ISRCTN11131689 https://doi.org/10.1186/ISRCTN11131689

Implementation of a digital intervention (Lumi Nova) to support children aged 7-12 years with anxiety in Greater Manchester

Submission date
09/09/2022

Recruitment status
No longer recruiting

Registration date
08/11/2022

Overall study status
Completed

Last Edited
09/09/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Half of all mental disorders start by the age of 14 years, yet up to 70% of children and young people don't get access to timely, appropriate support. The demand for support has increased by 50% in the last 10 years leaving services under tremendous pressure. Anxiety, and other mood disorders, are the most common problem affecting children.
In the UK, there were 4.3 million children living in poverty in 2019/20; children living in households in the lowest 20% income bracket are 2-3 times more likely to experience mental illness compared to those in the highest income bracket. Yet they also face the biggest barriers to accessing treatment.
Lumi Nova is a therapeutic mobile game that delivers timely access to elements of Cognitive Behavioural Therapy (graded exposures), in a child-led, non-stigmatising way. The game supports dialogue with parents, whilst providing professionals with recognised outcome scales to monitor progress remotely. Lumi Nova was initially built to appeal to the broadest range of children with anxiety; now, there is an opportunity to tailor Lumi Nova to meet the needs of disadvantaged children - specifically those living in poverty.
This implementation study intends to understand the barriers to take-up and usage for the most economically disadvantaged children in Greater Manchester, and use the findings to optimise Lumi Nova, and how its deployed, so that it can better serve these patients.

Who can participate?
Children aged 7-12 years of age who experience difficulties with anxiety can take part in the study. They must have English proficiency sufficient to be able to understand and participate in the study, and they must live within a postcode area indicating the lowest two deciles on the multiple deprivation index.

What does the study involve?
Participants use the Lumi Nova digital intervention (mobile gaming app) for 8 weeks. They may also be asked to speak with a researcher in an interview to talk about any difficulties experienced when using Lumi Nova; the interview is voluntary and they do not need to participate in an interview to use the game; the interview will take no longer than 60 minutes.

Participants may also be asked to participate in a co-design workshop to help refine Lumi Nova based on their experiences of using it.

What are the possible benefits and risks of participating?
There is a risk that children and young people might feel upset talking about their anxiety. There is also a risk that parents/guardians might feel upset talking about their children's anxiety. While the researchers expect this risk to be small, they will provide information about external support that families can approach from mental health organisations. They will not provide any clinical support directly from within the project team and will make sure this is clear in the participant information sheets. They will also remind children and their parents/guardians that they are free to withdraw from the study at any time without needing to provide a reason. Children may experience an improvement in their anxiety as a result of using Lumi Nova.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
March 2022 to December 2023

Who is funding the study?
NHS England (UK)

Who is the main contact?
Charlotte Stockton-Powdrell, charlotte.stockton-powdrell@manchester.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Pauline Whelan

ORCID ID
https://orcid.org/0000-0001-8689-3919

Contact details
Vaughan House
Portsmouth Street
Manchester
United Kingdom
M13 9GB
+44 (0)7554 227474
Pauline.whelan@manchester.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
313721

Central Portfolio Management System (CPMS)
52996

Study information

Scientific Title
Lumi Nova - a digital intervention supporting 7-12 year olds who experience symptoms of anxiety. An implementation study in Greater Manchester to optimise for economically disadvantaged children.

Study objectives
This implementation study intends to understand the barriers to take-up and usage for the most economically disadvantaged children in Greater Manchester, and use the findings to optimise Lumi Nova, and how its deployed, so that it can better serve these patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/08/2022, West Midlands – Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8010, +44 (0)207 104 8141; blackcountry.rec@hra.nhs.uk)m ref: 22/WM/0121

Primary study design
Interventional

Study design
Non-randomized; Interventional; Design type: Treatment, Education or Self-Management, Device, Psychological & Behavioural

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety

Interventions
The researchers have split the project into four work packages.

Work package 1 (WP1): during the first 2 months (M1-2), the researchers will complete the ethics application and prepare for the deployment of the intervention. This will include readying clinical operational and management teams in the two participating sites (Wigan and Bolton), setting up study sites that have been identified, onboarding the Mental Health Schools Teams (MHSTs), establishing software licences and preparing training materials.

