

EFFICACY AND USABILITY OF AN AI-ENHANCED MOBILE APP FOR NON-SUICIDAL SELF-INJURY (NSSI): DEVELOPMENT OF THE BE N.I.C.E PROTOCOLS

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Abstract: People who engage in non-suicidal self-injury (NSSI) face a heightened risk of future suicide attempts, highlighting the critical need for early and accessible intervention strategies. This study evaluates the effectiveness and usability of the smartphone application BE N.i.C.E (BElajar dan Latih Sehingga Cekap Emosi), which is tailored for individuals engaged in non-suicidal self-injury (NSSI). The app is intended not only for those who self-harm but also as an educational resource for healthcare practitioners, medical students, and allied health professionals to learn about and practice effective management strategies for NSSI. In this Phase I open trial, we assess the AI-enhanced BE N.i.C.E. app, aimed at early intervention for individuals displaying NSSI behaviours. This research utilises a single-arm pre- and post-test intervention design. The app features a mood-monitoring diary, cognitive-behavioural therapy-based mood-enhancing techniques, and direct access to emergency contacts. Fifteen individuals with a history of self-harm will be recruited from the psychiatry clinics of Hospital Sultanah Nur Zahirah (HSNZ) and Hospital Sultan Zainal Abidin (HOSZA). Data collection will occur through questionnaires and interviews at baseline and after a four-week follow-up to evaluate the app's effectiveness and usability. Additionally, clinicians will be interviewed to determine the app's feasibility in clinical settings. Recruitment is scheduled from December 1, 2024, to June 31, 2025. This study represents the first attempt to evaluate an AI-enhanced mobile app specifically designed for individuals who self-harm. The findings will guide whether

a feasibility trial is needed to test recruitment, randomisation, retention, and outcome measures.

Keywords: *Artificial intelligence, Mobile App, Non-suicidal self-injury, self-injury, suicide*

Introduction

The National Health Morbidity Survey 2022 reports an increase in suicidal ideation and attempts, with rates reaching 13.1% and 9.5%, respectively, among Malaysian adolescents aged 13-17 (Lew, Kølves, Lester, Ibrahim, & Siau, 2022). Self-harm (SH), defined as intentional self-poisoning or self-injury regardless of suicidal intent or other motivations, is a growing concern worldwide, frequently recurring and associated with suicide (Witt et al., 2021). It is a preventable cause of premature death, with suicide ranking as the fourth leading cause of death among adolescents (Tofique, Chaudhry, Kiran, Gire, & Husain, 2024). In the United States, unintentional injuries are the leading cause of death for people under 45 (Chen, Li, & Deng, 2022).

Non-suicidal self-injury (NSSI) refers to deliberate self-inflicted damage to body tissue without suicidal intent or socially acceptable purposes (Kamazaki & Dias, 2021). This behaviour, including cutting, bruising, scratching, and marking the skin, is distinct from suicidal behaviour as it is not aimed at ending one's life. NSSI must be differentiated from indirect self-destructive behaviours (Calvo et al., 2022).

Self-injurious thoughts and behaviours pose major public health challenges, affecting a wide demographic (Fox et al., 2020). Research indicates that NSSI is often linked to mental health and emotional issues (Chen et al., 2022). NSSI and suicide attempts are risky behaviours that can result in serious physical harm and death. When these behaviours co-occur, they significantly elevate the risk profile of individuals, who often display more severe psychological and behavioural challenges (Ye, Xiong, & Li, 2022).

Globally, suicide and self-harm are significant health and societal issues, particularly in low- and middle-income countries (Knipe, Padmanathan, Newton-Howes, Chan, & Kapur, 2022). These behaviours are especially prevalent among adolescents and young adults, creating considerable concerns for caregivers and institutions (Kamazaki & Dias, 2021). Although men generally have higher suicide rates, self-harm is more common among women (Knipe et al., 2022).

