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Group therapy for helping teens with personality disorders

Submission date
21/08/2023

Recruitment status
No longer recruiting

Registration date
22/08/2023

Overall study status
Completed

Last Edited
22/08/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This research is an experiment to see if a special kind of therapy (called MIT-G) is better than the usual treatment for teenagers who have some problems with their personalities. We want to find out if this new therapy helps them feel better and have better relationships with others.

We will look at a few main things: how severe their problems are, how well they get along with people, if they feel sad, if they like the therapy, and if their parents or caregivers feel less stressed and more confident in helping them. We'll also check if some things that might change during the therapy actually do change, like how they think about things, how well they understand their own emotions, and how impulsive they are.

Based on some earlier small studies, we think that the new therapy might work better than the usual therapy. We think that the teenagers who get the new therapy will get better with their problems and how they interact with others. We also think that the new therapy might help them understand their feelings better and be less impulsive.

We also guess that the teenagers who get the new therapy will like it and feel good about it. We hope this study will help us learn if the new therapy is a good choice for teenagers who need help with their personalities.

Who can participate?
Kids between the ages of 14 and 18 who are getting regular treatment might be included in this study. The researchers are looking at whether these kids have something called a "personality disorder" which is diagnosed by special doctors trained to understand mental health. They use a special interview called the "Structured Clinical Interview for DSM–IV Personality Disorders" to figure this out.

What does the study involve?
The kids who want to be part of the study will be chosen by chance, like flipping a coin. Some will get a special therapy called "MIT-G," and others will have to wait and get the normal help that's usually given. We will look at how they're doing before they start, then after about 4 months, and again after 6 months.

The doctors and scientists will make sure everything is fair and safe. If the kids who have to wait for normal help still need the special therapy later, they will get it too, even if we can't check on them after 6 months.

What are the possible benefits and risks of participating?
None provided

Where is the study run from?
Servicio Riojano de Salud (Spain)

When is the study starting and how long is it expected to run for?
May 2018 to December 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Félix Inchausti, PhD, ClinPsyD, finchausti@riojasalud.es

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

PI482

Study information

Scientific Title
Metacognitive Interpersonal Group Therapy for Adolescents (MIT-GA) with personality disorders: a randomized controlled trial

Study objectives
1. We predict that MIT-GA would lead to greater improvements in symptoms and interpersonal functioning than the control group
2. We predict that the putative mechanisms of change, ie, global metacognition, alexithymia – ie, awareness of one's own emotions – and impulsivity would improve more in the MIT-GA arm
3. Our hypothesis is that patients receiving MIT-GA will accept the treatment and subjectively experience it as positive and satisfactory.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/10/2018, Clinical Research Ethics Committee of La Rioja (CIBIR. C/ Piqueras, 98, Logroño, 26006, Spain; +34 941 278 855; cibir@riojasalud.es), ref: PI482

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

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
Personality disorders

Interventions
Participants will be randomly assigned (1:1) with permuted block sizes of three or five, to receive MIT–GA or waiting list plus treatment as usual (TAU). Assessments of symptoms, functioning and psychological processes will be conducted at 0 months (baseline), 4 months (post-treatment), and 6-month follow-up. Upon request of the ethics committee, participants in the waiting list

plus TAU arm will have to begin MIT–GA once both groups have been completed end-of-treatment assessment, without waiting for the follow-up, so TAU group will can not be evaluated at 6-month follow-up.

