Statistical Analysis Plan

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2 Administrative information

This Statistical Analysis plan was formulated based on the template of Michigan Institute for Clinical & Health Research (2018) and the guidelines by Gamble et al. (2017).

TRIAL FULL TITLE	Statistical analysis plan for the study on the effectivity of the Suicidal Crisis Intervention (SCI): A Randomized Controlled Trial with follow-up to assess effects of the SCI intervention for patients after a suicide attempt or suicidal crisis.
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TRIAL PRINCIPAL INVESTIGATOR	Prof. dr. Gwendolyn Portzky
SAP AUTHOR(s)	Pauline Stas, Eva De Jaegere

2.1 SAP Signatures

I give my approval for the attached SAP entitled Effectivity of the Suicidal Crisis Intervention dated 21/10/2022

Principal Investigator
Name: Prof. dr. Gwendolyn Portzky

Signature:

Date: 27/01/2023

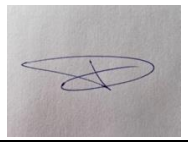
Researchers and authors of the SAP

Name: Pauline Stas

Signature:

Date: 27/01/2023

Name: Eva De Jaegere



Signature:

Date: 27/01/2023

3 Abbreviations and Definitions

AIC	Akaike's Information Criterion
ASSIP	Attempted Suicide Short Intervention Program
BHS	Beck Hopelessness Scale
BSS	Beck Scale for Suicidal ideation
CI	Confidence interval
D	Cohen's d
DS	Defeat Scale
ES	Entrapment Scale
FU	Follow-up
INQ	Interpersonal Needs Questionnaire
M	Mean
N	Sample size
PROM	patient reported outcome measure
RCT	Randomized Controlled Trial
SAP	Statistical Analysis Plan
SCI	Suicidal Crisis Intervention
SD	Standard deviation
TAU	Treatment As Usual

4 Introduction

4.1 Background and rationale

Research has extensively shown that a previous suicide attempt or a history of suicide attempts are important predictors of suicide (Harris & Barraclough, 1997; Hawton et al., 2003; Nordentoft, 2011). The risk of suicide is particularly increased during the first year after a suicide attempt, but remains elevated (de Moore & Robertson, 1996; Jenkins, 2002; Suominen, Isometsä, Ostamo, et al., 2004; Suominen, Isometsä, Suokas, et al., 2004; Tidemalm et al., 2008, 2015). Therefore, it is important to provide appropriate care after a suicide attempt to limit this risk. Unfortunately, the number of interventions developed for this risk group is limited.

In Switzerland, a short-term treatment program was developed specifically for this risk group: Attempted Suicide Short Intervention Program (ASSIP, Michel & Gysin-Maillart, 2015). A randomized controlled trial showed that ASSIP treatment was associated with an 80% reduced risk of making at least one suicide attempt (Gysin-Maillart et al., 2016). In addition, they spent less time in hospitals (Gysin-Maillart et al., 2016) and showed less dysfunctional coping and more problem-focused coping (Gysin-Maillart et al., 2020).

Based on these findings, a short-term treatment program was developed for people after a suicide attempt or a suicidal crisis in Flanders (i.e. part of Belgium), named Suicidal Crisis Intervention (SCI). This was inspired by ASSIP and the use of safety planning (Stanley & Brown, 2012) was included as an important part of the treatment. Moreover, this treatment emphasizes the importance of close ones and social support. Throughout this treatment, further (treatment) goals are drawn up, in order to generate hope for improvement and to facilitate continuity of care.

The research question is: "Is SCI an effective short treatment for people after a suicide attempt or suicidal crisis in terms of suicidal ideation and associated risk factors (namely hopelessness, defeat, entrapment, thwarted belongingness, perceived burdensomeness, and follow-up care) on short- and long-term, compared to treatment as usual?".

4.2 Scope of the analyses

These analyses will assess the short- (6 weeks (42 days) after randomization) and long-term (3 and 6 months after post-test, respectively 132 and 222 days after randomization) effectivity of the Suicidal Crisis Intervention (SCI) in comparison with Treatment As Usual (TAU) with respect to suicidal ideation, and associated risk factors namely hopelessness, defeat, entrapment, thwarted belongingness, perceived burdensomeness, and follow-up care and will be included in the clinical study report.