These behaviours result from a complex interaction of factors throughout the lifespan, influenced by gender, age, ethnicity, and geographic location (Knipe et al., 2022). Consistent with various theories, NSSI appears to function as a coping mechanism for managing difficult interpersonal experiences or fulfilling unmet needs. It may serve as an alternative to other, less harmful coping strategies (Peel-Wainwright et al., 2021). However, the varied demographics of study populations contribute to a lack of comprehensive understanding regarding the incidence and patterns of NSSI and suicide attempts, complicating clinical interventions and future research efforts (Ye et al., 2022).

Recent years have seen an increase in trials and therapeutic approaches for psychosocial interventions aimed at reducing self-harm in adults (Witt et al., 2021). Despite its prevalence and impact, treatments specifically designed for NSSI are limited, and little is known about factors influencing treatment responses (Andover, Schatten, Holman, & Miller, 2020). Although some clinical and public health interventions show promise, most evidence of their effectiveness comes from high-income countries. Predicting suicide remains challenging, necessitating both clinical and community-focused interventions, where every health professional has a critical role in prevention and treatment (Knipe et al., 2022).

Routine monitoring of students' emotional distress and timely intervention by counsellors can effectively prevent self-harm among college students (Chen et al., 2022). Relational therapies may be effective, especially when interpersonal processes play a role in NSSI (Peel-Wainwright et al., 2021). A systematic review found that Dialectical Behaviour Therapy (DBT) and Cognitive-Behavioural Therapy (CBT) are commonly utilised frameworks. Among the interventions, skills training based on these modules is frequently employed (Kamazaki & Dias, 2021). CBT may reduce the incidence of repeated self-harm over longer follow-up periods, though no immediate effects post-intervention have been observed, with evidence quality rated as low. Single trials or those from the same research group suggest that mentalization-based therapy (MBT) and group-based emotion regulation therapy warrant further exploration. DBT may also reduce the frequency of self-harm. Other interventions have been studied in single trials with moderate to very low-quality evidence, making their effectiveness currently inconclusive (Witt et al., 2021).

To scale effective suicide prevention in low-resource settings, strategies such as digitalising culturally adapted manual-assisted psychological interventions or using task-shifting approaches are needed (Tofique et al., 2024). Internet and mobile phone-based psychological interventions offer promising solutions to the barriers of traditional face-to-face therapy, potentially benefiting the widespread issue of self-injurious thoughts and behaviours globally (Arshad, Gauntlett, Husain, Chaudhry, & Taylor, 2020).

Although significant efforts have been made to develop and enhance treatments, their overall effectiveness is still uncertain, with only small effects observed, largely maintained at follow-up (Fox et al., 2020). Targeted interventions to address this behaviour are currently being developed and increasingly studied in empirical research. Nevertheless, several of these approaches have yet to be tested in controlled trials, leaving their clinical effectiveness unclear (Calvo et al., 2022). Despite the growing burden of NSSI in Malaysia, digital interventions remain scarce and poorly tailored to local cultural, religious, and linguistic contexts. This gap significantly limits the effectiveness and acceptability of such tools in low-resource settings.

Therefore, there is a need for early intervention first aid modules for healthcare providers to assist individuals with NSSI. The study aims to evaluate the effectiveness of an AI-driven mobile app for early intervention in NSSI by comparing pre- and post-intervention outcomes. Additionally, a Phase I trial will be conducted to assess the efficacy and usability of the BE N.i.C.E app for those who self-harm.

Methodology

This Phase I open trial invites eligible individuals with NSSI, identified by their mental health clinicians, to use BE N.i.C.E. The study will be conducted at Hospital Sultanah Nur Zahirah (HSNZ) and Hospital Sultan Zainal Abidin (HOSZA). A convenience sampling strategy was employed to recruit participants for this study.

Participants aged 18 and above with a history of repeated self-harm and who are receiving ongoing face-to-face psychiatric care are eligible for recruitment.

