

« SCT 45th Annual Meeting | Boston 2024

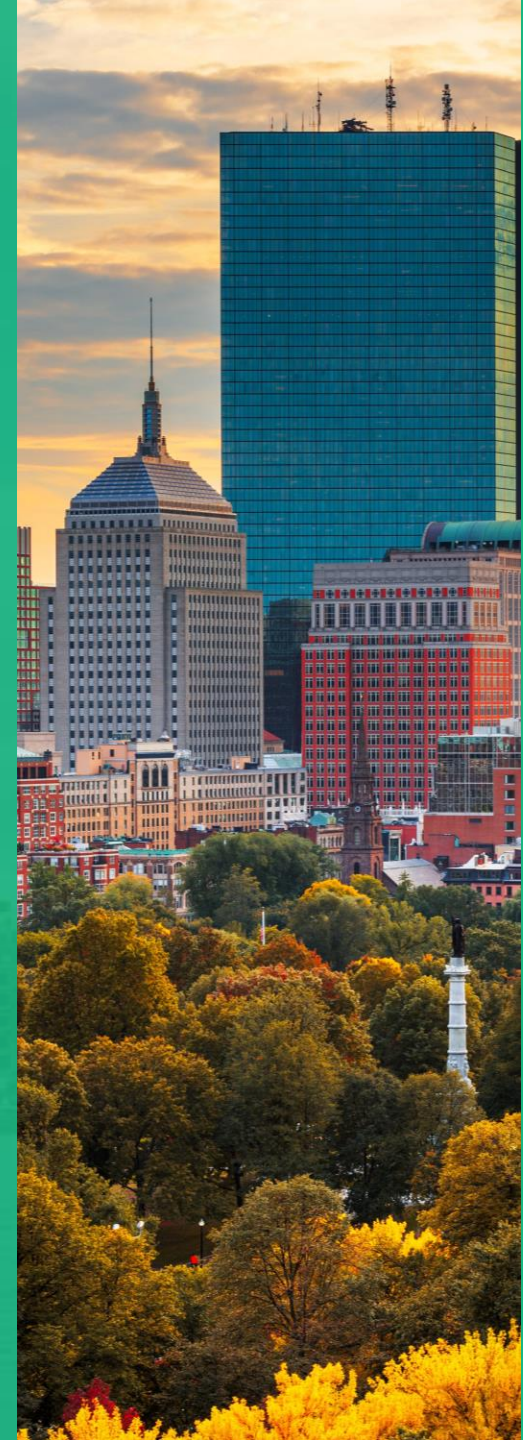
Considerations in Community-Based Clinical Trials

Key principles and groundwork
for conducting a community-based
clinical trial



Disclosures

The authors declare that they have no financial or non-financial conflicts of interest related to the content of this presentation.





