ISRCTN10290141 https://doi.org/10.1186/ISRCTN10290141

Comparison of the effectiveness of two group interventions for adolescents exposed to interpersonal trauma

Submission date
17/05/2021

Recruitment status
No longer recruiting

Registration date
19/05/2021

Overall study status
Completed

Last Edited
24/04/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In Chile, adolescents who have suffered interpersonal trauma (including childhood sexual, physical and/or emotional abuse and neglect) are cared for in the public system by private organizations (NGOs), principally funded by the National Service for Minors (SENAME). However, state-funded services are not able to fully meet the high demand for care. Specialist Centers throughout the country have long waiting lists, forcing adolescents to wait up to a year to access the specialist care they require. SENAME estimates that the waiting list in June 2020 included 6,796 cases.
Another difficulty in Chile is that there is not enough evidence of effective psychotherapeutic interventions to treat the internalizing and externalizing symptoms of interpersonal trauma. Internationally there is evidence supporting the use of structured models of psychotherapy, among which trauma-focused cognitive behavioral therapy (TF-CBT) stands out. TF-CBT has been tested individually and in groups in different parts of the world, but more evidence of its effectiveness in Chile is necessary.
Interpersonal Psychotherapy (IPT) has demonstrated effectiveness in young people with depressive symptoms. It has also been successfully used with adults with childhood trauma histories. Group IPT has equivalent outcomes in young people for depression. There is currently no published evidence of IPT being used to treat trauma symptoms in youth, or of group interventions for trauma in youth.
Due to the above, this study aims to evaluate the effectiveness of two group intervention models (TF-CBT and IPT) in stabilizing the psychosocial functioning of adolescent victims of interpersonal trauma who are on the waiting list or in a preliminary phase of engagement in specialist programs offered through the SENAME network.

Who can participate?
Young people aged 13 to 17 years old who have experienced interpersonal trauma and who are on the waiting list of specialist centers of the SENAME Network in Chile

What does the study involve?
Young people who agree to be involved in the study will be allocated at random to one of three

interventions: TF-CBT, IPT or an active waitlist control group. They will be asked to complete measures of psychological wellbeing and symptoms before and after the intervention and 2 months later. The interventions are group treatments that involve attendance at 12 weekly sessions split into two modules of six sessions. Young people allocated to the waiting list control group will receive regular review and art-based activities.

What are the possible benefits and risks of participating?
The study will allow adolescents who are victims of interpersonal trauma who are on the waiting list to receive specialist psychotherapy to access a group-based intervention sooner. CBT and IPT have both been proven to reduce emotional difficulties in young people across the globe. However, it is a pilot intervention and there is a possibility that the interventions are not effective. There is a very low possibility that the interventions could increase psychological distress. The research team will take the following measures to avoid risks in the participants:
1. Cultural adaptation of the intervention models
2. Limitation of the intervention only to psychoeducation, stabilization and basic strategies to cope with the symptoms, with an explicit agreement not to enquire into individual trauma memories
3. To work in collaboration with NGO clinical specialists
4. Suspension of the participation of any adolescent who cannot tolerate the group intervention, and access to individual treatment as soon as possible
5. The trial therapists will be psychologists with experience with this population. They will be trained by and will receive weekly supervision from the adapted intervention authors
6. Attention will be given to fidelity to the intervention protocols to ensure that participants receive only the promised intervention, and to avoid therapeutic drift.

Where is the study run from?
The study will be run on the premises of the NGO for the promotion and support of childhood "Paicabi", Chile, in collaboration with Universidad Santo Tomás (Chile) and The University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
October 2020 to October 2023

Who is funding the study?
Chilean National Research and Development Agency (ANID) (Chile)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Fondecyt 11200071

Study information

Scientific Title
Evaluation of the effect of two modalities of group interventions (trauma-focused cognitive behavioral therapy based and interpersonal therapy based) on stabilization of psychosocial functioning in adolescents exposed to interpersonal trauma

Acronym
IGATI

Study objectives
The objective of the project is to evaluate the effectiveness of two group intervention models (trauma-focused cognitive behavioral therapy (TF-CBT) and interpersonal therapy (IPT)) in stabilizing the psychosocial functioning of adolescent victims of interpersonal trauma who are on the waiting list for specialist psychotherapy in Chile.