Inclusion and Exclusion Criteria

Table 1: Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Two or more physical NSSI episodes in the past month.	Currently in specialized NSSI treatment (e.g., Dialectical Behavioral Therapy).
Ownership of a smartphone (iPhone or Android).	Under involuntary treatment.
Ability to install and use the app.	Active suicidal ideation (direct clinician assessment).
Provision of informed written consent.	Diagnosed with psychosis.
Age ≥ 18 years.	Significant learning disabilities.
Willing to provide self-report data at all assessment points	Recent abuse victims.
Internet access	
Able to read Malay and write in both Malay and English	

Recruitment and Study Procedures

The study will use convenience sampling to recruit participants from various psychiatry settings. Prospective participants will first receive detailed information about the project. This will be followed by meetings where the BE N.i.C.E app will be demonstrated. Clinicians will discuss the app with eligible participants and refer those interested to the research team, which will obtain written consent. Individuals interested in participating will contact the research assistant for additional information and enrollment. Instructions and support on how to use the app will be provided. Participants will engage with the app over a four-week period, during which they will be encouraged to either read AI-suggested materials or watch intervention videos weekly. They will also be expected to practice the skills shared by the AI and provide

feedback on the materials and exercises at the end of each week. All study sessions will take place at Hospital Sultanah Nur Zahirah (HSNZ) and Hospital Sultan Zainal Abidin (HOSZA).

