Syrian refugee young adults as community mental health workers implementing problem management plus: Protocol for a pilot randomized controlled trial to measure the mechanisms of effect on their own wellbeing, stress and coping

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ABSTRACT

This pilot randomized controlled trial protocol aims to (1) assess the impact on the wellbeing of Syrian refugee young adults (18–24 years) of being a community mental health worker (CMHW) implementing WHO's evidence-based psychosocial intervention - Problem Management Plus (PM+) - with adults in their community, and (2) identify the mechanisms associated with the outcomes of enhanced wellbeing and coping, and reduced stress among these CMHWs. Over 108 million people have been forcibly displaced as of the end of 2022. Mental health consequences of these displacements are significant, yet human resources for health are not sufficient to meet the needs. A large proportion of refugee populations are youth and young adults (YA). Evidence indicates their engagement in supporting their communities leads to their own enhanced wellbeing and that of their community. This trial trains Syrian refugees to serve their communities as CMHW (n=19) or tutors (n=19) and compare wellbeing, stress and coping outcomes between these two groups and a control group (n = 40). We will also assess 7 mechanisms as potential pathways for the interventions to influence outcomes. Surveys will assess outcomes and mechanisms, hair samples will measure stress cortisol. The primary analysis will use a Bayesian Hierarchical Model approach to model the trajectories of the mechanisms and primary study endpoints over time for individuals in each of the arms. Our results will elucidate critical mechanisms in which engagement of young adults to support their community enhances their own wellbeing.
Trial registration: National Institutes of Mental Health, NCT05265611, Registered prospectively in 2021.
Lebanon clinical trials registry #: LBCTR2023015206, Registered in 2023.

1. Background

At the end of 2022, 108.4 million people had been forcibly displaced globally and 35.3 million were refugees [1]. The protracted Syrian crisis, now in its 12th year, has resulted in one of the worst humanitarian crises in recent history with over 6.8 million Syrians fleeing their country [2]. Lebanon hosts 1.5 million Syrians refugees, 16 % of whom are between the ages of 15 and 24 years [3]. More than 39 % of Syrian refugees living

in Lebanon reside in the Bekaa region [4]. The mental health of Syrian refugees in Lebanon is affected by the trauma witnessed in Syria prior to displacement, as well as their precarious situation in Lebanon. Sixty-two percent of Syrians report they need but are unable to receive mental health care [5]. Syrian refugees emphasize that much of their mental distress is a result of economic difficulties, social isolation, lack of safety, and discrimination; and ask to be involved in community activities that can rebuild social networks [6,7]. Humanitarian crises increase Mental, Neurological, and Substance use (MNS) disorders, doubling the prevalence and increasing vulnerability of those who already have pre-existing MNS disorders [8–11].

Human resources for health are often insufficient to meet community needs in humanitarian settings [11–13]. The lack of adequate mental health providers is exacerbated in humanitarian settings [14], including among Syrian refugee communities [15,16]. Trained Community Mental Health Workers (CMHW) have been found to be effective in decreasing distress of the community served [11,17–19], including in humanitarian settings [20,21]. However, more research is needed to understand the mechanisms by which CMHW support reduces mental distress and enhances mental health in humanitarian settings [20]. Involving young adults (YA) in work that impacts their communities is a valuable goal that has positive outcomes for young adults' wellbeing and coping; as well as for their communities [22–25].

Our primary goal of this research is for YA (18–24 years) in contexts of displacement to be meaningfully and with dignity working to support their community leading to enhancement of their own wellbeing, and that of their community. Given the prevalence of mental health distress in refugee communities, YA will be trained as CMHW to deliver a low intensity mental health intervention. Although mental health indicators often focus on distress, mental health is defined more positively as "a state of well-being in which every individual realizes his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community" [26]. Seven key protective factors have been identified as the most important determinants of mental wellbeing: positive emotions, hope, relationships, meaning, accomplishments, autonomy, and engagement [27–34]. Each has been related separately to indicators of wellbeing [34,35], but recent research has indicated that the dynamic interaction amongst them may be critical to their collective impact on wellbeing [36,37]. Understanding protective factors as potential mechanisms for intervention-related change in wellbeing was identified as a priority for research in humanitarian settings [38]; and this research will take a positive mental health approach to measuring young adult wellbeing, and its mechanisms.

