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Peer-led family-centered Problem Management Plus for Immigrants (PMP-I) for mental health promotion among immigrants in the United States: a study protocol for a randomized controlled trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-061353
Article Type:	Protocol
Date Submitted by the Author:	22-Jan-2022
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Keywords:	EPIDEMIOLOGY, MENTAL HEALTH, PSYCHIATRY, PREVENTIVE MEDICINE

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Manuscripts

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3 **Peer-led family-centered Problem Management Plus for Immigrants (PMP-I) for mental**
4 **health promotion among immigrants in the United States: a study protocol for a**
5 **randomized controlled trial**
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Abstract

Introduction

Research is needed to investigate potential preventive strategies to reduce stress and mental health burden and assess effective implementation among refugees and immigrants. Problem Management Plus (PMP) is a low-intensity multicomponent psychological intervention developed by the World Health Organization (WHO) that trained laypeople can deliver. PMP has been adapted as a prevention intervention and developed as Problem Management Plus for Immigrants (PMP-I), including psychoeducation, problem-solving, behavioral activation, and mind-body exercise, to address immigrants' multiple socio-cultural and emotional stressors. This trial aims to estimate the magnitude of the difference between PMP-I vs. community support services pamphlets on the primary outcomes of interest (stress, anxiety, and depressive symptoms) to inform the design of a large-scale intervention.

Methods and analysis

This trial will test preliminary effects of PMP-I vs. community support services pamphlets in a randomized controlled trial (N=116 families; 58 families for each condition intervention and control) on stress, anxiety, and depressive symptoms (primary outcomes), chronic physiological stress assessed in hair cortisol (secondary outcomes), and coping, family conflict resolution, and social networking (targets), with assessment at baseline, post-intervention, and 3-month post-intervention. Eligibility criteria for the primary study participants include Bhutanese adults 18 years or older resettled in Massachusetts with a score of 14 or below on the Patient Health Questionnaire (PHQ-9), a screening tool to exclude individuals with depressive symptoms (score

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3 of 15 and more). All family members will be invited to participate in the family-based
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5 intervention (1-session/week for 5-week). Multilevel modeling will compare the longitudinal
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7 change in outcomes for each treatment arm while accounting for the clustering of participants
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9 within families.
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14 **Ethics and dissemination**

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17 The Institutional Review Board of the University of Massachusetts Amherst approved this study.

18
19 The study results will be disseminated in peer-reviewed journal and conferences.
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24 **Trial registration number:** NCT04453709

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26 Prospectively registered on 1st July 2020. Recruitment of participants was delayed due to the
27
28 COVID-19 pandemic and has started on August 17, 2021.
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33 **Keywords:** Anxiety; Depression; Emotional Wellbeing; Mind-Body Intervention; Refugees;
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35 Social Wellbeing; Stress
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40 **Running title:** Problem Management Plus for Immigrants in Bhutanese adults
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Strengths and limitations of the study

- Whereas existing mental health interventions for immigrants are primarily based on treatment models to improve the access and quality of care for those with diagnosed mental health problems, this study is focused on developing, implementing, and pilot testing an effect of a culturally-tailored preventative behavioral intervention to reduce stress and prevent mental health problems among immigrants.
- This study includes culturally-tailored psychoeducation, behavioral activation, problem-solving, and mind-body interventions that help to address multiple psycho-socio-cultural stressors through revitalizing resources at the individual, family, and community levels.
- The proposed intervention will be delivered to participants in their family environment by interventionists from the same community they trust and understand their language and problems from their cultural lens.
- This study will be among the first to link a preventive intervention with both biomarkers of stress (hair cortisol) and perceived stress and, using longitudinal data, to examine change over time in stress.
- This study relies on self-report measures of anxiety and depressive symptoms though the clinical diagnosis is the gold standard. Such an approach is not feasible in community-based studies.

Introduction

Refugees resettled in the United States are vulnerable to mental health problems,^{1, 2} such as anxiety and depression due to stress resulting from integrating into a new culture.³⁻⁵ Refugees' risk for mental health problems increases during their acculturative process due to exposure to multiple stressors, such as adjustment to a new culture with limited language and socio-cultural skills, perceived discrimination, and a lack of culturally mediated and protective social support resources.^{5, 6} Although mental health treatments are available to help alleviate the intrapersonal, social, and economic costs of mental disorders, refugees greatly underutilize these services.^{1, 7, 8} Thus, evidence-based, culturally tailored preventative mental health interventions are needed for the growing number of refugees in the United States.

Existing interventions are focused explicitly on treatment models to provide quality care for those with diagnosed mental health problems⁹ that do little to help reduce stress and prevent mental disorders for those who have not yet developed diagnosable symptoms. For prevention, a culturally tailored intervention that addresses multiple psycho-socio-cultural stressors, including social and cultural integration, holds good promise.^{10, 11} Community-based preventative interventions that promote positive impacts of social and cultural behaviors on mental health outcomes by protective resources are needed for the growing number of refugees dealing with life complexities.^{12, 13} A review of community-based mental health interventions in refugees resettled to the United States suggests¹⁴ that counseling, health promotion, and skill-building workshops facilitated by refugee peers¹⁵⁻¹⁷ are helpful to reduce the psychological distress of many refugees who may be struggling with individual or family difficulties. Specifically, the Centers for Disease Control and Prevention (CDC) recommends using a non-clinical, community support approach to prevent mental illness among refugees resettled in the United States.¹⁸

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3 Problem Management Plus (PMP) is a low-intensity evidence-based psychological
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5 intervention developed by the World Health Organization (WHO) that trained laypeople can
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7 deliver.^{19, 20} PMP systematically teaches four strategies: stress management through mind-body
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9 exercises,²¹⁻²⁴ problem-solving,²⁵ behavioral activation,²⁶⁻³³ and skills to strengthen social
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11 support for individuals with psychological distress. PMP has been proven successful in reducing
12
13 depression for women with mental disorders in Pakistan in a group setting.³⁴ We have adapted
14
15 PMP to develop our Problem Management Plus for Immigrants (PMP-I) following a successful
16
17 result of a pilot social and emotional wellbeing intervention. The pilot intervention included
18
19 psychoeducation, mind-body exercise, problem-solving, and social support and reduced more
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21 than 50% prevalence of anxiety and depression from pre- to post-intervention among Bhutanese
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23 refugees when delivered in either a group³⁵ or a family setting.³⁶ While promising, these pilot
24
25 results were drawn from only those receiving the treatment; no control group was available for
26
27 comparison. Thus, the present study is to apply the adapted PMP in a randomized controlled
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29 trial. The present study is indicated for several reasons: our intervention model demands
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31 integration of social and emotional stressors; promising results of PMP in a non-controlled pilot
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33 study; the need to test the efficacy of PMP using the more rigorous randomized controlled trial
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35 (RCT) study design; strong evidence of family and community ties in health care process; and
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37 growing consensus among community, scientists, and policymakers on the need for family-based
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39 care models that are sustainable.
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49 **Objectives and hypothesis**

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51 The main objective of this study is to pilot test the feasibility and acceptability of PMP-I among
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53 Bhutanese adults 18 years or older living in Massachusetts with a score of 14 or below on the
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3 Patient Health Questionnaire-9. Our central hypothesis is that PMP-I will reduce stress, anxiety,
4 and depressive symptoms. We will test preliminary effects of PMP-I vs. community support
5 services pamphlets in a randomized pilot trial (N=116 families; 58 families per intervention and
6 control) on perceived stress,³⁷ anxiety and depressive symptoms (primary outcomes).³⁸ chronic
7 physiological stress assessed in hair cortisol (secondary outcome), and self-efficacy,³⁹ coping,⁴⁰
8 family conflict resolution,⁴¹ family satisfaction,⁴² social support (targets),⁴³ and social networks⁴⁴
9 with assessments at baseline, post-, and 3-month post-intervention.
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19 20 21 **Methods**

22 **Design and setting**

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24 This study will be conducted among resettled Bhutanese adults living in Massachusetts. Since
25 2008, Bhutanese people have been resettled in various US states and are one of the largest
26 groups of South Asian refugees (about 90, 000).⁴⁵ They bear a high burden of mental health
27 problems both in the nation (depression: 20%; suicide rate: 21.5 per 100,000)¹⁸ and in western
28 Massachusetts (depression: 23.8%; anxiety: 34.5%).⁴⁶ Given the importance of family
29 relationships, communication, and coping in mental health,⁴⁷ the preventative social and
30 emotional wellbeing intervention was designed for resettled Bhutanese adults in western
31 Massachusetts using a community-based participatory research (CBPR) approach.³⁵
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47 **Study design:** This mixed-methods study will incorporate a two-arm randomized controlled
48 feasibility trial and qualitative evaluation of PMP-I intervention's acceptability to a range of
49 stakeholders. The study protocol has been reported following the Standard Protocol Items:
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3 Recommendations for Interventional Trials (SPIRIT). **Figure 1** shows the study flowchart, and
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5 **Figure 2** shows the SPIRIT figure.
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10 **Participant recruitment**

11 *Participant inclusion criteria using a screening measure*

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14 This study will include eligible parents and adult children aged 18 and above interested in
15 participating as primary study participants. At baseline, we will use a screening tool to identify
16 individuals without significant depressive symptoms, as we aim to evaluate the effect of our
17 intervention to prevent depression rather than treat depression. Eligibility criteria for our primary
18 study participants include Bhutanese adults 18 years or older (both parents and children of each
19 family) resettled in Massachusetts with a score of 14 or below on the Patient Health
20 Questionnaire (PHQ-9), a screening questionnaire for depression. Our statistical analysis will
21 focus on data from primary study participants only with baseline PHQ-9 scores 14 or below.
22
23 However, all other interested adult family members, both parents and their adult children,
24 regardless of PHQ-9 score, will be invited to participate in the intervention. The PHQ-9 scores of
25 participants will not be disclosed to anyone to maintain individual confidentiality. Besides,
26 individuals with PHQ-9 screening score '15-19' (moderately severe depression) and '20-27'
27 (severe depression) will be provided with feedback on their screening questionnaire outcomes
28 confidentially. They will be encouraged to consult their primary health care providers.
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49 *Participant exclusion criteria*

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51 Participants with clinically diagnosed mental disorders and those taking psychiatric medications
52 for any mental health problems will also be encouraged to participate in the family-based
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3 intervention activities. However, in our primary statistical analysis, we will not consider data
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5 from those participants with PHQ-9 scores of 15 or above or diagnosed with mental health
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7 problems.
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11 12 **Informed consent**

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14 The principal investigator (PI) has prepared an informed consent document including an
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16 explanation on study background, screening, recruitment criteria, sample size, data collection,
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18 and intervention, study risks and benefits, confidentiality, National Institute of Mental Health
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20 Data Archive (NDA) data sharing policy, and hair samples collection procedure. Trained
21
22 community research assistants (RAs) will inform screening and study procedures to each
23
24 participant using UMass Amherst Institutional Review Board (IRB)-approved single informed
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26 consent form visiting in-person. Once participants understand study details, RAs will request
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28 their signature or initials or fingerprint for those who cannot write in the consent form before
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30 data collection. Participants will be reminded that their participation in the study is voluntary and
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32 free to leave the study without penalty.
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40 **Sample size and power calculations**

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42 The goal of the pilot project is to estimate the magnitude of the difference between the
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44 preventive intervention and the education control on the primary outcomes of interest to inform
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46 the design of a large-scale intervention. We conducted a power analysis to detect an effect size
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48 (ES) as small as $ES = .30$ with $\alpha = .05$ and power of $.80$. We may find a larger effect in our
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50 pilot, but our understanding is that power estimates should be based on the smallest effect we
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52 want to detect rather than the size of the effect that we expect.⁴⁸ Analyses were performed using
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3 Optimal Design⁴⁹ by accounting for the intra-correlation among family members of .10 and alpha
4 = .05, we would have 80% power to detect a standardized difference of ES=.30 between two
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6 treatment groups of 116 families (58 per treatment arm) with an equal probability of being
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8 randomized to each of our two intervention arms.
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11 12 13 14 15 **Randomization**

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17 We will randomly allocate selected families into intervention and control groups using a random
18 sampling method after the baseline survey. RAs are not aware of which group the family will be
19 randomized to when collecting baseline data. Using a random number table, we will randomly
20 assign 116 interested families (58 families per intervention and control). For random allocation,
21 first, the PI will prepare the sampling frame that lists interested families, then assign a number to
22 each family in the sampling frame, and finally select 116 numbers using a table of random
23 numbers. We will assign a random number selected at the first attempt for intervention and the
24 second attempt for control.
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35 Procedures are in place for tracking the participants for intervention and follow-up (e.g.,
36 contact address and phone). RAs will visit selected families and brief them about study
37 procedures, informed consent, and procedures to protect human subjects. Two adult members of
38 selected families who meet the inclusion criteria and give informed consent will be recruited for
39 the study. We will follow up with all families randomized to either study arm. We will not
40 follow up with participants if they decide to end their participation at a particular time point of
41 our study. But, we will include their already collected data in our analysis. Given our strong
42 community networks and mobilization of community RAs, we anticipate low attrition rates in
43 practice.
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Problem Management Plus for Immigrants (PMP-I)

PMP-I is a 5-week, peer-led, culturally tailored mental health promotion program that includes psychoeducation, problem-solving, behavioral activation (90 minutes), breathing exercises, and yoga (90 minutes) in a family setting. PMP-I will use a structured approach, including once-a-week face-to-face sessions, yoga practice, breathing exercises, homework that includes practice activities, rebuilding individual skills, or learning new skills to reduce stress.

