ISRCTN14624359 https://doi.org/10.1186/ISRCTN14624359

Understanding whether a new digital tool to support communication about self-harm between practitioners and young people is acceptable and usable in clinical settings

Submission date
30/04/2026

Recruitment status
No longer recruiting

Registration date
26/06/2026

Overall study status
Completed

Last Edited
26/06/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Self-harm is a growing concern among young people, especially adolescent girls. It is linked to long-term mental health issues and increased suicide risk. Many young people do not seek help, and traditional therapies can be hard to access or engage with. New tools are needed to support better communication and shared understanding between young people and practitioners.
This study tests a new digital tool called the CaTS-App©, designed to help young people and practitioners explore the thoughts, feelings, and events surrounding self-harm. It aims to improve shared understanding, assessment and communication about an episode of self-harm in a collaborative clinical relationship.
Both practitioners and young people are participants in this study. Practitioners must be working with young people receiving support for self-harm within Nottinghamshire Healthcare NHS Foundation Trust (NHCFT) or Harmless, a NHCFT NHS specialist service provider. Young people aged 12–24 years receiving ongoing support for self-harm may be invited to take part if deemed eligible by their practitioner, based on clinical judgement. They must also be able to consent (or assent with parental consent), read and write in English, and not have clinical or accessibility concerns that would prevent participation.
The study will run at two sites: NHCFT and Harmless. Harmless are commissioned by the ICB in Nottinghamshire as an NHS provider of mental health services. The study uses a single-arm case study design. Eligible young people will use the CaTS-App© with a trained practitioner during routine in-person care for up to 12 weeks. Practitioners interested in using the app will have their service opened to recruitment during the study.
The study will explore how acceptable the CaTS-App© is to both young people and practitioners and how well it supports shared understanding, assessment and communication in clinical care.

Who can participate?
Practitioners who are working with young people currently receiving support for self-harm and working in an NHS setting or with an NHS provider in Nottinghamshire Healthcare Foundation Trust. Practitioners must attend a CaTS-App© Practitioner Promotion session, including detailed

information on expectations around involvement, ahead of signing up to take part. Practitioners then identify young people they are supporting within Nottinghamshire NHS services or from NHS service providers such as Harmless. These young people must be between 12 and 24 years old, able to read and write in English and able to consent for themselves to take part. If the young person is under 16, parental consent may be required, or the young person needs to show they are competent to consent for themselves through a procedure known as Gillick Competence.

What does the study involve?
Practitioners are recruited from within NHCFT services and the specialist provider Harmless through internal networks and ongoing collaborations. They are invited to attend an online CaTS-App© promotion session, where they receive a Practitioner Participant Information Sheet (PIS) and learn about the study. After the session, practitioners who express interest complete an online informed consent form and a demographics form. Once consent is obtained, the research team provides each practitioner with a tablet preloaded with the CaTS-App©, a Practitioner Manual, a Young Person's Workbook, a Scoring Booklet, and an End of Study Booklet, along with PIS documents for young people. These paper-based materials will be used for recording responses during the clinical study and will be returned to the research team once their involvement comes to an end. Practitioners are then responsible for identifying eligible young people from their caseloads and guiding them through the study process.
Practitioners use the manual to support young people through the CaTS-App© steps. They begin by helping the young person to complete a demographics form, complete baseline measures, including the RCADS (Pre) and the Pre-Clinical Impact Survey, and watch the introductory video together. First, they explore the app's features and complete reflection logs. Then, the young person completes their first full Card Sort, again followed by reflection. Finally, they review the completed Card Sort and discuss alternative actions with the young person. Practitioners may repeat these steps with the young person if beneficial. Once all sessions are complete, practitioners support the young person in completing post-measures. Once a practitioner has completed all dyads and reached the end of their involvement in the study they will complete their own post-measures, including the System Usability Scale (SUS) and an acceptability survey. Finally, practitioners are invited to participate in a 30-minute online feedback interview to share their experiences and insights about the CaTS-App© and its integration into their practice.
Young people are identified by their practitioner after the practitioner has completed their own consent process. They will receive an appropriate Participant Information Sheet (PIS) for their age and circumstances. Those aged 16 years and over provide written informed consent directly. Young people aged 12–15 years with parental involvement provide assent, while their parent or carer provides consent. For those aged 12–15 years without parental involvement, a Gillick Competence assessment is used to determine if they can consent independently. Once consent or assent is obtained, the young person begins the study.
The young person's journey starts with a baseline session where they complete the demographics form, RCADS (Pre) and the Pre-Clinical Impact Survey and watch the 'Why Use the CaTS-App©' video with their practitioner. If a young person in the service has completed the RCADS within the previous 2 weeks of giving consent, that assessment can be used as the RCADS baseline measure to avoid them completing it again. Firstly, the young person has time to explore the app's features and complete wellbeing checks and a reflection log. Then they are asked to complete their first full Card Sort, followed by further reflection. Finally, they review their Card Sort with their practitioner, reflect on their choices, and consider alternative actions. If helpful, these steps can be repeated for other episodes of self-harm. After completing the sessions, the young person completes post-measures, including the RCADS (Post), Post-Clinical Impact Survey, System Usability Scale (SUS), and an acceptability survey. They then receive a

debrief sheet explaining the study and next steps. If they opted in, they may also be invited to a 30-minute feedback interview to share their experiences with the CaTS-App© and its impact on their care.

