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

1. Project summary

Non-suicidal self-injury (NSSI) has become a significant public health concern. Online interventions specifically addressing NSSI may be more appealing to young people with NSSI and may help overcome existing barriers to face-to-face treatment access. This project aims to develop and evaluate a brief mobile app-based intervention program that specifically addresses NSSI. Adolescents and young adults engaging in NSSI will be recruited from both clinical and non-clinical settings and will be randomly assigned to receive either the newly developed NSSI-specific intervention (Int1, N=120) or a non-NSSI specific intervention (Int2; N=120). Before the Int1, the clinical group of patients (n=60) and a healthy control group (HC) will perform an fMRI session including a social rejection and physical pain task. We will use biological measures, along with self-report and momentary measures (collected from the APP) to predict app-based intervention outcomes of participants. Overall, findings may help bring us a step closer to the development of personalized treatment for youth who engage in self-injury and may help establish a newly developed intervention that is time and cost-effective and has the potential to reach large groups of young people with NSSI in both clinical and non-clinical settings.

2. General information

Protocol 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

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3. Rationale & background information

Non-suicidal self-injury (NSSI) is a public health concern that imposes a heavy burden on people who are struggling with it and on their families and exerts great costs on the health system and society. NSSI refers to the deliberate destruction of one's own body tissue in the absence of conscious suicidal intent (1,2), including methods such as cutting or burning oneself. NSSI especially affects adolescents and young adults from clinical and non-clinical samples. Around 17.2% of adolescents and 13.4% of young adults from community samples report at least one NSSI-episode in their lifetime (3). In clinical samples, the prevalence of NSSI is even higher, reaching up to 58% of adolescents (4). NSSI is associated with potentially detrimental consequences such as low interpersonal, academic, and daily functioning. Critically, NSSI is a significant predictor of suicide (5). Importantly, the World Health Organization has recognized NSSI as one of the top five major health threats to adolescents and has been included in the last version of the Diagnostic and Statistical Manual of Mental Disorders as an independent disorder requiring further research. NSSI emerges during early adolescence. Its pathogenesis has been associated with persistent psychosocial stress and rejection or victimization by peers (6).

To date, only few interventions have been developed that specifically target NSSI (7). Dialectical Behavior Therapy (DBT), Mentalization-Based Treatment and Cognitive Behavioral Therapy focus on improving emotion regulation, and can therefore be effective for treating NSSI, especially in the context of borderline personality traits or BPD (8,9). DBT is considered the gold-standard treatment for adolescents engaging in NSSI (10). However, access to these treatments is commonly restricted due to limited resources and a lack of specially trained clinicians. Less intensive treatment programs specifically addressing NSSI would be more useful or more appealing to young people with NSSI behaviors (11). Specifically, online, or app-based self-delivered brief interventions that exclusively focus on NSSI may show promise in reducing the treatment gap. However, to date, there are no available, effective, app-based interventions for adolescents and young adults engaging in NSSI.

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4. Study goals and objectives

General Objectives:

General Objective 1: To evaluate a newly developed app-based intervention program for adolescents and young adults engaging in nonsuicidal self-injury (NSSI).

General Objective 2: To assess predictors of treatment outcomes from this app-based intervention program

5. STUDY DESIGN

5.1. Methodology

Recruitment and treatment allocation

The recruitment of participants will be done considering different sources (Table 1). Participants completing the screening and fulfilling inclusion criteria (Table 2) will be randomly allocated to a treatment arm (see below). An additional healthy control group (HC) will be included. The final sample will comprise 300 adolescents and young adults. Of this sample, 240 will be participants with NSSI (NSSI group) and 60 will be healthy controls (HC group). The NSSI group will be composed of participants from a clinical and non-clinical sample (Figure 1). Procedure First, a website will be created which will serve to disseminate the project and to evaluate participants. Second, potential participants will receive an email with information about the study and with the link to the website. If prospective participants agree to participate, they need to sign the informed consent. In case of participants under 18 years old, parental consent will also be required. The informed consent asks about the possibility to contact each participant in the future (thus confirming a cohort of study). After providing informed consent, that website will offer the possibility to complete an online assessment.

The online assessment protocol will consist of sociodemographic information and self-report measures (1-6). Participants will be asked if they have self-injured in the past year or before. Only participants with NSSI must answer questionnaires (i) Non-about NSSI such as the Non-suicidal self-injury disorder scale (NSSIDS)(7), which assesses whether participants meet criteria for the DSM-5 NSSI disorder and the Inventory of Statements about Self-Injury (ISAS)(8), which assesses lifetime frequency and functions of NSSI behaviors.

Participants from the NSSI group will be included in the treatment phase of the study. The HC group be included in the fMRI experiment (see below). Participants will be randomly assigned to receive a specific treatment for NSSI (Int1) or a non-specific intervention (Int2). We will use an adaptive randomization method considering age (three groups: 14-16, 17-19 and 20-24 years old) and sex (male, female). Thus, the two groups of treatment will be matched by age and sex. Finally, four groups of 60 participants will be obtained (Figure 1 & 2).

The Int1 will be a specific intervention for NSSI based on elements of Cognitive Behavioral Therapy (CBT) and Dialectical Behavior Therapy (DBT). The Int2 will be a psychoeducational intervention. In addition, patients will receive a Treatment as Usual (TAU). This may include individual face-to-face psychological and pharmacological treatment (or both) in a public mental health unit. The design of the App will also follow an end-user centered design related to participatory design and cooperative inquiry. During the development phase, researchers will create a focus group of young volunteers. The intervention will be designed based on a momentary intervention design, where a brief quiz will be used to assess the status of participants and then provide a specific intervention (e.g., video, audio or image). Importantly, the App will collect data on the activity of each participant regarding the treatment (e.g., usage time). Researchers will offer participants the option to contact a member of the research group by chat. If any participant reports repetitive NSSI acts or shows a high risk of engaging in NSSI, a researcher will contact the participant by phone and will assess the situation and elaborate a safety plan.

