ISRCTN15091477 https://doi.org/10.1186/ISRCTN15091477

A randomised control trial assessing the effects of Group Interpersonal Therapy (IPT-g) on depression

Submission date
17/07/2024

Recruitment status
No longer recruiting

Registration date
17/07/2024

Overall study status
Completed

Last Edited
13/03/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Interpersonal group therapy (IPT-g) has received empirical support for its contribution to better mental health outcomes, most notably in treating depression in participants. However, no studies of its implementation in the Iraqi context were found. There is also a general paucity of research on the factors that influence therapeutic change in IPT. The main aim of this study is to examine whether IPT-g is effective in reducing depression levels, improving other well-being indicators compared with the control group. In addition, the aim is to explore whether effectiveness of IPT-g depends on different participants characteristics, including gender, age, level of depression and type of main problems. Also, the goal is to test whether therapeutic changes are mediated through changes in self-assessed social support, quantity and quality of social activity, interpersonal trust, loneliness and hope.

Who can participate?
Mosul residents aged 18 years or older who gave informed consent to participate, had a depression score of at least 10 on the PHQ-9 questionnaire, and were free of acute suicidality and neurological impairment.

What does the study involve?
Participants are randomly assigned to either the IPT-g group or a wait-list control group. Participants in the IPT-g group receive the intervention, which consists of 1 pre-group and 8 weekly group sessions, delivered according to the WHO manual. Groups for men and women are organised separately. Participants in the IPT-g group are required to complete pre-intervention questionnaires, post-session questionnaires, and one-week and one-month follow-up questionnaires. Participants in the control group do not receive IPT-g, but may receive treatment as usual, and are required to complete the baseline and post-assessment, one week and one month follow-up questionnaires.

What are the possible benefits and risks of participating?
IPT-g may have a positive impact on participants' mental health and reduction in depression levels. In addition, participation in the study may provide an opportunity to reflect on valuable

insights into their improvements and changes during their participation. The results of this study will provide practical and theoretical insights into the effectiveness of this intervention and the factors that influence its effectiveness, particularly in the Iraqi cultural context. This may be useful in formulating recommendations on how to plan and structure IPT in future projects to make them more effective.

The questions asked during the interview may be upsetting and distressing to participants. However, participants are informed that they can choose not to answer if they don't feel comfortable, will be offered the opportunity to withdraw from the study at any time with no consequences (including participation in the intervention), and will be offered the opportunity to talk about their thoughts and feelings about participating in the study. They will be offered individual counselling by the psychosocial workers if they face any distressing thoughts or feelings about their participation in the study.

An additional risk of the trial relates to the control group and their waiting time for IPT treatment. Importantly, participants in the control group will be contacted and followed up between assessments, and if they are assessed as having a serious worsening of their depression and as being at risk of self-harm, they will be advised to stop participating and informed of the options available to them, and the authorities will be contacted. Participants in the control group will not be discouraged from continuing with their usual treatment options and will be offered the opportunity to participate in IPT in the next cycle following their participation in the trial.

Where is the study run from?
Hudara gGmbH organisation, Berlin, Germany.

When is the study starting and how long is it expected to run for?
July 2023. to December 2024.

Who is funding the study?
Hudara gGmbH organisation, Berlin, Germany.

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of group Interpersonal therapy (IPT-g) on depression reduction in individuals with depression: A randomised controlled trial assessing process and post-therapy changes

Study objectives
Participation in IPT-g will lead to significant reduction in depression scores compared to the control group, on different measurement points (last session, and 1 week and 1 month follow up). Additional hypotheses are that participation in IPT-g will lead to significant increase in well-being and functioning, and decrease in problem-related distress, compared to control group participants on the different post-therapy measurement points.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 21/07/2023, Ethical committee at the Department of Psychology, Faculty of Philosophy, University of Belgrade (Čika Ljubina 18-20, Belgrade, 11000, Serbia; +381112639119; komocetis@f.bg.ac.rs), ref: #2023-55

Study design
Single centre interventional two-arm randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The intervention group participates in the IPT-g intervention, which is delivered by 2 psychosocial workers who have participated in the training and are regularly supervised. The implementation follows the WHO manual (WHO, 2016) for unstructured and unstable conditions and is carried out by supervised facilitators who may not have had any previous professional training in mental health. Potential participants attend the first meeting and are screened for eligibility. Those who meet the criteria are placed on the randomisation list, which is broken down into male and female participants. Randomisation is performed by the external person in the Excel file using the rand function and the participants' codes.

