ISRCTN13464512 https://doi.org/10.1186/ISRCTN13464512

Brief psychotherapeutic interventions for suicide attempters

Submission date	Recruitment status	[ ] Prospectively registered
14/10/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/10/2016	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/03/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The WHO estimates that about 800 000 individuals worldwide commit suicide every year. A history of attempted suicide is the single most important sign that a person is at risk of committing suicide, with around 10-20% of those who have previously attempted eventually succeeding. It is therefore important to develop treatment programs which help to reduce the risk of future suicide attempts. ASSIP is a promising new program which has been shown to be highly effective in reducing risk of repeating a suicide attempt. The aim of this study is to investigate the effectiveness of the ASSIP program in reducing suicide reattempts over the following two years, compared to usual treatment.

Who can participate?
Adults who have recently attempted suicide

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the ASSIP program. This is made up of three visits, with an optional fourth visit. The first visit involves patient telling in his/her own words the sequence of events leading to the suicide attempt, and this interview will be videotaped. During the next two visits the therapist and patients together watch the video, discuss it, and create a case formulation and individualized safety plan for possible future crises. Participants also receive letters from their therapist every three months for one year and then every six months for the next year. Participants in the second group receive usual care, which involves receiving a course of crisis counselling. This involves meeting with a trained counsellor for face-to-face individual treatment. The number of sessions varies from patient to patient, but the average is five sessions. Participants in both groups receive a follow up phone call one and two years after the start of the study so that suicidal thoughts and attempts can be recorded.

What are the possible benefits and risks of participating?
Participants benefit from receiving treatment for their mental health problems free of charge, either standard care or the new promising treatment. There are no known risks involved with participating, however in order to benefit, participants may need to remember and talk about experiences they may find distressing.

Where is the study run from?
The Finnish Association for Mental Health (Finland)

When is the study starting and how long is it expected to run for?
January 2016 to December 2019

Who is funding the study?
The Finnish Association for Mental Health (Finland)

Who is the main contact?
Prof. Erkki Isometsä
erkki.isometsa@hus.fi

Contact information

Type(s)
Scientific

Contact name
Prof Erkki Isometsä

ORCID ID
http://orcid.org/0000-0001-5956-2399

Contact details
University of Helsinki and Helsinki University Hospital
Department of Psychiatry
Helsinki
Finland
00014
+358 (0)9 47163728
erkki.isometsa@hus.fi

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized comparison of the brief ASSIP intervention vs. crisis counseling to prevent reattempting suicide

Acronym
LINITY

Study objectives
The brief ASSIP intervention is superior to crisis counseling in preventing suicide reattempts during a two-year follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Helsinki and Uusimaa Hospital District ethical committee, 24/03/2016, ref: 95/13/03/03/2016

Study design
Single-centre randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Suicide attempt (repeated)

Interventions
Participants are randomised to one of two groups using the Research Randomizer-program (www.randomizer.org) in blocks of 30 patients.

Group 1: Participants receive the manualised ASSIP brief psychotherapeutic intervention. This involves three visits, and regular letters being to the patients during the two-year follow-up. Letters are sent every three months during the first year and every six months during the second year. During the first ASSIP session a videotaped narrative interview is undertaken, the second session involves playback of the video with patient and therapist discussing it, and the third completing written case formulation and individualized safety strategies with the patient.

Group 2: Participants receive usual care which consists of crisis counselling. This involves meeting with a trained counsellor for face-to-face individual treatment. The number of visits is not predefined, but the mean number in clinical practice is five visits.

Follow up for all participants involves two telephone interviews by research assistants at the FAMH and blind to the treatment group. The first interview takes place one and the second two years after the intervention.

Intervention Type
Behavioural

Primary outcome measure
Suicide attempt rate is measured by telephone interview over the course of the two year follow up.

Secondary outcome measures
1. Number of suicide attempts is measured by telephone interview over the course of the two year follow up
2. Severity of suicidal ideation is measured by using the Columbia Suicide Severity Rating Scale (C-SSRS) by telephone interview over the course of the two year follow up
3. Use of psychiatric and other health care services is measured from the psychiatric and health care records of the City of Helsinki Services over the course of the two year follow up

Overall study start date
01/01/2016

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Recent suicide attempt (SA)
2. Somatic treatment of SA in the Haartman or Malmi general hospital emergency room in Helsinki
3. Fluency in Finnish
4. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Total final enrolment
239

Key exclusion criteria
1. Presence of psychotic features
2. Substance abuse or dependence hampering treatment participation.

Date of first enrolment
20/08/2016

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Finland

Study participating centre
The Finnish Association for Mental Health
Maistraatinportti 4 A
Helsinki
Finland
00240

Sponsor information

Organisation
The Finnish Association for Mental Health (FAMH)

Sponsor details
Maistraatinportti 4 A
Helsinki
Finland
00240

Sponsor type
Charity

Funder(s)

Funder type
Charity

Funder Name
Finland's Slot Machine Association (Raha-automaattiyhdistys)

Results and Publications

Publication and dissemination plan
Planned publication after trial end in international scientific journal(s).

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The dataset will not be publicly available due to constraints posed by the Finnish data protection legislation and ethical and research permissions.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results			07/01/2022	No	No
Results article		20/01/2022	21/01/2022	Yes	No
Results article		23/03/2022	24/03/2022	Yes	No