WORLD PSYCHIATRIC ASSOCIATION
Advance Psychiatry and Mental Health Across the World

Global treatment action to combat deterioration of mental health and suicide
Brief Motivational Intervention and Long-term Regular Follow-up Contact Program
(BIC)

Global similarities and regional specificities

Protocol of BIC study

This document presents the protocol of Brief Motivational Intervention and Long-term Regular Follow-up Contact Program (BIC), a pre-post study that aims to provide a global treatment action to combat suicide.

The study is based on the WHO protocol of the SUPRE-MISS study, part of the WHO worldwide initiative for prevention of suicidal behaviors (1) and the Veterans Affair Brief Intervention and Contact Program (VA BIC), a brief educational intervention and regular contacts for patients from a VA mental health unit (2). The current study will use sociodemographic, clinical, and psychosocial questionnaires in suicide attempters presenting at Emergency Departments.

I. BIC Study Protocol

Background

The Suicide PREvention Multisite Intervention Study on Suicidal Behaviors (SUPRE-MISS) was piloted by the WHO center in Geneva, along with the collaboration of the National Centre for Suicide Research and Prevention of Mental Ill-Health (NASP) at Karolinska Institutet, in the early 2000s. The SUPRE-MISS study was conducted in five countries (Brazil, India, Sri Lanka, the Islamic Republic of Iran and China) and evaluated in an RCT. In this RCT, suicide attempters who came to the emergency department were identified and allocated to either Treatment as usual (TAU) or TAU and Brief Intervention Contact (BIC). A total of 1867 suicide attempters were randomized to TAU (n=845) or to TAU and BIC (n=922). The BIC was an hour-long individual information session about reasons for suicide attempts and possibilities for help and treatment. After this information session, delivered by a person with clinical experience, suicide attempters were followed-up for 18 months with nine follow-up contacts in between. The primary outcome measure was suicide at 18-months follow-up.

The current study, BIC study, is a replication of the SUPRE-MISS pilot study where the results have been published in 2008. The current BIC study was initially developed to fit the context of the COVID-19 pandemic, but it is now being deployed in different centres despite being out of the COVID-19 pandemic circle.

Why the need for the BIC study?

- The Supre-MISS study has shown significant results
- Despite the COVID-19 being more prominent between 2020 and 2022, suicide rates initially decrease but then increase during crisis such as national epidemics.
- The impact of the COVID-19 pandemic will continue to overshadow the lives of many and precitate in negative life events such as increased alcohol consumption, smoking, worse mental health, worse somatic health, unexpected life changes and higher suicide rates.

The objectives of the BIC study are:

- To raise awareness about mental health, suicide and suicidal behaviors among health care professionals
- To inform good treatment routine among emergency doctors and psychiatry staff
- To raise awareness about mental health, suicide and suicidal behaviors among the general population
- To evaluate the effectiveness of a Brief Motivational Intervention and Long-term Regular Follow-up Contact Program in reducing death by suicide
- To assess the mechanism by which the BIC intervention works
- To draw similarities of suicide prevention and treatment effectiveness across different countries
- To pinpoint differences of suicide prevention and treatment effectiveness among different countries

Aim

The overall aim of the BIC study is to evaluate a treatment and prevention practice that aims at reducing morbidity and mortality associated with attempted and completed suicide, and to raise awareness about suicide, suicidal behaviours and mental health in different cultural and social backgrounds.

Methodology

The methodology is based on the SUPRE-MISS and Veternas study. The effectiveness of SUPRE MISS was evaluated and shown effective in an RCT where the treatment group received TAU reinforced with a brief intervention contact (BIC) with 9 follow-ups after discharge in comparison to control group receiving only TAU and a follow-up at 18 months after suicide attempt.

The BIC study is currently being carried out or is in the process of being carried out in four countries, namely Brazil, Sweden, India, and the USA. More countries are encouraged to carry out the BIC study.

II. BIC RCT Study

Trial design

The study will be a multicenter randomized (1:1) control trial (RCT). Enrolment including eligibility screening and randomization into either the intervention or control group will be conducted according to the WHO randomization methods. Suicide attempters assigned to the COVID-19 BIC group will receive in-person motivational and awareness increasing interview using the COVID-19 BIC method (Annex 1) described separately. These interviews will be conducted by trained health care professionals (eg: a doctor, a nurse, a psychiatrist, a psychologist) one day before or on the day of discharge. The training for the health care professionals will be given on a social medial platform where a group training will take place.

