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Reducing self-harm in a clinical sample using IF-THEN plans

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2021	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2021	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/01/2021	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Nearly 800,000 people die from suicide each year and a history of self-harm has been identified as a key predictor. Implementation intentions (IMPs) have recently shown promise in the reduction of self-harm behaviour. An area worthy of investigation is the cognitive abilities of self-harm patients. Theoretically cognitive abilities are essential for enabling IMPs to change behaviour and it is also known that there is substantial variation in cognitive abilities within samples of self-harm patients. The aim of this study is to test implementation intentions and identify key cognitive abilities that distinguish between those who successfully change their behaviour following an IMP intervention and those who do not. This study aims to:
1. Test the extent to which making implementation intentions reduce self-harm in the longer-term (3 months post-intervention) using objective outcomes (hospital readmission rates) in addition to self-reported outcomes (e.g., situation-specific self-harm behaviour)
2. Explore the profiles of cognitive abilities within self-harm patients and identify which are likely to help explain why making implementation intentions reduce self-harm and suicide outcomes for some patients but not others.

Who can participate?
Adults aged 18 and above who have been admitted to Forth Valley Royal hospital and referred to the Mental Health Unit following an incident of self-harm

What does the study involve?
All participants will receive treatment as usual before participating in the study. Participants will be asked to complete a questionnaire answering questions about current and previous self-harm, their psychological well-being and their motivation to stop self-harm. Following this, participants will be randomly allocated to one of three groups.
1. Implementation intentions: Participants in this group will complete a volitional help sheet (i.e., form implementation intentions) with the PhD researcher able to help if required. The volitional help sheet will present participants with 20 situations which might tempt them to self-harm (e.g., If I am tempted to self-harm when I want to get relief from a terrible state of mind) and 20 strategies they could use to overcome this temptation (e.g., Then I will recall all that I know about the dangers of self-harming). Participants are asked to draw a line from a situation to a strategy and can make a maximum of four situation and strategy pairs. The implementation

intentions intervention will require 5 to 10 minutes.
2. Implementation intentions plus reinforcement: Participants in this intervention group will complete the volitional help sheet (i.e., form implementation intentions) the same way as outlined above for the implementation intentions group, with the PhD researcher able to help if required. In addition, after the cognitive abilities have been measured, participants in this group will be asked if they can recall the implementation intentions they made earlier in the session. The implementation intentions intervention and the reinforcement task will require 15 minutes.
3. Control: Participants in the control group will be shown the situations from the volitional help sheet and asked to tick the four they think would tempt them to engage in self-harm in the next 3 months only. The control intervention will require 5 minutes.
In all groups cognitive ability will then be measured. Additionally, the participants allocated to the implementation intentions plus reinforcement will complete the reinforcement task after the cognitive ability measures have been taken. After 3 months, participants are asked to complete a questionnaire to see if the intervention has reduced their self-reported self-harm behaviour and hospital records will be accessed to see if the intervention has reduced re-admission to hospital self-harm.

What are the possible benefits and risks of participating?
There are no expected risks for participants. Participants might find the study beneficial in helping them reduce future self-harm.

Where is the study run from?
Forth Valley Royal Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2017 to May 2021

Who is funding the study?
Economic and Social Research Council (UK)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
261036

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 261036

Study information

Scientific Title
Testing the effectiveness of an implementation intentions intervention to reduce self-harm in a clinical sample and testing the moderating effects of cognitive abilities

Study objectives
1. The two conditions which include the completion of volitional help sheets (implementation intentions and implementation intentions plus reinforcement) will reduce the frequency of self-harm at three months post-intervention for (i) self-reported self-harm and (ii) readmission to hospital for self-harm compared to the control condition.
2. The implementation intentions and implementation intentions plus reinforcement conditions will be most effective in reducing self-harm behaviour for individuals who report greater ability in cognitive outcomes at baseline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 11/11/2019, North of Scotland Research Ethics Committee 2 (2 Eday Road, Aberdeen, Summerfield House, Scotland, AB15 6RE, UK; +44 (0)1244 558 503; gram.nores@nhs.scot), REC ref: 19/NS/0151
2. Approved 13/11/2019, University of Strathclyde Ethics Committee (Research & Knowledge Exchange Services, University of Strathclyde, Graham Hills Building, 50 George Street, Glasgow, G1 1QE, UK; +44 (0)141 548 3707; ethics@strath.ac.uk), ref: not applicable

Study design
Single-centre three-arm randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Self-harm (self-injury or self-poisoning irrespective of the motivation)

Interventions
At baseline, all participants will receive treatment as usual and complete a questionnaire measuring standard demographic information, current and previous self-harm, psychological well-being, and motivation to self-harm.
Following this, participants will be randomised to one of three conditions. Participants will be randomised using a random number generator (an online integer generator was chosen for the study to ensure randomisation across conditions was equal).