Metacognitive Interpersonal Therapy (MIT) has first manualized principle for individual therapy (Dimaggio et al., 2015, 2020) and then a protocol for a time-limited group treatment has been devised and empirically tested (Inchausti et al., 2020; Popolo et al., 2018, 2019, 2022). And on this basis, we built an adaptation of the group protocol for adolescents (MIT–GA) which we are testing here. The MIT–GA program therefore includes: (1) At least two individual sessions addressed to establish an optimal therapeutic alliance with group facilitators, to evaluate and enhance motivation to change, to collect assessment material for drafting a formulation shared with the patient, of dominant maladaptive interpersonal schemas, and to improve affect–modulating strategies, especially in adolescents with severe emotional and behavioural dysregulation; (2) Two psychoeducational group–sessions introducing the principles of the treatment; (3) 16 weekly group–sessions for adolescents; and (4) a further 5 MIT-G sessions for adolescent' parents or caregivers, scheduled concurrently to the adolescent group–sessions. The aims of the additional parents/caregivers' sessions are: (i) to help them understand common contemporary problems for adolescents and to acquire some useful emotional and behavioural tools to help adolescents feeling understood and validated, to support them in planning daily activities, in firmly setting boundaries when need, and using effective parenting strategies such as boost adolescent's self-esteem; (ii) to help caregivers improve awareness of their own mental states, i.e. thoughts, feelings, desires, intentions when relating with their children so to realize how their behaviour is not just guided by norms, but by their own personal subjectivity; (iii) to identify and understand their own maladaptive schemas and possible negative influence on the relationship with their young person. Thanks to this improved awareness of their own psychological functioning, they can start to communicate and behave with their children in healthier and more adaptive ways; and (iv) to recognize and promote the importance of parental self-care as a way to improve their emotional state and, in this way, improve their ability to reflect on themselves and their children. It is important to emphasize that, throughout the 5 parental sessions, significant emphasis is placed on healthy individual aspects in themselves, hence the focus on developing awareness of maladaptive schema alongside awareness of positive representations of oneself and the others, and the ubiquity of positive and understandable social drives within individuals.

Consistently with MIT–G structure (Popolo et al., 2019), the 16 group sessions each last approximately 120 minutes; individual sessions last 45–60 min, with one session, or more, before beginning the group, one session at the midpoint, and a last session after completion of the program. In general, the middle session enabled discussion of problematic issues in the group and if required, repair of alliance ruptures. The last session addressed how the patient experienced the group, summarized problems identified, and strategies learned, considered the groups utility in informing everyday functioning, and identified remaining treatment goals. It also included a reformulation letter to sustain and promote further changes (Dimaggio et al., 2015).

Group sessions will be divided into blocks of 2 or 3 sessions for each specific evolutionarily selected motive. MIT utilizes the creation of a shared formulation that makes patients sustained in the pursuit of these evolutionarily selected wishes, such as social rank, attachment, exploration, group inclusion and so forth (Dimaggio et al., 2015, 2020). During the first session of each block, each motivational system is described in simple language. Then, a series of video clips are presented, taken from movies or cartoons, demonstrating situations where actors' behaviour was driven by the specific motive. Systems were presented in the following order: (1) social rank/competition, (2) group inclusion/affiliation, (3) attachment, (4) caregiving, (5)

exploration, (6) sexuality, and (7) cooperation. After psychoeducation, therapists asked participants to write down a specific autobiographical memory where their actions were driven by that system. Therapists then selected one situation to be role–played. Across the program, all participants had to role–play at least one episode from their own life. The scene enacted was then replayed with the participant taking the part of the other. In the ensuing group discussion, the protagonist and other group members were asked to reason about what kind of mental states the participants might have experienced, further identifying verbal and nonverbal cues underpinning this position. In the second session concerning the same motive, participants were asked to attempt a problem–solving strategy during the roleplay, based on the mental states that they were experiencing at the time and the mental states they ascribed to others. Therefore, the second session (and the third in the case of cooperative system), focused on using psychological information in order to reach own goals, solve conflicts, and find and promote more fulfilling and cooperative relationships, termed metacognitive mastery (Semerari et al., 2003).

TAU will consist of weekly individual consultations with participants' usual clinical psychologists. TAU will be oriented to support participant's emotional suffering from a cognitive-behavioural approach. No interventions aimed at promoting metacognition or providing psychoeducation on motivational systems underlying social behaviour will be included in TAU. Psychiatric consultation will be available in both TAU and MIT–GA groups if clinicians will consider it necessary or if request by the participant. The physical health of all participants will be monitored throughout the study. Considering a context of routine practice in a public service, the minimal treatment received (adherence) for subsequent assessments will be defined as attending 8 or more sessions of MIT–GA or TAU. In the MIT–GA arm, parents or caregivers' group intervention will be delivered by the same group therapist. Attending at least 3 parent group sessions will be mandatory for subsequent analysis.