Problem Management Plus (PM+) is a low-intensity mental health intervention, developed by the World Health Organization (WHO), and delivered by non-specialized CMHWs [21]. PM+ is usually implemented by non-specialists who are at least high school graduates [39]. PM+ is effective for addressing common mental disorders (e.g. anxiety, mild depression), and also reducing mental distress and other problems (e.g., stress, unemployment, interpersonal conflict) that emerge in response to crises [21]. PM + has reduced mental health symptoms in conflict and humanitarian settings among those receiving the intervention [40,41], including Syrian refugees [42,43]. Adaptations to context have been encouraged through formative studies [21] and adapted interventions have generally shown better effectiveness [44].

While the impact of PM + on mental health of those receiving the intervention has proven effective, to our knowledge, no study has investigated or published any evidence around the impact of PM + on the mental health of those delivering it. In this pilot study, our aims are to evaluate both the impact of and the mechanisms related to being a CMHW (the intervention) implementing PM+ within their community on their own (CHMW) wellbeing, coping and stress.

2. Methods/design

Objectives and Outcomes: This protocol represents version 2.0 of this trial (dated Nov. 2022), any alterations to the trial protocol will be updated on the NIMH Clinical Trials registry (clinicaltrials.gov). Our study has two aims: (1) assess the impact of being a young adult (YA)-CMHW implementing PM + on the mental health of YA-CMHW, and (2) Identify the mechanisms associated with enhanced wellbeing and coping, and reduced stress among YA-CMHW. For aim 1, we propose to follow the intervention group (YA-CMHW), as well as two comparison groups (Fig. 1): an active intervention control group of Syrian refugee peers providing tutoring support to elementary school children (YA-TU), and a passive comparator of similar peers (YA-CG) who will only complete the assessments also completed by the other two arms. This is a parallel group design with three groups (n = 27,25,40) with randomization in one block at the beginning of the trial. Tutoring was selected as an active comparator group due to the identified need for enhanced support for education for Syrian refugees. The study will proceed as a randomized controlled trial (RCT) with parallel arms, and framework of superiority. Standard protocol items recommendations for intervention trials (SPIRIT) can be found in Table 1.

Participants will be assessed for outcomes and related mechanisms via survey measurement at baseline prior to training, 3 months into the intervention, at the end of the intervention period (6 months), and 6 months post intervention completion. Hair will be collected for hair cortisol measurement at those same 4 time periods, as well as at 9 and 12 months post intervention. The primary endpoints/outcomes targeted by the survey are wellbeing, coping, and perceived stress. The survey instruments used to assess these endpoints are described in Table 2. Cortisol in hair is a biomarker of chronic stress and also of changing exposure to stress as hair grows approximately 1 cm per month [45]. The 6 data points for hair cortisol ensure a robust comparison over time within and between participant. A few studies have linked hair cortisol levels to changes in stress related to intervention [45], including one in Jordan [46].

For aim 2, we will focus on the mechanisms driving our primary endpoints, beyond a simple comparison between the active and inactive study arms. We propose to study positive emotions, supportive relationships, engagement, meaning/life purpose, accomplishment, control/autonomy, and optimism/hope as mechanistic drivers of the main study outcomes. These will be assessed at the same survey-times as the primary endpoints, and the instruments are correspondingly described in Table 2.

Hypotheses: We hypothesize (1a) that participation as a YA-CMHW or a YA-Tutor will enhance wellbeing and coping, and decrease stress as compared to the YA-CG. Also, (1b) participation as a YA-CMHW will increase wellbeing and coping, and decrease stress over and above that of the YA-Tutor. We further hypothesize (2a) that the mechanisms of change will be jointly and non-linearly associated with wellbeing, coping, and stress, providing a synergistic benefit to participants. In addition (2b), we hypothesize that participation as a YA-CMHW and YA-Tutor will enhance the 7 key mechanisms of wellbeing as compared to the comparison group. (2c) CMHW will enhance the mechanisms to a greater extent than tutoring.

Setting: The site of the proposed study will be the Bekaa region of Lebanon.

