

# Self-criticism and self-injury: Testing a novel diary-based treatment approach

<b>Submission date</b> 05/03/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 13/03/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/06/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The motivation to avoid pain and injury is a fundamental instinct. This makes nonsuicidal self-injury (NSSI) a very perplexing phenomenon. NSSI involves deliberate acts of self-harm without a specific wish to die. Increasingly common, NSSI is now a serious public health concern. What makes NSSI even more troubling, however, is its strong association with suicidal behavior. People who engage in NSSI are at high risk for later suicide. Despite numerous efforts there are few specific treatments for NSSI.

Through our previous work we have identified a novel treatment target - self-criticism. People who engage in NSSI report extremely high levels of self-criticism and self-hatred. Profoundly negative beliefs about the self are important because they remove a key barrier to NSSI and also motivate individuals to engage in self-injurious behaviors. Simply put, if you view yourself as bad, toxic, worthless or similar, you are likely to care little about your body. Harming it in an effort to feel better or to atone for being bad thus becomes a viable and potentially appealing option.

New approaches to the treatment of NSSI are very much needed. Our approach is based on our prior empirical work as well as our past experiences with people who engage in nonsuicidal self-injury. We seek to develop and test a new treatment that can be delivered directly to consumers via the internet and email. If this exploratory project is successful, our approach may help change the direction of current interventions for NSSI and lay the groundwork for highly focused prevention efforts.

Self-criticism is a major risk factor for engagement in NSSI. Self-criticism may be a promising treatment target, with some research showing success in reducing engagement in NSSI through increasing positive self-worth. Other research shows that people who engage in NSSI are less willing to endure painful experiences after their self-worth is increased.

The autobiographical self-enhancement training (ASET) intervention condition will examine a novel approach to targeting the mechanisms that drive NSSI behavior. The ASET treatment procedure was developed specifically for this study. It represents an adaptation of an approach we have created and used successfully with NSSI participants. The procedure seeks to undermine negative beliefs about the self by activating positive self-schemas. Participants will

receive training in this approach. They will then use it daily for a period of 28 days, describing something specific and positive about themselves each day in brief writing task.

An expressive writing (EW) intervention will be used as a comparison treatment condition. EW involves writing about one's emotions and in the context of describing stressful or upsetting experiences. Previous research shows that EW improves physical health and wellbeing. This study will be the first to examine expressive writing in the context of NSSI.

A journal writing (JNL) intervention will form the control condition. It will ensure that all study participants complete writing tasks. Participants in the JNL condition will write about daily events in their lives without any focus on emotional issues.

The online format of this study means that the interventions we are using can be made available to people regardless of where they live.

Who can participate?

People who used online forums related to suicide and psychopathology, were fluent in English, had daily internet access, and who had engaged in 2+ episodes of nonsuicidal self-injury in the past month were eligible to participate.

Benefits and risks of participating?

We did not expect significant risks to be associated with participating in this study. There was a potential risk that participants could find questions about self-harm to cause negative feelings or make them think about self-harm. Similarly, some people may have felt upset when responding to personal questions or when completing journal entries. However, we did not anticipate that these feelings would last for more than a few minutes. Moreover, if we learned that a participant was thinking about harming themselves, we provided them with a list of hotlines and resources to help keep them safe.

Regarding benefits, there was no guarantee of direct benefit to participants. However, participants may have benefited from extra monitoring and greater awareness of their thoughts and behaviors. There was also a chance that the activities may help them control self-harming behaviors, self-critical thoughts, or depression.

Where is the study run from?

The study was run entirely online, using Qualtrics. This means that participants were from both in and outside of the US, and they participated from their laptops or smartphones.

When is the study starting and for how long?

The study began on June 25th, 2016. The final participant completed the study on January 8th, 2017.

How long will the trial be recruiting participants?

Recruitment is now closed. The trial recruited participants for approximately 3 months.

Who is the main contact?