1. Implementation intentions: Participants in this intervention group will complete a volitional help sheet (i.e., form implementation intentions) with the PhD researcher able to help if required. The volitional help sheet will present participants with twenty situations which might tempt them to self-harm (e.g., If I am tempted to self-harm when I want to get relief from a terrible state of mind) and twenty strategies they could use to overcome this temptation (e.g., Then I will recall all that I know about the dangers of self-harming). Participants are asked to draw a line from a situation to a strategy and can make a maximum of four situation and strategy pairs. The implementation intentions intervention will require 5 to 10 minutes.
2. Implementation intentions plus reinforcement: Participants in this intervention group will complete the volitional help sheet (i.e., form implementation intentions) the same way as

outlined above, for the implementation intentions group, with the PhD researcher able to help if required. In addition, after the cognitive abilities have been measured, participants in this condition will be asked if they can recall the implementation intentions they made earlier in the session. The implementation intentions intervention and the reinforcement task will require 15 minutes.
3. Control intervention: Participants in the control intervention will be shown the situations from the volitional help sheet and asked to tick the four they think would tempt them to engage in self-harm in the next 3 months only. The control intervention will require 5 minutes.

Three months later all participants will be invited to complete the follow-up questionnaire.

Intervention Type
Behavioural

Primary outcome measure
1. Self-reported self-harm behaviour overall and in critical situations measured using 9-point Likert scales at baseline and 3 months post-intervention
2. Re-admission to hospital for self-harm measured in weeks/months and collected from the patient's medical files on the basis that their permission has been obtained to do so during the informed consent process. This information will be collected at 3 months post-intervention.

Secondary outcome measures
1. Working memory measured using the List Sorting Test at baseline
2. Episodic memory measured using the Picture Sequence Memory Test at baseline
3. Executive function measured using the Flanker Test at baseline
4. Processing speed measured using the Pattern Comparison Processing Speed Task at baseline
5. Prospective memory measured using two event-based prospective memory items from the Royal Prince Albert Prospective Memory Test and the Prospective Retrospective Memory Questionnaire at baseline

Overall study start date
15/11/2017

Completion date
22/05/2021

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Aged 18 years and over, no upper age limit
2. Admitted to Forth Valley Royal Hospital and referred to the mental health unit for self-harm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
318 (106 participants in each trial arm)

Key exclusion criteria
1. Those who do not provide informed consent
2. Those who are unable to provide informed consent
3. Those not deemed medically fit to interview
4. Those who do not use English as a first language
5. Those who cannot provide follow-up contact information (as the intervention involves a telephone follow-up interview 3 months later)
6. Those who do not have normal or corrected to normal vision
7. Those who are participating in other research in Forth Valley
8. Those who present to an emergency department but are subsequently discharged without referral to the mental health unit at Forth Valley Royal Hospital
9. Those who are admitted to hospital for self-harm which is the result of excessive alcohol consumption or recreational drugs, mismanagement of a physical health condition, body piercing or starvation arising from anorexia nervosa

Date of first enrolment
31/01/2020

Date of final enrolment
03/02/2021

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Forth Valley Royal Hospital
Mental Health Unit
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Sponsor information

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University of Strathclyde

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Sponsor type
University/education

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ROR
https://ror.org/00n3w3b69

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. The study will be written up as part of a doctoral thesis and possible publication in a peer-reviewed journal
2. Additional documents will not be made available

Intention to publish date
22/05/2022

Individual participant data (IPD) sharing plan
Anonymous participant raw data was planned to be stored on the UK Data Service repository as permission to do so was provided during the informed consent process. The UK Data Service was chosen as it is the service provided for researchers who receive ESRC funding. Data is stored indefinitely in this repository.

The study was abandoned due to recruitment being suspended from March 2020 because of COVID-19. The study will now be reported as a feasibility pilot study only with a view to assess the procedure and methods that were employed and how well they worked. As a result, the data will no longer be stored in a data repository as it is incomplete.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No