Implementing and Evaluating a Wellness and Social-Emotional Learning Program for Refugee Children During the COVID-19 Pandemic: EMPOWER

(Emotions Program Outside the Clinic and Wellness Education for Refugees)

Protocol Number

2000030455

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Protocol and Statistical Analysis Plan

February 20, 2022

Version #3

Synopsis

Purpose

Our overall goal is to pilot an adaptation of an established Social-Emotional Learning (SEL) Program with novel wellness and COVID-19 safety components that are trauma-informed and culturally-specific in a resettled refugee community.

Objectives

In this pilot, "EMPOWER" (Emotions Program Outside the clinic and Wellness Education for Refugees), we aim:

1. To assess implementation outcomes (adoption, acceptability, and feasibility) of EMPOWER with refugee children and families during the COVID-19 pandemic through longitudinal evaluations and measurements of feasibility, acceptability, and attrition.
2. To evaluate the impact of EMPOWER by assessing (a) children's SEL competence and (b) children's and family's COVID-19 knowledge.

Study Population

The study population will include families who are connected with Elena's Light, a trusted community non-profit organization that supports refugee families in the New Haven region.

Because the model of adaptation and delivery will be culturally specific for Afghan refugees (the majority of recent refugees in the New Haven area are from Afghanistan), eligible participants will include Afghan refugee children, 5-15 years old, who have completed ≥1 year of school in US. One parent/guardian will also be surveyed in the pre- and post-evaluation on Zoom.

Number of Participants

A total of approximately 75 children from 30 family units will be recruited to participate, along with at least one parent/guardian from each family. This will include 50 children from 20 family units in the intervention group and 25 children form 10 family units in the control group.

Study Design

The overall objective of this study is to establish and evaluate the preliminary efficacy and implementation of an adapted social-emotional learning (SEL) and Wellness Program for refugees: EMPOWER (Emotions Program Outside the clinic with Wellness Education for Refugees). To achieve the two aims of this study, the study team will conduct a wait-list controlled pilot to establish and evaluate the preliminary efficacy of participation in EMPOWER by assessing (a) children's SEL competence and (b) measures of mental health, stress, quality of life and wellness before and after participation in the program (Aim 1). Then, the study team will assess the implementation of EMPOWER with refugee children by using mixed methods to perform a summative evaluation of implementation outcomes-including fidelity, sustainability, and reach-in the Afghan refugee community (Aim 2).

Study Duration

The EMPOWER curriculum will initiate with recruitment and enrollment beginning May 1, 2022 with program initiation occurring approximately 2-3 months after recruitment and enrollment initiation, and analysis occurring approximately 2-6 month after initiation. Data analysis is planned for until approximately two years after initiation.

Outcome Variables

Implementation outcome measures will include feasibility, attrition, and parent and child acceptability, measured via post-intervention qualitative evaluations of parents. Preliminary efficacy primary outcome measures will include COVID-19 knowledge and Social-Emotional Competence, measured via evaluation of symptoms and the Trait Meta-Mood Scale, respectively. Secondary outcomes will be measured using the Pediatric Quality of Life Inventory, Perceived Stress Scale, and the Afghan Symptom Checklist.

Locations/Facilities

Sessions will occur in Connecticut, USA, in safe outdoors spaces (e.g., parks, roped-off parking lots) within walking distance of family homes and on Zoom (with the ability to covert to 100% Zoom if needed because of weather and/or COVID-19 restrictions). Pre- and post- evaluations will occur on Zoom.

Abbreviations

Abbreviation	Explanation
CASEL	Collaboration for Academic Social and Emotional Learning
EMPOWER	Emotions Program Outside the clinic with Wellness Education for Refugees
PSC	Pediatric Stress
PEDS-QL	Pediatric Quality of Life Inventory
SEL	Social-Emotional Learning
TMMS	Trait Meta Mood Scale

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Protocol Revision History

Version Date	Summary of Substantial Changes
February 20, 2022	• Increase age range of study population from 6-14 to 5-15 • Remove randomization from study design • Afghan Symptom Checklist added and Child Behavioral Health Checklist removed

1 Background

1.1 Background

Refugee children have limited access to timely diagnosis and treatment for mental and/or behavioral health (MBH) problems, despite facing multiple risk factors. Children in immigrant families face barriers to receiving preventative MBH services and to receiving timely diagnoses and treatment. A study of first point-of-contact for mental health conditions found that immigrant patients accessed care in the Emergency Department more frequently than their non-immigrant peers.[1] Using data from the National Survey of Children's Health, we found that, among children who have an MBH diagnosis, those in immigrant families are also less likely to receive treatment.[2] Refugee children are at additional risk for MBH concerns, because many have faced trauma during pre-migration, migration, and post-migration experiences.[3–5] Additional MBH risks are related to potential toxic exposures; for example, elevated blood lead levels are common in refugee children depending on age and country of origin.[6]