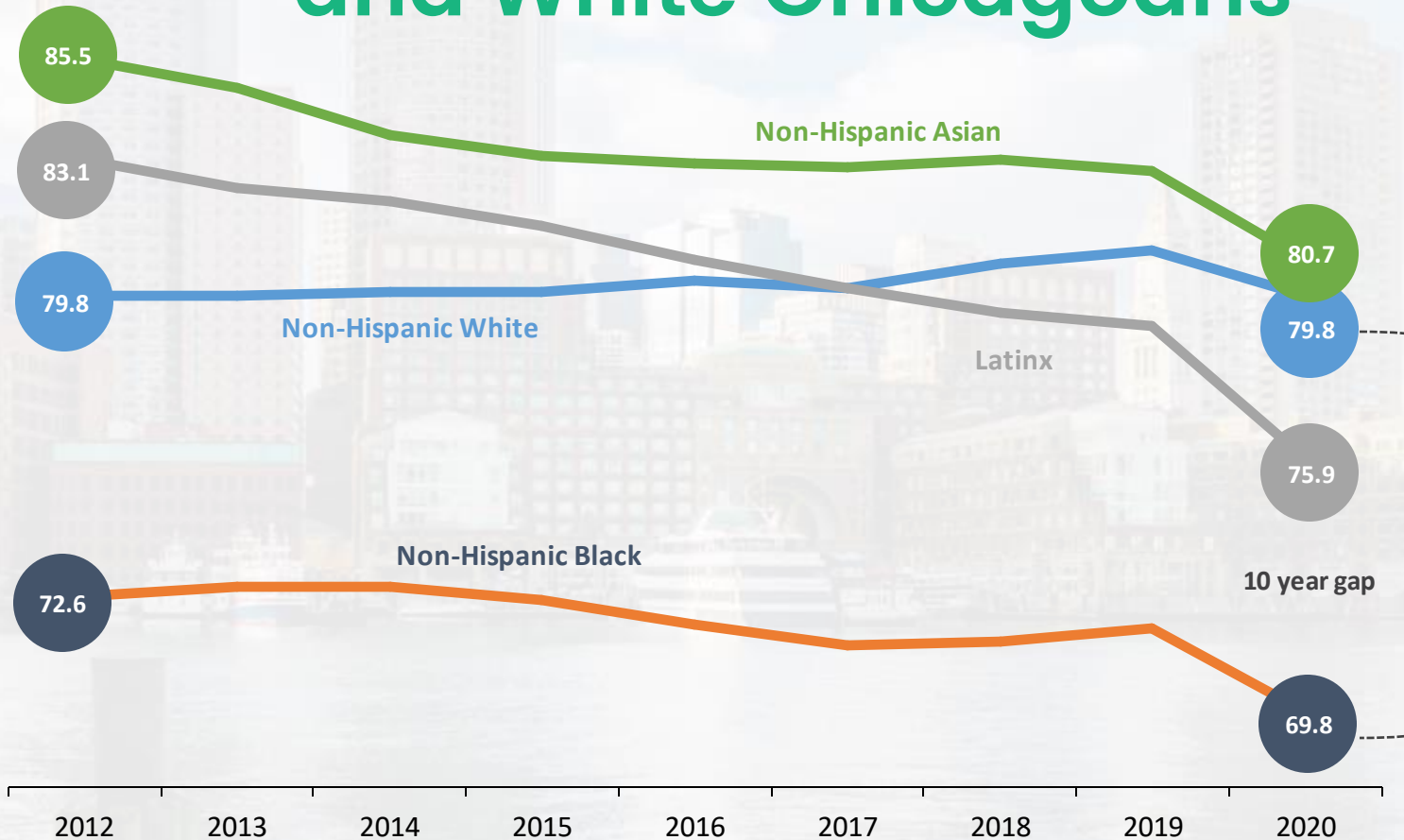
Elizabeth Lynch, PhD

Professor of Family and
Preventive Medicine

Key principles and groundwork for conducting a community- based clinical trial

Presenter

The life expectancy gap between Black and White Chicagoans



Mirrored in segregated urban areas all over the country

10 year gap

Causes of Gap



Implications

- **Bring chronic disease interventions to the community**
 - **Key health-related decisions are made outside of medical setting, where people live, work, pray and play**
- **Partner with trusted community leaders**

Why and How of Community Engagement

Why partner with the community?

- Increases trust and engagement
- Improves relevance of the research
- Cultural sensitivity of intervention
- More likely to be sustainable

Levels of Engagement	
Shared Leadership	Researcher and community partner are equal partners
Collaboration	Researcher runs the study with input from community
Consultation	Researcher consults with community about some aspects of study
Outreach	Researcher reaches out to community

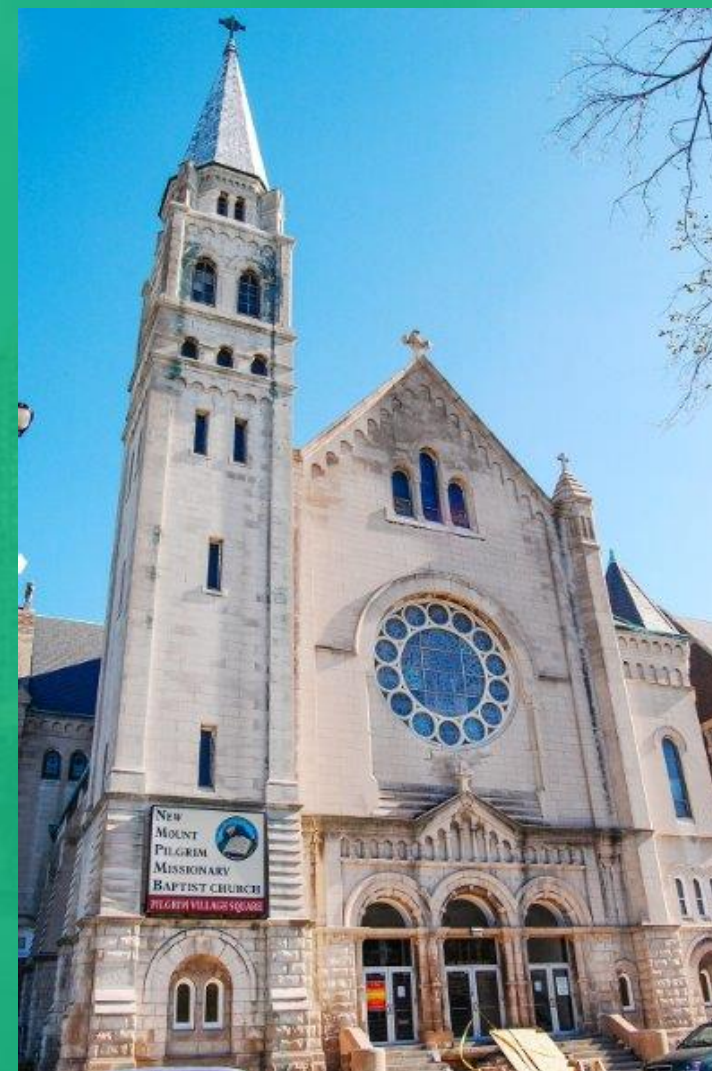
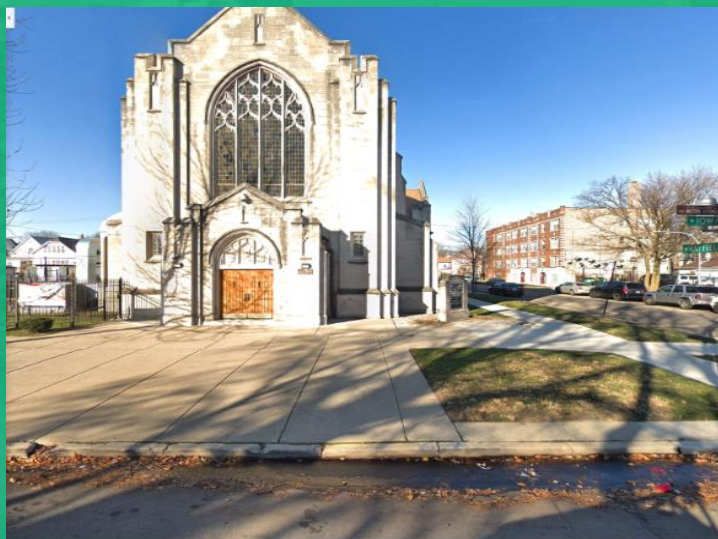
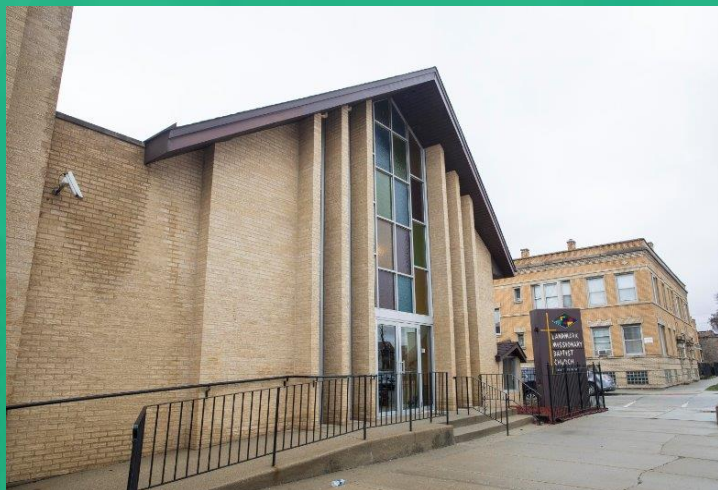
Challenges of Community Partnered Research