Baseline assessments will be conducted after randomization and last follow-up will be 18-month post intervention with intermediate follow-ups by online trained volunteers (eg: volunteers from NGOs, individuals working with mental health, community workers, medical students, research assistants) at the 1, 2, 4, 8, and 12 weeks and then at 4, 6, 12, and 18 months.

A back-up supervisory system will be established to support the health care professionals as well as for the volunteers if they encounter any problems during the interview or during the follow-ups.

Participants

All suicide attempters who visit the emergency department and meet the inclusion criteria during a 12-month period will be asked to participate in the study.

> *Suicide attempt* is defined as a nonfatal self-directed potentially injurious behavior with any intent to die as a result of the behavior. A suicide attempt may or may not result in injury. Suicide attempters will be diagnosed according to the ICD-10 as well as a score of 2 or above on the Medical Damage Scale (MDS) (5).

The number of participants for each of the site can be determined based on the catchment area, but the emergency department of the study unit should serve at least a population of 250,000. This

estimate was adopted from the MONSUE study, A European Multicentre Study on Suicidal Behaviour (6).

Each site in the respective country is requested to translate instruments used in this study into the local language. All suicide attempters will be included in the analysis, but a separate analysis will be conducted by stratifying suicide attempters according to their different MDS score.

Inclusion criteria

Participants are eligible to participate in the study if they fulfill the following inclusion criteria:

- aged 15 or above;

(**optional**: Each centre has the option to recruit suicide attempters below the age of 15. However, the instruments need to be adopted for the respective age group. Parental consent might be needed for suicide attempters younger than 15 and in some countries younger than 18 to participate in the study).

- attempted suicide who are admitted to the emergency department during the 12-months study period
- proficient in the local language
- consent to participate

Exclusion criteria

Participants are ineligible to participate for the following criteria:

- clinical condition not allowing for an interview (according to their MDS score)
- leaving against medical advice
- residence in a different catchment area
- inability to communicate in the local language

BIC Intervention

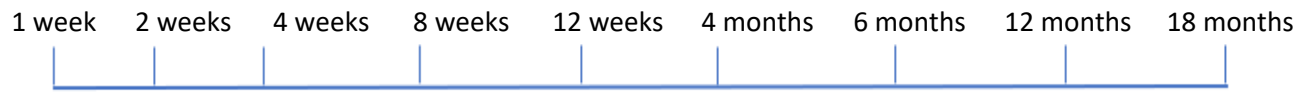
The intervention, including the educational session at discharge and the follow-up procedures, remains unchanged. All participants will receive the BIC intervention in addition to TAU, which is described in the next section. The BIC intervention will include nine follow-ups post discharge (1,2,4, 8, 12 weeks and at 4,6,12 months) with a final 18-months follow-up. Even though, the BIC is a brief one time one-hour motivational awareness increasing interview, there are regular follow-ups of up to 18-months which is a long follow-up.

The BIC intervention will include:

A. *time of discharge*: an hour individual educational motivational awareness increasing session as close to the time of discharge as possible (the day before or the day of discharge). The information session includes the following:
    - ✓ suicidal behavior as a sign of psychological/social distress
    - ✓ risk factors and protective factors
    - ✓ basic epidemiology of suicide and suicide attempt
    - ✓ alternative coping mechanisms instead of destructive behaviours
    - ✓ referrals for treatment or social support

Along with this educational motivational and awareness increasing session, patients will receive two pamphlets highlighting suicide prevention methods and risk factors for suicide (Annex 2- supplied later on).

A. *after discharge*: nine follow-ups via phone calls, physical visits, messaging or using tele-medicine (depending on the site) at:



The follow-ups will be conducted by a volunteer (eg: volunteers from NGOs, individuals working with mental health, community workers, medical students, research assistants), and these volunteers will receive training as well. Follow-ups can be either by phone call, physical visits, tele-medicine or messaging. If a center has the capacity and opportunity to do tele-medicine, tele-medicine should be the preferred follow-up method according to the WHO recommendation. An alternative contact person (eg: a friend or a spouse) who will be knowledgeable about the suicide attempter's outcome and situation will be recorded in case volunteers are unable to reach the patient.

