Official Title: Community-Based Participatory English as a Second Language Health Literacy Program to Prevent Lead Exposure in Flint

NCT Number: NCT04125680

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View: 05. Research Design
Section: 05. Research Design

05. Research Design

5.1* Is there a stand-alone scientific protocol document and/or research plan associated with this application?

◯ Yes ⬤ **No**

5.2* Will the involvement of ANY subjects in this study be limited to analysis of their existing data or specimens?

◯ Yes ⬤ **No**

5.3* Will the study involve recruitment and/or participation of subjects in order to produce new data (e.g., surveys, interaction, intervention)? *[Require sections 8-1 and 11-3]*

⬤ **Yes** ◯ No

5.4* List the inclusion and exclusion criteria for this study population and/or data set. (If covered in attached protocol, indicate section)

The inclusion criteria will be Hispanic/Latinx residents of Flint who are over the age of 18. They should be native speakers of Spanish. At this time, other immigrant populations will not be served by this program because we will be offering it bilingually in English and Spanish only. Children under 18 will not be part of the study population, though there will be child care available during the ESL health literacy program. We are focusing on residents of Flint as part of the response to the Flint water crisis. However, if there are Hispanic adult residents of Genesee County who are concerned about lead exposure and want to join the program, they will not be excluded.

5.5 Identify any racial, ethnic, or gender group(s) that will be specifically excluded from participation in this research study and provide a compelling justification for such exclusion:

No racial, ethnic, or gender groups will be excluded, but those whose first language is something other than Spanish will be excluded at this time. The reason is because the program will be bilingual in English and Spanish and we do not have the resources to add additional languages at this time (in the form of translated materials and interpreters).

5.6* Indicate the age range (in years) of the subject population in this study.

Minimum Age: 18
Maximum Age: 999 If no upper limit, enter "999"

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05-1. Research Design

In its review of research applications, the IRB considers whether research procedures are consistent with sound research design in order to yield the expected results. Scientific merit is examined in relationship to the risks and benefits of the research. This section covers the overall research design of the project. Later sections will ask more specific questions about benefits, risks, special review considerations, targeted populations, recruitment strategies, and experimental methodologies/procedures.

5-1.1* Objective: What is the overall purpose of this research study?

The purpose of this research is the development and evaluation of an ESL health literacy class for Hispanic adults that would focus on reducing lead exposure. The program will be evaluated for its effects on health literacy, health knowledge, and health behaviors as well as the community-engaged and participatory processes of establishing and analyzing the program.

5-1.2* Specific Aim(s): What is (are) the specific aim(s) of this study and/or what hypothesis (hypotheses) is (are) to be tested?

Specific Aim 1: Develop a community-based participatory ESL health literacy curriculum for lead exposure that can be used in other locations or programs.
Specific Aim 2: Determine the outcomes of the curriculum, including changes in knowledge about lead, access to health resources, and health behavioral changes to reduce lead exposure.
Specific Aim3: Use a community-based participatory research (CBPR) approach to evaluate the implementation of the ESL health literacy curriculum.

5-1.3* Background: What prior information or knowledge exists to support the conduct of this study?

This project aligns with the National Action Plan to Improve Health Literacy (2010) including (1) supporting local efforts to provide adult ESL instruction in culturally and linguistically appropriate ways; (2) building partnerships, including academic-community partnerships; (3) increasing the research, development, implementation, and evaluation of practices and interventions to improve health literacy; and (4) increase the dissemination and use of health literacy practices and interventions. This project will focus on Hispanic immigrants because research shows that they are more likely to experience limited health literacy (National Assessment of Adult Literacy, 2003). We are focusing on lead exposure prevention because there have not been any ESL curricula for health literacy that focus on lead, and because of the public health crisis that exposed the city of Flint to lead in their drinking water.
We will be drawing from established theoretical frameworks including Adult Learning Theory (Knowles 1984; Soto Mas et al. 2015), the Health Belief Model (Glanz et al., 2008), the Health Literacy Model (Sørensen et al., 2012), and the Health Promotion Model (Glanz et al., 2008). We will also draw from existing surveys to develop a health literacy test/survey. We will use this test/survey to gauge changes in participants' attitudes, knowledge, beliefs, and behaviors before and after the ESL Health Literacy Program. These surveys include the Chicago Lead Knowledge Test questionnaire, the National Health and Nutrition Examination Survey, the Behavioral Risk Factor Surveillance Survey, and the Fostering Literacy for Good Health Today (FLIGHT)/Vive Desarollando Amplia Salud (VIDAS) Test. Each of these surveys have been widely used and shown to be valid and reliable.

