Group Post-Admission Cognitive Therapy for Suicidality vs Individual Supportive Therapy for the prevention of repeat suicide attempts: a randomized controlled trial.

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Study protocol

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Abstract

Introduction: Suicide is a serious public health problem. The development and use of effective treatments for people hospitalized for suicide attempts remain a priority. Regarding psychosocial treatment, the evidence for treatments that effectively prevent suicide repetition of suicide attempts is extremely thin. There is some evidence that cognitive behavioural therapy may be effective for reducing suicide behaviour. The primary aim of this study is to compare Group Post-Admission Cognitive Therapy for Suicidality (GPACTS) versus Individual Supportive Therapy (IST) for preventing suicide. Methods and analysis: 240 participants with a high suicide risk score according to a Mini international Neuropsychiatric Interview will be randomly to either GPACTS or IST. This is a multicentre, parallel group, randomized (1:1 ratio), two-tailed-superiority trial with endpoint-assessor blinding. Patients meeting inclusion criteria during a screening visit will be enrolled in the study and randomized into two groups: one group will undergo six weeks of GPACTS, and the second group will undergo six weeks of IST. Following six weeks of interventional therapy, patients are followed-up for 12 months. Follow-up for both groups is identical and includes the administration of questionnaires at baseline and then within 10 days after the end of therapy sessions and then at 3, 6 and 12 months following the end of GPACTS/IST sessions. Discussion: To our knowledge, this is the first RCT of its kind to be conducted in France and so far, there are no studies in the literature on group psychotherapy for the treatment of individuals who have attempted suicide. The outcomes will provide clear guidance for professionals to apply psychological intervention with suicide attempts. The protocol respect ethical principles and ethical approval were obtained from the local ethics committee. The results will be disseminated through an original research published as original research in peer-reviewed manuscript, through a therapist manual for cognitive therapy, and presentations at research conferences.

Introduction

Suicide prevention is an international public health priority. Over 10,000 people die by suicide each year in France which represent one of the highest suicide rates in European countries [1]. The number of suicide attempts is close to 195,000 and is causing 90,000 hospitalizations each year [1]. In addition to the human cost, the economic burden of suicide or suicide attempts has been estimated in billions of euros per year in the USA, the UK, Canada, and New Zealand [2]. It is well documented in the literature that suicide risk is highest in the year after people have been discharged from a psychiatric hospital. A review of the literature confirms that patients recently discharged from hospitals have a risk 100 times higher compared with the general population and this risk peaks in the weeks immediately after discharge [3].

Numerous studies have been conducted to identify variables associated with suicide to help clinicians to determine who is at risk to attempt suicide. Attempted suicide is one of the strongest risk factors for completed suicide in adults. A meta-analysis of follow-up mortality studies estimated that individuals who attempted suicide were 38 to 40 times more likely to commit suicide than those who had not attempted suicide [4]. Other data suggest the need to develop early interventions for this population closer to hospitalization. Indeed, suicide attempters are estimated to have a risk of dying from suicide in

the first year following their attempt that is more than 66 times the annual risk of suicide in the general population [5].

The treatment of suicidal behavior (SB) is one of the most difficult challenges faced by clinicians. Pharmacological and psychosocial interventions are commonly proposed to suicide attempters and are usually offered in tandem. The development and use of effective treatments for people hospitalized for suicide attempts remain a priority. Regarding psychosocial treatment, the evidence for treatments that effectively prevent the repetition of suicide attempts is extremely thin [6]. One of the methodological difficulties associated with conducting these studies is that suicide rate is a rare event and a larger sample size is necessary to show statistically significant differences between and therapeutic group and a control group. However, there is some evidence that cognitive behavioural therapy (CBT) may be effective for reducing SB.