Jill M. Hooley (jmh@wjh.harvard.edu)

## Contact information

Type(s)

Scientific

**Contact name**

Dr Jill Hooley

**Contact details**

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**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**

The Eric M. Mindich Research fund for the Foundation of Human Behavior 373676.801263.0017

**Study information****Scientific Title**

Novel online daily diary interventions for non-suicidal self injury: A preliminary study

**Study objectives**

We predicted that, compared with the control intervention Daily Journaling (JNL), Autobiographical Self-Enhancement Training (ASET) would significantly reduce self-criticism, improve mood, and reduce the desire to self-injure and engage in Non-Suicidal Self Injury (NSSI). We also predicted that compared with JNL, Expressive Writing (EW) would provide general benefits and reduce feelings of depression.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Harvard University Institutional Review Board, 06/07/2016, IRB15-3940.

**Study design**

Randomized parallel trial

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Internet/virtual

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Non-suicidal self-injury

**Interventions**

Participants were recruited from online forums related to self-injury and severe psychopathology (e.g. reddit.com/r/depression). Forum members who met the inclusion criteria and were interested in participating completed an online consent form and a ~45-min baseline assessment. Participants were randomly assigned to one of three treatment groups (JNL, EW or ASET) using randomization software within Qualtrics. Each treatment was designed as a brief, daily diary treatment that could be completed from home or from a mobile device anywhere with internet access.

Participants assigned to ASET were asked to write for 5 min each day about something that happened that day that made them feel good about themselves as a person. Participants assigned to EW were asked to write for 5 min each day about something that bothered them or was on their mind that day. Participants in JNL were asked to write for 5 min each day about the events of the day in a general and factually descriptive way. For all groups, writing responses were monitored daily.

Participants were asked to complete daily writing assignments as well as four brief weekly follow-up assessments during the treatment month (i.e. 28 days). 4 weeks after the end of treatment, participants were contacted again (i.e. 1-month follow up/8 weeks after baseline to complete the first follow-up assessment. A final follow up assessment occurred 8 weeks later (i.e. 3-month follow-up/16 weeks after baseline).

**Intervention Type**

Behavioural

**Primary outcome measure**

Primary outcomes were self-criticism, depression, self-cutting episodes, and overall NSSI episodes (including self-cutting). Self-criticism (using the Self-Rating Scale - self-report questionnaire) and depression (using the Beck Depression Inventory-II) were assessed at baseline, week 1, week 2, week 3, and week 4 of treatment, 4 weeks post-treatment and 12 weeks post-treatment.

**Secondary outcome measures**

Secondary outcomes were desire to discontinue NSSI, likelihood of future NSSI, days of active suicide ideation, and days of suicide plans. A self-report questionnaire version of the Self-Injurious Thoughts and Behaviors Interview was used to obtain measures of NSSI, suicide ideation, suicide plans, and suicidal behaviors. Each of these thoughts and behaviors were measured at baseline, week 1, week 2, week 3, and week 4 of treatment. These were also measured over two follow-up time points, at 8 and 12 weeks post treatment.

**Overall study start date**

08/06/2016

**Completion date**

20/11/2018

## Eligibility

**Key inclusion criteria**

1.  $\geq 2$  NSSI episodes in previous month
2. Aged 18 years or over
3. Daily internet access
4. Fluent in English

**Participant type(s)**

Other

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

144

**Total final enrolment**

144

**Key exclusion criteria**

Inclusion criteria not met

**Date of first enrolment**

25/06/2015

**Date of final enrolment**

06/01/2017

## Locations

**Countries of recruitment**

Australia

Canada

Costa Rica

Germany

Hungary

Ireland

Japan

Netherlands

Portugal

Romania

Russian Federation

Sweden

United Kingdom

United States of America

**Study participating centre**

**Department of Psychology, Harvard University**

33 Kirkland Street, Cambridge, MA 02138

Cambridge

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## **Sponsor information**

**Organisation**

The Eric M. Mindich Research Fund for the Foundation of Human Behavior.

**Sponsor details**

Harvard University

Cambridge

United States of America

02138-2044

**Sponsor type**

University/education

## **Funder(s)**

**Funder type**

Not defined

**Funder Name**

The Eric M. Mindich Research Fund for the Foundation of Human Behavior

## Results and Publications

**Publication and dissemination plan**

We hope to submit a paper describing the full results of this study for publication.

**Intention to publish date**

30/11/2018

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	22/08/2018	27/06/2019	Yes	No