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Group Interpersonal Psychotherapy (IPT-G) by non-specialists for the improvement of depressive symptoms in community young adults in Brazil

Submission date
12/11/2025

Recruitment status
Recruiting

Registration date
19/11/2025

Overall study status
Ongoing

Last Edited
19/11/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Depression is a common mental health condition that affects mood, relationships, daily functioning, and quality of life. Many young adults do not receive timely psychological support, especially in settings with limited mental-health resources. This study aims to evaluate whether Group Interpersonal Psychotherapy (IPT-G), a structured group-based talking therapy recommended by the World Health Organization, can reduce depressive symptoms and improve social support and quality of life. The intervention in this study is delivered by trained non-specialist facilitators, such as medical or psychology students, under supervision.

Who can participate?
Young adults aged 18–24 years who are experiencing depressive symptoms may be eligible to take part. Participants must be able to attend weekly sessions and complete research assessments.

What does the study involve?
Participants first complete an eligibility assessment. Those who qualify are randomly assigned to either:
- Intervention group: eight weekly sessions of Group Interpersonal Psychotherapy (about 90 minutes each), or
- Control group (wait-list): continue with usual care and receive IPT-G after the study period if the intervention will be effective.
All participants complete questionnaires at baseline, during the intervention, after the final group session, and at a 6-month follow-up. Before joining the study, participants receive a full Participant Information Sheet and sign a written informed consent form.

What are the possible benefits and risks of participating?
Participants in the IPT-G group may experience improvements in mood, social relationships and quality of life . The wait-list group will also have access to the therapy after the study ends if it

proves effective. Risks are minimal and mainly relate to discussing personal or emotional topics, which may cause temporary discomfort. Support and referrals are available if needed. Participation is voluntary, and individuals may withdraw at any time.

Where is the study run from?
The study is run by the Hospital de Clínicas de Porto Alegre (HCPA) in partnership with the Universidade Federal do Rio Grande do Sul (UFRGS) .

When is the study starting and how long is it expected to run for?
The study began recruitment in March 2024. Follow-up assessments continue for approximately 6 months after the therapy. The study will complete in June 2026, with the overall project expected to run until end of 2028.

Who is funding the study?
1. Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq), Brazil.
2. Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES), Brazil.
3. Hospital de Clínicas de Porto Alegre Research Incentive Fund (FIPE), Brazil.

Who is the main contact?
Dr. Neusa Sica da Rocha, Hospital de Clínicas de Porto Alegre (HCPA) / Universidade Federal do Rio Grande do Sul (UFRGS), nrocha@hcpa.edu.br

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06480019

Protocol serial number
CAAE 73830223.7.0000.5327

Study information

Scientific Title
IPT-based group intervention by non-specialist for improvement of depressive symptoms in community young adults in brazil

Study objectives
To evaluate the improvement in depressive symptoms after eight sessions of IPT-G among young adults with depressive symptoms in a community setting, conducted by non-specialists in a randomized trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/10/2023, Research Ethics Committee (CEP) of Hospital de Clínicas de Porto Alegre (Av. Protásio Alves, 211 - Portão 4 - 5º andar do Bloco C - sala 5068 - Rio Branco, Porto Alegre, 90410-000, Brazil; +55(51)33596246; cepsecretaria@hcpa.edu.br), ref: 2023-0283

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Sequential

Purpose
Treatment

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Depression

Interventions
The trial is designed as a pragmatic, controlled, randomized, and longitudinal study, comprising an intervention group (experimental) and a control group (waiting list). The intervention group will receive an IPT-G intervention delivered by non-specialists, following an 8-week protocol. The intervention will focus on interpersonal relationships within the IPT model and will be delivered by a medical student and a medical doctor trained in IPT.

Intervention Group
Participants allocated to the intervention arm receive IPT-G delivered by non-specialists (a

medical student and a medical doctor). The intervention follows a structured manual and consists of weekly group sessions conducted over 8 weeks. Sessions take place in private therapy rooms at the Centro de Estudos Luis Guedes (CELG), a psychotherapy training centre affiliated with the Hospital de Clínicas de Porto Alegre (HCPA).