Brown et al. proceeded a randomized controlled trial (RCT) to evaluate the efficacity of cognitive therapy for the prevention of repeat suicide attempts [7]. The sample consisted of 120 patients who attempted suicide and who received a psychiatric evaluation within 48 hours of the attempt. Patients were randomly assigned to receive either CBT or treatment as usual. The cognitive therapy protocol consisted to receive ten individuals therapy sessions according to a treatment manual [7]. Follow-up assessments were conducted on all individuals over an 18-month period to determine whether they made another suicide attempt. The results showed that patients who received cognitive therapy were about 50% less likely to make a repeat suicide attempt during the follow-up period than those who did not receive cognitive therapy. Authors concluded that cognitive therapy was efficacious intervention for preventing suicide attempts.

A meta-analysis by Tarrier et al. confirms that CBT can reduce SB in the short term [8]. CBT does prove effective when compared with minimal treatment and was still effective when studies using control groups involving active psychological treatments were included in the analysis. This result suggests that CBT has a specific effect. Psychotherapy outcomes are generally thought of as consisting of both specific and non-specific effects. Non- specific effects like emotional support, therapeutic attention, empathic listening, implementation of therapeutic optimism and others are the result of every successful therapeutic relationship. These contrast with specific effects that are directly targeted by other types of therapy. One of the specific effects of CBT that is well documented is problem-solving strategies [9,10].

A more recent RCT study with 2 year-follow-up was conducted by Rudd et al. [11] who compared brief CBT to treatment as usual for the prevention of suicide attempts in military settings. Results show that soldiers in brief CBT were approximatively 60% less likely to make a suicide attempt during follow-up than soldiers in treatment as usual.

CBT could be an important contribution to the prevention of suicide. Moreover, treatment is more effective when directly focused on reducing a specific aspect of SB and less so when focused on other symptoms (such as depression or distress) aimed at reducing SB as a secondary effect. In other words, to be effective, specific CBT suicide prevention treatment programs need to be designed, tailored and

implemented to focus on suicidal behavior [8]. Despite these favorable preliminary results with CBT, the authors highlight the need for randomized controlled trials with sufficient power to detect treatment differences [11]. More controlled studies are required to establish psychotherapeutic techniques that will impact SB and that clinicians can be more confident with.

In order to respond to this need, this study will compare two types of psychosocial treatment: one with specific and non-specific effects (GPACTS) and the other (IST) with only non-specific effects. We choose to study CBT in a group format because the results of evaluative research on psychotherapy have demonstrated that the format of the therapy (individual versus group) does not appear to predict the outcome for several mental disorders [12]. In addition, the group format provides pragmatic advantages, such as more efficient use of human resources dedicated to patient care and subsequent cost savings. Thus, we hypothesize that GPACTS for suicide attempters can offer advantages in comparison with individual procedures, even if they cannot always perfectly fit the specific needs of every patient.

Methods

Hypothesis and objectives

We expect that patients in the IST group will reattempt suicide at an earlier date and a higher frequency as compared to patients enrolled in the GPACTS. The primary objective of this study is to evaluate the efficacy of a program of 6 sessions of GPACTS (as compared to 6 sessions of IST) designed for preventing repeat suicide attempts at 12 months post-psychotherapy in adults admitted to inpatient care for suicide attempts. The secondary objectives of this study are to assess the efficacy of GPACTS on: parameters describing the incidence of suicide and repeat suicide attempts, as well as suicide reattempt free follow-up time long-term changes in suicidal ideation, long-term changes in psychiatric symptoms (depression, hope for the future, hospitalization).

Study setting and design

The clinical aspects of this trial will take place within participating in academic or private hospitals (urban setting) located in France. Eight centres (seven academics and one private) have agreed to participate. This is a multicentre, parallel group, randomized (1:1 ratio), two-tailed-superiority trial with endpoint-assessor blinding. Patients meeting inclusion criteria during a screening visit will be enrolled in the study and randomized into two groups: one group will undergo six weeks of IST (the control group) and the second group will undergo six weeks of GPACTS (the experimental group). Randomization will be carried out by a designated person, who is not a follow-up assessor, following baseline assessments.

