Interpersonal Risk Factors and Preventative Interventions for Self-Harm

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A thesis submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology

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Declaration

I, the author, declare this is my own work. This thesis is submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology. This work has not been submitted for any other degree or to any other institution. No funding has been received for this thesis. No conflicts of interest declared.

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Lay Summary

A growing literature base implicates interpersonal risk factors in self-harm behaviours. Joiner's Interpersonal Psychological Theory of Suicide (IPTS) is a widely recognised theory in the sphere of suicide prevention and by extension, self-harm prevention. By understanding the associations between the interpersonal risk factors outlined in the IPTS and self-harm behaviours, we can begin to develop just-in-time adaptive interventions (JITAI). To inform preventative interventions for self-harm in psychiatric inpatient care in the National Health Service (NHS).

The first chapter explores associations between interpersonal factors as outlined in the IPTS and non-suicidal self-injury. It seeks to highlight the strength and direction of any correlations. After searching the current literature thirty-two eligible studies are reviewed. There are mixed findings with some studies highlighting strong positive associations between NSSI and IPTS constructs whilst others show no significant associations. Meta-analysis of studies demonstrates significant associations between three out of four of the IPTS constructs and NSSI. Findings are consistent with the wider literature base. Suggestions are provided for clinicians to incorporate regular exploration of interpersonal risk factors as part of routine risk management. As well as theoretical implications about circular relationships between IPTS constructs and NSSI.

The second chapter is a mixed method feasibility trial of a novel JITAI for the prevention of self-harm in psychiatric inpatient services in two NHS Trusts. The intervention is based on daily routine outcome monitoring of interpersonal risk factors to provide responsive interventions to prevent self-harm. Feasibility recruitment targets are not met, indicating the intervention is not feasible in its current form. A qualitative exploration of staff views on

feasibility provides insights to key barriers, enablers and ideas for future developments of the intervention. Ideas for development of the intervention include changes to the format and delivery, accounting for limited resources within the NHS.

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Part One: Literature Review

Joiner's Interpersonal Theory of Suicide (IPTS) and its relevance to Non-Suicidal Self-Injury (NSSI) a Systematic Review and Meta-Analysis.

Abstract

Background: Non-suicidal self-injury (NSSI) is an international public health concern and a known antecedent to suicide. Research into NSSI highlights key interpersonal aspects of NSSI. The Interpersonal Psychological Theory of Suicide (IPTS) provides a framework to examine relationships between interpersonal factors and NSSI. This review aimed to identify the strength and directions of associations between IPTS constructs and NSSI, if found, strong associations may implicate benefits for risk management processes in healthcare.

Methods: A systematic review (Open Science Framework protocol registration number: hdw7t) and meta-analysis was conducted searching Web of Science (Ovid), SCOPUS, PsycINFO (Ovid), Medline (Ovid) and Cochrane Library in July 2024 and re-run in September 2024. Included studies had adult populations, used validated measures of at least one IPTS construct, and recorded NSSI rates from self-reported, clinician reported or clinical records. Critical Skills Appraisal Programme (CASP) checklists were used for quality assessments. Study findings were summarised using a narrative synthesis, meta-analyses were run to examine correlations between NSSI and each IPTS construct. Further moderator analyses were run based on methodological features.

Results: A total of thirty two studies were included in the systematic review and twenty studies in the meta-analysis. Included studies employed cross sectional, retrospective and prospective longitudinal designs. Meta-analyses were run to explore correlations between IPTS constructs and NSSI, results demonstrated moderate positive correlations between Acquired Capability (AC)/ Perceived Burdensomeness (PB) /Thwarted Belongingness (TB) and NSSI with no significant correlation between hopelessness-NSSI. Moderator analyses

focusing on methodological study features demonstrated similar effect sizes as main analyses with low risk of bias studies showing a significant positive correlation between hopelessness and NSSI.

Conclusion: Due to varying levels of risk of bias in included studies and high levels of heterogeneity in all meta-analyses, results should be interpreted with caution. This review and meta-analysis propose there are weak to moderate positive correlations between TB/PB/AC and NSSI. Future research should study these correlates in larger sample sizes, using longitudinal designs, with considerations for cultural and clinical contexts. Findings promote consideration of interpersonal factors in routine risk assessments in mental health care.

Keywords: *NSSI, IPTS, Hopelessness, Thwarted Belongingness, Perceived Burdensomeness, Acquired Capability for suicide*

Practitioner Points:

- TB/PB and AC are indeed correlated with NSSI, with the strongest correlations between PB/AC and NSSI,
- Information about TB/PB and AC should be included as part of routine risk assessments in mental health care.
- It is recommended to regularly monitor TB/PB and AC to guide preventative interventions

Introduction

Non-suicidal self-injury (NSSI) is a global public health concern (Gillies et al., 2018; Lengel et al., 2022). There has been an attempt in the field to concisely capture the definition of NSSI for many years, this has implications for identification and treatment of NSSI as well as accuracy in investigating and comparing NSSI rates (Lengel et al., 2022). The most widely used definitions of NSSI in the literature are those provided by Nock (2009), within the DSM-V (APA,2013) and the International Society for the Study of Self-Injury (ISSS,2018). These definitions all encompass the following common features; the deliberate or intentional self-inflicting damage of the body's own tissue, without suicidal intent and excluding behaviours that are deemed socially acceptable e.g. body piercings.

Within the literature there are various terms used interchangeably with NSSI with some authors clearly defining what constitutes NSSI and others having more loose definitions. For the purpose of this review and for the ease of synthesis of findings, NSSI encompasses various terms including deliberate self-harm, self-harm, non-lethal self-injury etc.

Heterogeneity is shown to exist in NSSI behaviours, much like other psychiatric presentations, with variations in frequency, type, and severity of these behaviours (Goldberg et al., 2017; He et al., 2023; Wang et al., 2024). It is important to understand such variations as they have implications for associated risks and interplay with other psychiatric conditions (Hamza & Willoughby, 2013; Singhal et al., 2021).

Extensive research indicates NSSI is one of the strongest long-term determinants of future suicide attempts, more so than previous attempts (Ribeiro et al., 2016; Victor and

Klonsky., 2014). This highlights the importance of understanding determinants of NSSI behaviours in the interest of suicide prevention. Numerous studies have investigated the occurrence and consequences of NSSI (Liu, 2023, Wang et al., 2024).

The Interpersonal Psychological Theory of Suicide (IPTS) and NSSI

Historically the literature around NSSI has proposed the involvement of inter and intra-personal features (Klonsky et al., 2007; Peel-Wainwright 2021). Research has alluded to NSSI as a function to regulate interpersonal processes, such as expressing distress, eliciting support, or mitigating feelings of social disconnection (Hepp et al., 2021; Tas Torun et al., 2022; Tatnell et al, 2018). Interpersonal stressors like conflicts and perceived social failures can precipitate NSSI, serving as a maladaptive coping mechanism to manage negative social interactions.

The IPTS is a largely cited theory in the literature around suicide and self-harm (Forkmann et al. 2020) which posits that the simultaneous occurrence of interpersonal factors of perceived burdensomeness (PB) and thwarted belonging (TB) produces suicidal desire. The presence of hopelessness at one's TB and PB leads to suicidal ideation. TB and PB are argued to be important subjective interpersonal states that can cause someone a lot of despair but also PB may capture aspects of self-criticism that is predictive of NSSI. According to the IPTS suicidal behaviour is theorised to occur when one is simultaneously experiencing suicidal ideation and has the acquired capability (AC) to enact lethal self-injurious behaviours. Within the theory TB refers to an individual feeling like they do not belong, and PB refers to an individual perceiving themselves as a burden to others. AC is characterised by an increased pain tolerance as well as fearlessness about death due to prolonged exposure to painful or provocative experiences (Joiner, 2005; Van Orden et al.,

2010). Thus, according to the IPTS people are at higher risk to enact suicidal behaviours when they experience PB, TB and hopelessness about these interpersonal states, along with a history of exposure to painful and provocative experiences resulting in an acquired capability for suicide.

Current Review

In an epidemiological study by Liu (2023) looking at prevalence of NSSI in a sample of adults in England, the author highlighted the importance of research examining various psychological phenomena and their associations with NSSI. Research on the associations between IPTS and NSSI in adult populations have demonstrated varying findings, with the use of different study designs and focus on different IPTS constructs and NSSI. Numerous studies have investigated associations between singular constructs of IPTS and suicidal ideation and behaviour (Van Orden et al., 2010). For example, some studies found significant strong positive associations between hopelessness and NSSI (Gu et al. (2020); O'Connor et al., 2000 ; Shi et al., 2022) whilst others found negative or no associations (Marco Hose et al. 2015; Tsujii et al., 2020). Some studies investigating the relationship between NSSI and TB found significant positive associations (Assavedo et al. 2015.; Chu et al. 2016; Baer et al.2018) others have found no significant relationship (Kyron et al., 2023). Similarly, some studies show significant positive associations between NSSI and PB (Burke et al., 2016; Campos Rui et al., 2021; Kyron et al., 2020) vs non-significant associations (Kyron et al., 2023), some studies demonstrate significant positive associations between NSSI and AC (Burke et al., 2016; Gray et al., 2020; Rimkeviciene et al., 2015) and others found no significant correlations (Boffa et al. 2023; Gratz et al., 2020).

In the studies cited here and within the wider literature base, there are inconsistencies in strengths of associations between NSSI and IPTS constructs across different settings, populations and designs. Although most studies cited above had positive correlations, a small group of studies have highlighted negative correlations. For example, in a study by Chapman et al., (2014) findings demonstrated a weak negative correlation between hopelessness and NSSI. This may be explained by methodological limitations within the study, such as the inability to examine whether feelings of hopelessness precede NSSI. Other methodological issues such as the design of studies may impact inconsistency in findings, for example the use of cross-sectional studies versus daily diary studies. Conducting a systematic review and meta-analysis will allow aggregation of findings with the aim of clarifying the existence, strength and direction of the relationship between NSSI and IPTS constructs.

Arguably in the interest of suicide prevention and prevention of NSSI it is important to examine correlates of NSSI, and the IPTS provides a framework to allow for this. Given that within the literature NSSI is often presented as a precursor to suicidal ideation and behaviours, the author of this review was interested in examining associations between NSSI and IPTS constructs, to date there are no published systematic reviews and meta-analysis investigating these correlations.

Aims

Is there an association between hopelessness, acquired capability, thwarted belonginess, perceived burdensomeness and incidents of non-suicidal self- injury?

What is the strength and direction of these relationships?

Will moderator analyses based on sample type, outcome measure used, and risk of bias ratings reveal similar effect sizes to main meta-analytic findings?

Methods

Study Protocol and Design

This systematic review and meta-analysis is reported following guidance from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA; Page et al., 2021). The PRISMA reporting guideline can be found in Appendix A. The protocol was pre-registered and published in the Open Science Framework (OSF) prior to the review being conducted (protocol ID: hdw7t).

Search strategy

The inclusion and exclusion criteria described in Table 1 directed the development of a systematic search strategy combining key terms (related to NSSI and self-harm, hopelessness, thwarted belongingness, perceived burdensomeness and acquired capability for suicide), using Boolean operators (see Table 2). It should be noted within the PICOS strategy no parameters were set for type of interventions or outcomes to be included, as the review was not evaluating effectiveness of interventions, the primary focus was to investigate associations between variations in IPTS constructs and NSSI. Due to the vast number of studies in adolescent and adult populations, looking at associations between IPTS constructs and NSSI, it would not have been feasible to synthesise all data in a single review hence this review focused on adult samples. The search was limited to papers published in the English language and included grey literature, and was applied in July 2024 and rerun in September 2024, across five electronic databases: Web of Science (Ovid), SCOPUS, PsycINFO (Ovid), Medline (Ovid) and Cochrane Library. The search was re-run before analysis to ensure the most up to date and comprehensive evidence

was included. After rerunning the search no new papers were discovered. No restrictions were applied on publication dates. The full search strategy can be found in Appendix B.

Table 1

Inclusion and Exclusion Criteria

	Inclusion criteria	**Exclusion criteria**
Population	Participants who are aged 18 and over	Participants who are aged 17 and below
Intervention	-	-
Comparator	Studies examining an association between NSSI (either self-reported, clinician reported or recorded in clinical records) and at least one or more construct (Acquired capability, hopelessness, thwarted belongingness, perceived burdensomeness) of Joiner's Interpersonal Psychological Theory of Suicide (Joiner, 2005) as	Studies exclusively using unvalidated measures of IPTS constructs

	measured by a validated scale	
Outcomes	-	-
Study Design	Experimental and observational studies including cross-sectional, randomised control trial, longitudinal studies, prospective and retrospective cohort studies studies published in peer reviewed scientific journals and written in the English language, grey literature	Studies using continuation phase psychological or educational interventions editorials, newspaper articles and other forms of popular media literature sources not published in the English language

Table 2 Key Search Terms for each concept

Concept 1 (key terms relating to NSSI)	Concept 2 (key terms relating to psychological IPTS constructs)
"*acquired means of suicide*" OR "acquired capability" OR "thwarted belong" AND "non-suicid" OR "suicid behav" OR "suicid-behav" OR "self-harm" OR "self-harm" OR "self injur" OR "self-injur" OR	"*joiner* interpersonal theory of suicid" OR "joiner *model of suicid*" OR "interpersonal theory of suicid behav" OR "interpersonal-psychological theory of suicide"

"NSSI" OR "*non suicidal self injur*" OR "non-suicid self-injur" OR "non fatal suicid behav"	
“self-injurious thoughts and behav interview” OR “SITBI” OR “Deliberate self-harm inventory” OR “DSHI” OR “GSHS” OR “Paykel suicide scale” OR “PSS” OR “Suicide behaviour questionnaire revised” OR “Beck scale for suicide ideation	"Interpersonal Needs Questionnaire" OR "INQ" "burdensomeness" OR "hopeless" "ACS" OR "Acquired capability for suicide scale" OR "PHQ-9" OR "bhs" OR "Beck Hopelessness Scale" OR "Goldberg Depression Scale" OR "DSI-SS" OR "psychiatric Symptom Frequency Scale" OR "PSFS" OR "SSS" OR "Schuster Social Support" OR “SDQ” OR “Strengths and difficulties questionnaire” OR = OR ”perceived mastery scale”

Titles and abstracts were screened by the primary reviewer, and relevant information was collated using the Cochrane collaboration data extraction form (Higgins et al. 2024). Further reverse citation and reference list searches were conducted to identify any further relevant studies.

Data from the included studies were extracted by the main reviewer using a predefined excel sheet, any uncertainties were discussed with the research supervisor. The following study characteristics were extracted: study identifier (Author/s), year of publication, country of publication, IPTS domain measured and validated measure used, marker of NSSI rates (self-reported, clinician reported, clinical records), study setting (clinical/ non-clinical), time

points data collected, sampling method, sample size and demographic data and relevant statistical information (e.g. types of analysis used with narrative description of statistical findings). See Tables 2 and 3 for extracted data, further details including narrative descriptions of main statistical findings can be found in Appendix C. No authors were required to be contacted as there was no missing data in included studies.

Quality Assessment

The Critical Appraisal Skills Programme (CASP. ,2024) checklists were used to assess the quality of included studies (Please see Appendix D). The Cochrane risk of bias tool Sterne et al., (2019) was mentioned in the study protocol, however as none of the included studies employed a randomised control design this was not required. All eligible studies were reviewed by the primary reviewer and a second independent reviewer carried out a quality assessment for a third of included studies. There were no discrepancies in ratings between the primary and secondary reviewers hence an interrater reliability calculation is not reported, see Appendix E for quality ratings of all included studies.

Data Synthesis

A narrative synthesis (qualitative review) of all studies was conducted. A random effects meta-analysis was also calculated for all studies with sufficient statistical information, using the statistical R package Meta-Analysis via Shiny (MAVIS; Hamilton et al. 2016). Statistical information examining associations between NSSI and IPTS constructs was analysed, differences were standardised using Cohen's r coefficient to enable meta-analysis, with adjustment for unequal sample sizes across studies and to correct for small sample bias where relevant. Single pooled effect sizes were calculated for three studies in which more than one measure of an IPTS construct were used and where a single study examined associations between IPTS and NSSI in clinical and non-clinical samples. Q and I^2 statistics allowed for examinations of heterogeneity within studies (Higgins et al., 2003).

Rosenthal's method was utilised to calculate fail-safe N and weight function models to assess publication bias (Orwin,1983). Despite there being a total of twenty papers in the meta-analysis, analyses were run for each IPTS construct and associations with NSSI respectively. Hence, each analysis had a relatively small number of studies (<20), indicating the use of more thorough moderator analyses (Hansen, et al.2022; Rubio-Aparicio, et al.2017). Investigations of heterogeneity were carried out using moderator analyses based on methodological features of the studies (clinical vs nonclinical; validated measure used for IPTS construct; quality ratings (low/moderate risk of bias)).

Results

Study characteristics and Measures

Study selection is outlined in the PRISMA diagram in Figure 1. The initial search identified 4759 studies after deduplication. After abstract and title screening 215 studies remained for full text examination. Full texts were examined against inclusion/exclusion criteria (Table 1). Leading to a final total of 32 studies included in the review at hand. Reasons for exclusion of studies is included in the PRISMA diagram. Data from 12 studies were excluded from the meta-analysis due to missing data, however information pertaining to these studies is still included in the narrative synthesis.

Figure 1

PRISMA flow diagram of study selection

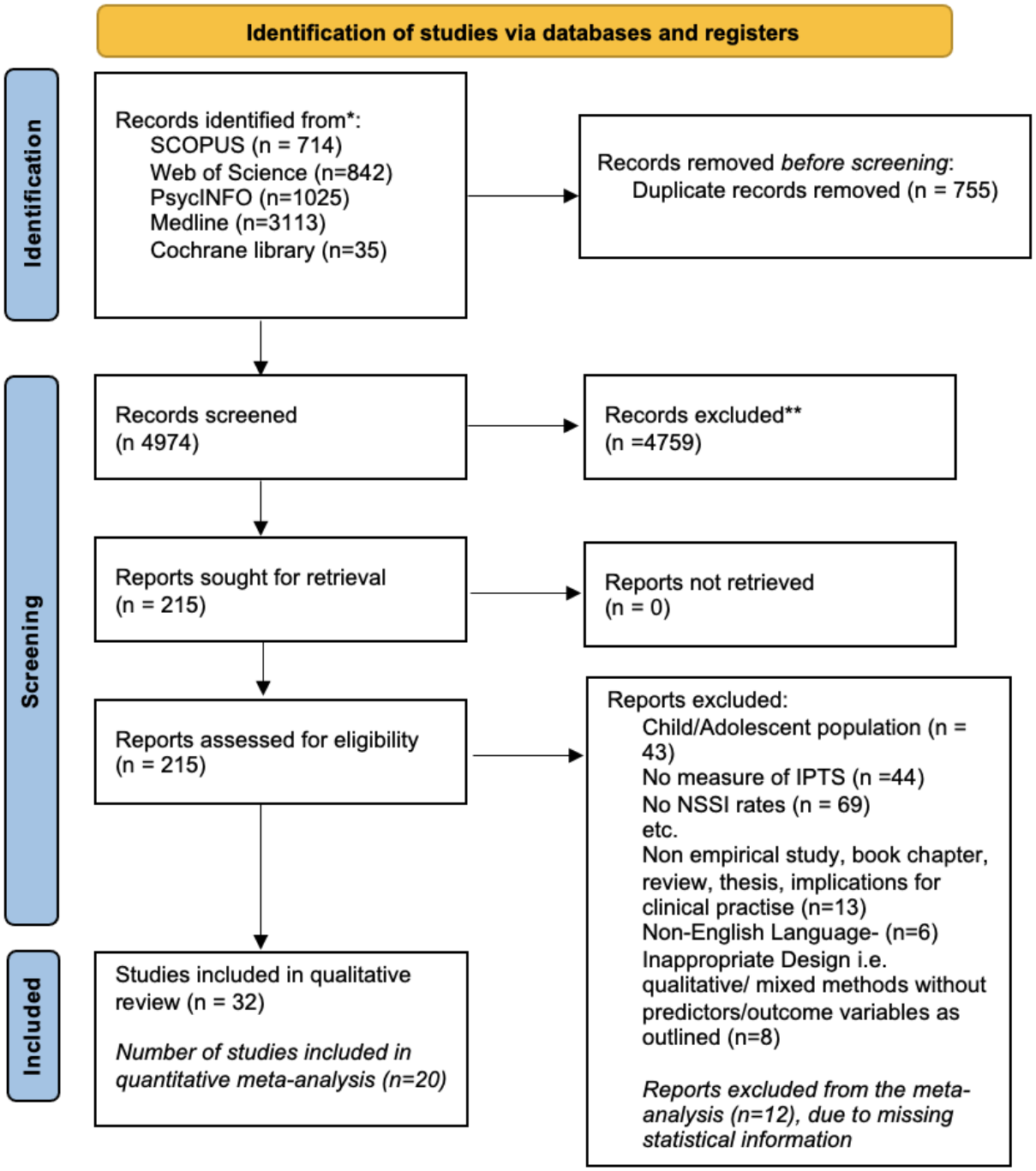


Table 3

Study Characteristics for included studies

Study Identifier (First author, year, country)	Study Design	Study Setting	Sample Size (Analysed N) and Sampling Method	IPTS Construct, outcome measure	Marker of NSSI rates	Time points data collected	Demographic information (sex, age, ethnicity)
Assaved o (2015), USA	Cross sectional	Non-clinical, online	999, convenience sampling	TB/PB INQ	Deliberate Self Harm Inventory (DSHI)	NA-single time point	Mean Age (21.18) Female (79.8%), Male (21.18%) Caucasian, (55.2%) African American (38.4%), Hispanic/Latino (1.3%) Asian Pacific Islander, (1.4%) Other (3.4%)
Baer (2018), USA	Cross Sectional	Clinical - Military psychiatric inpatients	62, convenience sampling	TB/PB/AC/Hopelessness INQ, ACSS,BHS	Columbia Suicide Severity Rating Scale (CSSRS)	NA-single time point	Mean age (28.7) Female (40.3%) Male (59.7%), Caucasian-(67.7%), African American (19.4%), Other(12.9 %)
Baralla (2021), Italy	Cross Sectional	Clinical-Those admitted to the National Institute for Health, Migration	169, convenience sampling	Hopelessness BHS	DSHI	NA-single time point	Mean Age – not provided Female (23.1%) Male (76.9%), African

		and Poverty (INMP) Ambulatory Care Unit					(78.7%), American (4.7%), Asian (8.8%), European (7.8%)
Boffa (2023),USA	Cross sectional	Non clinical - online, University students	58, convenience sampling	ACS ACSS-FAD	Self-reported frequency and type	NA-single time point	Mean Age (19.62) Female (86.2%), Male (13.8%), Caucasian/ White, (81%) 12.1%, African American/ Black, (12.1%) Asian, (1.7%) American Indian/ Alaskan Native, (1.7%) Biracial or Other. (3.5%)
Burke (2018), USA	Cross sectional	Non-clinical, University student Population	520, convenience sampling	AC ACSS	Form and Function of Self Injury(FAFSI)	NA-single time point	-
Burke (2016), USA	Cross sectional	Non-clinical, University student Population	447, convenience sampling	AC/TB/PB ACSS, INQ	DSHI	NA-single time point	Mean age 21.10 Female. (77.6%) Male, (22.4%) Caucasian (58.8%), African American (20.4%), East Asian (4%), South Asian (6.7%), Biracial and other (4.5%)

Campos Rui (2021)a, Canada/ Portugal	Cross sectional	Non-clinical, University student Population	Sample 1- Portugese Students, n= 384, sample 2- Canadian Students, n=247, total n= 631, convenience sampling	AC,TB, PB ACSS, INQ	Self-report Item	NA- single time point	Portugese Sample: Mean Age: 19.62 Female (50.3%), Male (49.7%), Caucasian (>95%) Canadian Sample: Mean Age (20.06) Female (88.7%) Male (11.3%) Caucasian (>80%)
Campos, Rui (2021) b, Portugal/ America	Cross sectional- survey design	Non-clinical community samples	Sample 1- Portugese community sample, n=414, Sample 2- American Community sample, n=290 , convenience sampling	TB/PB INQ	Self-report Item	NA- single time point	Portugese Sample: Mean Age (45.09) Female, (79%) Male, (21%) Ethnicity- not reported American Sample: Mean Age (37.76) Female (32%) Male (68%) Ethnicity- not reported
Chang (2024), USA	Longitudinal Web based design	Non-clinical, Online	473, convenience sampling	AC,TB, PB ACSS-FAD,INQ	Self Injurious Thoughts and Behaviours Interview Revised (SITBIR)	3 time points, T1 baseline, T2-1 month later, T3- 2	Mean Age (23.12) Gender: cisgender man (29.6%) cisgender woman

						months later	(49.3%) Transgender (21.1%) Asian (8%), Black or African American (5.3%), White (64.3%), Latinx (12.3%), Biracial or multiracial (8.7%) A different race (1.55%)
Chapman (2024), USA	Cross sectional, Mixed Methods	Non-clinical, Female Prison Inmates	104, convenience sampling	Hopelessness BHS	Adult Psychiatric Morbidity Survey (APMS)	NA-single time point	Mean Age (31.94) Female (100%) non-Hispanic White (71%), Native American (14%), Latino (10%)
Chu (2016),USA	Cross sectional prospective	Non-clinical, University student Population	49, convenience sampling	AC,TB, PB ACSS, INQ	SITBIR-SF	Three time points – *not specified*	77.6% female, 22.4% male, aged 18-23, Mean age (18.84) Female (77.6%) Male (22.4%) White/Caucasian (84%), Hispanic, (16%) Asian (10%), Black/ African American (4%) American Indian/

							Alaskan Native (2%)
Cleare (2021), Scotland	Cross sectional	Clinical-admitted to hospital following self-harm episode	500, convenience sampling	AC,TB,PB ACSS, INQ	APMS	NA-single time point	Mean Age (37) Female (60.6%) Male (39.4%), White (97.2%)
Gratz (2020), USA	Cross sectional	Sub study 1: Non-clinical community, Sub study 2- clinical those receiving treatment in a residential substance use disorder facility	sub study 1- n= 363, sub study 2 n= 198, convenience sampling	AC ACSS-FAD	DSHI	NA-single time point	Sub study 1: Mean Age (39) Female (59.2%) Male (40.8%) White (82.1%) Native American, (9.9%) Asian/ Asian American (5.3%), Black/ African American (1.9%) Sub study 2: Mean Age (35) Female (51%) Male (49%) White (60.1%), Black/ African American (36.9%)
Gray (2020), England	Cross sectional	Non-clinical, University student Population	267, convenience sampling	Hopelessness BHS, Hopelessness Implicit associations Test	Columbia Suicide Severity Rating Scale (CSSRS)	NA-single time point	Mean Age (29.3) Female (66.3%) Male (33.7%) Ethnicity not reported

Gu (2020), China	Cross sectional	Non-clinical, male prisoners	1042, convenience sampling	Hopelessness BHS short version	Inventory of Statements about Self Injury (ISAS)	NA-single time point	Mean age 38.45 100% Male Ethnicity not reported
Gu (2023), China	Cross sectional	Non-clinical, male prisoners	1042, convenience sampling	Hopelessness BHS short version	ISAS	NA-single time point	Mean age (38.45), Sex not reported Ethnicity not reported
Kyron (2023), Australia	Longitudinal Study	Clinical - psychiatric inpatient hospital	1265, convenience sampling	Hopelessness, TB,PB PMS,INQ	Self-reported daily	Daily measures	No demographics reported
Kyron (2020), Australia	Longitudinal Study	Clinical - psychiatric inpatient hospital	3740, convenience sampling	TB,PB INQ	Clinician reported	Daily measures	Mean Age (40.03) Female (72.28%) Male (27.72%) Ethnicity not reported
Larkin (2013), Ireland	Prospective Longitudinal Study/ cohort design	Clinical – General hospital emergency departments	n=29 at T1, n=19 at T2, convenience sampling	Hopelessness BHS	Clinician reported	Two timepoints: T1 Baseline, t2 3 month follow up	Mean Age 33.34, Female (58.6%) Male (41.4%) Ethnicity not reported
Marco, Jose (2015), Spain	Longitudinal Study	Clinical - public mental health services in Spain	N=80 at T1, n=67 at T2, consecutive sampling	Hopelessness BHS validated in Spanish	Self-reported NSSI frequency	Two timepoints: T1, Baseline, T2, Follow up- 1 year later	Mean Age Not reported Female (97%) Male (3%) Ethnicity not reported
Moseley (2022), England	Cross sectional	Non-clinical, online	n= 314 autistic sample, 312 nonautistic sample, convenie	ACS- ACWRSS	SITBI, NSSI-Implicit Association Test	NA-single time point	Mean Age (41.9) Female (72.9%) Male (26.8%)

			nce sampling				White (79.9%), Black (1.6%), Mixed race, (5.4%) Other (4.3%) 8.8% no response
Newman (2007), Canada	Case-control	Clinical-visited general emergency department following Parasuicide	507, convenience sampling	Hopelessness BHS	European Parasuicide Study Interview Schedule (EPSIS)	NA-single time point	Mean Age not reported Female, (67.3%) Male (32.7%) Ethnicity not reported
O'Connor (2000), Scotland	Case-control	Clinical-admitted to hospital following parasuicide, compared with hospital controls	40, convenience sampling	Hopelessness BHS	Based on hospital admission following parasuicide	NA-single time point	Mean Age (35.6) Female (42.5%) Male (57.5%) Ethnicity not reported
Perez Rodriguez (2017), Spain	Cross sectional	Clinical-Outpatient public and private MH hospitals	150, convenience sampling	Hopelessness BHS	Self-reported	NA-single time point	Mean Age (33.26) Female (84%) Male (16%) Ethnicity not reported
Rimkevicience (2015), Australia	Quasi-Experimental	Clinical-outpatient mental health clinic and non-clinical (community)-online	n= 55 clinical sample, n= 58 community sample, convenience sampling	ACS ACSS	Self-reported	Two time points	clinical sample: Mean Age (40.2) Female (78.2%), Male (21.8%) Community sample: Mean Age (43)

							Female (81%) Male (19%) Ethnicity not reported
Shi (2022), China	3 wave prospective design, longitudinal study	Non-clinical College students	T1, N=4191, T2, N=3985, T3, N=3871 Random Sampling	Hopelessness BHS shortened version	Self-reported	3 time points, T1 baseline, T2-1 year later, T3- 2 years later	Mean Age (19.13) Female (43.2%) Male (56.8%) Ethnicity not reported
Simms (2007), Ireland	Cross sectional	Clinical - psychiatric inpatient hospital	33, Random Sampling	Hopelessness BHS	Self-reported	NA-single time point	Mean Age not reported Female (33.3%) Male (66.7%) Ethnicity not reported
Sorgi-Wilson (2022), USA	Cross sectional	Non-clinical, University student Population	1357, convenience sampling	TB, PB INQ	ISAS	NA-single time point	Mean Age (20.10) Female (79.44%) Male (20.19%) Transgender (0.37%) White (59.40%) Asian, Black/ African American (15.33%) American Indian or Native Alaskan (14.15%), Native Hawaiian or Pacific Islander (0.29%) Other race (0.007%) more than one race (4.79%) and

							not reported (1.18%)
Tham Su-Gwan (2020), England	Retrospective cross-sectional study	Clinical-Secondary MH services	24444, Retrospective sampling	NCISH- clinician reported	National Confidential Inquiry into Suicide and Homicide (NCISH), clinician reported	NA-single time point	Mean Age not reported Female (66.1%) Male (33.9%) Black or minority ethnic group (7.3%)
Tsujii (2020), Japan	Longitudinal observational cohort study	Clinical - General Hospital Emergency and Psychiatric departments	805, convenience sampling	Hopelessness BHS	self-reported incidents of self-harm per person per year	NA-single time point	Mean age 42.2, female (54.9%) male (45.1%) Ethnicity not reported
Willoughby (2015), Canada	2 wave Longitudinal Study	Non-Clinical-Online University student population	782, convenience sampling	AC ACSS	ISAS	Two: Baseline and follow up- 1 year later	Mean Age (19.11) Female (70.5%) Male (29.5%) British (19%) Italian (16.8%) French (9.5%) German (9%)
Yamokoski (2011), USA	Correlational-Cross sectional	Clinical-veteran affairs medical centre outpatient mental health clinic	104, convenience sampling	Hopelessness BHS	Self Harm Behaviour Questionnaire	NA-single time point	Demographic data not reported

