Zero Self-Harm app – a mobile phone application to reduce non-suicidal self-injury: Study protocol for a randomized controlled trial

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Abstract

Background: Non-suicidal self-injury (NSSI) is a growing healthcare problem. Individuals with NSSI have an increased risk of suicidality. Because of stigma, they may self-injure in secret, which means they often seek help when events have escalated to suicidal ideation or a mental disorder. Previous studies have shown that interventions delivered via mobile phone applications have the potential to reduce self-injury. This protocol outlines a trial, which examines whether the Zero Self Harm-intervention, which is based on an app created for people with NSSI, can reduce the number of NSSI-episodes, suicide ideation, and depressive symptoms.

Methods: The trial will be conducted as a 6-month 2-arm, parallel-group, multicentre, pragmatic, randomized clinical superiority trial. The intervention group will receive the app and instructions on how to use it, while the control group will be allocated to a waitlist and allowed to download the app after 6 months. Participants will be asked to complete questionnaires at 3- and 6 months after date of inclusion and the primary outcome is the number of NSSI-episodes during the last month, as measured at the 3 months follow-up with the Deliberate Self-Harm Inventory. A total of 280 participants, 140 in each arm, will be included.

Discussion: This trial will assess the effectiveness of the Zero Self Harm-intervention to reduce the number of NSSI episodes. If effective, the app will have the potential to support to large group of people with NSSI. NSSI is stigmatised and often done in secret. Being both discreet and anonymous, the app might be an appealing option for support. In addition, people with current or former NSSI were involved in the development of the app. The app was developed with a focus on minimizing harm, not to end NSSI, which might also make the app appealing for a broader group of users.

Trial registration: ClinicalTrials.gov, NCT04463654. Registered on 7 June 2020

Background

The International Society for the Study of Self-Injury defines non-suicidal self-injury (NSSI) as “the deliberate, self-inflicted damage of body tissue without suicidal intent and for purposes not socially or culturally sanctioned” (1). Though challenging to estimate, overall prevalence of 17%, 13.4%, and 5.5% among adolescents, young adults, and adults, respectively, were suggested based on meta analyses (2,3). Based all hospital contacts for deliberate self-harm from 1994 to 2011, a Danish study noted an increase in the rate among young women (4); and a similar trend is possible for NSSI, although generally is characterised by wider definition.

NSSI is characterized by an early onset. In a US sample, about 27% reported to have begun self-injurious behaviour around the age of 15-16 years, while 38.6% commenced at the age of 17-24 years (5).

Individuals with NSSI have higher risks of dying, in particular by suicide, when compared to the general population (6–8). NSSI is, furthermore, associated with a range of mental health problems, such as...
anxiety, depression, eating disorders, and drug and alcohol abuse (9–12). The most common method of NSSI is cutting, while other behaviours include scratching, head banging, breaking bones and burning oneself (13). The majority use more than one method, and method versatility as well as an increased number episodes are considered markers of severe NSSI (14). NSSI can be an addictive and lead to repetitive behaviour; approximately half of adolescents with NSSI have done it more than once (15,16). Also, NSSI is often hidden due to stigma and shame (12,17,18).

It has been suggested that highly impulsive individuals are prone to act rashly when negative emotions arise and that this provides immediate relief from distress (19). As such, NSSI may be used as a coping strategy for regulating negative emotions, perhaps particularly among impulsive individuals (19). This is further supported by the fact that individuals with NSSI report greater difficulties with emotion regulation (20,21) and have high levels of emotion dysregulation (22).

It is estimated that only 1 in 8 persons present at hospital or seek help in the public health sector after NSSI (15,16). Often, people with NSSI are not considered as being in need of specialized treatment and, consequently, the behaviour has the potential to escalate to a point where the person becomes suicidal or has developed a serious mental illness (6,7).

Low-cost, easily delivered and scalable self-help mobile phone applications (apps) for people with NSSI have shown promising findings regarding reductions of NSSI-episodes (23). Findings from RCTs have demonstrated moderate reductions for self-cutting episodes and fewer self-reported self-injurious episodes (23). One app reported significant reductions in symptoms of depression and anxiety (23). Another app, Virtual Hope Box, has been linked to improvements in coping with unpleasant emotions and thoughts (23). Still, controlled trials across different settings are warranted to determine the true effectiveness of apps in reducing NSSI (24).