What are the possible benefits and risks of participating?
While young people have told us that they find the card sorting task helpful as a way of thinking about and talking about their experience of self-harm and many young people have told us that they like having a chance to contribute to research and the development of new tools to improve mental health services, being involved in the study might not have any direct benefits to young people or practitioners taking part.

Where is the study run from?
Nottinghamshire Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2026 to September 2026

Who is funding the study?
UK Research and Innovation, Digital Youth Programme award (MRC project reference: MR /W002450/1)

Who is the main contact?
Ellen Townsend, Ellen.Townsend@nottingham.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Dr Camilla Babbage

Contact details
University of Nottingham
Institute of Mental Health
University Of Nottingham Innovation Park
Triumph Road
Nottingham
United Kingdom
NG7 2TU
-
camilla.babbage@nottingham.ac.uk

Type(s)
Principal investigator

Contact name
Prof Ellen Townsend

ORCID ID
https://orcid.org/0000-0002-4677-5958

Contact details
University of Nottingham
School of Psychology
Nottingham
United Kingdom
NG7 2RD
+44 (0)115 84 67305
Ellen.Townsend@nottingham.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
360016

Central Portfolio Management System (CPMS)
71664

Medical Research Council (MRC) Grant Code
MR/W002450/1

Study information

Scientific Title
Acceptability, usability and development of the app-based Card-Sort Task for Self-Harm (CaTS-App) for clinical settings: a real-world pilot study with youth-practitioner dyads

Acronym
CaTS-App

Study objectives
Primary Objective:
The objectives for this study are as follows:
1. To explore and understand the acceptability of the CaTS-App© for young people in a clinical setting when working alongside a practitioner, measured through an acceptability questionnaire designed by the team, feedback in interviews and the willingness of practitioners and young people to take up CaTS-App©
2. To explore and understand the acceptability of the CaTS-App© for practitioners when working with young people in a clinical setting, measured through an acceptability questionnaire designed by the team and from feedback in interviews

Secondary Objectives:
1. To explore and understand the usability and user experience of the CaTS-App© in a clinical setting, delivered alongside a practitioner, measured by interview feedback on the app's ease of use, engagement with, functionality and user experience, and through the System Usability Scale and metrics collected via the app.
2. To explore the clinical impact of using the CaTS-App© in terms of self-harm and mental health outcomes before and after using the CaTS-App©. Impact will be measured using the CaTS-App© pre-post Clinical Impact Survey questionnaire for young people and practitioners and the pre-post RCADS developed by the team.

3. To gain feedback on the suggested framework for delivering the CaTS-App© as a component of practice-based support.
4. To investigate the safety of CaTS-App© through youth-focused emotional response and an iatrogenic risk question.
5. To explore user-insight for app-development (iterative prototyping). To gain knowledge in line with core tasks delivered across sessions (understanding, reviewing, sorting, creating a timeline, reviewing and identifying strengths, decision making, ownership) using specific features and functions (moving, storing, adding notes, creating reports etc. Measured through feedback interviews with practitioners and (optional) young people.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/01/2026, South West - Cornwall & Plymouth Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048071; cornwallandplymouth.rec@hra.nhs.uk), ref: 25/SW/0140

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Self-harm

Interventions
A real-world pilot, acceptability and usability study has been selected to understand how the CaTS-App© is implemented by practitioners in real clinical environments. This will help us to understand any adaptations that are required to the CaTS-App© early in its development to ensure the CaTS-App© is suitable for future implementation.

Ahead of a larger effectiveness trial, it is important to understand whether the app is acceptable to young people and practitioners, is usable in routine care and is safe to use. These are essential questions that must be answered before moving to a larger-scale trial as changes can be

implemented, preventing research waste. A feasibility study also allows researchers to identify and address any practical or ethical issues early on. Practitioners are recruited from within NHCFT services and the specialist provider Harmless through internal networks and ongoing collaborations. They are invited to attend an online CaTS-App© promotion session, where they receive a Practitioner Participant Information Sheet (PIS) and learn about the study. After the session, practitioners who express interest complete an online informed consent form and a demographics form. Once consent is obtained, the research team provides each practitioner with a tablet preloaded with the CaTS-App©, a Practitioner Manual, a Young Person's Workbook, a Scoring Booklet, and an End of Study Booklet, along with PIS documents for young people. These paper-based materials will be used for recording responses during the clinical study, and will be returned to the research team once their involvement comes to an end. Practitioners are then responsible for identifying eligible young people from their caseloads and guiding them through the study process.