5 Study Objectives and Endpoints

5.1 Research hypothesis

The null hypothesis is that there is no difference in suicidality and related risk factors between the intervention (SCI) and control (TAU) groups. The alternative hypothesis is that there is a difference between the two groups, more specifically, that suicidality is decreased at post-measure (short term effect) for the intervention group, compared with the control group, and that these effects remain at follow-up (long term effect). Additionally, the alternative hypothesis is that follow-up care is increased and suicidal behavior, hopelessness, defeat, entrapment, thwarted belongingness and perceived burdensomeness, are decreased at post-measure (short term effect) for the intervention group, compared with the control group, and that these effects remain at follow-up (long term effect).

5.2 Study Objectives

The primary objective of this trial is to determine the effectiveness of the SCI as an intervention for people after a suicide attempt or suicidal crisis, compared to treatment as usual, with respect to short term (6 weeks (42 days) after randomization) and long term (3 and 6 months after post-test, respectively 132 and 222 days after randomization) suicidal ideation.
The second objective is to examine this short- and long-term effect of SCI compared to treatment as usual, on other important aspects and risk factors of suicidality, namely hopelessness, defeat, entrapment, thwarted belongingness, perceived burdensomeness, and follow-up care.

5.3 Endpoints

Primary endpoint: Change from baseline in Beck Scale for Suicide Ideation (suicidality) at week 6. A higher score on BSS is considered worse, thus a decrease in BSS score following the SCI intervention would be a positive result, supporting the effectiveness of SCI.
Secondary endpoints: change from baseline in BSS at follow-up 1 (132 days after randomization) and follow-up 2 (222 days after randomization); change from baseline at 6 weeks, 132 days and 222 days after randomization in Beck Hopelessness Scale (BHS; hopelessness), Defeat and Entrapment Scale (DS and ES; Defeat and entrapment), Interpersonal Needs Questionnaire (thwarted belongingness and perceived burdensomeness), follow-up care. Positive changes would mean decreases in BSS, BHS,DS, ES and INQ scores and increases in frequency of follow-up care.
All outcomes will be administered online and will be self-reported, thus patient reported outcome measure (PROM).

6 Study Methods

6.1 General Study Design and Plan

This study is a longitudinal, randomized, parallel-group, controlled trial. Treatment allocation is a 1:1

ratio. Participants are randomized after providing informed consent and completing the baseline-measure (self-report outcomes). Participants are randomized to either SCI (intervention group) or TAU (control group). Randomization will be conducted through an online program using permuted block randomization with variable block sizes. The randomization schedule will be developed by an external statistician, to ensure blinding of the researchers. As described in the study objectives, effectivity of SCI compared to TAU is examined and the type of comparison is thus superiority, rather than equivalence. Additional attention will be given to potential adverse effects. The researchers and patients will be blind concerning which treatment they will receive during baseline assessments, which are performed before randomization. This study is thus a non-blinded RCT with baseline assessments before randomization.

Screening will be conducted upon enrollment. Upon arrival at the psychiatric department of the hospitals that are involved in this study, a first screening will be performed to see whether the patient is eligible for this study (see inclusion and exclusion criteria, 6.2). If the patient is found to be eligible, the study will be briefly presented and the patient will be asked to provide (online) informed consent. Participating hospitals and organizations will be asked to keep a screening logbook, registering the number of times they presented the study, and reasons for declining by participants or exclusion of the study.

If informed consent is obtained, the patient will be invited (by e-mail) to complete the online baseline questionnaire. After this, an online randomization will take place in which the participant is assigned to the control or intervention group. Participants assigned to the intervention group will receive the SCI intervention. In addition, participants assigned to the intervention group may receive any necessary treatment, with no limitations in duration or frequency. The intervention group is thus a TAU+SCI group. Participants in the control group will receive treatment as usual (TAU).

Self-report questionnaires will be administered at baseline, post-intervention and twice at follow-up. The questionnaires will all be administered online and will be self-reported. Post-measure will be conducted 6 weeks (42 days) after baseline. Follow-up measures will be administered 3 months and 6 months after post-measure (132 and 222 days after randomization) is completed.

This information is presented in figure 1.