Interventional therapies will take place once per week for six weeks in appropriate facilities at the participating centres. The psychologists in charge of interventional therapies will be trained prior to study start in order to homogenize practices between participating centres. The psychologists in charge of

group therapy are not the same as those in charge of individual therapy (to help avoid cross-contamination between arms); pre-study training is similarly separated by therapy type (i.e. a participating psychologist is trained in only one type of psychotherapy, which he/she administers during the study). We used the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Statement [13] to prepare the protocol manuscript. A SPIRIT diagram for enrolment, interventions, and assessments is shown in Fig. 1 and the SPIRIT 2013 cheklist is shown as additional file 1.

Outcomes and characterization of the sample

Following six weeks of interventional therapy, patients are followed-up for 12 months. Follow-up for both groups is identical and includes the administration of questionnaires at baseline and then within 10 days after the end of GPACTS/IST sessions and then at 3, 6 and 12 months following the end of GPACTS/IST sessions. The primary outcome of interest for this study is the duration of time free of suicide re-attempts. The null hypothesis for the primary outcomes for this study is that there will no significant differences in the duration of a suicide re-attempt-free follow-up period between the intervention and the control group.

Several secondary outcomes will be evaluated:

- The Columbia Suicide Severity Rating Scale (C-SSRS). This physician-administered scale prospectively measures the severity and intensity of suicidal ideation, the different types of suicidal behaviour and the lethality of suicide attempts [14]
- The Beck Scale for Suicide Ideation (BSSI) is a 21-item, validated, self-report questionnaire that can be used to identify the presence and severity of suicidal ideation [15,16]
- The Beck Depression Inventory (BDI-II) is a self-assessment scale. Its purpose is to quantify the intensity of depression [17]
- The Beck Hopelessness Scale (BHS) is a validated questionnaire designed to measure an individual's expectations about the future [18,19]
- The Mini International Neuropsychiatric Interview – 7 (MINI) is a tool that helps identify the psychopathology of a subject according to the DSM5 [20]
- The Risk rescue rating scale (RRRS) assesses the lethality of a suicide attempt, defined as the probability of inflicting irreversible damage. The underlying hypothesis is that lethality can be expressed as a ratio of factors influencing risk and rescue [20]
- Demographic forms and other assessments are used to characterize the sample and control for potential confounders.

These additional scales provide valid appraisals of factors related to suicidal behavior such as:

- Life events: the Social Readjustment Rating Scale (SRRS, [21]), the Childhood Experience of Care and Abuse Questionnaire (CECA-Q, [22])

- Personality traits: Spielberger's State-Trait Anger Expression Inventory (Staxi-2, [23]), Barratt Impulsiveness Scale (BIS11, [24]), State-Trait Anxiety Inventory (STAI, [25])
- Cognitive functioning : the Cognitive Reflection Test (MIT-IQ, [26])
- Severity of alcohol and tobacco dependence : the CAGE Questionnaire [27] and the Fagerström questionnaires [28]

Ethics, consent, and permissions

The study design is reported in line with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT, [13]). The study has received ethical approval from the University Medical Division Ethics Committee, Nîmes, France (#1994798 v0). All patients participating in the study will provide informed signed consent.

Eligibility criteria

Participant inclusion criteria:

- has given his/her informed and signed a consent
- must be insured or beneficiary of a health insurance plan
- is 18 years of age or older
- speaks fluent French
- is freely hospitalized (in centres or via emergency services) for the prevention of suicide
- has a high suicide risk score according to a MINI structured interview
- prior (or recent) suicide attempt within the last month
- is able to understand the study and capable of giving his/her informed consent
- is available during the weekly time slots proposed by the investigator

Participant exclusion criteria:

- is participating in another interventional study, or has participated in another

interventional study within the past 3 months

- is in an exclusion period determined by a previous study
- is under judicial protection, or is an adult under guardianship
- is impossible to correctly inform the patient, or the patient refuses to sign the consent
- emergency situations preventing proper study conduct
- history of schizophrenia or other psychotic trouble
- presence of psychotic symptoms at the initial interview
- serious cognitive impairment