Our intervention aims to develop skills in coping adaptively in a new culture, seeking help and support for mental health problems, and other life skills opportunities that can improve their quality of life. **Module 1: Managing Stress** includes yoga, breathing exercise, stress-management sessions, and practice exercises to develop coping strategies that are most helpful to reduce stress and then plan a strategy to carry out those solutions. **Module 2: Managing Problems** includes practice exercises to identify the problems causing the most concern, develop solutions that are most helpful in addressing the problem, and then plan a strategy to carry out those solutions. **Module 3: Behavioral Activation** includes communication skill sessions and practice exercises to identify pleasant activities (time to yourself; connecting with others; self-care), breaking down the task into smaller steps, and schedule tasks, and then plan a strategy to carry out those tasks. **Module 4: Strengthening Social Support** includes social skills sessions and practice exercises to identify at least one person or service from whom the participant feels comfortable getting some support, and to plan exactly what the participant is going to do, and then schedule a day to carry out the tasks. **Module 5: Staying Well** includes practice exercises to make a plan that helps to create a supportive family environment.

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3 Community interventionists (CIs) are trained community members with at least a high school
4 level of education, and no formal training or prior experience with mental health will deliver the
5 PMP-I. Dr. Christopher Martell, board-certified in cognitive and behavioral psychology and
6 clinical psychology and a Massachusetts Licensed Psychologist, will provide 12 days of training
7 to the interventionists in collaboration with the PI and Dr. Steven D. Hollon (Professor of
8 Psychiatry, Psychology and Human Development) following the World Health Organization
9 PMP Helpers' Training Guide⁵⁰ adapted for PMP-I. Classroom training includes information
10 about stress, depression, mental health problems, the rationale for each intervention strategy,
11 necessary helping skills, practice plan formulation, role-plays, peer observations, and group
12 discussion related to core intervention concepts, practices, and supervision skills. Supervision
13 involves discussing participants' progress and difficulties experienced when delivering strategies
14 and role-playing on managing problems or practicing skills. They will use the PMP-I
15 intervention manual to provide PMP-I to community members in family settings under field
16 supervisors and PI's supervision. We will conduct a formal evaluation of the interventionists'
17 readiness to implement/supervise the PMP-I intervention, such as using the manual, answering
18 questions, managing time, using a fidelity checklist, practicing exercise, and role play to provide
19 feedback as necessary.
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42 A licensed yoga trainer will provide 4 hours of breathing exercises and 16 hours of yoga to
43 CIs and field supervisors using a mind-body exercise training manual. Classroom training
44 includes theoretical and practices to guide participants in mind-body exercises for attention to
45 breath, body sensation, emotional awareness, and mental function on different postures of yoga
46 practices such as *Pranayama* (3 poses) and *Asana* (21 poses). Training will include practice
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3 assessment at the end to ensure that all field staff is trained, using a checklist, practice exercise,
4 and role-plays.
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10 **Community Support Service Program**

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12 Bhutanese community members expressed that knowing the health and life skill development
13 program available in their communities would benefit them in strengthening their life skills.⁵¹ By
14 considering their request, we have prepared pamphlets including names, contact, and service
15 details of community and health organizations in the area where they live. CIs will distribute
16 community support service program pamphlets to control families.
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26 **Primary outcome measures**

27 **Anxiety and Depressive Symptoms**

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29 The Hopkins Symptom Checklist-25 (HSCL-25) will be used to measure anxiety, and depressive
30 symptoms experienced over the past month.³⁸ It is composed of a 10-item subscale for anxiety
31 and a 15-item subscale for depression, with each item scored on a Likert scale from 1 (not at all)
32 to 4 (extremely). The scale has high internal consistency (Cronbach's α) for anxiety (0.95) and
33 depression (0.94) in the Bhutanese study.³⁵
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44 **Perceived Stress**

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46 The 10-item Cohen Perceived Stress Scale (PSS) will be used to assess perceived stress.³⁷ The
47 PSS uses a 5-point Likert scale (ranging from 0, "never" to 4, "very often") to assess
48 psychological stress experienced during the past month, including the extent to which situations
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3 felt unpredictable, uncomfortable, and overwhelming. In the Bhutanese study, the scale has high
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5 internal consistency (Cronbach's $\alpha = 0.80$).³⁵
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10 **Secondary outcome measures**

12 **Physiological stress**

14 We will use the enzyme-linked immunosorbent assay (ELISA) cortisol hair test (average
15 hormone levels over the past three months) as a biomarker to measure physiological stress. Hair
16 samples will be processed in the neuroendocrine lab at the University of Massachusetts
17 Amherst.^{52, 53} Sensitive and specific enzyme immunoassay (Arbor Assays) will be used for the
18 analysis. The assay has intra- and inter-assay coefficients of variation of <10%.
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28 **Other measures**

30 **Coping strategy**

32 Coping strategy will be measured using a 32-item Coping Strategies Inventory-Short Form (CSI-
33 SF).⁴⁰ The CSI-SF includes two overall coping factors, Engagement and Disengagement, and
34 four secondary factors, Problem Engagement, Problem Disengagement, Emotion Engagement,
35 and Emotion Disengagement. The CSI-SF scale (Cronbach's $\alpha = 0.95$) has high internal
36 consistencies in the Bhutanese study.³⁵ Participants were asked to rate their responses on a 5-
37 point Likert-type scale ranging from *not at all (1)* to *very much (5)*.
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49 **Coping Self-efficacy**

51 Self-efficacy will be measured using a 26-item Coping Self-efficacy (CSE) scale for coping with
52 challenges and threats.³⁹ Each item of the scale will be rated on an 11-point scale Likert-type
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3 scale ranging from (0) cannot do at all, (5) moderately certain can do, and (10) certain can do.

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5 The scale has high internal consistency (Cronbach's $\alpha = 0.96$) in the previous Bhutanese study.³⁵

6 7 8 9 10 **Social support**

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12 Perceived social support will be measured using a 12-item Multidimensional Scale of Perceived
13
14 Social Support (MSPSS),⁴³ including support from friends, family, and significant others. A
15
16 sample item for this scale is, "My family tries to help me." Each item of the scale will be rated on
17
18 a 5-point Likert-type scale ranging from *strongly disagree (1)* to *strongly agree (5)*. Graded
19
20 items will be summed up to provide a total score, and higher scores indicate high social support.

21
22 The scale has high internal consistency (Cronbach's $\alpha = 0.92$) in the previous Bhutanese study.³⁵

23 24 25 26 27 28 **Social network**

29
30 We will use a Lubben Social Network Scale-Revised (LSNS-R) to measure social networks
31
32 among family and friendships.⁴⁴ It consists of six questions, which assess kinship ties, and a
33
34 comparable set of six questions, which determine friend ties by replacing the word relatives with
35
36 the word friends. We prepared three questions to measure cross-cultural social ties following a
37
38 similar pattern. The scale has high internal consistency for kinship ties (Cronbach's $\alpha = 0.78$),
39
40 friendship ties (Cronbach's $\alpha = 0.80$), and cross-cultural social ties (Cronbach's $\alpha = 0.74$) in the
41
42 previous Bhutanese study.³⁵ These items will be scored on a five-point Likert scale ranging from
43
44 *none (0)* to *9 or more or always (5)*.

45 46 47 48 49 50 51 **Family conflict resolution**

1
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3 Family conflict resolution, including positive or negative resolution, effective communication,
4 and discussion of differences, will be measured using a 17-item version of the "Family Conflict
5 Resolution" scale.⁴¹ This scale has high internal consistency (Cronbach's $\alpha = 0.90$) in the
6 previous Bhutanese study.³⁵ Participants will be asked to respond on a 7-point Likert-type scale,
7 ranging from *never (1)* to *always (7)*.
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17 **Family satisfaction:** Family satisfaction with various aspects of family functioning, including
18 family closeness, flexibility, and communication, will be measured using a 10-item family
19 satisfaction scale.⁵⁴ Participants will be asked to respond on a 5-point Likert-type scale, ranging
20 from *very dissatisfied (1)* to *extremely satisfied (5)*.
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28 **Process evaluation**

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31 The PMP trainer's training guidelines provide specific tools for evaluating and monitoring the
32 intervention, which we use to monitor intervention delivery fidelity. These tools are PMP Quiz,
33 PMP Helper's Supervision Form, PMP Helper Classroom-based Competency Assessment, PMP
34 Helper In-field based Competency Assessment, PMP Trainer/Supervisor Competency
35 Assessment, and Session-by-Session Checklists for PMP Helpers.⁵⁰ We have adapted these tools
36 in the context of our program contents. Using these standard tools, we will evaluate session-by-
37 session classroom and in-field based competencies of community interventionists and field
38 supervisors and provide them feedback as needed using supervision forms, role-plays, group
39 discussion, and training.
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51 At the field level, field supervisors will monitor intervention sessions delivered by
52 community interventionists using standard checklists. Items include adherence to the manual,
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3 percent of intervention content administered, proper use of time/materials, and adequate response
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5 to participants' questions. They will also monitor participants' engagement, acceptability, and
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7 satisfaction via brief questionnaires with participants and interventionists during and after
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9 intervention completion. Moreover, community interventionists will be asked to complete a
10
11 structured checklist on the attendance, compliance, and satisfaction towards intervention
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13 components immediately after each session.
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17 The PI will conduct a focus group discussion (FGD) in the Nepali language with
18
19 interventionists, supervisors, and participants separately to collect information on barriers and
20
21 facilitators of intervention, perceptions about whether the intervention met participants' needs,
22
23 and feedback on how effectively the program team worked with participants. Interviews and
24
25 FGD will be documented verbatim in a written transcript for subsequent analysis. All qualitative
26
27 data will be analyzed using thematic content analysis.⁵⁵ Feedback provided by the field staff will
28
29 be reviewed and coded to identify recurrent themes regarding the intervention's acceptability.
30
31 Fidelity data will be used to assess intervention content and transmission.
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37 **Data management**

38
39 All interviews will be conducted with the utmost privacy and confidentiality. Each interested and
40
41 eligible adult participant in the family will be interviewed individually, in a private place where
42
43 they feel comfortable, by our trained community RAs. The RAs will ensure audio and visual
44
45 privacy at these sites, and ensure data confidentiality. RAs will reassure participants that
46
47 numerical codes would be used in place of names in all records to ensure confidentiality. The
48
49 survey materials (questionnaires, transcriptions, and field notes) will be stored in a locked
50
51 cabinet in the PI's office. Data entry will be done on the PI's office computer (encrypted and
52
53 password protected) under the full supervision of the PI. The original data will be kept on
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3 OneDrive, a secure, networked university data storage system. De-identified data sets will be
4
5 used for statistical analyses. The PI herself will do data analysis and documentation. All
6
7 information will be presented in aggregate form in the manuscript or conference abstract, and no
8
9 individual respondent will be identified.
10
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13

14 **Data analysis**

15
16 We will compare baseline characteristics of intervention and control groups using chi-square and
17
18 t-tests as appropriate. While differences between groups are not expected because of the
19
20 randomization used in the study design, variables showing significant differences between the
21
22 two groups will be included as covariates in primary analyses. The primary analyses will test
23
24 whether participants' outcomes in the PMP-I arm differ from those in the control arm. Multilevel
25
26 modeling will compare outcomes of each treatment arm while accounting for the clustering of
27
28 participants within families. Continuous outcomes will be analyzed using hierarchical linear
29
30 modeling, and dichotomous outcomes will be analyzed using multilevel generalized linear
31
32 models with a Bernoulli distribution appropriate to nonlinear binary outcomes.⁵⁶
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38 We expect approximately 2 to 4 members for each of the 58 families in each treatment arm,
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40 and the correlation among family members' responses will be accounted for in the model.