In the era of COVID-19, barriers to timely diagnosis and care as well as mental health risks have increased, especially for refugee populations. Risk factors during the COVID-19 pandemic that may exacerbate MBH concerns already faced by refugees include food insecurity, inability to social distance, and educational disruptions. Refugees are particularly vulnerable to exacerbations of language barriers, isolation, and economic insecurity.[7–10] Despite advances in vaccine development, children will not have early access to COVID-19 immunizations.[11] The ongoing need for mitigation measures, anticipated to continue into 2022, will likely further exacerbate COVID-19-related barriers and underscores the importance of equitable access to timely COVID-19 information and resources.

Robust evidence supports the value of SEL curricula in multiple domains. A recent systematic review and meta-analysis found that, compared with control groups, children who participated in SEL curricula demonstrated improvement in social and emotional competence, behavioral self-regulation, early learning skills, and social-emotional challenge behaviors.[12] Specifically, emotional competence—which includes the ability to identify one's own feelings, to identify the feelings of others, and the skills to communicate and cope with emotions to guide thinking and actions—is associated with successful school and work performances and decreased susceptibility to disease.[13–16]

1.2 Prior Experience

In response to stakeholder-identified concerns related to delayed identification of MBH problems and lack of coordinated referrals, we partnered with community members to conduct interviews with Afghan refugee parents. From this community-based participatory research (Rosenberg, J., Leung, J. K., Harris, K., Abdullah, A., Rohbar, A., Brown, C., & Rosenthal, M. S. (2021). Recently-arrived Afghan refugee parents' perspectives about parenting, education and pediatric medical and mental health care services. *Journal of Immigrant and Minority Health)*, we learned that many parents had not yet considered or reflected on MBH concerns because of higher priority concerns around safety and acculturation. Parents described priorities around health that were related to basic safety after living in war-torn regions. They described an emerging support system and an appreciation for an engaged and connected health system but expressed little trust in discussing MBH concerns with medical providers. Based on parents' identified needs and opportunities for engagement, we sought opportunities for education, prevention, and engagement with community members.

In summer 2020, we developed and launched an adaptation of an SEL curriculum, "EMPOWER," with 13 families to establish community trust, determine program feasibility,

and to promote public health by disseminating preventative COVID-19 information in preferred languages. We analyzed the program after its conclusion by surveying and interviewing parents of each participating family. Findings from this analysis, which were recently published in *Health Education Behavior* (Rosenberg, J., McDonough Ryan, P., O'Brien, C., Ganjavi, F., & Sharifi, M. (2021). Pilot Wellness Program With Adapted Social–Emotional Learning and COVID-19 Curriculum for Refugee Youth. *Health Education & Behavior*), suggest that the curricular components are likely to be feasible and acceptable. After the program, all 13 parents who participated correctly identified symptoms and protective measures for COVID-19 based on a published questionnaire that assessed disparities in COVID-19 knowledge.[17] Additionally, all parents responded that the program was worthwhile, that they were interested in re-enrollment, and that they would recommend EMPOWER to a peer. However, social desirability bias, a small sample, and the lack of a comparisons group limit our interpretation of these preliminary results.

2 Rationale/Significance

2.1 Rationale and Study Significance

Despite this robust literature on the value of SEL curricula, no studies, to our knowledge, have adapted curricula for refugee populations nor included COVID-19 pandemic safety**.** In this proposed pilot EMPOWER trial, we aim to improve the health and wellbeing of resettled Afghan refugee children by implementing and rigorously evaluating our adapted SEL curricular program, which is augmented with novel, trauma-informed and culturally-specific wellness and safety elements related to the COVID-19 pandemic and its aftermath.

2.2 Risks

Risks of the intervention and evaluations may include discomfort or confusion with some of the information provided and/or questions asked. Resources will be available for participants and family members should any discomfort arise, including direct connections with care coordinators, patient navigators, and mental and medical health providers. COVID-19 safety measures will be in place in line with CDC guidelines, with symptom screening, physical distancing, masking, outdoor-only activities, and emphasis on hygiene and cleanliness, so there is minimal risk of COVID-19 exposure based upon these safety measures.

2.3 Anticipated Benefits

Benefits for the participants will include access to COVID-19 safety information, access to information about social-emotional learning, and nutrition and exercise information, which can all contribute to health and wellness. Participants will also receive course materials (yoga mats, art materials, cleaning supplies) and gift cards. For society and/or science, the benefits will include information about the preliminary efficacy, feasibility, and acceptability of social-emotional learning and wellness curricula for refugees.