After randomization, participants will receive instructions to download the app and they will start with the assigned treatment. The clinical group will complete an fMRI session (Figure 2) and additional clinical information will be gathered in a face-to-face interview. We will use the Mini-

International Neuropsychiatric Interview (M.I.N.I.)(9) and we will collect additional information (e.g., drugs use, previous suicide attempts).

Participants in both groups will be assessed at three time points. Throughout the entire duration of the intervention (both Int1 and Int2) participants would have to use the App to report momentary information on their emotional status, perception of social support and the engagement in NSSI. fMRI experiment The clinical group (n=60) will complete a single fMRI session before they complete the treatment phase. In addition, the HC group will also complete the fMRI session (n=60).

5.2. Data management and statistical analysis

Sample size calculation

For the intervention, G*Power calculations have been performed considering a previous protocol (10). To detect a medium effect size (Cohen´s f = 0.27) in each sample (clinical and non-clinical) with power 1- β error probability=0.9 and alpha error probability=.05, and allowing for up to 20% attrition, we would need 100 per intervention arm (Int1 vs Int2). Considering potential dropouts, we consider 120 participants per group to be the optimal sample size for our current project. Regarding the fMRI study, based on G*Power calculations, we anticipate that we will need 51 participants per group to assess between-group differences (at tail=2; effect size d=0.6; α error probability=0.05; power (1- β error probability) = 0.85; allocation ratio=1). For correlation analyses within the NSSI group, we would need 50 participants (at tail=2; effect size |p| =0.4; α error probability=0.05; power (1- β error probability) = 0.85). Considering potential dropouts, we consider 60 participants per group to be the optimal sample size for our current project.

Statistical analysis

Mixed Models will be used to test the effect of the interventions on both the NSSI outcomes obtained through the App (e, g., frequency of NSSI) and the self-report measures. We will consider Time (T0, T1, T2, T3) as a within-subject factor and Intervention (Int1 vs. Int2) and Group (Clinical vs. non-Clinical) as between-subject factors. Time and Intervention will be entered as fixed effects, and the participants' intercept will be specified as random effect and time as random slope. On the other hand, quality control and preprocessing will ensure the quality of the BOLD signal in each task and condition of interest. First, we will conduct quality control analyses for motion and image quality for each subject and MRI sequence. Second, brain activation will be computed for each participant for each condition of interest using brain-mapping specific software freely available (SPM or FSL) as in our previous work. Subsequent statistical analyses will be done using Matlab and Python-based using code available at PENLab and the Cognitive and Affective Neuroscience Laboratory (https://github.com/canlab). First, we will implement a series of univariate analyses (i) one-sample t-tests of brain activation/connectivity for each condition of interest, (ii) two-samples t-test for between-group comparisons, (iii) correlations between brain features, clinical symptoms. Second, we will also use multivariate machine learning analysis approaches (SVM and lasso-PCR) to identify brain signatures of NSSI and predict patients' clinical response to the App intervention using neurobiological interpretable features.

We will use the momentary data provided by the App to build predictive models of NSSI. The ultimate goal of these models is to provide feedback to the App and make it more reactive to the situation the user is experiencing. Thus, if the model predicts a high probability of NSSI, the App will use this information to interact with the subject in order to avoid the (future) NSSI event. We will pay special attention to the interpretability of the models. Therefore, we will initially base our models on CART trees. However, we will also explore other systems such as

support vector machines (SVMs) and neural networks (NNs), with the intention of improving model results. We will use feature selection methods to rank the importance of the features used to build them. This will help to optimize the features collected through the App and to interpret the models obtained. Furthermore, we will explore multimodality by incorporating neurofunctional data into the models. Therefore, connectivity features will be extracted from the fMRI images of the subsample of participants undergoing image analysis, and new models will be derived, in two ways: (i) predicting the NSSI exclusively using neuroimaging data; (ii) fusing EMA and neuroimaging data, to increase the performance of the models and determining which brain characteristics are more prone to generate NSSI, which will be a value information for psychologists and psychiatrists working on that field.

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6. Expected outcomes of the study

At a social level, the results derived from this project could promote social actions to raise awareness about the importance of this type of behavior in the general population and, specifically, in populations at risk of suicide and psychopathology.
Results may also be able to facilitate preventive interventions that could contribute to the well-being of people who selfharm as well as their families and loved ones.
At an economic level, NSSI is an important cause of disability, which has been associated with problems in academic performance, low productivity, and worse functionality. In addition, it is the most important risk factor associated with suicide, which, in turn, is the most frequent cause of death among young people between 15 and 29 years of age. On the other hand, NSSI is closely associated with some mental disorders that generate a significant economic cost to the national health system. For example, in the case of borderline personality disorder, this represents a cost of 45.6 million euros per year in Catalonia. Therefore, developing novel, cost-effective interventions that specifically address NSSI could help reduce or mitigate the socio-economic cost of this debilitating behavior and associated mental disorders.
Psychological treatments including automated interventions though apps and/or online resources may be optimal for reducing loneliness, but they may also help minimize barriers to access mental health services and waiting lists. These technologies can also be used to monitor warning signs for mental illness by means of digital phenotyping. In addition, these technologies may be especially important for people engaging in NSSI, given that they constitute an especially vulnerable group due to their: (i) difficulties at the social level; (ii) tendency to overuse social media; (iii) emotion regulation problems; and (iv) reluctance to seek face-to-face psychological help.
Thus, results from the current study could improve the quality of life of people engaging in NSSI and their satisfaction with psychological (public) treatments. The analysis of predictors of treatment outcomes could help improve the cost-effectiveness of psychological interventions

(by guiding clinical decisions) and could help bring us a step closer to developing personalized treatments for NSSI.