Beneficial effects of apps for individuals with NSSI have also been noted in qualitative studies (23–25). These include the possibility of at-home, in-the-moment, private and anonymous help, which enhanced the acceptability of the app (23,24,26). Secondly, features for tracking daily mood, hence allowing for improved emotional self-awareness, have been emphasized (25). Consequently, self-help apps may support individuals with NSSI and can be delivered broadly, i.e. across the range of severity of NSSI (27,28).

This trial will investigate the effectiveness of the Zero Self Harm-intervention for people with NSSI. The intervention contains active onboarding to the Zero Self-Harm (ZSH) app which includes one phone call after the participants have had access to the app for one week. The goal of the Zero Self-Harm intervention is to motivate people with NSSI to reduce their self-injurious behaviour rather than to end it, which for many could feel unrealistic and thereby demotivate them from using the app. The ZSH app is developed from the MyPlan app, which was developed in 2012 and whose effect is currently being investigated regarding reducing suicide ideation (29,30). MyPlan has been previously tested by users and clinical staff with promising qualitative feedback (31,32).
The purpose of this trial is to investigate whether adults with NSSI who receive the ZSH app have fewer NSSI-episodes at 3 months follow-up when compared to adults with NSSI who do not receive the ZSH app in a randomized clinical superiority trial. We hypothesise that the ZSH app might help reduce the participants’ number of NSSI-episodes by enhancing coping skills to better manage impulsive urges. Ideally, working with the app might address emotional dysregulation and trait impulsivity, which are core features of NSSI, and thereby lower associated symptoms, e.g. suicide ideation and depression.

Methods And Design

The trial will be conducted as a 2-arm, parallel-group, multicentre, pragmatic, randomized clinical superiority trial. A total of 280 participants, 140 in each arm, will be included from clinical and non-clinical settings in Denmark and followed for 18 months (see figure 1). One group will receive the Zero Self-Harm intervention and the control group will be allocated to a waitlist condition. Recruitment of participants was initiated in October 2020.

Recruitment and criteria for inclusion and exclusion

Recruitment will target individuals with shorter duration and milder symptoms of NSSI who might not be in contact with mental healthcare facilities as well as individuals with more severe and chronic NSSI who are already attending treatment at Danish mental health facilities. Non-profit organizations, such as Danish Mental Health Fund (Psykiatrifonden), Girkalk and Cyberhouse, municipal service centres, educational institutions for individuals aged ≥18 years, psychiatric in- and outpatient clinics, and psychiatric and general emergency departments will be contacted with regard to recruitment. The trial will, furthermore, be announced through non-profit organizations’ websites and social media platforms as well as presented at educational institutions for individuals aged ≥18 years. The research assistant responsible for recruitment, will routinely visit relevant locations, such as in-patient clinics in the Capital Region of Denmark, and give reminders to participating venues through e-mails and phone calls.

Criteria for inclusion and exclusion

In order to be included, participants have to: (1) have had two or more physical NSSI-episodes in the past month, (2) own a mobile phone (iPhone or Android), (3) be fluent in Danish, (4) be able to install and use the ZSH app, (5) provide informed written consent, and (6) be ≥18 years. Participants who: (1) receive specialized treatment for NSSI, e.g. at newly established outpatient clinics in the Capital Region of Denmark (Dialectical Behavioral Therapy (DBT)), (2) are currently being involuntarily treated will be excluded from enrolling.

Enrolment and randomization
The research assistant will continuously contact recruitment venues by either calling them or visit them in person and present the project to potential participants. Furthermore, personnel at the recruitment venues are encouraged to inform about the project and encourage interested individuals to contact the research assistant through phone or e-mail. Potential participants will be given oral and written information about the study and be screened using the Mini International Neuropsychiatric Interview (MINI) (33). If needed, the participant will be encouraged to take time for consideration or conversation with a next of kin before deciding whether to enrol in the project. Informed consent will be obtained by sending an email from REDCap (34) to the trusted Danish secure platform E-boks. To ensure confidentiality, participants will be encouraged not to send any personal information through email and only provide this over the phone.