References
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U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2010). National Action Plan to Improve Health Literacy. Washington, DC: Author. Retrieved from https://health.gov/communication/initiatives/health-literacy-action-plan.asp

5-1.4* *Briefly* outline the special expertise and qualifications of the PI, Co-Investigators, and/or Faculty Advisors to conduct and/or oversee the particular procedures or activities involved in *this particular study*. This will supplement information provided in the study team CVs.

The PI for this project has created two ESL programs and curricula: (1) the Refugee Health and Employment Attainment Program (RHEAP), a community-based participatory ESL program for Iraqi refugees in the Sacramento area which focused on employment and health (Feuerherm 2016; Feuerherm & Roumani 2016), and (2) the Bridge Program at UM-Flint, consisting of credit-bearing ESL classes and an in-house placement exam (Feuerherm & Blumner, 2018). The executive community partners, Ace Community Health and GCHLC, have complementary expertise. ACE Community Health has experience with CBPR processes in health education programming, for example through the Sustainable Childhood Obesity Prevention through community Engagement (SCOPE) program (e.g. McIntosh, Daly, Masse, Collet, Higgins, Naylor, & Amed, 2015). GCHLC has expertise in: (1) research management, such as canvassing Hispanic residents affected by the water crisis, (2) participant recruitment, such as recruiting for research and events, (3) translation/interpretation between English and Spanish, and (4) health and water-crisis interventions and services such as free health clinics, water distribution, water testing, and filtration training. Therefore, the roles will be divided across these lines, building upon respective capacities.

The PI and GCHLC have collaborated on two needs-analysis research projects. The first was canvassing research of the Hispanic community affected by Flint's water crisis. This research included 95 households (a total of over 400 individuals) and findings indicated that 21 households (25% of respondents) want ESL educational services. This need for ESL programming was supported in the second collaborative research project: two needs-analysis focus groups with immigrants resulted in documentation of a need for ESL programming. Information on health, particularly in relation to lead exposure, was identified as a need in both of these needs-analysis research projects. Therefore, an

ESL health literacy program focusing on lead abatement would address both needs in one program.

References
Feuerherm, E. (2016). Building a participatory program for Iraqi refugee women and families: Negotiating policies and pedagogies. In Feuerherm & Ramanathan (Eds.). Refugee Resettlement in the United States: Language, Policies, Pedagogies. (74-94). Bristol, U.K.: Multilingual Matters.
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Distribution of responsibilities will be as follows.

• Principal Investigator (PI): Emily Feuerherm is the PI for this study, meaning that she is ultimately responsible for reporting to the Institutional Review Board (IRB) and Community Ethics Review Board (CERB) regarding any changes to the protocol or adverse events. She is also responsible for developing and administering the ESL Health Literacy curriculum and keeping the data secure and confidential.

• Co-Investigators GCHLC President and Staff: San Juana Olivares (President) and Bianca Ramirez (formerly a research assistant) are the co-investigators responsible for recruiting, onboarding, and exiting participants from the ESL health literacy program. They will also be responsible for interpretations and translations for the program and organizing food distribution during the program.

• Co-Investigator ACE Community Health: Bonnie McIntosh is the co-investigator responsible for the community-based participatory research process with the community advisory group. She is also responsible for consulting on health-related curricular issues and identifying/disseminating the research findings to relevant stakeholders in health fields.

• UM-Flint research assistant Olusola Atoyebi: Support for programing, data analysis, and technology.

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Danielle Hankerd and Reese Gunn have completed the Teaching English to Speakers of Other Languages (TESOL) certificate at UM-Flint and have studied Spanish for at least 6 years, reaching an advanced level of Spanish language fluency. Danielle and Reese are both native speakers of English and have experience teaching English to speakers of other languages online. Because of these qualifications, they will join the study team to support the Health and ESL Literacy Program as teaching assistants. Because research subjects (students) will be joining the program with various levels of English fluency and literacy, the program needs to be accessible to multiple levels of fluency/literacy. Reese and Danielle will help the PI address the learning needs of the participants using differentiated instruction and translingual pedagogies. These are instructional methods that use the native language (Spanish) to teach the second language (English) at an appropriate level to what the research subject/student already knows and wants to learn. For this reason, knowledge of TESOL and Spanish are necessary qualifications that these researchers bring to the study.

5-1.5* Methodology: Describe the design and procedures to be used to accomplish the specific aims of the study. Describe the advantages of any innovative methodologies.

