

THE TAKING TIME TO CONNECT RANDOMIZED CLINICAL TRIAL:

**HANDS ON EXPERIENCE FOR PUBLIC HEALTH STUDENTS IN
CLINICAL TRIAL RESEARCH WITH UNDERSERVED POPULATIONS**

**SOUTHWEST INSTITUTE FOR HEALTH DISPARITIES RESEARCH
STUDENT BROWN BAG SEMINAR**

APRIL 7, 2021



**PARTNERSHIP FOR THE ADVANCEMENT OF
CANCER RESEARCH**



Funding



PARTNERSHIP FOR THE ADVANCEMENT OF
CANCER RESEARCH

NCI grants U54 CA132383 (NMSU) and U54 CA132381 (Fred Hutch)

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health

Overview

- Meet the team!
- Study Phases
- What is the *Taking Time to Connect* (TTTC) Randomized Clinical Trial (RCT)?
- How is the TTTC RCT implemented?
 - Data Collection
 - Experimental Intervention
 - Control Intervention
- What the TTTC RCT means to me



Research Team

- **Dr. Rebecca Palacios, PhD, Principal Investigator**
- Clara Reyes, MPH, Program Manager
- Adriana Hernandez, BA, BPH, Health Educator
- Isela Garcia, MPH, Health Educator
- Lily Marquez, BS, Health Educator
- Leidi Collazos, Health Educator
- Cecy Corona, BS, Data Collector
- Annel Mena, BA, Data Collector



Study Phases

2016

Phase I:
Needs
Assessment

- Assessed the needs of Latina mothers diagnosed with cancer in the U.S.-Mexico border region

2017

Phase II:
Cultural
Adaptation

- Enhancing Connections → *Conexiones*
- Community Evaluation of *Conexiones*

2018

Phase III:
Feasibility
Study

- Pilot *Conexiones* with Latina mothers diagnosed with cancer in the U.S.-Mexico border region

2019

Phase IV:
Randomized
Clinical Trial

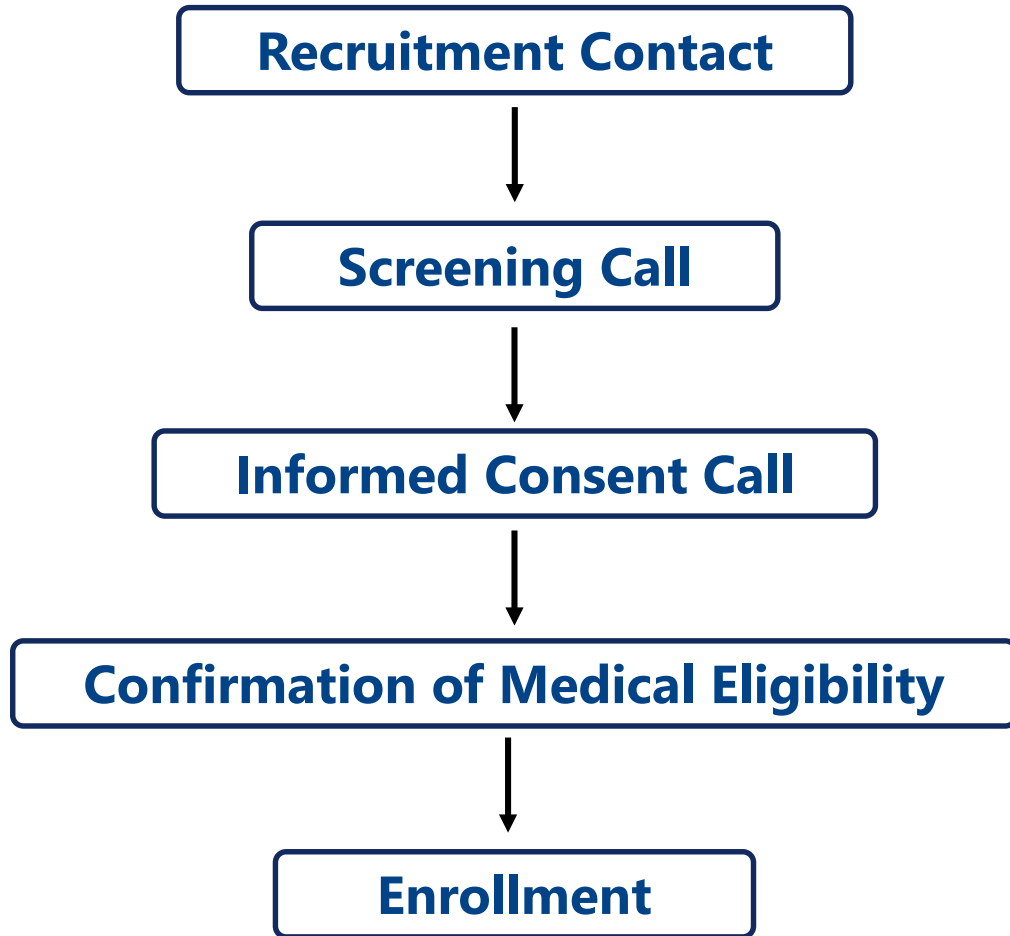
- Test the short-term efficacy of *Conexiones* with Latina mothers diagnosed with cancer in New Mexico & Texas

