ANCILLARY REVIEWS

Which ancillary reviews do I need and when do I need them? Refer to HRP-309 for more information about these ancillary reviews.			
Select yes or no	**Does your study…**	*If yes…*	**Impact on IRB Review**
☐ **Yes** ☒ **No**	Include Gillette resources, staff or locations	*Gillette Scientific review and Gillette Research Administration approval is required. Contact:* *research@gillettechildrens.com*	**Required prior to IRB submission**
☐ **Yes** ☒ **No**	Involve Epic, or Fairview patients, staff, locations, or resources?	*The Fairview ancillary review will be assigned to your study by IRB staff* *Contact:*	**Approval must be received prior to IRB committee / designated review.** **Consider seeking approval prior to IRB submission.**
☐ **Yes** ☒ **No**	Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection?	*STOP – Complete the Medical Template Protocol (HRP-590)* *The regulatory ancillary review will be assigned to your study by IRB staff* *Contact: medreg@umn.edu* *See https://policy.umn.edu/*	
☐ **Yes** ☒ **No**	Require Scientific Review? Not sure? See guidance on next page.	*ONLY REQURED BIOMEDICAL RESEARCH REVIEWED BY FULL COMMITTEE*	
☐ **Yes** ☒ **No**	Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco?	*Complete the CPRC application process.* *Contact: ccprc@umn.edu*	
☐ **Yes** ☒ **No**	Include the use of radiation? (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy)	*Complete the AURPC Human Use Application and follow instructions on the form for submission to the AURPC committee.* *Contact: barmstro@umn.edu*	**Approval from these committees must be received prior to IRB**

☐ **Yes** ☒ **No**	Use the Center for Magnetic Resonance Research (CMRR) as a study location?	*Complete the CMRR pre-IRB ancillary review* *Contact: ande2445@umn.edu*	**approval;** **These groups each have their own application process.**
☐ **Yes** ☒ **No**	Include the use of recombinant or synthetic nucleic acids, toxins, or	*STOP – Complete the Medical Template Protocol (HRP-590)*	
☐ **Yes** ☒ **No**	Include the use of human fetal tissue, human embryos, or embryonic stem cells?	*STOP – Complete the Medical Template Protocol (HRP-590)*	
☒ **Yes** ☐ **No**	Include PHI or are you requesting a HIPAA waiver?	*If yes, HIPCO will conduct a review of this protocol.* *Contact: privacy@umn.edu*	
☐ **Yes** ☒ **No**	Use data from the Information Exchange (IE)?	*The Information Exchange ancillary review will be assigned to your study by IRB staff* *Contact: ics@umn.edu*	**Approval must be received prior to IRB approval.** **These groups do not have a separate application process but additional informatio n from the study team may be required.**
☐ **Yes** ☒ **No**	Use the Biorepository and Laboratory Services to collect tissue for research?	*STOP – Complete the Medical Template Protocol (HRP-590)* *The BLS ancillary review will be assigned to your study by IRB staff.* *Contact: cdrifka@umn.edu*	
☐ **Yes** ☒ **No**	Have a PI or study team member with a conflict of interest?	*The CoI ancillary review will be assigned to your study by IRB staff* *Contact: becca002@umn.edu*	
☐ **Yes** ☒ **No**	Need to be registered on clinicaltrials.gov?	*If you select "No" in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff*	
☒ **Yes** ☐ **No**	Require registration in OnCore?	*If you select "No" or "I Don't Know" in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff*	**Does not affect IRB approval.**

PROTOCOL COVER PAGE

Protocol Title	MBI Intervention with war-affected families
Principal Investigator/Faculty Advisor	Name: Sarah Hoffman
	Department: School of Nursing
	Telephone Number: 512-470-7128
	Email Address: hoff0742@umn.edu
Student Investigator	N/A
Scientific Assessment	Clinical and Translational Science Institute (CTSI) pilot funding awards
Version Number/ Date:	Version 3/2/2022

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	8/2/2021	# of sessions to 14	Yes
2	9/10/2021	Update: no changes to youth curriculum	No
3	9/28/2021	Offering Zoom platform as an option in Phase 2 implementation. Adding video recording to the previously identified audio recording. Updated recruitment script to match modification #1.	No
4	10/04/2021	Expanding Karen recruitment source to targeted community partner referral	No
5	2/9/2022	Returning to group format for youth intervention and adding post program interview questions	Yes
6	3/2/2022	Included safety plan for if member of group experiences distress	No

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ABBREVIATIONS/DEFINITIONS

- *Strengths and Difficulties Questionnaire (SDQ I/S)*
- *Cognitive and Affective Mindfulness Scale-Revised (CAMS-R)*
- *Karen Mental Health Screener – Brief (KMHS-B)*
- *Emotion Regulation Skills Questionnaire (ERSQ)*
- *Family Adaptability and Cohesion Scale IV (FACES)*
- *Cohen-Hoberman Inventory of Physical Symptoms (CHIPS)*
- *Post Traumatic Stress Disorder (PTSD)*
- *Community Based Participatory Research (CBPR)*
- *FMBI (Family Mindfulness Based Intervention)*
- *CHWI (Community Health Worker Interventionists)*

1. Objectives

Purpose: Our study has two central research questions: 1) Is implementing a family mindfulness-based intervention with war-affected immigrant families through community based participatory research methods feasible?; and 2) Does the intervention demonstrate preliminary improvements in the social and behavioral health of war-affected caregivers and youth by addressing patterns of behavior that potentiate intergenerational trauma? Our objective in the proposed study is to use Community Based Participatory Research strategies to test the feasibility and acceptability of a mindfulness-based intervention for Karen refugee families living post-resettlement in the United States. A key focus in this phase of the pilot will be intervention adaptation and establishing fidelity monitoring and quality improvement procedures through which the PI and community health worker interventionists are trained and evaluated in the delivery of the intervention. In future phases of the research where were are able to expand the sample size, we will submit a modification to reflect protocol updates.

2. Background

2.1 Significance of Research Question/Purpose: Intergenerational trauma is a major public health problem impacting war affected families. Our specific research contribution will test the feasibility of a 7-week family mindfulness-based intervention addressing key mechanisms central to the health of war-affected families. The significance of our contribution is tied to the conceptual understanding that caregivers uniquely influence the ways in which their children process trauma, experience stressful events, and thrive socially, behaviorally and physically. The responses of youth, in turn, affect the wellbeing of their parents. Left unaddressed, intergenerational trauma will continue to negatively impact the health and life course of immigrant youth and families. Collectively, this contributes to: higher burden of unaddressed mental and physical health disturbances in caregivers and youth; disruptions in family systems and community structures that negatively impact educational achievement and other indicators of youth adjustment; and increased exposure to familial and community violence. If a mindfulness-based intervention delivered directly to war-affected families in their homes can demonstrate improvements in the behavioral and social health effects of war trauma experienced by caregivers and their youth, then this study has the potential to offer a novel, effective approach to disrupting the generational impacts of war on war-affected families. We will engage mothers, fathers, and youth to address intergenerational trauma fully. We will establish plans for collaborative dissemination with WellShare International in phase I of the CTRS pilot award, including academic dissemination (presentation and publication) as well as dissemination of results among key stakeholders and community members.

2. Preliminary Data:

   IRB Study #609S95262: Parenting adolescent refugees post-resettlement in Minnesota: A pilot intervention targeting Karen family cohesion (2016-2018)
   The purpose of the study was to assess the feasibility and acceptability of engaging Karen refugee mothers and fathers together in a seven-week culturally oriented parenting

curriculum. The group parenting intervention aimed to promote family cohesion and communication through parent education and skill building to address adolescent behavior and promote adolescent sense of belonging and positive identity. The sample included 30-40 Karen single parents or parent dyads with youth between the ages of 14 and 21. We conducted interviews with 10 adolescent-aged youth of participants to elicit perspectives on parent involvement in the program. Overall the project demonstrated that Karen mothers and fathers could be successfully engaged in a group parenting intervention. There was strong support for the program from caregivers and youth. Limitations of the intervention included a focus on functional skill building. We have since recognized through our research that the inclusion of emotion regulation and mindfulness elements will address additional factors in families that impact family functioning and youth adjustment. Though evidence-based and implemented with a diverse sample, we feel there are stronger programs that integrate elements of mindfulness. Barriers to participation included schedules and transportation. Thus we determined home based delivery is more likely to be successful in retaining participants.