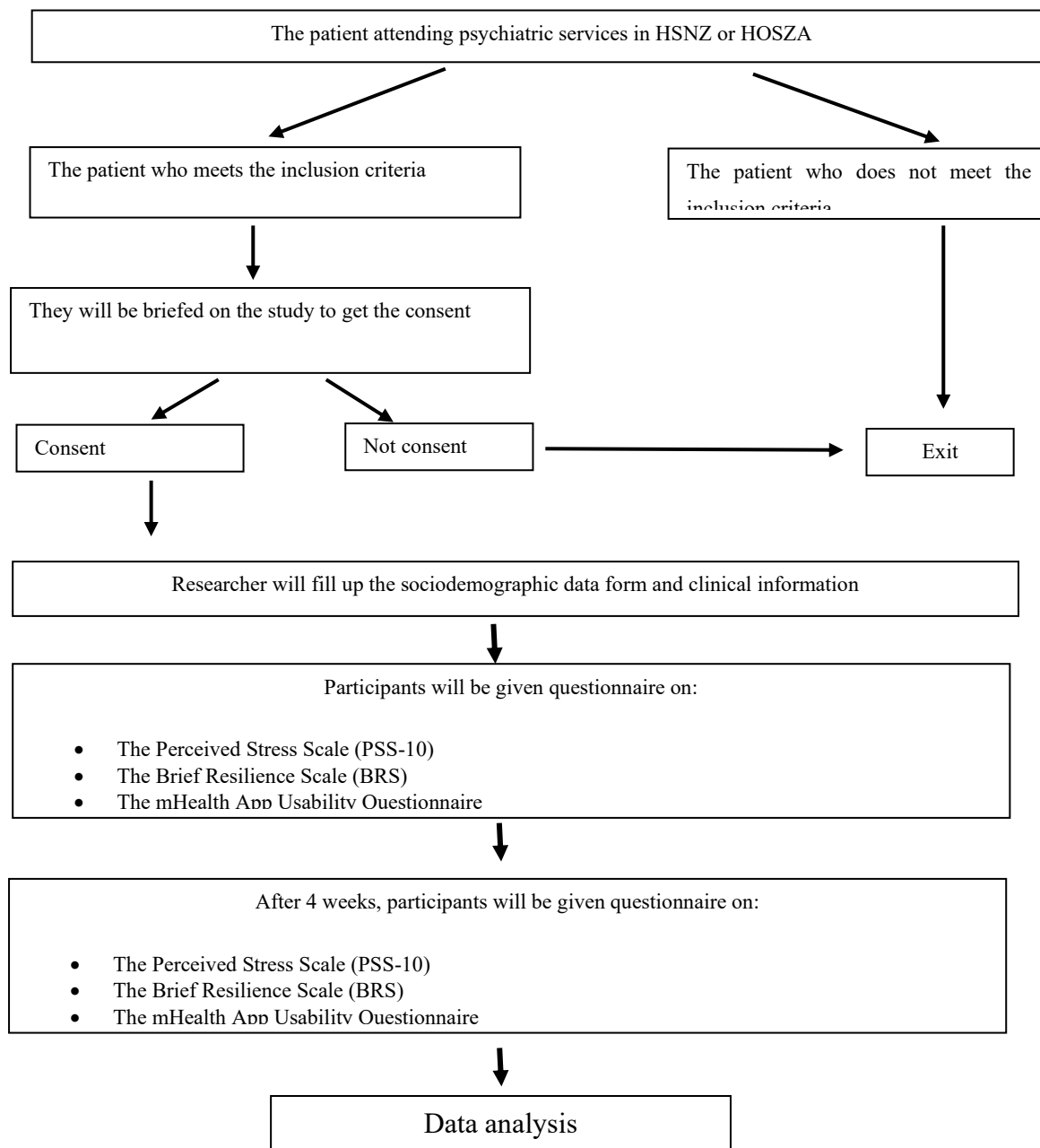


Figure 1: Recruitment

Ethics and Data Collection

Prior to starting the study, ethical approval was obtained from the MOH Medical Research Ethical Committee (MREC) and UniSZA Human Research Ethics Committee (UHREC). Data collection will primarily involve interviews with participants at HSNZ and HOSZA, Kuala Terengganu. Participants will receive a comprehensive explanation of the study's goals and procedures and will be asked to provide written consent via a Google Form if they decide to participate. After obtaining consent, participants will complete a series of surveys online, using a Google Form designed to minimize bias. Researchers will be available to assist participants

in filling out the form if needed. The study adheres to the principles of the Declaration of Helsinki and the Malaysian Good Clinical Practice (GCP) Guidelines. The protection of personal information is a priority to maintain confidentiality. The risk of adverse effects on participants' safety or health is minimal.

Intervention

The BE N.i.C.E app, enhanced by AI, includes various tools such as identifying warning signs, coping strategies, mood tracking, collecting positive media, reflecting on past NSSI episodes, and providing emergency contact information. The AI engine within the BE N.i.C.E app employs rule-based decision logic to deliver personalized coping strategies based on user mood logs and behavioral inputs. Future iterations will incorporate adaptive learning models. The app's onboarding process includes instructional emails, videos, and a follow-up call from the research assistant. Technical support will be available throughout the trial. The intervention focuses on using the AI-driven mobile app for early intervention in non-suicidal self-injury (NSSI). Participants with NSSI will be assessed for their suicide risk.

The module used in this study was specifically developed by the researcher, based on previous research and refined with input from experts, including psychiatrists and clinical psychologists. The module addresses key components for managing emotional pain and self-injury behavior, such as a safety plan, emotional regulation skills, mindfulness, self-efficacy, problem-solving, self-love, and guidance on seeking help. Emergency contact numbers are also provided for immediate support. Participants will familiarize themselves with the app before actively using it for four weeks, after which follow-up assessments will be conducted to evaluate its efficacy and usability.

Outcome Measures

This study employs an experimental design to assess the effects of the intervention by comparing pre- and post-intervention measurements. During the initial session, researchers will collect baseline sociodemographic data, including age, gender, race, marital status, and religion. Participants will complete validated Bahasa Malaysia versions of the mHealth App Usability Questionnaire, the Perceived Stress Scale-10 (PSS-10), and the Brief Resilience Scale. The same assessments will be conducted after four weeks. Data from clinicians and self-reports on self-harm incidents will be collected before and after app use.

Safety Measures

The first 15 participants will be interviewed after four weeks to assess any negative experiences. Any adverse effects (AEs) and serious adverse effects (SAEs) will be reported to the ethical committee, which will take necessary action, including the potential termination of the trial if needed.

Data Collection

Questionnaires will be administered at baseline (T0) and after four weeks (T1). Automated reminders and direct contact from the research assistant will encourage participants to complete the questionnaires. A small gift card will be provided as an incentive. Participants have the right to withdraw at any time, and their data will be deleted if they discontinue the study.

Sample Size

As this is an initial feasibility study, no formal power calculation was conducted. A feasibility study of the TechCare app for individuals with psychosis involved an initial test with 4 participants and a subsequent trial with 12. Despite the small sample, the authors deemed it sufficient to assess usability, explore preliminary effectiveness, and inform future research (Gire, 2019).