3 Study Purpose and Objectives

3.1 Purpose

Our overall goal is to pilot an adaptation of an established Social-Emotional Learning (SEL) Program with novel wellness and COVID-19 safety components that are trauma-informed and culturally-specific in a resettled refugee community. In this pilot, "EMPOWER" (Emotions Program Outside the clinic and Wellness Education for Refugees), we aim:

3.2 Hypothesis

The major question that guides this research is: can an adaptation of an established Social-Emotional Learning (SEL) curriculum effectively improve Social-Emotional wellness for refugee children and their families?

We hypothesize that participation in this program will (a) improve children's SEL competence and (b) lessen stress and improve quality of life for refugee families.

3.3 Objectives

In this pilot, "EMPOWER" (Emotions Program Outside the clinic and Wellness Education for Refugees), we aim:

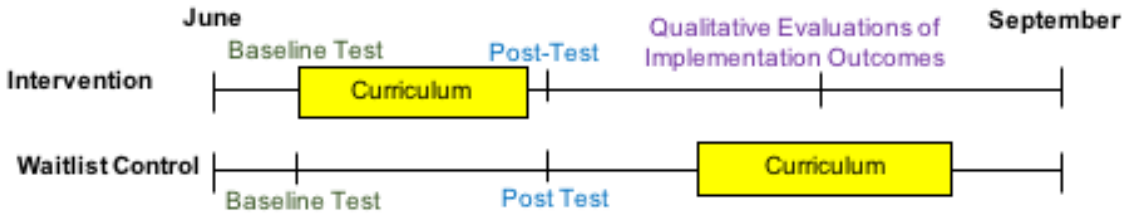
1. To assess implementation outcomes (adoption, acceptability, and feasibility) of EMPOWER with refugee children and families during the COVID-19 pandemic through longitudinal evaluations and measurements of feasibility, acceptability, and attrition.
2. To evaluate the impact of EMPOWER by assessing (a) children's SEL competence and (b) children's and family's COVID-19 knowledge.

4 Study Design

Overall Approach:

The overall objective of this study is to establish and evaluate the preliminary efficacy and implementation of an adapted social-emotional learning (SEL) and Wellness Program for refugees: EMPOWER (Emotions Program Outside the clinic with Wellness Education for Refugees). We will achieve these goals through two aims. We will conduct a wait-list controlled,pilot to establish and evaluate the preliminary efficacy of participation in EMPOWER by assessing (a) children's SEL competence and (b) measures of mental health, stress, quality of life and wellness before and after participation in the program (Aim 1). Then, we will assess the implementation of EMPOWER with refugee children by using mixed methods to perform a summative evaluation of implementation outcomes—including fidelity, sustainability, and reach—in the Afghan refugee community (Aim 2).

Figure 1. Timeline for Intervention, Waitlist Control, and Evaluations



EMPOWER Curriculum:

EMPOWER is an adapted SEL and wellness education initiative delivered to a community of refugee families that was developed through a pre-pilot in the New Haven Afghan refugee community in 2020. Unlike traditional school-based SEL curricula, EMPOWER partners with community organizations to provide translated and trauma-informed wellness education to family units. The program combines in-person (socially distant) and remote delivery of culturally-informed physical, emotional, and medical wellness tools adapted from evidenced-based behavioral medicine, refugee trauma and recovery, and community health research. Over two weeks, enrollees participate in six in-person sessions (two hours each). They also complete eight, one-hour, weekly Zoom sessions during and beyond the in-person curriculum. At-home Zoom technical support is provided as needed. Each family unit is guided through in-person and online components by a facilitator. The EMPOWER curriculum focuses on the core competency of self-awareness, a core element of emotional competence, from the Collaboration for Academic Social and Emotional Learning (CASEL) framework. Facilitators include interns, health-providers, and community partners. We have published a detailed EMPOWER manual, which we will iteratively modify, through an online request portal.

Intervention:

We will use implementation science methods and apply an Intervention Mapping framework to refine and assess the adoption, acceptability, and feasibility of EMPOWER. The program will include virtual and in-person SEL, COVID-19 safety, and physical activity instructions. Program administrators will also respond to and track disclosure of and/or identification of mental health, medical, or other needs.

Data Collection and Measures:

We will conduct a mixed methods evaluation—using concurrent qualitative and quantitative data collection and merged analysis—to survey parents and their children (over Zoom) at early and late time-points of their involvement in the program. Interview guides and survey

tools will be developed with community partners and will be based upon previously-studied measures used for war-affected families. In addition to demographic covariates (age, gender, languages, years in the US), we will collect data and assess implementation outcomes as well as primary and secondary outcome measures. Questions will be asked to parents about each child and to the children directly.