Intergenerational Trauma CE Studio (2019)
Facilitated through the University of Minnesota CTSI, a Community Engagement (CE) Studio is a structured guidance session that enables community experts to provide feedback on a particular health research topic. The initiative gives Minnesotans a meaningful way to contribute to research, while arming investigators with powerful insights that can inform their study. The study team held a CE studio that engaged 11 community experts with varying backgrounds, roles, and perspectives on refugee and migrant families and intergenerational trauma. Family based and parenting approaches were discussed, as was the important role of emotion regulation and mindfulness in family communication and problem solving.
3. From the CE Studio, the Community Leadership Board (CLB) was formed (2019-2020). The CLB was comprised of members from prominent refugee serving organizations who were themselves Karen and provided support to the Karen refugee community in their professional roles. The CLB met monthly through the study team's preliminary intergenerational project and discussed aspects of the proposed intervention, including the integration of emotion regulation into parenting-focused programs, as well as the inclusion of adolescent youth. We plan to reconvene the CLB, and plan that the group will play a pivotal role in guiding the intervention adaptation and implementation.
4. The IRB was reviewed and discussed in a CRSC Feasibility Review. The purpose of the review is to provide an objective review of study readiness by a panel of experts. Experienced research professionals from 7 research functions (see below) reviewed a complete protocol and assisted Dr. Hoffman in connecting with resources.

- Biostatistical Design and Analysis Center (BDAC)
- Research Prep Group (RPG)
- CTSI Regulatory Specialists

- Community Engagement to Advance Research and Community Health (CEARCH)
- Best Practices Integrated Informatics Core (BPIC)
- CTSI Regulatory Manager | Clinical Research Monitor Group
- Clinical Research Liaison | Recruitment

Reviewers provided detailed feedback, recommendations and specific language from the panel of experts; developed a list of action items for PI to complete, and provided follow up recommendation on next steps.

Through our preliminary research (UMN IRB STUDY00005512; STUDY00000729; STUDY00006402), we established the foundation for a novel approach to recovery from torture and war that will be used in the proposed feasibility pilot research plan. Preliminary data for this proposal is drawn from our previous community-engaged explanatory mixed methods research collected with maternal caregivers (N=96), and subsequently with paternal caregivers (N=48) and youth (N=72). Data collected from participants included self-perceived mental health status[28], family functioning (FACES IV)[29], youth adjustment (SDQ)[30], and physical health variables. Analyses have been completed with the sample of 96 Karen refugee maternal caregivers from Burma living in the United States with caregiving responsibility for youth between the ages of 11 and 23. Maternal caregivers self-reported primary torture (26%), secondary torture (26%), or war trauma exposure (48%).[23] We identified statistically significant and positive associations between maternal exposure to torture/trauma, maternal mental health distress, maternal physical health, and youth adjustment. We identified complex interactions as to how these domains influenced each other in this context through extensive qualitative data collected via interviews with participants.

Preliminary results of a multiple linear regression model to predict overall youth adjustment (total scores on SDQ) reported by maternal caregivers indicated that self-reported age, gender, maternal mental health and maternal torture status significantly predicted negative adjustment in youth under 18 years, $F(2, 166)= 6.111$, $p <.001$, $R^2 =.128$. Similar findings were shown for youth over 18 years, $F(4, 102)= 3.876$, $p=.006$, $R^2 =.132$. SDQ subscales of Hyperactivity, Prosocial and Emotional were significantly predicted by child gender: maternal caregivers reported greater hyperactivity behaviors for male youth; greater prosocial behaviors and emotional symptoms for female youth. In a bivariate linear regression model maternal torture exposure predicted higher emotional scores (more distress) in female youth (manuscript in review).[22]

Further analysis suggested the relationship between torture and war trauma experiences and youth adjustment was completely mediated by maternal mental health distress. Moderated mediation analysis demonstrated that physical health problems was found to moderate the degree to which maternal mental health distress mediated the relationship between torture and war trauma experiences and youth adjustment. A stronger impact of maternal mental health distress on associations between torture experiences and youth adjustment was observed in maternal caregivers who reported greater physical health

problems (i.e. pain, hypertension, gastrointestinal disturbances). Recently, we have begun to examine the direct and indirect effects of torture and war trauma experiences, family functioning, mental health distress, physical health problems, youth gender and youth trauma exposure on youth adjustment in the integrated dataset including maternal and paternal caregivers, and youth. Preliminary path analysis suggested parent torture and family functioning type have statistically significant direct effects on youth adjustment. Parent torture was found to have an indirect effect on youth adjustment through the mental health and physical health problems of parents, and the gender and trauma exposure of youth. Family functioning type demonstrated an indirect effect on youth adjustment through youth gender, youth trauma exposure, parent physical health problems and parent mental health. Thus, our preliminary findings have enhanced a mechanistic understanding that emotional and physiologic regulation are key targets for recovery from intergenerational effects of trauma. Our proposed research will directly address the intersection of mental and physiological health problems, youth adjustment, and family functioning in trauma recovery.[22]

2.3 Existing Literature: The UN estimates that 68.5 million people are forcibly displaced from their communities of origin because of fear of violence or persecution; 16.2 million people were newly displaced last year alone[1]. War trauma[2] is a silent, global epidemic. Its impacts are pernicious and far-reaching. Almost universally, civilian survivors of conflict are exposed to individual and/or collective war traumas. The direct exposure to psychological trauma or torture[3] leads to well-documented individual health consequences. Less well characterized are the inclusive effects of war trauma including sequalae impacting families and communities. Intergenerational trauma is defined as the passage of trauma-related dysfunction experienced by one generation onto members of future generations who were not themselves exposed to the original trauma.[4] It is a phenomenon documented among groups that have experienced collective trauma and systematic oppression, most notably, survivors of the Holocaust and First Nations/Native American communities.[5,6] An emerging body of evidence highlights the significance of intergenerational trauma among war-affected families.[7-15] In our proposed work, we will address the intergenerational transmission of emotional and behavioral disruptions due to parental trauma in war-affected families. We propose a mindfulness-based intervention (MBI) to target key underlying mechanisms identified in preliminary research. These include physical/somatic and psychological trauma related symptoms, and key constructs of family functioning, all germane to healthy youth development and family systems in war-affected youth and families. Our study will be the first to provide feasibility data for a family MBI to address patterns of behavior that potentiate intergenerational trauma in war-affected youth and families.

Youth adjustment in the context of forced displacement, migration, and intergenerational trauma

We define youth adjustment as the social, behavioral, cognitive, and relational characteristics of a young person in a war-affected family that influence adaptation and

integration during post-migration or resettlement. Observational intergenerational trauma studies describe that child attachment and psychosocial adjustment can be negatively affected by parental trauma history. Symptoms of depression and anxiety are reported at higher levels among children with traumatized parents[8], although factors such as family functioning and resilience strategies can influence these associations or function as protective factors.[9] For children whose parents have experienced torture, the effects can be particularly striking. Having a parent who experienced torture contributes to a higher likelihood of children's negative mental health outcomes.[8,10] Family narratives about trauma sequalae can also be important. For example, contradictions between what children of survivors are told and what they observe contribute to uncertainty and instability.[11]

Children from families affected by war and forced migration encounter a unique set of circumstances as they negotiate resettlement and integration. The capacity and resilience with which war-affected youth negotiate these circumstances is influenced by the strength of their familial and social networks. For example, among this group, familial factors such as intergenerational conflict or separation may protect or perpetuate trauma.[12-17] Intergenerational conflict is a highly relevant factor in the development of dual mental health and substance use disorders and overall adjustment among refugee youth.[18] Additionally, war-affected youth are considered particularly vulnerable to gang recruitment.[19] Poor familial dynamics are predictive of involvement in criminal and gang activity.[20] Gang-involved migrant youth had either experienced pre-migration trauma themselves or been impacted by their parents' pre-migration experiences. Family violence, disintegration of relationships, and forms of absent, permissive or hostile parenting are risk factors for gang involvement.[21] There is a dearth of research focused on refugee adolescent adjustment and health. The proposed work will move the field forward by developing and testing an intervention to address adolescent refugee adjustment.

3. Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome: Results will demonstrate the feasibility of community based participatory research strategies, recruitment, retention, fidelity, data collection procedures, and the acceptability and adaptability of the intervention. We are establishing training procedures where the PI and the community health interventionists will be trained and evaluated in the delivery of the intervention. Additionally we are merging two evidence based interventions, both of which will be adapted contextually to the context of a home-based intervention for war-affected families with adolescent youth.

Hypothesis 1a: The CBPR design utilizing CHWI will demonstrate high intervention impact measured by intervention fidelity, rates of completion of study milestones, and high participant and CHWI satisfaction.

Hypothesis 1b: Recruitment and retention will be robust. The study team will meet recruitment targets and 85% of families will complete FMBI sessions and structured assessments within 3 months of enrollment.

Hypothesis 1c: Acceptability and sustainability will be demonstrated through qualitative reports of engagement, safety of the intervention, readiness to adopt, uptake, and perceived cultural congruence.

3.2. Secondary Endpoint(s)/Event(s)/Outcome(s): Though purposely not powered to infer a causal relationship, we will examine trends in outcomes related to physical complaints and mindfulness related processes in youth and parents. These outcomes include: youth adjustment; mindfulness; emotion regulation; family functioning and physiological regulation.

Hypothesis: FMBI will demonstrate preliminary improvements in outcomes listed above.

4. Study Intervention(s)/Interaction(s)

1. Description: The Family Mindfulness Based intervention will consist of two evidence based interventions, adapted contextually to the circumstances of war-affected families in resettlement, and integrated. The first intervention is the After Deployment Adaptive Parenting Tools (ADAPT) intervention. This is a 14 session group-based mindful parenting intervention originally developed to increase emotion regulation among military caregivers with young children and improve youth adjustment.[33-36] Parents will be invited to participate in individual interviews post-program. The second intervention is Learning To BREATHE, a 6 session group-based intervention targeting adolescent mindfulness.[37-41] The adapted and merged intervention will be delivered to individual families (home-based) in twice weekly sessions over a 7-week period by two community health worker interventionists. Learning to Breathe was determined during pilot testing to be more effective in the group format and the study team will return to the original delivery format of 6 group sessions. In addition to intervention sessions, there will be an enrollment visit, where consent and pre-intervention assessments are completed. Post-assessments and focus groups will be conducted immediately post-intervention. The administrative and 7-week intervention period will cover topics as described in the following table.

Table 1. Schedule of visits including elements of the family mindfulness based		
Week	Caregiver (reflects adapted ADAPT intervention)	Youth (reflects adapted Learning to BREATHE intervention)
Pre-Intervention (120 minutes)	Enrollment and Consent Demographics Pre-assessments (listed table 2: caregiver, family, all)	Enrollment and Assent Demographics Pre-assessments (listed table 2: youth, family, all)

1 (60 minutes)	Building Blocks of Resistance Give Effective Directions	Body Check in and practice
2 (60 minutes)	Teach New Behavior Recognizing emotions	Reflection Check in and practice
3 (60 minutes)	Responding to Emotions Setting Limits	Emotions Check in and practice
4 (60 minutes)	Following Through Communicate with Children	Attention Check in and practice
5 (60 minutes)	Solving Problems Managing Conflict	Tenderness Check in and practice
6 (60 minutes)	Monitor children's activities Responding to Children's Emotions	Health Mind Habits Check in and practice
7 (60 minutes)	Building Skills: Linking home and school	
Post-Intervention (120 minutes)	Post intervention assessments	Post intervention assessments
Optional focus groups by role (60-90 minutes): Separate maternal, paternal, and youth focus groups		

5. Procedures Involved

5.1. Study Design:

We will test the feasibility of the family mindfulness-based intervention with a resettled population of war-affected families through a nonrandomized partial cluster feasibility trial with embedded qualitative procedures.

This will occur in 2 phases:

Phase 1: Intervention adaptation and Community Health Worker Interventionist (CHWI) training through the delivery of the intervention to Community Leadership Board (CLB) members and adolescent focus group

Phase 2: Preliminary feasibility testing of the FMBI with members of the Karen community

5.2. Study Procedures:

Phase 1:

Community Leadership Board

The CLB will be made up of 4-7 Karen professionals representing prominent local organizations supporting Karen refugees in resettlement. Representatives will have lived cultural and historical expertise as well as professional expertise supporting the resettled community from mental health and social services perspectives. The expertise of the board ensures culturally centered preparations for intervention dissemination. The CLB will take an active role in the adaptation of the intervention. At the end of Phase 1 the board will determine the frequency of meetings through Phase 2.

CHWI Training

- Watch 25 hour ADAPT training video
- 50 hours of training with certified ADAPT facilitator for training, role play, and feedback
- ADAPT facilitator will provide 80 hours coaching based on based on recorded sessions
- 15 hours training with certified Learning to Breathe facilitator

Adaptation/CHWI coaching

- In Phase 1 the CLB will meet twice per week for 6 weeks. At each meeting the CHWI will present an intervention module to the CLB via Zoom. This will be recorded and later watched by the intervention facilitator to provide coaching to the CHWI. Members of the CLB will be aware of and agree to the session recording.
- Zoom sessions will include a brief group debrief following session (questions below)
- Adaptations to intervention content will be made based on this work and summarized and submitted as modification to the IRB.
- Final CLB meeting where present summary of final program is presented and discussed.
- In phase 2, intervention sessions with families will be audio/video recorded for the purposes of coaching and fidelity monitoring. Videos will be stored in UMN Box and transcribed. The focus of the recording is the interventionist, not the research participant.

CLB debriefing questions (after each session and final related to overall program):
What did you like about this session?
What did you not like about this session?
What are some ways we improve the session?
Was there anything missing from the session?

Are there ways we should change the session to better meet the needs of Karen parents?
What will barriers be to participation?
What can the study team do to facilitate participation?

Youth Focus Group

CHWI from WellShare International will lead the recruitment of adolescent youth from the existing cohort of families. We will also reach out to organizational partners for recruitment support. If this is confirmed, we will submit recruitment materials to the IRB as a modification. We will conduct up to two focus groups via Zoom with 5-6 youth participants in each group. Consent/ assent procedures are described further.

Following assent, the CHWI will provide a description of the intervention including the focus of each of the 6 sessions, and the types of activities that will be part of the session. The CHWI will then ask participants to discuss the following:

Focus Group Questions:
Would consider participating in this program? Why or why not?
How do you think this intervention could be helpful to you?
What would kinds of things would you want to see included in the program?
What do you not want to see included in the program?
What would barriers to participating in the program be/what would prevent you from participating?
What could the project team to help make it possible for you to participate in the program?
What do you think about times during the program where you and your parents are learning together?

9/10/21 This update is relevant to youth participation in STUDY 00011195. We are not making any adaptations to the Learning to Breathe curriculum, and/or procedures proposed in the original protocol.

Six community health workers engaged in the migrant/refugee youth programming at WellShare International participated in the full Learning to Breathe intervention training with a goal of evaluating the acceptability of the intervention. It was highly endorsed and there were no recommended adaptations to the curriculum. We are still considering group-based versus individual delivery format, and will conduct a youth focus group following implementation to further exlore this. We will keep the proposed individual format as is through the fall pilot. This modification was based on the PIs conversation with the IRB committee and I am submitting this modification to confirm the activities has been completed.

Phase 2:

Phase 2 procedures are designed to test the feasibility of the of the family mindfulness based intervention and the preliminary impact of the program on key outcomes derived through early project phases. Specifically in this phase of the research our feasibility focus is the CBPR approach and intervention delivery by community health worker interventionists. Two Karen interventionists (who are both members of the Karen community, employed as community health workers at WellShare International) will lead the recruitment and enrollment of 10-12 families. Community health worker interventionists will be listed as study staff on the IRB submission. The 9-week study period will include: 7-week home-based intervention delivery (60 minutes per biweekly session) and 2 weeks of pre/post assessments (120 minutes each). Youth will participate in a group delivery format. The format will be in person groups consisting of 5-10 group members. The location of the group will be the Knyaw Baptist Church. Masks will be required and social distancing will be promoted. Groups will only consist of youth taking part in the intervention. Parents will have the option of transporting children, or transportation by the church van will be arranged as an alternative. Youth will be instructed that all content of the intervention sessions is to remain confidential. Youth will be reminded at the start of each session that the identities of their fellow participants and information shared are confidential, and they should only share what they would be comfortable with others knowing since there is no guarantee that this information will stay within the group.