[FIGURE 1 ABOUT HERE]

6.2 Inclusion-Exclusion Criteria and General Study Population

Inclusion criteria patient:

- Patients after a suicide attempt or suicidal crisis (acute suicidality). The specific period between the attempt or crisis and the start of the study is not an inclusion criterium. Ideally, study participation is within the first three weeks after the attempt. Duration since last attempt is included in the baseline questionnaire.
- 18 years or older
- Fluent in Dutch
- Have access to the internet (for questionnaire completion)

Exclusion criteria patient:

- Limited comprehension
- Unsuitable for individual therapy
- Cognitive impairment
- Psychotic disorder

Inclusion criteria close one:

- close one of the patient
- ≥ 18 years
- Dutch- speaking

6.3 Randomization and Blinding

After giving informed consent and completing baseline measure, participants will be allocated to either the control group (TAU) or intervention group (TAU + SCI).
In general there will be no blinding of participants, but baseline assessments take place before randomization (non-blinded RCT).
Randomization will be conducted through an online program using permuted block randomization with variable block sizes. The randomization schedule will be developed by an external statistician, to ensure blinding. Randomization will be stratified according to type of treatment facility [Mobile, residential, ambulant, semi-residential] where the patient is recruited. Treatment allocation is a 1:1 ratio.

6.4 Study Assessments

Both the participants from the intervention group and the participants from the control group receive online questionnaires at approximately the same times:

T0 (baseline): At the time of admission (before the start of treatment)
T1 (post-test): 6 weeks (42 days) after randomization
T2 (follow-up): three months after post-test (132 days after randomization)
T3 (follow-up): six months after post-test (222 days after randomization)

	Baseline	Post-Test	Follow-Up 1	Follow-Up 2
Target day of questionnaire		42	132	222
Protocol assessment time windows (days)		+ 31	+ 31	+31
Demographics	x			
Primary outcome				
Suicidality (BSS)	x	x	x	x
Secondary outcomes				
Suicidal behavior	x	x	x	x
Hopelessness (BHS)	x	x	x	x
Defeat (DS)	x	x	x	x
Entrapment (ES)	x	x	x	x
Interpersonal Needs (INQ)	x	x	x	x
(Prepared to follow) follow-up care	x	x	x	x
Treatment satisfaction		x		

For each point of measurement, a reminder will be sent after 7 days of first invitation to complete the questionnaire.
Assessments collected from 42 to 73 days post-randomization are identified as the post-test. Assessments collected from 132 to 163 days post-randomization are identified as follow-up 1. Assessments collected from 222 to 253 days post-randomization are identified as follow-up 2.

A cut-off period of one month will be used to exclude data. More specifically, if a questionnaire is completed more than one month after initial invitation to complete the questionnaire, data will not

be included.

The measures included in the questionnaires are described below:

Demographics

- Age in years
- Gender [male, female, other]
- Centre from which recruited [locations to be determined]
- Type of treatment department [residential, ambulant, mobile, semi-residential]

Additional information concerning the intervention

- How many close ones were involved in treatment [0, 1, 2, 3, >3]
- How many sessions were with a close one present [0,1,2,3,4]
- Which person was involved in treatment: list of 15 options [parents, sibling, friend,…]

Primary outcome: suicidal ideation

Suicidal ideation

Suicidal ideation will be assessed using the Beck Scale for Suicide ideation (BSS; Beck et al, 1979). This is a 21-item self-report questionnaire. Each item is rated on a scale from 0 to 2, resulting in a total score ranging from 0 to 38.

Secondary outcomes

Suicidal behavior

For assessing suicidal behavior, the participant will be asked whether, since the last measurement (baseline: ever/in the last 12 months) they experienced suicidal thoughts [yes/no] or attempted suicide [yes/no].

Hopelessness

Hopelessness will be assessed using the Beck Hopelessness Scale (Beck et al., 1974) is a 20-item self-report questionnaire to measure hopelessness. Respondents rate statements as 'true' (score= 0) or 'false' (score= 1) for themselves over the past week, resulting in a total score between 0 and 20.

Defeat and entrapment

Defeat and entrapment will be assessed using a short form of, respectively, the Defeat Scale (DS) and Entrapment Scale (ES), both developed by Gilbert and Allan (Gilbert & Allen, 1998; Griffiths et al., 2015). These two 4-item scales use a five-point Likert scale. Where 0=never/Not at all like me, 1=rarely/A little bit like me, 2=sometimes/Moderately like me, 3=mostly (a lot)/Quite a bit like me, 4=always/Extremely like me. The total range per scale is [0-16].

Interpersonal needs

Interpersonal needs will be measured using the short form of the Interpersonal Needs Questionnaire (INQ; Van Orden et al., 2012). This is a 10-item questionnaire where each item is rated on a 7-point Likert scale with 1= Not at all true for me, 4 = somewhat true for me and 7 = very true for me, resulting in a total score ranging [10-70].