Implementation measures (Aim 1) will include assessment of adoption, acceptability, and feasibility through parent and stakeholder evaluations and through rates of attrition. Outcome measures (Aim 2) will include (a) COVID-19 knowledge, measured via an established COVID-19 knowledge assessment and (b) children's SEL competence, measured by the Trait Meta-Mood Scale. Secondary outcomes and covariates will include the validated measures that may modify intervention effectiveness. While timeline and small sample size in this pilot will likely not allow detection of pre-post differences in quality of life or behavioral health concerns such as stress or depressive symptoms, we will examine patterns in secondary outcomes to form hypotheses in preparation for future, larger-scale trials.

Analysis Plan:

In this mixed methods study, we will perform concurrent qualitative and quantitative data collection and subsequent merged analysis. We will analyze quantitative data in Stata, with statistical support from a biostatistician. Qualitative responses will be transcribed and coded by members of the research teams using Dedoose. We will identify emerging themes using the constant comparative method. A repeated measures linear mixed model approach will be used for analysis. The primary analyses will compare changes in COVID-19 knowledge and of emotional competence before and after participation between the intervention and wait-list control groups. Similar analyses will be measured for secondary outcomes.

4.1 Study Duration

The EMPOWER curriculum will be conducted between June 1 and August 31 2022 for both the intervention and wait list control groups. Data collection will conclude by October 31, 2022, with data analysis continuing until August 30, 2023.

4.2 Outcome Variables/Endpoints

Outcomes of interest (in Table 1, below) will include (1) implementation outcomes (feasibility, attrition, acceptability) and (2) primary preliminary efficacy outcome measures (COVID-19 knowledge and Social-Emotional Competence). Additional exploratory outcomes of interest are related to quality of life, stress, and behavioral health. Measures were chosen based upon previously validated measures that can be adapted to other cultures and languages.

4.2.1 Primary Outcome Variables/Endpoints

As outlined in Table 1, below, primary implementation outcome measures will include feasibility, attrition, and parent and child acceptability, measured via post-intervention qualitative evaluations of parents.

Primary preliminary efficacy measures will include COVID-19 knowledge and Social-Emotional Competence, measured via evaluation of symptoms and the Trait Meta-Mood Scale, respectively.

4.2.2 Secondary and Exploratory Outcome Variables/Endpoints (if applicable)

Secondary outcomes will be measured using the Pediatric Quality of Life Inventory, Perceived Stress Scale, and the Afghan Symptom Checklist.

Table 1. EMPOWER Outcome Measures, Instruments, and Respondents		
Implementation Outcome Measures (via Qualitative Evaluations):		
Feasibility	Qualitative evaluation of parents' challenges with feasibility. Community partner stakeholders will be involved in this analysis.	Parents
Attrition	Participant attendance & reasons for absence	Parents
Parent and Child Acceptability	Qualitative evaluation of (1) parents' experiences (2) child completion of homework activities (3) referrals (for parents and children) related to mental, emotional, physical or behavioral health	Parents
Primary Outcome Measures (via Pre- and Post-Tests):		
COVID-19 Knowledge	Evaluation of Symptoms and prevention*[17]	Parents & Children
Social-Emotional Competence	Trait Meta-Mood Scale*[16]	Parents & Children
Secondary Outcomes Measures and Covariates (via Pre- and Post-Tests):		
Quality of Life	Pediatric Quality of Life Inventory (PEDS-QL)*	Parents & Children
Stress	Perceived Stress Scale (PSC)*[19]	Parents & Children
Depressive Symptoms	Afghan Symptom Checklist‡[20]	Parents & Children
Social Problems	Afghan Symptom Checklist‡[20]	Parents & Children
**To be translated according to World Health Organization Standards.*[22] *‡Pashto/Farsi translation available.*		

5 Study Participants

5.1 Study Population

Participants will include families who are connected with Elena's Light, a trusted community non-profit organization that supports refugee families in the New Haven region.

Waitlist control participants will receive written, translated program materials and begin the formal curriculum after the intervention group.

5.2 Number of Participants

We will recruit a total of 75 children from a total of approximately 30 family units.

After recruitment, we will assign participants to an intervention group (50 children from 20 family units) and a wait-list control group (25 children from 10 family units) and will stagger administration of the EMPOWER curriculum to the two groups.

5.3 Eligibility Criteria

Eligibility will be determined in partnership with our community partner, Elena's Light, with approval by the PI based upon eligibility status.

- Because we are recruiting by family unit, we will allow a wide age range of children, from 5-15 years old.
- The model of adaptation and delivery will be culturally specific for Afghan refugees (the majority of recent refugees in the New Haven area are from Afghanistan).
- Thus, eligible participants will include:
    - Afghan refugee children
    - 5-15 years old
    - Who have completed ≥1 year of school in US.
    - Who are able to safely attend outdoor sessions with one parent/guardian

5.4 Recruitment Procedures

Our community partner, Elena's Light, has identified eligible and interested families who are connected with their organization. Subjects will be asked by members of the community organization if they are interested in participation. For those who are interested, they will meet with the PI and collaborators over Zoom (with Zoom support provided as needed) for more information. Those who agree to participate will then undergo one-on-one Zoom sessions with the PI. Verbal informed consent in the participant's preferred language (Dari, Farsi, Pashto, Arabic, or English) will be provided prior to initiation of study.

