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Brief mobile app-based intervention for non-suicidal self-injury

Submission date
22/02/2025

Recruitment status
Recruiting

Registration date
13/03/2025

Overall study status
Ongoing

Last Edited
07/03/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Background and study aims
Non-suicidal self-injury behaviors (NSSI), like self-cutting, are becoming more common among adolescents and young adults worldwide. Although these behaviors are not intended to be suicidal, they are a significant risk factor for suicide and cause emotional distress for those affected and their families. NSSI is increasingly seen in the general population, making it a public health concern. Current treatments for NSSI are often expensive and hard to access. This study aims to develop a mobile phone app to provide an accessible treatment for NSSI, helping young people manage their self-injury and improve their emotional well-being.

Who can participate?
Young people aged 14 to 24 years who are dealing with mental health issues and NSSI can participate in the study.

What does the study involve?
Participants will first answer online questions about their clinical symptoms and NSSI behavior. Then, 300 participants will be selected for the second phase. Some of these participants will undergo brain scans to see how their brain processes physical and emotional pain. Over the next 5 weeks, one group will use the NSSI-specific app, while another group will use a different app not tailored for NSSI. This will help determine if the NSSI-specific app is effective.

What are the possible benefits and risks of participating?
Participants may benefit from the app-based intervention, which could help them manage NSSI and improve their emotional well-being. There are minimal risks, mainly related to the discomfort of answering personal questions and undergoing brain scans.

Where is the study run from?
Hospital Universitari de Bellvitge (Spain)

When is the study starting and how long is it expected to run for?
December 2022 to October 2026

Who is funding the study?
Fundació la Marató de TV3 (Spain)

Who is the main contact?
Daniel Vega, daniel.vegamo@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Mr Daniel Vega

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
La MArató 202233-30-31-32-33

Study information

Scientific Title
Design and analysis of the effectiveness of a brief mobile App-based intervention for Non-Suicidal Self-Injury: self-report, momentary and biological predictors of treatment outcomes

Acronym
KALMER-NSSI

Study objectives

- Hypothesis 1: We hypothesized that participants receiving a mobile App-based brief intervention for NSSI, will show a greater improvement of well-being and quality of life at the end of the treatment and at follow-up compared to participant receiving a non-specific App-based intervention.
- Hypothesis 2: Compared to healthy participants, youth with NSSI will report less physical pain intensity and unpleasantness in response to the same noxious pressure and higher distress during the social rejection task. Youth with NSSI will show reduced physical pain-evoked responses in the Neurologic Pain Signature in response to the same peripheral noxious input (same pressure) and similar brain marker responses when subjective pain is matched across groups. We anticipate significantly augmented rejection brain marker responses in response to social rejection in line with anticipated increases in ratings of affective distress for the NSSI group (vs. healthy peers).
- Hypothesis 3: In youth with NSSI, pairing social rejection with physical pain will evoke greater reductions in affective distress ratings compared with healthy peers and will lead to greater reductions in rejection brain marker responses while increasing activation in the reward system. Conversely, in NSSI patients (vs. healthy), handholding during social rejection will lead to less pronounced reductions in the rejection brain signature, less activation of the reward system, and less reduction in ratings of affective distress.
- Hypothesis 4: We anticipate that brain activity in medial and lateral PFC and ventral striatal reward circuitry will predict responses to App-based treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/12/2022, Research Ethics Committee of Bellvitge University Hospital (Hospital Universitari de Bellvitge, L'Hospitalet de Llobregat, Barcelona, 08907, Spain; +34-932607500; presidenciaceic@bellvitgehospital.cat), ref: PR336/22 (CSA PR4/2022)

Study design
Multicenter interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, University/medical school/dental school, Other

Study type(s)
Prevention, Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Non-suicidal self-injury