41
42 Hierarchical or multilevel modeling is suited to these data as it accounts for the clustering of
43
44 members within families and unbalanced designs (i.e., different family sizes).⁵⁶ This will be an
45
46 intention-to-treat type of analysis, as multilevel modeling allows retention of all participants
47
48 irrespective of the number of sessions attended (multilevel modeling uses maximum likelihood
49
50 estimation, one of the recommended ways of handling missing data). The analysis will estimate
51
52 endpoint outcomes based on repeated measures (Level 1) within individuals (Level 2) within
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3 families (Level 3). Separate models will be created to evaluate the relationships between
4
5 mediators (targets) and outcomes and explore mediators (e.g., coping) of intervention-outcome
6
7 relation. All analyses will be performed using SAS, version 9 (SAS Institute Inc, Cary, NC).
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11 12 **Independent Safety Monitor**

13
14 We will select an Independent Safety Monitor (ISM) with mental health expertise, whose
15
16 primary responsibility is to provide independent monitoring of this clinical trial in a timely
17
18 fashion. Overall, the ISM will review enrollment data, safety data, and data integrity to maintain
19
20 safety in the trial. The PI will submit data reports once a year to the ISM. The report will include
21
22 the key variables necessary for monitoring the safety and quality of data collection and the
23
24 integrity of the study, including inclusion criteria, informed consent, subject enrollment and
25
26 retention, data confidentiality, intervention compliance, drop outs, adverse events, protocol
27
28 compliance, data quality, and baseline characteristics of study participants. The ISM will have
29
30 access to all safety and data quality information collected and will have the authority to stop the
31
32 study if it is determined that there are unacceptable risks to participants. The ISM also will
33
34 review the study protocol, informed consent, and all relevant documents before the onset of the
35
36 study, and will review and approve amendments to these documents. The ISM will issue a
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38 monitoring report to the PI following each review. The PI will submit all review reports to the
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40 UMass Amherst IRB and NIMH Program Officer in annual progress reports.
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49 **Trial management**

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51 The PI will assume overall responsibility of trial management working together with the entire
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53 research team throughout the project, meeting monthly with Co-Investigators (psychiatrist,
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3 cognitive behavior therapist and epidemiologist) and once every week with field staff
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5 (supervisors, interventionists, and research assistants) via in-person or zoom or text message as
6
7 needed. During the trial, experienced field supervisors from the Bhutanese community, who are
8
9 trained as a community health worker and have worked with the PI in previous family-based
10
11 mental health intervention studies with depressive and suicidal ideation outcomes, will take
12
13 responsibility for the day-to-day oversight of the participants and field teams in the
14
15 implementation of the trial. Field supervisors will immediately report any noted adverse events
16
17 among participants to the PI. The PI will report adverse events data to the Independent Safety
18
19 Monitor (ISM), UMass Amherst IRB, and National Institute of Mental Health (NIMH) Program
20
21 Officer following NIMH guidelines for reportable events, as described below.
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28 **Adverse events reporting**

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30 Throughout the study period, all study participants will be monitored daily by the field
31
32 supervisors under the PI's supervision. Field supervisors will request study participants and their
33
34 family members to immediately report any unanticipated serious adverse events in their family,
35
36 such as 1) reporting suicidal ideation or attempts, hospitalization, disability, and/or death; 2)
37
38 discomfort with the PMP-I program content and/or evaluation procedures, and 3) risk of a breach
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40 of confidentiality, of the collected data and/or by program personnel to field supervisor or PI
41
42 directly. Field supervisors will immediately report details of such adverse events to PI. The PI
43
44 will be responsible for reporting them to the UMass Amherst IRB, ISM, and NIMH Program
45
46 Officer by secure email within ten business days of the study team becoming aware of any
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48 serious adverse events. The PI will be responsible for summarizing all adverse events that are
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3 deemed expected and/or unrelated to the study in the annual progress report submitted to the
4
5 UMass Amherst IRB, ISM, and NIMH Program Officer by secure email.
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10 **Discussion**

11
12 This study reports an RCT protocol that tests PMP-I's feasibility, acceptability, and preliminary
13
14 outcomes with trained community facilitators. This study is built on prior research that has
15
16 shown the effectiveness of social and emotional wellbeing intervention, including
17
18 psychoeducation, problem-solving, social support, and mind-body exercises, to reduce stress,
19
20 anxiety, and depressive symptoms among Bhutanese adults resettled in MA at a group³⁵ and
21
22 family settings³⁶ using a pre-and post-test intervention design. Our project designed for
23
24 Bhutanese immigrants includes evidence-based interventions of specific relevance to this
25
26 community, such as psychoeducation,⁵⁷ problem solving,²⁵ behavioral activation,²⁶⁻³³ mind-body
27
28 exercises,²¹⁻²⁴ and strengthening social support to address identified social (e.g., social isolation,
29
30 language difficulties) and emotional (e.g., lack of self-esteem or self-efficacy)⁵¹ stressors by
31
32 strengthening protective factors (e.g., resilience or coping).^{58, 59} This study is innovative as it will
33
34 be the first culturally tailored, preventive, family-based, multi-component behavioral
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36 intervention driven by the community to reduce stress. We will have pilot-tested a preventative
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38 mental health intervention for Bhutanese adults upon completion. This study can be expected to
39
40 impact reducing stress and promoting immigrants' mental wellbeing.
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47 Our project is likely to be replicated with other immigrant communities with minimal
48
49 adaptation over the long term for three reasons. First, our intervention is guided by a strengths-
50
51 based approach in which we plan to include community strengths. This principle can be applied
52
53 to capture and integrate the strengths of any community. Second, our program prioritizes the
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3 training of community members as interventionists, as these are individuals whom the
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5 community trusts, who share the same cultural lens as the community and thus can well
6
7 understand language and specific challenges, and who have a vested interest in the strength and
8
9 resilience of their community. This aspect of our intervention design is easily adaptable to other
10
11 populations. Finally, intervention is designed to be delivered in family settings where
12
13 participants are most comfortable, and family members can support each other throughout their
14
15 lives. This component is crucial in collectivistic societies where family bonds and group identity
16
17 are strong. Thus, our family-based strategies could be replicable in other immigrant groups,
18
19 where there are similarities in social and emotional stressors, challenges, community strengths
20
21 (coping, resilience, social support), strong family support, and cultural preference of native
22
23 community counselors for their mental health consultation. Our strength-based and peer-led
24
25 strategies promote community engagement and make the intervention sustainable.⁶⁰⁻⁶²
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33 **Patient and public involvement**

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35 Patients or the public were not involved in the design, or conduct, or reporting, or dissemination
36
37 plans of our research.
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42 **Trial status**

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44 At the time of manuscript submission, trial was ongoing. Results of this study are expected in
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46 mid 2024.
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List of abbreviations

CBPR: Community-Based Participatory Research; CDC: Centers for Disease Control and Prevention; CIs: Community Interventionists; CSE: Coping Self-efficacy; CSI-SF: Coping Strategies Inventory-Short Form; ELISA: Enzyme-Linked Immunosorbent Assay; ES: Effect Size; FGD: Focus Group Discussion; HSCL-25: Hopkins Symptom Checklist-25; IRB: Institutional Review Board; ISM: Independent Safety Monitor; LSNS-R: Lubben Social Network Scale-Revised; MSPSS: Multidimensional Scale of Perceived Social Support; NDA: National Institute of Mental Health Data Archive; NIMH: National Institute of Mental Health; PHQ-9: Patient Health Questionnaire; PI: Principal Investigator; PMP: Problem Management Plus; PMP-I: Problem Management Plus for Immigrants; PSS: Perceived Stress Scale; RAs: Research Assistants; RCT: Randomized Controlled Trial; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; WHO: World Health Organization

Declarations

Ethics and dissemination

The Institutional Review Board of the University of Massachusetts Amherst approved this study and certified that it was performed according to the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All participants enroll in the study will provide written informed consent. The results of this study will be disseminated through peer-reviewed scientific journals and conferences.

Consent for publication

Not applicable

Availability of data and materials

At the time of manuscript submission, trial was ongoing. Results of this study are expected mid 2024. The PI will have access to the final data trial set.

Competing interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

This trial is funded by the National Institute of Mental Health of the National Institutes of Health under Award Number R34MH118396 (PI: Dr. Kalpana Poudel-Tandukar). The content is solely

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2
3 the authors' responsibility and does not necessarily represent the official views of the National
4
5 Institutes of Health.
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10 **Authors' contributions**

11
12 KPT conceived the study and drafted the study and trial protocols. All authors were involved in
13
14 the design of the study; KPT, CSJ, CM, KCP, SR, RR, HL, JSM, ERBJ, and SDH were involved
15
16 in revising the study protocol for ethics review, and all authors were involved in commenting on
17
18 and revising the trial protocol. All authors read and approved the final manuscript.
19
20
21
22
23

24 **Acknowledgments**

25
26 Not applicable
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30

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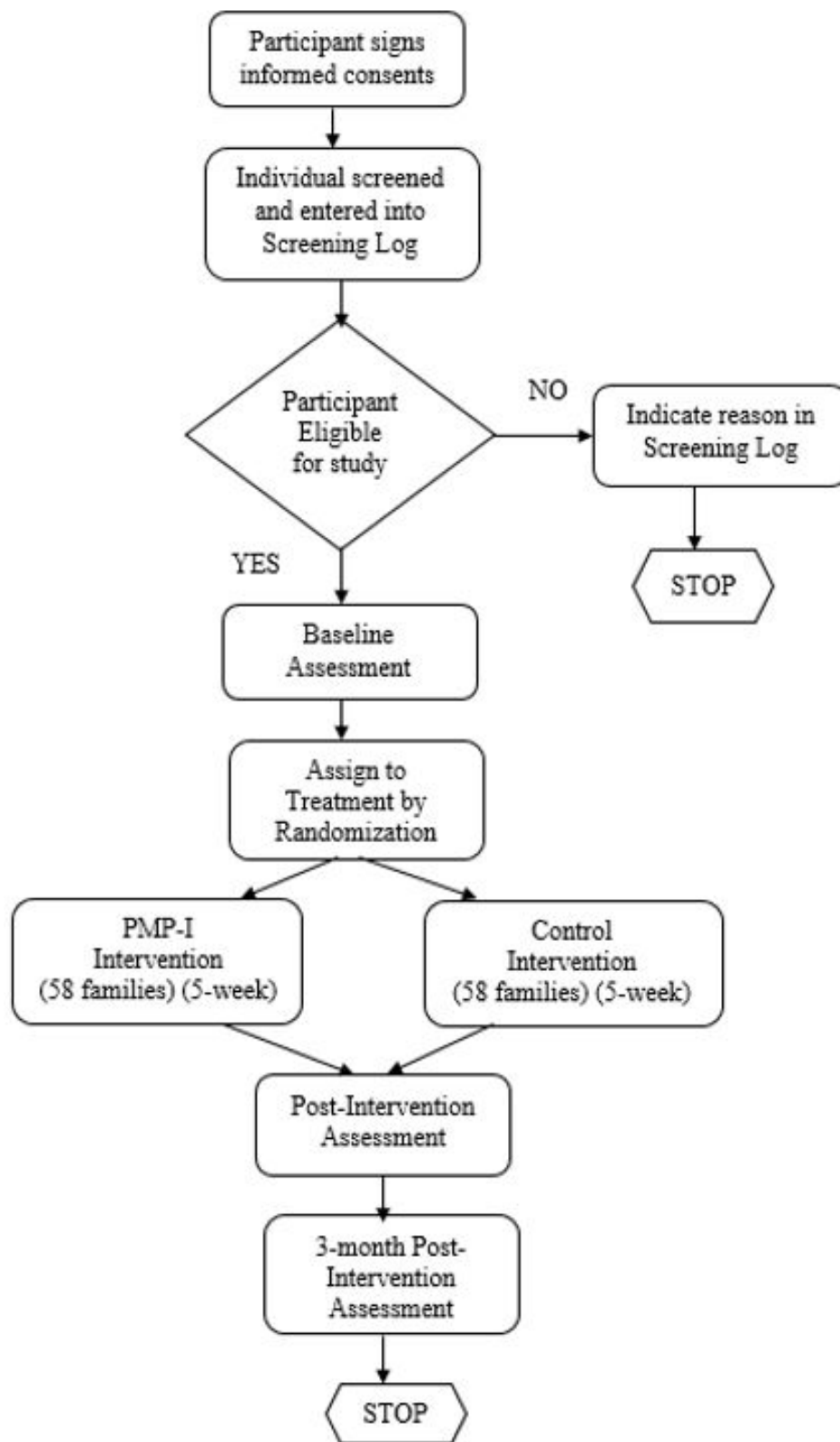