5.5 Consent/Assent Procedures/HIPAA Authorization

Consent of parents and assent of children will be obtained by the PI and research assistants with a qualified interpreter. Consent will be obtained over Zoom with a verbal informed consent. Privacy will be assured by keeping all respondent information on password protected computers. Understanding of the study will be assessed through confirmation of understanding with the interpreter during the consent process. To avoid undue influence,

participants will be given options to withdraw at any time. Assurances will be provided that the EMPOWER curriculum is in no way connected to clinical care.

- Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting procedures/administering study intervention.
- Consent forms will be Institutional Review Board (IRB)-approved and the participant/legally authorized representative (LAR) will be asked to listen to our reading of and review of the document. The research assistant and/or PI will be available to answer any questions that may arise. Conversations will occur over Zoom at the participants' convenience. Privacy will be insured by allowing participants to choose time, location, and if they would like to use video or not.
- Participants/LAR will have the opportunity to carefully review the verbal consent and will be offered a written version of the form and can ask questions prior to signing. The participants/LAR should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate.
- Participants/LAR must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants/LAR for their records.
- One or two parents/legal guardians may participate in the consent process.
- Assent will be obtained from child participants over Zoom. A verbal explanation in the child's preferred language will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants.

6 Study Methods/Procedures

6.1 Study Procedures

EMPOWER Curriculum: EMPOWER is an adapted SEL and wellness education initiative delivered to a community of refugee families that was developed through a pre-pilot in the New Haven Afghan refugee community in 2020. Unlike traditional school-based SEL curricula, EMPOWER partners with community organizations to provide translated and trauma-informed wellness education to family units. The program combines in-person (socially distant) and remote delivery of culturally-informed physical, emotional, and medical wellness tools adapted from evidenced-based behavioral medicine, refugee trauma and recovery, and community health research (Table 2). Over two weeks, enrollees participate in six in-person sessions (two hours each). They also complete four, one-hour, weekly Zoom sessions during and beyond the in-person curriculum. At-home Zoom technical support is provided as needed. Each family unit is guided through in-person and online components by a facilitator. The EMPOWER curriculum focuses on the core competency of self-awareness, a core element of emotional competence, from the Collaboration for Academic Social and Emotional Learning (CASEL) framework.[23] Facilitators include interns, health-providers, and community partners. We have published a detailed EMPOWER manual, which we will iteratively modify, through an online request portal.[24]

Table 2. EMPOWER Curricular Components
Pre-EMPOWER Preparedness
At Home: Consent Form Signed, Materials Delivered
At Home: Zoom Support, Zoom Orientation with Parents
Identification of Outdoor Space, Safe and Walkable
In-Person Curriculum (6 times, over 2 weeks)
COVID-19 symptom and temperature check
Hand-washing, clean space, social distance
Arrival art activity and materials provided
Lesson: COVID-19 Safety (symptoms and prevention)
Lesson: Physical Activity (eg breathing, yoga)
Lesson: Healthy Habits (eg healthy eating)
Lesson: SEL, Emotional Vocabulary (eg emotion bingo)
Lesson: Art Activity (eg painting emotions)
Wrap-Up: Homework, Breathing, Hand-Washing
Zoom Curriculum (1 time weekly, over 4 weeks)
Arrival: Mindfulness Exercises (eg 20 Questions)
Lesson: COVID-19 Safety (symptoms and prevention)
Breakout Lesson: Physical Activity (eg yoga)
Breakout Lesson: Homework check-in
Breakout Lesson: SEL, Emotional Vocabulary Games
Wrap-Up: Homework, Next Meeting

Intervention: We will use implementation science methods and apply an Intervention Mapping framework to refine and assess the adoption, acceptability, and feasibility of EMPOWER.[18] The program will include virtual and in-person SEL, COVID-19 safety, and physical activity instructions. Program administrators will also respond to and track disclosure of and/or identification of mental health, medical, or other needs.

Data Collection and Measures: We will conduct a mixed methods evaluation—using concurrent qualitative and quantitative data collection and merged analysis[25]—to survey parents and their children (over Zoom) at early and late time-points of their involvement in the program. Interview guides and survey tools will be developed with community partners and will be based upon previously-studied measures used for war-affected families.[26] In addition to demographic covariates (age, gender, languages, years in the US), we will collect data and assess implementation outcomes as well as primary and secondary outcome measures (Table 1). Questions will be asked to parents about each child and to the children directly.