Participants will be given an informed consent document to sign or to verbally agree to with a witness. After providing informed consent, the participant will complete a survey/test consisting of questions that focus on socio-demographic characteristics, knowledge of lead exposure prevention behaviors, adherence to lead exposure prevention behaviors, health literacy level, and use of community health services. Validated and reliable questions from the following surveys will be used: (1) Chicago Lead Knowledge Test questionnaire (Mehta, 1998), (2) The National Health and Nutrition Examination Survey (CDC, 2016), (3) The Behavioral Risk Factor Surveillance Survey (CDC, 2018), and (4) FLIGHT/VIDAS health literacy test (Ownby, 2015). The survey/test does not include the collection of any biological specimens, and the participants will be informed that they can skip any questions they do not want to respond to. The participants will be randomly assigned into one of two intervention sessions (ESL health literacy classes) lasting 7 weeks. The two sessions will not be held simultaneously, but will be held one after the other. This allows for a waitlist model of statistical design. The participants in the second session will re-take the survey/test before the health literacy classes begin (meaning that they will take the survey/test one more time than the other group), and both groups will take the survey/test at the end of the intervention (the ESL classes). The survey will be administered by GCHLC staff, multilingually, in person, using a paper-based survey. Data will be entered into Qualtrics, a secure survey tool which can export data into various other programs such as SAS. Any paper-based documents will be stored in the locked file cabinet in the locked office of the PI. They will be destroyed after 5 years.
The setting of the ESL health literacy program will be Monday evenings at GCHLC. According to GCHLC, most of the Hispanic community in the area work day shifts or in restaurants, meaning that Monday evenings from 5:30-8:30 are the most convenient times for the target community. GCHLC is located on the East side of Flint, which is the neighborhood with the largest Hispanic population in the area, making it an ideal location for this population.
The methods used in the ESL health literacy program will require a new pedagogical approach. Previous curricula have largely used traditional ESL grammar textbooks where the teacher leads instruction and students practice writing by filling in the blanks. This curriculum would follow Santos et al. (2014), who describe a health literacy program using pedagogies for health literacy as practice. This pedagogy was shown to be successful for improving health knowledge and behaviors, as well as increasing the sharing of health information with friends, family, coworkers, etc. During the class, participants will be asked to reflect on their health knowledge and behaviors and how they have changed since starting the program. The PI's field notes will document this growth through regular reflection on the class. The PI's field notes will not include any names of participants, but will be reflections on the effect of the curriculum on student learning. The field notes will be kept as a digital file in the PI's secure, password-protected and duo-protected (two-factor authentication) Mbox and in the qualitative data analysis software MAXQDA for analysis purposes.
Secondary Aim: Use CBPR approach to evaluate the implementation of this community-based lead exposure prevention education course to ensure that the program is delivered as intended. The methods for this part of the research will include meeting notes from research meetings with the Co-Investigators, meeting minutes from advisory group meetings, feedback from the advisory group members in the form of questionnaires/surveys.
Qualitative data on CBPR approaches and learning outcomes used in this program will be analyzed using a grounded theory approach to thematic analysis (Glaser & Strauss 2017; Strauss 1987). An

iterative process will be used to link codes into categories, categories into themes, and themes into major themes. An interim report will be created based on these themes for feedback from community stakeholders in the advisory group. A final report will be prepared by the co-PIs and disseminated based on that feedback. Qualitative data will be managed and analyzed using the PI's MAXQDA software on her office computer which is in a locked office and is password-protected.
Timetable:
Fall 2018:
- Meet with full advisory group made up of community representatives from other Hispanic organizations, health organizations, educational organizations, and other non-profit organizations. Present the program, plan recruitment, and get feedback on the process.
- Begin recruitment campaign: online, social media, flyer distributions, etc.
- Trial run of the survey/test and curriculum with Co-Investigators, staff at GCHLC, and volunteers from the advisory group.
Winter 2019:
- Participants receive informed consent and complete the survey/test before placing into one of the 2 sessions of the ESL Health Literacy classes
- ESL health literacy classes are held one after the other
- Meet with advisory board to report progress after the first ESL health literacy class
Spring/Summer 2019:
- Data analysis and development of reports
- Meet with advisory board to assess program and CBPR practices

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Recruitment
Recruitment will occur using social media (Facebook and Instagram) which has a link to the UMHealthResearch.org website and San Juana Olivares' phone number. We use the message templates in UMHealthResearch.org with Spanish translation for interaction with potential participants virtually. The PI responds to all messages and connects interested participants with GCHLC staff (San Juana Olivares) for screening and enrollment. Additionally, recruitment occurs directly by GCHLC staff by sharing the social media post directly with their clients. Lastly, recruitment occurs through word-of-mouth: There is a one-time $20 bonus for any participant who enrolls a friend in the program. Each enrollee is asked how they heard about the study and if they say it's from another person enrolled in the program, then that person will get the one-time $20 bonus.