(Prepared to follow) follow-up care

To assess whether participants receive follow-up care or are prepared to receive follow-up care, 14 questions were asked. About which psychological [none, GP, psychologist, psychiatrist, other health care worker, residential care, waiting list], medical [no medication, pain killers,

tranquilizers/anxiolytics, sleeping pills, antidepressants, antipsychotics, other] treatment they were currently receiving, they started/stopped/changed since the start of the study and or prepared to receive. The results on this questionnaire will not result in a total score. Instead, the results will be presented in a descriptive manner.

Treatment satisfaction

To investigate how patients of the intervention group experienced the SCI, some evaluative questions were asked. Participants were asked to indicate how many sessions they received, how they would rate the treatment [0-10], what they thought of the number and length of sessions [too little/short, good, too many/long], rate to what degree they agreed [strongly disagree, disagree, neutral, agree, strongly agree, not applicable] with 8 statements about the treatment, and 2 open questions about the strengths, weaknesses of the treatment.

7 Sample Size

A total sample size of 218 participants (109 in each group) is needed to achieve at least 80% power to detect a difference in mean change from baseline in BSS score at week 6 (from randomization) between groups (SCI versus TAU) of 3 points at the two-sided 5% significance level, when the standard deviations are 7.58 and 8.17 (De Jaegere et al., 2019). The total sample size has been increased to 221 participants to allow for an interim analysis for efficacy when 60% of the participants has been assessed, based on the O'Brien Fleming type I error spending function.
The total sample size has further been increased to 260 participants, to allow for a 15% drop-out rate. The sample size was calculated using the "gsDesign" package in R.

Previous similar interventional studies on a suicidal population have not succeeded in recruiting this number of participants.
e.g.:

- ASSIP RCT: 120 participants were randomized. (Gysin-Maillart et al., 2016)
- CAMS RCT: 80 participants were randomized (Ryberg et al., 2019)

Therefore, realistically, we are aware that this sample size might not be reached and the analyses will have to be performed on a smaller sample.

7.1 Interim analyses

An interim analysis for efficacy will be performed when 133 participants (60% of the final sample size) have been assessed at week 6. When the interim analysis for efficacy is significant at the two-sided 1% significance level, the trial can stop recruiting patients and all other analyses can also be performed and interpreted. When the interim analysis is not significant at the two-sided 1% significance level, the final analysis can test at the two-sided 4.6% significance level to control the nominal type I error rate at 5%.

[FIGURE 2 ABOUT HERE]

[FIGURE 3 ABOUT HERE]

8 General Analysis Considerations

8.1 Timing of Analyses

The final analysis will be performed after the last randomized participant has been followed for at least 8 months and after all data have been cleaned.
Interim analyses will be performed when 133 participants (60% of the final sample size) have been assessed at week 6.

8.2 Analysis Populations

All main analyses will be performed on the intention to treat population.
Differences on demographic variables and baseline outcome measures will be examined between the intention-to-treat sample and the per protocol sample.
In case the primary endpoint is not significant in the ITT population, sensitivity analyses will be performed using the per protocol population to examine possible differences with the ITT population.

8.2.1 Full Analysis Population (Intention to Treat)

All randomized patients (completed baseline) and analysis according to allocated treatment. Subjects with baseline BSS score of 0 will not be included in analyses.

8.2.2 Per Protocol Population

All randomized patients who (partially) completed the post questionnaire and who did not have any major eligibility or protocol deviations (e.g. questionnaires completed more than one month after initial invitation to complete questionnaire, see section 6.4). For the intervention group, subjects who received less than 4 sessions of the SCI treatment is seen as protocol deviation.

8.3 Covariates and Subgroups

Subgroup analyses for Age (continuous) and gender (categorical: male, female, other), type of department/service (categorical: ambulant, mobile, residential, semi-residential), history of suicide attempts (categorical: yes / no) and severity of suicidality at baseline (as measured by the BSS, continuous), and inclusion of a close one in treatment (categorial: yes/no) will be conducted exploratory by including a three-way interaction time*group*subgroup.

Subgroup analyses are explorative and are not taken into account when calculating the sample size. Interpretation of these results needs to take this into account.

8.3.1 Multi-center Studies

Participants will be asked at baseline which facility they were recruited from. Participants are recruited through hospitals thus each participants will indicate 1) which hospital and 2) which type of department or service (residential, mobile, ambulant, semi-residential). Hospital will be added to the linear mixed model as random effect, while type of department/service will be added as fixed effect.