- Time needed to build trusted relationships
- Identification of viable community partner
- Vast cultural divide between academia and community
 - e.g. deadlines, methodological requirements (e.g. control groups); operational challenges
- Studies end (along with funding)

« SCT 45th Annual Meeting | Boston 2024



A unique community-academic partnership blending wisdom and faith with scientific knowledge to improve the health and well-being of members of the African American community.



Structure of the Alive Faith Network



100+ churches currently in network



Health programming provided to all faith congregations (and community)

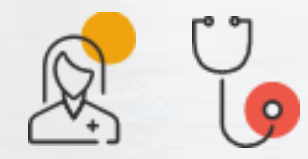
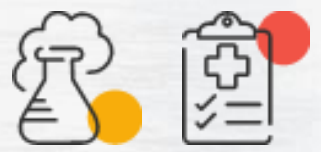
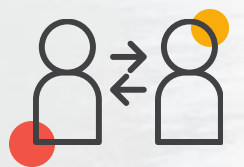
Interface for seeking funding and building community partnerships

Funders

Community Partners

Researchers

Health Care Institutions



How the AFN addresses challenges

- Relationship building is ongoing across studies
- Pastors are strong, trusted leaders in the community
- Trust builds patience to manage differences in expectations
- Programming and benefits are offered outside and beyond studies

We designed church-based interventions to decrease this gap

- 33% of the black-white life expectancy gap is due to conditions related to high blood pressure

- Heart disease
- Stroke
- Kidney disease



- 40% of conditions can be reduced by physical activity, yet high levels of functional limitations in black adults, even at young ages



« SCT 45th Annual Meeting | Boston 2024



Cluster Randomized Trial of a Church-based Intervention to Improve Physical Function in African Americans with Functional Limitations

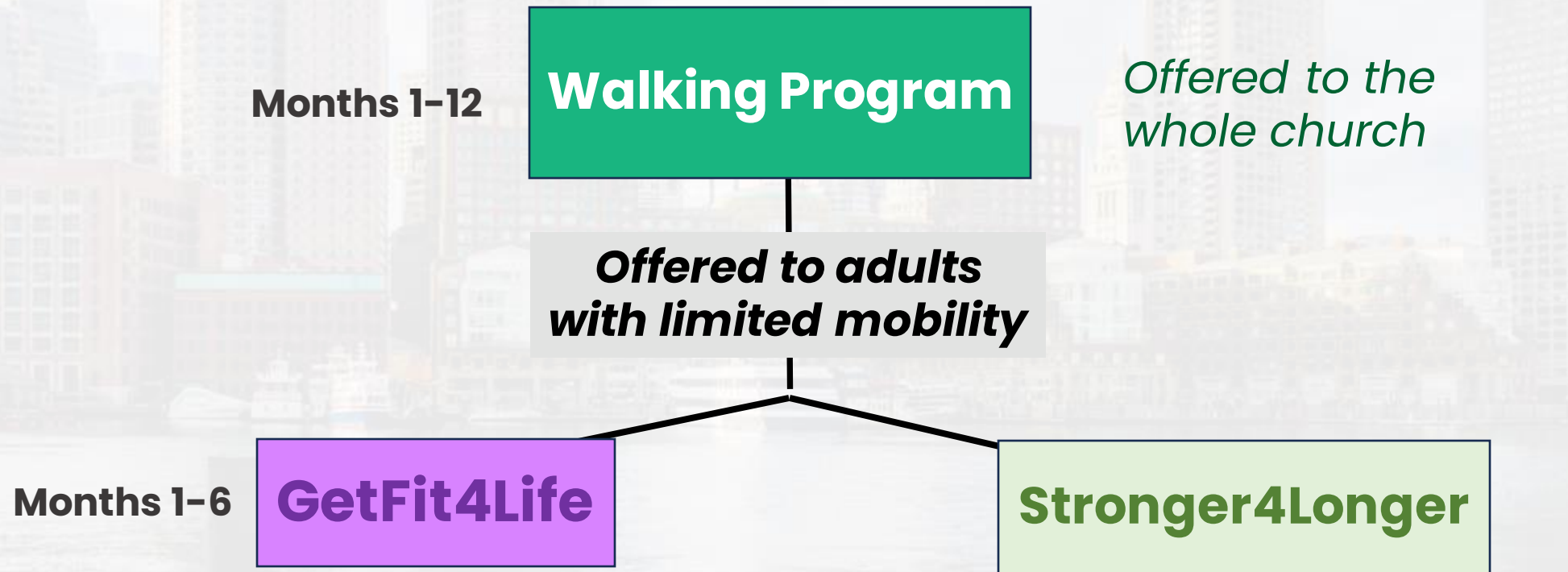
32 churches



The Keep it Movin' Program – 12 months

Study participants: Members of Black churches who have limited physical function

Primary outcome: Change in physical function at 6 months



- Self-Guided GetFit4Life Exercise Guide

- 24 weekly 90-minute group exercise classes held at church

« SCT 45th Annual Meeting | Boston 2024



Abundant
Living

Cluster Randomized Trial of a Church-based Intervention to Reduce Blood Pressure in African Americans with Uncontrolled Blood Pressure