2.1. Interventions

<u>YA-CMHW</u>: The primary intervention that is being tested is training and participation of young adults (18–24 years) as CMHW to implement the individual program of PM + [47] as contextualized for Syrian refugees. This contextualized version was reviewed and further adapted by team members at our partner field-based Syrian refugee-led NGO - Multi-Aid Programs (MAPs); and by a Community Alliance Committee composed of 12 Syrian refugees living in the Bekaa. All adaptations were
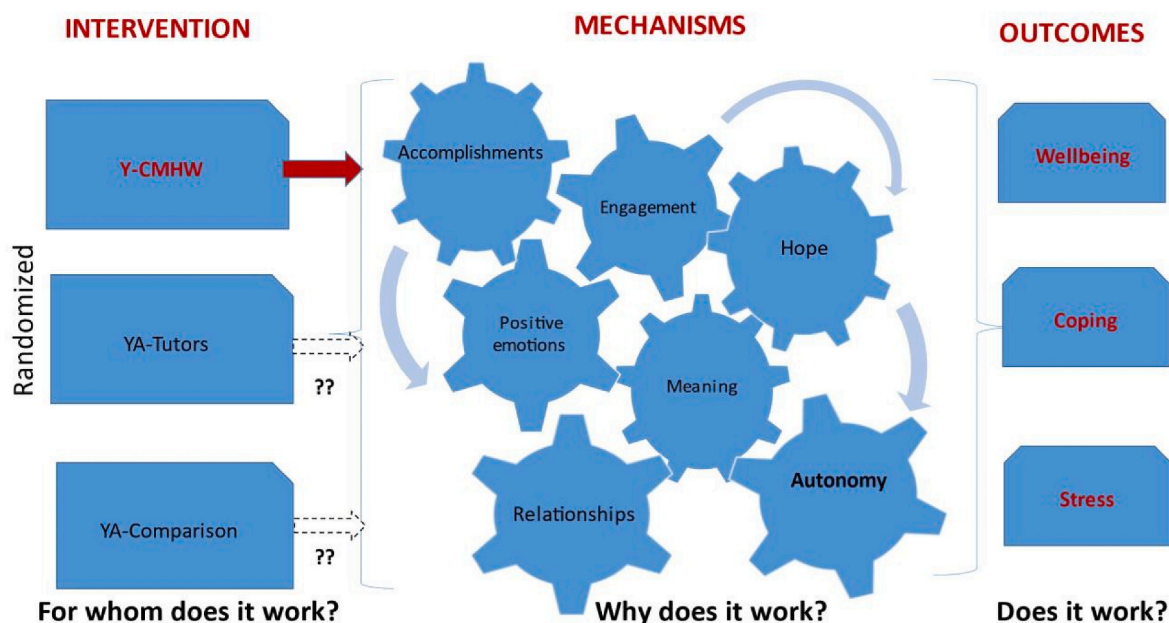
Fig. 1. Visual representation of the design of the trial.

made to further enhance the relevance to Syrian refugees living within the Lebanese context. PM + includes four evidence-based problem solving and behavioral treatment techniques: managing stress, managing problems, get going/get doing, and social support. These strategies are implemented over five weekly sessions of 90 min each. Twenty YA-CMHW will implement PM+ with a total of 400 community members over 6 months who self-request to receive the intervention. Our field team at MAPs will be responsible for assigning YA-CMHW to community members and tracking adherence to protocol. Our project psychologist (MH), who is also a PM + trainer, will meet with all YA-CMHW in groups each week to review challenges and ensure their own wellbeing. The psychologist (MH) will refer to Medecins Du Monde (MdM) any community member receiving PM + or CMHW implementing PM + who is experiencing acute distress at any time during implementation. MdM will provide services for free. To ensure fidelity, YA-CMHW implementers will fill out self-evaluation forms.

Training relevant to CMHW: The PM + manual outlines the required training including content for and length of the training, as well as guidance for supervised practice and regular supervision [47]. The YA randomized to the CMHW group (n = 27) will be trained as CMHW according to the manual [47] by our psychologist (MH) who is also a PM + trainer, and she will assess their competence to implement PM + using EQUIP [48]. Based on previous literature, we estimate that ~15 % will not be competent enough to move forward with the PM + implementation. We will select 20 with the highest competency scores to move forward with in the intervention.

YA-Tutors: The active comparator will be training and participation of young adults as tutors for elementary school Syrian refugee children in grades 2–5 attending MAPs schools in the Bekaa. The tutoring plan was developed by MAPs, that have a significant education portfolio; and Teach for Lebanon (TFL – https://teachforlebanon.org/oms/S_Index), a member of the global network Teach for All whose mission is to ensure quality education of children by training tutors. The tutoring plan was reviewed and improved by our CAC. Tutors will provide ten weekly sessions of 45 min each to elementary school students. Twenty YA-TU will provide tutoring support to a total of 200 children over 6 months. Our field team at MAPs will be responsible for assigning YA-TU to families requesting tutoring for their child(ren) and tracking adherence to protocol. Our project psychologist (MH) will meet with all YA-TU in groups once per month, and will be available for consultations anytime

to review challenges and ensure their wellbeing and health. MH will refer to MdM any TU who is experiencing acute distress at any time during implementation. To ensure fidelity, YA-TU implementers will fill out self-evaluation forms.