8.4 Missing Data

Participants with missing baseline values will not be included for randomization and thus not be included in this study.
Missing data in outcome variables will be assumed to be missing at random. Using linear mixed models (based on maximum likelihood), all available information will be included in the analyses. Considering the use of linear mixed models, no imputation will be used.

8.5 Multiple Testing

The nominal type I error rate is controlled at 5% using the O'Brien-Fleming error spending function. No adjustment for multiple testing because of multiple time points is made, because the changes from baseline in BSSI at 3 and 6 months are considered as secondary endpoints and will only be interpreted if significance on the primary endpoint can be demonstrated.
Subgroup analyses will be explorative.

9 Summary of Study Data

All continuous variables will be summarized using the following descriptive statistics: mean, standard deviation. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures. All summary tables will be structured with a column for the total sample (based on the non-missing sample size) and each treatment in the order 'Control' – 'Intervention' and will be annotated with the total population size relevant to that table/treatment. This will be based on the intention to treat sample

Only deviations from the general overview will be noted in the subsequent sub-sections within section 9.

9.1 Subject Disposition

Participants will be excluded from randomization in case

- They don't fit inclusion/exclusion criteria
- They don't provide informed consent
- They don't complete baseline
- They decline participation
- They die before randomization
- The study closes

A skeleton CONSORT flow diagram is provided in figure 1.

The summary statistics will be produced in accordance with section 9.

9.2 Derived variables

Not applicable

9.3 Protocol Deviations

See 8.2: per protocol or intention to treat populations. All main analyses will be performed on the intention to treat population, rather than the per protocol population. Major deviations would be not participating in the intervention and not completing questionnaire or completing questionnaire more than one month after initial invitation to complete the questionnaire, which will lead to exclusion in the per protocol population, but inclusion in the intention to treat population.

9.4 Demographic and Baseline Variables

Demographic variables will include age [continuous], gender [categorical: man, woman, other] and information about the close one(s) participating in treatment (number present and type of relation). The last variable, concerning close one(s) participating in treatment, will only be administered at post-test.

All outcome variables (6.4) will be administered at baseline.

The summary statistics will be produced in accordance with section 9.

9.5 Treatment Compliance

Participants from the intervention group will be asked how many sessions of the SCI intervention they received. Follow-up care, medical as well as psychological, are asked as outcome variable and will thus also be registered.

The summary statistics will be produced in accordance with section 9.

10 Efficacy Analyses

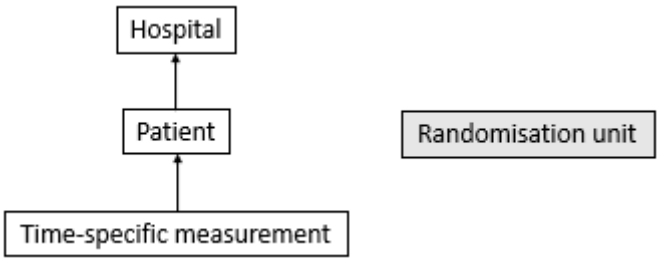
First, descriptive statistics (as described in section 9) will be calculated for baseline characteristics and outcomes. Moreover, differences between participants who completed baseline only, and participants completed at least one post-test measurement, will be calculated. The differences will be calculated using chi-square or Fisher's exact test (when there were less than 5 observations per cell) and t-tests. These results will be displayed as in table 1.

[TABLE 1 ABOUT HERE]

Additionally, data concerning the close one(s) present during the treatment in the intervention group, will be presented in a table, as illustrated in table 2.

[TABLE 2 ABOUT HERE]

The intention-to-treat sample (primary population) data will be analyzed using linear mixed models. Time-specific measurements will be nested within patients. Patients are nested within hospitals of recruitment. Randomization is on the patient level (i.e. some patients will be allocated to the intervention group, others to the control group).



For each of the outcomes, except suicidal behavior and (preparedness for) follow-up care (dependent variables), linear mixed models with two random intercepts: patient and hospital. The effect of the intervention is captured in the two-way interaction between time and treatment group.
Compound symmetry covariance matrix will be used for the primary analyses. Sensitivity analyses will be conducted by selecting covariance matrices using AIC.
Results obtained from the mixed models will be described as illustrated in table 3.

[TABLE 3 ABOUT HERE]

This study will be confirmatory (testing superiority) and look at the following primary hypotheses:
Null hypothesis: there is no difference between the intervention group and control group in mean change from baseline in suicidality at week 6, as measured by the BSS.
Alternative hypothesis: there is a difference between the intervention group and control group in mean change from baseline in suicidality at week 6, as measured by the BSS. More specifically, there

is a greater reduction in suicidality in the intervention group, compared to in the control group.