Intervention Type
Behavioural

Primary outcome measure
Measured at baseline, post-treatment, and 6-months follow-up:
1. The Mini–International Neuropsychiatric Interview for children and adolescents (MINI–KID 6.0) (Sheehan et al., 2010) will be used to detect comorbid mental disorders at baseline.
2. The Structured Clinical Interview for DSM–IV Axis–II Personality Disorders (SCID–II) (First et al., 1995) will be used to assess DSM–IV PDs. Sociodemographic information will be collected using an interview designed for this study at baseline
3. Global symptoms: The Global Severity Index (GSI) from the Symptom Checklist-90–Revised (SCL-90-R) (Aluja et al., 2015; Derogatis, 2002) will be used to rate psychopathological symptoms over the past week.
4. Interpersonal functioning: The Inventory of Interpersonal Problems (IIP–64) (Alden et al., 1990; Salazar et al., 2010) will be used to assess current interpersonal problems.
5. The Children's Global Assessment Scale (CGAS) will be used to assess social functioning based on information from the clinician administered interviews and medical records from the preceding 30-day period (Shaffer et al., 1983).

Secondary outcome measures
Measured at baseline, post-treatment, and 6-months follow-up:
1. Depression: The Beck Depression Inventory for Youth (BDI-Y) (Beck et al., 2012) will specifically be used to measure depression symptomatology.
2. Acceptability: Interventions acceptability and subjective impact will be assessed by an

anonymous self-report scale at the end of each session to evaluate the session's enjoyableness, usefulness, and effect on daily social functioning using a 5-point scale (1–5).
3. Parents/Caregivers: The Parental Stress Scale (PSS) (Berry & Jones, 1995) and the Brief Parental Self Efficacy Scale (BPSES) (Woolgar et al., 2013) will be used to respectively rate the degree of parenting stress and perceived self-efficacy.
4. Metacognition: Metacognition Assessment Scale–Abbreviated (MAS–A) (Inchausti et al., 2016; Lysaker et al., 2005; Semerari et al., 2003) will be used for assessing different forms of metacognitive activity within personal narratives. It contains four subscales: 'Self-reflectivity'; 'Understanding the Other's Mind'; 'Decentration' which evaluates the ability to perceive the world as existing with others having independent motives; and 'Mastery' assesses the ability to use mental state knowledge for the sake of purposeful problem solving. The MAS–A total score ranges from 0 to 28. Higher scores indicate better functioning. The Indiana Psychiatric Illness Interview (IPII) (Lysaker et al., 2002) was developed with the goal of eliciting the life story and illness history of the patient. The MAS–A will be scored from IPII transcripts.
5. Alexithymia and impulsivity: The Toronto Alexithymia Scale (TAS-20) (Martínez Sánchez, 1996; Bagby et al., 1994) will be used to assess the degree of alexithymia. The Barratt Impulsiveness Scale-11 (BIS-11) (Martínez-Loredo et al., 2015; Patton et al., 1995) will be used to assess impulsivity as a behavioural measure of self-reflection and self-control.

Overall study start date
01/05/2018

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Eligible participants aged 14–18 years will be receiving routine treatment and either meet criteria for a PD as diagnosed by trained psychiatrists or clinical psychologists through the Structured Clinical Interview for DSM–IV Personality Disorders (SCID–II) (First et al., 1995).
2. Participants will also have to show interpersonal or social problems as notified in case manager reports; for instance, difficulties with relatives, friends, or classmates, problems in sustaining intimate bonds or feeling chronically excluded from groups. The case managers of eligible patients will be consulted about whether potential participants are suitable for inclusion in the study. Upon referral, suitable participants will be invited to participate in the trial.

Participant type(s)
Patient

Age group
Child

Lower age limit
14 Years

Upper age limit
18 Years

Sex

Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Non-Spanish-speaking
2. Full or sub-threshold antisocial PD
3. Significant substance use defined as drinking or engaging in drug use to the point of intoxication, three or more times per week
4. High risk of suicide, defined as the presence of a current plan and/or intent to commit suicide
5. Severe depression, bipolar disorder, and/or psychosis
6. Impaired intellectual functioning, defined as Wechsler Intelligence Scale for Children–V Full–Scale IQ scores < 75
7. Major neurological illness
8. Any other mental disorder than PD as primary diagnosis
9. Lacking capacity for consent to research.

Date of first enrolment
01/07/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Spain

Study participating centre
Unidad de Salud Mental Infanto-Juvenil de Espartero
Avda. Pío XII s/n
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Sponsor information

Organisation
Servicio Riojano de Salud

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Sponsor type
Hospital/treatment centre

Website
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal in the field.

Intention to publish date
31/10/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request to the IP (Felix Inchausti: finchausti@riojasalud.es)

IPD sharing plan summary
Available on request