Enrolled participants will be administered a baseline questionnaire. Hereafter, participants will be randomly assigned to either the intervention or the waitlist control group (1:1 allocation), using a computer-generated sequence randomization generator in REDCap. The randomization will be stratified by sex and baseline score of number of NSSI-episodes, as measured by the Deliberate Self Harm Inventory, to avoid overrepresentation of participants with a high number of NSSI-episodes in one group. This stratification will be also facilitated through REDCap. The research assistant will contact the participants to inform them about their allocated group.

**Intervention**

Participants allocated to the intervention group will receive the ZSH app. The app was adapted to the target group based on three focus-group interviews with people with current or former NSSI. Based on their suggestions, the app contains following components: 1) warning signs – a component to identify warning signs for self-injurious thoughts; 2) strategies – a tool for identifying coping strategies when self-injurious thoughts arise, including a list of suggestions formed by others users; 3) mood rating – a daily mood tracking option, including pop-up reminders; 4) dreams – a place to write down dreams and how to reach them; 5) happy place – a place for collecting pictures, music, YouTube videos, which can cheer one up, and write positive message for oneself to practise a positive self-image; 6) reflections – a place to reflect on previous NSSI-episodes and read stories from other users, 7) direct phone links to emergency services and nearest map directions for emergency departments.

Participants will receive an email instructing them how to download the ZSH-app from Google Play or Apple Store where the app is listed under an undisclosed name to avoid that people not included in the project will find the app and thereby contaminate the data. Once an account has been set up, a pop-up message will invite the participant to watch instruction videos explaining them how to use the app. The intervention also includes active onboarding measures, in the form of a phone call one week after inclusion by the research assistant. Here, the participant will be asked where he/she has started using the app and about his/her experiences. The research assistant will give a guide to the app and encourage the participant to use it.
Participants allocated to the waitlist control group will be invited to download the ZSH app once answers to the last questionnaire have been submitted after 6 months.

**Outcomes**

The primary outcome, i.e. number of NSSI-episodes during the last month, will be measured at the 3-month follow-up (see Table 1) using the 17-item Deliberate Self Harm Inventory. This is a self-reported inventory, which includes questions on number of NSSI-episodes for the 17 most frequently used methods (e.g. cutting, burning, scratching etc.) (35). As the inventory uses a recall of 4 months (35), a modified version adapted to 1 month of recall will be used, e.g. “In the last month (since __ / __ / __ ), have you intentionally (e.g. on purpose) cut your wrist, arm or other part of your body (without the intention to take your own life)”. This is done to limit any recall bias regarding the number of NSSI-episodes. The inventory will also be used to assess the past month versatility of NSSI, i.e. number of different types of NSSI methods used, which has previously shown to be a marker of NSSI severity (36). The DSHI questionnaire will be collected at baseline and 3- and 6-months follow-up.

Table 1

SPIRIT Overview over time points and assessments
<table>
<thead>
<tr>
<th>Timepoint (T) (month)</th>
<th>Enrolment and allocation</th>
<th>Study period</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>$T_0$</td>
<td>$T_1$</td>
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<tr>
<td></td>
<td><em>(baseline)</em></td>
<td>3</td>
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</tbody>
</table>

**ENROLMENT**

- Eligibility screening
- Informed consent
- Allocation

**ASSESSMENTS**

**Primary outcome:**

- Deliberate Self-Harm Inventory

**Explorative outcomes:**

- Becks Suicide Ideation Scale (BSS)
- Major Depression Inventory (MDI)
- WHO Wellbeing Index (WHO-5)
- Difficulties in emotion regulation scale (DERS)
- Rosenbergs Self-Esteem Scale (RSE)
- Client Satisfaction Questionnaire (CSQ) modified
- Frequency of app use
- Registered deliberate self-injury (somatic and psychiatric hospital registers)
- Hospital utilization

Explorative outcomes include suicide ideation, depressive symptoms, quality of life, and self-esteem. Suicide ideation will be measured by the Becks Suicide Ideation Scale (BSS), a 21-item self-report questionnaire measuring suicidal ideation (37). Depressive symptoms will be measured using the Major Depression Inventory (MDI), a short questionnaire consisting of 12 items capturing depressive symptoms (38). It can be scored as a diagnostic tool, but also according to severity by a simple sum of the item scores (38). Quality of life will be measured by the WHO Wellbeing Index (WHO-5), a widely used short questionnaire to measure subjective psychological wellbeing, consisting of 5 simple and non-invasive questions (39)(40). Self-esteem will be measured by Rosenberg’s Self-Esteem Scale (RSE), which consists
of 10 items measured on a Likert scale (41). All explorative outcomes will be administered at baseline and 3- and 6-month follow-up.