Practitioners use the manual to support young people through the CaTS-App©'s stages. They begin by helping the young person to complete a demographics form, complete baseline measures, including the RCADS (Pre) and the Pre-Clinical Impact Survey, and watch the introductory video together. They then support the young person to become familiar with the app and the card-sorting process. The young person will complete a card-sort by reflecting on a specific episode of self-harm. Finally, the practitioner will work with the young person to review and reflect on their choices. These steps can be completed multiple times as per individual requirements. Once all sessions are complete, practitioners support the young person in completing post-measures. Once a practitioner has completed all dyads and reached the end of their involvement in the study they will complete their own post-measures, including the System Usability Scale (SUS) and an acceptability survey. Finally, practitioners are invited to participate in a 30-minute online feedback interview to share their experiences and insights about the CaTS-App© and its integration into their practice.

Young people are identified by their practitioner after the practitioner has completed their own consent process. They will receive an appropriate Participant Information Sheet (PIS) for their age and circumstances. Those aged 16 and over provide written informed consent directly. Young people aged 12–15 years with parental involvement provide assent, while their parent or carer provides consent. For those aged 12–15 years without parental involvement, a Gillick Competence assessment is used to determine if they can consent independently. Once consent or assent is obtained, the young person begins the study.

The young person's journey starts with a baseline session where they complete the demographics form, RCADS (Pre) and the Pre-Clinical Impact Survey and watch the 'Why Use the CaTS-App©' video with their practitioner. If a young person in the service has completed the RCADS within the previous two weeks of giving consent, that assessment can be used as the RCADS baseline measure to avoid requiring a young person to complete it again. The young person will start with time to become familiar with the app and the card-sorting process. When ready they will be asked to complete a card-sort by reflecting on a specific episode of self-harm. Finally, they will work with the practitioner to review and reflect on their choices and identify actions. These steps can be completed multiple times as per individual requirements. After completing the sessions, the young person completes post-measures, including the RCADS (Post), Post-Clinical Impact Survey, System Usability Scale (SUS), and an acceptability survey. They then receive a debrief sheet explaining the study and next steps. If they opted in, they may also be invited to a 30-minute feedback interview to share their experiences with the CaTS-App© and its impact on their care.

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CaTS-App©

Primary outcome(s)
1. The acceptability of the CaTS-App© in achieving its core objectives (improved communication, understanding, decision-making) measured using an 18-item survey of open and closed responses at endpoint

Key secondary outcome(s)
1. Symptoms of depression and anxiety measured using the Revised Child Anxiety and Depression Scale (RCADS) at baseline and endpoint
2. Frequency of self-harm/thoughts in the last week measured through a Pre-Clinical Impact Survey (Pre-CIS) at baseline
3. Participant engagement with the CaTS-App© measured through metrics collected by the app at the end of the study
4. Current emotional state measured using a Wellbeing Check through a visual analogue scale (VAS) at the start and end of each session using the app
5. Initial thoughts and feedback collected through Reflection Logs on completion of each step of the CaTS-App©
6. Frequency of self-harm/thoughts in the last week, and impact of the CaTS-App© on self-harm and suicidal thoughts measured through a Post-Clinical Impact Survey (Post-CIS) at endpoint
7. The usability of CaTS-App© measured through a 10-item Likert questionnaire, the System Usability Scale (SUS) adapted for CaTS-App©, at endpoint
8. Experiences of using the CaTS-App© collected using an online interview at endpoint

Completion date
24/09/2026

Eligibility

Key inclusion criteria
Practitioners:
1. Working with young people currently receiving support for self-harm
2. Working in an NHS setting or with an NHS provider in Nottinghamshire Healthcare Foundation Trust
3. Attendance at CaTS-App Practitioner Promotion session including detailed information on expectations to support decision-making

Young People:
1. Aged 12-24 years old (on date of consent)
2. Receiving ongoing support for self-harm within Nottinghamshire NHS services or from NHS service providers (confirmed by practitioner) with a practitioner, who is a participant in the study
3. Able to provide written consent or, if aged under 16 years, parental consent and written /verbal assent (confirmed during consent) or confirmed Gillick competent where appropriate
4. Can read and write in English

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 Years

Upper age limit
24 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Young People:
1. Clinical concerns that the young person is not appropriate to receive CaTS-App as support for self-harm or be involved in a research project (as confirmed by the practitioner, informed by the practitioner's attendance to the promotion session where expectations of a young person in the study will be clearly outlined to support this clinical decision)
2. Has a disability that would preclude their ability to engage with the CaTS-App alongside a practitioner

Date of first enrolment
24/03/2026

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
The Resource, Trust Hq
Duncan Macmillan House
Porchester Road
Nottingham
England
NG3 6AA

Study participating centre
Harmless
1 Beech Ave, New Basford
Nottingham
England
NG7 7LJ

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data will be retained for 7 years from publication. Data will be retained in an identifiable form until it is put into the Datamind repository. Identities are held on paper and these will be

destroyed at the point that the data is transferred to Datamind. Access to Datamind is strictly controlled and access is only given to approved researchers and authorized personnel who meet specific safety, ethical, and legal criteria. This information is included in participant information sheets.

IPD sharing plan summary

Stored in non-publicly available repository