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ThinkNinja for epilepsy: a cognitive behavioural therapy app to improve mental health in epilepsy

Submission date
23/02/2022

Recruitment status
No longer recruiting

Registration date
04/03/2022

Overall study status
Completed

Last Edited
16/05/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Epilepsy is a common condition that affects the brain and causes frequent seizures. About 1 in 100 people in the UK have a diagnosis of epilepsy with around 87 people being diagnosed every single day. Many individuals experience a lower quality of life after their epilepsy diagnosis and are more likely to develop mental health problems such as anxiety and depression. Early identification and treatment of mental health difficulties are vital to ensure better outcomes and improve their quality of life. This study aims to explore if a cognitive behavioural therapy (CBT) app, ThinkNinja for epilepsy, a text-based conversational virtual avatar app, is effective at improving the quality of life, mental health and emotional wellbeing in people with epilepsy.

Who can participate?
Adults aged 18-65 years with a self-reported diagnosis of epilepsy and clinical levels of anxiety

What does the study involve?
All participants will take part in an 8-week intervention delivered through an app based on CBT principles, ThinkNinja for epilepsy. The programme offers tools for monitoring epileptic seizures and helps participants to better understand and improve their mental health and emotional wellbeing. Participants are also offered the opportunity to chat with trained clinicians through a text-chat within the app and to access up to three live video-based sessions with a clinical psychologist to learn skills to manage anxiety and low mood. Participants will be asked to complete questionnaires at different time points during the study to look at their quality of life, anxiety, depression, impression of change and adherence to medications to investigate the effectiveness of the intervention.
Selected participants will be randomly assigned to either the ThinkNinja for epilepsy app condition (group A), or the waiting list control group (group B). Participants assigned to group A will receive access to ThinkNinja for epilepsy app first. The waiting list control group (group B) will receive the same full access to the ThinkNinja for epilepsy app as the participants in condition A after 8 weeks. After the study is completed, the ThinkNinja for epilepsy App will be available for all participants in both groups. Step-up level 1 and level 2 will be available to participants for the 8-week duration of the active participation section of the study.

What are the possible benefits and risks of participating?
All participants will take part in the 8-week intervention programme which may improve their quality of life and their mental health and emotional wellbeing. Participants might report risky behaviours and thoughts during the study period and are informed and encouraged in several ways to seek help in emergency situations. Moreover, they are informed that this intervention is not a replacement for seeking professional treatment if they have a diagnosed condition.

Where is the study run from?
Healios Ltd (UK)

When is the study starting and how long is it expected to run for?
August 2021 to April 2023

Who is funding the study?
UCB Pharma (UK)

Who is the main contact?
Dr Sonia Ponzo (VP of Science)
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Study website
https://healios.org.uk/thinkninja-epilepsy/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288576

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 288576

Study information

Scientific Title
A randomised controlled trial of a conversational virtual avatar-led cognitive behavioural therapy app intervention for improving the quality of life and mental health of people with epilepsy

Study objectives
Hypothesis 1: There will be an improvement in participants' self-reported quality of life scores as measured by the Quality Of Life in Epilepsy Questionnaire (QOLIE-10-P) as a result of the ThinkNinja for epilepsy app intervention.
Hypothesis 2: There will be an improvement in participants' self-reported anxiety, depression, impression of change and medication adherence scores as measured by the Generalised Anxiety Disorder Assessment (GAD-7), Patient Health Questionnaire (PHQ-9), Patients' Global Impression of Change questionnaire (PGIC) and Medical Acceptability Questionnaire (MAQ) as a result of the ThinkNinja for epilepsy app intervention.
Hypothesis 3: There will be a positive association between the level of engagement with the app and the primary and secondary outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/08/2021, Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)20 7104 8096; CambridgeEast.REC@hra.nhs.uk), REC ref: 21/EE/0128

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Mental health problems in people with epilepsy

Interventions
The current study is an exploratory randomised controlled trial aimed at investigating the clinical effectiveness of a cognitive behavioural therapy (CBT) app, ThinkNinja for epilepsy, in improving the quality of life and mental health and emotional wellbeing in people with epilepsy.

ThinkNinja for epilepsy is a mobile phone app with psychoeducational and CBT-based self-help emotional wellbeing content which includes an automated conversational virtual assistant (Wise Ninja) combined with the delivery of content on interactive visual screens. ThinkNinja for epilepsy is designed to support users' individual situations and to address mental health challenges with weekly mini-modules. These are guided by the Wise Ninja combined with interactive screens that are designed to cover an 8-week period, delivered at the user's pace. Each week new content is unlocked, allowing users to have time to digest the information, develop their understanding and practice coping and CBT skills to manage their epilepsy and mental health. As part of augmenting the 8-week structured self-management programme, within the app, there are two levels of 'step-up' to allow the user access to further clinical support via interaction with a trained clinician. Step-up level 1 is a continuation of the CBT intervention and is a text-based feature enabling a clinician to perform live problem solving, assessment of needs and signpost to additional support where required, all via a text-chat interface within the app. Step-up level 2 is a video-based brief goal-focused continuation of the CBT intervention involving up to three live video-based sessions with a clinician to learn skills to manage symptoms of anxiety and low mood using CBT techniques.