- medical incapacity to participate
- severe dependence on any substance (including alcohol and cannabis) according to the MINI
- current psychotherapy

Interventions

Description of individual supportive therapy

In the comparator group, the “intervention” corresponds to six 60-90 minutes IST sessions administered for 6 weeks (with one session per week). IST does not rely on specific theories or assumptions about the causes of suicide. IST will be focused on the patients’ daily life experiences. The role of the psychologist will be to structure the interview and its duration. However, with respect to specific processes related to the modification of suicidal beliefs, IST is not a specific treatment, and the strategies from cognitive and behavioural approach will not be used in any way.

Description of cognitive behavioural group therapy

In the experimental group, the “intervention” corresponds to six 90-120 minutes group cognitive therapy sessions administered for 6 weeks (with one session per week and 6 persons per group). Sessions must start within 8 weeks after the inclusion date for every patient.

The protocol was adapted from individual face-to-face therapy as described by Ghahramanlou-Holloway et al. [29,30] for preventing repeat suicide attempts and known as Post-Admission Cognitive Therapy (PACT). In reference to this work, we named our program GPACTS.

PACT was also adapted by the authors from a 10-session CBT program developed by Brown et al. [31] to prevent repeat suicide attempts. As pointed by the authors, PACT is based on Beck's theories of depression [32,33] and suicide [31] and serves as a foundation for GPACTS.

GPACTS will consist of six sessions with the same overall therapeutic goals identified by Ghahramanlou-Holloway et al. [29]: 1) to reduce suicidal recidivism, 2) to reduce the impact of psychological risk factors such as depression, chronic suicide ideation, and hopelessness, 3) to develop problem-solving skills and coping strategies by linking them to the problems that contributed to the suicidal act, 4) to develop the use of existing social support, 5) to improve the use of and the collaboration with mental health professionals, and 6) to help the patients in developing a safety plan including coping strategies to preventing relapse.

All GPACTS group session will be structured as follows: 1) Welcome and introduction to the agenda of the session, 2) Summarize the previous session and correction of exercises performed at home, 3) Work on today's theme (e.g. learning problem-solving techniques), 4) Presentation of exercises to do at home, and 5) Feedback from participants on the meeting and answering questions.

The six sessions are distributed in three modules as follow:

- Module 1 is called “Understanding” and consisting of sessions 1 and 2. Session 1 provides general information about the program, introduction to CBT and provide psychoeducation about the suicidal crisis. Session 2 is focused on collaboratively generating a cognitive and behavioural conceptualization based on a narrative review of the most recent suicide attempt.
- Module 2 is called “Mastering” and consisting of sessions 3, 4 and 5. In the session 3, the problem of hopelessness is introduced through the identification of personal reasons for living and the purpose of constructing a hope box containing different elements (such as letters from friends, coping strategies cards, pictures…). The objective of a hope box is to have tangible evidence that life is valuable and make the reasons for living concrete. Session 4 is focused on the impact of low emotional regulation and its contribution to the recent suicide attempt. The need to improve the coping strategies is introduced through teaching and practice progressive muscle relaxation and controlled breathing exercises. In session 5, the patients are introduced to the relationship between problem-solving deficit and suicidal crisis. The patients are invited to identify from their cognitive and behavioural conceptualization for their recent suicide attempts their personal problem-solving style. The classic steps of problem-solving will be reviewed with the patients: 1) identifying problems and emotions related 2) generating solutions, 4) weighing pros and cons of solutions, 5) choosing the most realistic solution, 6) carrying out the solution and assessing its outcome.
- Module 3 is called “Preventing”, consisting of session 6. This session is focused on relapse prevention and the construction of the safety plan. In order to prevent relapse, patients are asked from the most recent suicide attempt conceptualization, to imagine how the different strategies learned during GPACTS could influence positively the crisis unfold. Finally, a safety plan is individually constructed using an adaptation of the model presented by Stanley et al. [34]. In this form, patients are invited to develop a personal and hierarchically list coping strategies to use in future distressing situations.