34 churches

SCT 45th Annual Meeting | Boston 2024

The Abundant Living Program

Study participants: Members of Black churches who have uncontrolled blood pressure

Primary outcome: Change in systolic blood pressure at 6 months

Churches are randomized to:

INTERVENTION ARM

COMPARATOR ARM

Heart 2 Heart Program

Money Smart Program

OFFERED TO WHOLE CHURCH:

FOR STUDY PARTICIPANTS ONLY:

OFFERED TO WHOLE CHURCH:

MONTHS 1-6

- 24 1-hour virtual group sessions on heart healthy lifestyle & BP education
- 12 Bible Studies led by church pastor

- 1-on-1 Community Health Worker (CHW) assistance with BP management
- Remote BP monitoring

- 14 1-hour virtual group sessions on Financial Education
- 12 Bible Studies led by church pastor

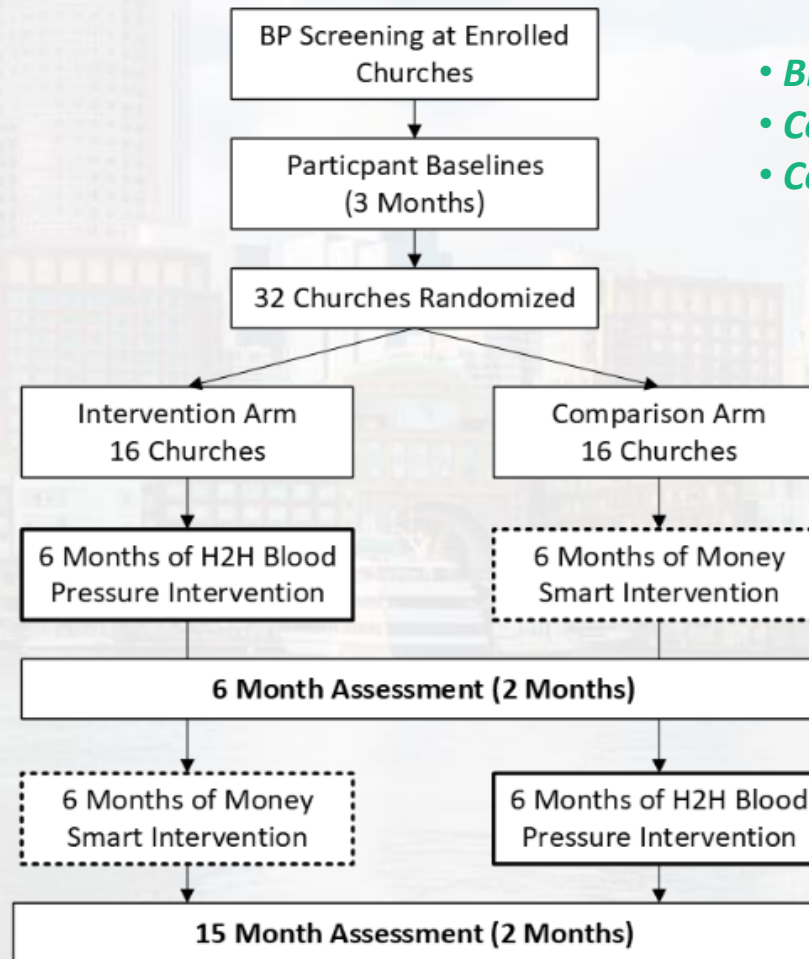
MONTHS 7-12

Money Smart Program

Heart 2 Heart Program



Study Design



- *Blinding to study hypothesis*
- *Control for community engagement process*
- *Comparator of value to community*

Cartwright, Cont Clin Trials, 2023



Steve Epting, MA
Co-Director
Alive Faith Network



LaDawne Jenkins, MS
Co-Director
Alive Faith Network

Importance of Community Engagement

Presenters

The Alive Faith Network

Foundational Pillars

Clergy Wellness

Programs to support the overall health and well-being of Pastors.

Community Health Ministry

An advisory council of AFN church members to help prioritize health issues/concerns and serve as a voice of the community

Research

Community-based Participatory Research Partnership with churches and community to address health inequities and improve the health and well-being of the African American community.

Partnership Development Process

Engage pastors
through Clergy
Wellness
Programming



Pastors engage
churches



Collaboratively
develop
and implement
programs



« SCT 45th Annual Meeting | Boston 2024

Engagement

The beginning of all relationship is trust!

Engagement and Trust Building

One network, many programs



Caring for the Caregiver

- 60 faith leaders took part in annual Soul Care retreats
- 115 faith leaders participated in mental resilience workshops
- 125 Faith leaders participated in COVID-19 vaccination event
- >250 faith leaders participated in Faith forums/lunch and learns



Engagement and Trust Building

One network, many programs



Empowering the Community

- Covid-19 tests were administered alongside Covid-19 education from a community health worker and nurse; SDOH screenings and referrals to the community
- Train church Health Ambassadors to provide direct service referrals through a community resource platform
- Developed monthly AFN newsletter
- Monthly Thrive Alive Health Talks for the Whole Community (>2000 views)

