansion plate is needed because you have a narrow upper jaw and the top back teeth bite down inside the bottom back teeth. The expander will be placed on your top teeth and will be one of the following:

1) Expander #1: this is the common type of expander which requires a separate key to turn.

2) Expander #2: this is the normal expander but it also includes two pins placed in the top of the upper jaw behind the teeth.

3) Expander #3: this is a new type of expander which has a built-in key to turn the expander.



Figure 3: Expander #3

Figure 1: Expander #1

Figure 2: Expander #2

**Who is doing the Study?**

The study is being conducted within Sydney Dental Hospital by Doctors Gordon Cheung, Shanya Hammond and Simone Mustac. It will be supervised by Professor M Ali Darendeliler and Doctors Oyku Dalci and Alexandra Papadopoulou.

**Which type of expander will I have?**

You will be randomly placed in one of the three treatment groups and you will be told which one at visit 1.

**What do I have to do?**

You will have to come in for a few appointments where we will make the expander to for you. After we glue the expander in, the expander needs to be turned. Someone at home will have to do this for you twice a day. While you are turning your expander, we will get you to come back and see us every week until we have finished turning. At the end of turning, we will take a break from your visits but will still see you at 3 months and at 6 months after the expander was put in. At the 6-month check-up, we will remove the expander. We then need to see you one last time 3 months later. After this, someone will continue treating you with braces to continue straightening your teeth.

**Do I have to do the Study?**

No you don’t. If you say no, that is okay. It is up to you.

Even if you take part at the beginning and change your mind later on and don’t want to be a part of the study, that is okay as well. All you need to do is tell the researcher that you don’t want to take part anymore. You also don’t need to answer any question that you don’t want to as well, that is okay too.

**Will anyone know that I am taking part or hear about what I tell you?**

No, no-one will know what information you gave to the researchers. You can tell them whatever you want and no-one will know that it came from you.

The only time the researchers would have to tell someone is if anyone hurt you or upset you in any way. The researchers would also have to tell someone if you said you might hurt yourself or someone else. If any of those things happen they would have to tell your parents and child protection services.

**Is there anything that might make me upset if I take part in the research?**

It is normal for the plate and pins to feel a bit strange during the first few days. It is a new thing for your tongue and your mouth to get used to. It is also normal to feel a little sore for the first few days when expanding the plate but this gets better quite soon. If it does get sore, your parents/carers might give you some pills to help with the pain. Once you get used to it, you will be able to eat and do things as you could before.

If anything you talk about during the research does make you upset you can stop the research. Your parents/carers will be told and you will be given the names of people you can talk to about what is making you upset, if that is what you want to do. The researcher can help you do that.

**What will happen to the information I tell you?**

The information you tell us will only be used by Sydney Dental Hospitalto help us find the best type of expander to help children like you.No-one else will be allowed to use this information. The information could be used with information from other young people in reports or papers about the research. You will not be able to be identified in these reports or papers.

The information you tell us will be stored in a computer where only the researchers have access to until the research is complete. Afterwards it will be kept for 5 more years and then the information will be wiped clean. It will be kept without your name on it so that no one can identify you.

If you have any questions please talk to us about it. You can reach us at:

Orthodontic department

University of Sydney

Level 2, Sydney Dental Hospital

2 Chalmers Street

Ph: 9293 3388

Email: sdhexpansion@gmail.com

Or, if you want ask Doctors Gordon Cheung, Shanya Hammond or Simone Mustac any question then please talk to them during the appointment and they we will be happy to talk to you about it.

**What will this cost?**

It will not cost you anything.

**This project has been approved by the Sydney Local Health District Human Research Ethics Committee. If you have any worries or questions about the study, please call the Research Ethics Manager on 9515 6766.**

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This information sheet is for you to keep.

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