An optional later 60-90 minute focus group will be offered 1-month post-intervention for youth. Parents will be invited to participate in individual interviews. Cost of transportation and childcare will be supported for focus group participants and each participant will receive a $15 gift card for participation. Questions will target success and challenges participants have had implementing the skills taught in the intervention, as well as general perceptions of the intervention 1-month after the program end. Coordinators will have participated in the *refinement and implementation* of the intervention in Aim 1. Study coordinators and local interventionists will be trained intervention facilitators based at the University of Minnesota. Fidelity observations will be made weekly by study team members/trainers. As part of feasibility testing we will monitor participant adherence to the study protocol and the challenges that prevent families' full participation in attending interventions sessions. Study visits that take place +/- 2 days of target visit date will be considered 'on time'. Visit outside of this timeframe will be considered delayed. If a family member misses a scheduled visit, it will be documented as "missed".

Activities of phase 2 are contingent on the completion of phase 1 and IRB approval of all modifications to the intervention and/or proposed study protocol.

Regarding in person versus remote interactions, we are developing two models, depending on the circumstances of Covid-19 in the Summer-Fall 2021 (intensive data collection phase). We plan to follow all Federal/CDC guidelines as appropriate. We anticipate a hybrid implementation in that we will have families that prefer the telehealth option and familes that prefer in person.

- Model A - WellShare CHWs are currently conducting telehealth visits by phone or video. If the circumstances surrounding Covid-19 persist into the summer-fall 2021 we will conduct all study procedures through remote technology.
- Model B – If the circumstances allow, we will plan for data collection and intervention sessions to be conducted in person, outdoors.

We are planning for study personnel and participant PPE should this be necessary. The School of Nursing Office for Nursing Research and Scholarship will provide PPE funds if necessary.

5.2.1.

The project is a pilot study and therefore all activities are occurring for research purposes.

5.2.2.

Pre and post assessments are listed in Table 2. These will be written assessments and will be available in English and Karen languages. In the case that a participant is not able to read or prefers to have the questions aloud, the community health worker interventionist will be delivered verbally.

Table 2. Aim 2 assessments

Instrument	Outcome	Characteristics	Item sample	Psychometrics	Citation
Youth (youth complete)					
Strengths and Difficulties Questionnaire (SDQ I/S)	Youth adjustment	A 25-item youth behavioral screening questionnaire	*Often complains of headaches, stomach-aches or sickness.*	α = 0.82 (total difficulties)	Goodman et al., 1998[28]
Cognitive and Affective Mindfulness Scale-Revised (CAMS-R)	Mindfulness	A 12-item assessment of mindfulness as a single construct	*It is easy for me to concentrate on what I am doing.*	α = 0.74-0.77	Feldman et al., 2007[29]

UCLA Brief Screen for Child/ Adolescent Trauma and PTSD	Youth trauma history, PTSD screening	A 11-item (+2 open ended) evaluation of trauma history and PTSD symptoms for identifying at-risk cases	*I have trouble concentrating or paying attention.*	α > .93	Rolon-Arroyo et al., 2020
Emotion Regulation Skills Questionnaire (ERSQ)	Emotion regulation	A 27-item assessment of emotion regulation skills described in the ART[83] model	*My physical sensations were a good indication of how I was feeling.*	α = .96	Grant et al. 2018[30]
Caregiver (caregivers complete)					
Karen Mental Health Screener – Brief (KMHS-B)	Parent mental health distress	5-item measure developed to screen for mental distress associated with MDD and PTSD	*In the past month, have you been unable to concentrate, remember things, or make decisions?*	α = 0.83	Brink et al., 2015[27]
Cognitive and Affective Mindfulness Scale-Revised (CAMS-R)	Mindfulness	A 12-item assessment of mindfulness as a single construct	*It is easy for me to concentrate on what I am doing.*	α = 0.74-0.77	Feldman et al., 2007[29]
Emotion Regulation Skills Questionnaire (ERSQ)	Emotion regulation	A 27-item assessment of emotion regulation skills described in the ART[83] model	*My physical sensations were a good indication of how I was feeling.*	α = .96	Grant et al. 2018[30]
Family Functioning (all complete)					

Family Adaptability and Cohesion Scale IV (FACES)	Family functioning	A 42-item assessment of cohesion & flexibility	*Family members are supportive of each other during difficult times.*	Alpha reliability range subscales: α = .77-.89	Olson, 2011[27]
Physiological Regulation (all complete)					
Cohen-Hoberman Inventory of Physical Symptoms (CHIPS)	Physical health status	A 39-item assessment of perceived burden from physical symptoms	*How much were you bothered by: Back pain Constipation Dizziness*	α = .88	Cohen & Hoberman, 1983[31]

5.3. Follow-Up: Currently we plan to collect pre/post intervention and focus group data only. If additional funds are obtained will add a 6 month follow up assessment. If this is the case, we will submit an addendum to this protocol. Parents who complete the ADAPT intervention will be invited to conduct a 1:1 in depth interview about their experiences in the program. This will occur in the home and an incentive of $10 will be provided.

5.4. Individually Identifiable Health Information: This study will include individually identifiable health information but will not include data from medical records. See section 18.0. Participants will be asked to sign a combined ICF/HIPAA form before completing any study procedures.

6. Data Banking

6.1. Storage and Access: De-identified data collected from the pre- and post- assessment measures in this study may be used in collated fashion for future peer-reviewed publications or other scientific communications.

6.2. Data: For subject screening we will be using a phone script. We will include an eligible/not eligible field in the RedCAP databased to document eligibility for each participant. Demographic data and pre/post will be collected during the enrollment visit via pen/paper. Demographic information and responses to pre/post instruments will be entered into a participant study record in RedCAP. Participant IDs will be assigned to participants and linked to identifying information in a spreadsheet housed in the UMN Box platform. Study records including hard copies of assessments will be destroyed three years after the close of the study. Community

health workers will not be collecting data during the intervention delivery. The PI or designated member of the study team will record study visits in an excel document housed in UMN Box. Intervention session visits will be tape (audio) and video recorded to evaluate intervention fidelity (i.e. focus of the recording is the delivery of the intervention by the Community Health Worker Interventionists). Portions of these recordings will be transcribed for coaching purposes. For Zoom sessions, Zoom's closed captioning will be used for transcription because we do not anticipate encountering during intervention sessions. We will seek a BAA exception for the HCC account. All transcriptions will be de-identified. Because the recordings will also be used in coaching sessions with an intervention facilitator involved in training the community health worker interventionists, they will not be immediately destroyed. Recordings will be destroyed along with hard copy study records within three years of the close of the study. Recordings will be downloaded as soon as possible following the study interaction and then deleted from the recording device. Recording devices will be in the possession of the study team member until the recording is deleted. All recordings will be stored in UMN Box.

6.3. Release/Sharing: Individual data will not be released. Community Health Worker Interventionists will participate in the analysis and interpretation of data. Aggregate findings will be disseminated to the community in partnership with WellShare International (community partner).

7. Sharing of Results with Participants

7.1. Individual data will not be shared among participants. Aggregate findings will be disseminated to the community in partnership with WellShare International (community partner).

8. Study Duration

8.1. Describe:

8.1.1. The duration anticipated for adolescents participating in Phase 1 focus group is 1 hour. The duration anticipated for an individual participant's participation in the Phase 2 activities of the study is approximately 20 hours over 8 weeks including intervention and administrative visits.