7. Dissemination of results and publications policy

- Dissemination to the scientific community: (i) Presentations at meetings and conferences; (ii) Publications in peerreviewed journals and Open Access.
- Dissemination to young people: We will engage directly with young people through social media, including demos of the website and app, sharing of testimonials. Links and potential partnerships with social care organisations focused primarily on prevention of mental health problems will also be established like foundations giving direct assistance to child and adolescents in psychosocial risk like Fundación ANAR (Helping Children and Adolescent in Psychosocial Risk), or other Youth Organisation offering programs for teenagers at risk.
- Dissemination to relevant healthcare, education, and social care professionals: Psychiatrists and psychologists, teachers, community workers and all involved with the medical and social care and
education of young people are targets for dissemination of information about the objectives and results of this projects.
- Dissemination to policy makers: The mental health and well-being of young people is a high priority. The potential of the project to provide an evidence base to support the adoption of a low cost highly scalable intervention to prevent and intervene in NSSI is of great interest to policymakers and healthcare systems.

8. Project management

This is a coordinated project including the participation of four different subgroups. Daniel Vega (G1) will do the coordination. The G1 will coordinate the project and develop the subproject 1. Regular meetings between the research subgroups are invaluable for exchanging information on progress and emerging results. Meetings will occur every 3 months (via videoconference), and a general meeting with all partners will be organized annually. Additional meetings will be organized as needed. Exchanges, travels, and short stays of PhD students and post docs at the different centers will be encouraged to improve the circulation of knowledge and contribute to the effectiveness and quality control of all studies and procedures. Each IP of the current project will monitor the daily progress of each subproject and will provide detailed updates to the investigators of the corresponding subgroup, ensuring team members have the supplies and resources they need to complete their assigned tasks on time and within their budget limits.
The coordinator will act as the communication facilitator of the partners, who are located in different cities, in order to promote fruitful collaborative work. Additionally, the coordinator will act as the intermediary for all communications between the beneficiaries and the funder ("Fundació La Marató"). He will monitor and control the project's work plan and ensure that the different tasks are implemented properly. He will also arrange subgroup meetings and subsequent reporting, and he will manage and coordinate the project's financial checks. Furthermore, the coordinator will supervise the elaboration of scientific papers and dissemination acts.
The Group 1 (Daniel Vega, G1) is composed by a group of clinicians and researchers who will develop the subproject 1. The goal of this subproject will be to recruit participants and to evaluate them by means of self-reported measures and clinical instruments (for the clinical sample). In addition, the goal of this subproject will be to develop clinical contents for the App-based brief intervention specifically tailored to address NSSI.
The Group 2 (Marina López, G2) will develop the subproject 2. The G2 will add an fMRI-based neurobiological component to this project. The goal of this subproject will be to collect and analyze functional magnetic resonance imaging (fMRI) data from 60 young people with non-suicidal self-injury (NSSI) and 60 matched healthy controls, while performing a social rejection

and a physical pain task. This subproject will allow us to identify functionally significant brain pathophysiology associated with NSSI and predict treatment outcomes based on these neural measures assessed at baseline.
The Group 3 (Jordi Solé, G3) will develop the Subproject 3. The goal of this subproject will be to perform Machine Learning analysis of the current project. This subproject will allow us to combine the different types of data (e.g., self-report, momentary, fMRI) obtained throughout the study, and to optimize the potential of the app in the treatment of NSSI.
The Group 4 (Azucena García, G4) is composed by researchers and technicians with an extensive experience in the development of psychological interventions supported by Information and Communication Technologies (including Apps) and will develop the Subproject 4. The goal of this subproject will be to design, prepare and implement the NSSI-specific App-based intervention (Int1) and the non-specific App-based intervention, as well as to develop the study website and the online
assessment protocol.

9. Duration of the project

The duration of the project will be 3 years

Stage	**Task**	**Researchers involved (responsible in bold)**	**Year 1 (quarters)**				**Year 2 (quarters)**				**Year 3 (quarters)**			
1. Phase 1:	1.1.	G1 and G4; **Daniel Vega**	x											
	1.2.	G1; **Daniel Vega**		x	x									
	1.3.	G1; **Daniel Vega**			x	x	x	x						
2. Phase 2	2.1.	G1; **Daniel Vega**	x	x	x									
	2.2.	G4; **Azucena García**	x	x	x	x								
	2.3.	G4; **Azucena García**				x								
	2.4.	G4 and G1; **Azucena García & Daniel Vega**					x	x	x	x				
	2.5.	G2; **Marina López**	x											
	2.6.	G2; **Marina López**		x										
	2.7.	G2; **Marina López**			x	x	x	x						
3. Phase 3	4.1.	G1, G2, G3, G4; **Jordi Solé**								x	x	x		
4. Other	4.1.	G1, G2, G3, G4; **Daniel Vega**								x	x	x	x	
	4.2.	G1, G2, G3, G4; D**aniel Vega**									x	x	x	x

Work plan. G1: Group 1 (IP: Daniel Vega); G2: Group 2 (IP: Marina López); G3: Group 3

(IP: Jordi Solé); G4: Group 4 (IP: Azucena García).