User satisfaction will be measured by a modified Client Satisfaction Questionnaire (CSQ-8) at 3-month follow-up among participants allocated to the intervention group.

Register-based outcomes, mortality, registered deliberate self-injury, usage of somatic and mental healthcare and hospital services will be obtained at 3 and 6 months. Using participant's personal id-number, data extracts from the National Hospital Register, Psychiatric Central Research Register, and the Cause of Death Register will be retrieved. Deliberate self-injury will be considered when a participant has been recorded with the main or sub-diagnosis, ICD-10: X60–X84, or where the reason for contact was listed as being deliberate self-harm.

**To investigate the safety concerning the app**

To assess potential harmful effects, the 20 first participants who receive the ZSH app will be contacted by phone after completing the 3-month questionnaire for an interview regarding their experiences. If potential harmful effects are identified, these will be discussed in the research group in order to decide on measures.

**Data collection**

Outcome measures will be collected at baseline, 3- and 6-month follow-up through self-administered, internet-based questionnaires. Participants will receive an email with a link to the online survey, where they can log on to REDCap. To enhance the response rate, participants who have not answered the questionnaire within one week will receive an email reminder and a phone call or text message at one-week intervals by the research assistant encouraging them to answer the questionnaire. Once the data collection is completed, all data from the participants will be exported from REDCap to a local secure drive where access is restricted to the researchers in the research group.

**Sample size**

Participants in the intervention group will be expected to have 3.5 fewer NSSI-episodes the last month at 6-month follow-up when compared to participants in the waitlist control group at follow-up after 6 months. The mean score is based on estimates from previous studies investigating the intervention's ability to reduce NSSI-episodes (28,42,43). A post-intervention standard deviation of 9 is assumed based on previous findings (42,43). If the true difference between the intervention and control groups is 3.5, a total of 140 participants should be included in each group in order to reject the null hypothesis with a power of 90% and a type I error probability of 0.05, implying a total of 280 participants.

**Statistical analysis**
The analysis will be conducted according to the intention-to-treat principle. All participants will be included in the analysis according to group assignment, regardless of adherence. For the primary analysis of the primary outcome, being the number of NSSI-episodes during the last month, as measured at the 3-month follow-up we will assess the intervention effect using linear regression with group allocation as the independent variable. In case more than 5% of the participants are missing at 3 months we will use multiple imputation to account for missing data. Imputation will be based on baseline NSSI, gender, age and baseline variables associated with missingness. Secondary analysis will include baseline NSSI, age, gender and baseline characteristics which differ between groups at baseline. Confidence intervals will be presented as well as significance level. All tests will be two-tailed and p values below 0.5 will be considered significant and interpreted with respect to the hierarchy of hypothesis recognizing that all outcomes, apart from the primary, are exploratory.

The analysis will be conducted using SPSS, version 22.0.

Blinding

Due to the nature of the intervention, neither participants nor the research assistant can be blinded to the intervention. Also, the collection of the primary and explorative outcomes will not be blinded. At study completion, a researcher not involved in the research project will extract data from REDCap into two separate files where group allocation will be coded as A and B to ensure blinding of the research assistant while analysing data, drawing conclusions and drafting of the first manuscript. The blinding will be unmasked when the researchers in the project have agreed on the conclusion based on blinded analyses of data.

Discussion

Emerging research suggest that specialized apps targeting self-injurious behaviour, which can be used anonymously and in private, have the potential to help people with NSSI (23,24). However, more randomized controlled trials are warranted to investigate the effectiveness of these apps (23,24). This paper describes the study protocol of a randomized controlled trial comparing a self-help app intervention’s ability to reduce NSSI-episodes with a wait-list control group.

The Zero Self-Harm intervention has several strengths. Firstly, by involving stakeholders and people with lived experiences in the development of the app is likely to make its content relevant for the target group. Secondly, by having a focus on minimizing harm, the app might be more appealing to a broader group of users. Thirdly, by listing the app under an undisclosed name, contamination of the trial’s data will be limited.