8.1.2. The duration anticipated to enroll Phase 1 study participants is 1 week. Duration anticipated to enroll all Phase 2 study participants is 3 months

8.1.3. The duration anticipated to complete all study procedures and data analysis is 12 months

9. Study Population

9.1 Inclusion Criteria:

Adult inclusion criteria:

a) Above the age of 18

b) Karen refugees resettled to the United States greater than one year prior to enrollment
c) Caregiving responsibility for at least one child between the ages of 11 and 18
d) Reported primary or secondary torture or war trauma exposure, based on assessments conducted during UMN IRB STUDY00000729
e) Participation in UMN IRB STUDY00000729 and having agreed to be contacted for future research

Youth inclusion criteria:
a) Ages 11 to 18
b) Living in the home with the primary caregivers
c) Considered a dependent of the primary caregivers (still in high school or transitioning from school to work force, not married and/or raising their own children – will take individual youth circumstances into consideration individually to make a determination of dependence)

9.2 Exclusion Criteria

Exclusion criteria (applies to both adult and youth participants):
a) Self-reported or study team observed severe or unstable mental or physical illness such as: acute psychosis, presence or risk of safety concerns, and/or a physical disability or illness, which prevents the potential participant from engaging in the study activities. Youth will be excluded if screening is positive for PTSD. Caregivers will not be excluded if mental health screening is positive for PTSD/severe depression.
b) Nonbiological caregiving relationships with child
c) If one member of the family declines to participate in the initial enrollment, the family will be excluded. If the randomly selected index youth declines to participate, we will open enrollment to other youth in the family that meet the inclusion criteria.

9.3 Screening: Karen families will be recruited from an existing cohort of 96 Karen families that participated in preliminary observational studies and gave consent to be contacted for potential involvement in future phases of the research (UMN IRB STUDY00005512 and STUDY00000729). Participation in previous study phases will not impact the proposed trial. Two Karen community health worker interventionists will be prepared to assist potential and assigned participants in all aspects of the study—from recruitment and consent processes, to intervention delivery, data collection, and final evaluation interviews.

In phase 1 our recruitment target is up to 12 adolescent youth age 11-18 to participate in 5-6 member focus groups, each group meeting up to 3 times. One parent will give verbal consent over the phone. Youth assent will be confirmed at the beginning of the focus group session. Focus group sessions will take place over Zoom and will be facilitated by the CHWI with the PI present. Zoom sessions will be audio only recorded and any Karen language discussion will be transcribed by CHWI. All transcriptions will be de-identified.

In phase 2 our recruitment target is N=10-12 families, inclusive of the maternal caregiver, paternal caregiver (when present), and one randomly selected index youth per family age 11-18. At the initial contact with potential participants (phone call), the community health worker/Karen interventionist will explain study procedures such as voluntary participation and what participation in the intervention entails. Potential participants will be offered the opportunity to ask questions about study procedures. A second, in person encounter will be scheduled if the potential participant expresses interest in study participation. At a second encounter (face to face in participant homes or preferred alternative location or via Zoom if remote is preferred) continued interest in participation will be assessed. Parents and youth will be screened for eligibility, and informed consent and assent will be obtained. Baseline data collection will be obtained at this second encounter. Intervention sessions will begin within one month of enrollment.

10. Vulnerable Populations

10.1.Vulnerable Populations:

Population / Group	Identify whether any of the following populations will be targeted, included (not necessarily targeted) or excluded from participation in the study.
Children	Targeted Population
Pregnant women/fetuses/neonates	Included/Allowed to Participate
Prisoners	Excluded from Participation
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	Excluded from Participation
Non-English speakers	Included/Allowed to Participate
Those unable to read (illiterate)	Included/Allowed to Participate
Employees of the researcher	Excluded from Participation
Students of the researcher	Excluded from Participation

Undervalued or disenfranchised social group	Targeted Population
Active members of the military (service members), DoD personnel (including civilian employees)	Included/Allowed to Participate
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded from Participation
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	Targeted Population
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	Included/Allowed to Participate
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	Included/Allowed to Participate
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	Included/Allowed to Participate

10.2 Additional Safeguards:

The study team will base a trauma informed approach on SAMHSA's 6 KEY PRINCIPLES OF A TRAUMA-INFORMED APPROACH:

1. Safety
2. Trustworthiness and Transparency
3. Peer Support
4. Collaboration and Mutuality
5. Empowerment, Voice and Choice

6. Cultural, Historical, and Gender Issues

The framework will be implemented through a number of strategies, including but not limited to: Karen community health worker interventionist model, stakeholder-led intervention development/adaptation, home-based intervention delivery, participant led consent and assent discussions, family involvement, and community advisory board input/oversight.

Illiterate:
Patients who are illiterate may not be known, research staff will not be asking a direct question about literacy to potential participants. However, if it's made known to us that the patient is illiterate we will take extra care to go through the consent form and read it to the potential participant. Vulnerability for this group will not be increased by participating in this study.
Undervalued and Disadvantaged:
Disadvantaged and disadvantaged people may not be known, research staff will not be asking a direct question about socioeconomic status to potential participants. Vulnerability for this group will not be increased by participating in this study.

Fear of Negative consequences:
Individuals with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior) are not targeted but may be enrolled. All participants will be fully informed that the study is completely voluntary and that they may withdraw participation at any time. They will also be reminded that their relationship with their provider or the UMN will not be affected by their decision whether or not to participate in this study.

10.1.1.Pregnant Women

The inclusion of pregnant women will be incidental. This study does not include an intervention, biologic or other greater than minimal risk procedure. No inducements, monetary or otherwise, will be offered to terminate a pregnancy. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
Individuals engaged in the research will have no part in determining the viability of a neonate. All participants will be provided assurance of confidentiality, the freedom to decline to participate and the right to withdraw at any time without penalty. All participants will be reassured that their decision to participate or not patriciate in this study will have no effect on their current prenatal care.

10.1.2.

NA

10.1.3.

NA

10.1.4.

Youth ages 11-18 will be recruited to participate in an adolescent mindfulness curriculum.

Children are the targeted population for this study because the study aims could not be assessed without children. Study procedures have been minimized to exclude all unnecessary procedures that would not contribute to the scientific objective. The investigators believe that the risks to participants are no greater than minimal in relation to the importance of the knowledge that may be expected to result. Permission by one or more parents or guardians and assent (when appropriate) by the child will be solicited. All participants will be provided assurance of confidentiality, the freedom to decline to participate and the right to withdraw at any time without penalty.

10.1.5.

NA

10.1.6.

Refugees inherently experience inequity of wealth and access. A majority of Karen refugees resettled in Minnesota are Karen-speaking only. Civilian survivors of conflict, almost universally, experience individual and/or collective war traumas. Psychological trauma and torture experienced by war-affected individuals is strongly associated with significant and long-term individual mental and physical health effects. It has more recently been observed that the effects of a trauma experienced by a parent negatively influence the health of the family system and healthy youth development. Trauma treatment offers important and effective elements in recovery in war-affected individuals, but these programs remain predominantly centered on individual recovery. The intergenerational impact of trauma is overlooked, thus deepening health disparities experienced by an already vulnerable population. With growing knowledge of the connection between mind, body and trauma, particularly informed by the emerging disciplines of neuroscience, developmental psychopathology, and interpersonal neurobiology, we understand that trauma experiences are felt, stored, and expressed by the body. This proposal integrates perspectives and methods from these and other disciplines to introduce, through mindfulness, a community-based intervention that promotes positive emotional and behavioral development of war-affected youth and family systems.

10.1.7.

See above for description of population and alignment with aims.

10.1.8.See above description of risk.

11. Number of Participants

11.1. Number of Participants to be Consented in phase 1: 10-12 youth; in phase 2: Estimated 50 or less (maternal, paternal, youth)

12. Recruitment Methods

12.1. Recruitment Process:

For youth participating in phase 1 focus groups, we recruit from the existing cohort. We will also reach out to organizational partners for recruitment support. If this is confirmed, we will submit recruitment materials to the IRB as a modification.