Training relevant to YA-tutors:. The YA-TU group (n = 25) will also receive training provided by TFL and MAPs. The training will focus on tutoring skills for grades 2–5 generally, and content-based skills in Arabic and Math (the two subjects that will be provided) for those grade levels. YA-Tutors will also shadow teachers in MAPs elementary schools to understand the context and process of tutoring. Their competence to tutors will be assessed by TFL staff using ENACT [49].

In addition, both intervention groups will receive information during their training on research ethics, conflicts of interest, working as a health worker in one's own community, and the protocol for referral in the case of acute distress experienced by those receiving the intervention.

YA-CG: The young adults randomized into the control group will not be participating in any intervention activities within this trial, and therefore will not receive any training.

YA-CMHW and YA-TU will receive equivalent compensation for their work and for completing surveys and hair samples. YA-CG will receive compensation for completing surveys and hair samples only.

Trial Participants: One hundred and fifteen Syrian refugee young adults (18–24 years) living in the Bekaa will be recruited, with equal numbers of males and females (see Fig. 2 for the recruitment and randomization process). This sample size is based on the power calculation (described below) and assumptions of ineligibility or loss to follow up at various stages of recruitment or implementation.

Inclusion criteria: (a) being a Syrian refugee, (b) being 18–24 years; (c) having graduated from High School; (d) living in the Bekaa at the time of screening; (e) having been involved in NGOs or service to their community; and (g) expressed motivation to serve their community.

Exclusion criteria: Experiencing acute distress as per clinical assessment conducted post recruitment, low competency level measured post training.

Sample size calculation and power analysis (see supplemental appendix for details of power calculations): Based on the flow chart (Fig. 2), we have powered this study assuming 19 participants in each of the intervention groups (YA-CMHW and YA-TU) and 40 participants in the YA-CG will continue for the duration of the study. This design would be powered at 80 % to detect a large Cohen's-D of 0.93 between intervention and

Table 1

Standard protocol items recommendations for intervention trials (SPIRIT). Schedule of enrollment, interventions and assessments for our trial.

				Study period				
	Enrollment	Allocation		Post-allocation				
TIMEPOINT		**0**	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**
ENROLLMENT:								
Eligibility screen	X							
Informed consent	X							
Psychiatric assessment	X							
Allocation		X						
INTERVENTIONS								
YA-CMHW				← →				
YA-TU				← →				
YA-CG								
ASSESSMENTS¥								
General information								
Sociodemographics			X	X	X	X		
Stigma			X	X	X	X		
Financial distress			X	X	X	X		
Outcomes (survey):								
Wellbeing			X	X	X	X		
Coping			X	X	X	X		
Perceived Stress			X	X	X	X		
Outcomes (hair sample):								
Cortisol for stress			X	X	X	X	X	X
Mechanisms:								
Accomplishments			X	X	X	X		
Hope			X	X	X	X		
Engagement			X	X	X	X		
Relationships			X	X	X	X		
Meaning			X	X	X	X		
Autonomy			X	X	X	X		
Emotions			X	X	X	X		

*T1=Baseline before training / T2=3months after beginning of intervention / T3=at end of intervention / T4=6 months after intervention ends /

T5=9 months after intervention ends / T6=12 months after intervention ends

¥for specific measurement instruments, see table 1 below.

Table 2
Measurement instruments to assess impact of intervention on youth outcomes and related mechanisms.