**THRIVE
ALIVE**

HEALTH TALKS FOR THE WHOLE COMMUNITY

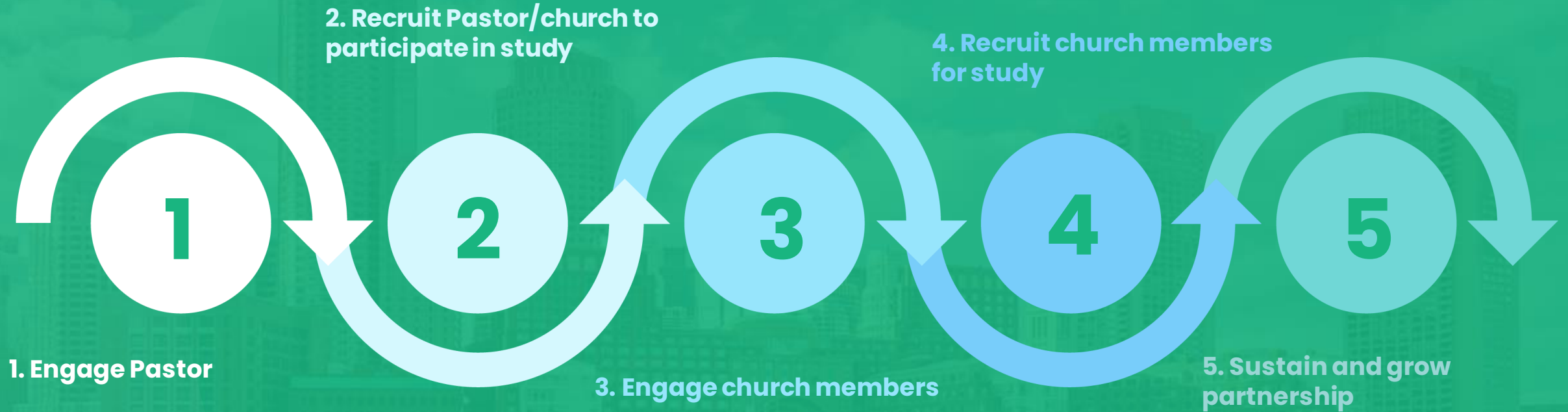


SUBSCRIBE



SHARE

Episode #1: What Does Health Mean to You?
A Conversation with Nurse Jazmine



Engagement and Recruitment Process Flow

« SCT 45th Annual Meeting | Boston 2024

Community Engagement and Recruitment



Community Recruitment Model

How to focus on the whole church,
not just on the study participants?
How is this done in the churches?

Trust

- Building trust with the community, which is the first phase of engagement and ideally starts long before the initiation of a study.
- Trust requires consistent presence in the community, even outside of the context of a particular research project.

Community Learning

- This allows the community to gain more understanding about their own health and how it affects the larger community.

Personal Responsibility

- This stage offers the necessary discipline and personally designed steps that lead to better health outcomes.

« SCT 45th Annual Meeting | Boston 2024

Recruitment is a Trust Process

Partnership Structure to Support Research Projects



Research Team
Principal Investigator
Project Coordinator
Community Liaison
Research Assistants



Rapid Community Engagement and Church Recruitment

Engagement	Feasibility Assessment	Readiness Planning
Invite pastors to info session	Feasibility survey reviewed by staff	Staff decides church eligibility
Hold information session	Stakeholder meeting scheduled	Communication and Planning meeting
Send Feasibility survey	Stakeholder meeting held (key church members attend)	Contract sent to church
Send program information (budget, etc)	Church wants to move forward	
Send job description for coordinator	Site visit	
	Church identifies coordinator	

Rapid Community Engagement and Church Recruitment

Training	Screening	Intervention and Data Collection
Coordinator Study training	Pastor announces program in church	Coordinator attends intervention sessions and takes attendance
Coordinator HIPAA and CITI training	Coordinator announcement and study video in church	Coordinator reminds participants to attend sessions
Pastor/Coordinator Research 101	Staff member attends church service	Coordinator schedules data collection visits
Technical training to use Study website	3 weeks of church screening (Sundays only)	
	Baseline Assessment	
	Coordinator training on intervention	



Yolanda Cartwright, PhD, MS, RD

Research Manager | Instructor

Rush University Medical Center
Department of Family & Preventive Medicine

Challenges in Operationalizing Community- based Clinical Trials

Presenter

Limited Funding

- Time and resources needed for community engagement can strain budgets and timelines.
- Often need to leverage other resources to conduct studies.



« SCT 45th Annual Meeting | Boston 2024

Staffing Challenges

- Finding staff members with research and community engagement experience.
- Cultural sensitivity when recruiting for studies in underrepresented groups.





SCT 45th Annual Meeting | Boston 2024

Staffing Challenges

- Balancing roles and responsibilities
- Travel/logistics
- Safety
- Blinding
- Retention/Burnout