Volunteers will use the follow-up template (Annex 2), also supplied later, that asks the suicide attempter how he/she is doing and if he/she needs any support. If the participant expresses a need for support, he/she will be referred to the appropriate channel. If the suicide attempter doesn't express a need for support, but a risk is noted, referral to an appropriate channel will be suggested.

Treatment as Usual

Treatment as usual will be administered to all suicide attempters who are admitted to the emergency department. Suicide attempters will receive TAU per the standard guidelines at the respective emergency departments (eg: routine or systematic psychiatric and/or psychological assessment). However, TAU should be described by each site before the start of the study. The description should not be very extensive but should be precise and concise enough to analyze which treatment was given. The following information will be filled by the centers for TAU:

a) What type of treatment they received (psychopharmacology, psychotherapy or combination)?
b) Names and dosage for drugs prescribed or type of psychotherapy, name of therapy and number of sessions
c) Number of suicide attempters who complied with treatment.

At 18 months after discharge, TAU's study participants will be followed up using the follow-up template in the intervention group (Annex 3).

Assessment and Evaluation

A comprehensive assessment will be conducted before the intervention to establish a baseline for each participant. Follow-up assessments will be conducted following follow-up time.

Primary Outcome

Hypothesis: The BIC will significantly lead to a reduced death by suicide at 18-months follow-up than treatment as usual.

Outcome measure: death from suicide at 18-month follow-up

Secondary Outcomes

Secondary outcomes will include:

a. Death due to other causes than suicide at 18-month follow-up.
b. General well-being at 18-months
c. Depressive symptoms at 18-months
d. Sleep quality and anxiety symptoms at 18-months
e. Social connectedness at 18 months

Evaluation Procedures

Evaluation procedures

Data will be collected at baseline and at 18 months follow-up for all participants. The details of the suicide attempt according to the ICD-10 codes and Medical Damage Scale (MDS) will also be evaluated at baseline along with a series of mental and physical health status.

The following scales are mandatory and will be administered at each site:

- *COVID-BIC Questionnaire (questions about Social, Economic and Health aspect)*- adopted from https://www.iasp.info/pdf/ICSPRC_COVID_advice_on_questions.pdf
- *Medical Damage Rating Scale (MDRS)* which assesses the degree of medical lethality of a suicide attempt (5)
- *The Patient Health Questionnaire (PHQ-9)* which measures depressive symptoms (7)
- *Athens Insomnia Scale (AIS)* which assesses any sleep difficulty (8)
- *Generalized Anxiety Disorder (GAD-7) Scale* which measures worry and anxiety symptoms (9)
- *Multidimensional Scale of Perceived Social Support (MSPSS)* which measures perceived social support from friends, family and significant other (10)
- *Interpersonal Needs Questionnaire-15 (INQ-15)* which measures thwarted belonginess (TB) and perceived burdensomeness (PB) (11)
- *Paykel Suicide Scale (PSS)* which measures suicidal ideation and attempts (12)
- *Suicide Related Coping Scale (SRCS)* which measures measure knowledge and confidence in using internal coping strategies and external resources to manage suicidal thoughts and urges (13)
- *WHO Well-Being Scale (WHO-5)* which evaluates mood, vitality, and general interests (14)

Additional questionnaires can be added if there are additional data that a site would like to collect. However, these additional questionnaires similar to the above scales should be translated into the local language of each site, adapted to consider the cultural specificities and pilot-tested to assess the validity (if it has not been used in similar settings before).

The following socio-demographic data will be collected at baseline: age, sex, country of birth, marital status, living arrangement, residence area, employment status, education level, income level, religion affiliation and sexual orientation.

There will be follow-up contacts at nine timepoints for those in the intervention group and one follow-up at 18-month for those in the control group. These follow-ups will be conducted using a questionnaire template (Annex 3) and will follow-up if the participant is still live, any consequent suicide attempt, and the well-being of the participant.

Sample size

The sample size will be estimated based on the SUPRE-MISS study that evaluated the effectiveness of BIC in suicide attempters that visited the emergency department. Centres recruit a minimum of 1730 subjects (865 per treatment group) considering a significance level of 95% (two-sided), power of 80% and assuming 3% suicides in the TAU and 1% in the BIC group at 18-months follow-up.