Phase 1: Recruitment
- Task 1.1.: Creation of website of the study
- Task 1.2.: Contact with eligible participants
- Task 1.3.: Recruitment of clinical sample

Phase 2: Treatment and fMRI
- Task 2.1.: To develop the clinical content of the interventions (both specific and non-specific)
- Task 2.2.: To develop, design and plan the app-based intervention (both specific and non-specific)
- Task 2.3.: Pilot usability tests on the app-based intervention
- Task 2.4.: Implementation of the App-based intervention by participants and assessment
- Task 2.5.: Preparation of paradigms
- Task 2.6: fMRI Pilots
- Task 2.7: fMRI experiments

Phase 3:
- Task 3.1.: Statistical analysis of the predictors of treatment outcomes using machine learning

Other tasks:
- Task 4.1.: Preparation and writing of scientific articles
- Task 4.2.: Dissemination of the results in scientific meetings and social media

10. Informed Consents

Informed consents (see supplementary matrial)

11. Tables and Figures

	Groups of study		
	Clinical	Non-clinical	Control
Cohort	X	X	X
Hospitals	X		
Universities		X	X
Schools and high schools		X	X
Social media (e.g., Facebook)		X	X

Table 1. Recruitment sources. The recruitment of participants will be done considering different sources. On the one hand, the research group will have access to a previous cohort. All participants of this cohort will be invited to participate in the current study. On the other hand, new participants will be recruited to complete the sample of study. To complete the NSSI group (clinical and non-clinical), participants with NSSI will be recruited from the seven different hospitals that participate in this project by means of a recruitment sampling method.

	Groups of study		
Inclusion/exclusion criteria	**Clinical**	**Non-clinical**	**Control**
Age: 14 to 24 years old	X	X	X
To provide informed consent online	X	X	X
To have a mobile phone	X	X	X
Absence of NSSI (past and/or present)			X
Not receiving psychological or psychiatric treatment		X	X
To have engaged in NSSI on at least five days during the last 12 months	X	X	
Absence of important clinical instability	X		