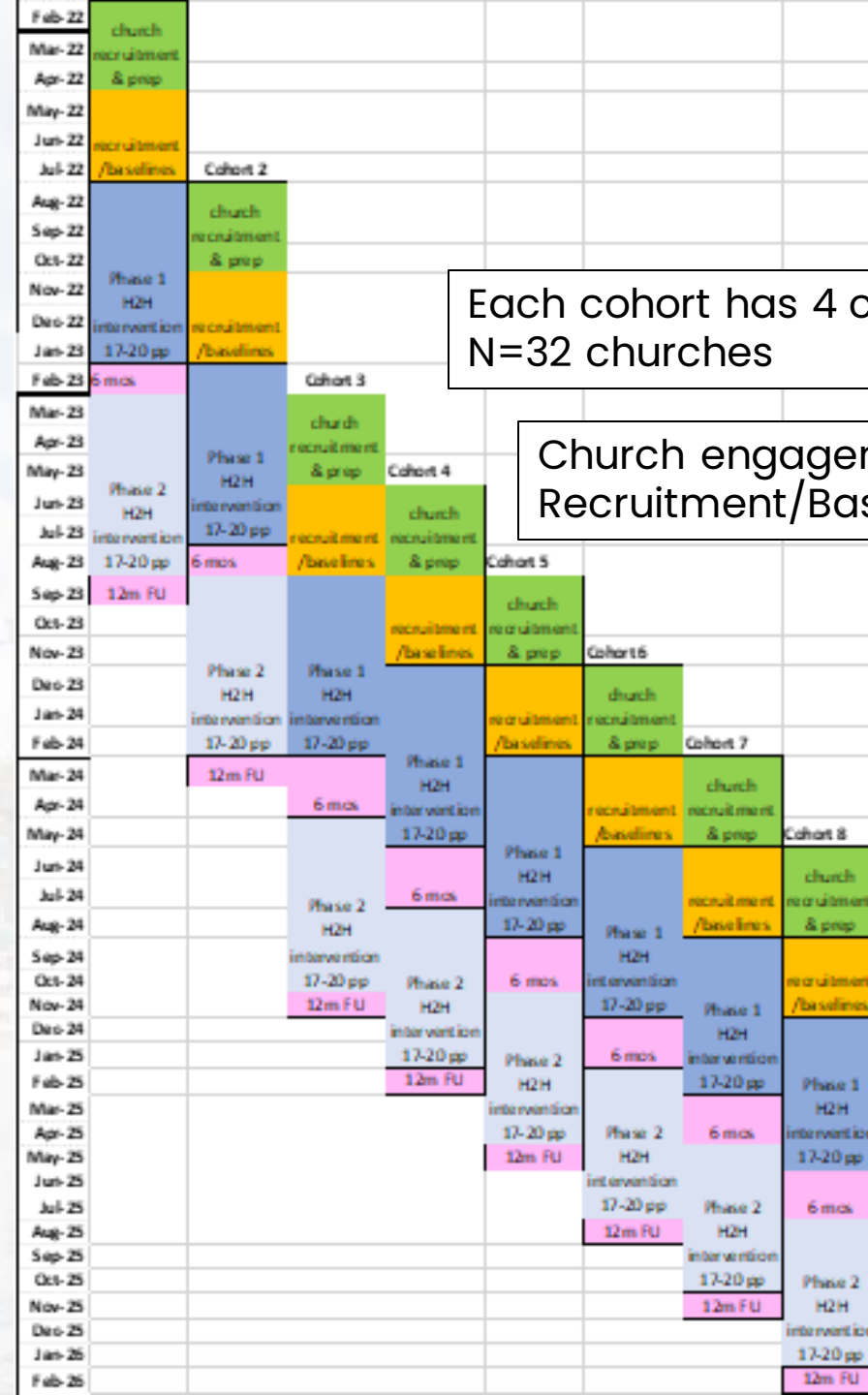
 RUSH

 ALIVE
FAITH NETWORK

SCT 45th Annual Meeting | Boston 2024

Abundant Living

Study Timeline



Each cohort has 4 churches
N=32 churches

Church engagement: 3 months
Recruitment/Baselines: 3 months

Hiring from within the community

- Fosters trust, authenticity, cultural sensitivity and promotes community ownership of research.
- Most community members are unfamiliar with the research process.
- Extensive training required to ensure privacy, confidentiality, and safety of participants.

Human Subjects Training

- Human subjects research training required for community members
- to be added to the study IRB



Completion Date 19-Jan-2023
Expiration Date 19-Jan-2026
Record ID 53760184

This is to certify that:

Jazmine Lampkin

Has completed the following CITI Program course:

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
Social/Behavioral Research Course
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Rush University Medical Center

Not valid for renewal of certification through CME.

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wf30df75e-7d20-47c1-9b21-ae478b07fa91-53760184

Project-specific Training

- Project-specific research training provided for Pastors, Church coordinators, and Community members of the research team
- 60-90 minutes virtual session

The Abundant Living Study

- Embedded within the Abundant Living Program is a research study.
- The goal of the study is to gather more evidence about the effectiveness of the Abundant Living Program at improving physical and financial wellness.
- We are aiming to recruit **at least 15 eligible members** from your church to participate in the study.

RUSH

What is Research?

- **Research** is a detailed study into a specific problem, concern, or issue using the scientific method. Research is a highly structured way to answer a question.
- In our study, we are assessing the effectiveness of the Abundant Living Program.
 - During our **pilot study** (done in 7 churches), we concluded that the program was effective.
 - Now we would like to show that the program is effective in a larger number of churches before disseminating it to more communities.
- We are documenting the process so that other communities can benefit from what we learn in your church.

RUSH

Rush University System for Health | 5/13/2024 12



Training on protocols

- Community members trained on logistics of study specific protocols



Community Support Team

- Community members of the research team assisting with blood pressure screenings

Paying Community Members



- Challenges with paying community members
- Delays in processing payments for non-employees
- Payments expedited using a third-party system

« SCT 45th Annual Meeting | Boston 2024

Logistical Challenges

- Coordinating staff schedules with availability of churches and community sites.
- Finding appropriate spaces for study activities and data collection



SCT 45th Annual Meeting | Boston 2024

Ethical Considerations

- Community environment less controlled than clinical environment
- Ensuring informed consent, confidentiality, and privacy protection requires constant consideration



Elizabeth Avery-Mamer

MS Statistician

Data Management and Analysis Center
Department of Family & Preventive Medicine
Rush University Medical Center

Application
of the Stages of
Implementation
to a faith-based
Clustered
randomized trial

Presenter

Data Management and Analysis Center
Department of Family & Preventive Medicine
Rush University Medical Center

Basic Steps in Study Enrollment

1. Study and AFN Pastors Recruit Church Pastors
2. Determine Feasibility of Study at Church
3. Train Church Coordinators and Pastors
4. Screen and Recruit Participants at Church

Our Challenges for Operations and Data Management In Church Based Studies:

1. Pre-Recruitment/Site Set-up and engagement is critical
2. Parts of the Study Protocol Happen outside of Study Staff Control/Observation
 - a. How do we make sure the protocol is being implemented?
 - b. How do we correct/change when protocol is done as planned?
3. Every Church is different, how do we capture that?

