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Assessing the effects of a nature-based group therapeutic intervention on well-being and distress

Submission date
07/10/2024

Recruitment status
No longer recruiting

Registration date
08/10/2024

Overall study status
Completed

Last Edited
07/10/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The nature-based intervention evaluated in this study is structured around the approach and exercises of Acceptance and Commitment Therapy, proven to reduce psychological symptomatology and improve well-being. Nature-based interventions have received empirical support for their contribution to the psycho-physical health of participants. However, the studies tend to be impact-oriented, and there is a lack of evidence on evaluations of such interventions in Iraq. The first aim of the present study is to evaluate a nature-based therapeutic intervention in improving well-being and reducing distress. An additional aim is to test whether therapeutic changes depend on factors such as participants' characteristics, including gender, age, previous negative life experiences, severity of initial concern, experienced autonomy and initial level of connection with nature and loneliness. Furthermore, the study will examine whether changes in well-being and distress are mediated by increases in cognitive flexibility, attention to the natural environment, connection to nature, and group belonging.

Who can participate?
Mosul residents aged 18 years or older who gave informed consent to participate, had a depression score of less than 3 on the PHQ-2 and anxiety score of less than 3 on the GAD-2, and were free of acute suicidality and neurological impairment.

What does the study involve?
Participants are randomly assigned to either the nature-based intervention group or a wait-list control group. Participants in the nature-based intervention group receive the intervention, which consists of 6 weekly group sessions. There will be separate groups for men and women. Participants in the control group do not receive the nature-based therapeutic intervention, but can receive treatment as usual. Both the nature-based therapeutic intervention and control groups are required to complete pre- and post-therapy questionnaires.

What are the possible benefits and risks of participating?
It is expected that participants' well-being will benefit from participating in a nature-based therapeutic intervention. Answering survey questions may provide an opportunity for

participants to reflect and gain valuable insights into their improvements. In addition, the results of this study will provide practical and theoretical insights into the effectiveness of this intervention.

Answering questions during the interview may be distressing for participants. Participants will be informed and reminded that they can skip questions and withdraw from the study at any time with no consequences (including participation in the intervention). Participants will also be offered individual counselling if they are experiencing distressing thoughts/feelings related to their participation in the study. An additional risk of the trial concerns the control group and their waiting time for treatment. However, it is important to mention that the risks will be minimised by recruiting people with low scores for depression or anxiety and who are free of suicidality. Also, 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 the nature-based intervention 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?
February 2024 to February 2025.

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

Who is the main contact?
Dr Lena Schmid, lschmid@hudara.org

Contact information

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Public, Scientific, Principal investigator

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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 a nature-based group therapeutic intervention on well-being and distress in participants with low levels of depression and anxiety: A randomised controlled trial assessing post-therapy changes

Study objectives
Participation in the nature-based therapeutic intervention is expected to lead to a significant improvement in well-being scores and a reduction in distress scores measured after the intervention, compared to the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/08/2024, Ministry of Health, Duhok Directorate General of Health (Duhok Directorate General of Health - Kurdistan Region of Iraq. Room 8, Floor 2, Dohuk, 42001, Iraq; +964 62 724 4601; info@duhokhealth.org), ref: #28082024-7-13

Study design
Single centre interventional two-arm randomised controlled study

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Well-being and distress

Interventions
The intervention group participates in the group nature-based intervention, which is delivered by 2 psychosocial workers who have participated in the training and are regularly supervised. The nature-based intervention is structured according to the Acceptance and Commitment exercises and consists of 6 weekly group sessions. Potential participants attend the first session and are assessed for eligibility. Those who meet the criteria are placed on the randomisation list, which is divided into male and female participants. Randomisation is carried out by the external person in the Excel file using the rand function and the participant codes. After randomisation, the control group is contacted to inform them that they have been randomly assigned to the control group. Participants in both the intervention and control groups complete pre- and post-therapy questionnaires.

Intervention Type
Behavioural

Primary outcome(s)
Well-being, measured by WHO-5 questionnaire at baseline (pre-therapy) and post-therapy (last session/6 weeks)

Key secondary outcome(s))
Distress, measured by Kessler 10 questionnaire at baseline (pre-therapy) and post-therapy (last session/6 weeks)

Completion date
15/02/2025

Eligibility

Key inclusion criteria
1. 18 or more years old
2. 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

Key exclusion criteria
1. Moderate to severe depression score (score of 3 or higher on PHQ-2)
2. Moderate or high anxiety score (score of 3 or higher on GAD-2)
3. Acute suicidality
4. Neurological impairments

Date of first enrolment
14/10/2024

Date of final enrolment
15/01/2025

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
Research organisation

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 is not part of the participants' informed consents.

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