Table 4

Features of Tools used in Included Studies

Name of Measure	Measuring IPTS or NSSI	Reliability/ Validity	Number of Items	Possible Scores	Focus (severity, intensity, frequency, type of injury)
Acquired Capability for Suicide Scale (ACSS)	IPTS- TB/PB	Cronbach's Alpha>0.8/ convergent validity with measures of pain tolerance, self-injury, and past suicide attempts.	20	Items rated on a 5 point Likert scale 1-5	Severity- 1 strongly agree , 5 strongly disagree
Acquired Capability for Suicide Scale Fearlesness About Death(ACSS-FAD)	IPTS-Fear about death	Cronbach's alpha ~0.80/ convergent validity with measures of suicidal behaviour and exposure to death-related experiences.	7	Items rated on a 5 point Likert scale 1-5	Severity- 1 strongly agree , 5 strongly disagree
Acquired Capability With Rehearsal for Suicide Scale (ACWRSS)	IPTS- AC	Cronbach's alpha >0.85/ correlated with related constructs of NSSI/suicide	5	Items rated on a 5 point Likert scale 1-5	Severity- 1 strongly agree , 5 strongly disagree
Adult Psychiatric Morbidity Survey (APMS)	NSSI-Self harm behaviours, consists of other validated measures	Aligns with established diagnostic criteria for Psychiatric conditions in the ICD 10, consistent across waves of testing with high Cronbach alpha values	No specific number, depends on iterations for each version	Interview conducted every seven years	Type, severity, intensity
Becks Hopelessness Scale (BHS)	IPTS-Hopelessness	Cronbach's alpha ~0.90, moderately correlates with the Beck Depression inventory	20	True/ False	Severity – 0= minimal hopelessness, 20= severe hopelessness
Columbia Suicide Severity Rating Scale (CSSRS)	NSSI- suicidal ideation/ behaviour / intensity of ideation	Cronbach's alpha between 0.73-0.95	11 (5 additional items if ideation present)	Yes/no or Likert scale 1-5	Frequency, duration, intensity and severity
Deliberate Self Harm	NSSI- self harm behaviours	Cronbach's alpha (0.82–0.84) high	17	Yes/No with f/u questions	Presence and method of self-harm,

Inventory (DSHI)		soecificty and sensitivy in predicting suicide and self harm			frequency, duration, medical severity
European Parasuicide Study Interview Schedule (EPSIS)	NSSI	Standardised administration, encompasses a range of parasuicidal behaviours and used across various contexts	524	-	Frequency, type, severity
Form and Function of Self Injury Scale (FAFSI)	NSSI	Cronbach's alpha >0.80,consistent with well-established theories of self injury	33	Likert scale 1(never)-5(always)	Frequency, severity, type of injury
Interpersonal Needs Questionnaire (INQ)	IPTS-TP/PB	Cronbach's alpha >0.85 for both subscales, internal consistency across populations concurrent with other measures of hopelessness and NSSI	25	Likert Scale 1(Not at all true)-7(very true)	Higher scores indicate greater TB/PB
Inventory of Statements about Self Injury (ISAS)	NSSI	Cronbach's alpha >0.80 for function subscales, correlates with clinical constructs such as depression and anxiety, used cross culturally	40	3 point Likert scale 0(not relevant)-2 (relevant) 2 sections , first focuses on behavioural pattern, second focuses on function	Higher scores indicate greater engagement in NSSI and stronger motivations
Lifetime Parasuicide Count (LPC-2)	NSSI	Used in numerous studies to differentiate between suicidal and non suicidal self injury	NA-assesses total number of Para suicidal behaviours across the lifespan	Cumulative number of Para suicidal acts reported, categorised into low, moderate high frequency	Frequency, greater scores indicate greater engagement in NSSI behaviours across the lifespan
National Confidential Inquiry into Suicide and Homicide (NCISH)	NSSI/ IPTS	N/A	NA/Data Source	-	Frequency, type, severity
Self Harm Behaviour Questionnaire	NSSI	Cronbach's alpha >0.80,preliminary validation in non clinical youth	27	Scored according to four dimensions 1- presence of behaviour	Presence, frequency, intent and severity

		populations, and used in clinical and research settings, with diverse populations		yes/no,2 frequency rated on Likert scale, 3 Intent-suicidal/non suicidal and 4mediacl severity, higher scores indicate higher frequency severity and higher risk self harm behaviours.	
Self Injurious Thoughts and Behaviours Interview Revised (SITBR)	NSSI	Cronbach's alpha >0.80, shown to have high internal consistency, high test – retest reliability, convergent validity with other established measures of self injury	72	Items scored either present/absent or yes/no, higher scores indicate higher frequency , severity more recent behaviours	Presence, frequency, severity and recency of behaviours
Self Injurious Thoughts and Behaviours Interview Revised – short form (SITBR-S)	NSSI	Cronbach's alpha >0.80, shown to have high internal consistency, high test – retest reliability, convergent validity with other established measures of self injury	18	Items scored either present/absent or yes/no, higher scores indicate higher frequency , severity more recent behaviours	Presence, frequency, severity and recency of behaviours

Table 5

Summary of Main Statistical Findings

Study Identifier (First Author, Year)	Statistical Analyses Used	Key Associations between IPTS Constructs and NSSI
Assavedo (2015)	Zero order correlations	TB-NSSI, r=0.27, p<0.01* PB-NSSI , r=0.24, p<0.01*
Baer (2018)	MANOVA and Mann Whitney U tests	TB-NSSI, p= 0.20* PB-NSSI, P=0.076* AC-NSSI, non sig
Baralla(2021)	Chi-square tests/ Fisher's exact test / univariate/multivariate -log binomial regression models	Hopelessness-NSSI PR=2.91,p<0.01* multivariate model- non sig
Boffa (2023)	Descriptive statistics, screening for skew, kurtosis and outliers, bivariate correlations	AC-NSSI r= 0.24, p=non sig
Burke (2018)	Correlational Analyses	AC – NSSI ACS Score, =0.1,p<0.05* ACS-FAD, r=0.5, non sig
Burke (2016),USA	Bivariate Correlations	AC-NSSI, r =0.12, p<0.05* TB -NSSI, r =0.27, p<0.05* PB -NSSI, r =0.28, p<0.05*
Campos Rui (2021)a	Pearson Product-moment correlations, canonical correlations, bootstrapping of variables was used, for interpretation canonical loadings were rotated to a varimax criterion	Portugese Sample: PB-NSSI r = 0.41, P<0.001* TB-NSSI r=0.29, P<0.001* AC- NSSI r=0.07, non sig Canadian Sample: PB-NSSI, r =0.38, p<0.001* TB -NSSI, r =0.31, p<0.001* AC-NSSI, r=0.16, p<0.05*
Campos, Rui (2021)b	Pearson Correlations between all	Portuguese Sample TB-NSSI, r = 0.29, *p* < 0.001

	demographic and clinical variables	PB-NSSI,r = 0.46, *p* < 0.001 American Sample, TB-NSSI r = 0.12, p < 0.05* PB-NSSI r = 0.32, p < 0.001*
Chang (2024)	Latent class analysis, one-way MANOVA with Bonferroni post-hoc tests, estimates of Cohen's d effect sizes. Chi-squared tests of independence.	PB-NSSI Lower NSSI class had lower PB than moderate NSSI class, d=0.66,p<0.001* TB-NSSI Lower NSSI class had lower TB than moderate NSSI class, d=0.35, p=0.35* AC-NSSI No significant difference for AC across NSSI classes
Chapman (2024)	Two tailed independent sample T-tests, Pearson product moment correlations, simultaneous logistic regression model.	Hopelessness-NSSI r =-0.06, p=0.42*
Chu (2016)	Bivariate Correlations	TB- NSSI TB- lifetime NSSI r=0.33, p=0.021* PB-NSSI PB- lifetime NSSI r = 0.41, p = 0.004*
Cleare (2021)	univariate binary logistic regressions	AC-NSSI, OR =1.07, 95% CI=1.03-1.11* TB-NSSI, OR=1.07, 95% CI= 1.04-1.10* PB-NSSI OR=1.07, 95% CI= 1.05-1.09*
Gratz (2020)	Correlation analyses, logistic regression	AC-NSSI r= -0.04,p= non sig
Gray (2020)	descriptive statistics, Spearman's correlation	Hopelessness-NSSI past NSSI- Hopelessness: r= 0.32, p<0.01* current NSSI-Hopelessness, r= 0.26, p<0.01*

Gu (2020)	descriptive statistics, correlation analysis	Hopelessness-NSSI r=0.32, p<0.001*
Gu (2023)	Latent class analysis, multinomial regression model	Hopelessness-NSSI High/ Low hopelessness significantly associated with NSSI frequency at p<0.001, p<0.01 levels.*
Kyron (2023)	multilevel vector autoregressive models conducted within the Dynamic Structural Equation Modelling (DSEM) framework.	PB-Same day NSSI, β=0.00, SE=0.03, 95% CI [-0.06, 0.06], p=non sig PB- Next day NSSI, β=-0.01, SE=0.027, 95% CI [-0.06, 0.05, p=non sig, TB- Same day NSSI- β=0.00, SE=0.024, 95% CI [-0.04, 0.05], p=non sig TB-Next day NSSI, β=0.01, SE=0.024, 95% CI [-0.04, 0.05], p=non sig Hopelessness – same day NSSI, β=0.05, SE=0.029, 95% CI [-0.01, 0.11], p=non sig. Hopelessness- next day NSSI, β=0.02, SE=0.028, 95% CI [-0.03, 0.08], p=non sig.
Kyron (2020)	Hierarchical logistic models, bivariate correlations	PB -NSSI PB significantly predicted next day NSSI: (β = 1.07, 95% CI =1.01 – 1.13, p = .015)* TB- NSSI TB did not significantly predict next day NSSI (β = 1.01, 95% CI =0.97 – 1.06, p =non sig)
Larkin (2013)	Descriptives, Shapiro Wilk test for normal distributions of all variables, Mann Whitney U tests, independent samples t tests , chi squared tests	Hopelessness- NSSI Hopelessness significantly associated with repeat vs non repeat NSSI, r=0.36, p=0.13*

Marco, Jose (2015)	Zero order correlations, multiple regression analysis - variation inflation factors calculated for multiple regression	Hopelessness- NSSI Hopelessness score at baseline not significant predictor of NSSI at follow up r=0.13, p= non sig B= -0.147, SEB=0.266,β=-0.117, t(-0.552),p=0.583
Moseley (2022)	Descriptives	-.
Newman (2007)	Univariate and Multivariate conditional regression analyses	Hopelessness – NSSI Univariate model Hopelessness score of 15< significant predictor of NSSI OR 21.6, 95% CI (7.9-59.1), p<0.001* Multivariate model Hopelessness score of 15 < significant predictor of NSSI: OR 9.4 , 95% CI (3.2-27.8), p<0.001*
O'Connor (2000)	Two-way ANOVA's	Hopelessness-NSSI F (1,36) =13.75, p= 0.001*
Perez Rodriguez (2017)	ANOVA's, Kruskall Wallis test for non-normally distributed data, chi-squared test for categorical variables, post hoc tests- Bonferroni and Mann Whitney U Test	Hopelessness-NSSI Higher hopelessness in NSSI group vs No NSSI group, p=0.003*
Rimkeviciene(2015)	Point biserial correlations	Community Sample AC- NSSI, r=0.05* Clinical Sample AC-NSSI, r=0.21*
Shi (2022)	Pearson Correlation Analysis, logistic regressions	Baseline Hopelessness-NSSI r= 0.16, p<0.001* Time point 1: Hopelessness, significant predictor of NSSI OR 2.11, 95% CI (1.87-2.39), P<0.05* Multivariate model, Hopelessness -NSSI

		OR 1.52, 95% CI (1.29-1.78), P<0.05*
Simms (2007)	Descriptive Statistics, Mann Whitney U tests, Chi-squared	Hopelessness-NSSI No significant differences in hopelessness between NSSI -No NSSI group (Z=-0.797, p = 0.426) Auditory hallucinations and NSSI- significantly higher hopelessness scores (z= -2.085, p =0.037) *
Sorgi-Wilson (2022)	Descriptive Statistics, bivariate correlations (Pearsons), t-tests, chi-squared	TB- NSSI, r=0.440 * PB-NSSI, r= 0.713 *
Tham Su-Gwan (2020)	Pearson's Chi Squared, Tetrachoric correlation analysis	Hopelessness- NSSI r=0.0726, n= 22591, SE= 0.0132, p<0.001*
Tsujii (2020)	Descriptive statistics, Univariate and Multivariate Cox regression analyses, univariate and multi variate Poisson regression analysis	Hopelessness- NSSI (IRR per 1-point increase in Hopelessness score, 1.05; 95%CI, 1.03–1.07; P < 0.001)*
Willoughby (2015)	Descriptive statistics, auto-regressive cross lagged paths analysis, Overall model fit was determined using the comparative fit index (CFI) and the root mean square error of approximation (RMSEA) indicators.	AC-NSSI Higher AC did not significantly predict NSSI B= 0.010, SE =0.015, p = 0.667 Higher NSSI frequency significantly predicted AC, B=0.066, SE=0 .044, p= 0.029*
Yamokoski (2011)	Pearson Correlation Analysis, Canonical Correlation Analysis	Hopelessness-NSSI r= 0.37, p<0.01*

NOTE. IPTS- Interpersonal Psychological Theory of Suicide, AC- Acquired Capability, PB- Perceived Burdensomeness, TB- Thwarted Belongingness, **significant association*

Study characteristics are outlined in Table 3 and 4. The majority of studies in the review (k=20) used cross-sectional designs, the review also included longitudinal studies (k=8), case control studies (k=3) and 1 study (Rimkeviciene, 2015) employed a quasi-experimental design. Most studies employed convenience sampling except for two studies using random sampling, one study using retrospective sampling and one using consecutive sampling. Sample sizes ranged between n= 29 to n= 24444. Of the studies which provided information on gender (k= 29), most studies had a higher proportion of female participants (k= 23) only three of the included studies presented information on non-binary gender categories.

Of the included studies k= 24 studies reported a mean age, therefore a pooled mean age of 30.14 was calculated. One study (Tham Su Gwan et al., 2020) had an age range of 10-100 and median age of 44, although this review excluded studies with adolescent or child participants, due to the large sample size in the study n= 24,444 it was decided it would be included in the review to avoid selection bias and excluding potentially important findings.

A similar number of studies were carried out in clinical (k=14) and non-clinical (k=16) settings with the studies by Rimkeviciene (2015) & Gratz (2020) using both clinical and non-clinical samples. Clinical samples included participants from: general and psychiatric hospitals, outpatient services, and community mental health services/clinics. Non-clinical samples included: University and College students and public. Most studies were carried out in-person with k= 6 studies conducted online. Most included studies (k= 12) were carried out in the USA, studies were also conducted in Australia, Canada, China, England, Italy, Ireland, Japan, Portugal, Scotland, and Spain.

All studies used validated self-report outcome measures for IPTS constructs (see Table 4). Similarly, the majority of studies (k=19) collected data on NSSI using validated self-report measures these included the DSHI, SITBR and ISAS. Some studies used lesser-known validated measures for NSSI such as the APMS used in the Cleare et al., 2020 study, however k= 9 studies relied on participants self-reporting NSSI information such as intensity, type and /or frequency without the use of a validated measure. The Gu et al., 2020 study used a structured interview designed specifically for the study to collect data on NSSI. k= 3, studies used clinician reported data on NSSI, the study by O'Connor et al., 2000, was the only study which used NSSI data from clinical records i.e. participants were recruited based on admission to hospital following parasuicide.

When measuring IPTS constructs the majority of papers used the following validated measures: Hopelessness -BHS, three papers used the shortened version and one study used a validated Spanish version, one study used the Pearlin Mastery Scale and one used both the BHS and a hopelessness IAT. For TB/PB all studies used the same validated outcome measure INQ, for AC most studies k=7 used the ACSS some papers k=3, used the ACS -FAD item as a measure of AC. None of the included studies explored associations between NSSI and all IPTS constructs, although the Baer et al., 2018 study used validated measures for all IPTS constructs, the Hopelessness score was used as a mediator in the analysis and direct associations between NSSI and hopelessness were not analysed or reported. Studies that investigated associations between NSSI-TB also reported associations between NSSI-PB, this is by virtue of the validated measure used-INQ which measures both TB and PB. Five papers examined associations between TB/PB/AC and NSSI, and the Kyron, 2023 study was the only study that looked at associations between hopelessness/PB/TB and NSSI.

Risk of Bias

Most studies were rated either moderate (k=15) or low (k=13) risk of bias with four studies rated high. Most studies were rated as high risk in results applicability due to the specific nature of each sample being studied as well as the specificity of the nature of the phenomena being studied i.e. NSSI rates as associated with IPTS, which limited generalisability. The majority of studies were rated as “somewhat” methodologically sound for the following reasons: most studies utilised self-report validated measures which could potentially introduce recall and selection bias from respondents (Smith & Noble, 2014). Additionally, most papers used cross sectional designs looking at associations which limited causality inferences and although a cross-sectional design was appropriate in relation to the study question (Sedgwick, 2013; Sedgwick, 2014), longitudinal studies would have allowed for more robust statistical analysis (Gibbons et al., 2010; Hopwood et al., 2022). Please see Table 5 for overall risk of bias ratings for each included study and Appendix E for information regarding quality appraisals for each study.

Table 6 *Risk of Bias Ratings*

Study Identifier	Risk of Bias
Assavedo (2015)	Moderate
Baer (2018)	Moderate
Baralla (2021)	low
Boffa (2023)	low
Burke (2018)	Moderate
Burke (2016)	Moderate
Campos Rui (2021)a	Moderate
Campos Rui (2021)b	Moderate
Chang (2024)	Moderate
Chapman (2024)	High
Chu (2016)	Moderate
Cleare (2021)	Low
Gratz (2020)	Low
Grey (2020)	Low
Gu (2020)	Low
Gu (2023)	Low
Kyron (2023)	Low
Kyron (2020)	Low
Larkin (2013)	Moderate
Marco Jose (2015)	Moderate
Moseley (2022)	High
Newman (2007)	Moderate
O'Connor (2000)	Moderate
Peres Rodriguez (2017)	High
Rimkeviciene (2015)	Moderate
Shi (2022)	Low

Simms (2007)	Moderate
Tham Su-Gwan (2020)	Moderate
Tsujii (2020)	Low
Willoughby (2015)	Low
Yamokoski (2011)	High

Narrative Synthesis of Findings

Key statistical findings are reported in Table 3. Thirteen studies observed associations between NSSI frequency and IPTS constructs at a single time point: of these studies only four studies found non-significant associations between IPTS constructs and NSSI frequency. Baer et al., (2018) found no significant association between NSSI and PB, and Burke et al., (2018) found no significant association between NSSI and AC, the Campos Rui et al., (2021a) paper found no significant correlation between AC and NSSI in the Portugese sample.

Other studies showed NSSI frequency was significantly associated with the respective IPTS construct under investigation: Burke et al., (2016) and Cleare et al., (2021) found significant weak associations between NSSI and AC/TB/PB. Campos Rui et al., (2021b) found significant weak associations between NSSI and TB/PB for both the American and Portuguese samples in the study. Rimkeviciene et al. (2015) studied only associations between NSSI and AC/ AC-FAD and found significant weak associations in both clinical and non-clinical samples studied. Other studies were examining only associations between hopelessness and NSSI and showed significant weak to moderate positive correlations (Tham Su Gwan et al., 2020; Gu et al., 2020; Yamokoski et al., 2011). The Newman & Bland, (2007), study showed scores of 15 or higher on the BHS were strong significant predictors of parasuicide and was the only study to specify the relationship

between specific scores on the IPTS measure used and NSSI. Interestingly the study by Simms et al., (2007) was the only included study which investigated associations between NSSI and hopelessness in the context of other psychological factors/symptoms, such as auditory hallucinations. They found that individuals who experienced auditory hallucinations with self-harm had significantly higher levels of hopelessness than those who experienced auditory hallucinations without self-harm.

Other studies (k=7) examined temporal effects, such as studies by Kyron et al., (2023) and (2020), who used daily measures of IPTS constructs to investigate associations between scores and same or next day NSSI. The 2020 study demonstrated PB significantly predicted next day self-harm with a moderate to strong association whereas TB did not significantly predict next day self-harm, the 2023 study showed no significant associations between scores on IPTS constructs of hopelessness, TB and PB and same or next day self-harm.

The Boffa et al., (2023) study examined correlations between past two weeks NSSI frequency and AC, findings indicated no significant correlation between ACSS-FAD score and NSSI frequency in the past two weeks.

Additionally in the Tsujii et al., (2020) study associations were examined between Hopelessness and NSSI episodes per person per year, which demonstrated moderate to strong significant associations between the number of overall NSSI episodes per person per year and hopelessness score. Interestingly they also found one-point increase in hopelessness score was significantly associated with NSSI incidents per person per year. Marco Jose et al., (2015) compared hopelessness and NSSI at baseline and one year

follow up and findings showed that hopelessness score at baseline was not a significant predictor of NSSI frequency at follow up.

The Grey et al., (2020) study looked at associations between past and current NSSI and hopelessness and found significant moderate positive correlations for both past and current NSSI and hopelessness. Shi et al., (2022) collected data at baseline, one year later and two years later, their findings indicated a strong positive significant correlation between hopelessness and NSSI at baseline additionally they demonstrated baseline hopelessness significantly predicted future NSSI.

Five of the included studies examined associations between lifetime frequency of NSSI and IPTS constructs, Baralla et al., (2021), found hopelessness to be a strong significant predictor of deliberate self-harm during the course of the lifetime. In the Chu et al., (2016) study data was collected at three time points, findings indicated a significant positive relationship between lifetime NSSI frequency and TB/PB. Gratz et al., (2020) was the only study to examine associations between lifetime frequency of NSSI and AC, findings demonstrated no significant correlation between the two. Both the Moseley et al., (2022) and Willoughby (2015) studies only provided descriptive data in relation to NSSI frequency across the lifespan with no data provided on the relationship between NSSI and AC.

The remaining studies (k=7) used comparative designs, in the Chapman et al., (2024), Perez Rodriguez et al., (2017) and Sorgi-Wilson et al., (2022) studies, samples were categorised based on whether they engaged in NSSI or not. In the O'Connor et al., (2000) study comparators were either parasuicide or hospital controls and Larkin et al., (2013) compared repeat and non-repeat self-harmers. Aside from the Sorgi-Wilson et al., (2022)

study which examined associations between TB/PB and engaging in NSSI/or not, all other studies focused on the construct of hopelessness.

The Chapman et al., (2024) paper showed a significant difference in hopelessness scores between the NSSI and non NSSI group however the logistic regression model demonstrated the effect of hopelessness score on likelihood of NSSI was non-significant. Contrary to the literature and other studies demonstrating significant correlations between hopelessness and NSSI in this review, Pearson's product-moment correlation indicated a weak negative correlation between NSSI and Hopelessness.

In the Perez Rodriguez et al., (2017) paper there was a significantly higher hopelessness score in the NSSI group when compared to the non-NSSI group. Similarly in the study by O'Connor et al., (2000) there was a significant difference in hopelessness scores in the parasuicide group in comparison to the hospital controls with increased hopelessness significantly associated with the parasuicide group. In the Larkin et al., (2013) study results approached significance for the repeat self-harm groups having significantly higher scores on hopelessness.

Latent class analyses were used in 2 studies, with both studies categorising classes by NSSI severity, with slight variations. Chang et al., (2024) categorised classes as ("low, moderate, high") and Gu et al., (2023) categorised classes as (non/negligible, moderate and high). The Chang et al., (2024) study assigned participants to classes based on number of NSSI methods used, lifetime frequency of NSSI, duration of NSSI and age of onset, reporting 0.89 for entropy of the model suggesting a high accuracy of NSSI class assignment. Statistical analyses provided interesting insights into the demographic makeup for each class, indicating that cisgender men were significantly more likely to be in

the lower class than moderate, and cisgender women were more likely to be in the moderate class than the lower class. No significant differences were observed based on sexual orientation or race/ ethnicity; more information provided in Table 2. The higher NSSI class did not differ significantly from the moderate or lower classes for any IPTS construct, however the lower NSSI class had lower PB/TB than the moderate class and no significant differences were found between AC and any NSSI class.

Unlike the Chang et al., (2024) study, the Gu et al., (2023) study assigned classes based on one characteristic which was the probability of endorsement of different kinds of NSSI behaviours. Additionally, the Gu et al., (2023) paper only looked at associations between hopelessness and classes of NSSI and did not include any other IPTS constructs. Hopelessness significantly predicted class membership based on NSSI and individuals with high NSSI were significantly more likely to be in the moderate NSSI class. Similarly, those with high hopelessness were significantly more likely than those with low hopelessness to be in the high NSSI class in comparison to moderate NSSI class.

Meta-analysis

Twenty studies (N= 28,508) provided sufficient data for inclusion in the meta-analysis, examining associations between IPTS constructs and NSSI rates. Separate meta-analyses were run to examine associations between NSSI and each IPTS construct (Hopelessness, TB, PB and AC). Subgroup analyses were conducted to examine the potential influence of methodological features on the magnitude of the observed effect sizes in the main analysis for each construct. Subgroup analyses were run based on the setting (for example clinical or non- clinical sample) and the validated measure used for

each IPTS construct. It should be noted subgroup analyses were not run for measures used for TB and PB constructs as all studies in the main analysis used the same measure, the INQ by Van Orden (2012).

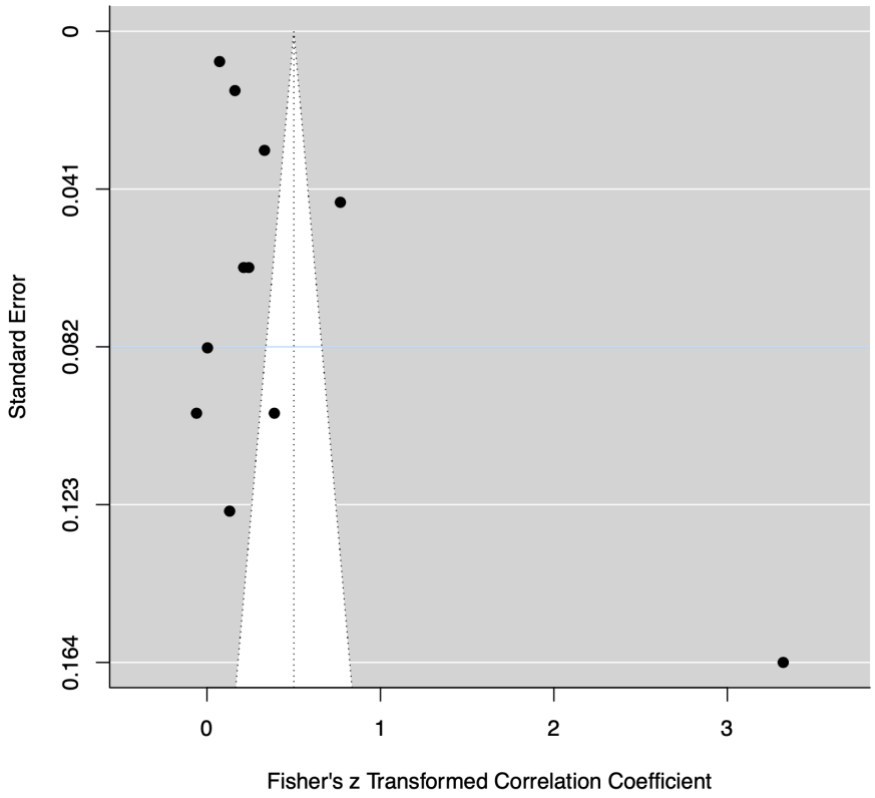
Subgroup analyses were also run based on quality ratings. Since none of the studies included in the meta-analysis had “high” risk of bias ratings sub-group analyses were based on either moderate or low risk of bias ratings, the decision as to which of the ratings to use for the subgroup analyses was based on which rating was higher for each construct (see Appendix E for more details on quality ratings).

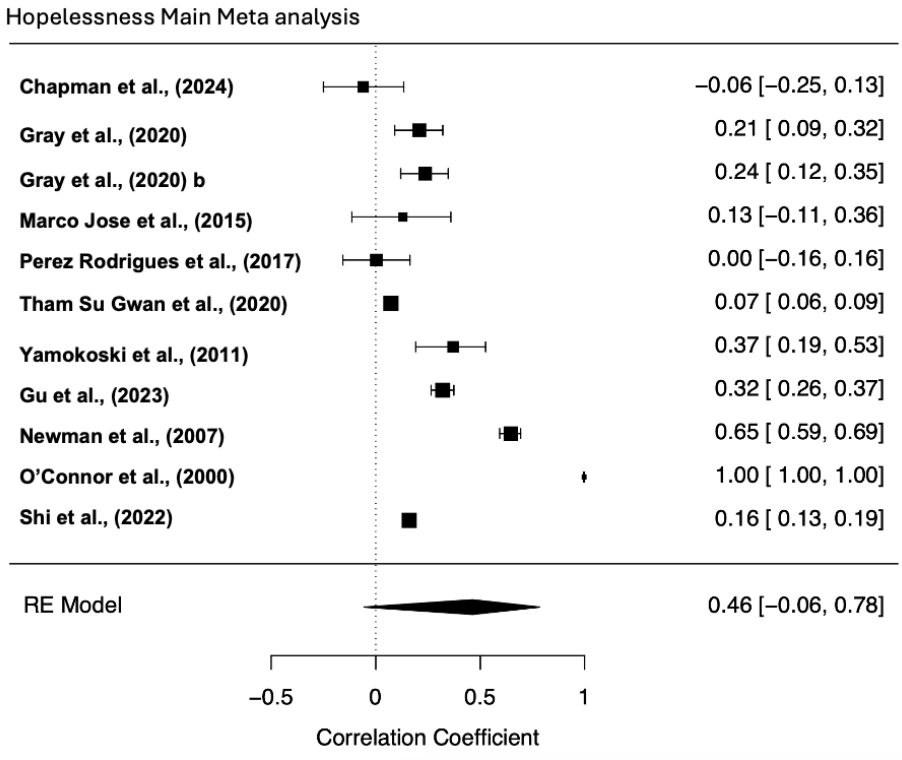
Main meta-analysis along with subgroup analyses for each IPTS construct and associations with NSSI are presented. Please see figures 2,3,4,5 for forest and funnel plots for the main meta-analysis for each construct. According to guidelines in the Cochrane handbook for systematic reviews, (Higgins et al., 2024) when reporting heterogeneity for each main analysis they are rated as low if $I^2 \leq 25\%$, moderate if $I^2 = 26$-50%, or high if $I^2 \geq 75\%$ (Higgins & Green 2011).