10.1 Primary Efficacy Analysis

The primary efficacy analysis will be a linear mixed model for outcome 'suicidal ideation' as measured by the Beck Scale for Suicidal Ideation (BSS). This mixed model will be conducted and presented as explained in section 10.
The summary statistics will be produced in accordance with section 9.

10.2 Secondary Efficacy Analyses

Secondary analyses will be linear mixed models for the outcomes hopelessness, defeat, entrapment and interpersonal needs. These mixed models will be conducted and presented as explained in section 10.
Additionally, secondary efficacy analyses will be performed for the outcomes suicidal behavior and (preparedness for) follow-up care. This will be done using generalized linear mixed models (cluster-specific, assumes MAR).
The summary statistics will be produced in accordance with section 9.

10.3 Exploratory Efficacy Analyses

Explorative secondary analyses will be performed for the primary efficacy endpoint, using the per protocol sample.

Age and gender will be included into analyses (described in section10) by including a three-way interaction between time*group*subgroup.

Subgroup analyses for type of department/service (categorical: ambulant, mobile, residential, semi-residential), history of suicide attempts (categorical: yes / no) and severity of suicidality at baseline (as measured by the BSS, continuous), and inclusion of a close one in treatment (categorial: yes/no) will be conducted exploratory by including a three-way interaction between time*group*subgroup.

11 Safety Analyses

No safety procedure will be used in this trial, as participants receive treatment as usual.

In case of a suicide attempt, case-by-case evaluation will determine if it is feasible and advisable to continue the SCI intervention.
Mortality will be described in descriptive statistics, in case this information is known to us. Reported suicidality will be divided in general mortality, mortality by suicide or unknown.

11.1 Extent of Exposure

The summary statistics will be produced in accordance with section 9.
As mentioned earlier, data concerning the close one(s) present during the treatment in the intervention group , will be presented in a table, as illustrated in table 2.

11.2 Adverse Events

See section 11. The summary statistics will be produced in accordance with section 9.

11.3 Deaths, Serious Adverse Events and other Significant Adverse Events

See section 11. The summary statistics will be produced in accordance with section 9.

11.4 Clinical Laboratory Evaluations

Not applicable

11.5 Other Safety Measures

Not applicable

12 Other Analyses

Patient and close ones (independently) who attended the treatment will be asked to rate their satisfaction with (several aspects of) the treatment, using open questions as well as multiple choice questions (such as rating statements on a 5 point Likert scale, or agree/disagree/neutral). These results will be described in a descriptive manner (according to section 9).

13 Reporting Conventions

P-values ≥0.001 will be reported to 3 decimal places; p-values less than 0.001 will be reported as "<0.001". The mean, standard deviation, and any other statistics other than quantiles, will be reported to one decimal place greater than the original data. Quantiles, such as median, or minimum and maximum will use the same number of decimal places as the original data. Estimated parameters, not on the same scale as raw observations (e.g. regression coefficients) will be reported to 3 significant figures.

14 Quality Assurance of Statistical Programming (As Applicable)

All analyses will be done using SPSS version 28 (IBM Corp., 2021).

The questionnaires in which the personal data are collected are completed online in REDCap. REDCap is a secure web platform that is secured and supported by Ghent University. The personal data remains on a secure network within Ghent University and does not leave the EU. Once the data is received, the data is pseudonymized. This is done using encryption. Each test subject is given a unique code. The key to that code is stored in a secure document that is only accessible to the researchers. The document is stored online on the secured UGent network. The research results will not be used to make decisions that directly affect individuals.

All data, code and output files will be stored on the secured UGent network.

The population to be used in a table or figure will be explicitly set at the start of a block of code that computes the output.

Any outputs will have the

- date and time included
- the name of the code file that produced the analysis
- the author

At the start of any code file there will be a set of comments that give

- the author
- the date and time of writing
- references to inputs and outputs
- reference to any parent code file that runs the child code file