Olivares will pre-screen participants and arrange for enrollment when contacted by any of the above means. Olivares will screen Interested participants to ensure they are 18 or over, primarily Spanish-speaking (Hispanic or Latinx ethnicity), living in or around Flint. Screening (eligibility) is tracked using REDCap. Olivares will enter screening information and contact information and the participant's name to the google sheet and give the participant their identification number for the research study. IDs will be a letter (a or b, according to the session they join) and a number (1, 2, 3 given as participants enroll). This linking google sheet will be only accessible to the PI and Olivares, saved on the UMICH google drive.

Enrollment
Olivares will screen participants and send the zoom link for enrollment. Olivares will also provide support for those who are unfamiliar with. Enrollment into the program will occur one-on-one with a staff member at GCHLC using zoom (either Bianca Ramirez or San Juana Olivares, both of whom are PEERRS certified and part of this research study). Participants will be told at this time when the educational program will begin. Because it is online, we will not need to give them bus passes or provide childcare. We will provide the zoom link. Once participants have been enrolled, GCHLC staff will arrange with them the best way to receive their compensation: either delivered to their homes or picked up at a designated time and place outdoors with social distancing maintained.

Participants enrolled in the health literacy program will receive the following compensation
• Enrollment and survey = $20
• Enroll a friend = $20 (one-time)
• Complete the program (minimum of 4 out of 6 classes) and final survey = $50
The funds will be distributed in cash and HSIP has agreed to let us distribute these funds without gathering names and addresses. The compensation will be offered for social distance pick up or delivery by Olivares. A hard copy of the consent form will be given at this time, also.

The program
The program will last 8 weeks (not 7 as listed above) if you count week 1 as the survey, followed by weeks 2-7 of intervention for the educational program, and week 8 would be the post-survey. We are not sure we'll have enough participants for a waitlist design, and believe that it would be harmful to ask some participants to wait longer than they already have for the program. The community has been eager to enroll and has been asking when they can start classes, so delaying would cause harm to these families. Instead, we'll allow participants to enroll on a first-come first-served basis. We will allow the first 25 people to sign up to take the first session, and the remaining 25 to attend the second session. No one can attend both sessions.

Each session will be the same, using the same curriculum and structure. The program will be on Monday evenings and last 6:00 until 8:00, not 5:30 - 8:30, since we're moving to an online format. Our timetable has shifted so that we will enroll participants in the winter of 2021, if the amendment is approved.

Some participants may be undocumented, but we are not asking about this information so it is unlikely we'll know if they are documented or undocumented. The consent process and surveys will not include information that could be identifiable or link the responses to the person. The linking document will only include information the participant feels comfortable providing (this could mean they use pseudonyms, a family member's phone number or address, or other information to hide their true identity). The linking document will only be accessible to the PI and Olivares of GCHLC, saved on UMICH google drive. We are also supported by a CoC through NIH.

The program will be moved online rather than in-person in order to protect participants' health during the COVID-19 pandemic. This means that we will not use GCHLC's brick-and-mortar location to hold the sessions. Instead we will use Zoom for virtual synchronous meetings in order to enroll, consent, and survey participants in week 1, and conduct the lessons in week 2-7, and for the post-survey in week 8.

Because we'll no longer be providing dinner and childcare as part of the program, we will instead be supplying boxes of fresh food through Flint Fresh. The boxes of food will be part of the compensation for the program and align with the content of the educational program (2 weeks devoted to nutrition). The delivery system will be the same for this as for the other, cash-based compensation: Olivares will either deliver the food boxes or will arrange a time and place for the boxes to be picked up outdoors in

a social-distanced way.

If participants stop attending the program Olivares will follow up with them to assess why they have chosen to stop coming. This is important because if the curriculum is the problem (it's too advanced or not advanced enough) we will need to know that in order to make curricular changes to make it more adjusted to the appropriate level for the participants. Olivares will report the findings orally to the PI so that curricular adjustments can be made.

We have removed the secondary aim regarding survey research with our advisory board. We are submitting an exempt IRB protocol for this separate research agenda.

