

Community Health Through Engagement and
Environmental Renewal

Study Protocol & Statistical Analysis Plan

NCT04362475

August 3, 2023

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1. Background & Rationale

This study is designed to address social and health disparities in vulnerable urban neighborhoods through a dual-level intervention model. Prior work demonstrates that family dynamics and community environments contribute significantly to youth risk behaviors and adult well-being. The CHEER protocol combines a family-based behavioral intervention with neighborhood-level environmental renewal to test the effects on family communication, adolescent risk behaviors, and community cohesion.

2. Study Objectives & Hypotheses

Objectives:

1. To evaluate the impact of the Family Youth Intervention (FYI) on family communication, boundaries, and adolescent outcomes.
2. To assess the Environmental Social & Physical Intervention (ESPI) effects on neighborhood cohesion, engagement, and perceived safety.
3. To determine the combined effect of multilevel interventions on long-term public health outcomes.

Hypotheses:

- FYI will improve parent-child communication, reduce adolescent risky behavior, and strengthen family mission development.
- ESPI will increase social cohesion, improve neighborhood environments, and foster positive resident engagement.
- Together, FYI and ESPI will have synergistic effects on community health.

3. Study Design

Design: Multilevel intervention with a wait-list control.

Components:

- Family Youth Intervention (FYI): 8 modules delivered to caregivers and youth aged 11–16.
- Environmental Social & Physical Intervention (ESPI): Neighborhood revitalization through repurposed lots and community association engagement.

Timeline: For FYI: Baseline, 1-week post-intervention, and 6-month follow-up. For ESPI: Baseline, 12-month follow-up, and 24-month follow-up.

4. Study Population

FYI Eligibility: Families with children aged 11–16 living in target neighborhoods.

ESPI Eligibility: Adults residing in designated BUN neighborhoods.

Recruitment: Via schools, neighborhood associations, and community events.

5. Interventions

Family Youth Intervention (FYI):

- 8-module program, 2-hour sessions held on weekends.
- Topics: family communication, boundaries, shared values, and problem-solving.

Environmental Social & Physical Intervention (ESPI):

- Community-driven vacant lot repurposing.
- Neighborhood association partnerships.
- Activities include adopt-a-lot initiatives and shared space design.

6. Data Collection & Measures

Surveys: Administered at baseline, post-intervention, 6 months, and 24 months.

Tools: Qualtrics, encrypted devices for field collection.

Measures: Demographics, family communication, adolescent risky behaviors, neighborhood cohesion, safety perceptions.

7. Statistical Analysis Plan

Sample Size: Calculated to detect moderate effect sizes with adequate power.

Analysis: Repeated measures ANOVA, stratified analysis by intervention group.

Approach: Separate analyses for FYI and ESPI, plus combined impact testing.

8. Data Management & Confidentiality

All data stored in encrypted files on secure servers.

Password-protected access limited to approved research staff.

De-identified datasets used for analysis.

9. Ethical Considerations

Study approved by Institutional Review Board (IRB).

Informed consent from caregivers and assent from minors.

Risks are minimal, primarily associated with survey sensitivity and group discussions.

Participants informed of benefits, including improved family communication and community engagement.

10. Dissemination Plan

Results shared with participants, community associations, and stakeholders.

Findings presented at public health conferences and published in peer-reviewed journals.

Community feedback sessions will ensure participants benefit from results.



Office of the Institutional Review Board for Human Use

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701 20th Street South
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APPROVAL LETTER

TO: Walker, Jeffery T

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)
IORG Registration # IRB00012550 (IRB 03)

DATE: 09-Mar-2022

RE: IRB-300004617
IRB-300004617-007
Community Health through Engagement and Environmental Renewal (CHEER)

The IRB reviewed and approved the Personnel Amendment submitted on 08-Mar-2022 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review: Expedited
Expedited Categories: 7
Determination: Approved
Approval Date: 09-Mar-2022
Expiration Date: 08-Mar-2025

Although annual continuing review is not required for this project, the principal investigator is still responsible for (1) obtaining IRB approval for any modifications before implementing those changes except when necessary to eliminate apparent immediate hazards to the subject, and (2) submitting reportable problems to the IRB. Please see the IRB Guidebook for more information on these topics.