Implementation measures (Aim 1) will include assessment of adoption, acceptability, and feasibility through parent and stakeholder evaluations and through rates of attrition. Outcome measures (Aim 2) will include (a) COVID-19 knowledge, measured via an established COVID-19 knowledge assessment[17] and (b) children's SEL competence, measured by the Trait Meta-Mood Scale.[16] Secondary outcomes and covariates will include the validated measures outlined in Table 1 that may modify intervention effectiveness. While timeline and small sample size in this pilot will likely not allow detection of pre-post differences in quality of life or behavioral health concerns such as stress or depressive symptoms, we will examine patterns in secondary outcomes to form hypotheses in preparation for future, larger-scale trials.

Intervention and Evaluation Schedule

	Info Session (All)	Pre-Evaluation (All)	EMPOWER (for Intervention Group)	Evaluation (Intervention)	Evaluation (Control)	EMPOWER (for Control Group)
Zoom Information Session	X					
Zoom Informed Consent		X				
Demographic Collected		X				
Outcome Evaluation						
COVID-19 Knowledge		X		X	X	
Trait Meta Mood Scale		X		X	X	
Secondary Outcomes: Afghan Symptom Checklist, PedsQL, PSC		X		X	X	
Implementation Outcomes				X		
EMPOWER Curriculum			X			X

6.1.1 Data Collection

After confirming verbal informed consent, data will be collected over Zoom with interpreters who speak the respondents' preferred languages.

- Translated Data Collection Instruments: Standardized data collection tools, which will be interpreted according to World Health Organization Standards include:
    - Trait meta mood scale[16]
    - Afghan symptom checklist[20]
    - Pediatric quality of life[27]
    - Perceived stress scale[19]
    - COVID-19 questionnaire,[17] previously administered (uploaded in supporting documents)
- Implementation Outcomes: A qualitative survey guide will be developed with stakeholders to discuss feasibility and acceptability with parents, based upon prior piloted survey tools (uploaded in supporting documents).
- Mode of Data Collection: All surveys and interviews will be conducted over Zoom. After verbal informed consent is read in the respondent's preferred language, with permission, responses will be audio-recorded. Interviews will be transcribed verbatim in real-time with post-interview proofreading and comparison to the audio recordings. It is expected that all interviews and surveys will be approximately one hour in duration.
- Compensation: A $25 gift card will be distributed to respondents after each interview. All interviews were approximately one hour in duration.

6.2 Method of Assignment/Randomization (if applicable)

Not applicable. Intervention and control group designations will be based upon geographic location to easily access the outdoor location of the EMPOWER program.

6.3 Adverse Events Definition and Reporting

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related.

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

Any adverse event will be evaluated determined severity and need for reporting to IRB.

6.4 Reaction Management

A referral network and network of experts in pediatric health, pediatric mental health, and adult refugee health have been compiled. If any medical, mental health, educational, or behavioral health needs are disclosed, patient navigators and the research team will ensure proper referrals and follow-up are followed.

6.5 Withdrawal Procedures

Participants may withdraw at any time by letting staff know or stopping attendance, and if requested, no new data will be collected, but previously collected data will be kept to maintain the integrity of the study.

6.6 Locations/Facilities

Locations will be secure, safe outdoor spaces near participants' homes (including, for example, outdoor parks, or parking lots) identified by and with refugee serving organizations in Connecticut, USA. Additional curricula will occur over Zoom, as will all surveys and interviews. Additionally, the entire curriculum is fully convertible to Zoom if needed, and if weather and/or COVID necessitates remote learning, this can happen at any point in the protocol.

7 Statistical Design

7.1 Sample Size Considerations

Following COVID-19 protocols, we will limit in-person attendance to a maximum of ten children from a maximum of four family units over five sessions. Therefore, we anticipate about 50 children from 20 family units, with 25 children from 10 families as waitlist controls. This is well within recommended pilot sample size of 15-25 to detect small to medium effect sizes.[28]

7.2 Planned Analyses

In this mixed methods study, we will perform concurrent qualitative and quantitative data collection and subsequent merged analysis. We will analyze quantitative data in Stata,[29] with statistical support from a biostatistician. Qualitative responses will be transcribed and coded by members of the research teams using NVivo®. We will identify emerging themes using the constant comparative method. A repeated measures linear mixed model approach will be used for analysis. The primary analyses will compare changes in COVID-19 knowledge and of emotional competence before and after participation between the intervention and wait-list control groups. Similar analyses will be measured for secondary outcomes.

7.2.1 Secondary Objective Analyses (if applicable)

See above.

7.2.2 Analysis of Subject Characteristics (if applicable)

Descriptive demographic characteristics will include: age, gender, languages, years in the US.

