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Effectiveness, patient acceptance, and cost estimation of 3D-printed retainer compared to Hawley retainer in expansion case: A randomized controlled trial

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Department of Orthodontics, Universiti Kebangsaan Malaysia (UKM)

PARTICIPANT INFORMATION SHEET

Research Title:
Effectiveness, patient acceptance, and cost estimation of 3D-printed retainer compared to Hawley retainer in expansion case: A randomized controlled trial

Introduction:
Changes in arch width during braces treatment can sometimes reverse over time. This reversal, known as relapse, means that teeth may move back to their original positions before treatment. Traditionally, Hawley retainers have been the go-to method for keeping teeth in place after expanding the upper jaw. Recently, 3D-printed retainers have been introduced, but their effectiveness in maintaining arch width after such expansion is still unknown.

Purpose of Study:
To compare how well 3D-printed retainers and traditional Hawley retainers keep the width of the upper jaw steady after patients have had their upper jaw expanded.

What will the study involve?
The type of retainer you will receive (3D-printed or Hawley) will be chosen at random by a secure computer system. This means neither you nor the researcher can decide which retainer you will get. You will receive a retainer within 24 hours or maximum within 3 days after your braces are removed, and you should wear it as instructed to prevent your teeth from shifting back. Follow-up appointments will be scheduled for 3 months, 6 months, and 12 months after you start wearing the retainer. During these visits, we will take impressions of your teeth using alginate material and measure some aspects of your teeth with a caliper. You will also be given a questionnaire to complete about your experience and satisfaction with the retainer.

Benefits:
(a) To participant?
You will receive a complimentary dental check-up and retainer assessment during follow-up visits. If any dental problems are detected during the check-up, they will be addressed accordingly.

(b) To the investigator?
By participating, you help us compare the effectiveness of 3D-printed and traditional Hawley retainers in maintaining arch width after expansion. Your involvement provides valuable data to improve retainer designs and orthodontic care.

Risks
The materials used to make both Hawley and 3D-printed retainers are safe and should not cause any risks or problems. Although we don't yet know how well 3D-printed retainers maintain arch width, the material used is designed to be strong and comfortable. The 3D-printed retainers are expected to stay in shape and provide good support for holding the arch width.

Do you have to take part?
Participation in this study is voluntary. If you agree to take part, then you will be asked to sign the "Informed Consent Form". You will be given a copy of the form and this Information Sheet.

Your treatment is not affected if you decide not to participant in this study. You need not have to explain why you prefer not to take part in the study and it will not affect your dental treatment

Should you decide to participate, you can still withdraw from the study without penalty. Your data will not be used and will be discarded. The researcher may also remove you from the study for a variety of reason. In this event, you will not be penalised or lose your rights as a patient.

Data & Confidentiality:
The data from this study will be made into a report which may be published. Access to the data is only by the research team and the REC UKM. The data will be reported in a collective manner with no reference to an individual. Hence your identity will be kept confidential.

Payment and compensation:
You do not have to pay, nor will you be paid to participate in this study. You do have to pay for the usual hospital charges.

Who can I ask about the study?
If you have any questions, you can direct them to the research team. You can also contact the REC UKM for clarifications.

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PARTICIPANT INFORMED CONSENT FORM

Research Title: Effectiveness, patient acceptance, and cost estimation of 3D-printed retainer compared to Hawley retainer in expansion case: A randomized controlled trial
Researcher's Name: Dr Asma Ashari & Dr Cheng Mei Ling

I, ……, IC No : ……..

- have read the information in the Participant Information Sheet **including information regarding the risk in this study.**
- have been given time to think about it and all of my questions have been answered to my satisfaction.
- understand that I may freely choose to withdraw from this study at anytime without reason and without repercussion
- understand that my anonymity will be ensured in the write-up.

I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.

……. ……..
(Signature) (Date)

…… Witness (if any) …… (Signature) …… (IC Number) …… (Date)	…… Researcher …… (Signature) …… (IC Number) …… (Date)