Associations between Hopelessness and NSSI

Figure 2

Hopelessness Forest and Funnel plots





When examining the association between NSSI and Hopelessness (k=11; N=22778), the weighted mean effect size was, r=0.46, (95% CI -0.06- 0.78), p=0.078, indicating there was no significant association between hopelessness score and NSSI rates (see forest plot). Cochran's Q-test (*Q* [10] =699.06, p<0.001) and the I squared statistic (99.89%) indicated a large magnitude of heterogeneity. The regression for funnel plot asymmetry and Kendall's tau indicated no significant evidence of publication bias, *t*(9) = 2.14, *p* = 0.061; Kendall's τ = 0.06, *p* = 0.814; Failsafe *N* = 2328.

Subgroup analyses for Hopelessness-NSSI associations

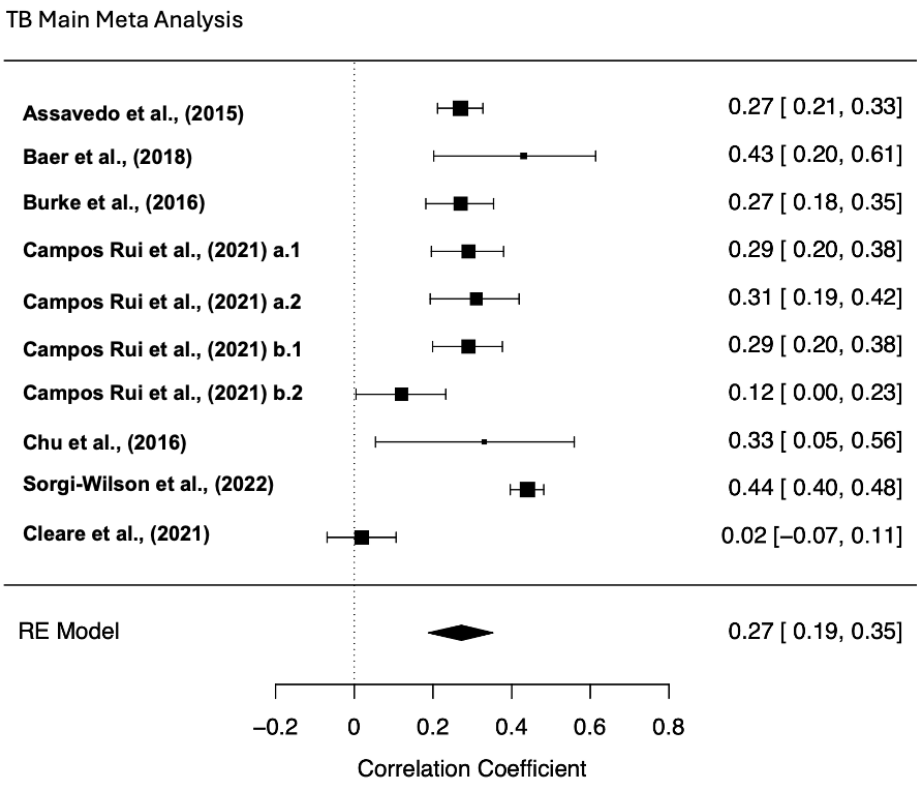
The effect size in the subgroup of studies using the BHS hopelessness measure (k= 9; N= 6472) was slightly higher when compared to the main analysis (r = 0.52, [95% CI -0.1, 0.85], *p* = 0.095) and with a large magnitude of heterogeneity (*Q* [8] = 546.58, *p* <0.001, I^2 = 99.79%).

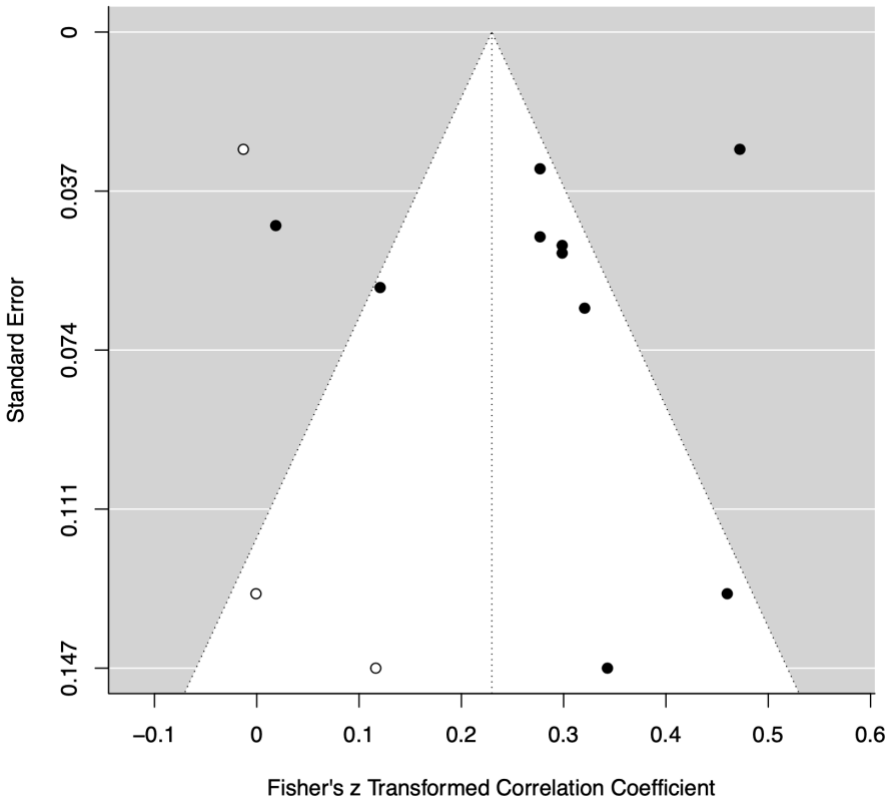
Similarly the effect size in the subgroup of studies using clinical samples (k=6; N=16907) was slightly higher when compared to the main analysis (r = 0.65, [95% CI -0.23, 0.95]), not statistically significant (p = 0.133), and with a large magnitude of heterogeneity (Q[5] = 631.33, p <0.001, I^2 = 99.81%).

The effect size in the subgroup of studies rated as having low risk of bias (k=3; N=5767) was smaller in comparison to the main analysis and statistically significant (r = 0.23, [95% CI 0.15, 0.31], p <0.001) indicating a weak correlation and with a large magnitude of heterogeneity (Q[3] = 24.71, p <0.001, I^2 = 81.82%).

Figure 3

TB forest and funnel plots





Upon examination all other IPTS constructs were shown to have significant associations with NSSI rates: examination of the association between NSSI and TB (k=10; N=4745), revealed a weighted mean effect size of r= 0.27, (95% CI 0.19-0.35), p<0.001, (see forest plot) indicating a weak correlation. Cochran's Q-test (*Q* [9] =91.04, p<0.001) and the I squared statistic (87.6%) indicated a large magnitude of heterogeneity. The regression for funnel plot asymmetry and Kendall's tau indicated no significant evidence of publication bias, *t* (8) = -0.822, *p* = 0.435; Kendall's τ = 0.333, *p* = 0.216; Failsafe *N* = 1197.

Subgroup analyses for TB-NSSI associations

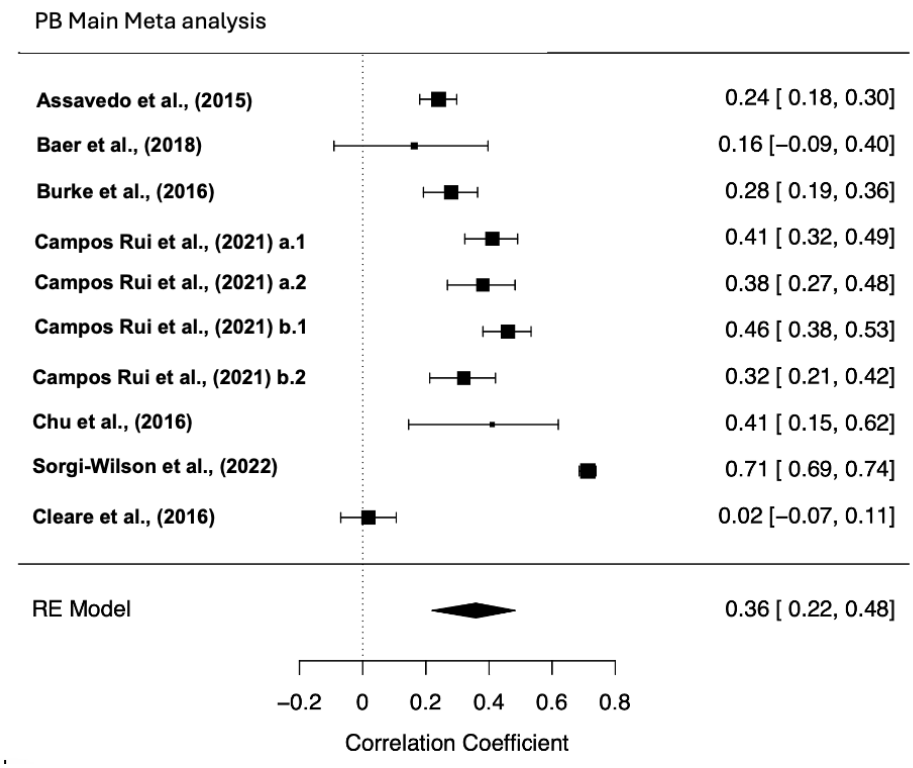
The effect size in the subgroup of studies using a non-clinical sample (k= 8; N= 4183) was similar to the main analysis (r = 0.29, [95% CI 0.22, 0.36], *p* <0.001) with a borderline moderate correlation and with a large magnitude of heterogeneity (*Q* [7] = 44.56, *p* <0.001, I^2 = 79.88%). The analysis demonstrated a smaller level of heterogeneity in the subgroup of non-clinical studies in comparison to the main analysis.

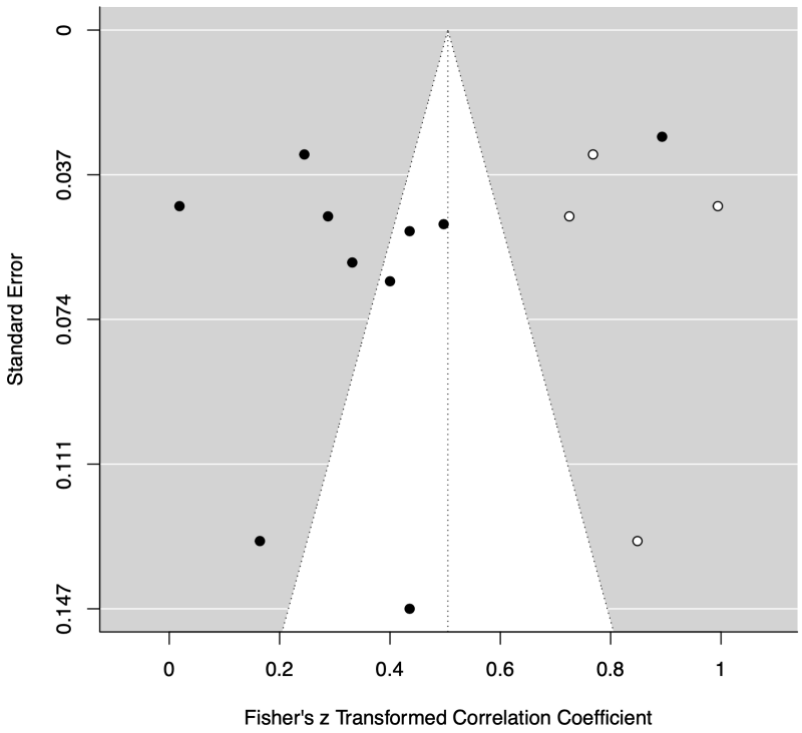
The effect size in the subgroup of studies rated as having moderate risk of bias (k=8; N=2888) was statistically significant and smaller when compared to the main analysis (r = 0.27, [95% CI 0.23, 0.31], p <0.001) indicating a weak correlation and with no significant heterogeneity (Q[7] = 9.97, p=0.19, I^2 = 11.4%).

Associations between PB and NSSI

Figure 4

PB Forest and Funnel plots





Associations between NSSI and PB (k=10; N=4745), revealed a weighted mean effect size of r=0.36, (95% CI-0.22-0.48), p<0.001, (see forest plot) indicating a moderate correlation. Cochran's Q-test (*Q* [9] =421.84, p<0.0001) and the I squared statistic (95.98%) indicated a large magnitude of heterogeneity. The regression for funnel plot asymmetry and Kendall's tau indicated no significant evidence of publication bias, *t* (8) = -1.17, *p* = 0.274; Kendall's τ = 0.111, *p* = 0.728; Failsafe *N* = 2457.

Subgroup analyses for PB-NSSI associations

The effect size in the sub group of studies using a non-clinical samples (k= 8; N= 4183) was slightly higher when compared to the main analysis (r = 0.42, [95% CI 0.29, 0.53], *p* <0.001) indicating a moderate correlation and with similar large magnitude of heterogeneity (*Q*[7] = 304.93, *p* <0.001, I^2 = 95.26%).

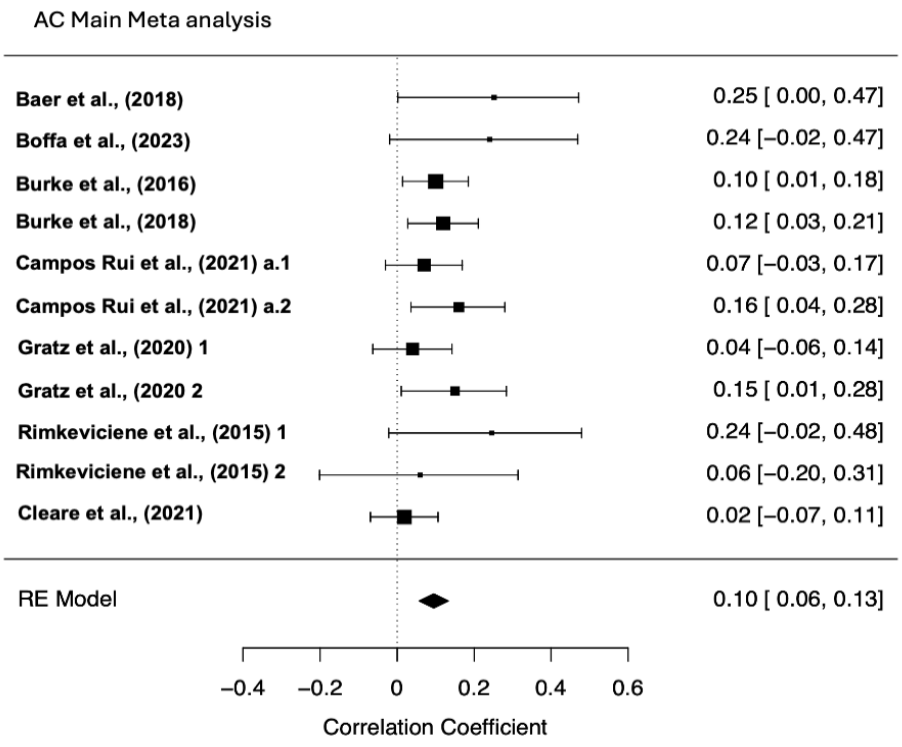
The effect size in the subgroup of studies rated as having moderate risk of bias (k=8;N=2888), was statistically significant and similar to the main analysis (r = 0.34, [95%

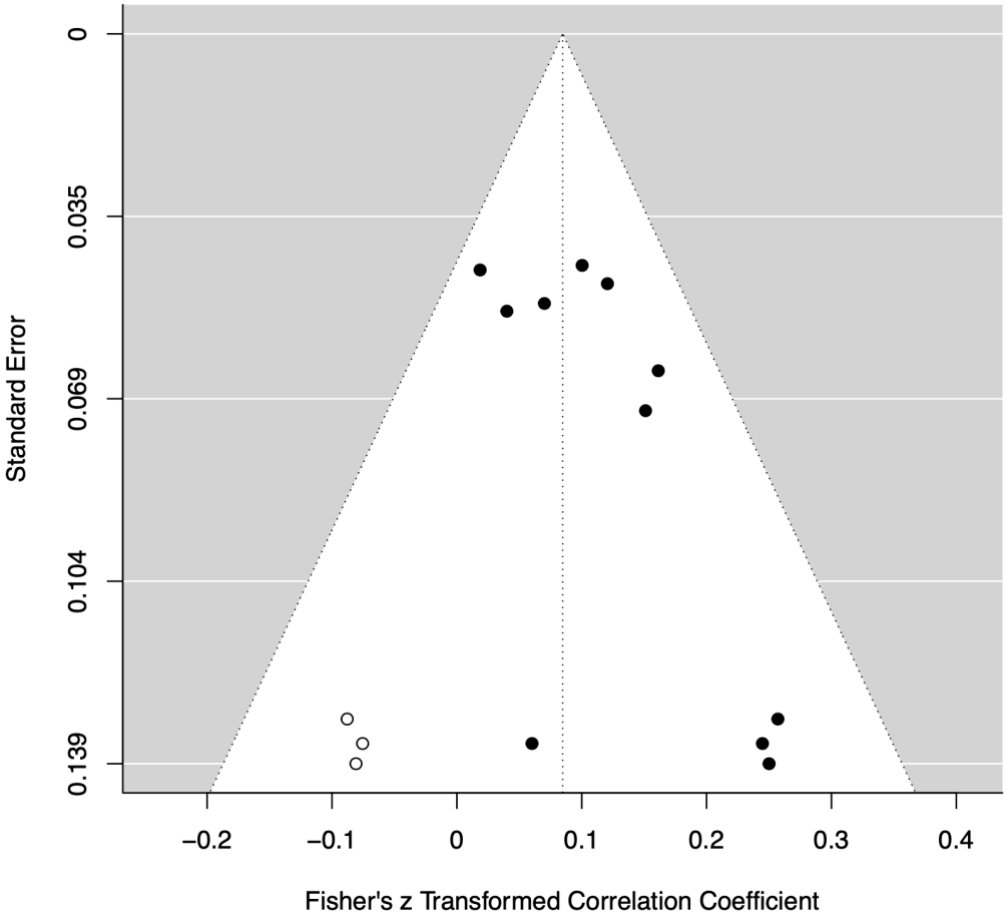
CI 0.27, 0.40], p <0.001), with a moderate correlation and with a large magnitude of heterogeneity which was smaller than the main analysis (Q[7] = 26.95, p <0.001, I^2 = 70.73%).

Associations between AC and NSSI

Figure 5

AC Forest and Funnel plots





Associations between AC scores and NSSI rates, revealed a weighted mean effect size of r=0.1, (95% CI-0.06-0.13), p<0.001, (see forest plot) highlighting a weak association. Cochran's Q-test (*Q* [10] =10.32, p=0.41) and the I squared statistic (4.69 %) indicated a negligible amount of heterogeneity. The regression for funnel plot asymmetry and Kendall's tau indicated significant evidence of publication bias $t(9) = 2.46$, $p = 0.036$; Kendall's $\tau = 0.478$, $p = 0.042$; Failsafe $N = 110$.

Subgroup analyses for AC-NSSI associations

The effect size in the subgroup of studies using the ACSS measure (k= 8; N= 1884) was similar to the main analysis and statistically significant with a weak correlation (r = 0.10, [95% CI 0.05, 0.15], p< 0.001) and with low levels of heterogeneity (*Q* [7] = 8.32, *p* = 0.305, I^2 = 18.88%).

The effect size in the subgroup of studies using non clinical samples (k=7; N=2077) was higher when compared to the main analysis and statistically significant (r = 0.65, [95% CI -0.23, 0.95], *p*= 0.003) indicating a strong correlation and with no significant heterogeneity, similar to the main analysis (Q[6] = 9.26, p = 0.160, I^2 = 37.69%).

The effect size in the subgroup of studies rated as having low risk of bias (k=7; N=1773) was similar to the main analysis and statistically significant (r = 0.12, [95% CI 0.07, 0.16], p < 0.001) and with no significant heterogeneity (Q[6] = 3.72, p= 0.714, I^2 = 0.00%).

Analysis of Publication Bias

Kendall's Tau demonstrated there was significant evidence of publication bias for the primary meta-analysis for AC. There was no significant evidence of publication bias for the primary meta-analysis for all other IPTS constructs. The failsafe N calculation for the hopelessness primary analysis showed 2398 studies with non-significant findings would be required to overturn the primary meta-analytic findings, 1197 studies with non-significant findings would be required to overturn the primary meta-analytic findings for TB and 2457 studies with non-significant findings would be required to overturn the primary meta-analytic findings for PB. Where the failsafe N value is high, this indicates even a large number of null studies are unlikely to significantly affect the statistical influence of meta-analysis results (Oswald & Plonsky 2010).

Discussion

Summary of Evidence

This systematic review and meta-analysis showed there were significant weak positive correlations between AC/TB and NSSI and a moderate significant positive correlation between PB and NSSI in adult populations. While hopelessness was not significantly associated with NSSI. There was a weak significant positive correlation for AC- NSSI (r=0.10), and all AC sub-study moderator analyses indicated significant positive correlations.

Although the primary meta-analysis for Hopelessness demonstrated no significant correlation between hopelessness and NSSI, the moderator analysis for studies rated as low risk of bias demonstrated a significant albeit weak correlation with NSSI (r=0.23). Moderator analyses for studies only using the BHS and clinical samples showed nonsignificant correlations with significant heterogeneity in agreement with the main analysis. The magnitude of correlations reported here are based on Cohen's guidelines (Cohen, 1992).

Methodological Issues

The primary meta- analysis for each IPTS construct demonstrated considerable heterogeneity. This can be attributed to several factors, including variations in measures and methodologies across the included studies. Despite conducting moderator analyses, significant and relatively large levels of heterogeneity persisted. Both NSSI and IPTS

constructs inherently exhibit variability, and these patterns are likely to change for individuals over the course of their lifespan (Kiekens et al. 2023). The literature suggests that other factors, such as adverse childhood experiences, impulsivity and individual differences in mental health status, may confound the observed effects of IPTS constructs on NSSI behaviours (Hird et al., 2022; Wu et al., 2023). When reviewing the quality of included studies, some explicitly accounted for confounders generally through the use of specific analyses. However, moderator meta-analysis focusing on specific quality ratings still exhibited high levels of heterogeneity.

Omitting the within- person nature of variability in IPTS and how this associates with NSSI behaviours could lead one to fall into Simpson's Paradox (Blythe, 1972). This occurs where between-person processes (for example higher scorers on hopelessness are more likely to enact NSSI behaviours) are expected to generalise within-person (for example if someone is feeling elevated levels of hopelessness compared to their own baseline, they are more likely to enact NSSI behaviours). Utilising longitudinal study designs enables adequate study of differences in between and within-person effects (Kuehn et al., 2022). However as aforementioned the majority of studies in this review used a cross-sectional design.

As outlined earlier, the USA accounted for the largest number of studies in this review conducted in one country (k=12). This has implications for the applicability and generalisability of findings due to the specificity of the cultural context, as well as aetiology of psychiatric disorders and presentations, and variations in healthcare practises in the USA. Furthermore, most included studies were conducted in the global West with a minimal number of studies conducted in East Asia. There is a lack of published research in the global South related to the topic of interest under review here. It may be more plausible

to suggest this research may not have been included due to exclusion of studies not published in the English language. When conducting a review, it is important to be cautious not to overly rely on geographically concentrated evidence bases (Davis et al. 2014; Delgado-Rodriguez. 2006).

Strengths and Limitations

This is the first review of its kind, examining associations between IPTS constructs and NSSI behaviours in adult populations. The review displays several features of good practice in systematic reviews; including preregistering the study on the open science framework prior to running searches, a well-defined and comprehensive search strategy with concise inclusion and exclusion criteria, forward and backward citation searches, searches including the grey literature, no limits on date of publication, risk of bias assessment independently rated, and a meta-analysis to quantitatively synthesise data.

Despite attempts to follow best practice the review was limited in that studies not published in the English language were excluded. Study designs such as feasibility, pilots and other designs where results were non-significant, may not have been published due to publishing bias, thus limiting insights into research in the area (Eldridge et al. 2016; Morgan et al. 2021). The search included grey literature in attempts to ensure most up to date data was included as it provides data that may not be found in scientific databases, additionally may provide insights into emerging research in the area of interest. Although the search included grey literature none of the studies in the final review were from the grey literature. The author notes the need for an emphasis to be made on critical appraisal as grey literature is often not peer reviewed and thus may be difficult to determine reliability of findings. The search included a vast number of studies making the screening

of studies more susceptible to bias and errors made due to fatigue. In future reviews this could be mitigated by screening studies with an independent researcher or research assistant. However, due to the lack of resources it was difficult to ascertain an independent researcher to aid with this process for the review at hand.

Additionally, as was apparent by the quality assessment of included studies not all studies were of a high quality thus restricting the robustness of data presented (Pigott & Polanin. 2020). Although moderator analyses were run for each construct considering study settings i.e. clinical or non-clinical, there was still considerable variability within sub-groups, which introduced degrees of heterogeneity limiting the applicability and generalisability of findings.

Not all included studies reported intensity or type of NSSI, some studies were limited to reporting just frequency of NSSI. Research demonstrates not only NSSI frequency but also the number of years engaging in NSSI behaviours across the lifespan are significant predictors of suicidal ideation, attempts and behaviours (Anestis et al. 2015; Assavedo & Anestis. 2016). Future reviews in which intensity, types and frequency of NSSI are investigated along with IPTS constructs would arguably provide greater insights into the associations being examined in this review.

As aforementioned this review focused on adult populations. However, research examining these associations in adolescent samples posit that the adolescent years are developmentally critical in being a predominant point of onset of NSSI behaviours. This has implications for engagement in NSSI behaviours throughout adulthood (Xu et al., 2024). Therefore, a future review examining these associations in an adolescent sample is

suggested as it will undoubtedly provide key insights with implications for research and practise.

The IPTS focuses on hopelessness regarding interpersonal states and although studies in the review were investigating associations between Hopelessness and NSSI. Studies included in the review examined hopelessness more broadly, not necessarily in relation to feeling hopeless about interpersonal states. It should be noted however that the two are not mutually exclusive for example, someone may consider themselves to be feeling hopeless because of increased feelings of TB or PB, or it could be a general sense of hopelessness at their circumstances which in turn results in increased TB or PB.

Inclusion criteria outlined studies could include either self or clinician reported measures. This decision was made to allow for in depth insights into associations between NSSI and IPTS constructs and acknowledging the various means by which IPTS constructs and NSSI rates can be measured. It was felt if either were excluded this would exclude significant data. Nonetheless it is noted in the meta-analysis it would be essential to differentiate between how the measure was reported, by conducting different meta-analyses for patient vs clinician reported, so as to not confound findings. This was not required as all studies in the meta-analyses were patient reported.

Implications for Clinical and Research Practise

NSSI is a growing public health concern internationally. Research into the precursors and factors leading to the enactment of NSSI behaviours can provide key insights into prevention and management. The meta-analysis and review at hand strengthens the idea that NSSI's have interpersonal correlates. The review sheds light on some moderate

positive correlations between AC/TB/PB and NSSI. The vast majority of studies are conducted on small specific samples, highlighting the need for studies on larger samples. As discussed earlier the heterogenous nature of NSSI's lends itself towards the need for research looking at specific samples considering cultural and clinical nuances in any given population. These findings have significant implications for psychiatric care (particularly in the context of assessment and treatment) by considering the influence of interpersonal states on NSSI. A suggested direction for future research may be to investigate the influence of confounding variables (such as mental health symptoms, cultural context, age, etc) on the relationship between IPTS constructs and NSSI.

This review adds to a growing literature base exploring relationships between interpersonal states and risks of NSSI and suicide. Having shed light on some moderate associations between certain IPTS constructs and NSSI, it begs the question as to what this means for clinical practise. It is argued here that mental health and suicide risk assessments should include an exploration of the IPTS constructs. This can be done by using clinical support tools which address questions around individuals fluctuating interpersonal states. Either using validated measures of IPTS constructs such as those cited in the studies included herein or as a narrative exploration with service users. Furthermore, regular monitoring of interpersonal states through routine outcome monitoring (ROM) can inform preventative interventions. Preliminary studies by Kyron et al (2020, 2023) and others demonstrate the usefulness of using ROM of interpersonal states to reduce the risk of self-harm and suicide, with promising findings.

Theoretical Implications

This review demonstrated positive correlations between TB/PB/AC and NSSI. Indicating increased feelings of thwarted belongingness or perceived burdensomeness are significantly associated with a higher likelihood of engaging in NSSI behaviours. One could speculate there may also be a case of NSSI influencing TB and PB for example if someone is ashamed of engaging in self-injury or the attention it gets from others this may cause them to feel a heightened sense of burdensomeness or isolation.

Furthermore, although this study reviewed correlates between NSSI and interpersonal states there are wider theoretical implications in terms of suicidal ideation. Joiner et al (2012) put forth how AC is linked with NSSI, demonstrating that PB/TB impact suicidal ideation directly but also influence the risk of suicide by increasing AC through NSSI behaviours. Hence it could be speculated that by proxy there is a correlation between TB/PB/AC and suicidal ideation also.

Conclusion

The results of this systematic review and meta-analysis demonstrate there are positive correlations between AC/TB/PB and NSSI behaviours, with PB having the strongest correlations out of the three. Hopelessness was found to have no significant correlation with NSSI behaviours, but the question is raised if this was due to the lens through which hopelessness was measured in included studies i.e. specifically in relation to interpersonal states or more broadly? Having noted these significant correlations, it is recommended for clinicians in mental health care to embed routine monitoring of AC/TB and PB when conducting risk assessments to inform preventative interventions. There is scope for further research exploring how NSSI may be correlated with the IPTS constructs whether this relationship is circular, unidirectional or bidirectional and future similar review

accounting for studies where hopelessness at one's interpersonal states are solely included.