The main hypothesis is: Both group interventions are expected to be effective in stabilizing the psychosocial functioning in victims compared to an active waiting list control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 28/10/2020, Comité de ética Zona Centro Norte, Universidad Santo Tomás (North & Central Zone Ethics Committee, Santo Tomás University, 1 Norte 3041, Viña del Mar, Chile, +56 (0)32 244 8006, cecentronorte@santotomas.cl), ref: 129/2020
2. Approved 17/11/2020, Comité Ético Científico, Hospital Gustavo Fricke, Servicio de Salud Viña del Mar- Quillota (Scientific Ethics Committee, Gustavo Fricke Hospital, Viña del Mar-Quillota Health Service, Calle Limache 1307, Viña del Mar, Chile; +56 (0)32 2759470; cec.hgf@redsalud.gob.cl), ref: 30/2020

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Psychosocial functioning (PTSD, depression, emotional regulation, and interpersonal problems) in victims of interpersonal trauma

Interventions
This project will be following the procedure of a randomized controlled trial with three groups: two intervention groups (TF-CBT and IPT) and an active control group (monitoring and art activities normally implemented during the waiting list period).

The study will recruit participants from the waiting list for specialist care in centres in the NGO Paicabi in the Valparaíso Region, Chile. All eligible participants will be invited into the trial. This will be mediated by professionals from the NGO for the promotion and support of childhood "Paicabi" after receiving training in assessment of eligibility. Once the participants have been recruited, the study will be single centre, carried out in the central offices of the NGO Paicabi in Viña del Mar, Chile.

The allocation will be randomized among adolescents who are on the waiting list and who voluntarily wish to participate in the research. Given that both therapeutic modalities include a psychoeducational component about the therapy being received it will be not possible to maintain blinding of group modality for participants.

Adolescents will be randomly assigned to an intervention group in 3-4 phases until the total sample size has been achieved. At the start of phase 1, eligible young people will be invited to participate in the study sequentially based on the length of time on the waiting list. Recruitment will continue until 30 eligible participants have consented to participate.

Once the first 30 participants have been recruited, a simple draw stratified by gender and city of residence will be made and 10 participants will be assigned to each group by a researcher without access to clinical information about the participants. Once the first phase has been completed, and the second phase is ready to be commenced, the researchers will repeat the recruitment and allocation process.

A professional member of the NGO - previously trained by the research team - will explain the project and request informed consent from potential participants and their guardians. In this session, the professional will provide a description of the project, the rights of the participants, the risks of the study, the measures taken by the NGO and the research team to prevent and face those risks, as well as the potential benefits of participation. Additionally, he/she will present a short video (less than 5 minutes) - made by the research team- that explains the scope of the study.

Each group of adolescents will participate in an individual pre-treatment session (session 0). Following this, adolescents will participate in an intervention consisting of two modules of 6 weekly group sessions of between 1.5 and 2 hours each (total 12 sessions). There will be a maximum of 10 adolescents in each group. Parents or guardians will participate in informational sessions of between 1.5 to 2 hours in sessions 1, 6, 7 and 12.

The three groups will have the same structure:
- A session 0. This session will be individual (for each adolescent and their guardian) and will last between 30 and 60 minutes. Its objectives will be: i) that the adolescents and parents/carers meet the therapist who will lead the intervention; ii) answer general questions about the trial and about the intervention; iii) collect baseline data using standardised measures.
- Two modules of six weekly sessions of 1.5 to 2 hours each (12 sessions in total) for adolescents
- Two information sessions per module (at the beginning and at the end of each module, equivalent to weeks 1, 6, 7 and 12) of 1.5 to 2 hours each (4 sessions in total) for parents/carers
- In keeping with phase-based approaches to complex trauma, both intervention arms are focused on the first phase: safety and stabilisation, and are intended as a preparatory treatment prior to individual trauma-focused therapy. As such, they will have a minimally intrusive modality. General principles around trauma will be addressed without delving into personal stories of trauma. It is anticipated that after participating in the research, young people will continue with the individual psychotherapy process provided by specialist services.

The three intervention arms will be different in content and theoretical approach.
1. Arm 1, based on TF-CBT: This model was specifically designed to apply the principles of cognitive-behavioural therapy to child and adolescent victims of traumatic events. TF-CBT has been found to have a direct effect on trauma symptoms in adolescent victims of interpersonal trauma. The program used in this research will include the first five components of the original individual protocol (Cohen, Mannarino, & Deblinger, 2006).
2. Arm 2, based on IPT: The main objective of IPT is to understand and improve the relationship between interpersonal functioning and emotional wellbeing, with a here-and-now focus. Preliminary studies have found that IPT can have a direct impact on trauma symptoms as well as depression. The program used in this study is novel.
3. Arm 3. active control group with monitoring activities and art activities.

