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Is the computer game Pesky gNATs an effective intervention for children experiencing low mood or anxiety?

Submission date
28/03/2019

Recruitment status
No longer recruiting

Registration date
02/04/2019

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Large-scale studies containing over 4000 participants aged 14 and under have indicated a high prevalence of anxiety (24% - including sub-threshold anxiety) and depression. In Ireland, recent evidence indicates that over 30% of Irish adolescents experience levels of anxiety and depression outside of a normal range. Similarly, it is estimated that by the age of 13, 1 in 3 young people in Ireland are likely to have experienced some type of mental disorder. Accordingly, anxiety and depression represent a significant public mental health issue.

Presently, cognitive behavioural therapy (CBT) is recommended as the first response stand-alone intervention for mild to moderate cases of depressive and anxiety disorders. However, due to the accessibility challenges faced by young people, the integration of technology in a stepped care model with traditional face-to-face therapies such as CBT is receiving increased attention by clinicians in Ireland.

Who can participate?
Young people aged 8-12 who are experiencing low mood and/or anxiety.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will receive the Pesky gNATs intervention, the other to a waiting list control group. Those taking part in the Pesky gNATs group will play the game with an assistant psychologist for up to 8 weeks. Those allocated to the control group will receive the intervention at a later date.

What are the possible benefits and risks of participating?
Technology-assisted CBT has been shown to be efficacious for children experiencing low mood and anxiety in different settings. In this study, eligible participants could benefit from this evidence-based CBT approach and experience clinically significant positive change. As with any mental health intervention for low mood and anxiety, some participants may have emotionally challenging experiences during the sessions. All researchers and intervention facilitators (assistant psychologists) are vetted, trained in the intervention, and supervised. Moreover, both

researchers and intervention facilitators will adhere to: Children First National Guidelines for the Protection and Welfare of Children (Department of Children and Youth Affairs, Ireland); and the Code of Professional Ethics (Psychological Society of Ireland). Due to these factors, this study is considered low-risk.

Where is the study run from?
This study is being run by University College Dublin and takes place in Primary Care Psychology Services within the Health Service Executive (HSE) across Ireland.

When is the study starting and how long is it expected to run for?
This study has commenced in one primary care site (21/09/18), with national extrapolation occurring from 1st February 2019.

Who is funding the study?
This project is funded by a European Union project called TEAM (Technology Enabled Mental Health for Young People). TEAM has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No. 722561.

Who is the main contact?
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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Technology-assisted cognitive behavioural therapy – a randomised controlled trial of Pesky gNATs for children

Study objectives
Is Pesky gNATs an effective intervention for children experiencing low mood or anxiety as delivered by assistant psychologists in a national primary care service?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/11/2018, the Human Research Ethics Committee (HREC) in University College Dublin (UCD Office of Research Ethics, Roebuck Castle, University College Dublin, Belfield, Dublin 4; + 353 1 716 8767; research.ethics@ucd.ie), ref: HS-18-76-McCashin-O'Reilly.
Approved 25/04/2018, the Research Ethics Committee at the University Hospital Limerick (Quality & Safety Department, University Hospital Limerick Dooradoyle Limerick; 061 482519), ref: UL Hospitals Group, 021/18.

Study design
Two-arm randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low mood and anxiety in children

Interventions
Technology-assisted cognitive behavioural therapy programmes such as Pesky gNATs (O'Reilly & Coyle, 2015) have been demonstrated as feasible tools to include in working with young people, or adults with intellectual disabilities who may be experiencing low mood and/or anxiety (Tunney et al., 2017; Cooney et al., 2017).

This study will examine the effectiveness of Pesky gNATs for children with anxiety and low mood. Using a randomised controlled trial (RCT) design, participants will be randomly assigned to receive the Pesky gNATs intervention or to a waitlist control condition. Those taking part in the Pesky gNATs condition will play the game with an assistant psychologist for up to 8 weeks. Those allocated to the control group will receive the intervention at a later date.

Participants will be randomly assigned to a Pesky gNATs intervention group, or to a waitlist control group. Those taking part in the
Pesky gNATs intervention condition will play the game with an assistant psychologist for up to 8 weeks (Pesky gNATs is a 7-level game, with each level representing one session; but 8 weeks is stated to allow for a screening session). Measures are collected at baseline (pre-intervention Time 1), post-intervention (Time 2), and at a 3-month follow-up (Time 3).

Those allocated to the waitlist control group will receive the intervention at a later date. Measures are collected at baseline (pre-intervention Time 1), 8 weeks after time 1 (Time 2), and at a 3-month follow-up (Time 3).

A random sequence of computer-generated numbers will be applied to the sample by the researcher, and communicated to intervention facilitators. This study will use a simple randomisation approach that can readily be applied to simple block randomisation for smaller samples and extrapolated out to multiple sites where required (Simon, 1999).

Full details on the intervention are openly available at: https://www.peskygnats.com/

Intervention Type
Mixed

Primary outcome(s)
Levels of low mood and anxiety are measured using the Child Behaviour Checklist (CBCL) Age 6-18 (Achenbach & Rescorla, 2001) – internalising score over a 6-month period.

Key secondary outcome(s))
1. Externalising psychological difficulty is measured using the Child Behaviour Checklist (CBCL) Age 6-18 (Achenbach & Rescorla, 2001) – remaining scales over a 6 month period.
2. Behavioural competency and behavioural problems are measured using the Youth Self Report (YSR) Age 11-18 (Achenbach & Rescorla, 2001) over a 6-month period.
3. Personal functioning, interpersonal relationships, social relationships and overall sense of wellbeing are measured using the Child Outcome Rating Scale (CORS) (Duncan, Miller and Sparks, 2003) during each level of Pesky gNATs.
4. The young person's perception of the therapeutic alliance is measured using the Child Session Rating Scale (CSRS) (Duncan, Miller and Sparks, 2003) during each level of Pesky gNATs.
5. Anxiety and depression are measured using the Revised Child Anxiety and Depression Scale (RCADS) (Chorpita et al., 2000) at the beginning (level 1) and end of Pesky gNATs (level 7).

Completion date
29/05/2020

Eligibility

Key inclusion criteria
1. Aged 8 to 12 (inclusive).
2. Parent-reported/clinically significant levels of low mood and anxiety – score on CBCL in the clinical range on the internalising scale.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
12 years

Sex
All

Key exclusion criteria
1. Formal diagnosis of intellectual disability.
2. Other interpersonal difficulties that could adversely impact participation: active psychosis, significant cognitive difficulties, and English language difficulties.

Date of first enrolment
21/04/2018

Date of final enrolment
29/02/2020

Locations

Countries of recruitment
Ireland

Study participating centre
Health Service Executive (HSE) Ireland - Primary Care Psychology Services
Dr. Steevens' Hospital
Dublin
Ireland
Dublin 8

Sponsor information

Organisation
University College Dublin

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to this research involving sensitive data regarding minors in primary care services who are experiencing clinically significant levels of psychological difficulties.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Qualitative sub study	01/12/2020	12/06/2023	Yes	No