(See above also, section 8.3). In phase 2 Karen families will be recruited from an existing cohort of 96 Karen families that participated in preliminary observational studies and gave consent to be contacted for potential involvement in future phases of the research (UMN IRB STUDY00005512 and STUDY00000729). Participation in previous study phases will not impact the proposed trial. Potential Karen participants will also be recruited through identical methods by targeted recruitment based on family engagement with community partner (WellShare International) programming, e.g. involvement in Karen youth programming, tobacco cessation programming, or via referral through established partnerships to WellShare parenting support programming. Two Karen community health worker interventionists will be prepared to assist potential and assigned participants in all aspects of the study—from recruitment and consent processes, to intervention delivery, data collection, and final evaluation interviews. Our recruitment target in phase 2 is N=10-12 families, inclusive of the maternal caregiver, paternal caregiver (when present), and one randomly selected index youth per family age 11-18. At the initial contact with potential participants (phone call), the community health worker/Karen interventionist will explain study procedures such as voluntary participation and what participation in the intervention entails. The eligibility of the selected youth will also be confirmed in this initial contact. Based on past studies this initial point of contact will likely be the maternal caregiver. Potential participants will be offered the opportunity to ask questions about study procedures. A second, in person encounter will be scheduled if the potential participant expresses interest in study participation. At a second encounter (face to face in participant homes or preferred alternative location) continued interest in participation will be assessed. Parents and youth will be met with individually, in private, and screened for eligibility, and informed consent and assent will be obtained. Youth can determine whether a parent remains present for study procedures. Baseline data collection will be obtained at this second encounter. Intervention sessions will begin within one month of enrollment. Participants will be given a copy of their signed and dated consent/ assent forms.

12.2. Source of Participants: An existing cohort.

12.3. Identification of Potential Participants:

Participants will be identified and recruited from an existing cohort or through CHWI identified potential participants based on family engagement with community partner (WellShare International) programming, e.g. involvement in Karen youth programming, tobacco cessation programming, or via referral through established partnerships to WellShare parenting support programming.

12.3.1.

NA

12.3.2.

WellShare Community Health Worker Interventionists (Karen)

12.3.3.

No medical records will be accessed.

12.4. Recruitment Materials:

Phone recruitment phone script submitted with ETHOS materials.

12.5. Payment:

In phase 1 youth will be compensated $20 per focus group session attended. In phase 2 individuals will be compensated $10 each at each study visit (2 data collection visits + 12 study visits over 6 weeks), totaling $140 per individual/$420 per family if full participation. Focus group participants will individually receive $15 per session. Transportation and childcare will be provided for focus group attendance. These amounts are based on community norms and the recommendation of WellShare International.

12.5.1.

See above, participants will receive visa gift card incentives.

12.5.2.In phase 1 youth could receive up to $60 if they participate in the maximum of 3 focus group sessions. In phase 2 families may receive up to $420. Individuals may receive up to $140. Individuals may receive an additional $15 for focus group participation.

12.5.3.

Visa gift card incentives will be given at each study encounter. Payments will not be prorated.

12.5.4.

Participants will receive gift cards.

12.5.5.

NA

12.5.6.

No, Greenphire ClinCard will not be used.

13. Withdrawal of Participants

13.1.Withdrawal Circumstances:

We do not anticipate circumstances under which this would occur. Participants are free to withdraw at anytime during the study.

13.2.Withdrawal Procedures:

If a participant wishes to withdraw or we determine that the participant should withdraw, we will terminate data collection and discuss with the participant the reasons for withdraw. All data collected up to that point will be used in analysis unless the participant wishes for their data not to be used. The date and reason for participant discontinuation or withdrawal from the study will be recorded on the participant's Case Report Form (CRF).

13.3.Termination Procedures:

If a participant withdraws from the study, the study team will request permission to use data collected up to the withdrawal point.

14. Risks to Participants

14.1. Foreseeable Risks:

Intervention response: Understood risks involved in participation in mindfulness-based interventions are minimal, particularly when developed and delivered through a trauma informed approach.

Instruments and Questionnaires: It is possible that structured and or qualitative assessments could bring up painful memories and/or participants could experience distress or psychological discomfort. This did not occur in the earlier phases of the project, where more sensitive questions were asked of participants in order to establish a mechanism of action from which to target intervention. Therefore, we consider the likelihood of occurrence of this degree of risk to be low. We will have a trained clinician available for consultation during and after each intervention session to guard against this concern. Negative reactions requiring a clinician's intervention, if any, will be an important indicator for refinements to the intervention.

If follow up services are required, participants who experience distress will be referred for same day services through the Wilder Foundation or Ramsey County Urgent Care for Adult/Child Mental Health. Both organizations have Karen linguistic and cultural resources available.

At the beginning of each intervention session, the facilitator will ask participants to disclose if they experience any negative feelings during the session. If this becomes the case, the participant will be asked if he/she wants to stop participation in the session. In the case of youth participants, the interviewer will inform the parent/guardian. If a participant reports significant distress, or otherwise emergent issue, data collection will

stop. The PI will be immediately contacted to discuss the situation. A safety plan will be developed with the study coordinator, one or both of the mental health resources identified above, and consultation with the mentor team and community partner organizations.

Distress may present in a variety of ways. If distress occurs, the community health worker interventionist will remain with the participant/family. The PI will always be available for consultation during study visits. Once the CHWI has reached the PI, a safety plan will be developed. In urgent or emergent circumstances, the Ramsey County Urgent Care for Adult/Child Mental Health will be consulted. The CHWI and/or PI and/or capable caregiver will stay with the participant to ensure safety until a safety plan is established and an appropriate crisis intervention handoff is established. The threshold for intervention or withdrawal will be determined by the participant, the community health worker interventionist, and the PI and will be based on the unique circumstances of the encounter. Referrals will be made upon request, and routinely in the event that a caregiver scores 4 or above on the Karen mental health screening tool or youth score 21 or higher on the DSM-5 PTSD diagnostic screener (if not already receiving services). Routine referrals will not automatically exclude a participant from participating or continuing in the research.

A support study team member/co-facilitator (Marry Htoo) will be present for each group session. The lead facilitator (Hsa Moo) will instruct youth to let the co-facilitator know if they become distressed. If this is the case the co-facilitator will locate a private space for her and the participant to address the response. The primary facilitator can then continue with the rest of the session. The PI will be immediately contacted by the co-facilitator to discuss the situation and develop a safety plan. The co-facilitator is Karen speaking and will also call to inform the parent/guardian. If a participant experiences significant distress the co-facilitator and PI will follow the steps outlined above. The co-facilitator will also have primary responsibility for monitoring for signs of distress during the group and inviting youth who show signs of distress to check in individually.

Risk of loss of confidentiality is unlikely, but could possibly occur as PHI is utilized as part of this study. The risk would be minimized by protections such as de-identification of participants via use of a study identifier, locked/secured/limited access to PH, and electronic data securely stored and password protected.

14.2. Reproduction Risks:

NA

14.3. Risks to Others:

NA

15. Incomplete Disclosure or Deception

15.1. Incomplete Disclosure or Deception:

15.1.1.

NA

15.1.2.

NA

15.1.3.

NA

16. Potential Benefits to Participants

16.1. Potential Benefits:

Individuals/families who participate in the intervention may learn new individual coping and mindfulness skills as well as family communication, conflict resolution, and problem-solving tools. Long term impact includes the development of a family mindfulness-based intervention that may be adapted across diverse cultural and migrant groups and is effective in regulating the effects of trauma through behavioral and environmental mechanisms.

17. Statistical Considerations

17.1. Data Analysis Plan:

Paired t tests will be used to examine intra-individual changes between baseline and post-group scores. Cohen's d effect sizes quantify the magnitude of potential changes detected in outcomes, .2 is small, .5 is medium and .8 or higher is large.[75] Within families, we will first evaluate congruence between the maternal-child dyad intervention response because we anticipate these data are more likely to have completeness. Within families, congruence in maternal and paternal caregiver intervention response will be evaluated. If there are differences between mothers and fathers, we will conduct a cluster analysis. Missing data will be handled through data imputation. Qualitative approaches will assess the feasibility of local interventionists and CBPR strategies. Interviews and focus group transcripts will be analyzed through content analysis and cross-case comparisons. Open coding will initiate the development of labels and concepts. Through pattern coding we will create categories of codes. Axial coding will allow for a consideration of relationships between categories. During data reduction analytic documentation will facilitate the arrangement of data into conceptual clusters.[76]

17.2. Power Analysis: The proposed pilot is underpowered.

A power analysis for the primary outcome youth adjustment for paired t tests between pre and post intervention outcome measures was performed a priori in nQuery Advanced to determine the adequate sample size with an alpha of 0.05, a

power of .80 and an effect size =.45 (small to moderate). The power analysis determined a total sample size of 41 (without attrition), to detect a difference in outcomes.