Treatment integrity

The coordinating psychologist will visit each participating center to present the interventional therapies and homogenize practice between centres. In each participating center, the psychologists will be

instructed about one of the interventional therapies (GPACTS or IST) and will receive a treatment manual. This treatment-manual will be used during the treatment to help the psychologists to stay focused on interventional therapies.

Sample size and recruitment

We will test the following hypothesis: The mean time to the next suicide attempt during the follow-up period is different between the two groups. The probability of a suicide reattempt-free follow-up period (PSRFFP) according to usual care was estimated at 60% by Brown et al. [7]. In this trial, a cognitive-behavioural therapy (10 sessions of individual therapy) was associated with an increase of 20% in the PSRFFP at 12 months.

In our study, the 10 sessions of individual therapy program are replaced by 6 sessions of a group therapy program. We expect a minimum benefit of 20% for this new strategy (60% in the control group versus 80% in the experimental group).

To our knowledge, no study has reported intra-class correlation coefficients associated with therapists or group therapy suicide re-attempt of the C-SSRS score. It is therefore difficult to anticipate an exact sample size that would take into account clustering effects caused by group therapy (or by therapist effects) in the primary outcome assessment.

Under the hypothesis of no cluster effects (at either the therapist or therapy-group levels) and using a log-rank-test, 186 subjects are required to detect 20% difference in PSRFFP at 12 months (60% in the control group and 80% in the experimental group), with a power of 85% and a bilateral alpha risk of 5%.

Given the possibility of cluster effects, we have increased this number to 216. Taking into account an anticipated rate of 10% lost of follow-up, 240 patients will be included (120 patients per group).

Patient consulting under emergencies for suicidal behaviour are common. It is more than reasonable to expect at least one case per day per centre on average, giving a minimum potential patient pool of about 1460 patients during the proposed recruitment period. To take into account the time necessary to organize group sessions and the probability that some patients might not want to participate, we proposed an inclusion averaging 5 patients per month per centre.

Study Calendar

The maximum study duration (i.e. starting at enrolment and ending at close-out) for a given patient is 15.5 months. The anticipated study calendar provides for 12 months of inclusion, 15 months of follow-up, 6 months of data management, and 6 months of statistical analysis and reports writing.

Statistical analysis

The statistical analysis will be performed by the Department of Biostatistics, Epidemiology, Public Health, and Health Economics of Nîmes Hospital Center using SAS statistical software, Carey, NC. A difference will be considered as statistically significant if the test gives a p-value of 0.05 or less.

Description of the population included and main parameters studied

Initial data analysis will describe the total population and the population per group. The Shapiro-Wilks test will be used to determine whether or not the quantitative variables show a normal distribution. Statistical results will be presented in the form of “mean ± standard deviation" for quantitative variables showing a normal distribution, and "median and interquartile intervals" for other variables. The number and associated percentage will be given for qualitative variables.

Analysis of the principal endpoints

The duration of a suicide reattempt-free follow-up period (SRFFP) will be assessed in the two groups using the Kaplan Meier method and compared by a log-rank test. This analysis will be completed by a modeling analysis to take into account clustering effects.

Indeed, in our study, randomization to treatment is done on an individual basis. However, the experimental treatment is administered to a group so that several individuals receive the intervention together by the same therapist. Observations within the group therapy will likely be correlated within groups (clustering effect). In contrast, control participants receive an individual intervention and their observations can reasonably be assumed to be independent. Either arm may also be influenced by cluster effects linked to a particular therapist. The latter clustering results in asymmetric, partially nested designs. Recently, statistical models were developed to appropriately evaluate treatment effects when using a partially nested design [35]. Based on these, we will use multilevel mixed-effects models to assess the treatment effect on the outcomes describing the suicidality:

- The duration of a suicide reattempt-free follow-up period (SRFFP),
- The suicide reattempt during the follow-up (yes/no) by adjusting for nested effects,
- The C-SSRS Score at 12 months by adjusting for nested effects and C-SSRS score at inclusion.