15 Summary of Changes to the Protocol and/or SAP

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16 References

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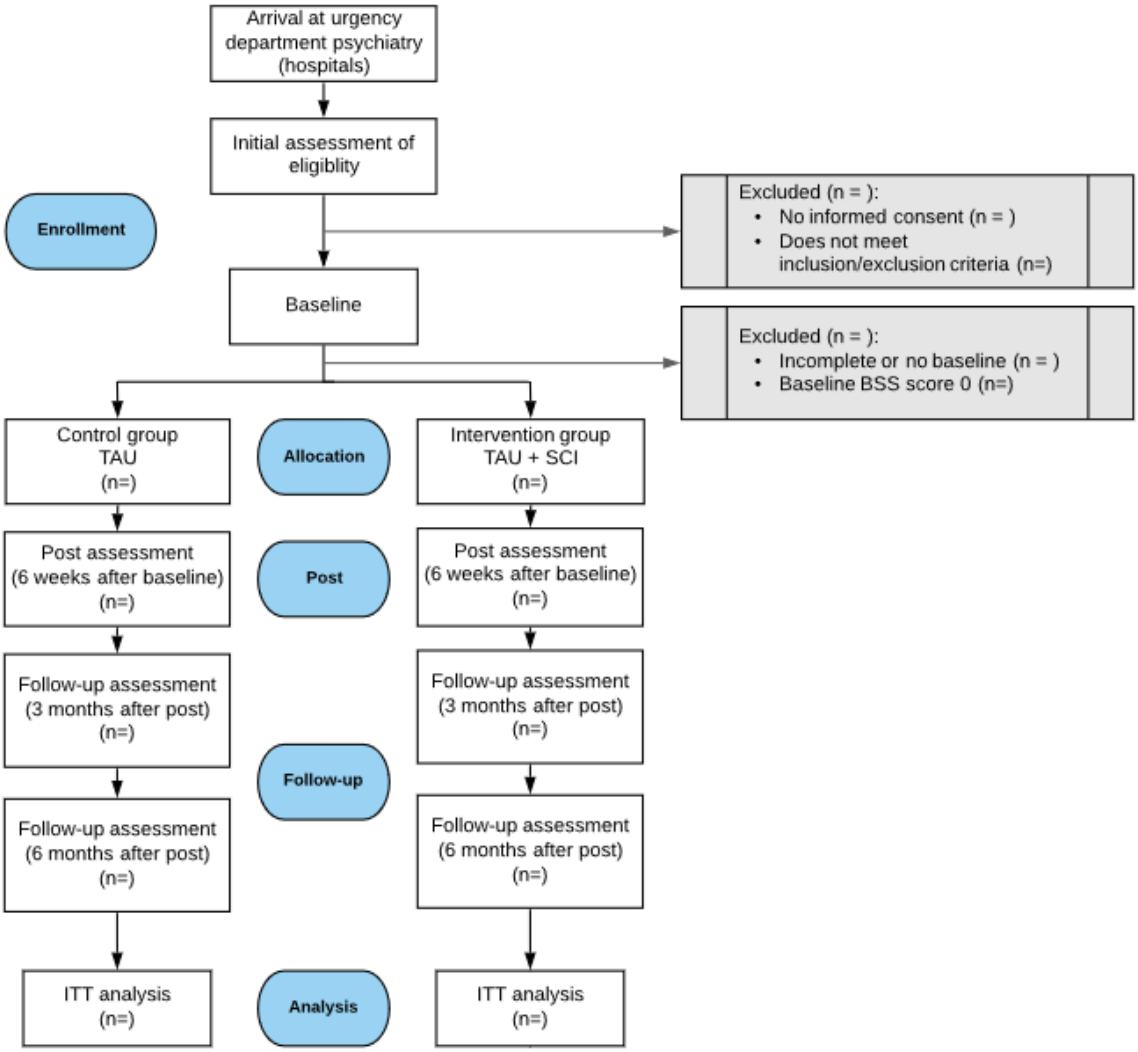
17 Listing of Tables, Listings and Figures

Figure 1. Participant flow.



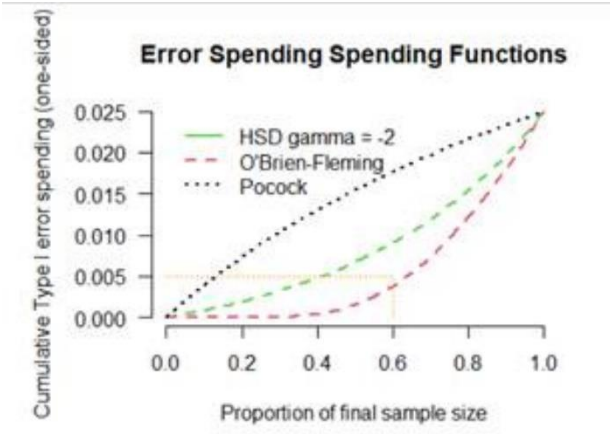


Figure 1. The O'Brien Fleming error spending function was chosen to control the nominal type I error rate. With 1 interim analysis at 60% of the final sample size, the two-sided significance level is set at 1%, using the O'Brien-Fleming error spending function..