Study participants assigned to the intervention group first participate in the second pre group session - which is foreseen as a pre-group phase within the WHO's manual, relevant for choosing the problem area that will be in participant's focus (grief, disputes, life change, isolation), setting the therapy goals, as well as completion questionnaires on mediation variables.The week after, weekly group sessions start - with the 8 weekly-session groups in total, with the specified protocol for initial, middle and termination group phase, relying on the techniques and strategies relevant for different problem areas in focus. Groups for male and females are implemented separately, and by the facilitator of the same gender. Participants in the intervention group complete questionnaires on outcome variables pre-session, during each session and one week and one month follow-up. They also complete questionnaires for mediational variables on a baseline and on the last session and one week and one month post-assessment.

After randomization, the control group is contacted to be informed that they are randomly assigned to be the control group, they complete questionnaires on a pre-group meeting (baseline) and during the week of the last IPT session in that cycle (end of therapy), and one-week and one month post-assessment phase. They are also contacted in between assessments to assure there is no deterioration to the point of risk of self-harm. Also, they are not discouraged to use their usual treatment, and are offered participation in the next IPT cycle, after the last assessment is done.

Intervention Type
Behavioural

Primary outcome(s)
Depression, measured by the validated Arabic version of the PHQ-9 questionnaire. For the intervention group, measured at an initial pre-group session (baseline), after each session (as part of the IPT intervention manual), at the final session, at a one-week and one-month follow-up. For the control group, it is measured at a pre-session (baseline), in the week of the last session of the intervention group, at a one-week follow-up and at a one-month follow-up.

Added 13/03/2025:
During the execution of the study protocol, an unintentional deviation occurred in the planned data collection. According to the trial protocol, follow-up data were scheduled to be collected at one-week post-intervention. However, due to an honest procedural oversight, these data were not collected. This deviation was identified upon review of the dataset. All other measurement points (baseline, post-assessment and one-month follow-up) were properly collected.

Key secondary outcome(s))
1. Well-being, measured by WHO-5 questionnaire. For the intervention group measured at a baseline, third group session, last session and one-week and one-month follow-up period. For the control group measured at baseline, last session and one-week and one-month follow-up period
2. Functioning, measured by WHODAS questionnaire. For the intervention group measured at a baseline, third group session, last session and one-week and one-month follow-up period. For the control group measured at baseline, last session and one-week and one-month follow-up period
3. Level of distress related to the main psychosocial problem - measured by different versions of PSYCHLOPS. Measured only for the intervention group, at a baseline (pre-therapy PSYCHLOPS; after each session (during therapy PSYCHLOPS), and at the last session (post-therapy PSYCHLOPS)

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Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. 18 or more years old
2. 10 or higher point score on baseline assessment with PHQ-9 questionnaire
3. Gave informed consent for participation.

Participant type(s)
Resident, Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
104

Key exclusion criteria
1. Presence of neurological impairment
2. Presence of acute suicidality

Date of first enrolment
24/07/2023

Date of final enrolment
08/09/2024

Locations

Countries of recruitment
Iraq

Study participating centre
Rawabet community center
Yarmok al thaniya-west side of Mosul city
Mosul city
Iraq
41001

Sponsor information

Organisation
Hudara gGmbH

Funder(s)

Funder type
Charity

Funder Name
Hudara gGmbH

Results and Publications

Individual participant data (IPD) sharing plan
It is not planned to make the datasets generated and/or analysed during the current study available, as this was not planned from the outset and was not part of the participants' informed consent.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes