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Efficacy of Mental Health First Aid training on increasing mental health literacy and first evidence on effects on recipients

Submission date
12/10/2024

Recruitment status
No longer recruiting

Registration date
16/10/2024

Overall study status
Ongoing

Last Edited
15/10/2024

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
Mental health literacy refers to understanding mental health issues, recognizing signs of illness, and knowing how to seek appropriate support. In Germany, limited mental health literacy hinders early intervention and support efforts. The Mental Health First Aid (MHFA) course program teaches the necessary knowledge and skills to approach individuals in a mental health crisis and provide first aid. There is evidence that participation in the MHFA course can improve mental health literacy. Only recently, the MHFA course program has been implemented in Germany.
The overall aim of the EMERALD study is to examine the efficacy of MHFA training in a cluster randomized controlled trial in 20 clusters in five further and higher education settings in Germany. It investigates whether participation in an MHFA course increases mental health literacy (primary outcome) in trainees compared to a wait list control condition 6-months post baseline. Secondary outcomes include confidence to provide first aid and attitudes towards individuals with mental health problems, stigmatizing attitudes, as well as own mental health and quality of life. The study will also examine how potential recipients of MHFA benefit in terms of mental well-being and help-seeking behavior.

Who can participate?
We will recruit 600 students at 5 educational settings (i.e., at university, university of applied science, college, police academy, and nursing college) in Germany i.e. 120 people per setting. Individuals are eligible for the study when they are aged 18 and above, are enrolled as students at one of the respective participating institutions, have basic German language skills and have the ability to give informed consent. Individuals who have previously participated in an MHFA course or who are unable to participate in the MHFA course due to current psychological distress will be excluded from participation.

What does the study involve?
Overall, participation in the study covers a time frame of 12 months. In a cluster-randomized controlled trial design, clusters of individuals will be randomized to either complete the MHFA course directly after the baseline assessment (experimental condition) or with a 6-month delay

(wait list control condition). All participants in the study will receive the 12h-MHFA courses at some point during the study. In addition, participants will complete questionnaires at baseline (T0), directly after the course, 6-months after baseline (T1), and 12-months after baseline (T2). Furthermore, at the 6-month post baseline appointment a mixed-methods study consisting of questionnaires and qualitative interviews will be conducted with course participants and recipients of mental health first aid to investigate which components of the MHFA courses are effective, for whom they are effective and under what conditions. For this purpose, 20 course participants and 20 aid recipients will be recruited for interviews.

What are the possible benefits and risks for participating?
Participants in the trial will need to invest time to participate in the study. Participation involves 3-4 assessments of 45 min each, plus the 12 hour MHFA course. However, all participants will be compensated for their time spent on assessments and the MHFA course will be provided free of charge. So far, there is no evidence of negative consequences of the MHFA training on trainee (mental) health. In the scope of the current project, we will assess adverse effects.

When is the study starting and how long is it expected to run for?
July 2024 to May 2027

Who is funding the study?
The study is funded by the Central Institute of Mental Health (CIMH) and the German Center for Mental Health (DZPG) (Germany)

Who is the main contact?
Please contact Ulrich Reininghaus for more information on the study, Ulrich.Reininghaus@zi-mannheim.de

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2024-605

Study information

Scientific Title
Efficacy of Mental Health First Aid training on increasing mental health literacy and first evidence on effects on recipients: a cluster randomized controlled trial in educational settings

Acronym
EMERALD

Study objectives
Objectives:
1. (a) Establish the efficacy of the structured Mental Health First Aid (MHFA) training on improving mental health literacy in MHFA trainees at 6-month post-baseline (primary outcome) compared to participants who neither receive MHFA training nor are in a cluster with MHFA trainees; (b) investigate if the effects of the MHFA training are sustained at 12-month post-baseline;

2. Quantify, for the first time, the effects of MHFA training on improving mental health, mental well-being, and help-seeking behavior in potential recipients of MHFA as delivered by MHFA trainees at 6-month post-baseline. This will involve comparing participants who will not receive MHFA training but are in the same cluster as MHFA trainees (and therefore potential recipients of MHFA) to those receiving neither MHFA training nor being in the same cluster as MHFA trainees;

3. Examine the effects of MHFA training on reducing stigmatizing attitudes, increasing beliefs about effective treatments, and improving confidence in mental health first aid behavior in MHFA trainees at 6-month post-baseline as compared to those receiving neither training nor being in the same cluster as MHFA trainees;

4. Understand how confirmed recipients of MHFA leverage the training to support their mental health and wellbeing and identify in vivo configurations of contexts, processes, mechanisms of change, putative side effects and how these are associated with outcomes of the training in both MHFA confirmed recipients and MHFA trainees in a realist evaluation.

To address the primary objective, we will test the hypothesis 1a that mental health literacy will be higher in the blocked nested experimental condition (bnEC, MHFA trainees) than in the cluster-level control condition (cCC, students who will neither receive MHFA training nor are in the same cluster as MHFA trainees) at 6-month post-baseline. Additionally, we hypothesize that this effect will be maintained at 12-months follow-up (hypothesis 1b).