Table 2. General exclusion/inclusion criteria

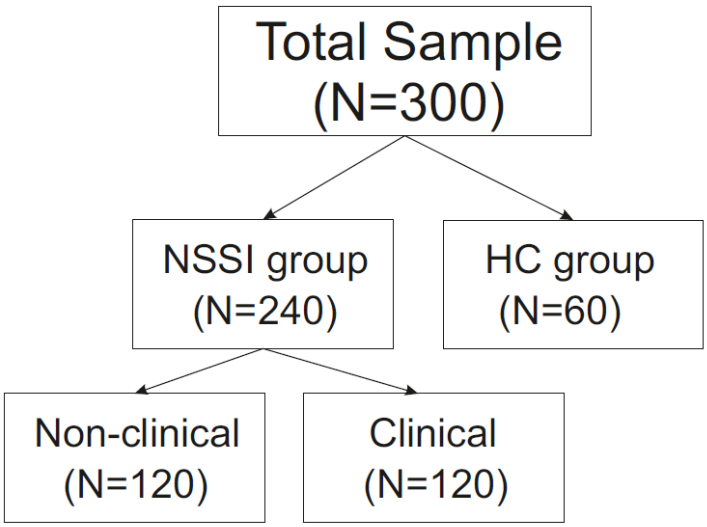

Figure 1. Sample and subgroups of study

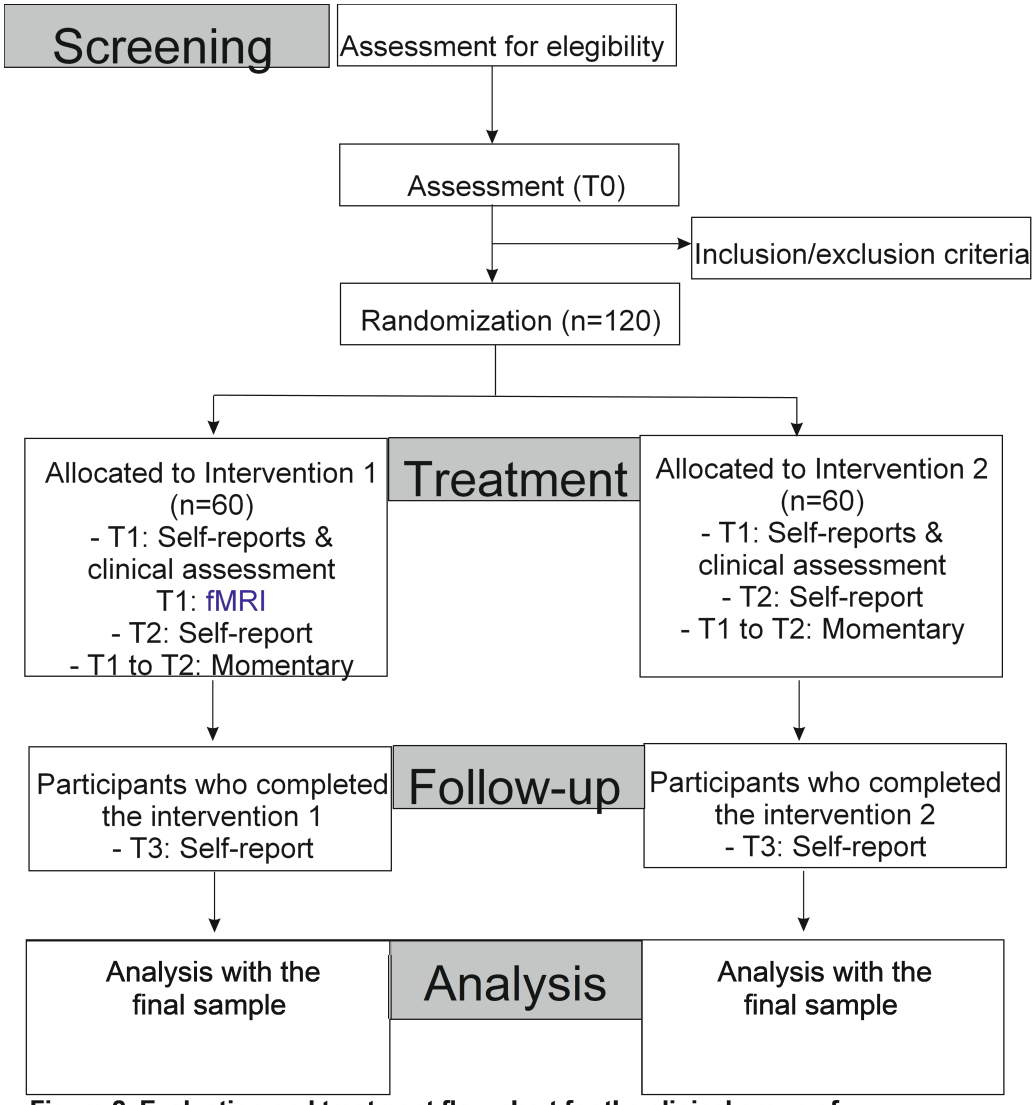

Figure 2. Evaluation and treatment flow chart for the clinical group of participants with NSSI. Participants will be randomly allocated to treatment a treatment harm (Int1 vs Int2). They will assessed in different times (T0, T1, T2, T3). In the T1, participants in the Int1 will also complete a single fMRI session.

12. Supplementary Material

a. Spanish Informed consent

CONSENTIMIENTO INFORMADO

Estudio multicéntrico: "Diseño y análisis de la eficacia de una intervención breve basada en una aplicación móvil para autolesiones no suicidas: medidas de auto-informe, momentáneas y biológicas como predictores de tratamiento"

Investigador Principal del proyecto multicéntrico

Dr. Daniel Vega Moreno, Consorci Sanitari de l'Anoia (CSA) & Fundació Sanitària d'Igualada (FSI)
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Investigador Responsable del proyecto en el Centro (XXXXXXX)

Dr./Dra. XXXXXXXXX
Servicio de XXXXXXX.
Hospital XXXXXX.
Teléfono: XXXXXXX

Lea esta información detenidamente:
Se le ha pedido que participe voluntariamente en un estudio que pretende medir la eficacia de una intervención terapéutica para la autolesión en un formato para teléfono móvil. Antes de que consienta participar en este estudio, por favor lea las líneas siguientes que abordan diferentes cuestiones directamente relacionadas con este estudio y su participación.

Propósito del estudio
El presente estudio pretende desarrollar un nuevo tratamiento basado en una App para móvil. Dicho tratamiento está dirigido a personas que están lidiando con la autolesión. Algunos estudios científicos sugieren que estas personas podrían estar sufriendo un importante malestar emocional, en especial durante la pandemia de la COVID-19.
Este tipo de tratamientos pueden resultar de ayuda para mejorar la sensación de apoyo, mejorar el manejo de las autolesiones y aumentar el bienestar. Además, pueden realizarse de manera sencilla, y autónoma.
Para poder evaluar la eficacia del tratamiento, puede que usted sea asignado a uno de los dos grupos de estudio. Uno de ellos es un tratamiento específico para la autolesión y el otro es un tratamiento que pretende mejorar la ansiedad y el malestar. Su asignación a uno de los dos grupos se hará de manera aleatoria.
La existencia de los dos tratamientos es importante para poder compararlos y valorar cual de los dos es más efectivo.
También nos interesa conocer cuáles son los predictores de la eficacia de dicho tratamiento.

PARTICIPACIÓN VOLUNTARIA

La participación en este estudio es completamente altruista y voluntaria. Podrá declinar su participación en todo momento enviando un mail al investigador principal del estudio.

Exactamente, ¿en qué consiste mi participación?

Si decide participar en el presente estudio, deberá realizar los siguientes pasos:
1. Antes de empezar deberá rellenar unos cuestionarios de manera virtual. Estos cuestionarios nos ayudarán a conocer su estado antes de iniciar el tratamiento.
En el caso de que sea seleccionado para las siguientes fases del estudio, recibirá un aviso del investigador principal del estudio. Entonces deberá completar las siguientes fases:
2. Se descargará la App del tratamiento y seguirá las instrucciones de éste. El tiempo máximo para realizar el tratamiento será de 3 meses. Durante el tratamiento podrá ver una serie de videos y podrá realizar algunos ejercicios.
3. Cada día, durante el tratamiento, la App le solicitará información sobre su estado emocional.
4. Al finalizar el tratamiento, deberá rellenar nuevamente una evaluación (igual que en el paso 1). Esta evaluación se repetirá 6 meses después de iniciar el tratamiento (aproximadamente 3 meses después de finalizarlo).
A parte de todo lo anterior, es posible que también se le solicite que realice una resonancia magnética funcional

Beneficios y riesgos

Se espera que su participación en el estudio comporte un beneficio terapéutico directo para usted. Su participación en el estudio también supone la contribución al conocimiento del tratamiento de las enfermedades mentales mediante nuevas tecnologías, lo que derivará en el desarrollo de mejores y más eficaces tratamientos en el futuro.

No existe ningún riesgo potencial derivado de la participación.

Coste/compensación

No existe ningún coste por participar en este estudio. Por su participación en el estudio:
- Podrá ganar 25 euros por completar la primera fase (se sorteará 25 premios de 25 euros entre todos los participantes). Este pago se hará mediante transferencia bancaria o mediante una tarjeta regalo de Amazon. Si resulta ganador recibirá un aviso del investigador principal del estudio.
- Si pasa a la siguiente fase del estudio (tratamiento) se le compensará con 45 euros al finalizar la última evaluación.
- En caso de realizar la resonancia magnética, se le compensará con 30 euros.