Borrow research from Implementation Science

Dr. Saldana's: The Stages of Implementation Completion[®] framework focuses on the 8 stages of implementation

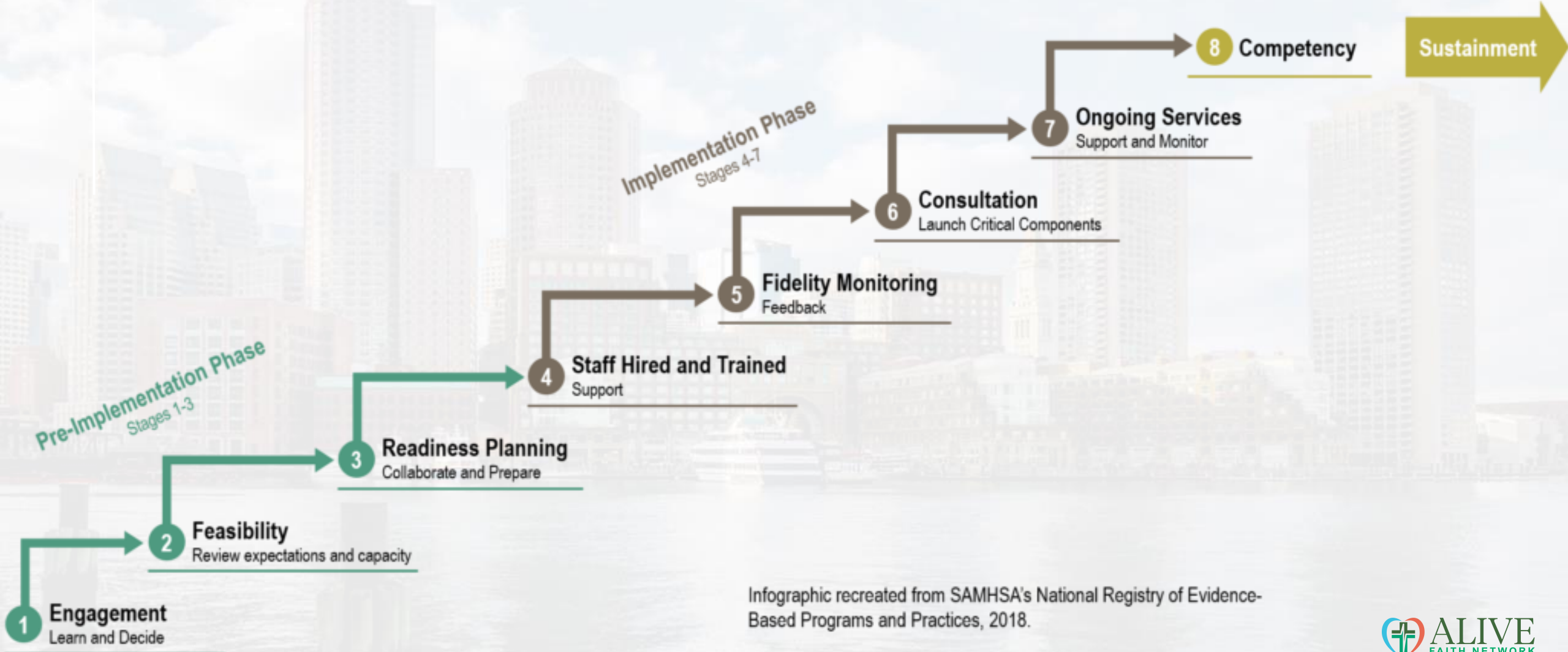
<https://www.oslc.org/sic/>

Chamberlain P, Brown CH, Saldana L. Observational measure of implementation progress in community based settings: the Stages of Implementation Completion (SIC). *Implement Sci.* 2011 Oct 6;6:116. doi: 10.1186/1748-5908-6-116. PMID: 21974914; PMCID: PMC3197550.

Saldana L, Chamberlain P, Wang W, Hendricks Brown C. Predicting program start-up using the stages of implementation measure. *Adm Policy Ment Health.* 2012 Nov;39(6):419-25. doi: 10.1007/s10488-011-0363-y. PMID: 21710257; PMCID: PMC3212640.

SCT 45th Annual Meeting | Boston 2024

The 8 stages of SIC Framework



Infographic recreated from SAMHSA's National Registry of Evidence-Based Programs and Practices, 2018.

Needed to Adapted SIC Our Framework

1. Five teams doing activities: investigators, community outreach team, study research team, data management , church coordinators & pastors
2. Every Church has distinct leadership, population, priorities and resources
3. Participant recruitment is a partnership between each church and study staff
4. Some activities are influenced by multiple teams

Intial Mapping of Activities to SIC and Tracking

Stage	Activities	How it was tracked
Engagement	Recruit Church Pastors Pastors Attend Information Session	community engagement staff used Excel and forms
Consideration of Feasibility	Feasibility Questionnaire Stakeholder Meetings Site Visit Identify Coordinator Determine Feasibility	community engagement staff used Excel and forms
Readiness Planning	Selection of Screening Dates Advertising Study via flyers Show Video Coordinator, Pastor and Study Staff Announcements	Not tracked well
Staff Hired and Trained	Coordinator Trained (Research 101, Study, CITI etc) Pastor Training (Research 101)	Citi and IRB portal
Fidelity Monitoring Consolation	Screening at Churches Return for Second Screening Intervention Tracking and Fidelity	Study Database
Ongoing Services	Outcomes assessments	Study Database

Where it Went Wrong

1. Pre-implementation activities
 - Using SIC website and staff solutions to track activities
 - Lack of communication between teams
2. Implementation and Fidelity of Readiness planning in first 2 cohorts of were rocky
3. Our disorganization caused problems with cohort 2 engagement
4. Church Coordinator activities were not monitored or tracked well