Figure 1 Flowchart of the study

<i>Assessment</i>	<i>Screening Visit 1</i>	<i>Baseline, Enrollment Randomization: Visit 1</i>	<i>Intervention Session 1 Visit 2</i>	<i>Intervention Session 2 Visit 3</i>	<i>Intervention Session 3 Visit 4</i>	<i>Intervention Session 4 Visit 5</i>	<i>Intervention Session 5 Visit 6</i>	<i>Post-intervention Visit 7</i>	<i>3-month Follow-up Final Visit</i>
<i>Informed Consent Form</i>	<i>X</i>								
<i>Screening tool</i>	<i>X</i>								
<i>Inclusion/Exclusion Criteria</i>	<i>X</i>								
<i>Demographics</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Blood pressure</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Bodyweight & height</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Waist circumference</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Hair samples</i>		<i>X</i>							<i>X</i>
<i>Stress, Anxiety & Depression</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Family & Social Support</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Coping Strategies</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Self-efficacy</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Family Conflict Resolution</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Family Satisfaction</i>		<i>X</i>							
<i>Enrollment/Randomization</i>		<i>X</i>							
<i>Intervention Session and its assessment using fidelity form</i>			<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>		
<i>Adverse Events</i>		<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>

Figure 2 Overview of the study measure



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___ 1 ___
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	___ 3 ___
	2b	All items from the World Health Organization Trial Registration Data Set	___ NA ___
Protocol version	3	Date and version identifier	___ NA ___
Funding	4	Sources and types of financial, material, and other support	___ 24-25 ___
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	___ 25 ___
	5b	Name and contact information for the trial sponsor	___ 24-25 ___
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	___ 24-25 ___
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	___ 19 ___

1 **Introduction**

2

3 Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention ___ 5 - 7 ___

4

5

6 6b Explanation for choice of comparators ___ 13 ___

7

8 Objectives 7 Specific objectives or hypotheses ___ 6 - 7 ___

9

10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) ___ 7 - 8 ___

11

12

13

14 **Methods: Participants, interventions, and outcomes**

15

16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained ___ 7 ___

17

18

19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) ___ 8 - 9 ___

20

21

22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered ___ 11 - 13 ___

23

24

25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) ___ 19 - 21 ___

26

27

28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) ___ 19 - 21 ___

29

30

31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial ___ NA ___

32

33

34 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended ___ 13 - 16 ___

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39

40 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) ___ 34 ___

41

42

1 Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including ___ 9 - 10 ___
 2 clinical and statistical assumptions supporting any sample size calculations

3
 4 Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size ___ 9 - 10 ___
 5

6 **Methods: Assignment of interventions (for controlled trials)**

7 Allocation:

8
 9
 10 Sequence 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any ___ 10 ___
 11 generation factors for stratification. To reduce predictability of a random sequence, details of any planned restriction
 12 (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants
 13 or assign interventions
 14

15
 16 Allocation 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, ___ 10 ___
 17 concealment opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
 18 mechanism
 19

20 Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to ___ 10 ___
 21 interventions
 22

23
 24 Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome ___ 10 ___
 25 assessors, data analysts), and how
 26

27 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's ___ NA ___
 28 allocated intervention during the trial
 29
 30

31 **Methods: Data collection, management, and analysis**

32
 33 Data collection 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related ___ 16 - 19 ___
 34 methods processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of
 35 study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known.
 36 Reference to where data collection forms can be found, if not in the protocol
 37

38
 39 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be ___ 10, 16 - 17 ___
 40 collected for participants who discontinue or deviate from intervention protocols
 41
 42

1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	__17 - 18__
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	__18 - 19__
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	__18 - 19__
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	__18 - 19__
11				
12				
13				
14	Methods: Monitoring			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	__19__
17				
18				
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20				
21				
22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	__19__
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	__20 - 21__
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	__NA__
29				
30				
31				
32	Ethics and dissemination			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	__24__
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	__19__
38				
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1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	___ 9 ___
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	___ NA ___
5				
6				
7	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___ 17 - 18 ___
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___ 24 ___
11				
12				
13	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	___ 24 ___
14				
15				
16	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___ NA ___
17				
18				
19				
20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	___ 17 - 18 ___
21				
22				
23				
24		31b	Authorship eligibility guidelines and any intended use of professional writers	___ NA ___
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	___ 24 ___
27				
28				
29	Appendices			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
32				
33				
34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____
35				
36				

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

BMJ Open

Peer-led family-centered Problem Management Plus for Immigrants (PMP-I) for mental health promotion among immigrants in the United States: protocol for a pilot, randomized controlled feasibility trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-061353.R1
Article Type:	Protocol
Date Submitted by the Author:	21-Mar-2022
Complete List of Authors:	Poudel-Tandukar, Kalpana ; University of Massachusetts Amherst, Elaine Marieb College of Nursing Jacelon, Cynthia; University of Massachusetts Amherst, Elaine Marieb College of Nursing Martell, Christopher; University of Massachusetts Amherst, Department of Psychological and Brain Sciences, College of Natural Sciences Poudel, Krishna; University of Massachusetts Amherst, Department of Health Promotion and Policy, School of Public Health and Health Sciences Rai, Shan; Bhutanese Christian Society of Western Massachusetts Ramdam, Razu; Bhutanese Christian Society of Western Massachusetts Laws, Holly; University of Massachusetts Amherst, Department of Psychological and Brain Sciences, College of Natural Sciences Meyer, Jerrold; University of Massachusetts Amherst, Department of Psychological and Brain Sciences, College of Natural Sciences Bertone-Johnson, Elizabeth; University of Massachusetts Amherst, Department of Biostatistics and Epidemiology, School of Public Health and Health Sciences Hollon, Steven; Vanderbilt University, Department of Psychology
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Epidemiology
Keywords:	EPIDEMIOLOGY, MENTAL HEALTH, PSYCHIATRY, PREVENTIVE MEDICINE

SCHOLARONE™
Manuscripts

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3 **Peer-led family-centered Problem Management Plus for Immigrants (PMP-I) for mental**
4 **health promotion among immigrants in the United States: protocol for a pilot, randomized**
5 **controlled feasibility trial**
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Abstract

Introduction

Research is needed to investigate preventive strategies to reduce mental health burden and assess effective implementation among immigrants. Problem Management Plus (PMP) is a low-intensity multicomponent psychological intervention developed by the World Health Organization that trained laypeople can deliver. PMP has been adapted as a prevention intervention and developed as Problem Management Plus for Immigrants (PMP-I), including psychoeducation, problem-solving, behavioral activations, and mind-body exercise, to address immigrants' multiple stressors. This pilot trial aims to assess the feasibility and acceptability of PMP-I and provide a preliminary estimate of the difference between PMP-I vs. community support services pamphlets on the primary outcomes of interest (stress, anxiety, and depressive symptoms) to inform the design of a large-scale intervention.

Methods and analysis

The feasibility and acceptability of PMP-I will be assessed by measuring recruitment, session attendance, retention rates, program acceptability, and the fidelity of intervention delivery. This pilot trial will test preliminary effects of PMP-I vs. community support services pamphlets in a randomized controlled trial ($N= 232$ participants from 116-families (2 members/family); 58 families randomized to condition intervention or control) on stress, anxiety, and depressive symptoms (primary outcomes), chronic physiological stress assessed in hair cortisol (secondary outcomes), and coping, family conflict resolution, and social networking (targets), with assessment at baseline, post-intervention, and 3-month post-intervention. Eligibility criteria for the primary study participants include Bhutanese ≥ 18 years resettled in Massachusetts with a score of ≤ 14 on

1
2
3 the Patient Health Questionnaire-9. All family members will be invited to participate in the family-
4 based intervention (1-session/week for 5-week). Multilevel modeling will compare the longitudinal
5 change in outcomes for each treatment arm.
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7

8 9 10 **Ethics and dissemination**

11
12 The Institutional Review Board of the University of Massachusetts Amherst approved this study
13 (Protocol: 1837). Written informed consent will be obtained from all participants. The study results
14 will be used to inform the design of a large-scale intervention and will be disseminated in peer-
15 reviewed journals and conferences.
16
17

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20
21 **Trial registration number:** NCT04453709. Prospectively registered on 1st July 2020.
22
23

24
25
26 **Keywords:** Anxiety; Depression; Emotional Wellbeing; Mind-Body Intervention; Refugees; Social
27 Wellbeing; Stress
28
29

30 31 32 **Strengths and limitations of this study**

- 33
34
35 • Whereas existing mental health interventions for immigrants are primarily based on treatment
36 models to improve the access and quality of care for those with diagnosed mental health
37 problems, this study is focused on developing, implementing, and pilot testing the effect of a
38 culturally-tailored preventative behavioral intervention to reduce stress and prevent mental
39 health problems among immigrants.
40
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- 42
43 • This study includes culturally-tailored psychoeducation, behavioral activation, problem-solving,
44 and mind-body interventions that could help to address multiple psycho-socio-cultural stressors
45 through revitalizing resources at the individual, family, and community levels.
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- The proposed intervention will be delivered to participants in their family environment by interventionists from the same community they trust and understand their language and problems from their cultural lens.
- This study will be among the first to link a preventive intervention with both biomarkers of stress (hair cortisol) and perceived stress and, using longitudinal data, to examine change over time in stress.
- Though clinical diagnosis is the gold standard, such an approach is not feasible in community-based studies, so this study relies on self-report measures of anxiety and depressive symptoms.

Introduction

Refugees resettled in the United States are vulnerable to mental health problems,^{1,2} such as anxiety and depression due to stress resulting from integrating into a new culture.³⁻⁵ Refugees' risk for mental health problems increases during their acculturative process due to exposure to multiple stressors, such as adjustment to a new culture with limited language and socio-cultural skills, perceived discrimination, and a lack of culturally mediated and protective social support resources.⁵ ⁶ Although mental health treatments are available to help alleviate the intrapersonal, social, and economic costs of mental disorders, refugees greatly underutilize these services.^{1,7,8} Thus, evidence-based, culturally tailored preventative mental health interventions are needed for the growing number of refugees in the United States.

Existing interventions are focused explicitly on treatment models to provide quality care for those with diagnosed mental health problems⁹ that do little to help reduce stress and prevent mental disorders for those who have not yet developed diagnosable symptoms. For prevention, a culturally tailored intervention that addresses multiple psycho-socio-cultural stressors, including social and cultural integration, holds good promise.^{10,11} Community-based preventative interventions that

1
2
3 promote positive impacts of social and cultural behaviors on mental health outcomes by protective
4
5 resources are needed for the growing number of refugees dealing with life complexities.^{12, 13} A
6
7 review of community-based mental health interventions in refugees resettled to the United States
8
9 suggests¹⁴ that counseling, health promotion, and skill-building workshops facilitated by refugee
10
11 peers¹⁵⁻¹⁷ are helpful to reduce the psychological distress of many refugees who may be struggling
12
13 with individual or family difficulties. Specifically, the Centers for Disease Control and Prevention
14
15 (CDC) recommends using a non-clinical, community support approach to prevent mental illness
16
17 among refugees resettled in the United States.¹⁸
18
19

20
21 Problem Management Plus (PMP) is a low-intensity evidence-based psychological intervention
22
23 developed by the World Health Organization (WHO) that trained laypeople can deliver.^{19, 20} PMP
24
25 systematically teaches four strategies: stress management through mind-body exercises,²¹⁻²⁴
26
27 problem-solving,²⁵ behavioral activations,²⁶⁻³³ and skills to strengthen social support for individuals
28
29 with psychological distress. PMP has been proven successful in reducing depression for women
30
31 with mental disorders in Pakistan in a group setting.³⁴ We have adapted PMP to develop our
32
33 Problem Management Plus for Immigrants (PMP-I) following a successful result of a pilot social
34
35 and emotional wellbeing intervention. The pilot intervention included psychoeducation, mind-body
36
37 exercise, problem-solving, and social support and reduced more than 50% prevalence of anxiety
38
39 and depression from pre- to post-intervention among Bhutanese refugees when delivered in either a
40
41 group³⁵ or a family setting.³⁶ While promising, these pilot results were drawn from only those
42
43 receiving the treatment; no control group was available for comparison. Thus, the present study is
44
45 to apply the adapted PMP in a randomized controlled trial. The present study is indicated for
46
47 several reasons: our intervention model demands integration of social and emotional stressors;
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49 promising results of PMP in a non-controlled pilot study; the need to test the efficacy of PMP using
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3 the more rigorous randomized controlled trial (RCT) study design; strong evidence of family and
4 community ties in health care process; and growing consensus among community, scientists, and
5
6
7
8 policymakers on the need for family-based care models that are sustainable.
9

10 11 12 **Objectives and hypothesis**

13
14 The main objectives of this study are:

- 15
16
- 17 a) To assess the feasibility and acceptability of PMP-I: i) recruitment, session attendance, retention
18 rates, and program acceptability; ii) feasibility of measures for assessing inclusion/exclusion and
19 fidelity of intervention delivery, and iii) barriers and facilitators of intervention using interview and
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21
22
23
24 focus group discussion with participants and facilitators.
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 - 26 b) To test the preliminary outcomes of PMP-I among Bhutanese adults 18 years or older living in
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Massachusetts with a score of 14 or below on the Patient Health Questionnaire-9 with trained
community facilitators. Our central hypothesis is that PMP-I will reduce stress, anxiety, and
depressive symptoms. We will test preliminary effects of PMP-I vs. community support services
pamphlets in a randomized pilot trial (N=232 participants from 116 families (two members per
family); 58 families per intervention and control) on perceived stress,³⁷ anxiety and depressive
symptoms (primary outcomes).³⁸ chronic physiological stress assessed in hair cortisol (secondary
outcome), and self-efficacy,³⁹ coping,⁴⁰ family conflict resolution,⁴¹ family satisfaction,⁴² social
support (targets),⁴³ and social networks⁴⁴ with assessments at baseline, post-, and 3-month post-
intervention.