ASSESSMENT CONCEPTS	MEASUREMENT INSTRUMENT	Number of items	ARABIC TRANSLATION/ VALIDATED IN ARABIC (reference)	Psychometric properties[a]
Mechanisms				
Positive emotions	Happiness Scale	4	Y/Y [55] Validated with college students in Lebanon	PFA confirmed single factor – eigenvalue of 1.81/Internal consistency α = 0.74
	Positive and Negative Affect Scale (PANAS)	12	Y/N [56]	
Supportive relationships	Multi-dimensional Scale of Perceived Social Support (MPSS)	12	Y/Y [57] Validated with Arab immigrant women in Detroit, MI, USA	CFA confirmed three factor structure/Internal consistency overall α = 0.74, range for three factors 0.73–0.89
	Adapted Social Capital Assessment Tool (SASCAT)	9	N/N [58]	
Engagement	Engagement scale		N/N [59]	
Meaning/Purpose in life	Antonovsky's Sense of Coherence Scale	29	Y/Y [60] Validated with Palestinian health providers in Palestine	CFA confirmed one factor structure/Internal consistency α = 0.732
Accomplishments	Accomplishment scale		N/N [59]	
	European Social Survey	3	N/N [61,62]	
Control/Autonomy	Uncertainty	3	Y/N [63,64]	
	Communal coping	2	Y/N [64]	
	Index of Autonomous Functioning	15	N/N [65]	
Optimism/Hope	Life Orientation Test (LOT)		Y/N [56]	
	Snyder's Hope Scale	8	Y/N [66]	
Outcomes				
Wellbeing	WHO-MH5	5	Y/Y [67] Validated with pharmacy students in Iraq	EFA confirmed one factor structure/Internal consistency α = 0.845–0.878 (3 separate samples)
	Subjective Vitality Scale	5	N/N [68]	
	Arizona Integrative Outcome Scale	2	N/N [69]	
Coping	Brief Cope scale	28	Y/Y [70] Validated with adults in Saudi Arabia	PCA did not support the 14 scale structure but supported a 3 factor structure (similar to other literature)/Internal consistency of the 14 2-item scales ranged from 0.2-0.7
Stress	Perceived Stress Scale (PSS)	10	Y/Y [71] Validated with female university students in Lebanon	EFA confirmed two factor structure/Internal consistency α = 0.74

[a] For scales validated in Arabic. PFA = principal factor analysis/CFA = confirmatory factor analysis/EFA = exploratory factor analysis. More details on psychometric results can be found in the referenced manuscript.

control groups using a simple *t*-test on a single assessment, or a medium effect of 0.42 on at least one of the three main assessments, assuming independence. To our knowledge, no prior studies have examined the effectiveness of being a YA-CMHW as an intervention, accordingly we use the closest available effect sizes and standard deviations available in the literature for a study in urban Kenya [50]. A three time-point longitudinal simulation based on these same effect sizes and standard deviations produces a power estimate of 0.93 for at least one of the three main treatment/control comparison (see supplemental appendix section 1.5). While prior studies of these interventions in the Lebanese context are limited, any effect size differentiating these two arms is expected to be strictly less than the effect size differentiating them from a true negative control group, so the choice of 40 true control samples is extremely conservative. This sample size permits a pairwise comparison of 19 vs. 40 for each sub-group, or an overall comparison of 38 vs. 40 in the event that the active arms are insufficiently distinguished. While this sample size is sufficient for the intended main comparisons, it is less likely that we will be able to make definitive conclusions in subgroups; for examples, we would expect investigation of any effect modification by gender to halve the effective samples size used in parameter estimation. Nevertheless, our use of Bayesian methods for the primary longitudinal comparison should mitigate some of these limitations. Bayesian methods quantify uncertainty about model parameters directly through probability, enabling us to clearly communicate which study findings are preliminary or definitive, and to conduct simulations to robustly motivate future larger scale RCT's with high frequentist power for main and sub-hypotheses. This advantage applies equally to the main

intended study comparison and to exploratory subgroup analysis.

Recruitment: Flyers describing this research project will be distributed and posted in MAPs and other NGO centers in the Bekaa. The flyer will invite interested young adults to complete an interest form within two weeks of the first distribution/posting. The interest form asks for basic sociodemographic information, and previous history of involvement with NGOs or service in their community, and a short paragraph describing their motivation to serve their community. The research team will review the forms and short list 115 candidates based on an eligibility assessment. Short listed YA will be invited to an informational session where the details of the project will be described. YA who remain interested will be provided with the consent form, and asked to discuss their involvement with anyone they would like before returning the consent form within three days.

Informed Consent: The informed consent process occurs prior to randomization and includes informed consent to be randomized to any of the three conditions with details of the conditions and assessment procedures, and to undergo a clinical assessment. Participants will complete a written consent form.

Clinical assessment: In keeping with PM + requirements, each of the 115 candidates will complete the PHQ9 and PSYCHLOPS instruments [51,52] and participate in a clinical assessment with licensed Lebanese psychiatrists (MZ, YC) to screen for acute distress and imminent harm to self or others. Any participant with acute distress or an imminent threat of harm to themselves or others will be referred to MdM for free follow-up, and not be selected to participate in the intervention.

