



Study Information Leaflet for Participants

We are a digital mental health company called Healios and are working on a new research project for people with epilepsy. UCB (a pharmaceutical company) is funding this study - they will not have access to any personal or identifiable data.

We would like to invite you to take part in the research project and this leaflet explains what it's all about. If you have any questions, please get in touch with us and we would be more than happy to discuss this research project with you.

What is the research project?

Healios has developed an app called ThinkNinja for epilepsy to support the mental health, emotional wellbeing and quality of life of people with epilepsy for epilepsy. ThinkNinja for epilepsy contains an 8-week therapeutic programme combined with epilepsy-specific content to provide a personalised support tool which is being evaluated in this research study.

What is the smartphone app?

ThinkNinja brings together the latest in technology with design and interactive therapeutic tools based on cognitive behavioural therapy (CBT) and mindfulness techniques that are personalised to your needs. You're guided through the app by a virtual assistant called the "Wise Ninja". Through a text-style chat with the Wise Ninja, you can discuss how you're feeling and learn how to stay mentally and emotionally well. You are also guided through an 8-week interactive therapeutic programme, based on CBT techniques, designed to support you if you're feeling low, stressed or anxious.

The app also helps you monitor and track areas such as mood, activity and seizures. If you would like any support with the app, or the therapeutic programme, then you will be able to click a button on your home screen and start a text conversation with a trained coach. Coaches are available 9am-6pm Monday to Friday. Healios Coaches, who have a minimum of a psychology degree, are supervised and supported by Clinical Psychologists. If a Coach thinks that you may need additional support, they will offer you a video consultation with a Healios CBT therapist or clinical psychologist. The app has been co-produced by mental health experts, neurologists and people with epilepsy. Some of the ThinkNinja's epilepsy content has been co-developed and approved in partnership with UCB.

What do I need to be part of the project?

The study is only enrolling people who have been diagnosed with epilepsy at least 6 months ago.

You will need access to a smartphone (such as an iPhone, Galaxy Samsung) that is running Apple iOS (v13 or higher) or Android (Marshmallow or higher) operating systems. We request that you enable push notifications for the app for the duration of the study.

You will also need access to the internet. Depending on your mobile data plan, normal

data usage charges may apply in downloading and usage of the app over a mobile connection. To avoid mobile data charges, we recommend connecting to your home broadband or to use free wifi hotspots in your area such as a local library, coffee shop, or restaurants.

Please note that your personal data is NOT stored within the app or on your smart device. Each time you login to the app, the app automatically fetches your personal information securely from Healios server. Using the app will not drain your phone battery life quickly.

Do I have to take part?

You do not have to take part in this project. You can choose whether you take part and you can change your mind later if you decide you want to stop, without giving a reason.

What will I be asked to do?

As part of this project, you will be asked to download the ThinkNinja for epilepsy app for free and use it for a specified amount of time. We will ask you to answer some questions online over the next few months. You will complete your own questionnaire which will ask you questions about your feelings, mood and how you interact with others. You will complete some short online questionnaires weekly, as well as slightly longer questionnaires three times during an 8-week period. You will also be asked follow-up questions 8 weeks after the end of the study. You may also be invited to participate in an optional post-study focus group. You may be randomly assigned to the initial group of participants who will receive access to the app straight away, or you may be asked to start completing questionnaires straight away but will need to wait for 8 weeks to start the programme. All participants in the study will complete the 8-week programme and get full access to the content of the app. Participants will be informed of the results post-study.

What will happen to my epilepsy medication during this study?

You should continue to take your epilepsy medication as prescribed by your doctor. You should also maintain any regular doctor visits and check-ups as required for your epilepsy management.

Possible benefits or risks of taking part

Possible Benefits: You will be part of a limited group of people with an epilepsy diagnosis to have first access to try a new intervention in the form of a smartphone app. Your involvement will help us learn more about the way technology can support mental health and emotional wellbeing in people with epilepsy.

Possible Risks: The therapy services are not designed to be a replacement for seeking professional treatment if you have a diagnosed mental health condition.

If you are experiencing mental health or emotional difficulties at any time during the project, you should consult professional help immediately.

What if I have a question

If you have any questions about the project, you can contact the project team by emailing info@healiosresearch.com

The project team will do their best to answer your questions quickly.

What will happen to my information?

Healios will act as the data controller for this study. This means that we're responsible for looking after your personal information and only processing your personal data for certain purposes with your consent. We'll keep your personal data safe and will remove all your identifiable information for analysing the study results which means no one will be able to identify you - this is called anonymous data. This means no one will be able to tell what you had said in the questionnaires you have completed. We'll be combining your anonymous data with other study participant data to publish the study results and to share the anonymous research data with UCB, the sponsor for this study, and other researchers, but only in a way that it is impossible for them to tell who has taken part. Any video sessions undertaken with a Healios Clinician will be recorded. Healios will keep identifiable information about you for three years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Anyone who looks at the project information will have promised to keep the information private.

Because we are keeping your research information private, we will not share what you tell us on the questionnaires or what you enter in the app. If you tell us something in the app which makes us think you may need extra support, we will follow-up with you via either telephone, text message or email. If you also tell us about a potential medication side-effect, we are required to inform our study sponsor UCB and we may need to pass your contact details to them so they can find out more information from you - this is a legal requirement for UCB.

If you choose to tell us something via telephone, message, letter, email, or face-to-face which made us think that you, or someone else, was at risk of serious harm, we might have to tell someone else about this and share with them some of your personal details such as your name and home address. If this happened, we would talk to you and only share information to keep you safe.

We may contact you again in the future to invite you to take part in further related projects. You will remain free to choose whether or not to become involved.

Healios is compliant with the General Data Protection Regulation (GDPR) and the new Data Protection Act. You can find out more about how we use your information and how to contact our Data Protection Officer at www.healios.org.uk/privacy-policy.

Who has checked this project?

This project has been reviewed by the Cambridge East Research Ethics Committee and MHRA.

Who is paying for this project?

The project is being paid for by UCB, a biopharma company.

Project trial management

Chief Investigator: Dr Frank Burbach

Website: Healios.org.uk Email: info@healiosresearch.com Tel: 0800 368 8890

Address: Healios Ltd, 4a Tileyard Studios, Tileyard Road, Kings Cross, London, England,

Complaints

If you would like to make a complaint, please contact us on info@healiosresearch.com or 0330 124 4222 for stages 1 and 2 of the Complaints procedure.

Our complaints process is supported by CEDR for mediation purposes to support Clients not satisfied with the internal complaints process. You can visit the following website which has further information:

<https://www.cedr.com/consumer/healthcare/privatehealthcaremediation/>

Thank you for reading this

What do I do now?

Please feel free to talk to your family, friends or Doctor about this project. You will be asked to sign the attached 'consent form' to agree to take part in the project.

We hope you will agree to take part, but you do not have to.

At the end of the research we will write to you about what we find out in the project. You are welcome to read this if you are interested.