Procedimiento resonancia magnética
Durante el estudio se adquirirán imágenes de su cerebro mediante Resonancia Magnética Funcional (fMRI). Permanecerá estirado en una camilla y la parte superior de su cuerpo se situará dentro de un cilindro horizontal que se encuentra dentro del aparato de resonancia magnética nuclear o escáner. Pondremos debajo y alrededor de su cabeza una serie de almohadillas de espuma que nos permitirán inmovilizar su cabeza de una forma cómoda para usted. Los cascos/auriculares que llevará durante todo el registro le permitirán escuchar la tarea y las instrucciones que le podamos dar, y están especialmente diseñados para amortiguar las frecuencias sonoras que emite el escáner.
Durante los 10 primeros minutos aproximadamente, se adquirirán imágenes o 'scans' anatómicos, con el objetivo de poder reconstruir su cerebro a nivel estructural. Esta fase es necesaria para poder superponer posteriormente la activación de distintas partes del cerebro en una plantilla estructural exacta de su cerebro. Durante este período, usted permanecerá tendido en el escáner sin hacer nada.
Una vez terminemos con la fase anterior, se empezarán a adquirir imágenes o 'scans' de alta velocidad. Durante esta parte de la prueba, tendrá que realizar una tarea para la que le hemos entrenado previamente. Escuchará una música a través de los auriculares y tendrá que realizar una serie de tareas en función del entrenamiento que ha recibido por parte de los experimentadores. Una vez terminada la tarea, podrá relajarse mientras adquirimos

unas imágenes que nos permitirán ver cómo funciona su cerebro en reposo. En esta fase, deberá tener los ojos cerrados.
La sesión completa se neuroimagen durará aproximadamente entre 60 y 75 minutos.
No existen y no son previsibles riesgos o efectos secundarios que se originen debido a procedimientos de resonancia magnética nuclear con 3 Tesla. Se exceptúan aquellas personas que tengan algún tipo de implante eléctrico, magnético o mecánico (como marcapasos cardíacos), o bien en aquellos casos donde existan grapas (clips) en los vasos sanguíneos del cerebro. También deben abstenerse de realizar la prueba las mujeres que estén o puedan estar embarazadas. No existen otro tipo de riesgos conocidos asociados a la técnica de neuroimagen fMRI de alta velocidad.
Se le requerirá que permanezca estirado e inmóvil, pero podrá escuchar y hablar con los experimentadores y técnicos mediante un aparato interlocutor. Cuando se están adquiriendo las imágenes, el escáner produce ruidos o sonidos tipo 'beep' de alta intensidad (aproximadamente de 90 dB). En principio no debería suponer ningún problema para usted tanto permanecer estirado e inmóvil como el ruido del escáner. Sin embargo, hay personas que propensas a tener miedo en espacios pequeños (ascensores, etc…) o que padecen claustrofobia. Si ese es su caso, comuníquelo al investigador responsable. Si ya se ha iniciado la sesión y se siente incómodo, infórmelo también a los profesionales que le estén atendiendo. Si ve que no puede aliviar la incomodidad que siente, la sesión acabará inmediatamente y de manera prematura. Usted puede pedir que la sesión de escáner se termine en cualquier momento. Para ello, dispondrá de un botón de alarma que permanecerá al alcance de su mano izquierda. Si pulsa este botón, inmediatamente entrará un técnico para sacarle del escáner. La sesión habrá finalizado en ese momento.

Garantía de confidencialidad

La Fundació Sanitària d'Igualada, es la responsable del tratamiento de sus datos. El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los participantes se ajustará a la legislación vigente [Ley Orgánica 3/2018 de 5 de diciembre de Protección de Datos Personales y, por extensión, Reglamento (UE) 2016/679 General de Protección de Datos].

Todos los datos estarán asociados a un código numérico al que solo accederán los investigadores del proyecto, de manera que ningún dato de carácter personal será difundido o utilizado, y se preservará en todo momento el nombre o dato. En concreto, los datos procedentes la encuesta online, se almacenarán en una nube de forma encriptada, anonimizada y disgregada, tal y como exige la ley anterior. Su identidad no estará al alcance de ninguna otra persona a excepción de una urgencia médica o requerimiento legal. Podrán tener acceso a su información personal los investigadores del estudio.

Usted puede ejercer los derechos de acceso, modificación, oposición, supresión, limitación del tratamiento y portabilidad (solicitar una copia o que se trasladen a un tercero) de los datos que ha facilitado para el estudio. Para ejercitar estos derechos, o si desea saber más sobre confidencialidad, deberá dirigirse al investigador principal del estudio o al Delegado de protección de Datos de la FSI/CSA (XXXXX) si no quedara satisfecho/a, a la Autoritat Catalana de Protecció de dades (http://apdcat.gencat.cat/ca/contacte/apdcat@gencat.cat) o a la Agencia de Protección de Datos (http://www.agpd.es/portalwebAGPD/CanalDelCiudadano/index-ides-idphp.php)

El Investigador principal del estudio conservará los datos recogidos para el estudio al menos hasta 10 años tras su finalización. Posteriormente, la información personal sólo se conservará por el centro para el cuidado de su salud y por el investigador para otros fines de investigación científica si el paciente hubiera otorgado su consentimiento para ello, y si así lo permite la ley y requisitos éticos aplicables.