51 52 **Methods and analysis**

53 54 **Design and setting**

1
2
3 This study will be conducted among resettled Bhutanese adults living in Massachusetts. Since 2008,
4
5 Bhutanese people have been resettled in various states of the United States and are one of the
6
7 largest groups of South Asian refugees (about 90 000).⁴⁵ They bear a high burden of mental health
8
9 problems both in the nation (depression: 20%; suicide rate: 21.5 per 100 000)¹⁸ and in western
10
11 Massachusetts (depression: 23.8%; anxiety: 34.5%).⁴⁶ Given the importance of family relationships,
12
13 communication, and coping in mental health,⁴⁷ the preventative social and emotional wellbeing
14
15 intervention was designed for resettled Bhutanese adults in western Massachusetts using a
16
17 community-based participatory research (CBPR) approach.³⁵
18
19
20

21
22 This mixed-methods study will incorporate a two-arm randomized controlled feasibility trial
23
24 and qualitative evaluation of PMP-I intervention's acceptability to a range of stakeholders. The
25
26 study protocol has been reported following the Standard Protocol Items: Recommendations for
27
28 Interventional Trials (SPIRIT). **Figure 1** shows the study flowchart, and **Table 1** shows an
29
30 overview of study measures.
31
32
33
34

35 **Participant recruitment**

36 *Participant inclusion criteria using a screening measure*

37
38 This study will include eligible parents and adult children aged 18 and above interested in
39
40 participating as primary study participants. At baseline, we will use a screening tool to identify
41
42 individuals without significant depressive symptoms, as we aim to evaluate the effect of our
43
44 intervention to prevent depression rather than treat depression. Eligibility criteria for our primary
45
46 study participants include Bhutanese adults 18 years or older (both parents and children of each
47
48 family) resettled in Massachusetts with a score of 14 or below on the Patient Health Questionnaire
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50 (PHQ-9), a screening questionnaire for depression. Our statistical analysis will focus on data from
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3 primary study participants only with baseline PHQ-9 scores 14 or below. However, all other
4
5 interested adult family members, both parents and their adult children, regardless of PHQ-9 score,
6
7 will be invited to participate in the intervention. The PHQ-9 scores of participants will not be
8
9 disclosed to anyone to maintain individual confidentiality. Besides, individuals with PHQ-9
10
11 screening scores '15-19' (moderately severe depression) and '20-27' (severe depression) will be
12
13 provided with feedback on their screening questionnaire outcomes confidentially. They will be
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15 encouraged to consult their primary health care providers.
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21 ***Participant exclusion criteria***

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23 Participants with clinically diagnosed mental disorders and those taking psychiatric medications for
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25 any mental health problems will also be encouraged to participate in the family-based intervention
26
27 activities. However, in our primary statistical analysis, we will not consider data from those
28
29 participants with PHQ-9 scores of 15 or above or diagnosed with mental health problems.
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35 **Informed consent**

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37 The principal investigator (PI) has prepared an informed consent document including an
38
39 explanation on study background, screening, recruitment criteria, sample size, data collection, and
40
41 intervention, study risks and benefits, confidentiality, National Institute of Mental Health Data
42
43 Archive (NDA) data sharing policy, and hair samples collection procedure (online supplemental
44
45 file). Trained community research assistants (RAs) will inform screening and study procedures to
46
47 each participant using UMass Amherst Institutional Review Board (IRB)-approved single informed
48
49 consent form visiting in-person. Once participants understand study details, RAs will request their
50
51 signature or initials or fingerprint for those who cannot write in the consent form before data
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1
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3 collection. Participants will be reminded that their participation in the study is voluntary and free to
4
5 leave the study without penalty.
6
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9

10 **Sample size and power calculations**

11
12 The goal of the pilot project is to estimate the magnitude of the difference between the preventive
13
14 intervention and the education control on the primary outcomes of interest to inform the design of a
15
16 large-scale intervention. We conducted a power analysis to detect an effect size (ES) as small as
17
18 $ES=.30$ with $\alpha = .05$ and power of $.80$. We may find a larger effect in our pilot, but our
19
20 understanding is that power estimates should be based on the smallest effect we want to detect
21
22 rather than the size of the effect that we expect.⁴⁸ Analyses were performed using Optimal Design⁴⁹
23
24 by accounting for the intra-correlation among family members of $.10$ and $\alpha = .05$, we would
25
26 have 80% power to detect a standardized difference of $ES=.30$ between two treatment groups of
27
28 116 families (58 per treatment arm) with an equal probability of being randomized to each of our
29
30 two intervention arms.
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38 **Randomization**

39
40 We will randomly allocate selected families into intervention and control groups using a random
41
42 sampling method after the baseline survey. RAs are unaware of which group the family will be
43
44 randomized to when collecting baseline data. We will randomly assign 116 interested families (58
45
46 families per intervention and control) using a random number table. For random allocation, first, the
47
48 PI will prepare the sampling frame that lists interested families, then assign a number to each family
49
50 in the sampling frame, and finally select 116 numbers using a table of random numbers. We will
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3 assign a random number selected at the first attempt for intervention and the second attempt for
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5 control.
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8 Procedures are in place for tracking the participants for intervention and follow-up (e.g., contact
9
10 address and phone). RAs will visit selected families and brief them about study procedures,
11
12 informed consent, and procedures to protect human subjects. Two adult members of the selected
13
14 families who meet the inclusion criteria and give informed consent will be recruited for the study.
15
16 We will follow up with all families randomized to either study arm. We will not follow up with
17
18 participants if they decide to end their participation at a particular time point of our study. But, we
19
20 will include their already collected data in our analysis. Given our strong community networks and
21
22 mobilization of community RAs, we anticipate low attrition rates in practice.
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28 **Problem Management Plus for Immigrants (PMP-I)**

29
30 PMP-I is a 5-week, peer-led, culturally tailored mental health promotion program that includes
31
32 psychoeducation, problem-solving, behavioral activation (90 minutes), breathing exercises, and
33
34 yoga (90 minutes) in a family setting. PMP-I will use a structured approach, including once-a-week
35
36 face-to-face sessions, yoga practice, breathing exercises, homework that includes practice activities,
37
38 rebuilding individual skills, or learning new skills to reduce stress.
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42 Our intervention aims to develop skills in coping adaptively in a new culture, seeking help and
43
44 support for mental health problems, and other life skills opportunities that can improve their quality
45
46 of life. **Module 1: Managing Stress** includes yoga, breathing exercise, stress-management
47
48 sessions, and practice exercises to develop coping strategies that are most helpful to reduce stress
49
50 and then plan a strategy to carry out those solutions. **Module 2: Managing Problems** includes
51
52 practice exercises to identify the problems causing the most concern, develop solutions that are
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3 most helpful in addressing the problem, and then plan a strategy to carry out those solutions.

4
5 **Module 3: Behavioral Activation** includes communication skill sessions and practice exercises to
6
7 identify pleasant activities (time to yourself; connecting with others; self-care), breaking down the
8
9 task into smaller steps, and schedule tasks, and then plan a strategy to carry out those tasks. **Module**
10
11 **4: Strengthening Social Support** includes social skills sessions and practice exercises to identify
12
13 at least one person or service from whom the participant feels comfortable getting some support,
14
15 and to plan exactly what the participant is going to do, and then schedule a day to carry out the
16
17 tasks. **Module 5: Staying Well** includes practice exercises to make a plan that helps to create a
18
19 supportive family environment.
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24 Community interventionists (CIs) are trained community members with at least a high school
25
26 level of education, and no formal training or prior experience with mental health will deliver the
27
28 PMP-I. Dr. Christopher Martell, board-certified in behavioral and cognitive psychology and clinical
29
30 psychology and a Massachusetts Licensed Psychologist, will provide 12 days of training to the
31
32 interventionists in collaboration with the PI and Dr. Steven D. Hollon (Professor of Psychiatry,
33
34 Psychology and Human Development) following the World Health Organization PMP Helpers'
35
36 Training Guide⁵⁰ adapted for PMP-I. Classroom training includes information about stress,
37
38 depression, mental health problems, the rationale for each intervention strategy, necessary helping
39
40 skills, practice plan formulation, role-plays, peer observations, and group discussion related to core
41
42 intervention concepts, practices, and supervision skills. Supervision involves discussing
43
44 participants' progress and difficulties experienced when delivering strategies and role-playing on
45
46 managing problems or practicing skills. They will use the PMP-I intervention manual to provide
47
48 PMP-I to community members in family settings under field supervisors and PI's supervision. We
49
50 will conduct a formal evaluation of the interventionists' readiness to implement/supervise the PMP-I
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3 intervention, such as using the manual, answering questions, managing time, using a fidelity
4 checklist, practicing exercise, and role play to provide feedback as necessary.
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7
8 A licensed yoga trainer will provide 4 hours of breathing exercises and 16 hours of yoga to CIs
9
10 and field supervisors using a mind-body exercise training manual. Classroom training includes
11 theoretical and practices to guide participants in mind-body exercises for attention to breath, body
12 sensation, emotional awareness, and mental function on different postures of yoga practices such as
13 *Pranayama* (3 poses) and *Asana* (21 poses). Training will include practice assessment at the end to
14 ensure that all field staff is trained, using a checklist, practice exercise, and role-plays.
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24 **Community Support Service Program**

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26 Bhutanese community members expressed that knowing the health and life skill development
27 program available in their communities would benefit them in strengthening their life skills.⁵¹ By
28 considering their request, we have prepared pamphlets including names, contact, and service details
29 of community and health organizations in the area where they live. CIs will distribute community
30 support service program pamphlets to control families.
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40 **Feasibility and acceptability assessment**

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42 The PMP trainer's training guidelines provide specific tools for evaluating and monitoring the
43 intervention, which we use to monitor intervention delivery fidelity. These tools are PMP Quiz,
44 PMP Helper's Supervision Form, PMP Helper Classroom-based Competency Assessment, PMP
45 Helper In-field based Competency Assessment, PMP Trainer/Supervisor Competency Assessment,
46 and Session-by-Session Checklists for PMP Helpers.⁵⁰ We have adapted these tools in the context
47 of our program contents. Using these standard tools, we will evaluate session-by-session classroom
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3 and in-field based competencies of community interventionists and field supervisors and provide
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5 them feedback as needed using supervision forms, role-plays, group discussion, and training.
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7
8 At the field level, field supervisors will monitor intervention sessions delivered by community
9
10 interventionists using standard checklists. Items include adherence to the manual, percent of
11
12 intervention content administered, proper use of time/materials, and adequate response to
13
14 participants' questions. They will also monitor participants' engagement, acceptability, and
15
16 satisfaction via brief questionnaires with participants and interventionists during and after
17
18 intervention completion. Moreover, community interventionists will be asked to complete a
19
20 structured checklist on the attendance, compliance, and satisfaction towards intervention
21
22 components immediately after each session.
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25
26 The PI will conduct a focus group discussion (FGD) in the Nepali language with
27
28 interventionists, supervisors, and participants separately to collect information on barriers and
29
30 facilitators of intervention, perceptions about whether the intervention met participants' needs, and
31
32 feedback on how effectively the program team worked with participants. Interviews and FGD will
33
34 be documented verbatim in a written transcript for subsequent analysis. All qualitative data will be
35
36 analyzed using thematic content analysis.⁵² Feedback provided by the field staff will be reviewed
37
38 and coded to identify recurrent themes regarding the intervention's acceptability. Fidelity data will
39
40 be used to assess intervention content and transmission.
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47 **Primary outcome measures**