17.3. Statistical Analysis: See above.

17.4. Data Integrity:

Data will be entered by a member of the study team and accuracy of data entry verified by a second team member. We will implement a team approach to analysis, meaning that community health worker interventionists and members of the study team including the PI will jointly analyze and interpret results.

18. Health Information and Privacy Compliance

Select which of the following is applicable to your research:

☐ My research does not require access to individual health information and therefore assert HIPAA does not apply.

☒ I am requesting that all research participants sign a HIPCO approved HIPAA

Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

Appropriate Use for Research:

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

18.1. Identify the source of Private Health Information you will be using for your research (Check all that apply)

☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

☒ I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

☐ Other. Describe:

18.2. Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

All data collected will be self report.

18.3.Approximate number of records required for review:

NA. All data collected will be self report.

18.4. Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

☒ Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants.

Initial recruitment, scheduling and intervention visit reminders will occur through telephone communication. Main study interactions and data collection will be in person.

18.5.Access to participants

NA

18.6. Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐ In the data shelter of the Information Exchange (IE)

☐ Store ☐ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store ☐ Analyze ☐ Share

☒ In REDCap (recap.ahc.umn.edu)

☒ Store ☒ Analyze ☐ Share

☐ In Qualtrics (qualtrics.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐ In OnCore (oncore.umn.edu)

☐ Store ☐ Analyze ☐ Share

☒ In the University's Box Secure Storage (box.umn.edu)

☒ Store ☒ Analyze ☒ Share

☐ In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

☐ Store ☐ Analyze ☐ Share

☒ In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

PI device # 20201033

☒ Store ☐ Analyze ☐ Share

☐ Other.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐I will use a server not previously listed to collect/download research data

☐I will use a desktop or laptop not previously listed

☐I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

18.7. Consultants. Vendors. Third Parties.

NA. No data sharing agreement is needed.

18.8.Links to identifiable data:

De-identified data (immediately deidentified) will be stored in a secure, UMN administered RedCAP database. Study documents that include identifying information will be stored in private, password protected, encrypted project folders hosted by the UMN server in the UMN

Box domain. Contact information for participants who agree to future contact and participation will be stored in UMN Box folders. There will be a single document linking identifying information with study IDs stored in the UMN Box folder. Deidentified information will be released to WellShare International Community Health Worker Interventionists, as they will participate in data analysis and interpretation. No other information will be released any additional parties without the written consent of the study participant.

18.9. Sharing of Data with Research Team Members.

Data will be shared via UMN Box and REdCAP.

18.10. Storage and Disposal of Paper Documents:

All paper documents will be locked in a secure file cabinet in a locked research office and kept for at least 3 years after study completion.

19. Confidentiality

19.1. Data Security:

Confidentiality will be maintained by identifying each subject on research records with only a study number. Therefore, no hard copy forms will contain identifiable participant data. Data will be stored in a secure, University of Minnesota administered, RedCAP database. Electronic study documents that include identifying information will be stored in private, password protected, encrypted project folders hosted by the University of Minnesota server in the University of Minnesota Box domain. Examples of this type of document are files that contain participant name and contact information, or records that link the participant ID to the participant name. To minimize the likelihood of a breach of privacy or confidentiality, only deidentified information will be released to WellShare International Community Health Worker Interventionists, as they will participate in data analysis and interpretation. No other information will be released any additional parties without the written consent of the study participant. All study team members will be required to complete the CITI course in the Protection of Human Research Subjects. Data will be collected with youth and the maternal and paternal participants separately to ensure privacy unless an otherwise preference is indicated.

To help protect the privacy of participants, the National Institutes of Health has granted a Certificate of Confidentiality for this study. The researchers can use this Certificate legally to refuse to disclose information that may identify the participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court

subpoena. The researchers will use the Certificate to resist any demands for information that would identify the participants, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

The Certificate of Confidentiality does not prevent the participant or a member of their family from voluntarily releasing information about themselves or their involvement in this research. If an insurer, medical care provider, or other person obtains their written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

20. Provisions to Monitor the Data to Ensure the Safety of Participants

There is a potential risk for psychological or social discomfort when completing surveys and attending group intervention meetings. This risk is considered minimal; the alternative is to not answer the questions or to not participate in the group conversations that elicit discomfort.

20.1. Data Integrity Monitoring.

20.1.1.

Considering the study rationale, population, procedures and the risk: benefit profile, the overall risk level for participation in this study is classified as minimal. The Data Safety Monitoring Plan (DSMP) for this pilot award will focus on close monitoring by the principal investigator (PI) in conjunction with project advisors, who will be available to review and recommend appropriate action regarding individual reports of serious adverse events, adverse events, and other safety issues. The Community Advisory Board and community-based organizational partners will also serve as resources if incidental findings emerge. The PI will have the primary responsibility to monitor this study.

20.1.2.NA

20.1.3.

Principal Investigator (PI). Dr. Sarah Hoffman, will have the primary responsibility to monitor this study. The PI will review data on such aspects as participant enrollment, study procedures, forms completion, data quality, losses to follow-up, and other measures of adherence to the protocol.

20.1.4.

See above.

20.1.5.

The study team does not plan to implement a data safety monitoring board or an independent safety monitor at this time due to: 1) anticipated low risk of harm to participants; 2) clinical trial designation (Phase 1); and 3) the mentor team involvement in supporting the candidate (PI) to protect the safety of research participants and the validity and integrity of study data.

20.1.6.NA

20.2. Data Safety Monitoring.

20.2.1.

Considering the study rationale, population, procedures, and the risk: benefit profile, the overall risk level for participation in this study is minimal. The DSMP for this pilot award will focus on close monitoring by the PI in conjunction with project advisors, who will be available to review and recommend appropriate action regarding individual reports of serious adverse events, adverse events, and other safety issues. The community advisory board and community organizational partners will also serve as resources if incidental findings emerge. The PI will review all possible and real events, and seek recommendations from the study team in real time regarding all adverse events. The PI will be responsible for submitting necessary reports concerning adverse events to the University of Minnesota IRB within the required reporting timeframes.

20.2.2.

Reports of participant distress.

20.2.3.

At study visits and via telephone calls with participants.

20.2.4.

Data collected pre/post intervention. Safety data monitoring beings with pre-intervention data collection.

20.2.5.

NA

20.2.6.

The study PI.

20.2.7.

The PI will routinely review study activities and data collection weekly.

20.2.8.

Qualitative self report. Statistical tests not applicable.

20.2.9.

Depending on context surrounding data collection, a covid-19 positive test of a participant and or study team member would temporarily suspend research procedures.

21. Compensation for Research-Related Injury

21.1. Compensation for Research-Related Injury:

NA

21.2. Contract Language:

NA

22. Consent Process

22.1. Consent Process (when consent will be obtained):

Consent in phase 1 will take place via phone. Consent in phase 2 will take place in person, in participant homes.

22.1.1.

Participants will be contacted by telephone initially. If they are interested in possible enrollment, a visit will be scheduled in the participants home to more fully explain study procedures, conduct consent, and enrollment. The period between the initially phone call and obtaining consent will vary based on when the community health worker interventionist and the family are able to find a mutual time in their schedules.

22.1.2.
In phase 1 the parents of potential youth focus group parents of potential participants will be contacted by phone. The focus group will be explained in detail to the parent. Verbal consent for participation will be requested from one caregiver. The Community Health Worker interventionist will then contact the participant to assess willingness to participate. The assent form will be read to the youth over the phone. If the participant agrees, the Community Health Worker interventionist will invite the youth to the focus group. Assent will be reiterated with the group at the start of the focus group.