Los resultados obtenidos en el estudio podrán ser publicados en libros o revistas científicas, o pueden ser utilizados con finalidades didácticas. Sin embargo, su nombre u otros posibles identificadores no se utilizarán en ninguna publicación o materiales de enseñanza. En el caso de que se realice algún estudio colaborativo con terceros o investigadores de otros países, la garantía de confidencialidad será al menos equivalente a la que garantiza la normativa española.

Tratándose de un estudio multicéntrico, sus datos podrán ser accesibles por los investigadores principales de cada uno de los organismos participantes.

Con la finalidad de poder evaluar algunos aspectos a largo plazo, desde una perspectiva longitudinal, se le solicitará su consentimiento para volver a localizarle en aproximadamente 1 a 3 años. En caso de que acceda a ello, se le volverá a solicitar un nuevo consentimiento informado, y podrá declinar su participación una vez se le vuelva a contactar, sin ninguna consecuencia ni explicación adicional.

Al firmar esta hoja de consentimiento, se compromete a cumplir con los procedimientos del estudio que se le han expuesto.

HOJA DE CONSENTIMIENTO INFORMADO DE LOS PARTICIPANTES EN EL PROYECTO (mayores de edad)

*Título del estudio: "**Diseño y análisis de la eficacia de una intervención breve basada en una aplicación móvil para autolesiones no suicidas: medidas de auto-informe, momentáneas y biológicas como predictores de tratamiento.**"*

Código del proyecto: ANSAPP2022

Yo, mayor de 18 años, confirmo que,

- He leído la hoja la información sobre el estudio y tengo suficiente información

- Comprendo que mi participación es voluntaria.

- Comprendo que puedo retirarme del estudio si lo deseo.

- De conformidad con lo que establece el Reglamento UE 2016/679 del Parlamento Europeo y del Consejo de 26 de abril de 2016 relativo a la protección de las personas físicas en cuanto al tratamiento de datos personales y la libre circulación de datos, declaro haber sido informado de la existencia de un fichero o tratamiento de datos de carácter personal, de la finalidad de la recogida de éstos y de los destinatarios de la información.

__ Doy mi consentimiento para que participar en el estudio.

__ Doy mi consentimiento para que se me contacte en el futuro en caso de que se estime oportuno añadir nuevos datos a los recogidos en la actualidad, para lo que se solicitará un nuevo consentimiento informado

HOJA DE CONSENTIMIENTO INFORMADO DE LOS PARTICIPANTES EN EL PROYECTO (menores de edad)

*Título del estudio: "**Impacte de les mesures de distanciament social durant la pandèmia del COVID-19 en adolescents i adults joves amb conductes d'autolesió: anàlisis de cohort i desenvolupament d'una intervenció psicològica específica basada en una app.**"*

Código del proyecto: ANSAPP2022

Participante

Yo confirmo que,

- He leído la hoja la información sobre el estudio y tengo suficiente información

- Comprendo que mi participación es voluntaria.

- Comprendo que puedo retirarme del estudio si lo deseo.

- De conformidad con lo que establece el Reglamento UE 2016/679 del Parlamento Europeo y del Consejo de 26 de abril de 2016 relativo a la protección de las personas físicas en cuanto al tratamiento de datos personales y la libre circulación de datos, declaro haber sido informado de la existencia de un fichero o tratamiento de datos de carácter personal, de la finalidad de la recogida de éstos y de los destinatarios de la información.

__ *Doy mi consentimiento para que participar en el estudio.*

__ *Doy mi consentimiento para que se me contacte en el futuro en caso de que se estime oportuno añadir nuevos datos a los recogidos en la actualidad, para lo que se solicitará un nuevo consentimiento informado*

Progenitor/tutor legal

Yo Sr/Sra ……..…….. con DNI……..……, domiciliado en ……..……..…….. padre/madre/tutor de ……

- He leído la hoja la información sobre el estudio y tengo suficiente información

- Comprendo que la participación de mi hijo/hija es voluntaria.

- Comprendo que mi hijo/hija puede retirarme del estudio si lo deseo.

- De conformidad con lo que establece el Reglamento UE 2016/679 del Parlamento Europeo y del Consejo de 26 de abril de 2016 relativo a la protección de las personas físicas en cuanto al tratamiento de datos personales y la libre circulación de datos, declaro haber sido informado de la existencia de un fichero o tratamiento de datos de carácter personal, de la finalidad de la recogida de éstos y de los destinatarios de la información.

__ *Doy mi consentimiento para que mi hijo/hija participe en el estudio.*

__ Autorizo que mi hijo/hija contactado/a en un futuro en caso de que se estime oportuno añadir nuevos datos a los recogidos en la actualidad, para lo que se solicitará un nuevo consentimiento informado

b. English translated Informed consent

INFORMED CONSENT
Multicenter Study:
"Design and analysis of the effectiveness of a brief intervention based on a mobile application for non-suicidal self-injury: self-report, momentary, and biological measures as treatment predictors."

Principal Investigator of the multicenter project:
Dr. Daniel Vega Moreno, Consorci Sanitari de l'Anoia (CSA) & Fundació Sanitària d'Igualada (FSI)
Contact: dvega@csa.cat

Responsible Investigator at the Study Site (XXXXXXXX)
Dr. XXXXXXXX
Service of XXXXXXXX
Hospital XXXXXXX
Phone: XXXXXXX

Please read this information carefully:
You are being asked to voluntarily participate in a study that aims to evaluate the effectiveness of a therapeutic intervention for self-injury in a mobile phone format. Before you agree to participate, please read the following sections, which cover various issues directly related to this study and your participation.

