Cerina Feasibility Pilot RCT Among Ulster University Students in Northern Ireland

Introducing Cerina

Cerina is a mobile application (MHRA-certified **Software as a Medical Device**) that delivers **symptom-specific** psychological therapy in a **self-guided** manner.

Cerina offers:

1. Screening of clinical symptoms and alerting high-risk individuals
2. Signposting to help students navigate to appropriate services.
3. Evidence-based treatment for mild-moderate anxiety using Cognitive Behavioural Therapy

Core Therapy

The platform offers psychoeducation, speech-to-text, and anxiety management tools like a Worry Diary and mood tracking, with visual self-report score charts culminating in a Journey Report. A conversational AI-powered chatbot enhances app interactions; a self-care page with resources and an integrated admin panel streamline the experience.

Hedgie – Your AI Pal

- AI powered emotional chatbot built safely and securely with clinical psychologists
- Engages in daily chit-chat to learn about users' days.
- Provides emotional support and listens to users' concerns.
- Offers comfort and talks through problems with empathy.
- Leads meditation sessions to help alleviate anxiety and worry.
- Accessible for general mental health support and companionship.
- Uses gentle prompts to encourage positive thinking and relaxation.

Accreditations

Healthcare Recognitions

Medicines & Healthcare products Regulatory Agency

MHRA-certified Software as a Medical Device. Cerina has been affixed with the Class 1 UKCA mark under the Medical Devices Directive 93/42/EEC as transposed into UK legislation.

NICE
National Institute for Health and Care Excellence

We are pleased to be featured in the recent NICE early value assessment of 'Digitally enabled therapies for adults with anxiety disorders

ORCHA

We have completed ORCHA digital health review and we have obtained 93% scores.

Top of our competitors

Grants

MEDILINK MIDLANDS

Cerina was awarded an R&D grant, Innovation Support Grant, from Medilink Midlands for the development of AI features.

CYBER ESSENTIALS CERTIFIED

Cerina follows strict Cybersecurity Protocols, ensuring user data safety and confidentiality. In addition, Cerina recently acquired Cyber Essentials Certification.

Consultancy Spotlight

Altus Consulting
People | Passion | Partnership

Altus Consulting Insurtech has curated a snapshots shining a spotlight on the range of technology & propositions that are being brought to market. These are mapped against industry reference model to provide an unbiased & comparable view.

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Outline

RESEARCH APPROACH AT CERINA

PILOT FEASIBILITY RCT AMONG ULSTER UNIVERSITY STUDENTS IN NORTHERN IRELAND (COMPLETERS ANALYSIS)

NEXT STEPS

Research Process

Background

- IT4 Anxiety Interreg project- a large-scale project funded by the European Union.
- Cerina partnered up with Ulster University to design a pilot feasibility RCT.
- Clinical trials registration: ClinicalTrials.gov ID NCT06146530

Background (continued)

WHO World Mental Health International College Student Project (WMH-ICS) data in NI:

22.6% (N=739) of students reported GAD symptoms

Receipt of treatment was low (37.8%) (N=392), particularly among males and those with lifetime mental conditions

Lower perceived need, and being unsure about where to go for help were important barriers to help-seeking

Early interventions addressing this unmet need are crucial

Cerina offers a significant scope to improve the reach and access of digital CBT through its interactive UI, user-centred approach, and clinical rigor

Cerina Study Design

Condition	Pre-test T0		3 weeks T1	6 weeks follow-up T2	
Treatment	X	Cerina	X	X	
Wait-list Control	X	Routine Care	X	X	Cerina

Figure 1. Participant flow through the trial

RCT and Process Evaluation Results

- We are invited to submit our RCT results to the Journal of Frontiers in Digital Health , therefore we are currently not able to disseminate them in a written format. We have permission from the journal to present our findings and acknowledge that we presented them in meetings/ conferences in our manuscript. Please contact us for the future presentation of the results.

Where does this fit into the existing student mental health landscape?

- Evidence, evidence, evidence!
- Ensuring maximum utilisation, maximum effectiveness and minimum load on university wellbeing services
- Incorporate necessary customisations to smoothly integrate into care pathway
- The case for Guided

  There is suggestive evidence from Randomised Controlled Trials indicating larger effect sizes for guided cognitive behavioural-based interventions compared to unguided ones (Cuijpers et al., 2010).

Next Steps

Publication of Protocol Paper in BMJ Open Access & Submission to the Frontiers in Digital Health

Scale up Cerina together with AI-powered triage to meet the demands for psychological help in University settings & establish its effectiveness with a full-scale RCT.

Establish the effectiveness of Cerina for treating mild to moderate GAD symptoms among a clinical population in NHS settings.

Thank You

Further questions about the RCT and/or research at Cerina:

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