In phase 2 potential participants will be contacted by phone by a Karen community health worker interventionist. A brief description of the project will be provided over the phone. If members of the family express interest, an in-person meeting will be scheduled in the potential participant's home or a preferred alternative location. During the in-person meeting, participants who confirm interest in study

participation and who are qualified to participate will be given a detailed description of the study activities. Caregivers and youth will be given a copy of the informed consent/assent forms printed in English and Karen language where study requirements, procedures, and risks and benefits are detailed. Explanations will be given (or in some cases the form may be read aloud) in the preferred language of prospective participants. Informed consent will be obtained by the delegate of the PI who is also approved by the IRB to obtain informed consent and youth assent on the project. The informed consent form will be signed in the presence of another person and participants will be given the opportunity to ask questions about the procedures outlined in the informed consent form. A copy of the IRB-approved informed consent document and HIPAA agreement will be given to the participant in their preferred language. Adult participants will consent for themselves, as well as grant permission for youth under 18 to be involved in the project.

We will request one signed parental permission and one verbal parental permission for all two parent households. The same protocol was followed with Karen study participants in earlier study phases and aligned with Karen norms and values. Typically, it was the mother who provided written permission. Following the consent process with adult (parent) participants, details of the study will be provided to youth in a similar manner (read or verbal) and in their preferred language, English, Karen, or a hybrid. Youth will have an opportunity to ask questions and discuss participation with their families prior to assenting. Youth assent will take place in the presence of the signing maternal/paternal participant in the study. In the circumstance that a parent consents to participate, but the youth does not assent, the family will be considered ineligible for participation.
Ongoing consent to participation will occur at the start of each intervention session.

Participants will be given a copy of their signed and dated consent/assent forms.

22.2. Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception):

NA

22.3. Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained):

NA

22.4. Non-English Speaking Participants:

Karen

- All consent documents will be transcribed in the Karen language. Community health worker interventionists are themselves Karen and will conduct intervention sessions in the Karen language.

- When the PI is present for study interactions, the community health worker interventionists (who also function in their roles as expert interpreters) will interpret the interactions. Otherwise, the study will be conducted in the language of participants and without interpretation.
- Enrollment of non-English speakers is expected.

22.5. Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):

22.5.1. Adult study participants will identify their children 11-18 who are eligible and interested in study participation.

22.5.1.1.

22.5.1.2. NA

22.5.1.3. See above. Consent will be attained from one parent verbally (phase 1); and both parents when available, one verbal and one signed (phase 2).

22.5.1.4. For single parent households where the other parent is living separately or out of state, we will obtain from consent only from the primary caregiver.

22.5.2. NA

22.5.3. All.

22.5.4. Youth assent will be documented in the study record.

22.6. Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent: NA

22.7. Adults Unable to Consent: NA

23. Setting

23.1. Research Sites: Participants will be asked their preference of in person study visits or Zoom study visits. Due to the Covid pandemic, we are altering our initial plan for study interactions to be exclusively home-based. One CHWI will interact with participants preferring an in person option in their homes as planned. The second CHWI will deliver the intervention via Zoom sessions. The focus group will take place in a location that is accessible and known to the community. We are planning for in person focus groups. Zoom sessions and in person sessions will be video and audio recorded for fidelity monitoring and coaching purposes.

Youth L2B intervention sessions will be delivered in a group format at the Knyaw Baptist Church.

23.1.1.

Participants will be recruited from an existing cohort that participated in earlier phases of the study. All participants gave permission to the study team to contact them with further opportunities to participate in the project.

23.1.2.

In participant homes or via Zoom. Home-based services is a model of care familiar to the refugee community in Minnesota. WellShare International (our community partner) provides home-based services routinely in their operations. During the pandemic it was typical for organizations to offer tele-health appointments with clients. Community members are now more accustomed to this platform and may prefer this approach. Our initial phases of implementation with youth demonstrated that a group format would be more engaging, thus we are returning to the original model of intervention delivery for the Learning to Breathe intervention.

23.1.3.

A community advisory board developed in early phases of the study will continue to provide input on the adaptation of the intervention and study procedures. The community advisory board is comprised of representatives from key community organizations serving the refugee community in Minnesota.

23.1.4.

23.1.4.1. NA

23.1.4.2.NA

23.2. International Research: NA

23.3. Community Based Participatory Research:

23.3.1.WellShare International is a primary study partner and will be involved at all stages of the research.

23.3.2.Community Health Workers will compete CITI training. Ongoing and regular discussions about human protections, privacy, confidentiality, and autonomy will take place during weekly study team meetings. Community health worker interventionists will be listed as study team members on the IRB submission.

23.3.3.See supporting documents in Ethos.

24. Multi-Site Research

NA

25. Coordinating Center Research

NA

26. Resources Available

26.1. Resources Available:

26.1.1. At this point we do not have a student investigator involved in the project.

26.1.2. Our sample is very small given that the focus of this phase of the feasibility trial is refining the CBPR approach, interventionist training, and fidelity monitoring procedures. The ability to recruit the target sample size is feasible. We have access to 96 Karen families through an existing cohort. We are targeting 10% of those families for the current study phase.

26.1.3. The PI will allocate at least 10 hours per week to the project. Community health worker interventionist time will vary based on the phase of the study. Administrative support at WellShare International has allocated 1-4 hours per month for oversight of activities.

26.1.4.

The **University of Minnesota (UMN)** has an outstanding research reputation and is ranked in the top 25 research institutions in the United States by the Center for Measuring University Performance at Arizona State University. Both a state land-grant university and Minnesota's only research university; it is one of the leading recipients of federal research awards in the U.S. In fiscal year 2017, the University received more than $744 million in grant and contract awards from federal, state, and private sources and ranked in the top 10 of all public and private research universities. The University conducts 98 percent of all sponsored academic research in Minnesota. The University is one of the most comprehensive universities in the United States with more than 370 fields of study and over 65,000 students. The Graduate School offers more than 150 masters and doctoral degree programs covering virtually every area of academic inquiry. The wide breadth of program offerings provides graduate students with multiple opportunities for interdisciplinary study.

The **Academic Health Center (AHC)** is home to six colleges and schools, and more than 90 centers, institutes, and hospitals and clinics. About 70 percent of Minnesota's health care providers train through the AHC, including doctors, nurses, dentists, pharmacists, public health workers, and veterinarians. Innovations for patient care happen because of inter-professional collaboration across the health sciences.

The **Clinical and Translational Science Institute** (CTSI; UL1TR002494) is building an integrated network of research services and support at the University of Minnesota that provides comprehensive support for the entire spectrum of clinical and translational research through a single point of entry. High quality and cost-

effective research services include informatics tools, expert consultations, biostatistical support, regulatory support, and clinical research facilities. CTSI's **Community Engagement to Advance Research and Community Health (CEARCH)** office provides an infrastructure for community groups and University-based researchers to work together to address health issues in ways that are truly relevant to the community.

Established in 1909, the mission of the **UMN School of Nursing** is to generate knowledge and prepare nurse leaders who will create, lead, and participate in holistic efforts to improve the health of all people within the context of their environments. The school has two locations: one in the heart of the Twin Cities of Minneapolis and St. Paul, and the second in Rochester, home of the Mayo Clinic. Original scholarly inquiry is at the core of the rich synergy of research, education and practice at the School of Nursing. Opportunities for collaborative research abound with nursing colleagues, colleagues from other disciplines at the University of Minnesota's renowned Academic Health Center (AHC), in other academic areas throughout the university, and with community partners in this progressive, health-oriented community. Focal areas of research in the School of Nursing include: Health Promotion among Vulnerable Populations; Prevention and Management of Chronic Health Conditions; Symptom Management; Health/ Nursing Informatics and Systems Improvement. In the School of Nursing, the *Center for Child and Family Health Promotion Research (CCFHPR)* mission is to improve the health of infants, children, adolescents, parents, and families through the development and dissemination of evidence-based knowledge of effective interventions and best practices in primary and secondary prevention.

26.1.5. See description of resources described in Foreseeable Risks 13.2. We will ensure readily available resources in the case that participants experience unanticipated consequences of the research.

26.1.6. In this phase we are collaboratively developing and refining the study protocol and research procedures, WellShare interventionists will be involved in the development of these process. The PI will have weekly meetings with the interventionists where we will discuss all aspects of research activities.

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