Purpose of the Study

This study aims to develop a new treatment based on a mobile application. This treatment is designed for people who engage in self-injury. Scientific studies suggest that these individuals may experience significant emotional distress, especially during the COVID-19 pandemic.
This type of treatment may help increase feelings of support, improve self-injury management, and enhance well-being. In addition, it can be done easily and autonomously.
To evaluate the effectiveness of the treatment, you may be assigned to one of two study groups. One group will receive a treatment specifically focused on self-injury, while the other group will receive a treatment focused on reducing anxiety and distress. Your assignment to one of the two groups will be random.
The existence of two treatments is important to compare their effectiveness.
We are also interested in identifying predictors of treatment effectiveness.

VOLUNTARY PARTICIPATION

Participation in this study is entirely voluntary and altruistic. You may withdraw at any time by sending an email to the study's principal investigator.

What does my participation involve exactly?

If you decide to participate, you will be asked to complete the following steps:

1. Before starting, you will complete some online questionnaires. These will help us understand your condition before treatment begins.
   If you are selected for the next phases of the study, the principal investigator will notify you. You will then complete the following:

2. Download the treatment App and follow its instructions. The maximum duration for completing the treatment is 3 months. During the treatment, you will watch several videos and complete some exercises.
3. Each day during the treatment, the App will ask you to report on your emotional state.
4. At the end of the treatment, you will complete the same evaluation you completed at the beginning (Step 1). This evaluation will be repeated 6 months after starting treatment (approximately 3 months after finishing it).

In addition, you may be asked to undergo a functional magnetic resonance imaging (fMRI) scan.

Benefits and Risks

It is expected that participating in this study will provide you with direct therapeutic benefits. Your participation also contributes to advancing knowledge about the treatment of mental health conditions using new technologies, which could lead to better and more effective treatments in the future.
There are no anticipated risks associated with participation.

Costs/Compensation

There is no cost to participate in this study. As compensation for your participation:

- You may win €25 for completing the first phase (25 prizes of €25 will be raffled among all participants). Payment will be made by bank transfer or Amazon gift card. If you win, the principal investigator will notify you.
- If you proceed to the treatment phase, you will receive €45 after completing the final evaluation.
- If you undergo the fMRI scan, you will receive an additional €30.

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fMRI Procedure

During the study, images of your brain will be acquired using functional Magnetic Resonance Imaging (fMRI). You will lie on a table, and the upper part of your body will be placed inside a horizontal cylinder within the MRI scanner. Foam pads will be placed around your head to keep it comfortably still.
Headphones will allow you to hear the tasks and instructions, and these headphones are designed to reduce the noise from the scanner.

For approximately the first 10 minutes, anatomical images will be acquired to reconstruct your brain structurally. This step is necessary to overlay brain activity maps onto an exact structural template of your brain. During this phase, you will remain still, doing nothing.
Next, high-speed functional images will be acquired. During this phase, you will perform a task for which you will have been trained beforehand. You will hear music through the headphones and follow task instructions from the experimenters. After the task, you can relax while additional images are taken to observe your brain at rest. During this phase, you will keep your eyes closed.
The entire neuroimaging session will last about 60 to 75 minutes.

There are no expected risks associated with 3 Tesla fMRI procedures. Exceptions include people with electronic, magnetic, or mechanical implants (such as pacemakers), and those with surgical clips in brain blood vessels. Pregnant women or those who may be pregnant should not undergo this scan.
During scanning, you will need to remain still, but you will be able to communicate with the technicians through an intercom. The scanner produces loud "beep" sounds (about 90 dB). While this is generally tolerable, people with claustrophobia should inform the investigator beforehand.
If you feel uncomfortable during the scan, you can notify the staff at any time. If you cannot relieve the discomfort, the session will end immediately. You will have access to an alarm button at all times, which you can press if you want to stop the procedure. Pressing the button will immediately summon a technician to remove you from the scanner.

Confidentiality Guarantee

Fundació Sanitària d'Igualada is responsible for processing your data. Processing, sharing, and handling of personal data will comply with current legislation (Organic Law 3/2018 and EU Regulation 2016/679 - GDPR).
All data will be coded with a numeric identifier, accessible only to project researchers, ensuring no personal data will be disclosed or used. Online survey data will be encrypted, anonymized, and stored in secure cloud storage. Your identity will only be revealed in case of medical emergency or legal requirement. Study researchers will have access to your personal data.

You have the right to access, modify, oppose, delete, limit processing, and request data portability. To exercise these rights or learn more about confidentiality, you can contact the principal investigator or the Data Protection Officer (XXXXX). If you are not satisfied, you may contact the Catalan Data Protection Authority (http://apdcat.gencat.cat/en) or the Spanish Data Protection Agency (http://www.aepd.es).
The principal investigator will store study data for at least 10 years after study completion. After that, personal data will only be kept if you consent to further research and if allowed by law and ethical guidelines.
Study results may be published in scientific journals or used for educational purposes, but no identifying information will be used. If collaborative research with third parties or researchers from other countries occurs, the confidentiality guarantee will be equivalent to Spanish regulations.
As this is a multicenter study, your data may be accessed by investigators from all participating centers.

To evaluate long-term aspects, you will be asked for permission to contact you again in 1 to 3 years. If you agree, you will sign a new informed consent form at that time, and you will have the right to decline further participation without any consequences.

PARTICIPANT CONSENT FORM (ADULTS)
Study Title:
"Design and analysis of the effectiveness of a brief intervention based on a mobile application for non-suicidal self-injury: self-report, momentary, and biological measures as treatment predictors."
Project Code: ANSAPP2022

I, over 18 years old, confirm that:

- I have read the study information sheet and have sufficient information.
- I understand that my participation is voluntary.
- I understand I can withdraw at any time.
- I have been informed about data processing and my rights under EU Regulation 2016/679.
  __ I consent to participate in the study.
  __ I consent to be contacted in the future for further data collection, with a new consent form requested.