7.2.3 Interim Analysis (if applicable)

N/A

7.3 Data Relevance

The data collected will specifically answer the research question of: can an adaptation of an established Social-Emotional Learning (SEL) curriculum effectively improve Social-Emotional wellness for refugee children and their families? By evaluating emotional competence and exploring secondary outcomes related to mental and behavioral health, we will be able to understand the impact of EMPOWER on refugee children's health.

7.4 Data Coding

We will use the constant comparative method to analyze themes in the qualitative data and iteratively refined the interview guide over the course of the interviews.[30] A two-person coding team will analyze written transcripts using grounded theory methodology.[30]

Discrepancies will be resolved by discussion, and the research team will then review codes and emerging themes and agreed upon trends and themes from qualitative responses. The mixed-method results will be integrated with merged analysis which compared and contrasted divergences.[25]

7.5 Data Analysis Tools

Both Dedoose and Stata will be used in analysis.

7.6 Data Monitoring

Data will be kept on a password protected computer of the PI and/or in Yale's secure Box location.

7.7 Handling of Missing Data

A biostatistical consultant will be part of the research team who can help to determine how to handle missing data, depending on quantity of missing data. We will consider dropping certain individual responses and/or imputation methodology depending on how much data is missing.

8 Data/Specimen Handling and Record Keeping

8.1 Subject Data Confidentiality

Participant confidentiality and privacy is strictly held in confidence by the participating investigators, their staff, and the sponsor(s)/funding agency. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence.

All research activities will be conducted in as private a setting as possible.

Representatives of the Institutional Review Board (IRB), regulatory agencies or study sponsor/funding agency may inspect all documents and records required to be maintained by the investigator for the participants in this study. The study site will permit access to such records.

The study participant's contact information will be securely stored at each study site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, regulatory, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored on password-protected Yale Box server. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the password protected computer of the PI.

Taping of Zoom conversations will be recorded, with permission. Transcriptions and audio files will not include participant's demographic data and will also be kept on password protected Yale Box and Dedoose files.

8.2 Data Quality Assurance

In order to maintain quality control, all researchers will follow and update the EMPOWER manual, available via request through an online server.[24] Training of research assistants will include observed data collection sessions.

8.3 Data or Specimen Storage/Security

As noted above, data will be deidentified with participant IDs, which will be indexed on the PI's password protected computer. Deidentified data, which will include responses to validated instruments, transcripts and audio recordings without demographic data, will be stored on password-protected Yale Box.

8.4 Study Records

The PI will be responsible for maintaining study records on a password protected computer. These records will include:

- Documentation of informed consent

- COVID symptom screening records (administered for in-person classes) and attendance records (for Zoom and in-person classes)
- Participant identifier ID index

Additional records will be kept on Yale secured box:

- Audio recordings and transcripts without participant demographic data
- Responses to all validated survey tools

8.5 Access to Source

Source documents (all electronic word documents) will include all data collection materials completed over Zoom with families. Qualitative and quantitative responses will be compiled into Dedoose and Stata for analysis, respectively. Deidentified documents will be available in Yale Box, shared with co-investigators. Identifiable data will be kept on the PI's password protected computer.

8.6 Retention of Records

Records will be kept for at least 3 years on the PI's password protected computer and indefinitely, or until the PI chooses to destroy it, in Yale Box.

8.7 Data and Safety Monitoring Plan

We do not anticipate any adverse events. The principal investigator (PI) will monitor the data, assure protocol compliance, and conduct the safety reviews at least annually. The PI evaluate whether the study should continue unchanged, require modifications, or close to enrollment. Any Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly, probably, or definitely related) Unanticipated Problems Involving Risks to Subjects or Others will be reported to the IRB and any appropriate funding and regulatory agencies. Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or permanent interruption of study activities (if possible) with be reported, followed by a written report within 5 calendar days of my becoming aware of the event to the IRB and any appropriate funding and regulatory agencies. The PI will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project. The PI will report all UPIRSOs and adverse events that occur during the conduct of this research project to other applicable oversight bodies as required within applicable reporting timeframes.

9 Study Considerations

9.1 Institutional Review Board (IRB) Review

The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol will require an approved IRB amendment before implementation. The IRB will have final determination whether informed consent and HIPAA authorization are required.

Study closure will be submitted to the IRB after all research activities have been completed.

Other study events (e.g. data breaches, protocol deviations) will be submitted per Yale policies.

9.2 Research Personnel Training

All individuals assisting with conduct of research will receive and/or have received human subjects research training. Community members have completed CITI human subjects research training. Research assistants will be involved in curriculum administration and data collection over Zoom, with training and oversight by the PI.