Potential limitations should be noted. Firstly, although the app was developed in collaboration with individuals with NSSI, it might not address all needs; individuals with NSSI are characterized by broad age-spans, diagnoses, severity and versatility of NSSI, and co-morbidities. Moreover, a contribution and
insights from next of kin and professionals who have experience with individuals with NSSI could also have been ideal in getting a broader perspective.

Furthermore, it is possible that the app might sustain or possibly worsen NSSI. To assess this, the first 20 participants will be asked after three months about whether they have had any negative experiences or side effects of the app. Other potential limitations regarding the app could be the part of learning how to use an app, which for some participants can be difficult and maybe even overwhelming. It might result in that some of the participants will use the app only few times or not at all. Even though a good onboarding is carried out, a more continuous and structured support might improve the usage of the app. Another way of combining a more structured support with technology could also have been by using for instance automatically collected smartphone sensor data, which is not included in this trial. In general, having a self-help app as an intervention can be challenging since technological development is an ongoing process. Some of the app features designed to be user-friendly, can potentially get outdated during the trial. Once the trial is started, the app cannot undergo larger changes, which could limit the possibility of continuously ensuring the relevance of the app and its design.

The broad recruitment strategy might imply that participants using a range of mental health services will be included, which potentially could affect the treatment outcome. By collecting information on received treatment, we can adjust for this in the analysis. However, there might be a difference in how the general experience of the app is, depending on the knowledge level of NSSI and the degree and duration of the NSSI. The broad variation of participants, which includes both individuals with milder symptoms of NSSI and more severe and chronic NSSI, can make it difficult to distinguish a potential difference in maybe the usage of the app, how relevant the app is perceived and the outcome of the app. Also, specialized treatment for NSSI is an exclusion criterion which can furthermore make the recruitment more difficult.

The questionnaires in the trial covers different topics such as NSSI, suicidal ideation, depressive symptoms and self-esteem which for some of the participants can be hard to reflect on. Avoidance of these topics might occur and make it more difficult to get the questionnaires answered, especially since it is self-administered questionnaires. The questionnaire is sent out three times with a 3-month interval and that can also be an obstacle since it requires time and effort which can lead to participant dropout.

Lastly, neither participants nor the research assistant will be blinded to the assignment of treatment condition due to the nature of the intervention. However, the research assistant will remain blinded during the analysis and drafting of the manuscript.

A worsening of condition of a participant may occur during the trial. To ensure the participants know where to seek help, the research assistant will inform all participants in the enrolment interview about other relevant support options such as Livslinien and the emergency services, such as 1318, 112. As part of the onboarding process, the intervention group will get an introduction by phone on how the app can be used as a safety plan and important phone numbers to emergency services are pre-installed in the app etc. Lastly, the research assistant will be available to answer questions regarding the app or the survey forms and give technical support throughout the trial.
Declarations

**Ethics approval and consent to participate:** The trial is approved by the Regional Ethics Committee in the Capital Region of Denmark as H-19024725 and the Danish Data Protection Agency as P-2019-84. The trial is registered under Clinicaltrials.gov as NCT04463654. Following the Consort guidelines, we will publish positive, neutral and negative findings.

Potential participants will be informed about the project both verbally and with written information and the opportunity for consideration or a chat with a next of kin before deciding whether to enrol in the project. Participants will be informed about confidentiality and anonymity in the study and encouraged not to email any personal information but only provide this over the phone. Furthermore, to ensure confidentiality and anonymity, informed consent will be obtained through REDCap to the trusted Danish secure platform E-boks. It will be stressed that participation is voluntary, and participation and written consent can be withdrawn at any time. The withdrawal will not have any consequences for future treatment possibilities.

**Competing interests:** None of the authors have competing interests.

**Availability of data and material:** Following the Consort guidelines, we will publish positive, neutral and negative findings.

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**Authors contributions:** All the above mentioned authors (KA, LL, NB, JL, JK, RT, EG, LL, KL, AE, MN) have been involved and contributed in the conception and design of the study protocol, drafting, and revising the manuscript. All authors will participate in the final interpretation of result.

**Acknowledgements:** none

**References**


Figures

![Diagram](image.png)

280 participants with non-suicidal self-injury (NSSI)

140 participants allocated to the Zero Self-Harm intervention

140 allocated to waitlist control group

Figure 1
Flow diagram of the Zero Self-Harm intervention