To meet the second objective, we will test the hypothesis 2 that mental health, psychological well-being, and help-seeking behavior will be higher in the blocked nested control condition (bnCC, students who will not receive MHFA training, but are in the same cluster as MHFA trainees: potential recipients of MHFA) than in the cluster-level control condition (cCC) at 6-month post-baseline.

To meet the third objective, we will test the hypothesis 3 that mental health stigma will be lower and beliefs about effective treatments, and confidence in mental health first aid behavior will be higher in the bnEC than in the cCC at 6-month post-baseline;

To meet the fourth objective, we will conduct a realist evaluation (Pawson & Tilley, 1997) with confirmed recipients and trainees of MHFA.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/09/2024, Ethics Committee II of the Medical Faculty Mannheim, Heidelberg University (Theodor-Kutzer Ufer 1-3, Mannheim, 68167, Germany; +49 (0)62138371770; ethikkommission-II@medma.uni-heidelberg.de), ref: 2024-605

Study design
Cluster randomized controlled trial coupled with a blocked nested randomized controlled trial and process evaluation

Primary study design
Interventional

Study type(s)
Other, Prevention

Health condition(s) or problem(s) studied
Mental health literacy in students

Interventions
In five educational settings, we will randomly allocate clusters (as unit of randomization). These clusters constitute semesters within faculties/specializations (i.e., randomization blocked by institution), e.g., first-year law students. In a balanced 1:1 ratio, the clusters will be assigned to one of two cluster-level conditions:
(1) the ‘cluster-level experimental condition (cEC)’, in which students from the same clusters will

be randomized to either receive the 12 hour Mental Health First Aid (MHFA) training or not (please see below: individual randomization),
2) the 'cluster-level wait list control condition' (cCC), in which the clusters will not receive the MHFA training till after the 6-month post-baseline period (i.e., participants will neither be exposed to MHFA training nor are in the same class with MHFA trainees).

Individual randomization
Clusters in the cEC are part of the blocked-nested RCT. Here, students within a cluster (as unit of randomization and clusters as blocks for block randomization) will be randomly assigned to one of two individual conditions:
(a) the 'blocked-nested experimental condition' (bnEC), in which students will receive the MHFA training (bnEC trainees),
(b) the 'blocked-nested wait list control condition' (bnCC), in which students will not receive the MHFA training till after the 6-month post-baseline period. Students in this condition reflect potential recipients of MHFA as delivered by MHFA trainees (after completion of the MHFA training) over a 6-month follow-up period.

There will be three assessments for the trial participants: T0 (baseline and pre-MHFA course assessment), T1 (6-months post-baseline) and T2 (12-months post-baseline) and one post-training evaluation.

Intervention Type
Other

Primary outcome(s)
Mental health literacy assessed using the Mental Health Literacy Scale (O'Connor & Casey, 2015) at 6-months post-baseline

Key secondary outcome(s))
Measured at T0 (baseline and pre-MHFA course assessment), T1 (6-months post-baseline) and T2 (12-months post-baseline) and one post-training evaluation:
1. Knowledge about mental health assessed using case vignettes as used previously in evaluations of MHFA courses (Kitchener & Jorm, 2002)
2. Social distance and stigmatizing attitudes using the Social Distance Scale (SDS; Link et al., 1999), the Internalized Stigma of Mental Illness (ISMI) scale (Boyd Ritsher et al., 2003; Sibitz et al., 2013), affiliate stigma items from the Children of Parents with Mental Illness – Stigma Questionnaire (COPMI-SQ-r; Stracke et al., 2024) and items in line with Griffiths et al.(2004)
3. Mental health first aid behavior assessed using the Mental Health Support Scale (MHSS-intended and MHSS-provided; Morgan et al., 2023) as well as beliefs about effective treatment and confidence in mental health first aid behavior
4. Mental health of MHFA trainees and MHFA recipients assessed using the 18-item version of the Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983)
5. Quality of life using the World Health Organisation Quality of life assessment [short version] (WHOQol-Bref; Skevington et al., 2004) and mental wellbeing using the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS; Tennant et al., 2007)
6. Help seeking behavior using the Attitudes Toward Seeking Professional Psychological Help ATSSPH (Picco et al., 2016), the General Help Seeking Questionnaire (GHSQ; Wilson et al., 2005), the Barriers to Access to Care Evaluation scale (BACE; Clement et al., 2012) and pathways to care; and service use in trial participants using the Client Service Receipt Inventory (CSRI; Chisholm et al., 2000)

Completion date
30/05/2027

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Enrolled at one of the participating settings as student at inclusion to the study
3. Willing to participate in the study
4. Able to provide informed consent

Participant type(s)
Learner/student, Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Insufficient command of German so that the MHFA training cannot be followed
2. Individuals with an acute mental health problem according to self-report, will be encouraged not to participate in the MHFA training in line with MHFA guidelines
3. Individuals who already participated in the MHFA training in the past

Date of first enrolment
14/10/2024

Date of final enrolment
30/05/2025

Locations

Countries of recruitment
Germany

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Central Institute of Mental Health
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Sponsor information

Organisation
Central Institute of Mental Health

ROR
https://ror.org/01hynnt93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Central Institute of Mental Health in Mannheim

Funder Name
German Center for Mental Health

Results and Publications

Individual participant data (IPD) sharing plan
Data will be made available upon request to the principal investigator.
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IPD sharing plan summary
Available on request