



Assent Form for Research Participation

Version or version date of the assent form:				Version 1.0 date 2024.08.27		
Study Title:	A Prospective, Single-Center, Standard Treatment Parallel-Controlled, Randomized, Superiority, Confirmatory Clinical Trial to Evaluate the Clinical Efficacy and Safety of NeuroWorld DTx Digital Therapeutics on Attention Function and Symptoms in Children Diagnosed with ADHD					
Simple Research Title:	The Impact of Game-Based Digital Programs on Attention Function in Children with ADHD					
Principal Investigator:	(Name)	Na-Yeong Kong	(Affiliation)	Keimyung University Dongsan Hospital Department of Psychiatry	(Contact Information)	053-258-4882

1. What is research (clinical trial)?

What we are about to do is a study to investigate the effect of alleviating symptoms through a simple game. The purpose of this study is to examine whether applying this program improves your attention

2. Why are you telling me this?

We are trying to help you. The program we are proposing in this study is thought to be helpful for your attention, which is why we brought up this research. However, participating in the study may not necessarily help you, but it could help you as well. Please carefully consider the information provided below and think about whether or not you want to participate in the study. Some of the information we are discussing might be difficult to understand. If you are unsure about anything, feel free to ask your parents or your doctor at any time. Also, you don't have to decide right now whether or not to participate. Please listen to your doctor's explanation, go home and talk to your parents, and then let us know what you would like to do when you come back to the hospital.



3. Why is this study being conducted?

A new treatment method called digital therapeutics, which uses games, is being used recently. Unlike medication-based treatments, digital therapeutics have gained significant attention worldwide because they allow for continuous treatment and monitoring of patients anytime and anywhere, regardless of location or time. Therefore, we aim to research the improvement effects on the core symptoms and associated symptoms of ADHD by offering you the NeuroWorld DTx game, developed using IT/SW technologies, big data, and artificial intelligence, as an adjunctive therapy that can be applied in the same way as traditional medication-based treatments.

4. What will happen to me if I participate in the study?

A total of 88 people will participate in this study.
You will receive a tablet PC from the hospital and will perform the NeuroWorld DTx program on the tablet PC at home with your parents five times a week for one month. Each session will take about 25 minutes.

5. Are there any benefits to participating in the study?

Using the digital program in this study may improve your attention. Additionally, it can help inform others with similar symptoms about this program.

6. Are there any disadvantages to participating in the study?

This study has been designed to be safe and to minimize risks, so no direct risks or side effects are expected from participating in this study. However, if dizziness or headaches occur occasionally due to using the tablet PC, immediate treatment will be provided by the attending physician, and you can rest without any disadvantage.



7. Will my privacy be protected?

By participating in the study, you will have many discussions with your parents and doctors. The information and test results discussed during the study will be seen by the researchers and doctors involved in the study at the hospital. Additionally, hospital staff and government agencies responsible for monitoring the safety of the study may also have access to the information.

However, it will remain confidential to others. To ensure confidentiality, personal identifiers in the collected data will be coded, and the collected data will not be used for purposes other than the research.

8. What if I don't want to do it?

If you feel scared or do not want to participate in the study, it is perfectly okay not to join. The decision to participate in this study is yours to make together with your parents. No one will get angry or tell you that you cannot receive treatment at the hospital in the future just because you do not want to participate in this study.

9. Is there no other option?

If you do not participate in the study, your current treatment will continue as it is. However, you will not be using the additional game-based digital program.

10. What if I don't want to continue in the middle?

If you start and then feel that it becomes too difficult or you feel very unwell, it is okay to say that you want to stop at any time. No one will dislike you or be angry if you decide to stop in the middle. You can choose to stop whenever you want. Additionally, the doctor will monitor your condition, and if they believe that continuing in the study is not good for you, they can suggest stopping at any time. The doctor will explain why stopping is necessary.



11. Are there any rules I must follow?

You must follow the usage frequency of the digital program (five times a week for one month). This is an addition to the treatment method that was previously being used at the hospital.

12. Research Participant Consent

If you still do not understand the study well, feel free to ask your doctor any questions you have. You can also ask your parents. The study can only begin if both you and your parents agree to participate.

If you do not want to participate, that is perfectly fine, and if you want to stop in the middle of the study, that is also okay. Whenever you are ready, please write your name and sign below.

Research participant name: _____

Signature: _____ Date: _____

(If applicable)

Name of Participant's

Representative: _____ Relationship to Participant: _____

Signature: _____ Date: _____

13. Investigator Confirmation

I have explained the purpose, procedures, and potential risks of this study to the aforementioned research participant.

As of the time of obtaining consent, the participant is a minor aged 6 years or older but under 13 years old and, under current laws, lacks the legal capacity to provide consent.

However, age-appropriate explanations were provided to the participant, and it has been confirmed that the participant understands the study and agrees to participate.

Principal Investigator /

Co-investigator name: _____

Signature: _____ Date: _____

This consent form has been reviewed and approved for use by the Institutional Review Board (IRB) of Keimyung University Dongsan Medical Center and is valid only if it bears the hospital's watermark.