Statistical Analysis

Data analysis will be conducted using SPSS version 27. Descriptive statistics will describe the sociodemographic characteristics of the participants. Mean and standard deviation will be used for continuous variables, while frequency and percentage will be used for categorical variables. All data will be analyzed for normality of distribution. The dependent variables include PSS-10 and BRS scores pre- and post-intervention. A p-value of less than 0.05 will be considered statistically significant.

Blinding

Due to the nature of the intervention, blinding is not feasible for participants or research assistants.

Discussion

The incidence of non-suicidal self-injury (NSSI) is increasing in Malaysia, yet there is a significant gap in available interventions to help healthcare providers offer brief, effective support to individuals engaging in NSSI. The development of an AI-enhanced mobile app for early intervention is both necessary and practical in today's technology-driven era to meet the needs of those exhibiting NSSI behaviours. This app not only provides an innovative intervention tool but also strengthens the connection between NSSI users, mental health professionals, healthcare providers, and supporters, thereby enhancing mental health support and fostering a broader understanding of NSSI within the community.

Additionally, the app aligns with Malaysia's Rangka Kerja 10-10 Sains, Teknologi, Inovasi dan Ekonomi (MySTIE) framework and the Sustainable Development Goals (SDGs), particularly SDG 3, which focuses on good health and well-being through technological innovation. The project significantly contributes to societal well-being by potentially improving productivity among users, creating new job opportunities in the technology and healthcare sectors, and supporting environmental sustainability through its digital approach. The app also supports users with NSSI and could create new job opportunities by training individuals to become mental health coaches. Through the app, users can learn to provide peer support, which could evolve into a scalable model where they train others, fostering a community-driven support network that contributes to long-term mental health resilience.

The app's development and research will also benefit individuals with mental disabilities (OKU mental) and NGOs by offering a tailored digital tool that enhances accessibility and support. Designed to meet diverse cognitive and emotional needs, the app makes mental health resources more accessible, allowing NGOs to improve their services, introduce new intervention methods, and gather valuable data on the effectiveness of digital mental health tools.

Given the rising prevalence of NSSI, there is also a need for specialised training for future healthcare professionals. The BE N.i.C.E app serves as an innovative e-learning platform designed to equip medical and allied health students with essential knowledge and practical skills for effectively managing NSSI. The app uses a range of multimedia resources, including instructional videos, diagrams, and pictures, to create an immersive learning experience. Core topics covered include basic presentations of NSSI, suicide risk assessment, and evidence-based intervention strategies. The app's user-friendly interface enhances knowledge retention and helps develop practical skills.

Upon completing the training, students will apply their newly acquired knowledge in real-world settings, such as psychiatric wards and outpatient clinics, under the supervision of a psychiatrist. This practical experience ensures students are well-prepared for clinical practice, ultimately contributing to improved mental health outcomes. By preparing future healthcare providers for the complexities of mental health care, particularly in managing NSSI, BE N.i.C.E ensures that students are equipped to deliver high-quality care to patients with NSSI in their professional practice.

Conclusion

While AI-enhanced digital tools have been explored in general mental health care, there is a lack of applications specifically targeting NSSI, particularly in Southeast Asia. Our study aims to bridge this gap. The BE N.i.C.E app offers an effective and innovative approach to addressing NSSI. The app's comprehensive, multimedia-based learning modules equip future healthcare professionals with the knowledge and skills necessary for effective NSSI management. Future research should explore the long-term impact of BE N.i.C.E in managing NSSI and other mental health conditions and its effect on students' competencies. This will provide further insights into the app's effectiveness and potential for broader application in medical education and training.

The expected outcomes of this research include increased awareness and understanding of NSSI, leading to improved mental well-being through the app's early intervention modules. A reduction in NSSI incidents and enhanced ability to manage emotional stress are anticipated. Additionally, the project aims to create new employment opportunities by training individuals to become mental health coaches, thus establishing a stronger and more supportive community network for ongoing mental health support.

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Conflicts of Interest

None declared.

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