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Appendices

Appendix A. PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	2
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	2/5-8
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	8-9
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	10
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	10
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	49
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	13
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	14
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	14
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	14
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	11
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	14
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	14
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data	33

Section and Topic	Item #	Checklist item	Location where item is reported
		conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	14
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	33
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	33
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	-
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	-
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	33
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	13
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	13
Study characteristics	17	Cite each included study and present its characteristics.	14
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	50
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	19-25
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	25-28
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	33-41
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	33-41
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	-
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	33-41
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	43
	23b	Discuss any limitations of the evidence included in the review.	44-46
	23c	Discuss any limitations of the review processes used.	44-46

Section and Topic	Item #	Checklist item	Location where item is reported
	23d	Discuss implications of the results for practice, policy, and future research.	46
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	9
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	9
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	9
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	47
Competing interests	26	Declare any competing interests of review authors.	47
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	-

Appendix B. Full Search Strategy

("*joiner* interpersonal theory of suicid" OR "joiner *model of suicid*" OR "interpersonal theory of suicid behav" OR "interpersonal-psychological theory of suciide" OR "burdensomeness" OR "hopeless" OR "*acquired means of suicide*" OR "acquired capability" OR "thwarted belong" AND "non-suicid" OR "suicid behav" OR "suicid-behav" OR "self-harm" OR "self-harm" OR "self injur" OR "self-injur" OR "NSSI" OR "*non suicidal self injur*" OR "non-suicid self-injur" OR "non fatal suicid behav" OR "ACS" OR "Acquired capability for suicide scale" OR "Interpersonal Needs Questionnaire" OR "INQ" OR "PHQ-9" OR "bhs" OR "Beck Hopelessness Scale" OR "Goldberg Depression Scale" OR "DSI-SS" OR "psychiatric Symptom Frequency Scale" OR "PSFS" OR "SSS" OR "Schuster Social Support" OR “SDQ” OR “Strengths and difficulties questionnaire” OR “self-injurious thoughts and behav interview” OR “SITBI” OR “Deliberate self-harm inventory” OR “DSHI” OR ”perceived mastery scale” OR “youth risk behaviour survey questionnaire” OR “GSHS” OR “Paykel suicide scale” OR “PSS” OR “Suicide behaviour questionnaire revised” OR “Beck scale for suicide ideation

Appendix C- Narrative description of Main statistical findings

Study Identifier (First Author, Year)	Narrative Summary of Key Statistical Findings examining associations between IPTS Constructs and NSSI
Assavedo (2015)	Results indicated a significant positive correlation between NSSI frequency and TB (r=0.27, p<0.01) at the zero-order level. Additionally, NSSI frequency was significantly and positively correlated with PB (r=0.24, p<0.01) at the zero-order level. Amongst those with a prior history of NSSI but no suicidal behaviour, NSSI frequency was significantly associated with both TB (r = 0.24; p = 0.002) and PB (r = 0.16; p = 0.03). Amongst those with a history of both NSSI and suicidal behaviour, NSSI frequency was not significantly associated with TB (r = 0.17; p = 0.12) or PB (r = 0.06; p = 0.60).
Baer (2018)	Participants endorsing a history of NSSI reported significantly greater TB, U = 1384.5, z = 2.32, p = .020, d = 0.43, and AC, t (119) = 2.86, p = .005, d = 0.52, but did not report significantly greater PB, U = 1487, z = 1.78, p = .076, d = 0.33, than those without past NSSI.
Baralla(2021)	Descriptives: 26.6% declared a DSH episode in their lifetime, with an age of onset of DSH ranging from 18 to 57 years, M = 29; SD = 8.65). The univariate log-binomial regression demonstrated hopelessness significantly predicted the risk of DSH behaviours. PR=2.91 (95% CI [1.39-6.11]), p<0.01. The multivariate log-binomial regression demonstrated no significant relationship between Hopelessness score and the risk of DSH behaviours: PR adj.= 2.01 (95%CI [0.95- 4.22], p= non sig.
Boffa (2023)	Descriptives: Past 2-week frequency of NSSI ranged from 0 to 13 times (M = 0.40, SD = 1.83). Total instances of NSSI during the previous 2 weeks evidenced positive skew (skew = 6.18, SE = .31) and kurtosis (kurtosis = 41.02, SE = .62) because most participants (89.7%) reported zero instances of NSSI, resulting in all nonzero cases (n = 6) being outliers. Log transforming this variable did not eliminate skew (skew = 4.17, SE = .31) and kurtosis (kurtosis = 18.73, SE = .62), and the pattern of results was the same regardless of whether the transformed variable was used. Bivariate correlations showed no significant correlation between previous 2-week frequency of NSSI and ACSS-FAD score, r= 0.24, p=non sig

Burke (2018)	Within the study 4 subgroups were created namely: suicide ideation, suicide plan, suicide attempt without intent and suicide attempt with intent, analyses indicated significant differences on NSSI frequency by suicide status, p<0.001, Pairwise comparisons revealed that all groups were significantly different from each other (all ps < .001,ds= 0.68 –1.50), with the exception of those who reported a suicide attempt without an intent to die and those with a suicide plan (p=0.75).Results demonstrated a significant positive correlation between NSSI frequency and ACS score, r=0.1,p<0.05, the ACS FAD subscale had no significant correlation with NSSI frequency, r=0.5, p=not sig.
Burke (2016),USA	In the study there were significant positive weak associations between ACS, TB, PB and NSSI frequency. ACS r (447) =0.12, p<0.05 , TB r (447)=0.27,p<0.05, PB r (447)=0.28, p<0.05
Campos Rui (2021)a	Portugese Sample: NSSI-PB r (384) = 0.41, P<0.001, NSSI-TB r (384)=0.29,P<0.001, NSSI-ACS r(384)=0.07- not sig Canadian Sample: NSSI-PB r (247) =0.38,p<0.001, NSSI-TB r (247)=0.31,p<0.001, NSSI-ACS r(247)=0.16,p<0.05
Campos, Rui (2021)b	Portuguese Sample, SHB significantly correlated with thwarted belongingness, $r(412) = .29$, $p < .001$, and with perceived burdensomeness, $r(412) = .46$, $p < .001$ American Sample, SHB showed a significant correlation with thwarted belongingness, $r(288) = .12$, $p < .05$, and with perceived burdensomeness, $r(288) = .32$, $p < .001$
Chang (2024)	Descriptives: n= 62 (13.1%) of the sample required medical attention for NSSI, mean number of perceived likelihood of future NSSI was 1.45 SD-1.38, Mean NSSI duration in years was 6 SD4.71, and the mean number of NSSI methods used was 3.76 SD 2.24, the mean NSSI age of onset was 14.11 SD 3.34, with a mean lifetime NSSI frequency of 90.98 SD545.44, mean scores on IPTS constructs were PB- 16.31(9.75 SD), TB- 34.211 (SD 12.90) and mean ACS 14.65 (SD 7.11), for the analysis three groups (classes) were created "lower NSSI", "moderate NSSI" and "higher NSSI" with an entropy for the model of 0.89, suggesting a high accuracy of NSSI class assignment the lower NSSI group consisted of n=299 (63.2%), moderate n=147 (31.1%) and higher n- 27 (5.7%), classes were based on number of NSSI methods used, lifetime frequency of NSSI , duration of NSSI and age of onset. For gender, the model was significant, $\chi2$ (4) = 16.39, p = .003, φ = 0.13. Follow-up z-tests indicated that cisgender men were more likely to be in the lower NSSI class (34.8%) compared to the moderate NSSI class (20.4%). Cisgender women were more likely to be in the moderate NSSI class (57.1%) compared to the lower

	NSSI class (46.5%). TGD individuals were more likely to be in the higher NSSI class (40.7%) than the moderate (22.5%) or lower (18.7%) NSSI classes. For race/ethnicity, the model was not significant, χ2 (10) = 8.51, p = .579. NSSI class membership did not differ based on a person's race/ethnicity. For sexual orientation, the model was not significant, χ2 (2) = 4.05, p = .132. NSSI class membership did not differ based on a person's sexual orientation. there was a significant multivariate effect of NSSI class on ITS constructs, F(6, 936) = 6.08, p < .001, η2 = 0.04. The higher NSSI class did not differ from the moderate or lower NSSI classes for any ITS constructs (ps ranged from .563 to .975). However, the lower NSSI class had lower perceived burdensomeness than the moder- ate NSSI class (p < .001, d = 0.66 [moderate effect]). Also, the lower NSSI class had lower thwarted belongingness than the moderate NSSI class (p = .035, d = 0.57 [moderate effect]). There were no differences across NSSI classes for ACS. A significant difference was found across NSSI groups in terms of perceived burdensomeness, F(2, 470) = 16.71, p < .001, η² = .07. This indicates that 7% of the variance in perceived burdensomeness is explained by the NSSI groups. The Moderate NSSI group (M = 19.89, SD = 10.84) reported significantly higher levels of perceived burdensomeness compared to the Lower NSSI group (M = 14.44, SD = 8.59). The Higher NSSI group (M = 17.63, SD = 10.39) also had higher levels of perceived burdensomeness compared to the Lower NSSI group, but there were no significant differences between the Moderate and Higher NSSI groups. There was also a significant effect of NSSI group on thwarted belongingness, F(2, 470) = 3.36, p = .036, η² = .01. This suggests that 1% of the variance in thwarted belongingness is attributable to the NSSI group. The Moderate NSSI group (M = 36.32, SD = 13.41) reported significantly higher levels of thwarted belongingness compared to the Lower NSSI group (M = 33.05, SD = 12.70). No significant differences were observed between the Higher NSSI group (M = 35.59, SD = 11.00) and the other groups.no significant group differences were found for acquired capability for suicide, F(2, 470) = 2.40, p = .092, η² = .01. Although the means indicated that the Higher NSSI group (M = 16.00, SD = 5.94) had slightly higher acquired capability scores compared to the Lower NSSI group (M = 14.12, SD = 7.08) and Moderate NSSI group (M = 15.50, SD = 7.31), these differences were not statistically significant.
Chapman (2024)	The t test revealed a statistically significant difference in hopelessness between the NSSI and no NSSI group t=2.50, p>0.01,d= 0.49, A binomial logistic regression was conducted to assess the impact of hopelessness score on the likelihood of NSSI. The regression coefficient for hopelessness was B=0.04, with an odds ratio (OR) of 1.04 (95% CI [0.94, 1.16]). The Wald test statistic was 0.64, and the p-value was 0.42, indicating that the effect of hopelessness on the likelihood of NSSI was not statistically

	significant. A Pearson product-moment correlation was conducted to assess the relationship between hopelessness and NSSI. The results indicated a weak negative correlation r(49)=-0.06
Chu (2016)	Findings indicated a significant positive relationship between lifetime NSSI frequency and TB (Time 1: r = 0.33, p = 0.021) and PB (Time 1: r = 0.41, p = 0.004; Time 3: r = 0.32, p = 0.037); no significant relationship emerged at other time points (p > 0.80). NSSI frequency in the last year was only significantly related to PB (Time 1: r = 0.40, p = 0.004; Time 2: r = 0.39, p = 0.012; Time 3: r = 0.44, p = 0.004) and not related to TB at any time point.
Cleare (2021)	Univariate binary logistic regressions were conducted to examine the relationship between TB/PB/ACS and the likelihood of NSSI. ACS: OR =1.07, 95% CI=1.03-1.11, TB: OR=1.07, 95% CI= 1.04-1.10, PB: OR=1.07, 95% CI= 1.05-1.09.
Gratz (2020)	Sub study 1: Descriptives- 23% of participants reported NSSI history. Participants with NSSI reported an average of 84.62 (SD = 211.78) lifetime acts of NSSI (three outliers were removed in calculating this statistic) and an average of 1.76 (SD = 1.17) different NSSI behaviours. NSSI frequency was found to have a skewness of 19.10, following log-transformation the NSSI frequency variable approximated a normal distribution, skewness =3.0, a Pearson correlation analysis revealed no significant correlation between ACS and NSSI frequency: r(363)= -0.04,p= not significant. Similarly the logistic regression demonstrated lifetime frequency of NSSI was not significantly associated with ACS: β=-0.358 (p =0.505), in sub study 2 the Pearson correlation analysis demonstrated a significant correlation between NSSI frequency and ACS r(198)= 0.15,p<0.05,
Gray (2020)	Mean Score for BHS: 4.8, SD- 5.1, mean score for hopelessness IAT: -0.33, SD-0.48, percentage of people reporting past NSSI- 60.3% none, 6.2% once, 11.2% two to four, 10.1%, five to ten, 12% more than ten times, current NSSI: 89.1 % none, 4.9% once, 4.9% two to four, 0.7%, five to ten, 0.4% more than ten times. Correlations: there was a significant positive correlation between past NSSI and BHS score: r= 0.32, p<0.01, as well as current NSSI and BHS score: r= 0.26, p<0.01. There was also a significant positive correlation between past NSSI and hopelessness IAT r= 0.14, p<0.05, and current NSSI and hopelessness IAT r= 0.15, p<0.05. There was no significant correlation between low NSSI and BHS score- ρ= 0.18, p<0.05-
Gu (2020)	n= 154 had engaged in NSSI, Mean Hopelessness score in NSSI group- 1.42, SD- 0.32. There was a significant moderate positive correlation between hopelessness and NSSI, r=0.32, p<0.001

Gu (2023)	3 classes of NSSI were identified, class 1 "high NSSI class", class 2 "moderate NSSI class", class 3 "no or negligible NSSI class" classes were characterised by probability of endorsement of different kinds of NSSI behaviours e.g. biting, cutting etc. Hopelessness significantly predicted class membership based on NSSI, compared to members in the. no or negligible NSSI class individuals with high hopelessness were more likely to be in the moderate NSSI class OR =4.62, 95% CI: 1.96-10.91, p<0.001, or high NSSI class OR=45.18, 95%CI:9.23–221.19, p<0.001. Individuals who had high hopelessness were more likely than those in the low hopelessness group to be in the high NSSI group OR=9.77, 95% CI- 1.75–54.70, P<0.01 as compared with moderate NSSI class.
Kyron (2023)	Descriptives: 62.6% of patients engaged in NSSI on one occasion whilst in hospital, 19.5% on two occasions, 17.9% on three or more occasions, with a total of 2274 NSSI events. At the individual level the DSEM and MSEM models showed no significant associations between IPTS constructs and same day or next day NSSI: Same day NSSI- PB β=0.00, SE=0.03, 95% CI [-0.06, 0.06], p=non sig, same day NSSI-TBβ=0.00, SE=0.024, 95% CI [-0.04, 0.05], p=non sig, same day NSSI- hopelessness β=0.05, SE=0.029, 95% CI [-0.01, 0.11], p=non sig. Next day NSSI -PB β=-0.01, SE=0.027, 95% CI [-0.06, 0.05, p=non sig, Next day NSSI-TB β=0.01, SE=0.024, 95% CI [-0.04, 0.05], p=non sig, next day NSSI- Hopelessness β=0.02, SE=0.028, 95% CI [-0.03, 0.08], p=non sig.
Kyron (2020)	Descriptives n=219 people enacted NSSI behaviours. Bivariate correlations demonstrated PB significantly predicted next day self-harm (β = 1.07, 95% CI =1.01 – 1.13, p = .015), TB did not significantly predict next day self-harm (β = 1.01, 95% CI =0.97 – 1.06, p =non sig)
Larkin (2013)	At baseline BHS scores were not normally distributed, a Mann-Whitney U test was conducted to compare BHS scores between cutting group (n = 5) and the overdose group (n = 21). The results revealed a significant difference between the two groups, p = 0.04. the cutting Group had a median score of 14 (IQR = 7-16.8), whereas the overdose group had a median score of 5.5 (IQR = 3-13.50). The effect size was r = -0.39, indicating a medium effect size. a Mann Whitney U test was conducted to compare scores between BHS scores for prospective repeat and non-repeat self-harmers, the results approached a significance difference between the two groups p=0.13, the repeat self-harm group(n=5) had a median score of 13.5 (IQR 7-17.5), whereas the non-repeat self-harm group (n=14) had a median score of 6 (IQR 3.75-15.25). With an effect size of r=-0.36, indicating a medium effect size.

Marco, Jose (2015)	During 1 year follow up 38.8 %, n=26, of participants engaged in NSSI (M=2, 82; SD=6.97), with a range from 1 to 40. Hopelessness was not significantly correlated with NSSI at follow up: r=0.13, p= not sig. variance inflation factors were calculated for all predictors in the regression model, none were above 10 therefore no multicollinearity was detected. Overall the regression model significantly accounted for 18% of variance in NSSI frequency at follow up (R2=0.18, t(61,5)=2.64, p<0.05), however hopelessness score at baseline was not a significant predictor of NSSI frequency at follow up: B= -0.147, SEB=0.266, β=-0.117, t(-0.552),p=0.583
Moseley (2022)	Descriptives, 72.6% of the sample had lifetime history of NSSI, 36.3% enacted NSSI behaviours over the last two years, 8.8% between 1-2 years ago, 6.6% between 6 months to 1 year ago, 13.6% between 1 and 6 months ago, 34% in the last 4 weeks, Average score on ACWRSS 29.9, SD- 13.2 range, 0-56.
Newman (2007)	descriptives: 31% of the sample scored above 15 on BHS, 65.1% had previous parasuicide events, methods of parasuicide: 83.9% overdose, 11.6% cutting/piercing, 4.6% other. In the univariate model BHS score of 15 or greater was a significant predictor of parasuicide: OR 21.6, 95% CI (7.9-59.1), p<0.001, similarly in the multivariate model BHS score of 15 or greater was a significant predictor of parasuicide: OR 9.4 , 95% CI (3.2-27.8), p<0.001
O'Connor (2000)	The parasuicides differed significantly from the hospital controls on measures of hopelessness, whereby increased hopelessness was significantly associated with parasuicide (F (1,36) =13.75,p= 0.001)
Perez Rodriguez (2017)	There were statistically significant differences in hopelessness scores between groups, (K-W(2) = 21.92, ηp 2 = .20, p< =.001) with higher hopelessness in the NSSI group p=0.003 compared to those with no NSSI or Suicide Attempt
Rimkeviciene(2015)	In the community sample the correlation between the ACSS 20 -item and self-harm was r=0.05, 7 item ACSS-FAD and self-harm was r=0.07, in the clinical sample the correlation between the ACSS 20 item and self-harm was r= 0.21, 7 item ACSS-FAD and self-harm was r=0.27 and in the combined samples the correlation between the 20 item ACSS and self-harm was r=0.16 and 7-item ACSS FAD and self-harm was r= 0.15.
Shi (2022)	Hopelessness at baseline was significantly positively correlated with NSSI at baseline: r= 0.16, p<0.001. The univariate regression model demonstrated that hopelessness score at T1 was a significant predictor

	of NSSI: OR 2.11, 95% CI (1.87-2.39), P<0.05 , the multivariate regression model also demonstrated Hopelessness is significantly associated with NSSI : OR 1.52, 95% CI (1.29-1.78), P<0.05
Simms (2007)	Descriptives: 51.5% of the sample had engaged in previous self-harm, mean frequency of self-harm acts was 3.0 (SD=1.837, range 1-7). There were no significant differences in hopelessness score between the self-harm and no self-harm group (Z=-0.797, p = 0.426) Patients in the study who experienced auditory hallucinations and engaged in self-harm acts had significantly higher levels of hopelessness than those who experience auditory hallucinations with no history of self-harm: (z= -2.085, p =0.037) with a mean Hopelessness score of 9.2
Sorgi-Wilson (2022)	Descriptives: n= 473, 34.85% of sample reported lifetime history of NSSI, the NSSI group had higher proportions of females, (residual=3.98, p<0.001), as well as white (residual=3.25, p=0.001) There was a significant positive correlation between TB and NSSI r=0.440 as well as between PB and NSSI , r= 0.713. The group with NSSI history scored significantly higher than the non NSSI history group on PB and TB items.
Tham Su-Gwan (2020)	Descriptives: Self harm history n=16039, There was a significant positive correlation between hopelessness at last contact with MH services and history of self-harm: r=0.0726, n= 22591, SE= 0.0132, p<0.001
Tsujii (2020)	Descriptives: Total mean Hopelessness score 11.98 (SD 5.14) Incidence of first subsequent self-harming episode per person per year not significantly associated with hopelessness score, HR per 1-point increase in BHS score, 1.02; 95%CI, 0.98–1.05; P = 0.38, the number of overall self-harm episodes per person per year were significantly associated with hopelessness score IRR per 1-point increase in BHS score, 1.05; 95%CI, 1.03–1.07; P < 0.001, similarly there was a significant association between total hopelessness score and the number of NSSI episodes per person per year (IRR per 1-point increase in BHS score, 1.05; 95%CI, 1.03–1.07; P < 0.001).
Willoughby (2015)	Descriptives Time 1, 20.9% of the 782 participants indicated that they had engaged in NSSI at some point during their lifetime but not in the past year, 3.9% of the participants indicated that they engaged in NSSI once in the past year, 4.3% engaged in NSSI 2– 4 times, 2.1% engaged in NSSI 5–10 times, 1.6% engaged in NSSI 11–50 times, 0.4% engaged in NSSI 51–100 times, and 0.3% engaged in NSSI more than 100 times. At Time 2, 26.0% of the participants indicated that they had engaged in NSSI during their lifetime but not in the

	past year, 2.8% of the participants indicated that they engaged in NSSI once in the past year, 2.2% engaged in NSSI 2– 4 times, 1.5% engaged in NSSI 5–10 times, 1.1% engaged in NSSI 11–50 times, 0.3% engaged in NSSI 51–100 times, and 0.4% engaged in NSSI more than 100 times. Model fit was good, 2 (1) 1.383, p 0.240, CFI =1.000, RMSEA =0.022 (.000.101). The results of the path analyses indicated that higher frequency of past year engagement in NSSI significantly predicted higher levels of acquired capability for suicide over time, B=0.066, SE=0 .044, p= 0.029. This relationship was not found to be bidirectional; that is, higher levels of acquired capability for suicide did not predict NSSI over time, B= 0.010, SE =0.015, p = 0.667.
Yamokoski (2011)	Descriptives: The mean number of self-harm incidents was 3.45, SD5.53, the mean score on the hopelessness scale was 9.73, SD 6.22. There was a significant positive correlation between hopelessness score and Self harm r= 0.37, p<0.01

Appendix D. CASP Tools Used

CASP Checklist:
For Descriptive/Cross-Sectional Studies

Reviewer Name:	
Paper Title:	
Author:	
Web Link:	
Appraisal Date:	

During critical appraisal, never make assumptions about what the researchers have done. If it is not possible to tell, use the "Can't tell" response box. If you can't tell, at best it means the researchers have not been explicit or transparent, but at worst it could mean the researchers have not undertaken a particular task or process. Once you've finished the critical appraisal, if there are a large number of "Can't tell" responses, consider whether the findings of the study are trustworthy and interpret the results with caution.

1

Section A: Are the results valid?	
1. Did the study address a clearly focused issue?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *A question can be 'focused' in terms of* • *the population studied* • *the risk factors studied* • *is it clear whether the study tried to detect a beneficial or harmful effect* • *the outcomes considered*	
2. Did the authors use an appropriate method to answer their question?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *Is a descriptive/cross-sectional study an appropriate way of answering the question* • *did it address the study question*	
3. Were the subjects recruited in an acceptable way?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *We are looking for selection bias which might compromise the generalisability of the findings:* • *Was the sample representative of a defined population* • *Was everybody included who should have been included*	
4. Were the measures accurately measured to reduce bias?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *Look for measurement or classification bias:* • *did they use subjective or objective measurements* • *do the measurements truly reflect what you want them to (have they been validated)*	
5. Were the data collected in a way that addressed the research issue?	☐ Yes ☐ No ☐ Can't Tell

CONSIDER: • *if the setting for data collection was justified* • *if it is clear how data were collected (e.g., interview, questionnaire, chart review)* • *if the researcher has justified the methods chosen* • *if the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews were conducted?)*	
6. Did the study have enough participants to minimise the play of chance?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *if the result is precise enough to make a decision* • *if there is a power calculation. This will estimate how many subjects are needed to produce a reliable estimate of the measure(s) of interest.*	
7. How are the results presented and what is the main result?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *if, for example, the results are presented as a proportion of people experiencing an outcome, such as risks, or as a measurement, such as mean or median differences, or as survival curves and hazards* • *how large this size of result is and how meaningful it is* • *how you would sum up the bottom-line result of the trial in one sentence*	
8. Was the data analysis sufficiently rigorous?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *if there is an in-depth description of the analysis process* • *if sufficient data are presented to support the findings*	
9. Is there a clear statement of findings?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *if the findings are explicit* • *if there is adequate discussion of the evidence both for and against the researchers' arguments* • *if the researchers have discussed the credibility of their findings* • *if the findings are discussed in relation to the original research questions*	
10. Can the results be applied to the local population?	☐ Yes ☐ No ☐ Can't Tell

CONSIDER: • *the subjects covered in the study could be sufficiently different from your population to cause concern.* • *your local setting is likely to differ much from that of the study*

11. How valuable is the research?	☐ Yes ☐ No ☐ Can't Tell

CONSIDER: • *one descriptive/cross-sectional study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making* • *if the researcher discusses the contribution the study makes to existing knowledge (e.g., do they consider the findings in relation to current practice or policy, or relevant research-based literature?)* • *if the researchers have discussed whether or how the findings can be transferred to other populations*

APPRAISAL SUMMARY: *List key points from your critical appraisal that need to be considered when assessing the validity of the results and their usefulness in decision-making.*		
Positive/Methodologically sound	**Negative/Relatively poor methodology**	**Unknowns**

CASP Checklist:
For case control studies

Reviewer Name:	
Paper Title:	
Author:	
Web Link:	
Appraisal Date:	

During critical appraisal, never make assumptions about what the researchers have done. If it is not possible to tell, use the "Can't tell" response box. If you can't tell, at best it means the researchers have not been explicit or transparent, but at worst it could mean the researchers have not undertaken a particular task or process. Once you've finished the critical appraisal, if there are a large number of "Can't tell" responses, consider whether the findings of the study are trustworthy and interpret the results with caution.

Section A: Are the results of the study valid?	
1. Did the study address a clearly focused issue?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *An issue can be 'focused' In terms of* • *the population studied* • *whether the study tried to detect a beneficial or harmful effect* • *the risk factors studied*	
2. Did the authors use an appropriate method to answer their question?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *is a case control study an appropriate way of answering the question under the circumstances* • *did it address the study question*	
3. Were the cases recruited in an acceptable way?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *We are looking for selection bias which might compromise validity of the findings* • *are the cases defined precisely* • *were the cases representative of a defined population (geographically and/or temporally)* • *was there an established reliable system for selecting all the cases* • *are they incident or prevalent* • *is there something special about the cases* • *is the time frame of the study relevant to disease/exposure* • *was there a sufficient number of cases selected* • *was there a power calculation*	
4. Were the controls selected in an acceptable way?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *We are looking for selection bias which might compromise the generalisability of the findings* • *were the controls representative of the defined population (geographically and/or temporally)* • *was there something special about the controls* • *was the non-response high, could non-respondents be different in any way* • *are they matched, population based or randomly selected* • *was there a sufficient number of controls selected*	

5. Was the exposure accurately measured to minimise bias?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *We are looking for measurement, recall or classification bias* • *was the exposure clearly defined and accurately measured* • *did the authors use subjective or objective measurements* • *do the measures truly reflect what they are supposed to measure (have they been validated)* • *were the measurement methods similar in the cases and controls* • *did the study incorporate blinding where feasible* • *is the temporal relation correct (does the exposure of interest precede the outcome)*	
6. a) Aside from the exposure, did the groups have similar characteristics?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *List the ones you think might be important, that the author may have missed* • *genetic* • *environmental* • *socio-economic*	
6 b) Have the authors taken account of the potential confounding factors in the design and/or in their analysis?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors*	
Section B: What are the results?	
7. Was the treatment effect large?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *what are the bottom-line results* • *is the analysis appropriate to the design* • *how strong is the association between exposure and outcome (look at the odds ratio)* • *are the results adjusted for confounding, and might confounding still explain the association* • *has adjustment made a big difference to the OR*	
8. Was the estimate of the treatment effect precise?	☐ Yes ☐ No ☐ Can't Tell

CONSIDER: • *size of the p-value* • *size of the confidence intervals* • *have the authors considered all the important variables* • *how was the effect of subjects refusing to participate evaluated*	
9. Do you believe the results?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *big effect is hard to ignore!* • *can it be due to chance, bias, or confounding* • *are the design and methods of this study sufficiently flawed to make the results unreliable* • *consider Bradford Hills criteria (e.g. time sequence, does-response gradient, strength, biological plausibility)*	
Section C: Will the results help locally?	
10. Can the results be applied to your patients/the population of interest?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *the subjects covered in the study could be sufficiently different from your population to cause concern* • *if your local setting is likely to differ much from that of the study* • *can you quantify the local benefits and harms*	
11. Do the results of this study fit with other available evidence?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *all the available evidence from RCT's Systematic Reviews, Cohort Studies, and Case Control Studies as well, for consistency*	

Remember One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making. However, for certain questions observational studies provide the only evidence. Recommendations from observational studies are always stronger when supported by other evidence.

APPRAISAL SUMMARY: *List key points from your critical appraisal that need to be considered when assessing the validity of the results and their usefulness in decision-making.*		
Positive/Methodologically sound	**Negative/Relatively poor methodology**	**Unknowns**

CASP Checklist:
For Cohort Studies

Reviewer Name:	
Paper Title:	
Author:	
Web Link:	
Appraisal Date:	

During critical appraisal, never make assumptions about what the researchers have done. If it is not possible to tell, use the "Can't tell" response box. If you can't tell, at best it means the researchers have not been explicit or transparent, but at worst it could mean the researchers have not undertaken a particular task or process. Once you've finished the critical appraisal, if there are a large number of "Can't tell" responses, consider whether the findings of the study are trustworthy and interpret the results with caution.

Section A: Are the results valid?	
1. Did the study address a clearly focused issue?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *A question can be 'focused' in terms of* • *the population studied* • *the risk factors studied* • *is it clear whether the study tried to detect a beneficial or harmful effect* • *the outcomes considered*	
2. Was the cohort recruited in an acceptable way?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *Look for selection bias which might compromise the generalisability of the findings:* • *was the cohort representative of a defined population* • *was there something special about the cohort* • *was everybody included who should have been*	
3. Was the exposure accurately measured to minimise bias?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *Look for measurement or classification bias:* • *did they use subjective or objective measurements* • *do the measurements truly reflect what you want them to (have they been validated)* • *were all the subjects classified into exposure groups using the same procedure*	
4. Was the outcome accurately measured to minimise bias?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *Look for measurement or classification bias:* • *did they use subjective or objective measurements* • *do the measurements truly reflect what you want them to (have they been validated)* • *has a reliable system been established for detecting all the cases (for measuring disease occurrence)* • *were the measurement methods similar in the different groups* • *were the subjects and/or the outcome assessor blinded to exposure (does this matter)*	
5. (a) Have the authors identified all important confounding factors?	☐ Yes ☐ No ☐ Can't Tell

CONSIDER: • *list the ones you think might be important, and ones the author missed*	
b) Have they taken account of the confounding factors in the design and/or analysis?	☐Yes ☐ No ☐ Can't Tell
CONSIDER: • *look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors*	
6. a) Was the follow up of subjects complete enough?	☐Yes ☐ No ☐ Can't Tell
CONSIDER: • *the persons that are lost to follow-up may have different outcomes than those available for assessment* • *in an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort*	
b) Was the follow up of subjects long enough?	☐Yes ☐ No ☐ Can't Tell
CONSIDER: • *the good or bad effects should have had long enough to reveal themselves*	
Section B: What are the results?	
7. What are the results of this study?	☐Yes ☐ No ☐ Can't Tell
CONSIDER: • *what are the bottom line results* • *have they reported the rate or the proportion between the exposed/unexposed, the ratio/rate difference* • *how strong is the association between exposure and outcome (RR)* • *what is the absolute risk reduction (ARR)*	
8. How precise are the results?	☐Yes ☐ No ☐ Can't Tell
CONSIDER:	

• *look for the range of the confidence intervals, if given*	
9. Do you believe the results?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *big effect is hard to ignore* • *can it be due to bias, chance or confounding* • *are the design and methods of this study sufficiently flawed to make the results unreliable* • *Bradford Hills criteria (e.g. time sequence, dose-response gradient, biological plausibility, consistency)*	
Section C: Will the results help locally?	
10. Can the results be applied to the local population?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *Is a cohort study the appropriate method to answer this question* • *If the subjects covered in this study could be sufficiently different from your population to cause concern* • *If your local setting is likely to differ much from that of the study* • *If you can quantify the local benefits and harms*	
11. Do the results of this study fit with other available evidence?	☐ Yes ☐ No ☐ Can't Tell
12. What are the implications of this study for practice?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *one observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making* • *for certain questions, observational studies provide the only evidence* • *recommendations from observational studies are always stronger when supported by other evidence*	

APPRAISAL SUMMARY: *List key points from your critical appraisal that need to be considered when assessing the validity of the results and their usefulness in decision-making.*		
Positive/Methodologically sound	**Negative/Relatively poor methodology**	**Unknowns**

Appendix E- Summary of quality ratings for included studies

Study Identifier	Is the design valid	Methodologically sound	Results	Applicability of results	Comments on quality appraisal
Assavedo (2015)	Y	S	Y	S	clearly defined research question, appropriate study design, however longitudinal design would allow for causal inferences to be made, large sample size indicates statistical power, however sample was predominantly female reducing generalisability, appropriate statistical analyses used with results aligned to extant literature, limited applicability due to less variance in sample and specificity of population studied. Some useful implications for clinical practise.
Baer (2018)	Y	S	Y	S	clearly defined question, No power calculation or confidence intervals reported, validated measures, no confounding variables mentioned- however the analysis accounts for this , as the study was carried out on a sample of veterans results are not more widely applicable however explain enough detail for that population
Baralla (2021)	Y	S	Y	S	clearly defined question, appropriate sample with decent sample size, validated measures , convenience sampling introduces potential selection bias, certain confounding variables were accounted for via the analysis however other confounding variables potentially associated with trauma have been missed dichotomisation of variables =moderate loss of info.