48 **Anxiety and Depressive Symptoms**

49
50 The Hopkins Symptom Checklist-25 (HSCL-25) will be used to measure anxiety, and depressive
51
52 symptoms experienced over the past month.³⁸ It is composed of a 10-item subscale for anxiety and
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3 a 15-item subscale for depression, with each item scored on a Likert scale from 1 (not at all) to 4
4
5 (extremely). The scale has high internal consistency (Cronbach's α) for anxiety (0.95) and
6
7 depression (0.94) in the Bhutanese study.³⁵
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10 11 12 **Perceived Stress**

13
14 The 10-item Cohen Perceived Stress Scale (PSS) will be used to assess perceived stress.³⁷ The PSS
15
16 uses a 5-point Likert scale (ranging from 0, "never" to 4, "very often") to assess psychological stress
17
18 experienced during the past month, including the extent to which situations felt unpredictable,
19
20 uncomfortable, and overwhelming. In the Bhutanese study, the scale has high internal consistency
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22 (Cronbach's $\alpha = 0.80$).³⁵
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28 **Secondary outcome measures**

29 30 **Physiological stress**

31
32 We will use the enzyme-linked immunosorbent assay (ELISA) cortisol hair test (average hormone
33
34 levels over the past three months) as a biomarker to measure physiological stress. Hair samples will
35
36 be processed in the neuroendocrine lab at the University of Massachusetts Amherst.^{53, 54} Sensitive
37
38 and specific enzyme immunoassay (Arbor Assays) will be used for the analysis. The assay has
39
40 intra- and inter-assay coefficients of variation of <10%.
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47 **Other measures**

48 49 **Coping strategy**

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51 Coping strategy will be measured using a 32-item Coping Strategies Inventory-Short Form (CSI-
52
53 SF).⁴⁰ The CSI-SF includes two overall coping factors, Engagement and Disengagement, and four
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3 secondary factors, Problem Engagement, Problem Disengagement, Emotion Engagement, and
4
5 Emotion Disengagement. The CSI-SF scale (Cronbach's $\alpha = 0.95$) has high internal consistencies in
6
7 the Bhutanese study.³⁵ Participants were asked to rate their responses on a 5-point Likert-type scale
8
9 ranging from *not at all (1)* to *very much (5)*.
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14 **Coping Self-efficacy**

15
16 Self-efficacy will be measured using a 26-item Coping Self-efficacy (CSE) scale for coping with
17
18 challenges and threats.³⁹ Each item of the scale will be rated on an 11-point scale Likert-type scale
19
20 ranging from *(0) cannot do at all, (5) moderately certain can do, and (10) certain can do*. The scale
21
22 has high internal consistency (Cronbach's $\alpha = 0.96$) in the previous Bhutanese study.³⁵
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28 **Social support**

29
30 Perceived social support will be measured using a 12-item Multidimensional Scale of Perceived
31
32 Social Support (MSPSS),⁴³ including support from friends, family, and significant others. A sample
33
34 item for this scale is, "My family tries to help me." Each item of the scale will be rated on a 5-point
35
36 Likert-type scale ranging from *strongly disagree (1)* to *strongly agree (5)*. Graded items will be
37
38 summed up to provide a total score, and higher scores indicate high social support. The scale has
39
40 high internal consistency (Cronbach's $\alpha = 0.92$) in the previous Bhutanese study.³⁵
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46 **Social network**

47
48 We will use a Lubben Social Network Scale-Revised (LSNS-R) to measure social networks among
49
50 family and friendships.⁴⁴ It consists of six questions, which assess kinship ties, and a comparable set
51
52 of six questions, which determine friend ties by replacing the word relatives with the word friends.
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3 We prepared three questions to measure cross-cultural social ties following a similar pattern. The
4
5 scale has high internal consistency for kinship ties (Cronbach's $\alpha = 0.78$), friendship ties
6
7 (Cronbach's $\alpha = 0.80$), and cross-cultural social ties (Cronbach's $\alpha = 0.74$) in the previous
8
9 Bhutanese study.³⁵ These items will be scored on a five-point Likert scale ranging from *none (0)* to
10
11 *9 or more or always (5)*.
12
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14 15 16 17 **Family conflict resolution**

18
19 Family conflict resolution, including positive or negative resolution, effective communication, and
20
21 discussion of differences, will be measured using a 17-item version of the "Family Conflict
22
23 Resolution" scale.⁴¹ This scale has high internal consistency (Cronbach's $\alpha = 0.90$) in the previous
24
25 Bhutanese study.³⁵ Participants will be asked to respond on a 7-point Likert-type scale, ranging
26
27 from *never (1)* to *always (7)*.
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33 **Family satisfaction:** Family satisfaction with various aspects of family functioning, including
34
35 family closeness, flexibility, and communication, will be measured using a 10-item family
36
37 satisfaction scale.⁵⁵ Participants will be asked to respond on a 5-point Likert-type scale, ranging
38
39 from *very dissatisfied (1)* to *extremely satisfied (5)*.
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44 45 **Data management**

46
47 All interviews will be conducted with the utmost privacy and confidentiality. Each interested and
48
49 eligible adult participant in the family will be interviewed individually, in a private place where
50
51 they feel comfortable, by our trained community RAs. The RAs will ensure audio and visual
52
53 privacy at these sites, and ensure data confidentiality. RAs will reassure participants that numerical
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3 codes would be used in place of names in all records to ensure confidentiality. The survey materials
4
5 (questionnaires, transcriptions, and field notes) will be stored in a locked cabinet in the PI's office.
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7 Data entry will be done on the PI's office computer (encrypted and password protected) under the
8
9 full supervision of the PI. The original data will be kept on OneDrive, a secure, networked
10
11 university data storage system. De-identified data sets will be used for statistical analyses. The PI
12
13 herself will do data analysis and documentation. All information will be presented in aggregate
14
15 form in the manuscript or conference abstract, and no individual respondent will be identified.
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21 **Data analysis**

22
23 We will compare baseline characteristics of intervention and control groups using chi-square and t-
24
25 tests as appropriate. While differences between groups are not expected because of the
26
27 randomization used in the study design, variables showing significant differences between the two
28
29 groups will be included as covariates in primary analyses. The primary analyses will test whether
30
31 participants' outcomes in the PMP-I arm differ from those in the control arm. Multilevel modeling
32
33 will compare outcomes of each treatment arm while accounting for the clustering of participants
34
35 within families. Continuous outcomes will be analyzed using hierarchical linear modeling, and
36
37 dichotomous outcomes will be analyzed using multilevel generalized linear models with a Bernoulli
38
39 distribution appropriate to nonlinear binary outcomes.⁵⁶
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44 We expect approximately 2 to 4 members for each of the 58 families in each treatment arm, and
45
46 the correlation among family members' responses will be accounted for in the model. Hierarchical
47
48 or multilevel modeling is suited to these data as it accounts for the clustering of members within
49
50 families and unbalanced designs (i.e., different family sizes).⁵⁶ This will be an intention-to-treat
51
52 type of analysis, as multilevel modeling allows retention of all participants irrespective of the
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3 number of sessions attended (multilevel modeling uses maximum likelihood estimation, one of the
4 recommended ways of handling missing data). The analysis will estimate endpoint outcomes based
5
6 on repeated measures (Level 1) within individuals (Level 2) within families (Level 3). Separate
7
8 models will be created to evaluate the relationships between mediators (targets) and outcomes and
9
10 explore mediators (e.g., coping) of intervention-outcome relation. All analyses will be performed
11
12 using SAS, version 9 (SAS Institute Inc, Cary, NC).
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19 **Independent Safety Monitor**

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21 We will select an Independent Safety Monitor (ISM) with mental health expertise, whose primary
22 responsibility is to provide independent monitoring of this clinical trial in a timely fashion. Overall,
23
24 the ISM will review enrollment data, safety data, and data integrity to maintain safety in the trial.
25
26 The PI will submit data reports once a year to the ISM. The report will include the key variables
27
28 necessary for monitoring the safety and quality of data collection and the integrity of the study,
29
30 including inclusion criteria, informed consent, subject enrollment and retention, data
31
32 confidentiality, intervention compliance, dropouts, adverse events, protocol compliance, data
33
34 quality, and baseline characteristics of study participants. The ISM will have access to all safety and
35
36 data quality information collected and will have the authority to stop the study if it is determined
37
38 that there are unacceptable risks to participants. The ISM also will review the study protocol,
39
40 informed consent, and all relevant documents before the onset of the study and will review and
41
42 approve amendments to these documents. The ISM will issue a monitoring report to the PI
43
44 following each review. The PI will submit all review reports to the UMass Amherst IRB and NIMH
45
46 Program Officer in annual progress reports.
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53 **Trial management**

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3 The PI will assume overall responsibility of trial management, working together with the entire
4 research team throughout the project, meeting monthly with Co-Investigators (psychiatrist,
5 cognitive behavior therapist, and epidemiologist), and once every week with field staff (supervisors,
6 interventionists, and research assistants) via in-person or zoom or text message as needed. During
7 the trial, experienced field supervisors from the Bhutanese community, who are trained as a
8 community health workers and have worked with the PI in previous family-based mental health
9 intervention studies with depressive and suicidal ideation outcomes, will take responsibility for the
10 day-to-day oversight of the participants and field teams in the implementation of the trial. Field
11 supervisors will immediately report any noted adverse events among participants to the PI. The PI
12 will report adverse events data to the Independent Safety Monitor (ISM), UMass Amherst IRB, and
13 National Institute of Mental Health (NIMH) Program Officer following NIMH guidelines for
14 reportable events, as described below.
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33 **Adverse events reporting**

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35 Throughout the study period, all study participants will be monitored daily by the field supervisors
36 under the PI's supervision. Field supervisors will request study participants and their family
37 members to immediately report any unanticipated serious adverse events in their family, such as 1)
38 reporting suicidal ideation or attempts, hospitalization, disability, and/or death; 2) discomfort with
39 the PMP-I program content and/or evaluation procedures, and 3) risk of a breach of confidentiality,
40 of the collected data and/or by program personnel to field supervisor or PI directly. Field
41 supervisors will immediately report details of such adverse events to PI. The PI will be responsible
42 for reporting them to the UMass Amherst IRB, ISM, and NIMH Program Officer by secure email
43 within ten business days of the study team becoming aware of any serious adverse events. The PI
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3 will be responsible for summarizing all adverse events that are deemed expected and/or unrelated to
4 the study in the annual progress report submitted to the UMass Amherst IRB, ISM, and NIMH
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8 Program Officer by secure email.
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12 **Patient and public involvement**

14 Patients or the public were not involved in the design, or conduct, or reporting, or dissemination
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16 plans of our research.
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22 **Ethics and dissemination**

24 The Institutional Review Board of the University of Massachusetts Amherst approved this study
25
26 (Protocol ID: 1837) and certified that it will be performed according to the ethical standards laid
27
28 down in the 1964 Declaration of Helsinki and its later amendments.
29

31 Before enrolling participants in the study, written informed consent will be taken from each
32
33 person after a complete description of the study. All participants will have the opportunity to
34
35 discuss any questions or issues (online supplemental file).
36

37 The study data will be shared via the National Institute of Mental Health Data Archive. Access
38
39 to data used in the proposed project will be considered for sharing in compliance with the NIH
40
41 Grants Policy on Sharing Unique Research Resources. The study results will be used to inform the
42
43 design of a large-scale intervention and will be disseminated in peer-reviewed journals and
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45 conferences.
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49 **Discussion**

51 This study reports an RCT protocol that tests PMP-I's feasibility, acceptability, and preliminary
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53 outcomes with trained community facilitators. This study is built on prior research that has shown
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3 the effectiveness of social and emotional wellbeing intervention, including psychoeducation,
4 problem-solving, social support, and mind-body exercises, to reduce stress, anxiety, and depressive
5 symptoms among Bhutanese adults resettled in MA at a group³⁵ and family settings³⁶ using a pre-
6 and post-test intervention design. Our project designed for Bhutanese immigrants includes
7 evidence-based interventions of specific relevance to this community, such as psychoeducation,⁵⁷
8 problem-solving,²⁵ behavioral activations,²⁶⁻³³ mind-body exercises,²¹⁻²⁴ and strengthening social
9 support to address identified social (e.g., social isolation, language difficulties) and emotional (e.g.,
10 lack of self-esteem or self-efficacy)⁵¹ stressors by strengthening protective factors (e.g., resilience
11 or coping).^{58, 59} This study is innovative as it will be the first culturally tailored, preventive, family-
12 based, multi-component behavioral intervention driven by the community to reduce stress. We will
13 have pilot-tested a preventative mental health intervention for Bhutanese adults upon completion.
14 This study can be expected to impact reducing stress and promoting immigrants' mental wellbeing.