The detailed statistical plan will be provided before data extraction and un-blinding.

The models will also provide valuable estimates of intracluster correlation coefficients for the different psychological outcomes of our study in the context of behavioural group therapy; these data are

necessary to optimize the sample size of further studies in the area of psychological research.

Analysis of the secondary endpoints

Multilevel mixed-effects models will be used to assess treatment effects on the evolution of the C-SSRS score and the suicidal ideation (BSSI Score) and of the psychiatric symptoms (BDI-II, BHS).

Guess-the-group

To control for the success of blinding, outcomes assessor responses to the “guess-the-group” question will be compared to true responses using the Kappa agreement coefficient.

Methods used to manage data that are missing, unused or invalid

For the primary analysis, the data are censored for the primary outcomes (SRFFP); it is not relevant to replace missing values. For the other outcomes, we do not have a replacement method for missing data.

Choice of patients to be included in the analyses

All patients included and randomized in the study will also be included in the analysis (intent-to-treat analysis). The conclusions of the study will be based on this analysis. Exploratory Per protocol analysis will be also performed.

Discussion

This is the first randomized controlled trial to evaluate a manualized group cognitive behavioural therapy for preventing repeat suicide attempts. The expected results of this study are likely to have multiple benefits.

For the patient, demonstrating the efficacy of GPACTS to prevent repeat suicide attempts will provide relief from the mental suffering that occurs in the aftermath of a suicide attempt. Repeat suicide attempts preventions also constitutes in itself a direct and immediate therapeutic advantage. If proven effective, this therapy would greatly improve the management of suicidal patients.

Considering the economic burden represented by the management, particularly in terms of hospitalization, of patients following a suicide attempt, an important benefit is expected in terms of public health. If proven effective, GPACTS would provide a less expensive option (when compared to individual therapy) and a pragmatic solution for the prevention of repeat suicide attempts.

The rationale for the control intervention

Ethical questions and the current state of knowledge about the effectiveness of psychosocial treatment for suicidal persons helped guide us to the choice of IST (instead of “usual care”) as a comparator for GPACTS. For example, the notion of "usual care" can lead to a large variation in the quality and efficacy of what happens in the comparator arm. Also, several studies indicate benefits associated with

psychosocial interventions (all interventions) when compared with usual care, thus suggesting IST to be a better and more conservative choice. Individual supportive therapy was chosen instead of group supportive therapy because the latter is not suitable for suicidal attempters, given the informal aspect of it and the risk of contagion of thoughts and/or behaviours among participants.

Innovative aspects

Here we describe the study protocol of an RCT comparing GPACTS versus IST that will provide sound results on which to base recommendations for the prevention of new suicide attempts among patients currently seeking treatment for SB. According to Tarrier et al.[8], the number of studies that compared CBT with another active treatment was comparatively low, and to our knowledge, no team has yet to compare GPACTS with IST for the prevention of repeat suicide. To our knowledge, this is the first RCT of its kind to be conducted in France and so far there are no studies in the literature on group psychotherapy for the treatment of individuals who have attempted suicide. In a randomized controlled trial, Brown *et al*.[7] demonstrated the effectiveness of a 10-session cognitive therapy to prevent repeat suicide attempts for adults who recently attempted suicide. Participants in the cognitive therapy intervention had individual face-to-face sessions. In our study, we will rather offer a group therapy intervention that should prove to be efficient while reducing the cost of care.

Trial registration: ClinicalTrials.gov, NCT02664701, registered January 19, 2016, and last updated October 27, 2016. PHRC-N funded number (Clinical Research Hospital Program, Governmental Fund, Health Ministry): 14-0241.

Trial status

The current protocol version (5.0) was approved on 15 October 2018. The study is currently ongoing. Recruitment of patients started in November 2017 and will be completed in June 2020. The first groups, one that started with GCBT and the other with IST, received treatment from December 2017 to January 2018. The trial is currently ongoing.