Boffa (2023)	Y	S	Y	N	clearly defined question, validated measures, analysis accounted for confounding variables, longitudinal design would possibly have been more appropriate, cannot apply data to a wider sample due to nature of study aims and cross sectional design/ small sample size
Burke (2018)	Y	S	Y	S	Specific population therefore not generalisable to other populations eg, clinical samples, controlled for several confounding variables but others such as MH history/diagnoses not included, validated measures used to investigate variables.
Burke (2016)	Y	S	Y	S	validated measures used, convenience sampling can introduce selection bias, self-report measures can introduce desirability effects and recall bias, results , controls for confounders in analysis but some may be missed
Campos Rui (2021)a	Y	S	Y	S	Each sample used different means to complete the measures, one being online and one in person, there was a significant difference in the gender proportions in each sample, validated measures self-report- potential biases of recall and desirability, convenience sampling therefore potential for selection bias. Bootstrapping of data used due to non-normal distribution. the analysis accounted for confounding variables to an extent i.e. comments on loading of certain variables. results cannot necessarily be applied to general population due to specificity of samples, both were non clinical therefore lack of generalisability. cross sectional design limits causal inferences.
Campos Rui (2021)b	Y	S	Y	S	study design appropriate for what was being studied also allows for wider applicability of the study, different recruitment strategies used- American sample via social media and Portuguese sample via a different medium- amazon

					link mTurk, the Portuguese sample was reimbursed for participation and the American sample were not, bootstrapping used for variables that were not normally distributed contributing to internal validity. cross sectional design limits causal inferences.
Chang (2024)	Y	S	Y	S	Validated measures used, SD for lifetime NSSI frequency seemed abnormally high? Participants received compensation for completing baseline $3.25, 1 month f/u-$1.62 and 2 months f/u-$0.54 assessments with participants who. Completed all three receiving a $1 bonus. validated self-report measures used.
Chapman (2024)	Y	N	Y	S	Clearly defined question, longitudinal design would potentially be more appropriate, no incentives for taking part and participation did not affect treatment both of which reduce bias, no inter rater reliability for interviews used within the study, validated measures however self-report measures introduce bias such as recall or underreporting. cross sectional design limits causal inferences.
Chu (2016)	Y	S	Y	S	Clearly defined aims and appropriate study design utilised, small sample study not powered enough to make causal links, paper does not provide details on timescales simply that data were collected at three time points making it difficult to replicate the study. non clinical sample therefore not generalisable to general public, appropriate analyses used that account for confounders however other potential confounders missed cross sectional design limits causal inferences.
Cleare (2021)	Y	Y	Y	Y	clearly defined question, appropriate design of study, large sample size able to generalise findings to others at risk of NSSI/Suicide, analyses accounted for important confounding factors such as age and NSSI history, cross sectional design limits causal inferences.

Gratz (2020)	Y	Y	Y	S	clearly defined question, different samples allowed for greater generalisability, validated measures some of which are demonstrated to have low internal construct validity, analyses accounted for key confounders, cross sectional design limits causal inferences.
Grey (2020)	Y	Y	Y	S	clearly defined question, validated and reliable measures used with high reported construct validity, appropriate stats used including non-parametric tests which add to the quality, limited generalisability due to non-clinical sample used.
Gu (2020)	Y	S	Y	S	Clearly defined research question, design was appropriate however limits causal relationships, self-report measures may introduce recall bias, validated measures used, non-random sample may introduce selection bias and reduces generalisability, the statistical analysis was very robust with detailed descriptions of moderating and mediating analyses, and bootstrapping used to confirm significance of mediation effects which adds to the reliability of the study. Although the study provides valuable insights to the sample studied with implications for interventions, the specificity of the sample restricts generalisability of findings.
Gu (2023)	Y	Y	Y	S	Clearly defined aims and appropriate study design- however cross sectional design limits causal relationships and analyse regressions used for associations and Latent class analysis was appropriate as groups were being compared, fit indices, odd ratios and effect sizes were reported this adds to the robustness of the data. the data adds to a small literature base of studies done on incarcerated male prisoners and NSSI, and provides appropriate directions for future research.
Kyron (2023)	Y	S	Y	Y	clearly defined research question, appropriate analysis, sampling method was non-random and based on voluntary admission to a private psychiatric

					inpatient facility potentially introducing selection bias as only voluntary patients included- however this is justified based on the study questions, high response rates and electronic data collection increased reliability of data collected, the use of MSEM and network modelling was a robust statistical approach which allowed associations of same and next day between study variables. implications for future research and improving short term risk assessments based on daily fluctuations in various risk factors.
Kyron (2020)	Y	S	Y	Y	clearly defined research question , appropriate design , but specific sample reduces generalisability, validated measures were used which were supplemented by staff reports increasing validity of data, design was appropriate and robust machine learning and cross lagged design provided robust statistical findings to indicate key predictors of risk, the non-random and specific nature of the sample reduces generalisability however nonetheless the study is of high value in terms of clinical implications in the area of risk management in psychiatric inpatient settlings.
Larkin (2013)	Y	S	Y	S	clearly defined research question, appropriate methodology used ot address the research question, small sample size and non-random sample- from emergency departments, introduces potential selection bias and limits generalisability of findings, detailed interviews including validated measures allowed for the researchers to capture the data in depth covering relevant areas of interest, appropriate statistical tests used with clear results, some valuable insights but the small sample size reduces ability to make meaningful generalisations more widely.
Marco Jose (2015)	Y	S	Y	N	clearly defined research question, consecutive sampling was appropriate given the research question however the sample was overwhelmingly female which

					introduces limitations to generalisability, high retention rate for f/u design with low attrition rates all dropouts accounted for and authors showed no statistical significance in sample after participants were lost to f/u, appropriate statistical methods used, results cannot be generalised due to specificity of sample being from MH services, and predominantly female, stats indicated moderate variance from the model therefore other factors could've been explored further
Moseley (2022)	Y	S	Y	N	clearly defined research question, relied on self-report for autism diagnosis information which introduces recall bias, autistic sample mainly comprised of late diagnosed and female sample reducing generalisability to wider autistic population, appropriate statistics used with bootstrapping to account for issues with normality of data, the autistic vs non autistic samples are non-comparable introducing confounding factors, longitudinal design may be more appropriate. results are not applicable to wider samples of autistic population or general population due to issues with the sample disproportionately representing certain groups
Newman (2007)	Y	Y	S	S	clearly defined question, with clearly defined cases and controls based on clear exclusion and inclusion criteria, key confounding variables were accounted for based on statistical method used, low responses potentially introduces selection bias, limited generalisability due to low response rate
O'Connor (2000)	Y	Y	S	S	clearly defined question, with clearly defined criteria for cases and controls, validated measures used, small sample size, confounders such as controls health status and possible psychological implications of this which can impact on results, other confounding variables not

					accounted for, low statistical power due to small sample size
Peres Rodriguez (2017)	Y	S	S	S	clearly defined question, appropriate design for question but cannot make assumptions fo causality with this design, sample consisted of participants from various MH services increasing ability to generalise however small samples could limit statistical power, NSSI was self-reported without validated measure thus introducing potential variability in answers and biases in reporting, potentially important confounding factors not accounted for such as other MH conditions, study lacks generalisability due to high proportion of sample with eating disorders, cultural considerations, and relatively small sample size.
Rimkeviciene (2015)	Y	S	Y	S	clearly defined research question, community sample may be subject to selection bias whereas the clinical sample was appropriately recruited, the study design is appropriate and test retest allows researchers to observe temporal changes, however a longer f/u period would have improved the generalisability and reliability of findings, validated self-report measures used which improve validity of results however there may potentially be recall of selectivity bias, key confounding factors are not considered by the authors, appropriate statistical analyses used however moderate effect size limit the acceptability of results.
Shi (2022)	Y	Y	Y	S	clearly defined research question, random sampling reduces selction bias and allows for an appropriate amount of variance in the sample, the statistical method used were appropriate given the study aims with a high retention rate however data collection at more than three points would have increased robustness of findings, the authors accounted for key confounders. Results are in line

					with existing literature, and although they provide key insights the specific study population and cultural context should be considered when thinking about applicability of findings.
Simms (2007)	Y	S	S	S	clearly defined research question, appropriate sampling method from a suitable population to address the question, appropriate statistical analyses used however small sample size limits statistical precision as well as generalisability of findings, validated measures used however self-reported data may introduce recall and bias and underreported findings, a longitudinal design may have been more robust in providing insights into correlations between study variables over time, authors account for some important confounding variables however consideration of other factors such as medication effects may have added to robustness, results appear credible however the generalisability of findings is limited due to small sample size and specificity of population studied i.e. inpatient settings
Tham Su-Gwan (2020)	Y	S	Y	S	clearly defined research question, large sample size indicates high statistical power of the sample. One of the largest data sets studying constructs related to suicide and self-harm. Cross sectional design limits causality. Certain constructs used subjective clinician reports this introduces bias as different clinicians may have different ratings etc, results align with other literature in the field, although it provides key insights an important subset of individuals is missed i.e. people who died by suicide without any contact with MH services.
Tsujii (2020)	Y	Y	Y	N	clearly defined research question, large sample size from various settings allows for greater statistical power, longitudinal design with longer f/u of five years increases validity allowing for investigations into correlations and relationships between study variables over time i.e. predictive ability of measure used.

					Appropriate statistical analysis however observational design limits causal inferences . Exclusion of adolescents and others who do not access mental health services following suicide attempts reduces applicability of findings.
Willoughby (2015)	Y	S	Y	S	clearly defined research question, the longitudinal design is appropriate and large sample size adds to the validity of findings, validated measures for variables being studies but self-reporting can introduce potential biases such as recall bias or misreported data, the study accounted for various key confounders which adds to the validity of the study investigating effects of the variable under study. longitudinal design is well fitted to research question however longer f/u period will add to the quality of the study, the results were precise and statistically significant however small effect sizes were reported as is common in longitudinal designs. Results are not necessarily generalisable to clinical and non-university populations. Key implications for clinical practise are reported.
Yamokoski (2011)	Y	S	S	S	Clearly defined research question, study design is appropriate however longitudinal design would allow for causal associations, the sample was specific to veteran population which was majority male, limiting generalisability. Validated measures were used which add to validity however potentially introduce self-report and recall bias, Certain key confounders were not controlled for such as for example MH history, medication effects etc, results are in line with existing literature however have limited generalisability due to specificity of the sample studied

Note Y=Yes, S= Somewhat, N=No

Part Two- Empirical Study

Feasibility Trial of a Just in Time Adaptive Intervention (JITAI) to prevent self-harm events in an inpatient care setting.

Abstract

Background: Inpatient psychiatric care features high rates of self-harm. Research indicates interpersonal correlates of self-harm. By monitoring interpersonal risk factors through daily assessment, responsive *Just In Time Adaptive Interventions* (JITAI) can allow for timely interventions to reduce/ prevent the occurrence of self-harm.

Methods: A stepped-wedge randomised controlled trial investigated the feasibility of implementing a JITAI to reduce rates of self-harm on psychiatric inpatient wards. The intervention involved routine outcome monitoring of patient risks; this was supported with one-to-one time with ward staff to implement indicated interventions to manage identified risks. A mixed methods approach was used, descriptive statistics were used to quantify the number of patients using the intervention, multi-level modeling allowed comparison of self-harm rates between study phases. Feasibility was assessed using qualitative interviewing (analysed with framework analysis).

Results: Feasibility outcomes indicated the intervention in its present format was not feasible to implement. Feasibility was hindered by lack of staffing resources, limited time, and elements of the intervention design/booklet, as well as factors related to patients' presentation.

Conclusion: The JITAI intervention in its current format is not feasible to implement in Psychiatric inpatient care in the NHS. Due to systemic pressures including staffing resources and patient related factors. Practical solutions to increase future feasibility are provided, such as changing the format of the intervention to digital, keeping elements, such as training package and allocating the intervention to staff.

Keywords: *Self-Harm, IPTS- Interpersonal Psychological Theory of Suicide, JITAI, Just-In- Time Adaptive Interventions, Feasibility, Stepped Wedge Control Design*

Practitioner Points

- There is potential for JITAI to be used in the reduction of self-harm in inpatient psychiatric care, through routine outcome monitoring of pertinent risk factors
- A further control trial of an updated electronic version of the intervention is recommended

Introduction

Self-harm behaviours are a growing public health concern (Saunders and Smith 2016). Definitions of self-harm encompass intentional self-injurious behaviours through various means, irrespective of the presence of suicidal intent (Skegg 2005, Nock & Favazza., 2009). Furthermore, self-harm behaviours are a consistent predictor of suicide attempts and a natural antecedent to death by suicide (McMahon et al., 2024).

Self-harm in psychiatric inpatient care

Inpatient psychiatric services within the National Health Service (NHS) have increasing self-harm rates, mirroring broader trends at a population level (Mughal et al., 2023). A common feature of psychiatric inpatients is engagement in self-harm behaviours (Carroll et al., 2016) and self-harm often co-presents in various psychiatric conditions (Osuch et al., 1999). Furthermore, Self-harm in psychiatric inpatient care significantly affects nursing staff (James et al., 2012). Reducing self-harm incidents promptly, benefits patients and services by alleviating stress, costs, and time pressures (Tsiachristas et al., 2020).

The reduction of self-harm

Preventing self-harm requires an understanding of its underlying mechanisms. Key theories, such as the Integrated Motivational Volitional (IMV) model (O'Conner, 2011) and the Three-Step Theory (Klonsky & May, 2015), share common features of separating intention and action into separate phases and draw out different facets of what moves towards action. Self-harm behaviour and risk are not linear (e.g., it does not necessarily escalate continuously over time). Risk of self-harm can suddenly escalate, necessitating dynamic, responsive interventions (Rogers et al., 2023). The fluid vulnerability theory of

suicide by Rudd, (2006), outlines the need for ongoing assessment of risk factors predicting self-harm and suicide.

Monitoring changes in self-harm behaviors and related risk factors could be a method of identifying high-risk cases in a timely way, in the interest of prevention. The widely cited Interpersonal Psychological Theory of Suicide (IPTS) by Joiner (2005) highlights interpersonal factors that may precipitate self-harm behaviors. These being, thwarted belongingness(TB) which constitutes feeling isolated and a lack of connection to others. Perceived burdensomeness (PB) whereby an individual misperceives themselves as posing a burden to others. Hopelessness in relation to these interpersonal states and acquired capability (AC). If an individual has repeatedly been exposed to painful or fearsome experiences, they become habituated to these. Making it more likely for them to have an acquired ability to overcome the fear of pain and death required to attempt suicide. (Joiner et al., 2005; Van Orden et al., 2010).

The IPTS helps improve our understanding of why suicide risk develops and provides directly targetable cognitive constructions that aid interventions. Various studies have indicated significant positive associations between IPTS constructs and likelihood of engaging in self-harm. For example, studies by Burke et al., (2016) and Cleare et al., (2021) found increases in AC, TB and PB were associated with higher rates of self-harm. Similarly, a study by Tsujii et al., (2020) found higher hopelessness scores were significantly associated with higher numbers of self-harm episodes per year. Thus, IPTS constructs potentiate a series of relevant risk factors which can be monitored with the view of self-harm prevention.

JITAI approaches

Just In Time Adaptive Interventions (JITAI) are a relatively novel concept in the field of psychology with useful applications in clinical psychology and mental health. These approaches provide the opportunity to intervene at precise points, allowing for personable and flexible responses (Nahum Shani et al., 2016; Suh et al., 2024). JITAI approaches provide a solution by predicting risk and intervening at the relevant time point to manage said risk (Coppersmith et al., 2022).

Preliminary Research Using Intensive Psychological Assessments

JITAI approaches are dependent on an in-depth knowledge of which factors are most proximally connected to increased risk of suicide risk and self-injury. This way, we can accurately identify who is most at-risk, but also directly targetable factors. An issue is that prior research has tended to rely on cross-sectional or long-term longitudinal data that fail to capture the dynamics of suicide risk. In addition, given the difficulties with intensive assessments of patients (e.g., daily, hourly), particularly those most at-risk of suicide, there is a limited amount of knowledge of what precedes increases in suicidal ideation and self-harm, and how effectively these shifts can be predicted.

Ben-Zeev et al., (2012) and Kleiman et al. (2017) were among the first to examine temporal fluctuations of suicidal ideation and related risk factors using multiple assessments per day. Findings highlighted risk factors associated with suicidal ideation varied considerably over a few hours and these significantly predicted suicidal thoughts. Similarly, Kyron et al. (2018), conducted a daily diary study in an Australian private psychiatric inpatient facility. Participants completed daily questionnaires studying interpersonal factors such as PB and TB. Where patients indicated high levels of either, they were then asked to complete further assessments of suicidal thoughts. Findings suggested suicidal ideation was a significant predictor of future non-suicidal self-injury

(NSSI). Data from the study was used to create a prediction model, which was adopted for use in the trial at hand. Notably there are key differences between the provision of care in private Australian psychiatric healthcare and NHS England. The most profound of which is arguably the level of resource, in the Australian setting every patient has access to their own iPad through which they would complete the daily assessments, due to limits to funding in NHS England settings this is not typically provided to psychiatric inpatients. The patient mix is also different with typical diagnoses of personality disorder in the Australian private provision, whereas in NHS England typical diagnoses of psychiatric inpatients are psychosis and schizoaffective disorders as well as mood disorders. Hence adaptations were required to be made to enable use of the intervention in NHS settings which included adapting the format to paper rather than electronic, which is a more accessible resource in NHS England settings.

Rationale for the proposed study

A feasibility trial is employed when an intervention has little to no research in support of its implementation, or if a population has been shown to require unique consideration of a topic or intervention (Bowen et al., 2009). Prior research has tended to employ short-term intensive research into what may predict short-term shifts in suicide and self-harm risk, but little research has examined the practical implementation of routine monitoring systems to facilitate JITAI. Although preliminary research has been conducted in an Australian private psychiatric healthcare context (Kyron et al., 2020/2023). The literature is limited in terms of the use of JITAI approaches in self-harm prevention in the UK and to our knowledge the intervention has never been employed in the NHS.

Furthermore, the National Institute for Clinical Excellence (NICE) guidelines for the assessment and management of self-harm outline the need for any assessment and intervention of self-harm to be tailored to the person’s individual needs with an emphasis

on harm minimisation. Stipulating that treatment should be delivered by trained professionals, not be delayed and should aim to reduce the harm before it has occurred (NICE, 2022). A JITAI approach for prevention of self-harm considers all facets of the guidelines by providing a preventative approach, delivered by staff who have received training, using real time information provided by patients which necessitates a personalised approach, with emphasis on harm minimisation strategies.

The proposed study aims to explore the feasibility of such an approach being implemented in inpatient psychiatric settings in the NHS. As well as exploring staff views on the acceptability and feasibility of the intervention. If the study is feasible, it will allow scope for a larger randomised controlled trial to allow further investigation into whether dynamic interventions will reduce the number of adverse events within psychiatric inpatient settings. Additionally, by conducting this feasibility trial we aim to add to the current literature base on JITAI approaches which is lacking in the field of mental healthcare.

A stepped wedged-cluster randomised trial is employed in this study. This design has growing evidence supporting its use in feasibility studies (Kristunas et al., 2019). As it allows for the robust exploration of implementation of interventions, utilizing comparisons of outcomes between different clusters at different time points, controlling for the intervention being used (Hemming &Taljaard, 2020).

Research Aims

To evaluate the feasibility of a JITAI to prevent suicidal self-harm events in NHS psychiatric inpatient care settings and to assess whether rates of self-harm reduce. Feasibility of the JITAI in this setting will be evaluated with reference to a series of indicators, as outlined below.

Feasibility Study Objectives:

- To quantify the proportion of inpatients who consent to participate in the study across each ward, from the total of potentially eligible inpatients approached
- To ascertain number of patient recruits according to predefined target of sixteen to demonstrate feasibility
- To quantify the percentage of consenting participants who complete the JITAI intervention, for at least half of the length of their inpatient admission.
- To define the rate of staff attendance at the JITAI training.
- To explore staff self-efficacy in risk management after attending training.
- To explore staff views on barriers and enablers to implementing the JITAI method in psychiatric inpatient settings in the NHS.
- To assess rates of self-harm and compare number of incidents between intervention and control wards to inform sample size calculations for future trials.

Method

Ethics

Ethical approval was obtained from an NHS Research Ethics Committee (REC REF: 23/WS/0087) and the study was approved by the Health Research Authority (25/10/2023). See appendices A/B for evidence of approvals. The study protocol was also registered in a publicly available repository (ISRCTN11247151).

Design

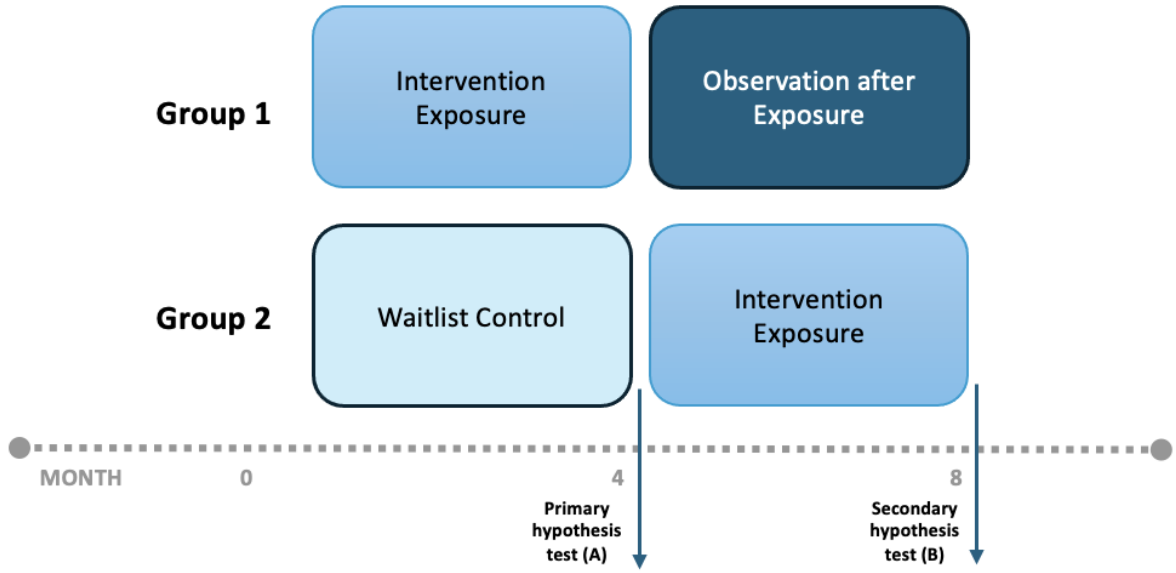
This study was a mixed-methods design of a stepped-wedge randomised control trial with additional staff interviewing.

Design- Quantitative Sub Study

Participating inpatient care wards across two NHS Trusts were randomly assigned to two groups, using a computerised randomisation schedule (applying a simple 1:1 randomisation schedule, generated by an independent research assistant). The study was carried out in two phases as illustrated in Figure 1.

Figure 1

Feasibility, delayed intervention randomised controlled trial design



At the start of the study period -month 0, participating wards in each NHS Trust were randomised to either Group one or Group two to control for site differences. During the first phase months one to four of the study, Group one had immediate access to the JITAI training and intervention. Group two served as a delayed-intervention control during this

phase. After four months, Group two was trained and had access to the JITAI training and intervention. During this second phase, Group one continued to use JITAI. This feasibility, delayed intervention randomised controlled trial design assumes that significant differences in the primary clinical outcome (e.g., number of self-harm incidents during a 4-month period) would be found after phase one (primary hypothesis test A). No significant differences would be found after phase two (secondary hypothesis test B). Further details about recruitment, clinical and data collection procedures are outlined below. The trial was designed according to the CONSORT checklist for randomised pilot and feasibility trials (Eldridge et al., 2016), please see Appendix C for completed checklist.

JITAI Intervention

The intervention was informed by routine outcome monitoring (ROM) principles to identify cases at risk of a poor outcome, and to facilitate early adaptive interventions (see Barkham et al., 2023). The intervention involved use of psychometric outcome measures to support [a] the development of a risk management plan; [b] the daily monitoring of risk indicators; [c] the facilitation of risk management interventions led by clinical staff; [d] creation of coping skills to prevent self-harm. Appendix D contains excerpts from the intervention booklet, training material and supplementary guides provided to staff participants.

Staff Training

Staff were trained by the lead researcher, supported by clinical psychologists and research governance team members, each NHS Trust was offered two face to face training sessions one in the morning and the next in the afternoon (using Microsoft PowerPoint see Appendix D). Training covered the IPTS (Joiner, 2005) and the JITAI method, focusing on obtaining patient consent, structuring 1:1 sessions, responding to risk, and facilitating therapeutic dialogue based on daily questionnaire feedback.

The JITAI Booklet

Inpatient participants completed a questionnaire at study induction, with results entered into an Excel-based risk calculator providing a 0-100% probability of self-harm. This informed clinicians' risk assessments and management plans. The risk calculator was based on an algorithm and provided a baseline risk estimate in a percentage. The algorithm was created by researchers in Australia (Kyron et al., 2023) by accessing over five years of data relating to self-harm, suicide attempts, and a range of risk and protective factors. A Least Absolute Shrinkage and Selection Operator (LASSO) regression model was trained and tested to predict short-term risk of events, which updates its prediction daily when new data is received. Daily interpersonal problems and suicidal ideation were found to be the strongest predictors of self-harm.

The risk calculator score was recorded in the patient's booklet and integrated into their risk management plan, tailored to risks identified in the admission questionnaire. Inpatients completed a daily 17-item questionnaire (see Appendix D) during one to one sessions with staff. Details of the validated measures used are specified below. Staff then manually calculated scores and plotted them on the monitoring chart for interpersonal constructs (TB, PB, suicidal ideation, and hopelessness), contained within the intervention booklet.

Daily monitoring charts helped staff track risk fluctuations and identify increases, prompting just-in-time adaptive interventions. The intervention involved conversation with the patient and action plans to address the risk area that day. Overall, this procedure aimed to enhance routine risk assessment and management.

Measures- quantitative sub study

All inpatient participants completed an initial questionnaire, followed by daily questionnaires during the intervention phases. Below is a list of the questionnaire battery used. Other data, such as number of self-harm incidents throughout study phases were collected from each NHS Trust's incident reporting systems.

Measures in Initial Questionnaire:

The initial questionnaire comprises of a battery of the following questionnaires: the Depression Anxiety Stress Scale, DASS-21 (Lovibond and Lovibond., 1995). The DASS-21 is a validated measure of depression, anxiety, and stress (Henry and Crawford., 2005).

The Health of the Nation Outcome Scales (HoNOS), (Wing et al.,1998) , is a 12-item questionnaire. In studies of the internal consistency of the HoNOS, Cronbach's alpha has ranged from 0.59 to 0.76, indicating a moderately high internal consistency (Pirkis et al., 2005). The HoNOS was originally developed t to be used as a standardised routine outcome monitoring tool for adults with mental illnesses as part of the UK national health strategy and measures mental health and social behavioural functioning (Pirkis et al., 2005 & Wing et al.,2000).

Quality of life enjoyment and satisfaction questionnaire (Q-LES-Q) was developed by Endicott et al. (1993) and is a tool to measure quality of life in clinical settings and measures of severity of illness. Cronbach's alpha was 0.89 (Pitkanen et al., 2012). The Q-LES-Q showed sound test-retest reliability and sensitivity (Stevanovic 2011).

Questions regarding distress tolerance, trauma exposure, substance use, prior suicide attempts, and prior NSS1 were also included in the daily measures, as used by (Kyron et

al., 2018). The questions were all based on sound psychological measures, further details can be found in the Kyron et al. (2018) paper.

Daily measure questionnaire for inpatient participants:

The Daily Index (DI-5) by Dyer et al. (2014) is a validated measure with high construct validity which measures index of affective psychological distress, the measure was designed to be used in conjunction with the World Health Organization Wellbeing Index (WHO-5) (Bech et al.,1996), which is another validated measure used as part of the daily measures in this trial.

Items from the Perceived Mastery Scale (PM) by Pearlin et al.(1981) were also used as part of the daily measures. The PM is frequently used in health research and allows the study of the extent to which individuals feel they have control over their own lives.

Design- Qualitative sub study

Epistemological framework

The author adopts a critical realist position and acknowledges that narratives provided by participants are shaped by their cultural and social contexts while seeking to understand the broader systemic or structural realities influencing those narratives (Bhaskar, 1978; Maxwell 2012). Framework analysis was flexibly applied to prioritise insights most relevant to the feasibility objectives. The author balanced inductive coding with predefined categories to enhance applicability of findings. Themes were iteratively developed and guided by the participants narratives and the researcher's interpretations allowing a grounded understanding of overarching feasibility objectives (Finlay,2002).

This study is aligned with the view that knowledge is cocreated and aims to gain insights into actionable points in relation to feasibility. The framework analysis approach is often associated with pragmatism given its systemic and structured approach to data analysis, hence its wide applicability in healthcare research across disciplines (Ritchie & Spencer, 1994).

Arguably other qualitative approaches such as thematic analysis (Braun & Clarke, 2006) or interpretative phenomenological analysis (Smith et al., 2009) would have provided insights to the participants thoughts and experiences in relation to the intervention. However, framework analysis was used because the researcher was interested in the practical applicability of participant's sense making of the phenomena being studied according to a predefined framework of feasibility.

According to Ritchie and Spencer (1994) framework analysis serves to resolve four types of research questions these being contextual, diagnostic, evaluative and strategic. This study seeks to appraise the feasibility of the intervention (evaluative) and identify novel plans and actions for future use (strategic).

Framework analysis follows five stages, the first is familiarization, at this stage the researcher re-read all transcripts, noting any key ideas or statements related to the research aims. The second stage is developing the theoretical framework, here the author began to generate a series of themes based on participants statements, prior knowledge about inpatient psychiatric care as well as any patterns emanating across the datasets (see Appendix E for the preliminary Thematic framework). The next stage is indexing, during which the author assigned themes from the prior stage by hand to the data, during this stage all the data is scrutinised (see Appendix F for examples of indexing). At the

fourth stage -charting, the author converted the data into thematic charts using Microsoft Word. Where rows correspond to participants and columns correspond to themes/ subthemes. During this stage, data can be assigned to multiple themes and multiple charts are constructed where required (see Appendix G for excerpts of thematic charting). The final stage is mapping and interpretation. During this stage the author extracts patterns from the data and makes conclusions (this stage is presented in the results section). The final framework consisted of three key areas which were barriers, enablers and ideas for future developments of the intervention.