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31 Our project is likely to be replicated with other immigrant communities with minimal adaptation
32 over the long term for three reasons. First, our intervention is guided by a strengths-based approach
33 in which we plan to include community strengths. This principle can be applied to capture and
34 integrate the strengths of any community. Second, our program prioritizes the training of
35 community members as interventionists, as these are individuals whom the community trusts, who
36 share the same cultural lens as the community and thus can well understand language and specific
37 challenges, and who have a vested interest in the strength and resilience of their community. This
38 aspect of our intervention design is easily adaptable to other populations. Finally, intervention is
39 designed to be delivered in family settings where participants are most comfortable and family
40 members can support each other throughout their lives. This component is crucial in collectivistic
41 societies where family bonds and group identity are strong. Thus, our family-based strategies could
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3 be replicable in other immigrant groups, where there are similarities in social and emotional
4 stressors, challenges, community strengths (coping, resilience, social support), strong family
5 support, and cultural preference of native community counselors for their mental health
6 consultation. Our strength-based and peer-led strategies promote community engagement and make
7 the intervention sustainable.⁶⁰⁻⁶²

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9
10 Although our study design has several strengths, it also has some methodological limitations.
11 We measured anxiety and depressive symptoms using the HSCL-25 scale, which was validated
12 with clinical DSM-IV diagnoses of major depressive disorder⁶³ among refugees in Nepal⁶⁴ and
13 other countries.⁶⁵ Although clinical diagnosis is the gold standard; such an approach is not feasible
14 in community-based studies. We have started implementing an intervention during the COVID-19
15 pandemic, so we may need to be flexible in the time frame for conducting surveys and
16 implementing intervention sessions while waiting for participants to recover from COVID-19
17 infections they might have contracted during the study period.

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20 In conclusion, our trial will provide information on the feasibility of PMP-I among the
21 immigrant population and effect size estimate to design a larger-scale randomized controlled trial
22 intervention study.

23 24 25 **Trial status**

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28 Recruitment of participants was delayed due to the COVID-19 pandemic and started on August 17,
29 2021. At the time of manuscript submission, trial was ongoing. Results of this study are expected in
30 mid-2024.

31 32 33 **List of abbreviations**

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3 CBPR: Community-Based Participatory Research; CDC: Centers for Disease Control and
4 Prevention; CIs: Community Interventionists; CSE: Coping Self-efficacy; CSI-SF: Coping
5 Strategies Inventory-Short Form; ELISA: Enzyme-Linked Immunosorbent Assay; ES: Effect Size;
6
7 FGD: Focus Group Discussion; HSCL-25: Hopkins Symptom Checklist-25; IRB: Institutional
8 Review Board; ISM: Independent Safety Monitor; LSNS-R: Lubben Social Network Scale-
9 Revised; MSPSS: Multidimensional Scale of Perceived Social Support; NDA: National Institute of
10 Mental Health Data Archive; NIMH: National Institute of Mental Health; PHQ-9: Patient Health
11 Questionnaire; PI: Principal Investigator; PMP: Problem Management Plus; PMP-I: Problem
12 Management Plus for Immigrants; PSS: Perceived Stress Scale; RAs: Research Assistants; RCT:
13 Randomized Controlled Trial; SPIRIT: Standard Protocol Items: Recommendations for
14
15 Interventional Trials; WHO: World Health Organization
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31 **Contributors**

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33 KPT conceived the study and drafted the study and trial protocols. All authors were involved in the
34 design of the study; KPT, CSJ, CM, KCP, SR, RR, HL, JSM, ERBJ, and SDH were involved in
35 revising the study protocol for ethics review, and all authors were involved in commenting on and
36 revising the trial protocol. All authors read and approved the final manuscript.
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45 **Competing interests**

46
47 The author(s) declared no potential conflicts of interest with respect to the research, authorship,
48 and/or publication of this article.
49
50

51 **Funding**

1
2
3 This trial is funded by the National Institute of Mental Health of the National Institutes of Health
4
5 under Award Number R34MH118396 (PI: Dr. Kalpana Poudel-Tandukar). The content is solely the
6
7 authors' responsibility and does not necessarily represent the official views of the National Institutes
8
9 of Health.
10

11 **Consent for publication**

12
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14 Not applicable.
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17 **FIGURE TITLES**

18 **Figure 1. Study flowchart**

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For peer review only

Table 1. Overview of study measures

<i>Assessment</i>	<i>Screening Visit 1</i>	<i>Baseline, Enrollment Randomization: Visit 1</i>	<i>Intervention Session 1 Visit 2</i>	<i>Intervention Session 2 Visit 3</i>	<i>Intervention Session 3 Visit 4</i>	<i>Intervention Session 4 Visit 5</i>	<i>Intervention Session 5 Visit 6</i>	<i>Post-intervention Visit 7</i>	<i>3-month Follow-up Final Visit</i>
<i>Informed Consent Form</i>	<i>X</i>								
<i>Screening tool</i>	<i>X</i>								
<i>Inclusion/Exclusion Criteria</i>	<i>X</i>								
<i>Demographics</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Blood pressure</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Bodyweight & height</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Waist circumference</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Hair samples</i>		<i>X</i>							<i>X</i>
<i>Stress, Anxiety & Depression</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Family & Social Support</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Coping Strategies</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Self-efficacy</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Family Conflict Resolution</i>		<i>X</i>						<i>X</i>	<i>X</i>
<i>Family Satisfaction</i>		<i>X</i>							
<i>Enrollment/Randomization</i>		<i>X</i>							
<i>Intervention Session and its assessment using fidelity form</i>			<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>		
<i>Adverse Events</i>		<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>

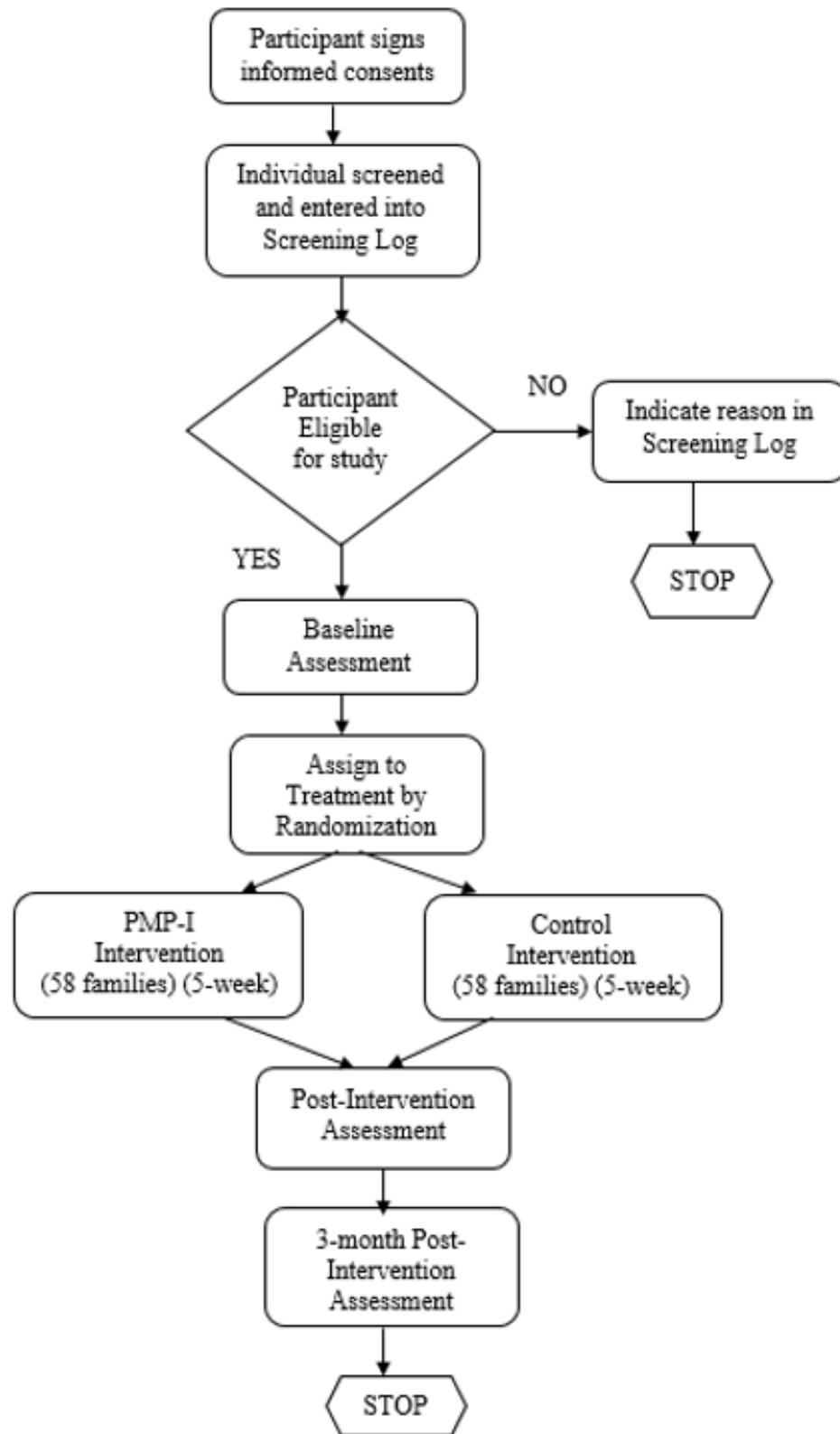


Figure 1 Flowchart of the study

Consent Form for Participation in a Research Study
University of Massachusetts Amherst

Researcher(s): Kalpana Poudel-Tandukar, Assistant Professor, College of Nursing
Study Title: Reducing stress, anxiety, and depressive symptoms via a family-centered preventative intervention for immigrants: A randomized controlled feasibility trial
Study Funder: National Institute of Mental Health, National Institutes of Health

1. WHAT IS THIS FORM?

“This form is called a Consent Form. It will give you information about the study so you can make an informed decision about participation in this research. We encourage you to take some time to think this over and ask questions now and at any other time. If you decide to participate, you will be asked to sign this form and you will be given a copy for your records.”

2. WHAT ARE SOME OF THE IMPORTANT ASPECTS OF THIS RESEARCH STUDY THAT I SHOULD BE AWARE OF?

This study plans to implement mental health promotion program among Bhutanese adults resettled in Massachusetts through trained community interventionists in collaboration with church leaders. The overall objective of this study is to assess preliminary effect of a family-centered mental health promotion program (Problem Management Plus for Immigrants: PMP-I) to improve coping, family wellbeing, and social networking that would be helpful to reduce stress, anxiety, and depressive symptoms among Bhutanese adults resettled in Massachusetts. We will determine your eligibility by asking questions of Patient Health Questionnaire-9 (PHQ-9), a screening tool for depression. You are eligible to participate in this study as a primary study participant if your PHQ-9 score is 14 or below. If you are eligible and interested, we will take an informed consent prior to take about an hour interview before, after, and 3-month after program. We will request you to attend about 2-3 hours mental health promotion program each week for 5-week. You will be randomly assign into one of our program, PMP-I program or talk program using a community support service pamphlet. If you are assigned to talk program now, we will provide you PMP-I program after completion of 3-month follow up survey. You do not need to answer the questions, which you do not feel comfortable. Your information will be kept confidential and will not be documented with your name. Please find risks and benefits of study and other important details in the rest of the consent document.

3. WHY ARE WE DOING THIS RESEARCH STUDY?

Existing mental health interventions for immigrants are largely based on treatment models to improve the access and quality of care for those with diagnosed mental health problems, however culturally-tailored preventative behavioral interventions aimed at reducing stress and preventing mental health problems among immigrants are limited. Thus, we aim to develop, implement, and pilot test the preventive behavior intervention driven by community members to reduce stress and prevent mental health problems among immigrants.