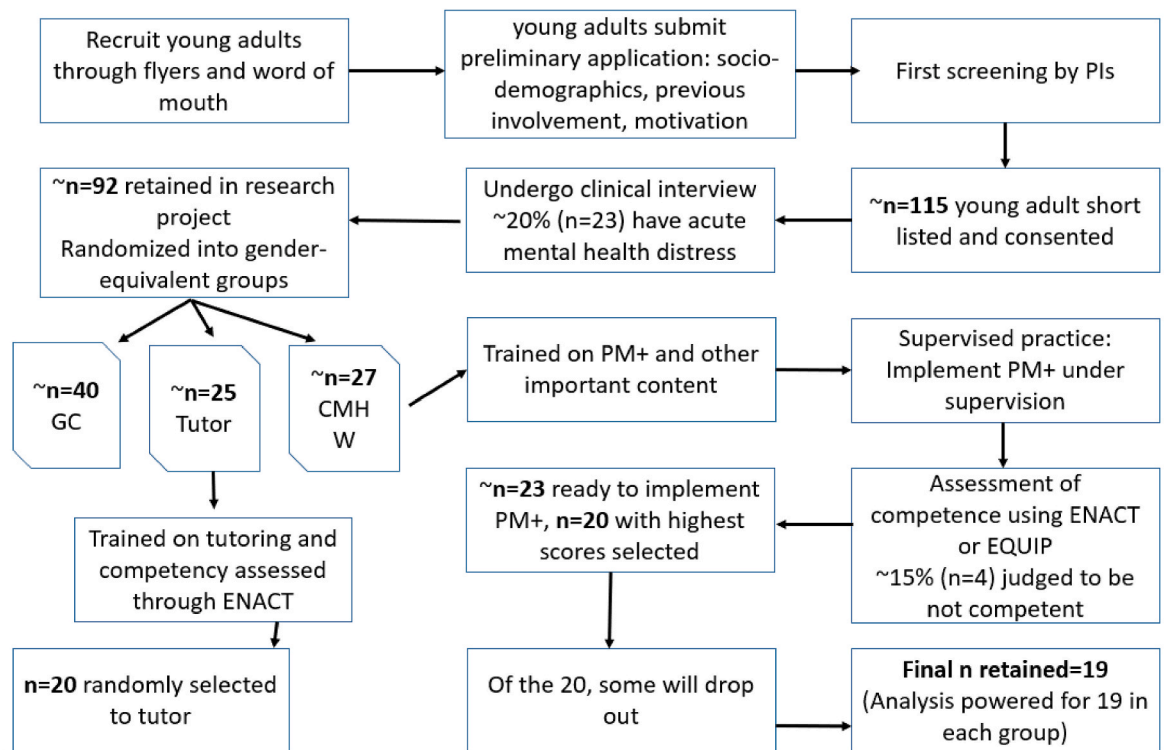Randomization: The 92 remaining young adults (18–24 years) will

Fig. 2. Flow chart of recruitment, selection, training, retention/Young adults.

be randomized by the project biostatistician (GB) into three groups: 27 into the YA-CMHW group and 25 into the YA-Tutors, and 40 into the YA-CG. Randomization will be conducted in one block at the beginning of the trial, after recruiting participants. Participants will be randomly assigned to intervention groups proportionally to the group sizes within strata defined by age group (18–21, 22–24), gender (M,F), and consent to participate in the hair cortisol measurement (yes, no).

Survey measures and hair sample collection: We will collect quantitative data from young adults using a survey that measures Wellbeing, Coping, and Stress; and each of the 7 mechanisms (see Table 2). The survey will be in Arabic. YA in all three arms will complete the surveys 4 times: baseline prior to training, 3 months into the intervention, at the end of the intervention period (6 months), and 6 months post intervention. An online survey platform CommCare® (https://www.dimagi.com/commcare) will be used for data collection on tablets or phones while ensuring data consistency and quality. Data processing will be conducted using reproducible Rmarkdown reports and associated scripts, stored in version control for documentation. Data will be standardized for inclusion in the NIMH Data Archive as a de-identified limited data set. In addition, two trained barbers (one male and one female) will collect hair samples to measure hair cortisol from the YA-CMHW and the YA-TU 6 times: the first 4 at the same time as the survey and subsequently at 9- and 12-months post intervention. Both survey data and hair samples will be labeled using a code and no identifying information will be collected. For the stress measured through hair cortisol analysis, we will follow the procedures implemented in a previous [46] study in Jordan.