List Of Abbreviations

BDI: Beck Depression Inventory; BHS: Beck Hopelessness Scale; BIS: Barratt Impulsiveness Scale; BSSI: Beck Scale for Suicide Ideation; SB: Suicidal Behaviour; CPP: Committee for the Protection of Persons; C-SSRS: Columbia Suicide Severity Rating Scale; CBT: Cognitive Behavioral Therapy; CECA-Q: Childhood Experience of Care and Abuse Questionnaire; GPACTS: Group Post-Admission Cognitive Therapy for Suicidality; IST: Individual Supportive Therapy; MIT-IQ: Cognitive Reflection Test; MINI: Mini International

Neuropsychiatric Interview; PACT: Post-Admission Cognitive Therapy; PSRFFP: Probability of a Suicide Reattempt-Free Follow-up Period; RCT: Randomized Controlled Trial; RRRS: Risk Rescue Rating Scale; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; SRRS: Social Readjustment Rating Scale: STAI: State-Trait Anxiety Inventory; STAXI: Spielberger's State-Trait Anger Expression Inventory.

Declarations

Ethics approval and consent to participate: The study was granted ethics approval by the Institutional Review Board of the University Hospital of Nîmes, on November 26, 2016 (ANSM 2015-A01585_44). The research was implemented after a favorable opinion from independent French ethics committees (Committee for the Protection of Persons [CPP]). The current protocol version (5.0) was approved on 15 October 2018. Any modifications to the protocol will be approved by the CPP before being implemented. An informative letter will be presented to the participants and will state: the purpose, the objectives and conduct of the study at any time. Participant consent will be sought and obtained before the entry thereof in the study. A copy of the signed consent will be given to the patient and a copy will be retained by the investigator; a third copy will be retained by the sponsor. Participation is voluntary and participants were informed that they could leave the study at any time.

Consent for publication: not applicable

Availability of data and material: Raw data will be available from the corresponding author upon reasonable request. Transfer of clinical data will require approval from the Institutional Review Board.

Competing interests: The authors declare that they have no conflict of interests.

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Author's contributions: CL conceived the IST program and adapted the GPACTS program from the work of Drs. Marjan Ghahramanlou-Holloway, Daniel Cox and Farrah Greene (Uniformed Services University of the Health Sciences, Bethesda, Maryland, USA). CL, LCJ, and AM contributed to the study design and methodology. CL drafted the manuscript and all the research team members contributed significantly to it. The final manuscript was read and approved by all the authors.

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Figures

Figure. 1 Schedule of enrolment, interventions, and assessments according to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) Diagram.

	STUDY PERIOD							
	Enrolment	Baseline evaluations	Allocation	Interventional therapy sessions	Follow-up visits			
TIMEPOINT	*w-14 to w-6*	*After enrolment and before allocation*	After baseline evaluations and before start of interventional therapy session	*The end of IST or GPACTS sessions defines "t0". w-6 to t0*	*T0 + 1 to 10 days*	*M3*	*M6*	*M12 (close-out)*
ENROLMENT AND RANDOMIZATION:								
Eligibility screen	X							
Study information	X							
Informed consent	X							
Randomization			X					
INTERVENTIONS:								
6 GPACTS sessions in the experimental arm				X				
6 IST sessions in the comparator arm				X				
ASSESSMENTS:								
Baseline variables and questionnaires		X						
Reasons for living		X				X		
Endpoint evaluated by blinded outcomes assessor: C-SSRS, BSSI, BDI-II, BHS		X			X	X	X	X
Pain evaluation (VASs)		X			X	X	X	X
Cumulative days of hospitalization					X	X	X	X
Time to end of an SRFFP					Throughout the study			
Other variables that may potentially affect results: pharmaceutical prescriptions and consumption								
If required: verification of vital status, cause of death								X
Harms assessments (adverse events)		X			X	X	X	X

Figure 1

Schedule of enrolment, interventions, and assessments according to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) Diagram.

Supplementary Files

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