WP2: M3-7 will be the feasibility study which involves conducting a non-randomised study to test the feasibility of implementing Lumi Nova with 120 children and young people (CYP) in the two economically disadvantaged areas of Wigan and Bolton. This WP will also involve qualitative interviews with 10 individual stakeholders from three groups: CYP who participated in the intervention, parents/guardians of CYP participants, and service delivery managers. The

interviews will be conducted 1-1 by the research associate.
1. Participants will use the Lumi Nova intervention for 8 weeks.
2. 10 x individual interviews with parents of CYP who have been recruited to the study to explore usability/acceptability, barriers/enablers to uptake and to determine the most suitable primary outcome for a future trial.
3. 10 x individual interviews with CYP, recruited to explore usability, acceptability, barriers /enablers to uptake and most suitable primary outcome for a future trial.
4. 10 x individual interviews with service-delivery managers to understand implementation barriers/enablers and unintended consequences.

WP3: M7-9 will involve refining the software (Lumi Nova) to optimise its use with children from economically disadvantaged areas. The researchers will conduct 2 x co-design workshops with volunteer CYP who were part of the implementation study and use the insights generated to author an intervention refinement plan for the technical changes to the intervention, building on the quantitative/qualitative data analysis in WP2.
A rapid product development sprint will be conducted, using Agile software methodologies to deliver against the refinement plan. Beta-testing of the new version of the software will be conducted with five volunteers to ensure the software is fully functional and defect-free.

WP4: M8-9 is when the analyses, write-up and dissemination will take place. The researchers will prepare a report for submission to an academic peer-reviewed journal (e.g. Journal of Medical and Internet Research; JMIR), will share the findings through social media and digital mental health networks, and will host an event to share findings with CYP, parents/carers, schools, and children and adolescent mental health services (CAMHS) teams.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome(s)
1. The barriers and enablers to the usage and engagement of Lumi Nova within an economically-disadvantaged group of children and young people, assessed using interviews on completion of the intervention
2. Stakeholders' views on a primary outcome for a future trial, assessed using interviews throughout the study

Key secondary outcome(s)
1. The proportion of service users who:
1.1. Complete more than three challenges within the game Lumi Nova
1.2. Show a reduction in anxious expectations over treatment duration as measured pre- and post-exposure using in-game worry scale scores
1.3. Show improvement in Goal Based Outcome rating (parent-reported)
Measured at the end of the intervention period
2. Service users able to access Lumi Nova on a mobile device, assessed using feedback obtained during qualitative interviews and refinements to Lumi Nova to increase accessibility
3. Proportion of parents/guardians who are able to shortlist goals at the start, measured using

app usage data at the start of using the intervention
4. Proportion of parents/guardians who are able to support CYP with at least two out-of-game exposures, measured using app usage data at the end of the intervention period
5. Parents/guardians are able to complete the Child Outcome Rating Scale (CORS) at the start and end of CYP's study engagement, measured using app usage data at the start and end of the intervention period

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Postcode indicating the lowest two deciles on the multiple deprivation index and further screening criteria to confirm household income
2. Children aged 7-12 years
3. Parent/guardian able to be involved as a point of contact with the practitioner
4. Experiencing difficulties with anxiety
5. English proficiency is sufficient to be able to understand and participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
All

Total final enrolment
113

Key exclusion criteria
1. Not meeting the above inclusion criteria
2. CYP deemed to be in crisis (as assessed)

Date of first enrolment
12/10/2022

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wigan CAMHS Mental Health Support Team
155 Manchester Road
Higher Ince
Wigan
United Kingdom
WN2 2JA

Study participating centre
Wigan CAMHS School Link Team
155 Manchester Road
Higher Ince
Wigan
United Kingdom
WN2 2JA

Study participating centre
Bolton CAMHS Team Around The School
Royal Bolton Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NHS England; Grant Codes: SBRIH19P3025

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made 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?
HRA research summary			28/06/2023	No	No
Preprint results		16/05/2024	09/09/2024	No	No