Reflexivity

Please find a statement of reflexivity in Appendix 8. Excerpts of a reflexive diary are included in Appendix I.

Holmes (2020) highlights the importance of qualitative researchers outlining their positionality to acknowledge any potential biases arising from their background or experiences. For transparency, the researcher is a female, trainee clinical psychologist with extensive clinical experience working with people engaging in NSSI behaviors, has prior experience working in psychiatric inpatient and community settings and was involved in designing the intervention being studied.

Setting

This study was conducted with inpatients and staff teams across adult psychiatric inpatient care settings in Rotherham Doncaster and South Humber NHS Foundation Trust (RDaSH) and Sheffield Health and Social Care NHS Foundation Trust (SHSC). The services

included acute mixed and single gender inpatient wards. Written informed consent was obtained from all participants.

Inclusion and Exclusion Criteria- Quantitative sub study

Patient and staff were recruited if they met the criteria outlined in Table 1 and 2 below.

Table 1

Patient Participants Inclusion Criteria

Inclusion	Exclusion
Aged between 18-65	Not fluent in English
Inpatient on one of the participating wards	Patients in seclusion
Must be recruited to the study within the first seven days of admission	Patients assessed not to have capacity to consent to take part- **as capacity may fluctuate, patients who may gain capacity during the active phase of data collection after not having capacity can be included**

Table 2

Staff participants inclusion criteria

Inclusion	Exclusion
must have completed all the relevant mandatory Trust risk management training	Agency staff
Works on one of the participating wards and attended JITAI training (this includes bank staff, nursing assistants and other professionals)	
Any participating staff who are not qualified members of staff must have check ins with nursing team after completing intervention with patients	

Table 3

Inclusion and Exclusion Criteria- Qualitative sub study

Inclusion	Exclusion
Must be a member of staff working on participating ward and completed JITAI training Must be fluent in the English language	Did not attend JITAI training

Sample size requirements- quantitative sub study

The purpose of a feasibility trial is to evaluate whether clinical and methodological procedures are indeed possible to implement as intended in a specific population, serving as a preliminary pilot to inform the design and sample size of future effectiveness trials (Donald, 2018; Pearson et al., 2020).

Guidelines from the EASE feasibility trial by Varese et al. (2021) put forth a traffic light system to quantify number of participants required to demonstrate feasibility. The traffic light system is as follows, Green: Feasibility is demonstrated where an average of at least three participants are recruited per month. Amber: If at least two participants are recruited per month, a future trial will be feasible with additional strategies to support recruitment. Red: If an average of one participant is recruited per month over the recruitment period (< 8 participants), feasibility within the current design will not be demonstrated. According to these guidelines the aim was to recruit at least sixteen participants to demonstrate feasibility, as the study was conducted over eight months,

Sample size requirements- qualitative sub study

When conducting framework analysis within a focused population such as in the current study, recruitment should reflect heterogeneity of the population. Whilst allowing in depth exploration of participants experiences. Although framework analysis is commonly used in large sample sizes, anywhere between five -fifty participants are recommended (Goldsmith, 2021). Hence this study aimed to recruit sufficient participants across different staff groups to ensure a heterogenous sample with sufficient data to reach saturation.

Procedures

Data Collection- quantitative sub study

Wards were randomly assigned to immediate or delayed exposure groups. Feasibility data was collected to quantify the number of patients completing the JITAI intervention, for at least half of their inpatient stay. To quantify the number of staff who attended the training. In order to satisfy secondary aims of feasibility, self-harm incident data and the number of unique patients involved were extracted from Trust incident reports and used to compare self-harm rates across study phases.

Questionnaire for staff participants:

Staff were requested to complete the Risk Assessment and Management Self-Efficacy Scale (RAMSES) by Delgadillo et al. (2014) when they first started the trial and again at the end of the trial. This measure is used to quantify task specific self-efficacy in relation to risk management following training. The measure has a Cronbach's alpha value of 0.96 indicating high internal validity (Delgadillo et al., 2014).

Data Collection- qualitative sub study

Trained staff who consented to participate were invited to a thirty minute semi-structured interview (see Appendix K for the interview topic guide). Interviews were held face-to-face in confidential ward spaces, with drop-in sessions available. Participants were informed of the interview's purpose and could ask questions beforehand. Audio recordings were transcribed verbatim, anonymised, and analysed using framework analysis (Ritchie & Spencer, 1994). The primary researcher analysed the data, with a second reviewer independently analysing two interviews.

Recruitment- quantitative sub study

During the intervention phase, staff identified potentially eligible participants, primarily during admission. Study posters were displayed in visible areas of participating wards, including staff offices and communal areas (see Appendix L). Staff informed eligible participants about the study using the information sheet (Appendix M), consent form (Appendix N), and a copy of the intervention booklet (Appendix D).

The primary researcher distributed information sheets and promotional posters to participating wards, tailored separately to staff and patients. Staff were recruited via emails to ward clinical psychologists and by signing up for training sessions. They were encouraged to promote the study during routine patient interactions. Each ward had a research champion (assistant or clinical associate psychologists) to promote the study and support adherence. Recruitment was further supported by the research team, including the lead researcher, ward clinical psychologists, and senior leadership. Through drop-in sessions with inpatients authorised by ward managers. Four wards were recruited from two NHS Trusts: two wards with eighteen beds each from one trust and wards with twelve and sixteen beds from the other Trust.

All participating wards were general acute inpatient wards with similar admission criteria and staffing structures. Teams typically included a ward manager, consultant psychiatrists, nurses, healthcare/nursing assistants, occupational therapists, patient flow coordinators, advanced prescribers/practitioners, and psychological professionals. Nursing staff were mostly temporary, and psychological professionals often worked part-time.

Recruitment- qualitative sub study

Purposive convenience sampling was used to recruit staff participants who were already consented into the trial. Participants were invited to an interview via the email they provided when signing up.

Data Security

All participants were assigned unique anonymous identifiers, and data was anonymised before analysis. Signed consent forms were securely scanned and stored on a restricted University of Sheffield network drive. Copies of patient consent forms were also uploaded to electronic clinical records, and paper copies were shredded after digitization. Electronic consent forms will be deleted after five years. Qualitative interviews were digitally recorded, saved under anonymised identifiers, and deleted post-transcription. Transcripts will be securely stored on the University network drive and deleted after analysis.

Data analysis strategy

Descriptive statistics were used to summarise participant demographics, intervention use (e.g., frequency, mean IPTS construct scores), and staff self-efficacy in risk management at baseline and after eight months (time point two). Exploratory analyses were used to compare self-harm incidents (SHI) between groups one and two at months four and eight (Figure 1) using descriptive statistics and effect size indices (Cohen's d). Multilevel modelling assessed

group outcomes, adjusted for SHI at phases one and two, and clustering by wards, using a two-level model with patients nested within wards. The dependent variable was SHI at the end of each phase, with group allocation as the independent variable and SHI as a covariate. The intracluster correlation coefficient (ICC) was utilised to estimate between-ward variability in SHI to inform future sample size calculations for a fully powered cluster RCT (Campbell & Walters, 2014).

Results- quantitative sub study

Data on feasibility

Feasibility targets were not met, with fewer than one participant recruited per month on average. Overall, six patients consented to participate and used the intervention, representing 60% of potentially eligible patients. Ages ranged from 33 to 58, with 83% male. Five participants completed at least one daily measure, with 1-17 measures completed (mean 7.2, SD 6.85). Only 33.33% completed the booklet for at least half of their admission, all from SHSC. Two participants were recruited in phase one, and the rest in phase two. Four patients completed the admission questionnaire. One participant withdrew after completing the questionnaire due to staff unavailability to assist with daily measures, though consented for their data to be included. Mean scores were as follows: hopelessness 4.36 (SD 2.6), thwarted belongingness (TB) 6.97 (SD 2.49), perceived burdensomeness (PB) 8.26 (SD 3.51), and suicidal thoughts 2.66 (SD 0.44).

A total of 33 staff members consented and attended training, with 32 from SHSC and 11 from RDaSH. One staff member from RDaSH withdrew after training without providing a reason. Staff ages ranged from 23 to 57, with a mean age of 37.17 (SD 10.39). Most identified as White British (69%), with 24% Black British and 7% Asian. The majority were female (72%) and nursing professionals (67%). Psychological professionals and

healthcare support workers each made up 15%, while psychiatry accounted for 3%. Senior managerial roles were also held by 15%. Professional group representation was comparable across Trusts, except psychiatry, which was only represented in RDaSH.

Staff self-efficacy in risk management was assessed using the RAMSES scale (Delgadillo et al., 2014). Of the 33 staff participants, 30 (91%) completed baseline measures, but no follow-up measures were completed despite email invitations. Baseline scores ranged from 2.28 to 10, with a mean of 7.58 (SD 1.83). High self-efficacy (scores >8) was reported by 40%, moderate (scores 4-8) by 46.7%, and low (<4) by 6.67% of participants.

Secondary / exploratory analyses on incidents of self-harm

The stepped wedge randomised control design enabled analysis of self-harm incident (SHI) differences between wards at different study phases. Cohen's d effect sizes for groups 1 and 2 showed large effects in both phases (phase 1: d=0.835; phase 2: d=0.869).

A multi-level Poisson regression model examined SHI rate variability between wards across phases. See Tables 4/5/6 for SHI rates by phase by group and fixed coefficients models. Due to the small sample size, results should be interpreted with caution. Random intercepts at the ward level accounted for unobserved heterogeneity. For both phases, ICC=0.000, and random effects models were not statistically significant, indicating ward clustering accounted for 0% variability. Both phase one and two fixed coefficient models were also non-significant, suggesting no systematic ward-level SHI trends.

Table 4

SHI rates per ward per study phase

Ward	Number of SHI Phase 1	Number of SHI Phase 2
SHSC – Ward A[1]	14 (within 3 patients)	42 (within 10 patients)
SHSC – Ward B[2]	98 (within 13 patients)	92 (within 13 patients)
RDaSH- Ward C[1]	15 (within 5 patients)	5 (within 5 patients)
RDaSH- Ward D[2]	7(within 5 patients)	23 (within 11 patients)

Note, 1-Randomised to start study in phase 1, 2- randomised to start in phase 2

Table 5

Fixed Coefficients for SHI Phase 1

Model Term	Coefficient	Std Error	t	P value	95 % Confidence Interval	
					Upper	Lower
Intercept	3.750	4.345	0.863	0.479	-14.943	22.443
Group 2	3.472	2.342	1.482	0.276	-6.606	13.550

Note: Random effects model was not significant and the icc=0.000

Table 6

Fixed Coefficients for SHI Phase 2

Model Term	Coefficient	Std Error	t	P value	95 % Confidence Interval	
					Upper	Lower
Intercept	8.936	39.204	0.228	0.841	-159.746	177.618
Group 2	27.864	4.782	5.827	0.028*	7.288	48.439

*Note: Random effects model was not significant and the ICC=0.000, * significant*

Results- qualitative sub study

Eleven staff members consented to semi-structured interviews (82% female, 64% White British, 27% Black British, 9% Asian British). Participants included nursing professionals

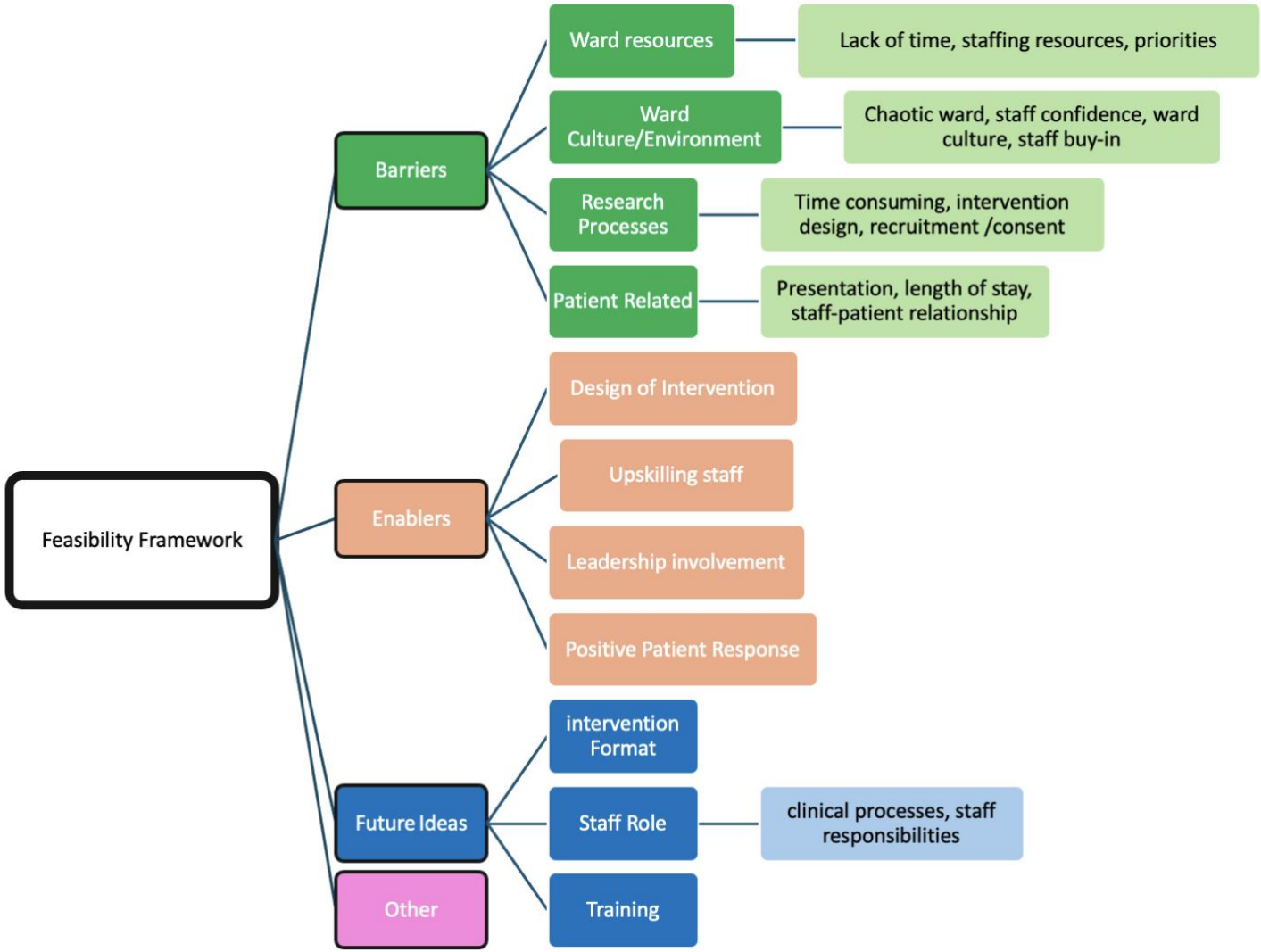
(55%), support workers (18%), and psychological professionals (27%), with three holding managerial roles. Six were from SHSC and five from RDaSH.

Using a feasibility framework (barriers, enablers, and future directions), verbatim responses were charted by outcome, with additional notes for significant quotes. Four themes emerged for both "barriers" and "enablers," and three for "future directions." Table 4 outlines themes and subthemes, including participant contributions. Excerpts with direct quotes are in Appendix G. In keeping with the mapping and interpretation stage the results presented here demonstrate interpretations of the author highlighting patterns and feasibility outcomes identified, see Figure 2 for thematic map.

The analytic framework was based around three key areas: barriers and enablers to implementation and ideas for future development.

Figure 6

Thematic Map



Barriers to Implementation

Barriers encompassed physical and logistical barriers, whilst also referring to more transient issues such as the interplay between interpersonal factors and the “feeling” of the ward. Interestingly an emergent theme was in relation to the role of specific research processes in causing a hindrance to implementation of the intervention.

Theme 1- ward resources

Lack of Time

Three participants spoke of the impact of having less time on being able to implement the intervention. The author noticed all participants who contributed to this theme belonged to different professional groups, which indicates universal pressures of time across professional groups within the ward system.

> *“It’s just so busy on this ward that often you want to do it (intervention) but you haven’t physically got the time to give it that it needs” (P3)*

Staffing Resources

Staffing resources were cited as a key barrier by most participants (n= 9), some participants referred to there being less staff trained in the intervention on shifts at any given time and others implicating overall low staffing levels. Additionally, some

participants referred to the composition of staff on shift at any time i.e. less qualified nurses or more temporary agency staff all of which they described as a barrier.

> "…*general NHS problems you know lack of staffing, you know not enough staff, staff changing all the time*" p10

> *"We have to provide support to other wards so we might have a nurse that's trained to do the JITAI work but they might get moved to another ward" (p6)*

Priorities

Six participants highlighted that the intervention was not a priority in their daily ward roles, ranking below other clinical tasks. Overlapping with reduced staffing issues, they noted that not being directly assigned the intervention acted as a barrier.

> "…when patients are admitted to the ward I feel like there's other things they need to do that's far more important to be dealing with than that (*intervention*)" (p5)

> *"I've not been assigned to do this (intervention) again so I've not had the ability to do it" (p2)*

Theme 2 – ward culture and environment

Chaotic Ward

Wards were described as hectic ever-changing places, some participants discussed patients' presentation as feeding into this hectic nature whilst others spoke about the inconsistency of the ward environment and busyness of staff tampering with implementation of the intervention.

> *"… I think it's a very busy kind of ever-changing environment and for the booklet to work I think there has to be consistency" (p10)*

> *"…adds to that sense of kind of chaotic transient climate and in a chaotic transient climate the stuff like this (intervention) becomes more difficult* (p11)

Staff lack confidence

A small number of participants (n=3) spoke about their perceived lack of competence in using the intervention, whether this was related to the design of the intervention or a loss of skill through less use of the booklet, which then led to avoidance of future use of the booklet.

> "…*when you haven't done it (intervention) in a while then you lose that confidence and avoid doing it" (p3)*

Ward culture

This subtheme reflects staff perceptions of research and systemic changes. Contributions came from three participants—two senior ward staff and one psychological professional. The author theorises how these contributions may be directly linked to the nature of participants professional role affording them the space to consider more systemic issues.

> "…changing a culture is something that takes a bit of time. So embedding anything new is something that's always difficult and a challenge…"(p6)

> *"research is seen very much as a burden rather than something that is going to improve clinical practise" (p10)*

Staff buy-in

For some participants (n=3) securing staff commitment to the intervention was crucial in implementing it, especially from senior management as well as nursing staff.

> *"I think as a leadership team if they really emphasised that this is important, and we need to get it done then I genuinely think that it would have got done." (p4)*

Theme 3- research processes

Time consuming

This subtheme overlaps with a prior subtheme and is highlighting lack of time as a barrier. However here participants were referring to how research processes involved in the intervention expended staffs already limited time.

"We have back to back obs (patient observations) just enough time to grab a drink so when I have a small break the last thing I want to do is think of the booklet " (p5)

Intervention design

Participants indicated issues around the format of the intervention causing hindrance to enable its use. One participant commented on inaccessibility by virtue of the wordiness of the intervention for specific groups such as those with learning disabilities. Another explicitly mentioned exclusion criteria as causing a barrier by excluding potentially eligible patients who were non-English speakers.

*"…*if someone with a learning disability were to use it, would it be as clear for them? Would it have been as helpful? I don't know*" (p10)*

"…you would get someone who would be the perfect candidate, but English was not their first language, so I think there's learning in terms of the inclusion and exclusion criteria" (p11)

Recruitment and consent

Part of the inclusion criteria was for patients to be recruited within seven days of admission, three participants alluded to this causing a hindrance. One participant mentioned recruitment being difficult due to lack of engagement from patients upon admission. Others implied the seven-day recruitment window as being too short, hence hindering implementation.

"It's difficult to recruit people isn't it within that seven-day period there's not a lot of time, it would feel better if it was more open ended" (p3)

Theme 4- Patient related

Patient presentation

This subtheme addresses patient presentation, including mental state at admission, reduced engagement when acutely unwell, boredom with the intervention, and adjustment periods post-admission. Most participants (n=9) contributed, highlighting its significance across NHS trusts and professional groups.

> *"When people do come into hospital, they are a lot more acutely unwell so people being able to engage at the point of admission is quite often something that's a challenge for us" (p6)*

> *"When they (patients) are first admitted they are very distressed it's a new environment for them so it's quite hard to implement such things so quickly"* (p9)

Length of stay

N=5 participants contributed to this subtheme referring to issues such as short admissions whether these be due to an out of area patient placement or quick turnovers from admission to discharge. Or overall pressures on wards to discharge as soon as possible due to the need of beds for others.

> *"It's a barrier for us at the other end where we're doing the trial but then all of a sudden that person has become slightly better so then there's a lot of pressure to discharge them from hospital and to move them on." (p6)*

Staff-patient relationship

Three participants discussed the importance of building a relationship, patients trusting staff and connecting with them to be able to complete the intervention. Where these was not established prior to initiating the intervention they were cited as hindrances to implementation.

"Trust in staff enables communication and facilitates intervention" (p1)

Enablers to Implementation

According to participants four key areas allowed ease of implementation. These being elements of the design of the intervention, the experiences of both staff and patients taking part and the role of senior leadership in promoting the intervention.

Theme 1 – Design of intervention

Participants shared positive feedback on the training, noting the intervention was well explained. Five found the booklet easy to use, with one appreciating it as a visual aid for patients. Another mentioned senior staff support facilitated its use on the ward.

"Once I'd used it once I was confident to do it again" (p2)

"The questionnaire bits they were easy to use and understand then even like scoring and plotting it on the graph was relatively straightforward as well" (p3)

Theme 2- Upskilling staff

Participants (n=4) described the intervention as a tool that improved conversations about self-harm and suicide, boosting staff confidence and skills. A senior manager observed improved risk management skills among trained staff.

> *"I do think that the booklet is a very good way to monitor risk and kind of have those conversations" (p4)*

> *"it's made a lot of the junior nurses a lot more aware and focused and thinking about kind of suicide self-harm behaviours" (p6)*

Theme 3- leadership involvement

Participants discussed how senior leadership buy-in improved their ability and the wider staff group's ability to be able to use the intervention on the wards.

> *"…the way it was introduced into the leadership team …massively helped with the success of trying it" (p6)*

Theme 4- positive patient response

This theme encompassed positive feedback from patients which reinforced staff confidence in using the intervention regularly. Suggesting the intervention helped bonding with the patient and willingness to engage in the intervention.

> *"The two patients I've used it with they've been quite positive and engaged with it and willing to fill it in" (p3)*

Future Direction

This theme referred to ideas around development of the intervention in relation to the format of the booklet, the role of staff members and the staff training session.

Theme 1- Intervention format

All participants shared ideas for improving the intervention. One felt the design was fine as is, while others suggested an electronic or app-based format for better accessibility and efficiency. Suggestions on frequency varied, with some advocating for more than once daily to track mood changes, and others for less frequent use. Some proposed making the intervention less "psychological."

> *"If the patient just had it on the iPad or on the phones it'd be so much easier for them to do it and it doesn't put as much strain on the staff team with short staffing and everything." (p4)*

Theme 2-staff role

Feeding into existing clinical processes

Some participants (n=4) shared thoughts on fitting the intervention into existing processes or meetings. Citing the benefits of being able to share patients progress and risk monitoring information in formulation meetings or multidisciplinary meetings on the ward to aid understanding of patient difficulties.

> *"I think formulation meetings this could really nicely feed into that to feedback what we're kind of exploring those causes" (p7)*

Staff responsibilities

Participants discussed staff roles in implementing the intervention. Suggestions included allocating it as a task (n=2), designating champions to support others (n=3), training staff to supervise, and assigning it to psychological professionals.

"*Training should be split up, so some staff are trained to supervise other staff" (p2)*

"…if it's (intervention) on allocations it is something that has to be done otherwise we (staff) get asked why it's not done" *(p5)*

Theme 3- training

Participants discussed training a higher proportion of staff as well as offering refresher training sessions, to ensure momentum whilst others commented on the usefulness of the training even if the intervention was changed to be delivered in an electronic format.

"*There's a lot of permanent staff who have not been trained." (p5)*

"*I think more training would have been great kind of maybe refresher training" (p7)*

"you'd still need the training I think it's really important for staff to understand why we're doing it" (p10)

Other themes

Other key insights noted at the end of the thematic charting (Appendix G), which felt significant for the feasibility outcomes are described here. This included issues around the setting in which the intervention was tested, one participant alluded to differences in patient presentation in NHS vs private settings and how this may act as a barrier. Another commented on trying the intervention on the psychiatric intensive care wards rather than

general acute wards. The use of study posters to promote the intervention was cited as an enabler. Another key discussion was about focusing on cultural shifts and the time it takes to promote change in a system.

Discussion

This was the first study to test a feasibility trial of a JITAI intervention to prevent self-harm and suicide in NHS psychiatric inpatient care settings. A mixed method approach was used with an emphasis on qualitative data. Due to a lack of patient recruits, feasibility recruitment targets were not met. Feasibility within the current design was not demonstrated, as on average less than one patient participant was recruited per month.

Multi-level modelling demonstrated a significantly higher number of incidents were reported in phase two of the study. Although the study was insufficiently powered, and the analysis should be interpreted with caution. It can be speculated that factors outside of the intervention could potentially account for this observed difference. Such as high patient turnover, or influx of new potentially eligible patients in the second phase of the trial. Data on patient diagnoses were not collected, however trends in SHI could have been assigned to the patient mix, as individuals with certain psychiatric diagnoses may be more likely to engage in self-harm behaviours (Sansone et al., 2005).

Key findings *from qualitative analysis*

Whilst creating the framework for analysis and throughout subsequent processes of analysis the author noticed overlaps in findings across the areas being explored, this fitted with the topic guide being designed to ascertain insights to key areas of the intervention as questions targeted similar areas across barriers/enablers and future ideas.

Barriers

Barriers to implementation were largely organisational and systemic, such as reduced and less trained staff on shift and time constraints. Participants also highlighted issues related to the intervention's design and research processes. These align with literature on NHS austerity, where underfunded and overstretched services operate at full capacity (Cummins, 2018; Fahy et al., 2023; Price, 2024).

Research in NHS psychiatric inpatient care faces well-documented challenges, including obtaining ethical approval and informed consent from unwell patients, complexities of inpatient settings, and low research output quality (Jacobsen et al., 2018). Similarly, participants in this study noted the patient mix and presentation hindered intervention completion.

Enablers

Participants identified enablers such as positive patient feedback, ease of use, and senior management support. Psychological concepts like positive reinforcement (Bandura, 1977; Skinner, 1953; Thorndike, 1898) explain how patient responses boost staff confidence and encourage reuse, while senior management "buy-in" fosters a top-down approach to implementation. Trust in leadership has been linked to greater employee engagement and facilitates systemic change (Hillberg, 2024; Ortega et al., 2014).

The intervention was also seen as enhancing staff risk management and conversational skills. Research shows discussing risk with patients improves outcomes and reduces risk (Blades et al., 2018), suggesting the intervention's confidence-building effect benefits improves implementation and patient outcomes.

Future development ideas

Development ideas included practical suggestions such as an electronic format, integrating the intervention into routine clinical meetings, reducing its frequency to ease staff workload, and retaining training in future iterations. Participants also emphasised the value of dedicated staff roles to support implementation, providing clear guidance for future development.

The use of JITAI approaches particularly those involving electronic features are a growing area in the field of healthcare (Egerson & Adeleke 2024; Guan et al., 2024; Hsu et al., 2024). Offering the intervention digitally through an app-based interface, would address a number of key issues with feasibility in the current format. Firstly, by reducing the responsibility of staff. Using less NHS resources, whilst empowering patients to have more ownership. Ideas around using data from the intervention to feed into routine clinical practice sounds a useful concept. With the researcher having worked in inpatient care, they see the value in being able to use information gathered in this way. The use of a data driven approach has the potential to improve accuracy of data shared, and the researcher feels this would come as a natural byproduct of regular use of the intervention.

Strengths and limitations

This study is the first in the NHS to trial a feasibility trial of a JITAI approach to prevent self-harm in inpatient psychiatric care. As was evident in the results, sample size targets for feasibility were not met. Despite being stipulated due to the increased risk of self-harm during the first week of admission (Mitchell & Dennis, 2006; Saab et al., 2022) the recruitment window of seven days may have impacted the number of participants being recruited into the study. Of the participants who did participate, only one was female and all were white British, thus raising questions about the accessibility of the intervention and

generalisability of findings. All participating wards were based in a concentrated geographical location- South Yorkshire. This raises questions about nuances in contextual factors potentially limiting generalisability. However, some research indicates although there may be specific demographic or cultural factors in a geographically concentrated population, this does not necessarily compromise the value of findings (Varpio et al., 2021).

Due to its pragmatic nature, framework analysis was deemed to be a good fit for analysis of the data. With benefits such as ensuring key aims are met through the research. As well as transparency as demonstrated through a clear audit trail from raw data to interpreted outcomes (Goldsmith, 2021). Only staff were interviewed about feasibility outcomes, conducting patient interviews would have provided valuable insights. However due to the small number of patients recruited, there would have been insufficient data to draw substantial conclusions from. Interviewees included a mixture of ethnicities, gender and professional roles allowing for a range of key perspectives. For some themes there were contributions from a mixture of participants indicating the significance of the point in question.

It would be challenging to assess fidelity to this intervention. By nature of the intervention itself being flexible, the way in which NHS trusts, ward staff teams or individual practitioners respond to “at risk” patients differ. Hence if assessing effectiveness this may be ascribed to the intervention used in each individual case. The author recognises the need for flexibility in the intervention as ward resources vary as well as training and experience of staff from site to site. The author argues the essence of the intervention is the Just-in-time-adaptive element, i.e. responding early when risk (s) are identified. Therefore, in assessing fidelity to the intervention it would be a case of assessing a) whether staff identify at risk patients in a timely manner and b) whether an intervention is

carried out as soon as an “at risk” patient is identified. Thereby effectiveness of the intervention would be best determined by how fast risk cases are identified and whether interventions to reduce risk follow immediately.

Implications

The findings have clear practical implications such as tangible changes to the design, format and delivery of the intervention. When considering methodological implications there is evidence suggesting lack of feasibility in the current design. However, in adopting ideas about development, there is scope for further feasibility trials using a more refined intervention. Whilst taking on board factors that hindered, enabled and could potentially improve implementation. The author puts fourth some suggestions for future directions:

- The author suggests a further delayed exposure research trial based on recommendations and insights from the current study
- Adapting the intervention to be presented in a digital format which is easily accessible on a tablet or mobile- thereby reducing pressures on staff
- Ensuring any wards on which future versions of the intervention are trialed are offered in depth training around the underlying IPTS theory and JITAI approaches

Conclusion

Results from the current study have demonstrated limited feasibility of the JITAI intervention being studied in its current design. Qualitative feedback from staff indicated usefulness of the intervention in risk monitoring and management. Implying patient satisfaction with the intervention. The use of framework analysis allowed exploration of feasibility, providing clear direction for future development of the intervention. The author is aware of the infancy of JITAI interventions in NHS psychiatric inpatient care but remains optimistic for its eventual use in routine clinical practise.