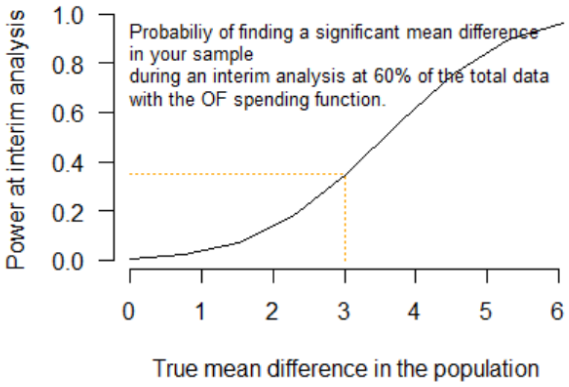


Figure 1. The interim analysis will have 35% power when the true mean difference in change from baseline in BSSI at week 6 between the groups is 3 points.

Table 1

Demographic and baseline clinical characteristics.

Characteristics	Total	Control	Intervention
Gender, *n* (%)			
Female			
Male			
Other			
Age, *M* (*SD*)			
Type of department/service, *n* (%)			
Residential			
Mobile			
Ambulant			
Semi-residential			
Current treatment for psychological problems, *n* (%)			
No			
Yes			
General practitioner			
Psychologist			
Psychiatrist			
Inpatient			
Other			
Waitlisted			
Prepared to start treatment for psychological problems, *n* (%)			
No			
Yes			
General practitioner			

Psychologist		Note:
Psychiatrist		
Inpatient		
Other		
Waitlisted		
Use of medication (current), *n* (%)		
No		
Yes		
Analgesics		
Sedatives/anxiolytics		
Hypnotics		
Antidepressants		
Antipsychotics		
Other		
Prepared to start use of medication, *n* (%)		
No		
Yes		
Analgesics		
Sedatives/anxiolytics		
Hypnotics		
Antidepressants		
Antipsychotics		
Baseline outcome measures		
BSS, *M* (*SD*)		
Previous suicidal thoughts, *n* (%)		
Yes, once		
Yes, more than once		
No		
Previous suicide attempt, *n* (%)		
Yes, once		
Yes, more than once		
No		
BHS, *M* (*SD*)		
Entrapment, *M* (*SD*)		
Defeat, *M* (*SD*)		
INQ, *M* (*SD*)		

Significance tests for categorial variables performed with χ^2-test, for continuous variables with t-test. BSS = Beck Scale for Suicide Ideation. BHS = Beck Hopelessness Scale. INQ = Interpersonal Needs Questionnaire

Table 2

Characteristics of close one(s) present during the treatment for the intervention group.

Characteristics	*n* (%)
Number of close ones present	
0	
1	
2	
3	
>3	
Number of sessions with close one(s) present	
0	
1	
2	
3	
4	
Type of close one(s)	
Parent	
Step-parent	
Child	
Step-child	
Partner	
Ex-partner	
Sibling	
Step-sibling	
Half-sibling	
Uncle/aunt	
Cousin	
Friend	
Colleague	
Acquaintance	
Other	

Table 3

Mean changes from baseline to post-treatment and to both follow-up measures and effect sizes on

Measure	Time	Control (*n* =)		Intervention (*n* =)		
		M (95% CI)	*p*-value	*M* (*95%CI)*	*p*-value	*p*-value
Suicidal ideation (BSS)	Baseline - Post					
	Baseline – FU1					
	Baseline – FU2					
Hopelessness (BHS)	Baseline - Post					
	Baseline – FU1					
	Baseline – FU2					
Defeat (DS)	Baseline - Post					
	Baseline – FU1					
	Baseline – FU2					
Entrapment (ES)	Baseline - Post					
	Baseline – FU1					
	Baseline – FU2					
Interpersonal Needs (INQ)	Baseline - Post					
	Baseline – FU1					
	Baseline – FU2					

the outcome measures with two-sided p value.

Note: FU = Follow-up. *CI* = Confidence interval. *d* = Cohen's *d* (0.20-0.30 small effect, 0.50 medium effect, >0.80 large effect). BSS = Beck Scale for Suicide Ideation. BHS = Beck Hopelessness Scale. DS = Defeat Scale. ES = Entrapment Scale. INQ = Interpersonal Needs Questionnaire.