Participant retention and complete follow-up will be promoted through incentives provided to all YA that are based on progress in the intervention. For example, YA will be provided with an incentive at the completion of training (CMHW and TU), after completing implementation with 2 clients, then an additional 5 clients, etc. They will also receive incentives each time they complete assessments. We anticipate these financial incentives to be important retention strategies in this low SES community, In addition, our strategy for retention includes close follow-up by our field team at MAPs with all YAs in order to ensure that

the intervention is proceeding according to plan, that challenges are addressed, and that all data collection tools are completed. It is estimated that over 112,000 Syrian refugees living in tented settlements in the Bekaa are between the ages of 14–24 years [4]. We are recruiting 115. In case of attrition, we will renew a recruitment call.

2.2. Data management and analysis

Initial comparisons between study arms (Aim 1) will be made with the same analysis techniques used to motivate the power calculations made previously (t-tests and linear mixed models). The primary analysis, however, will jointly model the trajectories of the mechanisms and primary study endpoints over time for individuals in each of the three arms, and to capture the relationship between these factors. We propose to use a Bayesian Hierarchical Model (BHM) approach. We propose to longitudinally model the survey-based mechanistic factors over time, with random effects for individuals and a vector-autoregressive error structure; this will allow us to extract aggregate posterior differences between study arms, as well as characterize individual heterogeneity. In addition, we will couple the mechanism model to the primary endpoints via a Gompertz growth curve model, capturing the nonlinear relationship between the true wellbeing, ω_{it}, and the true values of functioning on each of seven mechanisms. This relationship is described by the following function: $\omega_{it} = \alpha e^{-\beta e^{-\gamma \eta_{it}}}$. Here, α is the highest value of wellbeing expressible by the instrument used to measure it, β and γ are parameters capturing the displacement of the growth curve along the domain axis and the growth rate, respectively. The linear predictor η_{it} captures the weighted total functioning across the seven mechanisms via regression weights $\{\delta_k\}$. This model component also includes a subject-specific random effect, which is interpretable as a systematic "setback" or "advantage" estimated for each individual along the axis relating the functional mechanisms to wellbeing. The same approach relates the seven mechanisms to stress. This structure can easily incorporate interactions, allowing us to evaluate synergistic or antagonistic contributions of combined mechanisms to wellbeing.

Finally, the process model relating cortisol measurements to

underlying estimates of stress levels, coping, wellbeing, and key mechanisms must account for the fact that the relationship between cortisol and stress is complex and person specific. We draw upon the work of Dajani et al. (2018) [46], who propose three cortisol expression phenotypes with relationships to trauma and stress history: hypersecretion, hyposecretion, and medium secretion. We will introduce a latent, three level factor corresponding to each of these categories, and use a multinomial logistic model to relate baseline characteristics and history to the cortisol secretion category. Cortisol measurements will be modeled using a separate regression component with autoregressive errors for each category. We will preserve model identifiability by introducing constraints requiring a negative relationship between stress (as informed by the Perceived Stress Scale items) and cortisol for the hypersecretion group, a positive relationship for the hypo secretion group, and an effect of either sign, but strictly lesser magnitude for the normal secretion group. While Bayesian models of this type do not require extra assumptions, we do need to hypothesize a parametric form for the model; we will examine model adequacy and fit via the use of posterior-predictive p-values, as well as the comparison of the qualitative findings of the BHM approach to simpler Bayesian and frequentist models evaluating the longitudinal trends for each of the mechanisms and outcome separately as compared between groups. Bayesian models will be fit; and results reported, in accordance with the Bayesian Analysis Reporting Guidelines (BARG) [53], including conducting appropriate sensitivity analyses on the prior structure. Missing data will be handled in two ways. First, we will examine predictors of missingness in order to better identify sources of missingness and evaluate the reasonableness of different imputations strategies. Second, we will employ model-based imputation, if appropriate. Using the machinery of Bayesian models, missing values are naturally treated as latent quantities to be estimated along with model parameters. In addition to Bayesian techniques, we will also utilize exploratory predictive methods, including Bayesian Additive Regression Trees (BART) to flexibly predict changes in physiology related to stress observed at each study point using data available at baseline and prior time points. This will allow us to evaluate the degree to which model assumptions aid in elucidating the mechanisms at play, or unduly constrain them.