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Appendices

Appendix A- REC Favourable opinion letter

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Dr Jaime Delgadillo
Professor of Clinical Psychology
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Date 15 August 2023
Direct line 0141 314 0212
E-mail WoSREC3@ggc.scot.nhs.uk

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

Dear Dr Delgadillo

Study title:	**Feasibility Trial of a Just in Time Adaptive Intervention (JITAI) to prevent self-harm events in an inpatient care setting**
REC reference:	**23/WS/0087**
Protocol number:	**2**
IRAS project ID:	**324004**

Thank you for your letter of 28 July, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

	Condition
1	In the patient PIS, in the section "What will happen if I take part? What will I have to do", please insert the following sentence to the end of the last paragraph; "The safety planning will be based on the usual treatment for a patient who is at increased risk, for example increasing medication, increasing the use of observations for the time when you feel most at risk of harming yourself, and considering whether detention under mental health legislation is necessary."
	Recommendation
1	The Sub-Committee would like to note, that whilst it is satisfied the exclusion of those in seclusion has been justified for this feasibility trial, it would recommend this is re-visited for a full scale trial. This is because those patients will be at higher risk, and this intervention may provide useful for those at highest risk.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for

research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any

projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]	1	03 May 2023
IRAS Application Form [IRAS_Form_11052023]		11 May 2023
Letter from funder [Funding letter]	1	10 May 2023
Letters of invitation to participant [Staff ICF Version 1 26.07.2023]	1.0	26 July 2023

Document	*Version*	*Date*
Other [SHSC Managerial Supporting Letter Version 1 26.07.2023]	1.9	26 July 2023
Other [RDASH Managerial Support Letter Version 1 26.07.2023]	1.0	26 July 2023
Other [Response to NHS REC [July 2023]]	1	28 July 2023
Participant consent form [Staff consent form]	1	09 May 2023
Participant consent form [Patient ICF Version 2 26.07.2023]	2.0	26 July 2023
Participant information sheet (PIS) [PIS Patients Version 2 26.07.2023]	2.0	26 July 2023
Participant information sheet (PIS) [PIS Staff Version 2 26.07.2023]	2.0	26 July 2023
Referee's report or other scientific critique report [Scientific review confirmation]	1	02 May 2023
Referee's report or other scientific critique report [Independant Scientific Review Letter 26.07.2023]	1	26 July 2023
Research protocol or project proposal [Research Protocol Version 3 26.07.2023]	3.0	26 July 2023
Summary CV for Chief Investigator (CI) [CV]	1	03 February 2023
Summary CV for student [CV]	1	03 February 2023
Summary CV for supervisor (student research) [CV]	1	27 January 2022
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow Diagram Summary]	1	03 February 2023
Validated questionnaire [Validated Questionnaires]	1	03 February 2023

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 324004 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Email:wosrec3@ggc.scot.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers"

After ethical review guidance for sponsors and investigators – Non CTIMP Standard Conditions of Approval]

Copy to: Miss Jeannie Mckie, RDASH NHS Foundation Trust

Lead Nation England: approvals@hra.nhs.uk

West of Scotland REC 3

Attendance at Sub-Committee of the REC meeting on 15 August 2023

Committee Members:

Name	*Profession*	*Present*	*Notes*
Miss Megan Donnelly	Assistant Psychologist	Yes	
Dr Brian Gillatt	Consultant Forensic Psychiatrist	Yes	
Professor Alex McConnachie	Professor of Clinical Trial Biostatistics	Yes	
Dr John Murphy	Consultant Haematologist (Retired)(Alternate Vice-Chair)	Yes	Chair of meeting

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Ashley Nisbet	REC Manager

Appendix B- HRA approval letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Jaime Delgadillo
Professor of Clinical Psychology
University of Sheffield
Clinical Psychology Unit, University of Sheffield
Cathedral Court, Floor F
1 Vicar Lane, Sheffield
S1 1HD

Email: approvals@hra.nhs.uk

25 October 2023

Dear Dr Delgadillo

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Feasibility Trial of a Just in Time Adaptive Intervention (JITAI) to prevent self-harm events in an inpatient care setting**
IRAS project ID:	**324004**
Protocol number:	**2**
REC reference:	**23/WS/0087**
Sponsor	**Rotherham and Doncaster and South Humber NHS Foundation Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **324004**. Please quote this on all correspondence.

Yours sincerely,
Juliana Araujo

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Miss Jeannie Mckie, RDASH NHS Foundation Trust*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Completed Amendment Tool [Amendment Tool]	NSA001	19 October 2023
Covering letter on headed paper [Cover letter]	1	03 May 2023
IRAS Application Form [IRAS_Form_11052023]		11 May 2023
Letter from funder [Funding letter]	1	10 May 2023
Organisation Information Document [OID]	1	09 May 2023
Other [Staff PIS v1.1]	1.1	09 May 2023
Participant consent form [Staff consent form]	1	09 May 2023
Participant consent form [ICF]	1.1	09 May 2023
Participant information sheet (PIS) [Patient PIS Tracked Changed]	2.2	19 October 2023
Participant information sheet (PIS) [Patient PIS]	2.2	19 October 2023
Referee's report or other scientific critique report [Scientific review confirmation]	1	02 May 2023
Research protocol or project proposal [Protocol Tracked Changes]	3.1	19 October 2023
Research protocol or project proposal [Protocol]	3.1	19 October 2023
Schedule of Events or SoECAT [SoECAT]	1	09 May 2023
Summary CV for Chief Investigator (CI) [CV]	1	03 February 2023
Summary CV for student [CV]	1	03 February 2023
Summary CV for supervisor (student research) [CV]	1	27 January 2022
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow Diagram Summary]	1	03 February 2023
Validated questionnaire [Validated Questionnaires]	1	03 February 2023

IRAS project ID	324004

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Research activities and procedures as per the protocol and other study documents will take place at participating NHS organisations.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study in accordance with the contracting expectations detailed.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other agreement to be used with participating NHS organisations of this type. No funds will be allocated to the sites as indicated in the Organisation Information Document.	IT is not clear if the funding has been secured. Study funding arrangements are detailed in the Organisation Information Document Even though the funding award letter has been received, Question A65 of the IRAS application form indicates that the funding is still in progress. Please confirm if the funding for this research has been secured. If this is not the case, please let us know how the study will be financially supported. Funding has now been confirmed, please see industry support letter attached. Any costs not covered by this will be met by the sponsor organisation.	A Principal Investigator should be appointed at participating NHS organisations.	Where an external individual who does not already hold an NHS employment contract will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold an Honorary Research Contract. External staff holding pre-existing NHS employment contracts should obtain a Letter of Access. These should confirm Occupational Health Clearance. These should confirm enhanced DBS checks and appropriate barred list checks.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix C – CONSORT Checklist

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	101
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	102
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	104-107
	2b	Specific objectives or research questions for pilot trial	108
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	109-110
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	114-115
	4b	Settings and locations where the data were collected	114
	4c	How participants were identified and consented	120-121
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	118-119
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	119,109-110
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	-
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	106-107
Sample size	7a	Rationale for numbers in the pilot trial	108,115-116
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
109:			
Sequence generation	8a	Method used to generate the random allocation sequence	109
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	109

Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	109
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	109
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	118-119
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	108
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	122
	13b	For each group, losses and exclusions after randomisation, together with reasons	123-125
Recruitment	14a	Dates defining the periods of recruitment and follow-up	108
	14b	Why the pilot trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	-
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	124
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	124
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	121-142
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
	19a	If relevant, other important unintended consequences	-
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	137-142
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	137-138
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	137-142
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	141
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	109
Protocol	24	Where the pilot trial protocol can be accessed, if available	109
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	-
	26	Ethical approval or approval by research review committee, confirmed with reference number	155

Appendix D- Intervention Booklet Main Pages and Training material

Introduction

Clearly, things have been really difficult for you lately, and this is why you have had to come into the hospital.

As a ward staff team, we really care about your health and wellbeing. This Workbook has been designed to help us to work together to manage your safety and wellbeing while you are in the hospital ward.

When people are admitted to a hospital ward, this is often because they are at risk of self-harming in some way.

The purpose of this Workbook is to help you to learn why sometimes you might feel like hurting yourself, and to learn how you can manage these situations to stay safe and well.

We know that sometimes people feel like hurting themselves, but this feeling can change from day to day. Just because you feel hopeless one day doesn't mean that you will feel like this forever. Sometimes people feel very hot too, when they have a fever or a headache, but this usually goes away after a while and eventually people feel cooler and more comfortable. Urges to self-harm also cool down eventually, even though it might seem like these feelings might last forever when they are happening.

The main message in this Workbook is:

"Take it one day at a time, speak to the ward staff about how you feel, and things might get better tomorrow."

This is why this Workbook has been set out in a day-by-day format. In order to make conversations with staff as helpful as possible, the Workbook is organized in different sections that are completed by you and the ward staff each day.

How will this Workbook help me?

- It will help you and the ward staff team to know how you are feeling on a day-to-day basis.
- It will help you to notice patterns that influence your urges to self-harm.
- It will help you to learn how to manage your feelings and how to stay safe during your stay, and after you leave the hospital.

How to use this Workbook

We know that it's very difficult to talk about thoughts of self-harm or suicide. This is why people often choose not to talk about these things. But keeping this to yourself makes things worse and more difficult to tolerate. Using this Workbook will make it easier to talk about these things, and talking is likely to help you to feel better. That's why it's very important for you to be open and honest with the answers you provide in this Workbook. Your conversations with the ward staff team are intended to help you to keep safe and well each day.

To use this Workbook, you will need to do this, each day of your stay on the ward.

You will:

1. Complete some questionnaires each day, to help to track your thoughts and feelings.
2. Discuss the results with the ward staff team
3. Work together with the ward staff team to come up with a safety and wellbeing plan

The Workbook is organized to help you to work through the above tasks throughout your stay in the hospital. Overall, there are 3 phases covered by this Workbook. Each phase is described in detail below.

Using the Workbook in 3 Phases

PHASE ONE: the initial risk thermometer

Early on during your admission to hospital you will answer some questions about your thoughts and feelings in general. This initial questionnaire is in pages X-X of this Workbook.

This information will help to work out if you are at risk of hurting yourself. A member of the staff team will show you how the answers you provide can be translated into a number, using something called a "risk calculator". The number that is worked out using the calculator can range between 0 to 100%, which is then mapped on to a "risk thermometer" like the picture shown in this page. The hotter the temperature the greater the risk. The idea behind this is that we can measure how intense and difficult the thoughts of self-harm are, just like we can measure someone's temperature using a normal thermometer. It's helpful to get this measure, because it helps you and the ward staff team to understand what is going on and to start to make things better right at the start of your ward stay.

This exercise will be the first opportunity to discuss better ways of communicating and managing that risk. This is not something to fear, but rather an opportunity to learn to manage your difficult thoughts and feelings. At the end of this exercise, you and the ward staff team will discuss and agree a plan to help to keep you safe and well during your hospital stay.

Using the Workbook in 3 Phases

PHASE TWO: the daily monitoring charts

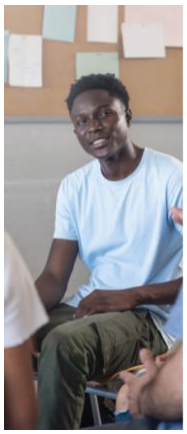
Each day on the ward you will be asked to complete a questionnaire about your thoughts and feelings that day. The answers can be marked as scores. These daily scores will go up and down according to how you feel. These scores will be plotted on "monitoring charts" each day to show the trend and pattern in your risk and wellbeing over the course of your stay. We expect that these scores will be higher at the start of your hospital stay, and they may get better as time goes on and as you go through your treatment and support plan. There are 4 scores and monitoring charts that you will use each day.

You will complete the Workbook in your one-to-one time with the ward staff team each day. This will help you to:

- Notice when you may be starting to struggle
- Identify triggers that make these feelings worse
- Identify things and activities that make these feelings better
- Talk about these things with the staff ward team, who will help you to come up with a plan for each day

The daily monitoring charts are based on research, which indicates that people can feel like hurting or killing themselves if and when they experience an increase in one or more of the following:

1. **Hopelessness:** when we think that our future is bleak, depressing and totally unchanging.
2. **Belonging:** when we feel detached from others, as if we don't belong and are not part of any social group or family.
3. **Burden:** when we think that we are burdening or bothering others, and that "others would be better off without me".
4. **Suicidal ideas:** when we think about hurting or killing ourselves themselves.



Using the Workbook in 3 Phases

PHASE THREE: planning for the future, after your stay in hospital

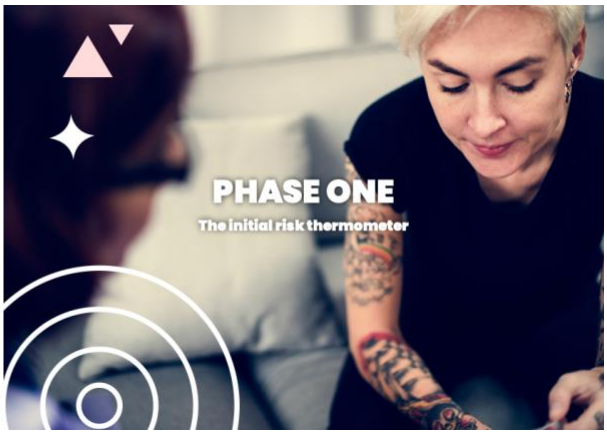
Using this Workbook will also help you to plan how to stay safe and well after the end of your stay in hospital. In this third and final phase, you will complete two Workbook sheets described below. Staff will prompt you to complete these on the last day of your hospital stay, or shortly before then.

1. **My "Staying Well" Plan:** Here, you will write down what you have learned during your stay in hospital about keeping yourself safe and well. This will help you to remember the strategies that have been most useful for you and will help you to think about how to keep these strategies going when you leave the hospital. This is called a "staying well" plan. This sheet is detachable so that you can take it home with you.
2. **Saying "Goodbye":** This is where the ward staff team will write messages that they wish to communicate to you at the end of your stay. This sheet is also detachable so that you can take it home with you.

Summary

In summary, using this Workbook will help you to understand triggers for thoughts and feelings of self-harm, and to learn to manage these feelings effectively, in order to stay safe and well during and also after the end of your hospital stay. This Workbook will help to guide your conversations with the ward staff team, so that you can develop a trusting and collaborative relationship with them, and so they can be as helpful as possible to you. The changes that the ward staff team will suggest to you are small changes that will be helpful in changing your mental health. Please don't feel like you need to make big changes all of a sudden. Slow and steady change is probably best for people during their stay in hospital.

The staff ward team will guide you on how to complete all of the next sections of this Workbook, and they will explain how this all works. Most importantly, remember to **take it one day at a time.**



Some questions about alcohol use

0 Never
1 Monthly or less
2 2 to 4 times per month
3 2 to 3 times per week
4 4 times or more per week

Question	Answer (0-4)
How often do you have a drink containing alcohol?	
How many units of alcohol do you drink on a typical day when you are drinking?	
How often have you had 6 or more units if female, or 8 or more if male, on a single occasion in the last year?	
How often during the last year have you found that you were not able to stop drinking once you had started?	
How often during the last year have you failed to do what was normally expected from you because of your drinking?	
How often during the last year have you needed an alcoholic drink in the morning to get yourself going after a heavy drinking session?	
How often during the last year have you had a feeling of guilt or remorse after drinking?	
How often during the last year have you been unable to remember what happened the night before because you had been drinking?	
Have you or somebody else been injured as a result of your drinking?	
Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested that you cut down?	
Total	

Some questions about how satisfied you feel with life

Taking everything into consideration, during the past week how satisfied have you been with your...

1 Very
2 Poor
3 Fair
4 Good
5 Very Good

Question	Answer (1-5)
Physical health?	
Mood?	
Work?	
Household activities?	
Social relationships?	
Family relationships?	
Leisure time activities?	
Ability to function in daily life?	
Sexual drive, interest and/or performance?*	
Economic status?	
Living/housing situation?*	
Ability to get around physically without feeling dizzy or unsteady or falling?*	
Overall sense of wellbeing?	
Medication? (if not taking any check here_____ and leave item blank.)	
How would you rate your overall life satisfaction and contentment during the past week?	
Total	

Some questions about you

How old are you? _____

What is your gender? _____

What ward are you on? _____

Some questions about how you have been feeling over the past week...

Provide a numerical answer, based on the below scale:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree or a good part of time
3 Applied to me very much or most of the time

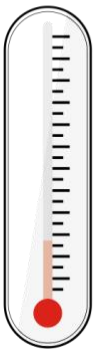
Question	Answer (0-3)
I found it hard to wind down	
I was aware of dryness of my mouth	
I couldn't seem to experience any positive feeling at all	
I experienced breathing difficulty (eg excessively rapid breathing, breathlessness in the absence of physical exertion)	
I found it difficult to work up the initiative to do things	
I tended to over-react to situations	
I experienced trembling (e.g. in the hands)	
I felt that I was using a lot of nervous energy	
I was worried about situations in which I might panic and make a fool of myself	
I felt that I had nothing to look forward to	
I found myself getting agitated	
I found it difficult to relax	
I felt downhearted and blue	
I was intolerant of anything that kept me from getting on with what I was doing	
I felt I was close to panic	
I was unable to become enthusiastic about anything	
I felt I wasn't worth much as a person	
I felt that I was rather touchy	
I was aware of the action of my hear in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	
I felt scared without any good reason	
I felt that life was meaningless	
Total	

Rating problems in your life

Rate each item on a scale of 1-12 . Rate the most severe problem that occurred during the period rated

0 no problem
1 minor problem requiring no action
2 mild problem but definitely present
3 moderately severe problem
4 severe to very severe problem

Question	Answer (0-4)
Overactivity, aggression	
Non accidental self-injury	
Problem drinking or drug-taking	
Cognitive problems	
Physical illness or disability problems	
Problems associated with hallucinations or delusions	
Problems with depressed mood	
Other mental and behavioural problem	
Problems with relationships	
Problems with activities of daily living	
Problems with living conditions	
Problems with occupation and activities	
Total	



Risk Thermometer and Safety Plan

Mark an X on the Risk Thermometer to measure the degree of risk at admission to hospital

What are the triggers that would make the X move higher up?

How can you tell if you are getting worse? What are the signals? Consider external and internal (thoughts, feelings, sensations) experiences. Write down your triggers and signals.

What usually helps to manage these thoughts and feelings? What might help during your hospital stay to move the X lower?

Risk Thermometer and Safety Plan

PLAN: Write down what will help in order to keep you safe and well.

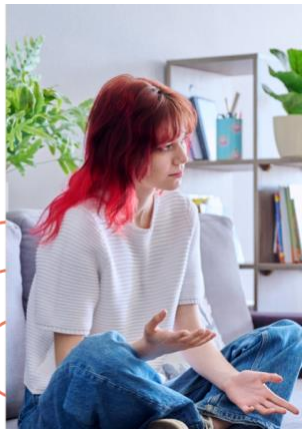
CONSIDER: how to get through right now; how to make your situation safer; things that calm or lift your mood; things that distract you; people you can talk to; how to communicate what you want and need; people who can support you in an emergency; small acts of kindness to yourself

Guidance

Please complete each of the 4 questionnaires every day together with a member of staff. You will find several blank questionnaires in pages X-X of this Workbook.

A member of staff will help you to work out the score for each of them. Next, they will mark today's score on the monitoring chart for each of the four areas: hopelessness, belonging, burden, suicidal ideas. There are blank monitoring charts in pages X-X of this Workbook.

Finally, a member of staff will have a conversation with you about what the questionnaires are showing and what you need to do that day to cope with, improve or manage your emotions



Monitoring chart – Month 1 _____

Date of inpatient admission _____

Chart to monitor my feelings of hopelessness

Chart to monitor my sense of belonging

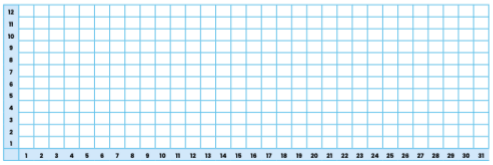


Chart to monitor my sense of being a burden on others

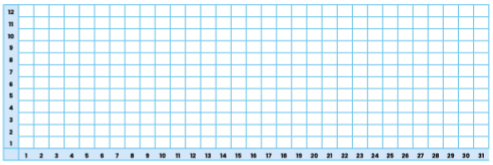
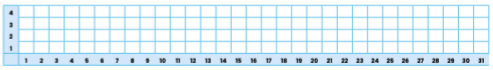


Chart to monitor my suicidal thoughts



My notes

My notes

Daily monitoring questionnaire

Date: _____

Some questions about your wellbeing *Provide a numerical answer, based on the below scale:* 1. all no time 2. some of the time 3. less than half the time 4. more than half the time 5. most of the time 6. all of the time	In the past 24 hours	(1–6)
	I have felt cheerful in good spirits	
	I have felt calm and relaxed	
	I have felt active and vigorous	
	I have woken up feeling fresh and rested	
	Total	

Some questions about your psychological distress *Provide a numerical answer, based on the below scale:* 1. at no time 2. some of the time 3. less than half the time 4. more than half the time 5. most of the time 6. all of the time	In the past 24 hours...	(1–6)
	My life has been filled with things that interest me.	
	I have felt anxious	
	I have felt depressed	
	I have felt worthless	
	I have thoughts about killing myself	
	I have felt that I am not coping	
	Felt my death would be a relief to others	
	Felt like a burden on others	
	Felt supported by others	
	Felt close to others	
	Total	

Some questions about your wish to live and die *Provide a numerical answer, based on the below scale:* 1. none 2. weak 3. moderate 4. strong	In the past 24 hours...	(1–4)
	My wish to die has been	
	My wish to live has been	
	Total	

Provide a numerical answer, based on the below scale: 1. not true for me at all 7. very true for me	In the past 24 hours...	(1–7)
	I have felt there is no way I can change many of the important things in my life	
	Total	

Daily monitoring questionnaire

Date: _____

Some questions about your wellbeing *Provide a numerical answer, based on the below scale:* 1. all no time 2. some of the time 3. less than half the time 4. more than half the time 5. most of the time 6. all of the time	In the past 24 hours	(1–6)
	I have felt cheerful in good spirits	
	I have felt calm and relaxed	
	I have felt active and vigorous	
	I have woken up feeling fresh and rested	
	Total	

Some questions about your psychological distress *Provide a numerical answer, based on the below scale:* 1. at no time 2. some of the time 3. less than half the time 4. more than half the time 5. most of the time 6. all of the time	In the past 24 hours...	(1–6)
	My life has been filled with things that interest me.	
	I have felt anxious	
	I have felt depressed	
	I have felt worthless	
	I have thoughts about killing myself	
	I have felt that I am not coping	
	Felt my death would be a relief to others	
	Felt like a burden on others	
	Felt supported by others	
	Felt close to others	
	Total	

Some questions about your wish to live and die *Provide a numerical answer, based on the below scale:* 1. none 2. weak 3. moderate 4. strong	In the past 24 hours...	(1–4)
	My wish to die has been	
	My wish to live has been	
	Total	

Provide a numerical answer, based on the below scale: 1. not true for me at all 7. very true for me	In the past 24 hours...	(1–7)
	I have felt there is no way I can change many of the important things in my life	
	Total	

My 'Staying Well' Plan

Looking through your risk thermometer and your daily monitoring charts, what have you learned about the risk factors for your thoughts and feelings of self-harm? Make a note of the things that seem to make these thoughts and feelings worse.

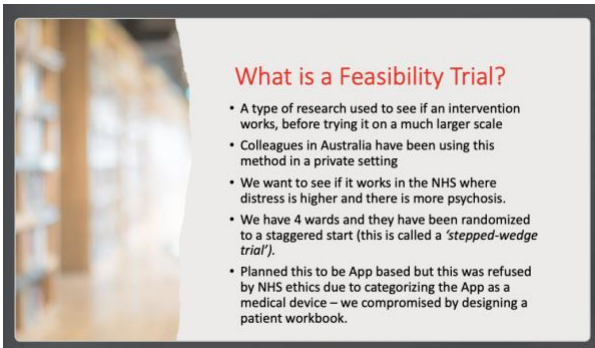
During your hospital stay you had conversations with staff to find ways to stay safe and well. What have been the most helpful learning points from these conversations? What actions or coping strategies have worked better for you?

FUTURE PLAN: Consider what you will do to keep yourself safe and well after leaving the hospital.
Look through the notes in the above two sections and then work out a specific plan using the format:
IF ..... THEN .....

For example "IF I start to feel like I don't belong here and nobody cares about me THEN I will do activity X to help me to feel close to others".

My notes

My 'Goodbye' Sheet
To be completed by the ward staff team

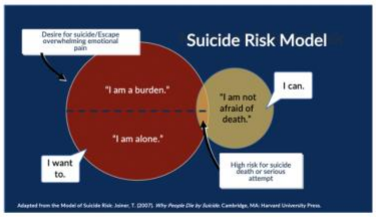


What is a Feasibility Trial?

- A type of research used to see if an intervention works, before trying it on a much larger scale
- Colleagues in Australia have been using this method in a private setting
- We want to see if it works in the NHS where distress is higher and there is more psychosis.
- We have 4 wards and they have been randomized to a staggered start (this is called a *'stepped-wedge trial')*.
- Planned this to be App based but this was refused by NHS ethics due to categorizing the App as a medical device – we compromised by designing a patient workbook.

5

Joiners Interpersonal Theory of Suicide



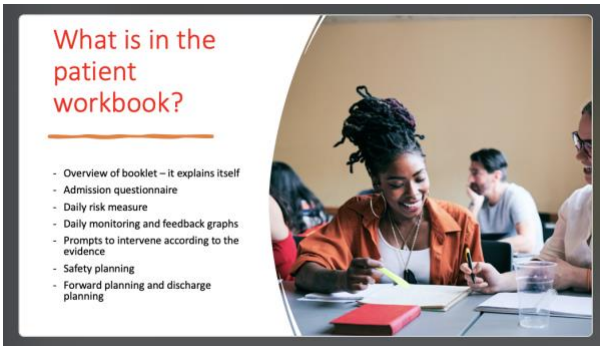
6

What will the approach look like in daily ward activities and practices?

Training of ward staff	Advertise study	Consent taken
Daily questionnaires	High score= intervention	Start the conversation

1. advertise the study

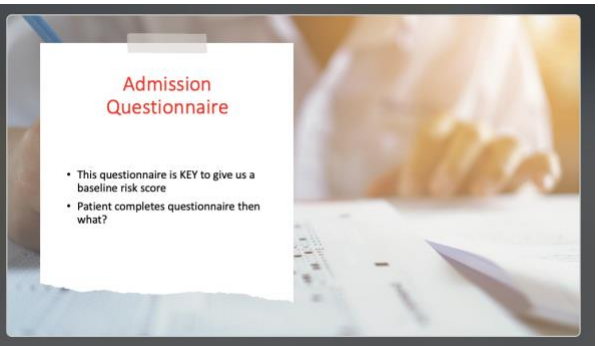
- Suicide prevention and self harm reduction
- Information sheets
- Consent form- completed after gaining INFORMED CONSENT
- Patient ID must be completed on front page of booklet:
  - **Patient initials followed by last 6 digits of the NHS number**



What is in the patient workbook?

- Overview of booklet – it explains itself
- Admission questionnaire
- Daily risk measure
- Daily monitoring and feedback graphs
- Prompts to intervene according to the evidence
- Safety planning
- Forward planning and discharge planning

9



Admission Questionnaire

- This questionnaire is KEY to give us a baseline risk score
- Patient completes questionnaire then what?

10

Admission Risk Calculator

- You will input the scores into an excel file- "the risk calculator"
- This will tell you about the risk a patient has and is based on previous research

Admission Risk Calculator

- Having a go…

Daily measures and monitoring graphs

- The brief measure should be completed with the patient in one to one time, and scores can be plotted straight onto the daily monitoring graphs
- You will be able to see if the patients scores in any particular domain are decreasing or increasing
- This can be used to prompt an intervention conversation

13

Starting the conversation

During your 1:1 session with the patient you will complete daily questionnaires
After helping the patient to mark their score on the monitoring chart, get them to notice any patterns or trends that occur over time.

Next, use the VERA process to have a discussion about what the scores mean.

Validate: Acknowledge and accept the patient's thoughts and feelings. It's common for people to feel this way, and understandable in this situation.

Explore: Use the charts to try to understand the triggers for any changes (worsening or improvements), and the signals that the person may have noticed when the change was occurring.

Reassure: Reassure the patient that these are thoughts and feelings (not facts), and they fluctuate and change over time. You will work together to develop an action plan for that day, to manage these thoughts and feelings. Remember to take it one day at a time.

Action: Signpost and support the patient to consider activities and coping skills that will mitigate risks of self-harm and will also help to improve their wellbeing. It could be helpful to write down today's action plan in the "notes" section at back of the daily monitoring charts. Over time, this will help to learn which actions and coping skills seem to be more effective than others. The action plan is focused on managing these immediate thoughts and feelings, rather than to solve wider life problems and issues.

14

Different actions for differing issues identified by the daily charts

After exploring the chart and identifying which area the patient is struggling with, use this to inform your action prompts and keep this simple…

Hopelessness: when a person thinks that their future is bleak, depressing and totally unchanging. Use behavioural activation to change hopelessness. **Identify a behaviour the patient that day can do that will increase mastery or pleasure.**

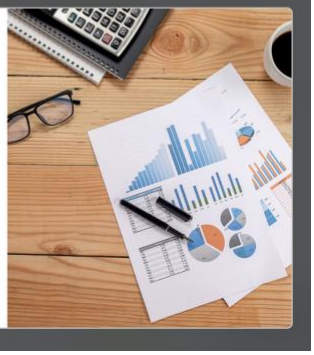
Belonging: when a person feels detached from others, as if they don't belong anywhere or as part of any social group or family. ***Signposting into therapeutic activities, Connecting with staff in the ward, Connecting with family and friends***

Burden: when a person thinks that they are burdening or bothering others, and that "others would be better off without me". Ask the patient to ***notice when you're pulling back from others, come to us, we're here to help. What has helped when you have felt a burden/this way before?***

Suicidal ideas: when people think about hurting or killing themselves. ***A) is this increasing? b) intent (do they intend to harm themselves, is this increasing), and c) planning (have they got plans, how far have plans developed). Talk to the patient about impulse control strategies.***

15

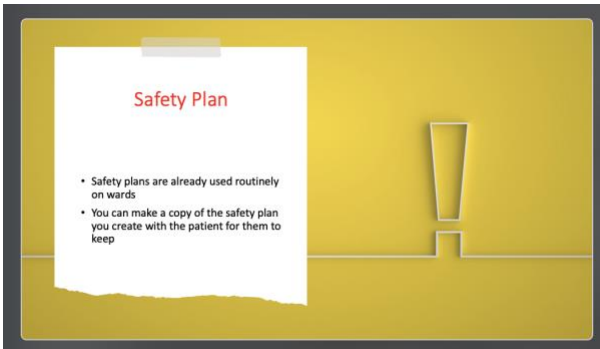
Daily measures and monitoring graphs



- Role play and practice

16

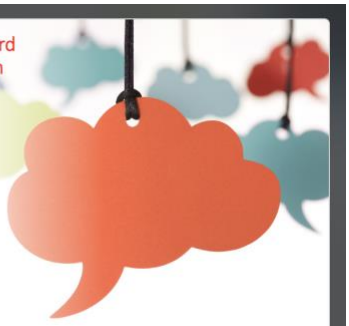
Safety Plan



- Safety plans are already used routinely on wards
- You can make a copy of the safety plan you create with the patient for them to keep

17

Looking back at the ward stay to move forward in the community



- Turn to back of book
- Patients will be able to keep the final pages which will include farewell messages from staff and peers
- This section of the booklet encourages patients to look back at times when risk was high or low and think about what was useful to carry this on in the future
- Acknowledges an ending

18

Storing the booklets securely

- As the booklet is being used for research purposes, we must keep them secure
- This means once the patient is done using their booklet for the day, you need to ensure it is locked away in the identified cabinet for your ward , in a locked office
- Steve and Claire can inform you where this is located for your ward

19

Any concerns or worries or feedback?

