Young adults as community mental health workers in humanitarian settings

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Main Information

Primary registry identifying number
LBCTR2023015206

Protocol number
R34MH121558

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
24/11/2022

Primary sponsor
American University of Beirut

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
24/01/2023

Date of registration in national regulatory agency
24/11/2022

Public title
Young adults as community mental health workers in humanitarian settings

Acronym

Scientific title
Young adults as community mental health workers in humanitarian settings: A pilot test of the mechanisms of effect on their own well-being

Acronym

Brief summary of the study: English

Young adults are resources and agents of change in their communities when they are employed efficiently. Involving young adults in work that influences their communities has positive outcomes for young adults' wellbeing; and for their communities. Still, young adults are often marginalized, particularly in humanitarian settings. If young adults are to be meaningfully engaged as intervention agents, their work should focus on a community need. In the context of a humanitarian crises, has shed light on the need for human resources supporting mental health distress. For this reason, a team of researchers in the United stated and Lebanon in partnership with MAPs a Lebanese local NGO, decided to utilize the youth vibrant capacities in Lebanon; targeting Syrian Refugee youths residing in the Beqaa region in particular. Training 25 Young adults (18-24 years of age) on providing an attenuated form of mental health support through the intervention of Problem management plus (PM+) to 400 adults exposed to mental health distress. The aim is to observe the effectiveness of being elements of support to their communities on their own wellbeing, coping mechanisms, and stress. In comparison to being community mental health workers, the team will employ also a group of 20 young adults, who will be trained of tutoring techniques and topics, to deliver tutoring sessions to 200 students from families of the same community and an additional control group of 40 young adults who will only submit survey data.

Brief summary of the study: Arabic

الشباب هم موارد وعوامل للتغيير في مجتمعاتهم. إن إشراك الشباب في العمل الذي يؤثر على مجتمعاتهم له نتائج إيجابية على رفاهية الشباب ؛ ولمجتمعاتهم. ومع ذلك ، غالبًا ما يتم تهميش الشباب ، لا سيما في سياق الأزمات الإنسانية. إذا كان الشباب سيشاركون بشكل هادف كوكلاء تدخل يجب أن يرتكز توجيه عملهم على حاجة المجتمع. في سياق الأزمات الإنسانية ، الموارد البشرية التي تدعم ضائقة الصحة النفسية لا تكفي ، لاجئًا سوريًا شابًا ليكونوا عاملين في مجال الصحة النفسية المجتمعية لتوفير تدخل دعم نفسي واجتماعي20ستعمل هذه الدراسة على تدريب بالغ في مجتمعهم. تهدف الدراسة إلى تقييم فعالية كون الشباب عاملين400إلى (PM +) منخفض الكثافة يسمى المعالجة المطورة للمشكلات مجتمعيين على عايتهم النفسية و نسب التوتر والتعامل على الشباب أنفسهم من خلال جمع البيانات و عينات الشعر لتحليل نسب الكورتيزول. سيتم طالب في200 شابًا سيتم تدريبهم لتقديم الدعم التعليمي إلى 20) 1تقييم هذه النتائج بين العاملين المجتمعيين الشباب ومجموعتين للمقارنة: (شابًا سيقدمون بيانات المسح فقط. ستقيم الدراسة أيضًا جدوى ومقبولية الشباب الذين يقدمون الدعم40) 2 في نفس المجتمع ، و (6-1الصفوف النفسي والاجتماعي للبالغين في مجتمعاتهم.

Health conditions/problem studied: Specify

Managing stress and improving mental health in vulnerable communities through problem management interventions.

Interventions: Specify

In this pilot study, we aim to evaluate the feasibility, acceptability and fidelity of Syrian refugee young adults as community mental health workers (YA-CMHW), and the impact of this work on outcomes of wellbeing, coping and stress. In addition, we aim to assess the mechanisms leading to any changes in these outcomes.

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion Criteria: a) being Syrian refugee, (b) being18-24 years; (c) having completed high school (44); (d) living in one of catchment areas (ITS) in the Bekaa at the time of screening; (e) having been involved in NGOs or service to their community; (f) expressed motivation to serve their community.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

24

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion criteria: acute mental distress assessed through clinical interview and scales (PHQ9 and PSYCHLOPS) administered by psychiatrist.

Type of study

Interventional

Type of intervention

Behavioral treatment

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation

Randomized controlled trial

Study design: Masking

N/A

Study design: Control

Active

Study phase

0 (explanatory trials)

Study design: Purpose

Prevention

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

N/A

Therapeutic indication

N/A

Therapeutic benefit

N/A

Study model

Ecologic or community studies

Study model: Specify model

community

Study model: Explain model

Observing the effect of delivering social support (low scale mental health intervention) on the mental health, wellbeing of the young adults delivering the intervention rather

Time perspective

Prospective

Time perspective: Specify perspective

N/A

Time perspective: Explain time perspective

We will be following young adults for one year and a half. They will complete a survey 4 times over that time period, and we will collect hair cortisol 6 times over that time period.