Additional sensitivity analyses will be conducted analyzing cortisol data separately. Cortisol data will be log-transformed to normalize the distribution, and data points more than +2SD from the mean excluded, following previous work [46]. Bayesian growth curve models will be used to test the hypotheses, being robust to missing and/or unequally spaced data, allowing e.g. model-based imputation. We will study longitudinal cortisol trajectories with latent growth mixture modeling in MPlus v7.3. This technique captures heterogeneity in cortisol over time in k number of groups, each with a distinct trajectory, enabling us to test whether there were multiple trajectories of cortisol production, such as individuals with patterns of hyper, normal, or hypo-cortisol production [46]. These models will allow us to detect differences in cortisol levels before and after the intervention, for the cohort as a whole and/or for sub-groups with different patterns of cortisol production. Differential non-adherence between study arms will be investigated to fully describe limitations in the populations present in the final sample. The final trial data set will be available to PIs and co-Is (RA, RN, LG, GB, CPB). Results will be communicated to the trial participants through presentations at MAPS, and to academic audiences through peer-reviewed publications and scientific conference presentations. Author eligibility guidelines will follow ICMJE criteria [54].

Data safety, oversight and monitoring: The RCT trial has been approved by the Institutional Review Boards (IRBs) of the American University of Beirut (IRB#: SBS-2022-0018; SBS-2022-0118; SBS 2022-0375) and the University of Iowa (IRB# 202107337) and Clinical trial.gov (NCT05265611) and the Lebanon Clinical Trials Registry (#: LBCTR2023015206). Any important protocol modifications will be communicated immediately to the IRBs, and the trial registries. The data safety and monitoring board (DSMB) consists of 5 faculty or staff with

expertise in biostatistics and research ethics and/or humanitarian settings; and 2 community advocates. The DMSB will meet quarterly to 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. Finally, the DMSB will guide any decisions related to continuation or discontinuing the trials. All the above will be done with utmost attention to the confidentiality of all trial data.

Any adverse or serious adverse event, or unanticipated problems will be reported within 24 h to the IRB at AUB and the Data Safety Monitoring Board. The mental health team (psychiatrist MZ and YC - and psychologist MH) will provide immediate guidance on management of any events. If more than 1/3 of the YAs 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.

3. Discussion/conclusion

As noted in the introduction, over 108 million people have been forcibly displaced as of the end of 2022, including about 35 million refugees [1]. Mental health consequences of these displacements are significant [8–11], with a dearth of licensed mental health providers to support healing [12–14]. In these low resources settings, task sharing that allows for training of community mental health workers (CMHW) has been found to be effective [11,18–20,50]. Problem management plus is a WHO-developed low-intensity psychosocial intervention that has been found to be effective in decreasing distress of displaced persons in context of uncertainty, including in humanitarian setting [21]. A significant proportion of refugee populations are youth and young adults and evidence indicates that capacity to support their communities effectively leads to enhanced wellbeing of the young adults and their broader community [22–25]. This intervention combines the need for CMHW in humanitarian setting with the capacity of young adults to be positive implementers of needed support in their communities, to test the impact of that support on young adults themselves, specifically among Syrian refugees in Lebanon. The scope of the Syrian refugee crisis, the clear need for interventions to decrease the burden of mental distress among Syrian refugees, and the large number of unengaged young adults that can be positive resources in their community provides an important context in which to explore our aims. Our results will (a) elucidate critical mechanisms in which engagement of young adults to support their community enhances their own wellbeing; and (b) inform research around humanitarian/refugee settings, mental health, and YA-CMHW interventions. Although we are assessing the impact of young adults as CMHW in the Syrian refugee context, the premise of this intervention and its results are equally relevant and applicable to emergency situations (natural or person-made) anywhere.

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CRediT authorship contribution statement

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Conceptualization. **Lilian Ghandour:** Writing – review & editing, Supervision, Project administration, Methodology, Conceptualization. **Grant Brown:** Writing – original draft, Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Catherine Panter-Brick:** Writing – review & editing, Writing – original draft, Funding acquisition, Conceptualization. **Hailey Bomar:** Writing – review & editing, Writing – original draft, Conceptualization. **Malak Tleis:** Writing – review & editing, Project administration, Conceptualization. **Hanan Al Masri:** Writing – review & editing, Project administration, Conceptualization. **Marwa Fares:** Writing – review & editing, Project administration, Investigation, Conceptualization. **Fadi Al Halabi:** Writing – review & editing, Conceptualization. **Yamen Najjar:** Writing – review & editing, Conceptualization. **Bayan Louis:** Writing – review & editing, Conceptualization. **Maha Hodroj:** Writing – review & editing, Project administration, Conceptualization. **Yara Chamoun:** Writing – review & editing, Project administration, Conceptualization. **Myriam Zarzour:** Writing – review & editing, Project administration, Conceptualization. **Rima A. Afifi:** Writing – review & editing, Writing – original draft, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2024.101325.

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