- If you have any concerns or questions you can email the lead researcher
- Any feedback?
- There will be a dedicated research champion in each Trust who can help with any queries

20

Just in Time Adaptive Intervention JITAI Trial

Guidance for inpatient ward staff

1

STUDY AIM AND PROCEDURES

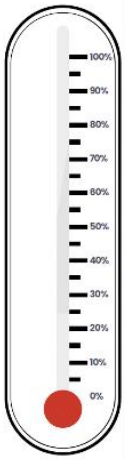
Thank you for your willingness to participate in the JITAI Trial, which aims to reduce self-harm events that occur in inpatient care wards.

This video describes the study purpose, design and procedures: https://youtu.be/GNHtKnAzUrY

To support the study, please follow these steps:

Please put the trial on the PIPA agenda so that new patients can be considered as potential participants.

1. Encourage new inpatients (admitted within the last 7 days) to read the participant information sheet and to complete a consent form. These printed forms are available on the ward. Signed forms should then be stored in a designated and locked cabinet. This is where the patient Workbooks are also stored.
2. Once a patient consents, take some time to show them a copy of the patient Workbook called "Taking one day at a time". Make sure to complete "**phase 1**" of the Workbook, which involves completing an admission questionnaire (pg. 8-11) at the earliest opportunity within that first week of admission.
3. Use the risk calculator you have received by email to work out a "risk thermometer score" and complete the initial safety plan (pg. 12-13) in collaboration with the patient. Here is a video explaining how to use the calculator: https://youtu.be/SANgbFH4Ly4
4. After the above steps, support the patient to follow "**phase 2**" of the Workbook, which involves completing daily questionnaires (pg. 28-74), tracking changes in the monthly monitoring charts (pg. 16-25), and making notes to learn about triggers and improving coping strategies to reduce risk and improve wellbeing.
5. Finally, support the patient to complete "**phase 3**", which involves completing a "staying well plan" (pg. 76-77) and you can also add some goodbye messages for the patient in pg. 78 from the staff team. Please make sure you photocopy these final sections and provide copies to the patient at the time of discharge from the ward.



2

GUIDANCE FOR PHASE 2: SUPPORTIVE CONVERSATIONS USING THE VERA PROCESS

During your 1:1 daily session with the patient you will help them complete daily questionnaires and to record the scores in the monitoring charts. Please note that the "days" scale in these monitoring charts refers to the specific dates of the month when the patient starts to use the Workbook. So, start to track these scores on the relevant date when the patient starts to engage with this process during the first month of their inpatient admission.

After helping the patient to mark their score on the monitoring chart, get them to notice any patterns or trends that are occurring over time in their chart. Draw attention to what is changing over time, which risk factors may be particularly stuck/problematic, and explore why.

Next, use the **VERA** process to have a collaborative discussion about what the scores mean.

Validate: Acknowledge and validate the patient's difficult thoughts and feelings. Please don't get drawn into challenging these thoughts and feelings as the first thing you say.

Explore: Use the daily charts to try to understand the *triggers* for any changes (worsening or improvements), and the *signals* that the person may have noticed when the change was occurring. Show a curiosity for understanding these patterns, to support the patient to develop a similar sense of interest and curiosity to learn from these patterns.

Reassure: Reassure the patient that these are thoughts and feelings (not *facts*), and they fluctuate and change over time. Normalize that it's common for people to feel this way, and understandable in this inpatient ward situation. Say that you will work together to develop an action plan for that day, to manage these thoughts and feelings. Remember to take it one day at a time.

Action: Signpost and support the patient to consider activities and coping skills that will mitigate risks of self-harm and will also help to improve their wellbeing. It is helpful to write down that day's action plan in the "notes" section at back of the daily monitoring charts. This will help staff the next day. Over time, this will help to learn which actions and coping skills seem to be more effective than others. The action plan is focused on managing these immediate thoughts and feelings, rather than to solve wider life problems and issues.

3

GUIDANCE FOR PHASE 2: SUPPORTIVE CONVERSATIONS FOCUSING ON KEY RISK FACTORS

It might be useful to revisit the safety plan with the patient to see what helps them when they are struggling.

After exploring the chart and identifying which area the patient is struggling with, use this to inform your prompts. The scores on the daily measure will indicate what area you need to work on that day.

Hopelessness: when a person thinks that their future is bleak, depressing and totally unchanging.
Messages of validation and hope: "You're in the right place, we're here to help you" . Inviting them to consider change: "What could you do today that could move you away from that" Use behavioural activation with the patient. Focus on changing behaviour that day that will then change mood. Target and prescribe agreed actions for that day.

Belonging: when a person feels detached from others, as if they don't belong anywhere or as part of any social group or family.
Signposting the patient into therapeutic activities to improve connectivity with others, encouraging connecting with staff on the ward, encouraging connecting with family and friends.

Burden: when a person thinks that they are burdening or bothering others, and that "others would be better of without me".
Reinforce the message that the ward team is here to help. Helping the patient talk to others without any guilt. Encourage appropriate help seeking behaviours by the patient that day.

Suicidal ideas: when people think about hurting or killing themselves.
Ask (a) is this increasing (b) what is their intent today and (c) whether they are active planning today (have they got plans, how far have plans developed). Talk to the patient about impulse control. When they have strong impulses and urges to self-harm, how they can contain that urge. How they can redirect, diffuse and distract from the urge into a safer place.

4

CONTACT DETAILS

If you have any questions about any of the daily tasks and procedures, please contact the Principal Investigator for your NHS Trust to obtain guidance:

RDaSH NHS Trust: Dr Stephen Kellett (stephen.kellett@nhs.net)
SHSC NHS Trust: Dr Claire Bone (Claire.Bone@shsc.nhs.uk)

If you would like to speak to a member of the University of Sheffield research team to discuss any aspects of the study, to raise any concerns, or to provide feedback, you can contact:

Study coordinator: Ibreeze Ahmed (iahmed6@sheffield.ac.uk)
Chief investigator: Dr Jaime Delgadillo (j.delgadillo@sheffield.ac.uk)

THANK YOU FOR ALL YOUR HELP

University of Sheffield · The University of Western Australia · NHS Rotherham Doncaster and South Humber NHS Foundation Trust · NHS Sheffield Health and Social Care NHS Foundation Trust · perth Clinic

5

Appendix E- initial Framework

Research objectives: To explore staff participants barriers and enablers to implementing the JITAI method with inpatients.

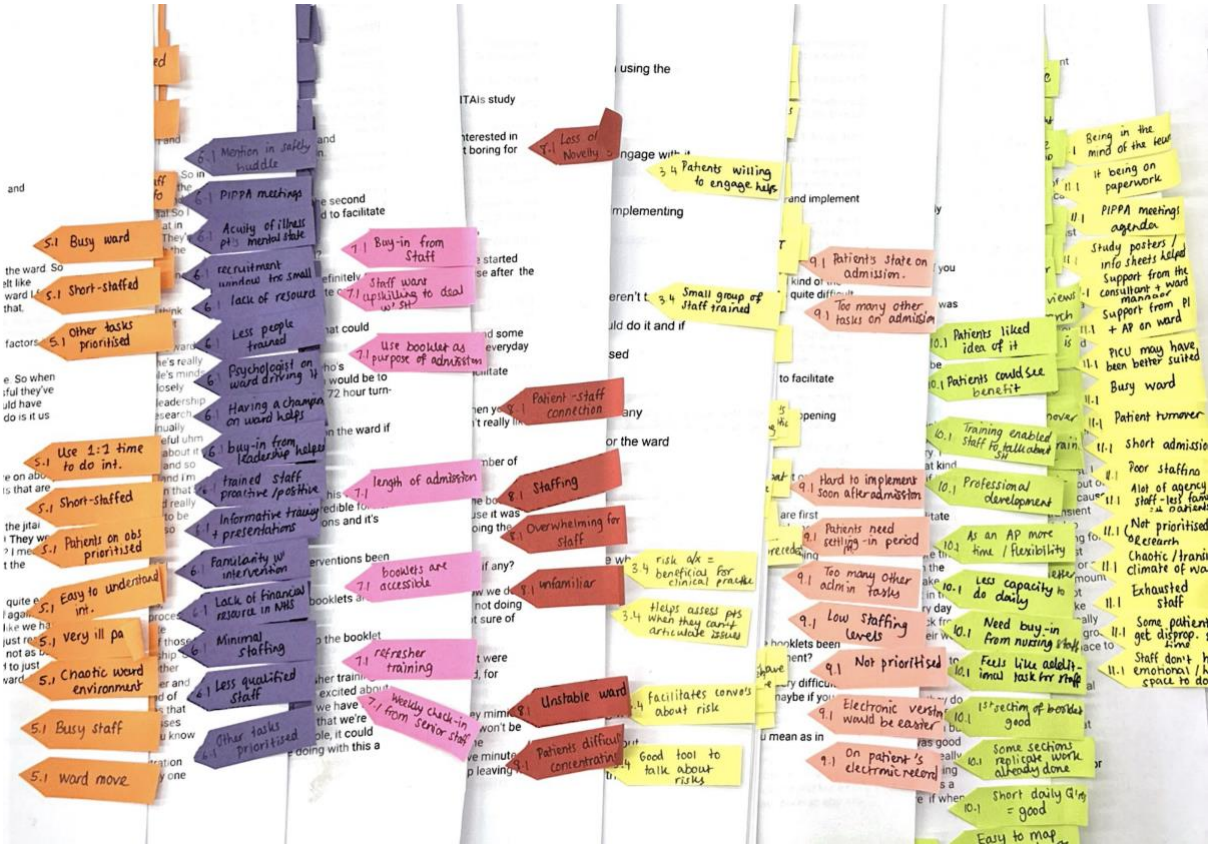
Topic/ themes to consider:
- Staffing issues
- Not understanding the intervention
- Time restraints
- Too much work
- Bank staff?
- High levels of acuity on the ward
- Perceiving patients are not appropriate for the study
- No new patients

Framework:
Issues with staffing
- Staffing issues
- Time restraints
- Too much work
- Bank staff?

Inpatient factors
- High levels of acuity on the ward
- Perceiving patients are not appropriate for the study
- No new patients

Training / JITAI intervention materials
- Not understanding the intervention

Appendix F- Framework Analysis, Indexing Excerpts



Appendix G – Excerpts of Thematic Charting

Charting for Themes pertaining to Barriers to Implementation of Intervention

	Theme 1: Ward Resources		
	1.1 Lack of time	1.2 Staffing resources	1.3 Priorities
Participant 1	Sometimes you know the ward is quite busy Nurses don't have a lot of time to spend with the patient I thought I was going to have the time to be able to do this but you know my job is just it's become really demanding of late	They(*staff*) don't have that time to go and sit with the patient because they are needed somewhere When they (*staff*)are short staffed, they don't have time to sit down and do it (*JITAI intervention*)	
Participant 3	It's just so busy on this ward that often you want to do it (*intervention*) but you haven't physically got the time to give it that it needs You just don't get time if say the patient goes on leave or like its end of shift or shift crossover time then it easily gets missed	We've had a few staff members who were trained and who could use it leave There was only like a very small handful of staff that could do it and if obviously them people weren't on shift then it would obviously get missed	Its not a priority because other clinical tasks come before it People constantly want things like medication rounds and like physical health checks, so it just gets missed

Participant 5		I think they've upped the staffing now but at first it was really low Being short staffed I just feel like its been that busy on the ward so short staffed We're that short staffed at the moment we are giving that 1-1 time to patients that are on obs, but the patients that aren't we're hardly giving them time because we can't	Obviously its nurses that deal with patients when they come in when patients are admitted to the ward I feel like there's other things they need to do that's far more important to be dealing with than that (*intervention*) It's (intervention) not really a priority when there is all this other stuff going on (*referring to ward move*)

	Theme 3: Research Processes			Theme 4: Patient Related	
	3.1 Time consuming	3.2 intervention design	3.3 Recruitment and consent	4.1 Patient's presentation	4.2 Length of stay
Participant 1		Needed to be clear that you need to be there and discussing with the patient jointly		If somebody's really unwell they cant engage Sometimes patients when they	

				are really unwell they don't concentrate or just do things anyhow	
Participant 6		Understanding how this works on a tablet sounded as though it would really have a massive impact on the ability to implement this much more successfully. So I think that's been a massive barrier and a hindrance to us. and there's something for me about when we do something like this that the patient should have ownership so they have something to look back and reflect on sometimes some of the interventions might be too kind of psychologicall y minded and	They (*patients*) might not be ready in that first week to be able to engage with the project. So I think something that's been a little bit of a barrier for us in that you have to recruit someone within that first seven days. Because of NICE guidelines and evidence base where it all states that people need very short hospital inpatient admissions then I think that again the time frame of	There's a lot of issues sometimes in terms of how quickly we can get people involved depending on their mental state. The acuity of their illness When people do come into hospital they are a lot more acutely unwell so people being able to engage at the point of admission is quite often something that's a challenge for us due to the acuity of their illness because they can't access the bed earlier	It's a barrier for us at the other end where we're doing the trial but then all of a sudden that person has become slightly better so then there's a lot of pressure to discharge them from hospital and to move them on. We've got a chap in at the moment who's suitable, but his discharge is going to be on Wednesday so it's like very very short admissions .

		that people might not feel confident or competent enough to be able to kind of undertake that.	that (7 days recruitment) is making it quite challenging.	on in their relapse.	

Other quotes:

Participant 11

- trying it on another ward
- Enablers: presence, regularity it being in the mind of the team, it being on paperwork

PIPPA meetings there's a clear flow of information that people can identify a newly admitted patient and they knew the inclusion and exclusion criteria

- There are study posters up in the staff office and the ward
- Being on paperwork
- I look back at whether we should've done it on the PICU and just done a small you know because it's a six bedded unit and there's more kind of control there
- Barrier- I think Australian private inpatient psychiatric settings are clearly quite different to English public psychiatric setting, and I think there's a different patient mix and I think the system is probably under a bit less stress , they will be better funded I think there's time and space for doing this type of developmental work.
- I think with a project like this focus on cultural shifts and therefore it being a longer project so more staff consultation more setting it up more education taking a test patient and showing what it looks like.

Participant 7

- And I know early intervention is kind of a different vein but with the new complex emotional needs pathway it could really fit in there and could be fed into the reflection sessions and ahead of formulation sessions and again that in reach to the staff teams could be led by the clinical leads in the community teams.

Participant 10

- I think in the long term it would alleviate pressures from staff

Appendix H- Reflexive statement

As the researcher applied framework analysis through the lens of a critical realist position, they acknowledge their position as a reflexive agent whereby the knowledge generated through their analysis is not only reflecting reality but rather a co-constructed outcome of how they engage with said reality (Bhaskar,1978; Bhaskar, 2013). Throughout the analysis the researcher theorises conversations with participants based on their perspective, apriori knowledge and their analytic framework (Danermark et al., 2019). Due to the researcher's active role in co-constructing knowledge with the participants it is key for the researcher to continuously engage in a process of reflexivity to critically examine their own assumptions, biases and influence throughout the research (Given, 2008). Furthermore, although framework analysis is typically conducted by a team of researchers, it is possible to be applied by a single researcher, in this case it is important for the researcher to maintain clear records, paying clear attention to transparency and reflexivity, where possible seeking feedback from others to validate interpretations (Gale et al., 2013; Ritchie et al., 2014). This was addressed by keeping a reflective diary .The researcher also used forums such as meetings with senior psychologists in participating trusts as well as research supervision to discuss any emerging thoughts, dilemmas and emotional reactions arising throughout the research process.

Appendix I- reflexive journal excerpt

- It was difficult to get hold of this participant for the interview as she was on 1:1 time with a patient and then straight after went on leave with another. Of course, it's difficult to fit in anything else when so much responsibility is on one person's head? I assume this will transpire in the interview; I need to be mindful not to allow these assumptions to steer the conversation. – to take to supervision

- An interesting point was raised in this interview about the research being done in general rather than PICU wards. I'm surprised I did not consider what the research would look like on a PICU given personal experience of working on an adolescent PICU. I recall numerous self-harm incidents throughout the day with nursing staffs' time consumed by managing everything that comes with a self harm event. Perhaps the participant is right and if we tried the study on a PICU we would have a better chance at recruiting and using the intervention. Or is it a case of the grass looks greener and a need to understand why it has been so difficult to implement the intervention in routine care. This interview has given me a lot of food for thought for future directions of the research.

- I am mindful of my position as the lead researcher on the project and having played a big role in designing the booklet I wonder if in some interview's participants are wary of disappointing me? I am reflecting on the layers of power imbalances between myself and participants and mindful of keeping a neutral stance of whoever I am interviewing regardless of their position relative to mine. - to discuss with Site PI's.

- Having familiarised myself with the transcripts I am instilled with confidence that despite recruitment at times feeling impossible, people are just as excited as I am about the potential for this project and what it could look like. Staff on the "shop floor" know best from their own experiences.

- As I go into my seventh interview, retrospectively I am picking up on some participants frustrations. At times this seems to be directly correlated with the research other times

more towards wider issues such as ward dynamics/politics or the NHS context as a whole.

Appendix J- Actions from PPI consultations

Consultation with	Resulting Amendments
Staff teams from both trusts, including ward managers, patient flow manager, psychologists, nurse	Booklet layout changed to have charts earlier in booklet
Expert by experience panel at SHSC, patients and staff	Booklet layout changed to be split into sections for ease of reading and clearer structure (e.g. phase 1 how to use the booklet, phase 2 daily measures phase 3 discharge planning)
Consultation with research collaborators	Updated booklet design to include a key to help staff and patients recognise which questionnaire item scores are plotted on which graph
Experts by experience Current patients on wards Research collaborators	Changed language throughout the booklet to make it easier to read and included layman terms to introduce measures rather than actual names of the validated measures for both the daily and admission questionnaires (e.g. the following questions are about stress)
Research collaborators	Tweaked questions in the interview schedule as some questions seemed repetitive/irrelevant
Senior ward staff, patients	Patient participant consent form updated to include example questions from intervention booklet
Research collaborators	Consent forms and information sheets separated for staff and patients rather than one of each for the overall project

Appendix K- Interview Topic guide

Interview Topic Guide

Research question: To explore staff participants views on barriers and enablers to implementing the JITAI study booklet in psychiatric inpatient settings in the NHS.

Objectives following on from the research question:

1. Explore staff participants views of implementing the JITAI study booklet.
2. Explore staff participants perceptions of obstacles to implementing the JITAI study booklet.
3. Explore staff participants perceptions of what factors facilitated implementation of the JITAI study booklet (if they had the opportunity).
4. Obtain suggestions for improvements of the JITAI study booklet/ booklet.

Interview Schedule

Initial orientation

- Confirm your name and role as a member of the research team.

- Outline purpose of the meeting by stating the above research question and objectives.

- Remind participants that they provided consent to audio record the interview, assure them no personal details will be used in transcripts and their answers will remain confidential. Ask again for permission to start the recording.

- Reassure participant: “I won’t say your name during the interview, I’ll let you know when I start and stop recording. If there’s anything you’d like to discuss out of the recording we can do so at the end. Any information you provide after the recording stops will not be included in the analysis.”

- Confirm the number of questions (6) and estimated length of the interview (approximately 30 minutes).

- Orientation to the agenda: “The interview questions are divided into two general topics. Firstly we’ll consider what it was like to implement the JITAI study booklet in routine practice. We’ll then move on to some questions exploring usefulness, barriers and enablers to implementing the JITAI study booklet. Finally we’ll move on to your overall impression about the JITAI study booklet and any suggestions you have to inform further development of the JITAI study booklet. Is there anything you’d like to check out before we begin?”

Interview questions and prompts

1. **Was it possible for you to recruit patient participants and implement the JITAI study booklet in routine practise after attending the training session?**

Prompts: If yes- how soon after attending training did you recruit your first participant. How did patients respond to you using the booklet? How did the JITAI study booklet influence your clinical practise? If no – what made it difficult to recruit patients to the trial?

2. **What factors in the ward environment or personal factors helped to facilitate implementing the JITAI study booklet on the ward if any?**

Prompts: were there any factors that made this easier within your role such as staffing levels on the day, number of patients on the ward etc. Were there any elements of the booklet itself which made it easy to implement the JITAI study booklet? Did seeing other colleagues implementing the method make it easier for you to implement? Did team dynamics on the ward act as an enabler?

3. **What were the barriers to implementing the JITAI study booklet on the ward if any?**

Prompts: were these barriers outside of your control or personal? Were any of the barriers related to the design of the booklet or the way you were trained to use it? Did you encounter resistance from patients when using the booklet? Did team dynamics on the ward act as a barrier?

4. **Were there any aspects of the JITAI study booklet that were useful in your clinical practise or for the ward more generally?**

Prompts: did the JITAI study booklet help in managing risk on the ward, were there any specific situations i.e meetings etc where the JITAI study booklet was useful?

5. **Were there any aspects of the JITAI study booklet that were unhelpful or caused any hindrance to your clinical practise or for the ward more generally?**

Prompts: did the JITAI study booklet get in the way of other areas of clinical practise or ward activities?

6. **What was your overall impression of using the JITAI approach and is there anything else you would like to share about your experience of using the JITAI study booklet? Do you have any suggestions for future developments?**

Appendix L- Study Poster

University of Sheffield

NHS Sheffield Health and Social Care NHS Foundation Trust

NHS Rotherham Doncaster and South Humber NHS Foundation Trust

Calling For Service Users

Taking one day at a time, suicide, and self-harm prevention feasibility trial

Are you an inpatient on the ward? if yes, we invite you to take part in this study!

Why are we doing this study?

Research tells us asking about suicidal thoughts- reduces them!

Prevention is better than cure.

if we work with you to monitor your self-harm and suicidal ideation daily – we can predict when you are most likely to act on these thoughts and intervene early!

This trial is the first of its kind in the NHS & we want **YOU** to be a part of it!

If you are interested in taking part or wish to find out more about this study please speak to a member of the ward team.

What will it involve?

If you choose to take part, you will work through a booklet daily with a member of staff.

This booklet will include questionnaires and space for you to make notes on what is going well and what helps when you are struggling.

The booklet will help us to help you stay safe and well whilst you are on the ward.

A bit about the researcher:

My name is Ibreeze, I am a final year Trainee Clinical Psychologist at the University of Sheffield.

I want to see if a new intervention to reduce self-harm will work in NHS inpatient services

This research forms part of my doctoral thesis in clinical psychology

Appendix M- Participant Information Sheet for patients

Participant Information Sheet

Feasibility Trial of a Just in Time Adaptive Intervention (JITAI) to prevent self-harm events in an inpatient care setting.

You are being invited to take part in a research project on a Feasibility Trial of a Just in Time Adaptive intervention (JITAI) to prevent self- harm events in an inpatient care setting. Before you decide whether or not to participate, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If anything is not clear or if you would like more information, please ask us; our contact details are at the end of this information sheet.

What is the purpose of this study?

Suicide is a leading cause of death worldwide and one of the major reasons why people are admitted to psychiatric inpatient settings in the NHS. Tragically, 5583 people died by suicide last year in the UK. Research has shown that suicidal ideation varies greatly over time and the factors leading up to someone enacting suicidal behaviours vary depending on an individual's personal context. Current methods of management and treatment of suicidal behaviours and self-harm tend to come into action once someone has carried out the behaviour.

We would like to study if using a Just in Time Adaptive Intervention to prevent self-harm incidents will be feasible and acceptable within the current context of the NHS.

Why am I being asked to take part?

We would like you to take part as you are currently an inpatient on a psychiatric inpatient ward that has been identified as appropriate for this research project. We would like you to complete a questionnaire daily for the duration of your inpatient stay. You would be asked about many aspects of your mental health and wellbeing as well as suicidal ideation and risk (e.g. symptoms of anxiety and depression), some of the questionnaires you may already complete.

We are also collecting additional information from you including your age, ethnicity, gender and confirmed psychiatric diagnoses. We will be looking at how all these factors may be related to the number of self-harm incidents reported on the wards.
We would like to look at all these factors as part of our analysis.

Do I have to take part?

No, taking part in this research is entirely voluntary. If you do not wish to take part, there will be no negative consequences. Deciding not to take part will have no impact on the care you receive. You may also discontinue your participation at any time, without giving a reason why. It is up to you to decide whether or not to take part. If you decide to take part you will be asked to sign a consent form before you participate.

What will happen if I take part? What will I have to do?

You will have a booklet which will contain questionnaires. Initially you will complete an admission questionnaire, staff will put your score in a risk calculator and this will give them an estimate of your risk. This will be recorded in your booklet and will help staff to monitor changes in your risk regularly.

You will be asked to complete the questionnaires in a 1:1 session with a staff member in a booklet, it is recommended for this to be daily. This will involve several statements you will have to rate according to how you have felt in the last day. You will also be asked how often you have had thoughts of self-harm or suicide.

The staff member will score your questionnaires and plot your scores in a chart within your booklet. This chart will help staff to monitor your risk with you. If your chart shows your risk of self-harm is increasing the staff member will speak to you about safety planning and managing your risk.

Example statements include:

In the past 24 hours I have felt calm and relaxed

1	*2*	*3*	*4*	*5*	*6*
All of the time					*At no time*

In the past 24 hours I have felt like a burden on others

1	*2*	*3*	*4*	*5*	*6*
All of the time					*At no time*

What are the possible disadvantages and risks of taking part?

The questionnaires ask about topics that may be upsetting. If you are feeling distressed by any of the questions you can speak to the member of staff about this in the 1:1 session.

What are the possible benefits of taking part?

The project is a new way of monitoring risks on the ward and can help staff to intervene early. Whilst there are no immediate benefits for people participating in the project, it is hoped that this work will help us to see if this type of intervention method can be used in inpatient settings in the NHS and will provide us with enough data to do a preliminary randomised control trial.

Will my taking part in the project be kept confidential?

All the information that you provide will be kept strictly confidential and will only be accessible to members of the research team. The only exception for this would be if information arose which caused the research team concerns for the safety of you or others. In these circumstances we would have a duty of care to pass the information on. You will not be identified in any reports or publications unless you have given your explicit consent for this. If you agree to us sharing information you provide with other researchers (e.g. by making it available in a data archive) then your personal details will not be included unless you explicitly request this.

What is the legal basis for processing my personal data?
According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest ' (article 6 (1)(e)).

As we will be collecting some data that is defined in the legislation as more sensitive (i.e. information about your ethnic origin and health), we also need to let you know that we are applying the following condition in law: that the use of your data is 'necessary for scientific or historical research purposes'.

What will happen to the data collected, and the results of the research project?

Your data will be stored securely at the University of Sheffield, accessible only to members of the research team. Data will be anonymised as you will be assigned a unique participant number/ pseudonym. The research team will take and store copies of completed booklets, fully anonymised, for up to 10 years, these will be held securely at the University of Sheffield.

You may withdraw your data without giving a reason why up until March 2024, which is when we will begin analysing the data. To do so you can contact the lead researcher (please find details at the end of this information sheet). Up until commencement of data analysis your pseudonym will be stored securely with your data, so we can

withdraw your data if you wish. However, after data analysis commences your pseudonym will be erased and you will no longer be able to withdraw your data from the study.

The results of this research will form part of a Clinical Psychology Doctoral thesis. We also aim to publish the results in an academic journal. As stated above you will not be personally identified in any reports or publications.

Due to the nature of this research, it is very likely that other researchers may find the data collected to be useful in answering future research questions. We will ask for your explicit consent for your data to be shared in this way.

Who is organising and funding the research?

This study is being conducted by Ibreeze Ahmed (Clinical Psychologist in Training), as part of the qualification towards becoming a Doctor of Clinical Psychology at the University of Sheffield. Ibreeze is being supervised by Dr Jaime Delgadillo, who is also based at the University of Sheffield. The research is being carried out in collaboration with the NHS, specifically Rotherham Doncaster and South Humber NHS Foundation Trust (RDASH) and Sheffield Health and Social Care NHS Foundation Trust (SHSC).

The University of Sheffield will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly.

Who has ethically reviewed the project?

This project will be reviewed by the NHS ethical review board. This means that it has been agreed that the project is safe to be conducted in NHS settings.

What if something goes wrong and I wish to complain about the research?

If you wish to make a complaint about this project in the first instance you should contact the lead researcher or their supervisor. If you do not feel satisfied that your complaint has been dealt with appropriately you can contact the Head of the Psychology Department, who can be contacted at the following address: Department of Psychology, University of Sheffield, Cathedral Court, 1 Vicar Lane, Sheffield, S1 2LT.

If your complaint relates to how your personal data has been handled, additional information about how to raise a concern can be found in the University's Privacy Notice:

Contact Details

Lead Researcher

Ibreeze Ahmed
Department of Psychology, University of Sheffield,

Cathedral Court, 1 Vicar Lane,
Sheffield, S1 2LT.
Email: iahmed6@sheffield.ac.uk
Telephone: Please leave a message with research officer Amrit Sinha on 0114226650 and Ibreeze will return your call.

Supervisor

Dr Jaime Delgadillo
Department of Psychology, University of Sheffield,
Cathedral Court, 1 Vicar Lane,
Sheffield, S1 2LT.
Email: j.delgadillo@sheffield.ac.uk
Thank you very much for taking time to read about the project

Appendix N- Consent form for patient participants

Feasibility Trial of a Just in Time Adaptive Intervention (JITAI) to prevent self-harm events in an inpatient care setting.

Consent Form

Please tick the appropriate boxes	**Yes**	**No**
Taking Part in the Project		
I have read and understood the project information sheet, or the project has been fully explained to me. (If your answer is No to this question, please do not proceed with this consent form until you are fully aware of what your participation in the project will mean.)		
I have been given the opportunity to ask questions about the project.		
I agree to take part in the project. I understand that taking part in the project will involve me completing daily questionnaires.		
I understand that my participation is voluntary and that I can withdraw from the study at any time. I do not have to give any reasons for why I no longer want to take part and there will be no adverse consequences if I choose to withdraw from the project.		
How my information will be used during and after the project		
I understand my personal details such as name, age, gender, diagnoses etc will not be revealed to people outside the project.		
I understand and agree that my words may be quoted in publications, reports, web pages and other research outputs, only if they agree to preserve the confidentiality of the information as requested in this form.		
I understand and agree that other authorised researchers may use my data in publications, reports, web pages and other research outputs, only if they agree to preserve the confidentiality of the information as requested in this form.		
I understand and agree that other authorised researchers will have access to this data only if they preserve the confidentiality of the information as requested in this form.		
So that the information you provide can be used legally by the researchers		

I agree to assign the copyright I hold in any materials generated as part of this project to The University of Sheffield.		

Name of Participant: Signature: Date:

_____

Name of Person taking consent: Signature: Date:

_____

Project contact details for further information

Lead Researcher: Ibreeze Ahmed (iahmed6@sheffield.ac.uk)
Supervisor: Dr Jaime Delgadillo (j.delgadillo@sheffield.ac.uk)

In the event of a complaint, please contact Head of Psychology Department:

Address: Department of Psychology, University of Sheffield, Cathedral Court, 1 Vicar Lane, Sheffield, S1 2LT.