Target follow-up duration

1

Target follow-up duration: Unit

year

Number of groups/cohorts

3

Biospecimen retention

Samples without DNA

Biospecimen description

Hair cortisol samples will be collected to monitor stress level over the period of the study

Target sample size

40

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

01/02/2023

Date of study closure: Type

Anticipated

Date of study closure: Date

30/08/2024

Recruitment status

Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan

Yes

IPD sharing statement description

Oversight responsibility: Drs. Afifi and Nakkash (co-PIs) will provide oversight to the trial and the ultimate responsibility for all data safety issues rest with them.
The overall framework for safety monitoring and what information will be monitored: Study data will be accessible at all times to the co-PIs, the site PI (Dr. Ghandour) and to our mental health team. We will be monitoring mental health indicators for the YA-CMHW and ECG groups. The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable): For both groups (YA-CMHW and ECG), we will be collecting survey data at 4 points
in times but also experience sampling method (ESM) data every three weeks (2-3 questions). This will allow the identification of acute distress or imminent threat of harm to self or others. The data will be reviewed within 24 hours of receipt by our psychiatrist and one of the co-PIs or site PI (Afifi or Nakkash or Ghandour). In addition, the psychologist will be meeting with the YA-CMHW group weekly in group and individual meetings. S/he will assess acute distress or imminent threat of harm to self or others at these meetings. If s/he identifies any CHMW with such outcomes, s/he will immediately refer to MDM, and inform our project psychiatrist and Afifi or Nakkash or Ghandour.
If more than 1/3 of the YA-CMHW exhibit acute distress or imminent threat of harm to self or others at any time during the implementation of the intervention, we will stop this trial.
Any adverse or serious adverse event, or unanticipated problems will be reported within 24 hours to the IRB by Dr. Ghandour and to the chair of the DSMB by Dr. Afifi or Nakkash. The project mental health team (psychiatrist and psychologist) will provide immediate guidance on management of the AEs and SAEs. We have a letter of commitment/support from Médecins Du Monde to provide mental health care free of charge to those referred (see letter
of support).Data Safety Monitoring Board (DSMB): We will establish an independent data monitoring and safety board that meets quarterly or more frequently as needed. The board will consist of 5 faculty or staff with expertise in biostatistics and research ethics and/or humanitarian settings; as well as at least 2 community advocates. Three of the faculty/staff board members will be from Lebanon, and 2 from the US; all community advocates will be from Lebanon, and Syrian if possible. The DMSB will also monitor and evaluate the progress of the trial, recruitment of participants, retention, processes and timeliness of data collection, risk and benefits, and other aspects of the progress of the study that might affect outcomes. The DSMB will also highlight external factors that may be important to the progress of our research trials, including concerns about repercussions based on the socio-political situation in Lebanon, or related to scientific advancements relevant to the project. Adverse events involving risks to participants will be reported by the PIs (Nakkash or Afifi) to the DMSB and to the University's IRB as per their policy. Finally, the DMSB will guide any decisions related to continuation or discontinuing the trials. All the above will, of course, be done with utmost attention to the confidentiality of all trial data.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

No Numbers

Sources of Monetary or Material Support

Name
NIH

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Lilian Ghandour	Lebanon	Lebanon	+961 3 644 544	lg01@aub.edu.lb	AUB
Scientific	Rima Afifi	USA	Lebanon	+1 (319) 471-5333	rima-afifi@uiowa.edu	IOWA university

Centers/Hospitals Involved in the Study

No Centers/Hospitals

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	13/12/2022	Lina Onsi	le08@aub.edu.lb	1-350000 or 1 374374, ext: 5445

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

No Problems Studied

Interventions

Intervention	Description	Keyword
delivering PM+	Effect of delivering PM+ on the mental health and wellbeing of young adults delivering it to members of their community	PM+
delivering tutoring	effect of doing a task (tutoring school kids) on the mental health and wellbeing of young adults delivering it	social intervention

Primary Outcomes

Name	Time Points	Measure
wellbeing	4 and 6	survey and hair samples
stress	4 and 6	survey and hair samples
resilience	4 and 6	survey and hair samples

Key Secondary Outcomes

Name	Time Points	Measure
autonomy	4	survey
Engagement	4	survey
Hope	4	survey
meaning	4	survey
accomplishment	4	survey
positive emotions	4	survey
relationships	4	survey

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files