Data tracking and security
MICHR supports REDCap, so we will use that survey tool instead of Qualtrics. Survey responses will be added directly into REDCap by the GCHLC staff member administering the survey. The need for paper has been removed by moving the program online. The enrollment, consent, and survey questions will be read by a staff member of GCHLC in the language of the participants' choice: Spanish or English. The pre- and post-surveys will include the participants' ID numbers so that they can be linked from pre- to post-survey.

REDCap data will be de-identified. Following the program, data will be stored in Deep Blue, UM's data repository. The google sheet linking participants' IDs to their name and contact information will be saved on UM's google drive and shared only between the PI and Olivares. The research is supported by NIH through MICHR, so includes a CoC to protect participants' identities.

MAXQDA is an approved software for use on university computers. The PI has this software on her university computer and will only use the software to keep notes using de-identified ID numbers if/when referencing research subjects. The notes will track the program and curriculum development/implementation, and will not include individual participants.

Revised timetable:
Winter 2020:
• Meet with community advisory group for review of plan (pre-pandemic)
• Postpone program because of pandemic
Spring/Summer/Fall 2020
• Re-assess plan in the wake of the pandemic
• Explore capacity for online programming
Winter 2021
• Meet with community advisory group for review of plan (moved to online)
• Recruit, enroll, and obtain informed consent
Spring/Summer 2021
• Programs 1 & 2 run
Fall 2021
• Data analysis
• Meet with community advisory board to assess program and review data

The program will follow the original curriculum outlined below:
Week 1: Take survey
Week 2: Is my water safe? Describe experiences, identify health needs, develop goals for the program. Language goals include asking questions, using tenses, basic health vocabulary
Week 3: Testing water: How to get and use free water tests and filters. Language goals include vocabulary for testing water, giving and following directions using the imperative and modals
Week 4: Blood-lead test: When where and how to get tested for lead, managing health after lead exposure, making appointments and talking with health professionals. Language goals include vocabulary for health providers, making appointments, writing your family health history
Week 5: Nutrition: Identify healthy and unhealthy foods, reading food labels, plan for healthy eating. Language goals include nutrition vocabulary, writing and sharing healthy recipes, sharing what food is available in your neighborhood
Week 6: Nutrition: Discuss food desserts and accessing healthy fresh food, evaluate barriers to good nutrition, discuss ways to overcome barriers and improve eating habits. Language goals include how to sign up for and follow programs to meet healthy eating goals.
Week 7: Review and assess goals and learning. Review grammar and vocabulary.
Week 8: Take survey

Other information
Our website contains information about the program and has links to UMHealthResearch.org for screening. The website is for communicating with our advisory board and potential stakeholders in the community. It will contain the curriculum. It can be accessed at https://healthesl.weebly.com/.
After someone expresses interest in the program (such as through UMHealthResearch.org) they will be screened to ensure they meet the criteria for enrollment. They will be connected with GCHLC to schedule their first meeting for enrollment into the program, consent to participate in the research study, and completion of the pre-survey. All this will happen in either English or Spanish, as the person chooses.

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We will hold the program twice a week on T/Th for 3 weeks based on feedback from our community advisory board and participants in the first session. This will make the total time for the program 5 weeks (week 1 and 5 will still be for the assessments).

5-1.6* Statistical Design: Describe the statistical design of the research study, including methods used to analyze data.

A pilot trial will be used with a waitlist design: this involves a process in which study participants are randomly assigned into treatment and control groups, where the control group is put on a waiting list to receive the intervention after the intervention group (Byrd-Bredbenner et al. 2017). The control group will take the survey and health literacy test three times (registration, first class, last class), while the intervention group will take the survey and test twice (registration, last class). To maintain randomization balance between the intervention and control groups, stratified randomization will first be used. That is, individuals will be identified based on important covariates (age group and sex) and then randomization will occur in each strata using random computerized allocation. The study will be powered to 80% with an alpha that is equal to .05. Random attrition from the program can allow for greater statistical power from a study in assessing the efficacy of the health literacy interventions in a community-based design. In order to both limit and understand the factors related to the attrition, GCHLC will send out follow-up messages to those who miss a class to inquire about reasons for non-attendance and remind participants of the cash incentive to rejoin the program ($50 to complete the program). Factors associated with attrition will be assessed using a logistical regression analysis, and correcting for this bias will follow Miller & Hollist (2007). Time to attrition may also be examined using a

Cox proportional hazard model, if there are enough measurement occasions derived from class attendance to assess levels of attrition and meet the proportional hazard assumption (Lin and Wei 2012).

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We will not be able to randomize for a waitlist design and so will register and place participants on a first-come, first-served basis. This will result in a study with a correlation rather than causation design.