The following populations are approved for inclusion in this project:

- Children – CRL 1

Documents Included in Review:

- IRB PERSONNEL EFORM

To access stamped consent/assent forms (full and expedited protocols only) and/or other approved documents:

1. Open your protocol in IRAP.
2. On the Submissions page, open the submission corresponding to this approval letter. NOTE: The Determination for the submission will be "Approved."
3. In the list of documents, select and download the desired approved documents. The stamped consent/assent form(s) will be listed with a category of Consent/Assent Document (CF, AF, Info Sheet, Phone Script, etc.)

CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: **Community Health through Engagement and Environmental Renewal (CHEER)**
Environment: Social and Physical Intervention (ESPI)

UAB IRB Protocol #: IRB-300004617

Principal Investigator: Susan Davies, PhD

Sponsor: Centers for Disease Control and Prevention

Sponsor Protocol #: U48DP006404

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described below.
Purpose	The purpose of the study is to improve the run-down appearance in the neighborhood by turning vacant lots into places that community members can gather and be proud.
Duration & Visits	You will be in this study for three years.
Overview of Procedures	This study will include completing a baseline survey and two follow-up surveys.
Risks	The most common risks include psychological stress from neighborhood discussions and completing surveys.
Benefits	You will benefit from participating in this research because the neighborhood will look better, you will have places to interact with others in the neighborhood, and the neighborhood will be improved overall.
Alternatives	If you do not want to take part in the study, you do not have to take part in it.

Purpose of the Research Study

We are asking you to take part in a research study. The purpose of this research study is to encourage social interactions to enhance neighborhood unity and confidence. You will help us target negative factors in the neighborhood (e.g. vacant and overgrown lots) that impact social connectedness and physical appeal of the neighborhood. You are being asked to join because you live in the neighborhood and can tell us how best to address the neighborhood's needs. There will be 500 participants enrolled.

Study Participation & Procedures

If you agree to join the study, you will complete surveys at three interview sessions.

- You will complete a baseline survey that will take about 60 minutes.
- You will complete two 30-minute follow-up surveys about a year apart
- You will also be invited to attend meetings in your neighborhood to discuss which vacant lots to improve and how, and what neighborhood activities should be planned.
- If you are entered and complete the entire study, you will be in the study for three years.

Risks and Discomforts

You may have some psychological stress that may arise from being a part of neighborhood discussions on which vacant lots to address and what to do with that vacant lot; however, this discomfort is common during group decision making.

Benefits

This study may help us better understand how neighborhood upkeep can influence social connectedness and interactions among neighbors and reduce negative factors within the neighborhood such as crime. You will benefit from participating in this research because the neighborhood will look better, you will have more places to interact with others in the neighborhood, and the neighborhood will be improved overall.

Alternatives

The alternative is to not participate in this research study.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- the Centers for Disease Control and Prevention (CDC)
- the Office for Human Research Protections (OHRP)

The information from the research may be published or presented for scientific purposes; however, your identity will not be given out in those publications. A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation and Withdrawal

It is your choice whether or not to take part in this research study. There will be no penalty if you decide not to take part. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this study at any time. Contact any member of the study staff if you want to withdraw from the study.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation

You will be paid \$30 for completing the baseline interview and \$20 for each of the follow-up interviews in Years 2 and 4. Payments will be made at the end of each study visit. The maximum total payment you may receive is \$70. If you do not finish the entire study, you will be paid for your participation up to the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Questions

If you have any questions, concerns, or complaints about the research, please contact the study doctor. You may contact Dr. Susan Davies at 205-975-5448.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or have had read to you) the information provided above and agree to participate in this study. You will receive a signed copy of this consent form.