Facilitators receive structured training prior to delivery and weekly supervision during the intervention. Treatment fidelity is monitored through audio-recorded sessions and standardized fidelity checklists. After completing the 8-week intervention, participants are invited to a 6-month follow-up meeting to discuss maintenance of therapeutic strategies.

Control Group (Waitlist)
Participants allocated to the control arm are placed on a waitlist and continue receiving any usual care available in the community. They complete the same assessments at all the same time points as the intervention group. If the intervention proves effective, all control participants are offered access to the IPT-G program after completing their final assessment.

Randomization
Participants are randomly allocated in a 1:1 ratio to the intervention or waitlist control group using a computer-generated sequence via the REDCap randomization module. Allocation is conducted by an independent researcher who is not involved in intervention delivery. Randomization occurs in blocks after every 20 participants complete baseline assessments, ensuring balanced allocation across the recruitment period. Given the nature of the intervention, participants are not blinded to group allocation. However, data collectors and data analysts remain blinded to minimize bias.

Total Duration per Arm:
Intervention: 8-week IPT-G + 6-month follow-up
Control: Waitlist for equivalent period

Intervention Type
Behavioural

Primary outcome(s)
1. Depression and anxiety symptoms measured using Hospital Anxiety and Depression Scale (HADS) at baseline, during treatment (sessions 1–8), and post-treatment (6 months)

Depression and anxiety symptoms (HADS)

Key secondary outcome(s))
1. Quality of life, measured using the WHOQOL-BREF at baseline, during treatment (sessions 1–8), and post-treatment (6 months)
2. Social support, measured using the Medical Outcomes Study Social Support Survey (MOS-SSS) at baseline, during treatment (sessions 1–8), and post-treatment (6 months)
3. Depressive symptoms, measured using the Patient Health Questionnaire-9 (PHQ-9) and the Beck Depression Inventory (BDI) at baseline, during treatment (sessions 1–8), and post-treatment (6 months)
4. Clinical impressions, measured using Clinical Global Impression scales at baseline, during treatment (sessions 1–8), and post-treatment (6 months)

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Live, work, or study in the geographic area of Porto Alegre
2. Express a desire to voluntarily participate in the research and sign an informed consent form
3. Be aged 18 to 24 years
4. Be able to attend all 8 meetings
5. Score ≥5 on the Patient Health Questionnaire (PHQ-9), without indication of suicidal ideation as assessed by item 9 (≤ 1) of the scale

Participant type(s)
All, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
24 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Manic or hypomanic episode (current)
2. Psychotic syndrome (current or past)
3. Substance dependence or substance abuse (last 12 months, except tobacco/nicotine)
4. Moderate or high suicide risk, as operationalized by the MINI
5. Diagnosis of other types of depression, such as bipolar disorder

Date of first enrolment
01/03/2024

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Brazil

Study participating centre
Hospital de Clínicas de Porto Alegre (HCPA)
Rua Ramiro Barcelos, 2350
Porto Alegre
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90035-903

Sponsor information

Organisation
Hospital de Clínicas de Porto Alegre

ROR
https://ror.org/010we4y38

Organisation
National Council for Scientific and Technological Development

ROR
https://ror.org/03swz6y49

Organisation
Coordination for the Improvement of Higher Education Personnel (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil: CAPES)

Funder(s)

Funder type
Not defined

Funder Name
Conselho Nacional de Desenvolvimento Científico e Tecnológico

Alternative Name(s)
Brazilian National Council for Research and Development, National Council for Scientific and Technological Development, CNPq - Conselho Nacional de Desenvolvimento Científico e Tecnológico, National Council for Scientific and Technological Development (Conselho Nacional de Desenvolvimento Científico e Tecnológico), CNPq

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Brazil

Funder Name
Hospital de Clínicas de Porto Alegre Research Incentive Fund (FIPE)

Funder Name
Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES)

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data will not be shared publicly because of confidentiality requirements and the sensitive nature of mental-health information. Only de-identified, aggregated data will be included in publications. Researchers who wish to access de-identified datasets for secondary analyses may contact the principal investigator, nrocha@hcpa.edu.br (Neusa Rocha), and requests will be evaluated by the research team and ethics committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			19/11/2025	No	No
Poster results			19/11/2025	No	No