4. WHO CAN PARTICIPATE IN THIS RESEARCH STUDY?

Bhutanese adult aged 18 years or older living in the Massachusetts with a score 14 or below on the Patient Health Questionnaire (PHQ-9) and are willing to participate in the study voluntarily will be requested to participate in the study as primary study participants. This includes parents and their adult children aged 18 and above. Bhutanese adults with PHQ-9 scores 15 or above or with clinically diagnosed mental disorders or taking psychiatric medications for any mental health problems will not be eligible to participate in this study as a primary study participant. However, all interested adult family members both

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University of Massachusetts Amherst-IRB

Protocol #: 1837

IRB Signature: *Nancy C. Swett*

1 parents and their adult children, regardless of PHQ-9 score and mental health status, will be encouraged to
2 participate in our mental health promotion intervention at family settings.
3

4 **5. WHERE WILL THIS RESEARCH STUDY TAKE PLACE AND HOW MANY PEOPLE** 5 **WILL PARTICIPATE?** 6

7 This study will be conducted among Bhutanese adults resettled in the Massachusetts at their family
8 settings. We plan to enroll 232 participants from 116 families in this study. The entire study is expected to
9 complete in three year time period.
10

11 **6. WHAT WILL I BE ASKED TO DO AND HOW MUCH TIME WILL IT TAKE?**

12 If you agree to take part in this study, we will take your 5-minutes time asking short questions of Patient
13 Health Questionnaire, which is a screening tool for depression. If you are eligible to participate in this
14 study, we will take your informed consent first. Then, we will take about 45 to 60 minutes of your time
15 for questionnaire survey before and after program and 3-month after program (thrice). The questionnaire
16 consists of questions related to socio-demographic information, depression, perceived stress, family
17 satisfaction, coping behavior, family/social support, family wellbeing, social network, sleep quality, and
18 health information and program assessment information. We will also measure your body weight, height,
19 waist circumference, and blood pressure. We will also take your 3-cm hair sample before and 3-month
20 after program (twice). We request you not to write your name in the questionnaire. You may skip any
21 question you feel uncomfortable answering. We will also take about two to three hours of your time to
22 attend mental health promotion program each week for 5-week.
23

24 **7. WILL BEING IN THIS RESEARCH STUDY HELP ME IN ANY WAY?**

25 You may not directly benefit from this research; however, we hope that your participation in the study
26 may find useful learning about mental health promotion activities.
27

28 **8. WHAT ARE MY RISKS OF BEING IN THIS RESEARCH STUDY?**

29 We believe there are minimal risks associated with this research study; however, a risk of breach of
30 confidentiality always exists and we have taken the steps to minimize this risk as outlined in section 9
31 below. Some of the questions that we ask may put you in trouble or you may hesitate to answer, for
32 example, questions on suicidal intention. You are free to skip such questions or also withdraw yourself
33 from participating the whole study. As researchers, we are not qualified to provide counselling services
34 and we will not be following up with you after this study. If you feel upset during the study, or find that
35 some questions or aspects of the study triggered distress, you may contact the PI. The PI will assist you
36 (in your native Nepali language) and help you to connect with mental health support services in
37 coordination with the field supervisor. You may want to contact your counsellor at nearby health
38 institutions such as Baystate Medical Center (Phone: 413-794-0000) and Caring Health Center (Phone:
39 413- 739-1100), Springfield. Field supervisors from community will provide necessary support to you for
40 setting up your appointment with primary health care providers if needed.
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43 **9. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?**

44 Your privacy and confidentiality is important to us. The following procedures will be used to protect the
45 confidentiality of your study records. All the information collected during the study will remain
46 confidential. We will conduct survey in a private location, only allowing authorized research team members
47 to meet with research participants. We will not record your name in the questionnaire. We will assign you
48 numerical code that would be used in place of your name in all records to ensure confidentiality. We
49 would like to assure you that your information will be kept confidential and will not be disclosed in your
50 name in any of our record, report, publications, and presentations. Data will be stored securely in
51 password protected computer and will be made available only to the PI. The PI will keep all study records,
52 including any codes to your data, in a password protected computer. All signed consent documents will be
53
54

<p>IRB OFFICE USE ONLY</p> <p>University of Massachusetts Amherst-IRB Protocol #: 1837 IRB Signature: <i>Nancy C. Swett</i></p>
--

1 stored securely and separately from the research data in the separate locked cabinet. All hardcopies of study
2 materials will be stored securely in the locked cabinet of PI's office. Research records will be labeled with a
3 code. A master key that links names and codes will be maintained in a separate and secure location. The
4 master key and questionnaires will be completely destroyed six years after the close of the study. All
5 electronic files containing identifiable information will be password protected. Any computer hosting such
6 files will also have password protection to prevent access by unauthorized users. Only the PI will have access
7 to the passwords. At the conclusion of this study, we plan to publish the study findings. Information will be
8 presented in summary format and you will not be identified in any publications or presentations.

9
10 The hair sample will be stored in a clean dry white envelope with your ID number on top of the
11 envelope. The hair samples will be stored in the College of Nursing's laboratory during the data
12 collection process. At the end of survey, the collected hair samples will be sent to the laboratory in UMass
13 Amherst. Hair samples will be processed in the laboratory for cortisol measurement. If sample remains
14 after measurement procedure completion, it will be disposed according to the safety rules and regulation
15 of the laboratory.

16 For this study you will be assigned a global unique identifier (GUID). This GUID is generated as a
17 subject ID that allows researchers to share raw data such as number or percentage specific to a study
18 participant without exposing personally identifiable information. The GUID is made up of random alpha-
19 numeric characters and is NOT generated from personally identifiable information or protected health
20 information. This identifier will be kept separate from your paper consent file and will be stored in a
21 password protected electronic file. Descriptive/raw data will be submitted semi-annually. Access to raw
22 data used in the proposed project will be considered for sharing in compliance with the NIH Grants Policy
23 on Sharing Unique Research Resources. Any raw data to be released for sharing will not contain
24 identifiers (such as name, address, birthdate and phone number) of the study participants.

25
26 During and after the study, we will send deidentified study data to the National Institute of Mental
27 Health Data Archive (NDA). Experts at the NIH who know how to keep your data safe. The study
28 researchers will make every attempt to protect your identity. The study data provided to NDA may help
29 researchers around the world learn more about mental health and how to help others who have problems
30 with mental health. NIMH will also report to Congress and on its website about the different studies using
31 NDA data. You will not be contacted directly about the study data you contributed to NDA. You may
32 decide now or later that you do not want your study data to be added to the NDA. You can still participate
33 in this research study even if you decide that you do not want your data to be added to the NDA.

34 This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The
35 researchers with this Certificate may not disclose or use information, documents, or hair samples that may
36 identify you in any federal, state, or local civil, criminal, administrative, legislative, or other actions.

37 A description of this study will be available on <http://www.ClinicalTrials.gov>. This Web site will not
38 include information that can identify you. At most, the Website will include a summary of the results,
39 when they are available. You can search this Web site at any time. The registration number for this study
40 is NCT04453709.

41 42 **10. WHAT IF THERE IS AN UNEXPECTED FINDING ON TESTS CONDUCTED ON MY** 43 **HAIR SAMPLES?**

44 The investigators for this research project are not licensed or trained diagnosticians or clinicians. The testing
45 performed in this project is not intended to find abnormalities, and the data collected do not comprise a
46 diagnostic or clinical study thus we would not be returning/sharing the results of tests that are conducted on
47 your hair samples.

48 49 **11. WILL MY INFORMATION (HAIR SAMPLES OR PRIVATE INFORMATION) BE USED** 50 **FOR RESEARCH IN THE FUTURE?**

51 Your information or hair samples will not be used or distributed for future research studies even if identifiers
52 are removed.

<p>55 IRB OFFICE USE ONLY</p> <p>56 <small>University of Massachusetts Amherst-IRB</small></p> <p>57 <small>Protocol #: 1837</small></p> <p>58 <small>IRB Signature: <i>Nancy C. Swift</i></small></p> <p>59</p>

1
2
3 **12. WILL I BE GIVEN ANY MONEY OR OTHER COMPENSATION FOR BEING IN THIS**
4 **RESEARCH STUDY?**

5 You will be interviewed about 45 to 60 minutes for three times (before and after program and 3-month
6 after program). We will provide total \$25 cash for each participant after completion of each survey.

7 After baseline survey: \$25 per individual

8 After post-intervention survey: \$25 per individual

9 After 3-month follow up survey: \$25 per individual

10 After intervention: \$50 per family (\$10 per session)

11 Exercise mat: One per individual
12

13 **13. WHO CAN I TALK TO IF I HAVE QUESTIONS?**

14 Take as long as you like before you make a decision. We will be happy to answer any question you have
15 about this study. If you have further questions about this project or if you have a research-related problem,
16 you may contact the researcher, [Dr. Kalpana Poudel Tandukar; email: kalpana@umass.edu; Tel: 1-413-545-
17 5095). If you have any questions concerning your rights as a research subject, you may contact the University
18 of Massachusetts Amherst Human Research Protection Office (HRPO) at 1-413-545-3428 or
19 humansubjects@ora.umass.edu.
20

21 **14. WHAT HAPPENS IF I SAY YES, BUT I CHANGE MY MIND LATER?**

22 You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your
23 mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that
24 you do not want to participate. You will be notified of all significant new findings during the course of the
25 study that may affect your willingness to continue.
26

27 **15. WHAT IF I AM INJURED?**

28 The University of Massachusetts does not have a program for compensating subjects for injury or
29 complications related to human subjects research, but the study personnel will assist you in getting
30 treatment.
31

32 **16. SUBJECT STATEMENT OF VOLUNTARY CONSENT**

33 When signing this form I am agreeing to voluntarily enter this study. I have had a chance to read this
34 consent form, and it was explained to me in a language which I use. I have had the opportunity to ask
35 questions and have received satisfactory answers. I have been informed that I can withdraw at any time. A
36 copy of this signed Informed Consent Form has been given to me.
37
38

39
40 _____
41 Participant Signature:

42 _____
43 Print Name:

44 _____
45 Date:

46 By signing below I indicate that the participant has read and, to the best of my knowledge, understands
47 the details contained in this document and has been given a copy.
48

49 _____
50 Signature of Person
51 Obtaining Consent

52 _____
53 Print Name:

54 _____
55 Date:

56 **IRB OFFICE USE ONLY**

57 University of Massachusetts Amherst-IRB
58 Protocol #: 1837
59 IRB Signature: *Nancy C. Swett*
60



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___ 1 ___
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	___ 3 ___
	2b	All items from the World Health Organization Trial Registration Data Set	___ NA ___
Protocol version	3	Date and version identifier	___ NA ___
Funding	4	Sources and types of financial, material, and other support	___ 24-25 ___
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	___ 25 ___
	5b	Name and contact information for the trial sponsor	___ 24-25 ___
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	___ 24-25 ___
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	___ 19 ___

1 **Introduction**

2

3 Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention ___ 5 - 7 ___

4

5

6 6b Explanation for choice of comparators ___ 13 ___

7

8 Objectives 7 Specific objectives or hypotheses ___ 6 - 7 ___

9

10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) ___ 7 - 8 ___

11

12

13

14 **Methods: Participants, interventions, and outcomes**

15

16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained ___ 7 ___

17

18

19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) ___ 8 - 9 ___

20

21

22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered ___ 11 - 13 ___

23

24

25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) ___ 19 - 21 ___

26

27

28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) ___ 19 - 21 ___

29

30

31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial ___ NA ___

32

33

34 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended ___ 13 - 16 ___

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39

40 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) ___ 34 ___

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45

46

1	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	___ 9 - 10 ___
2				
3				
4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___ 9 - 10 ___
5				
6				
7	Methods: Assignment of interventions (for controlled trials)			
8	Allocation:			
9				
10	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	___ 10 ___
11				
12				
13				
14				
15				
16	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	___ 10 ___
17				
18				
19				
20	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	___ 10 ___
21				
22				
23				
24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	___ 10 ___
25				
26				
27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___ NA ___
28				
29				
30				
31	Methods: Data collection, management, and analysis			
32				
33	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	___ 16 - 19 ___
34				
35				
36				
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38				
39		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	___ 10, 16 - 17 ___
40				
41				
42				

1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	__17 - 18__
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	__18 - 19__
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	__18 - 19__
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	__18 - 19__
11				
12				
13				
14	Methods: Monitoring			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	__19__
17				
18				
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20				
21				
22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	__19__
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	__20 - 21__
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	__NA__
29				
30				
31				
32	Ethics and dissemination			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	__24__
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	__19__
38				
39				
40				
41				
42				

1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	___ 9 ___
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	___ NA ___
5				
6				
7	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___ 17 - 18 ___
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___ 24 ___
11				
12				
13	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	___ 24 ___
14				
15				
16	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___ NA ___
17				
18				
19				
20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	___ 17 - 18 ___
21				
22				
23				
24		31b	Authorship eligibility guidelines and any intended use of professional writers	___ NA ___
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	___ 24 ___
27				
28				
29	Appendices			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
32				
33				
34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____
35				
36				

37 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
 38 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons
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 40