Signature of Participant

Date

Signature of Person Obtaining Consent

Date

**CONSENT FORM TO BE PART OF A RESEARCH STUDY
(For Intervention)**

Title of Research: **Community Health through Engagement and Environmental Renewal (CHEER)**
Family-Youth Intervention (FYI)- Intervention

UAB IRB Protocol #: IRB-300004617

Principal Investigator: Susan L. Davies, PhD

Sponsor: Centers for Disease Control and Prevention

Sponsor Protocol #: U48DP006404

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to improve coping skills that will make family interactions better.
Duration & Visits	You will be in this study for one year and have three interview sessions.
Overview of Procedures	This study will include three interview sessions and completing an 8-module educational series that focuses on family connectedness through teaching parental coping skills and childhood resilience.
Risks	The most common risks include psychological stress while discussing sensitive topics with caregiver.
Benefits	You may benefit by learning new skills that will increase family relationships.
Alternatives	If you do not want to take part in the study, you do not have to take part in it.

Purpose of the Research Study

We are asking you to take part in a research study. The purpose of this research study is to test a family strengthening intervention with caregivers and one child. The 12 module intervention is designed to improve family functioning through increasing coping and communication skill of the parents and to examine resilience in the child. There will be 400 parent-child pairs participants enrolled at UAB.

Study Participation & Procedures

The parent-child pairs will be asked to complete assessments during three interview sessions. You will also be asked to complete the educational activities designed for the month. If you agree to join the study, you will complete surveys at three interview sessions and a 8-module educational series.

- You will complete a baseline survey that will take 90 minutes.
- You will complete two 90-minute follow-up surveys. One follow-up 5 months after the baseline and the other one year after your first follow-up.
- You will also complete monthly educational activities that are delivered through text messages and a website.
- If you are entered and complete the entire study, you will be in the study for one year.

Risks and Discomforts

You may have some psychology stress that may arise from talking with your child about sensitive topics and your child discussing their feelings and conflicts; however, this discomfort is common during parent-child conversations about sensitive topics. The 8-module educational series is designed to teach you techniques to deal with these conversations. There is a risk of breach of confidentiality; however, we have taken measures to ensure that this possibility is minimal.

Benefits

This study may help us better understand how parents and children communicate and interact to increase family connectedness. You will benefit from participating in this research because you will learn skills that will help you interact with your child(ren).

Alternatives

The alternative is not participate in this research study.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Centers for Disease Control and Prevention (CDC)
- the Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your identity will not be given out in those publications. A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this study at any time. Contact any member of the study staff if you want to withdraw from the study.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation

If you participate in the FYI study, you will be paid \$ \$25 ($\$25 + \$25 + \$25 = \75) for each interview and your child will be paid \$25 for each interview ($\$25 + \$25 + \$25 = \75). Payments will be made at the study visit. You will also have the opportunity to complete educational modules. You will be paid \$50 ($\$50 \times 8 \text{ modules} = \400) for each module that you complete. The total for completing this study is \$475 for parents and \$75 for child. If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Questions

If you have any questions, concerns, or complaints about the research please contact the study doctor. You may contact Dr. *Susan Davies* at 205-975-5448.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant 14 Years of Age and Older

Date

Signature of Parent or Guardian

Date

Signature of Person Obtaining Consent

Date

CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: Community Health through Engagement and Environmental Renewal (CHEER)
Family-Youth Intervention (FYI)

UAB IRB Protocol #: IRB-300004617

Principal Investigator: Susan L. Davies, PhD

Sponsor: Centers for Disease Control and Prevention

Sponsor Protocol #: U48DP006404

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described below.
Purpose	The purpose of the study is to improve coping and communication skills in order to improve family interactions.
Duration & Visits	You will be in this study for 1 year.
Overview of Procedures	This study will include 3 interview sessions where you complete surveys about family connectedness.
Risks	There are minimal risks to completing the surveys.
Benefits	You may not directly benefit from this study. However, this study will help us learn more about family connectedness.
Alternatives	If you do not want to take part in the study, you do not have to.