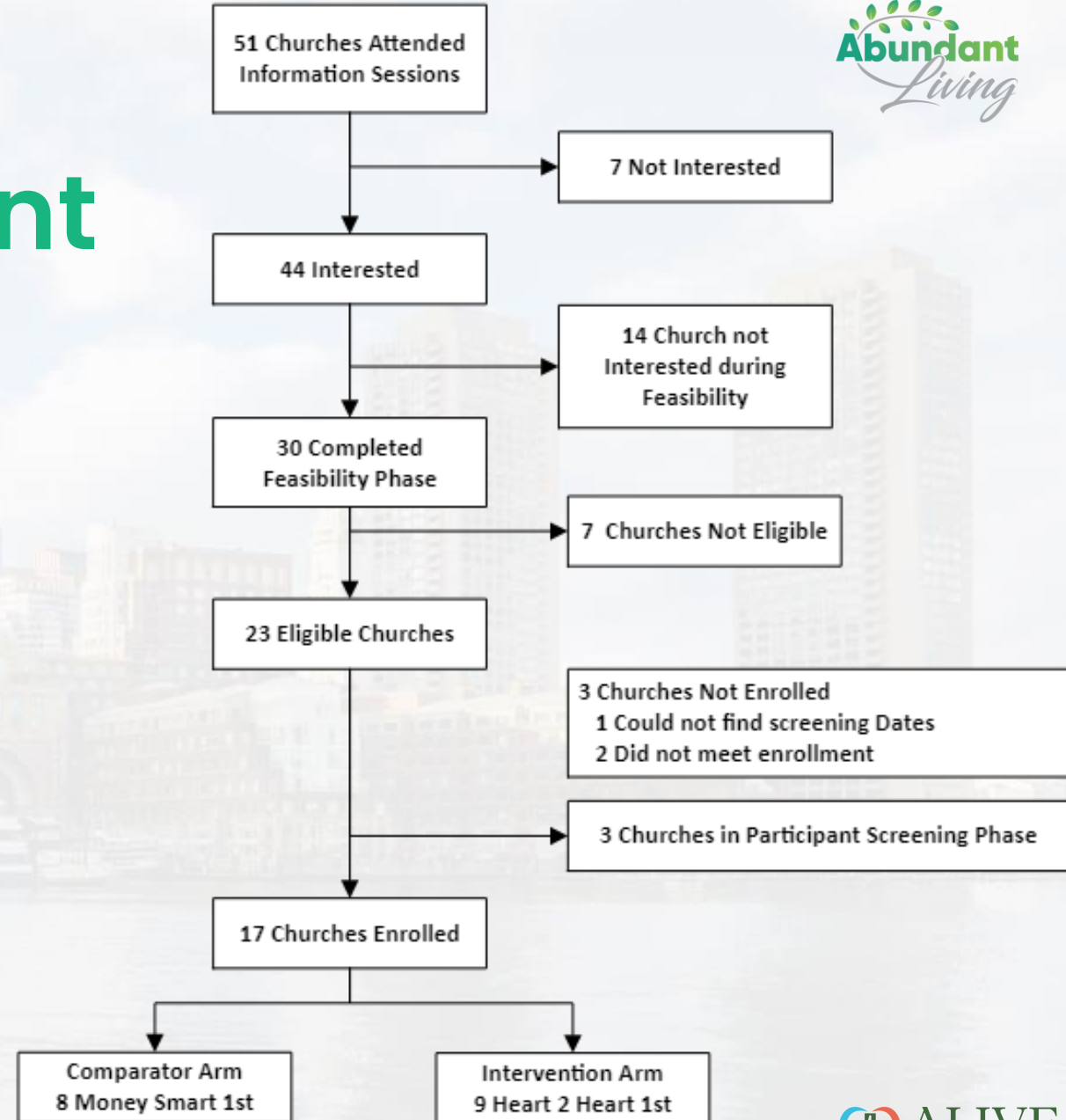
How We Improved It

1. A new staff member to be the point person for church communications
2. Data Management group met with staff in charge of each activity to identify all the steps that should be tracked
3. In an iterative process to create new flexible data capture tools
4. New reports and online dashboards of SIC Activities
5. Weekly questionnaire completed by church coordinators

Study Operations Improved

1. Better communications between study teams
2. Improved engagement and communications from churches
3. Identify when more staff effort will be needed
4. Problems during pre-implementation phase are caught quickly
5. Study pre-implementation fidelity has increased

Church Recruitment



Benefits of using the SIC Framework

1. SIC helped us frame and select what we should monitoring before the study began
2. Can be adapted for most clustered community/organization trials
3. Increases study protocol fidelity
4. Gives us cluster level implementation metrics that can be used in the analysis phase

« SCT 45th Annual Meeting | Boston 2024



**Thank You to Our
Awesome Team**

Alive Faith Network Team

- LaDawne Jenkins*
- Pastor Steve Epting*
- Yolanda Cartwright
- Cassaundra Jackson*
- Jamilia DeLaughter-Young
- Jazmine Lampkin
- Willie Love
- Daniel Madock
- Liz Avery
- Joyce Hudnall*
- Tami Olinger
- Jessica Brown
- Willie Mims
- Barbara Mascitti
- Sumi Suzuki
- Christy Tangney
- Todd Rupparr
- Viju John
- Steve Rothschild
- Amber Deckard
- Sheila Dugan
- Brittney Lange-Maia
- Chen Yeh
- Zaria Armstead
- DaTaasha Brown
- Rachel Boutee
- Selby Wright
- LaMorris Hampton*
- Natalie Brown
- Pastor Darryl Jenkins*
- Pastor Cy Fields*
- Valerie Press
- Heng Wang
- Gwen Brown

All the AFN churches, pastors, and coordinators

Funders





« SCT 45th Annual Meeting | Boston 2024

Thank You

