



UNIVERSITY OF ALBERTA

ASSENT FORM

SKELETAL, FUNCTIONAL AND DENTAL CHANGES DURING TREATMENT OF MILD TO MODERATE CLASS II MALOCCLUSIONS WITH FIXED CLASS II CORRECTORS: A RANDOMIZED CLINICAL TRIAL.

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What is a research study?

- A research study is a way to find out new information about something. Children do not need to be in a research study if they don't want to.

Why are you being asked to be part of this research study?

- You are being asked to take part in this research study because we are trying to learn more about the best way to correct your bite type. About 90 children will be joining this study.

If you join the study what will happen to you?

- Everything we will do in your mouth is normally done during treatment with braces.
- Your treatment will involve one of two options. You either will get a bite corrector before or near the end of the treatment. In either case braces will also be used.
- You will be in the study for around 24 to 36 months, which is usually how long it takes for braces to work.
- x-rays (pictures) of your mouth and teeth will be taken before and after the treatment.
- Some fancy pictures, called MRI, will be taken before and after treatment. For the MRI, you will lie down on a scanning table that moves into the middle of the MRI machine. When the scan starts you will hear some loud sounds. The MRI scan lasts about 30 minutes.
- The orthodontist will have to check on you mouth movement and your teeth health.
- You will also be asked to answer some questions about your experience with the bite corrector.

Will any part of the study hurt?

- The level of discomfort that you may feel is similar to the one would experience under any treatment with braces.
- Being in the MRI machine might be a little uncomfortable, but you will be able to talk to the person running the MRI machine and you can stop if you want.

Will the study help you?

- No. The information collected will only be useful for future patients with similar bites.

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and
Dental
Hygiene*

*Excellence in
Dental Health*

Do your parents know about this study?

- This study was explained to your parents and they said that we could ask you if you want to be in it. You can talk this over with them before you decide.

Who will see the information collected about you?

- The information collected about you during this study will be kept safely locked up. Nobody will know it except the people doing the research.
- The study information about you may be given to your parents. The researchers will not tell your friends or anyone else.

What do you get for being in the study?

- You and your parents will not get anything for participating in the study.

Do you have to be in the study?

- You do not have to be in the study. No one will be upset if you don't want to do this study. If you don't want to be in this study, you just have to tell us. It's up to you.
- You can also take more time to think about being in the study.

What choices do you have if you say no to this study?

- This study is extra, so if you don't want to do it you will be provided with the option of a standard orthodontic treatment.

What if you have any questions?

- You can ask any questions that you may have about the study. If you have a question later that you didn't think of now, either you can call or have your parents call Dr. Al-Saleh at (780) 993-8844.

Other information about the study.

- If you decide to be in the study, please write your name below.
- You will be given a copy of this paper to keep.

☐ Yes, I will be in this research study.

☐ No, I don't want to do this.

Child's name

signature of the child

Date

Person obtaining Assent

signature

Date

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