Purpose of the Research Study

We are asking you to take part in a research study. The purpose of this research study is to enhance parental coping and management of emotions to positively influence parenting practices and parent-child communication and to reduce family conflict and adolescent behavior. The parent-child pairs will be asked to complete assessments during three interview sessions. There will be 120 parent-child pairs enrolled at UAB.

Study Participation & Procedures

If you agree to join the study, you will complete surveys at three interview sessions

- You and your child will complete a baseline survey that will take about 90 minutes.
- You and your child will complete two 90-minute follow-up surveys; one follow-up survey approximately 5 months after the baseline and the other follow-up approximately 12 months later.
- If you complete the entire study, you will be in the study for 1 year.

Risks and Discomforts

There is minimal risk associated with completing the surveys.

Benefits

While you may not personally benefit from this study, the study may help us better understand how parents and children communicate and interact, in order to help us develop ways to increase family connectedness.

Alternatives

The alternative is to not participate in this research study.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- the Centers for Disease Control and Prevention (CDC)
- the Office for Human Research Protections (OHRP)

The information from the research may be presented or published for scientific purposes; however, your identity will not be given out in those publications. A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation and Withdrawal

It is your choice whether or not to take part in this study. There will be no penalty if you decide not to participate. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this study at any time. Contact any member of the study staff if you want to withdraw from the study.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation

If you participate in the FYI study, you will be paid \$25 for each of 3 interviews, for a maximum interview payment of \$75. Your child will be paid \$25 for each of 3 interviews, for a maximum interview payment of \$75. Payments will be made at the end of the study visit. If you do not finish the entire study, you will be paid for your participation up to the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Questions

If you have any questions, concerns, or complaints about the research, you may contact Dr. Susan Davies at 205-975-5448.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or have had read to you) the information provided above and agree to participate in this study. You will receive a signed copy of this consent form.

Signature of Participant 14 Years of Age and Older

Date

Signature of Parent or Guardian

Date

Signature of Person Obtaining Consent

Date

ASSENT FORM

TITLE OF RESEARCH: **Community Health through Engagement and Environmental Renewal (CHEER)**
Family-Youth Intervention (FYI)

IRB PROTOCOL: IRB-300004617

INVESTIGATOR: Susan Davies, Ph.D.

SPONSOR: Centers for Disease Control and Prevention

The investigator named above are doing a research study.

These are some things we want you to know about research studies:

We are asking you to be in a research study. Research helps us learn new things. This research study will test new ideas about how families communicate.

Whether or not to be in this research is your choice. You can say Yes or No. Whatever you decide is OK.

Why am I being asked to be in this research study?

You are being asked to be in the study because you live in one of the four CHEER neighborhoods in the study (North Titusville, South Titusville, Belview Heights, or Rising-West Princeton) and are between the ages 11 and 13.

What is the study about?

This study aides parents and their 11-16 year old children in reducing stress and coping with difficult situations.

What will happen during this study?

If you agree to be in this study, you

- Will complete a survey at three different times, which will take about 90 minutes each time.
- May have to complete educational activities if selected.

What are the good things that might happen?

People may have good things happen to them because they are in a research study. These are called “benefits.” One benefit might be that the conversations you have with your parent will make it easier for you to talk with them when you need to. This might make you feel more connected to your parent or it may not make you feel more connected. The researchers hope to learn about the best way to help families feel more connected.

What if I don’t want to be in this study?

You do not have to be in the study if you do not want to.

Who should I ask if I have any questions?

If you have any questions about this study, you or your parents can call Dr. Susan Davies at (205) 975-5448.

Do I have to be in the study?

No, you do not have to be in the study. Even if you say yes now, you can change your mind later. It is up to you. No one will be mad at you if you don't want to do this.

Signatures

Before deciding if you want to be in the study, ask any questions you have. You can also ask questions during the time you are in the study.

If you sign your name below, it means that you agree to take part in this research study.

Your Name (Printed)

Age

Your Signature

Date

Signature of Person Obtaining Consent

Date

Signature of Witness

Date