Data will be input into the R Minirand programme for randomisation and participants will be assigned to either the ThinkNinja for epilepsy app arm (Condition A) or the waitlist control arm (Condition B) using minimisation techniques. The prognostic factors over which the data will be minimised include age, sex at birth and education level. Each prognostic factor will be minimised over two distinct categories: age (over 40 years and under 40 years), sex at birth (male and female) education level (below degree level and degree plus). Prognostic factors will have an equal weighting in randomisation. As there isn't a requirement to blind this trial (both clinicians and patients will be aware of whether they receive treatment or not), a deterministic approach is satisfactory, therefore the significance level on which participants are randomised is $p = 1$.

Participants will be randomly assigned to either the ThinkNinja for epilepsy app condition (Arm A) or the waiting list control group (Arm B). Participants assigned to Arm A will receive access to ThinkNinja for epilepsy app first. The waiting list control group (Arm B) will receive the same full access to the ThinkNinja for epilepsy app as the participants in condition A after 8 weeks. After the study is completed, the ThinkNinja for epilepsy App will be available for all participants in both conditions. This design allows an initial between-subjects analysis between the two conditions (those who receive the intervention straight away versus those who wait for access) as well as a within-subject analysis (this includes those who receive the intervention straight away as well as those who receive it after the waiting period).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ThinkNinja cognitive behavioural therapy app

Primary outcome measure
Quality of life measured by the Quality of Life in Epilepsy questionnaire (QOLIE-10-P) at baseline (T0), 4 weeks after the beginning of the intervention (T1), at the completion of the intervention (T2) and at follow-up 8 weeks post study (T3)

Secondary outcome measures
1. Anxiety measured using the Generalised Anxiety Disorder Assessment (GAD-7) at baseline (T0), 4 weeks after the beginning of the intervention (T1), at the completion of the intervention (T2) and at follow-up 8 weeks post study (T3)
2. Depression measured using the Patients Health Questionnaire (PHQ-9) at baseline (T0), 4 weeks after the beginning of the intervention (T1), at the completion of the intervention (T2) and at follow-up 8 weeks post study (T3)
3. Medication adherence measured using the Medical Acceptability Questionnaire (MAQ) at baseline (T0), 4 weeks after the beginning of the intervention (T1), at the completion of the intervention (T2) and at follow-up 8 weeks post study (T3)
4. Impression of change measured using the Patients' Global Impression of Change (PGIC) at the completion of the intervention (T2) and at follow-up 8 weeks post study (T3)

Overall study start date
20/08/2021

Completion date
30/04/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 16/05/2022:
1. Adult aged 18-65 years
2. UK resident
3. Fluent in English

4. Scoring ≥5 on the GAD-7 indicating at least mild anxiety at screen-in (incl. diagnosed/non-diagnosed)
5. The participant is willing and able to receive notifications and email messages
6. Have a confirmed Epilepsy diagnosis (6 months minimum time since diagnosis, suspected cases are not permitted). Diagnosis to be confirmed ideally by participant submitting a photograph of their current medication and/or letter/report from their healthcare provider
7. Stable epilepsy and anxiety/depression medication regime (anti-epileptic, antidepressant, anxiolytic drug etc. A stable medication regimen for the present study refers to no change in medication in the last 4 weeks. Questions to cover this at all data collection time points. Should participants change medication during the study period, this will not affect their inclusion, however, this will be explored in the analysis.

Previous inclusion criteria:
1. Adult aged 18-65 years
2. UK resident
3. Fluent in English
4. Clinical levels of anxiety (≥10 on the GAD-7) at screen-in (incl. diagnosed/non-diagnosed)
5. The participant is willing and able to receive notifications and email messages
6. Have a confirmed Epilepsy diagnosis (6 months minimum time since diagnosis, suspected cases are not permitted). Diagnosis to be confirmed ideally by participant submitting a photograph of their current medication and/or letter/report from their healthcare provider
7. Stable epilepsy and anxiety/depression medication regime (anti-epileptic, antidepressant, anxiolytic drug etc. A stable medication regimen for the present study refers to no change in medication in the last 4 weeks. Questions to cover this at all data collection time points. Should participants change medication during the study period, this will not affect their inclusion, however, this will be explored in the analysis.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
184

Total final enrolment
255

Key exclusion criteria
1. Have a subclinical score on the GAD-7 at screening
2. Have a score ≥20 on the PHQ-9 indicating severe depression at screen in or if they answer

‘more than half of the days’ or ‘nearly every day’’ to the question ‘Over the last 2 weeks, how often have you been bothered by thoughts that you would be better off dead or of hurting yourself in some way?’
3. Sensitivity to mobile phone screen exposure
4. Currently receiving counselling or psychological therapy (however, will not be excluded if they seek support during the study)
5. Individuals involved in current or ongoing research
6. Pregnant or has given birth in the past 12 months
7. Diagnosis of a severe mental illness (severe depression including suicidal ideation, schizophrenia, bipolar, psychosis, personality disorder, PTSD, substance misuse)
8. Severe learning disability and individuals requiring a carer for their epilepsy
9. Does not have access to a smartphone (iPhone with iOS 9 or greater capabilities, or an Android with OS 7 or greater capabilities)

Date of first enrolment
14/03/2022

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Healios Ltd
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Sponsor information

Organisation
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Sponsor type
Other

Website
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Funder(s)

Funder type
Industry

Funder Name
UCB Pharma

Alternative Name(s)
UCB Pharma Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A copy of a high-level final study report will be supplied to UCB. Results of the study will be written up as soon as possible thereafter, with the intention of publishing the outcomes in high-quality peer-reviewed journals.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.5	07/02/2022	25/02/2022	No	Yes
Protocol article		21/11/2022	22/11/2022	Yes	No
HRA research summary			28/06/2023	No	No