9.3 Study Monitoring

The internal team will monitor the study. A research mentor will not be involved directly in study administration or evaluation but will provide oversight of accuracy and rigor of evaluation. The research mentor, Mona Sharifi MD MPH, will meet with the PI weekly and will review and contribute to all research products.

9.4 Unanticipated Problems and Protocol Deviations

A protocol deviation is any noncompliance with the protocol. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site investigator to identify and report deviations within 10 working days of identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the study sponsor, and the reviewing Institutional Review Board (IRB) per their policies.

Unanticipated problems involving risks to participants or others include, in general, any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

If the study team becomes aware of an unanticipated problem (e.g. data breach, protocol deviation), the event will be reported to the IRB by the PI contacting the IRB.

The UP report will include the following information:

Protocol identifying information: protocol title and number, PI's name, and the IRB project number;

- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs will be reported to the IRB within ten days of the investigator becoming aware of the event.

9.5 Study Discontinuation

The study would be discontinued if there were any concerns related to safety or efficacy by any members of the research team and/or the IRB and/or the study sponsor.

9.6 Study Completion

Data analysis is expected to be complete around March 2023, and IRB will be notified upon completion**.**

9.7 Conflict of Interest Management Plan

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership in conjunction with the appropriate conflict of interest review committee has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

All investigators will follow the applicable conflict of interest policies.

9.8 Funding Source

This work is funded in part by the Academic Pediatrics Association, Yale University Department of Pediatrics and NIH/NCATS.

9.9 Publication Plan

It is expected that the PI, Julia Rosenberg, will hold the primary responsibility for publishing the study results, with guidance from the funding agencies (listed above) and from her mentor in the Department of Pediatrics, Dr. Mona Sharifi.

The PI of this proposal are committed to the open and timely dissemination of research outcomes. The data generated in this grant will be presented at national or international conferences and published in a timely fashion. All final peer-reviewed manuscripts that arise from this proposal will be submitted to the digital archive PubMed Central.

The principal investigator will ensure that clinical trial(s) under the award are registered and results information is submitted to ClinicalTrials.gov as outlined in the policy and according to the specific timelines stated in the policy. The recipient institution has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements. The principal investigator will also be responsible for aggregate results reporting and AE reporting at the conclusion of the project.

10 List of Tables

Table 1. EMPOWER Outcome Measures, Instruments, and Respondents		
Implementation Outcome Measures (via Qualitative Evaluations):		
Feasibility	Qualitative evaluation of parents' challenges with feasibility. Community partner stakeholders will be involved in this analysis.	Parents
Attrition	Participant attendance & reasons for absence	Parents
Parent and Child Acceptability	Qualitative evaluation of (1) parents' experiences (2) child completion of homework activities (3) referrals (for parents and children) related to mental, emotional, physical or behavioral health	Parents
Primary Outcome Measures (via Pre- and Post-Tests):		
COVID-19 Knowledge	Evaluation of Symptoms and prevention*[17]	Parents & Children
Social-Emotional Competence	Trait Meta-Mood Scale*[16]	Parents & Children
Secondary Outcomes Measures and Covariates (via Pre- and Post-Tests):		
Quality of Life	Pediatric Quality of Life Inventory (PEDS-QL)*	Parents & Children
Stress	Perceived Stress Scale (PSC)*[19]	Parents & Children
Depressive Symptoms	Afghan Symptom Checklist (CBCL)‡[20]	Parents & Children
Social Problems	Afghan Symptom Checklist (CBCL)‡[20]	Parents & Children
**To be translated according to World Health Organization Standards.*[22] *‡Pashto/Farsi translation available.*		

Table 2. EMPOWER Curricular Components
Pre-EMPOWER Preparedness
At Home: Consent Form Signed, Materials Delivered
At Home: Zoom Support, Zoom Orientation with Parents
Identification of Outdoor Space, Safe and Walkable
In-Person Curriculum (6 times, over 2 weeks)
COVID-19 symptom and temperature check
Hand-washing, clean space, social distance
Arrival art activity and materials provided
Lesson: COVID-19 Safety (symptoms and prevention)
Lesson: Physical Activity (eg breathing, yoga)
Lesson: Healthy Habits (eg healthy eating)
Lesson: SEL, Emotional Vocabulary (eg emotion bingo)

Lesson: Art Activity (eg painting emotions)
Wrap-Up: Homework, Breathing, Hand-Washing
Zoom Curriculum (1 time weekly, over 4 weeks)
Arrival: Mindfulness Exercises (eg 20 Questions)
Lesson: COVID-19 Safety (symptoms and prevention)
Breakout Lesson: Physical Activity (eg yoga)
Breakout Lesson: Homework check-in
Breakout Lesson: SEL, Emotional Vocabulary Games
Wrap-Up: Homework, Next Meeting