Interventions
This study is a randomized controlled trial (RCT) designed to evaluate the effectiveness of two App-based interventions for non-suicidal self-injury (NSSI) in adolescents and young adults. Participants will be recruited through multiple sources and screened for eligibility based on predefined inclusion and exclusion criteria. A total of 300 participants will be included: 240 with a history of Non-suicidal self-injury (NSSI) and 60 healthy controls (HC group). Participants with NSSI were recruited from clinical sites (i.e., Clinical group, N=120) as well as from the community (i.e., Subclinical group, N=120)
Participants with NSSI (both clinical and subclinical) will be randomly allocated to one of two intervention arms: (1) a specific App-based intervention (Int1) incorporating elements of Cognitive Behavioral Therapy (CBT) and Dialectical Behavior Therapy (DBT), or (2) a psychoeducational intervention (Int2). Randomization will follow an adaptive procedure, stratified by age (14-16, 17-19, and 20-24 years) and sex, ensuring balanced groups.
Participants will complete an online assessment at multiple time points (baseline, post-treatment, and follow-ups). Self-report measures will include: (i) The Non-Suicidal Self-Injury Disorder Scale (NSSIDS) to assess DSM-5 criteria for NSSI; (ii) The Inventory of Statements About Self-Injury (ISAS) to evaluate lifetime frequency and functions of NSSI.
Additionally, participants will undergo a structured diagnostic interview (Mini-International Neuropsychiatric Interview, M.I.N.I.). The Clinical group and the HC group will complete an fMRI session to assess neural correlates of NSSI.
Momentary assessments through the App will capture real-time data on emotional state, social support, and NSSI behaviors. The collected data will also be used for machine learning models to predict NSSI risk and personalize interventions.

Intervention Type
Other

Primary outcome measure
Frequency of non-suicidal self-injury (NSSI) episodes and thoughts is measured using Momentary Assessments via the App (participants will report NSSI behaviors and thoughts in real-time throughout the intervention phase) and Self-Report Measures at baseline, 1 week, 5 weeks, 9 weeks (1 months follow-up) and 17 weeks (3 months follow-up).

Secondary outcome measures
1. Emotional Regulation and Psychological Symptoms measured using self-report questionnaires at baseline, 1 week, 5 weeks, 9 weeks (1 months follow-up) and 17 weeks (3 months follow-up)
2. Emotional Regulation and Psychological Symptoms measured using momentary assessments (participants will report their emotional status through the App to track changes over time) at baseline, 1 week and 5 weeks
3. Neural pain processing and social rejection processing as biological predictors of treatment measured using Neuroimaging Measures (fMRI) at baseline
4. Engagement and Treatment Adherence using App Usage Metrics after treatment ends (ie., 5 weeks)
5. Risk of non-suicidal self-injury engagement using momentary data and neuroimaging features after ends the follow-ups

Overall study start date
12/12/2022

Completion date
01/10/2026

Eligibility

Key inclusion criteria
For all participants:
1. From 14 to 24 years old
2. Provide informed consent (including parental consent for participants under 18)
3. Have access to a mobile phone.

For the control group:
1. No history of non-suicidal self-injury (NSSI), either past or present
2. Not receiving any psychological or psychiatric treatment.

For the subclinical group:
1. Have engaged in NSSI on at least five days during the last 12 months
2. Not receiving psychological or psychiatric treatment.

For the clinical group
1. Have engaged in NSSI on at least five days during the last 12 months
2. Under psychological or psychiatric treatment

Participant type(s)
Healthy volunteer, Patient, Population

Age group
Mixed

Lower age limit
14 Years

Upper age limit
24 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
For participants eligible to neuroimaging:
1. Pregnancy
2. Neurological disorders
3. Claustrophobia
4. Metal implants or medical devices

For the clinical group:
1. Important clinical instability at the time of recruitment

Date of first enrolment
01/07/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Spain

Study participating centre
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Study participating centre
Hospital Sant Joan de Déu de Barcelona
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Study participating centre
Hospital de la Santa Creu i Sant Pau
Carrer de Sant Quintí, 89
Barcelona
Spain
08025

Study participating centre
Hospital Fundació Althaia
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Manresa
Spain
08243

Study participating centre
Hospital Universitari Mútua de Terrassa
Plaça del Doctor Robert, 5
Terrassa

Spain
08221

Study participating centre
Hospital Clínic de Barcelona
Carrer de Villarroel, 170
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08036

Study participating centre
Consorci Corporació Sanitària Parc Taulí
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08208

Study participating centre
Universitat de Barcelona
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Study participating centre
Universidad Jaume I
Avinguda de Vicent Sos Baynat, s/n
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12006

Study participating centre
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Sponsor information

Organisation
Fundació la Marató de TV3

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Sponsor type
Other

Website
https://www.3cat.cat/tv3/marato/fundacio/

Funder(s)

Funder type
Other

Funder Name
Fundació la Marató de TV3

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/10/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Daniel Vega (daniel.vegamo@gmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			07/03/2025	No	No