

Economic evaluation of an integrated individual and family therapy model for self-harming adolescents

Submission date 08/07/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/09/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/10/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Self-harming behaviors in adolescents cause great suffering and can lead to considerable costs to the healthcare system. The aim of the study is to investigate the cost of an integrated individual and family therapy (Intensive Contextual Treatment: ICT) and to compare the adolescent's healthcare consumption 1 year before and 1 year after treatment.

Who can participate?

Adolescents (aged 13-19) with repetitive self-harm behavior within the past 3 months and their families

What does the study involve?

ICT is an intensive, short term (3-6 months) treatment. It is an outreach treatment conducted in the families residences and by two therapists. The frequency of the intervention is 2-3 meetings per week, the duration of the intervention is on average 4.5 months. The follow-up is 6 and 12 months after the intervention for the outcome measures, and healthcare consumption data is collected 1 year before, during and 1 year after treatment.

What are the possible benefits and risks of participating?

Participation in this follow-up study requires nothing more than written consent. Compilation of data is at a group level and therefore no individuals can be identified. Regarding benefits, the results of the present study can inform decision-makers in prioritizing. In times when resources in healthcare are scarce in relation to needs, it is important to be able to document healthcare utilization.

Where is the study run from?

Uppsala academic hospital (Sweden)

When is the study starting and how long is it expected to run for?

October 2017 to November 2019

Who is funding the study?
Uppsala academic hospital (Sweden)

Who is the main contact?
Moa Bråthén Wijana
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Dnr: 2018/1902-32

Study information

Scientific Title
Impact of an integrated individual and family therapy model for self-harming adolescents on overall healthcare consumption. A pilot study of a Swedish sample

Acronym
ICT - healthcare consumption

Study objectives

The primary hypothesis is that the patients would reduce their need for specialized healthcare consumption when comparing a 1-year period before and an equal period after treatment. The secondary hypothesis was that there would be a relationship between treatment effects and the changes in healthcare consumption.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 03/10/2018, Regional Ethical Review Board in Stockholm (Regionala etikprövningsnämnden, Karolinska Institutet, Tomtebodavägen 18 A, 171 65 Solna, Sweden; +46 (0)852480000; no email provided), ref: Dnr: 2011/1593-31/5, Dnr: 2018/1902-32

Study design

Interventional study, within-group design with repeated measures

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Self-harm and suicidal behaviors in adolescents

Interventions

ICT (integrated individual and family therapy model for self-harming adolescents) is an intensive, short term (3-6 months) treatment. It includes components from dialectical behavior therapy and functional family therapy. It is an outreach treatment conducted in the families residences and by two therapists. ICT has a contextual focus and close collaboration with schools is desirable. The frequency of the intervention is 2-3 meetings per week, the duration of the intervention is on average 4.5 months. The follow-up is 6 and 12 months post-intervention for the outcome measures, and for healthcare consumption, data is collected retrospectively 1 year before, during and 1 year after treatment.

Intervention Type

Behavioural

Primary outcome measure

1. Self-harm measured using self-assessment Deliberate Self-Harm Inventory (DSHI-9r) at pre- and post-treatment and 6 and 12 months follow-up

2. Healthcare consumption measured using medical records 1 year before, during and 1 year after treatment

Secondary outcome measures

General mental health symptoms measured using youth self-report (YSR) at pre- and post-treatment and 6 and 12 months follow-up

Overall study start date

01/10/2017

Completion date

25/11/2019

Eligibility

Key inclusion criteria

1. Aged 13-19
2. Repetitive self-harm behavior within the past 3 months, defined as both deliberate self-poisoning and self-injury, or suicidal thoughts, threats or plans
3. Live together with at least one primary caregiver

Participant type(s)

Patient

Age group

Child

Lower age limit

13 Years

Upper age limit

19 Years

Sex

Both

Target number of participants

50

Total final enrolment

25

Key exclusion criteria

1. Reported psychiatric disorder (e.g., schizophrenia) requiring intensive in-patient stabilization (as assessed at baseline with a semi-structured diagnostic interview)
2. Insufficient comprehension of Swedish language
3. Severe substance abuse
4. Developmental disabilities

Date of first enrolment

10/10/2018

Date of final enrolment

25/11/2019

Locations

Countries of recruitment

Sweden

Study participating centre

IKB-teamet, BUP, akademiska sjukhuset

Dag Hammarskjöldsväg 13

Uppsala

Sweden

75237

Sponsor information

Organisation

Karolinska Institute

Sponsor details

K8 Klinisk neurovetenskap

Nobelsväg 7

Stockholm

Sweden

17177

+46 (0)706112920

moa.brathen.wijjana@ki.se

Sponsor type

University/education

Website

<http://ki.se/en/startpage>

ROR

<https://ror.org/056d84691>

Funder(s)

Funder type

Charity

Funder Name

Stiftelsen Sven Jerrings Fond

Alternative Name(s)

Jerringfonden

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Results and Publications

Publication and dissemination plan

The manuscript is ready to be submitted at the time of registration.

Intention to publish date

01/08/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Moa Bråthén Wijana (moa.brathen.wijana@ki.se). The data is raw data and scale scores in SPSS files or Excel files. There is no time limit for data access and it is available from now on. Data is primarily available for persons who may be involved in a review of the manuscript. The data files are all anonymized so there should be no problems with confidentiality. The consent from participants applies to analyzes at group level, i.e. descriptive statistics and group comparisons.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/07/2021	27/10/2022	Yes	No