The three groups will be facilitated by clinical psychologists trained in the intervention model. The control group will be led by a Clinical Psychologist from the NGO hosting the study, who has previous training and experience in Art Therapy and routinely delivers this kind of intervention. For the TF-CBT and IPT arms, the research team will train Clinical Psychologists to lead the group interventions. To ensure fidelity to the respective models the following measures will be taken: i) the lead therapists of each model should have participated in training in their respective model in the original, individual format (Online IPT training Level A: 16 hours in the IPT institute, & Online TF-CBT basic training in MUSC: 12 hours); ii) the authors of the adaptations of the intervention models will develop and provide a treatment manual (objectives, activities, times, and techniques) for each model; iii) the lead therapists for both models will be trained in their respective group intervention by the authors of the adapted groups interventions (12 hours in the IPT group model and 16 hours in the TF-CBT); iv) The lead therapist will be supervised weekly by the authors (12 hours).

To provide clinical governance and respect to the rights of the participants, the NGO sponsoring the study will monitor compliance with the internal trauma-informed protocols of the institution and the Chilean regulations. To provide ethical governance, the ethics committees which approved the project will monitor the trial each 4 months. In the event that it is suspected that any of the three interventions is causing emotional harm to a participant, his/her participation will be suspended, and will be referred to individual attention in the specialist centres of the NGO sponsoring the study. In the case it is suspected any of the three interventions is causing emotional harm to a group of participants, the whole intervention will be suspended, and all their participants will be referred to the classical individual attention. A review of the protocol and delivery would ensue to isolate and resolve any issues before the intervention is reinstated.

Quantitative evaluations of the symptoms of adolescents will be carried out in sessions 0, 6, 7 and 12, and 2 months after the end of the intervention.

Additionally, a qualitative evaluation will be carried out on the acceptability of each type of intervention to adolescents in sessions 6 and 12.

Intervention Type
Behavioural

Primary outcome measure
1. PTSD symptoms measured using the Child PTSD symptom scale at sessions 0, 6, 7, 12, and follow up
2. Depressive symptoms measured using the Depression Self-Rating scale at sessions 0, 6, 7, 12, and follow up.
3. Interpersonal problems measured using the Inventory of Interpersonal Problems, short form at sessions 0, 6, 7, 12, and follow up
4. Emotional dysregulation measured using the Chilean version of the difficulties in emotion regulation scale at sessions 0, 6, 7, 12, and follow up

Secondary outcome measures
1. Adherence to the intervention, measured using the percentage of adolescents in each group who completed each phase of the intervention, at sessions 6 and 12
2. Acceptability of each of the three interventions by the adolescents, assessed using written open-ended questionnaire at sessions 6 and 12

Overall study start date

01/10/2020

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Between 13 years and 0 months to 17 years and 11 months old
2. According to the opinion of family courts, has suffered interpersonal trauma in an extra- or intra-family context, defined as sexual abuse, sexual exploitation, physical maltreatment by a caregiver, phycological or emotional abuse, chronic neglect, or witness of violence within his/her family
3. On the waiting list for psychotherapy in specialist attention centers in Valparaíso Region in Chile
4. Give informed consent to participate in the research
5. Parent or guardian has given informed consent to participate

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
84 participants (28 in each group)

Total final enrolment
78

Key exclusion criteria
1. People with severe psychiatric psychopathology, intellectual disability or severe psychological disorder (high risk of suicide, substance addiction, borderline or lower intellectual development level, having carried out sexual assaults or having been convicted of violent crimes against other people or society)
2. People who are not in a protected context (e.g. who continue being abused or threatened by the aggressor)

Date of first enrolment
15/03/2022

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
Chile

Study participating centre
NGO for the promotion and support of childhood "Paicabi"
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Sponsor information

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Sponsor type
University/education

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Sponsor type
Hospital/treatment centre

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Funder(s)

Funder type
Government

Funder Name
Agencia Nacional de Investigación y Desarrollo (ANID)

Results and Publications

Publication and dissemination plan
Please use the contact details to request any additional information such as the study protocol or statistical analysis plan.

The researchers intend to publish three papers:
1. The quantitative results of the clinical trial (published in English)
2. A paper that describes the TF-CBT group intervention carried out in Chile and initial findings of acceptability and feasibility (published in Spanish)
3. A paper that describes the IPT group intervention carried out in Chile and initial findings of acceptability and feasibility (published in Spanish)

Intention to publish date
30/03/2024

Individual participant data (IPD) sharing plan
The data provided by the participants will be encoded numerically, anonymized, and passed to an Excel file. This file will be stored for 5 years by the responsible researcher Dr Cristóbal Guerra in a password-protected device at the Universidad Santo Tomás. After 5 years the data will be deleted. Given the sensitive nature of the stored data, these will not be available to be shared publicly.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Spanish	31/12/2022	12/06/2023	Yes	No
Results article		22/04/2024	24/04/2024	Yes	No