Phase 4: Taking Time to Connect RCT

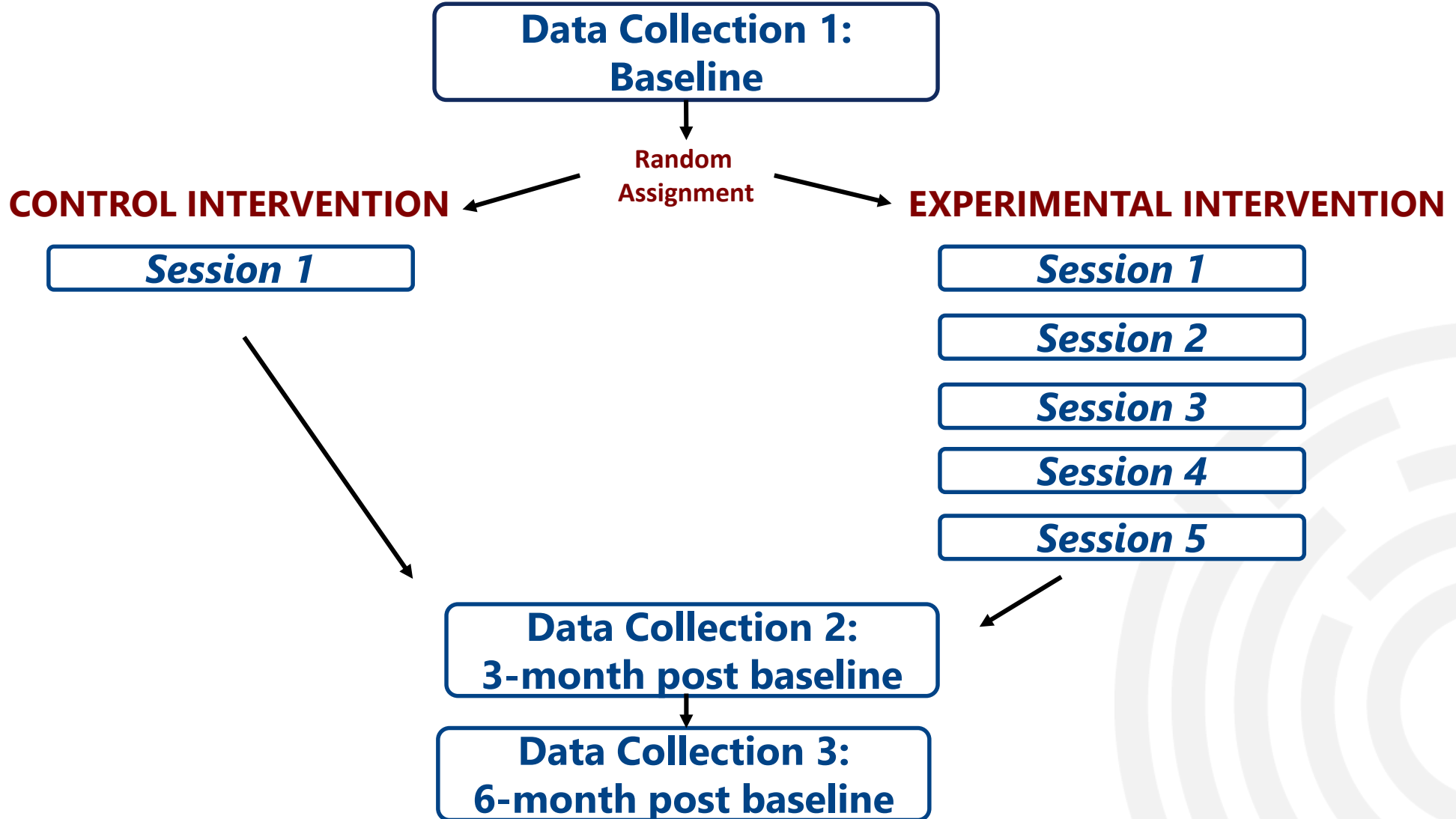
Comparing the Efficacy of Two Education Programs for Latina Mothers Diagnosed With Cancer & Their Children

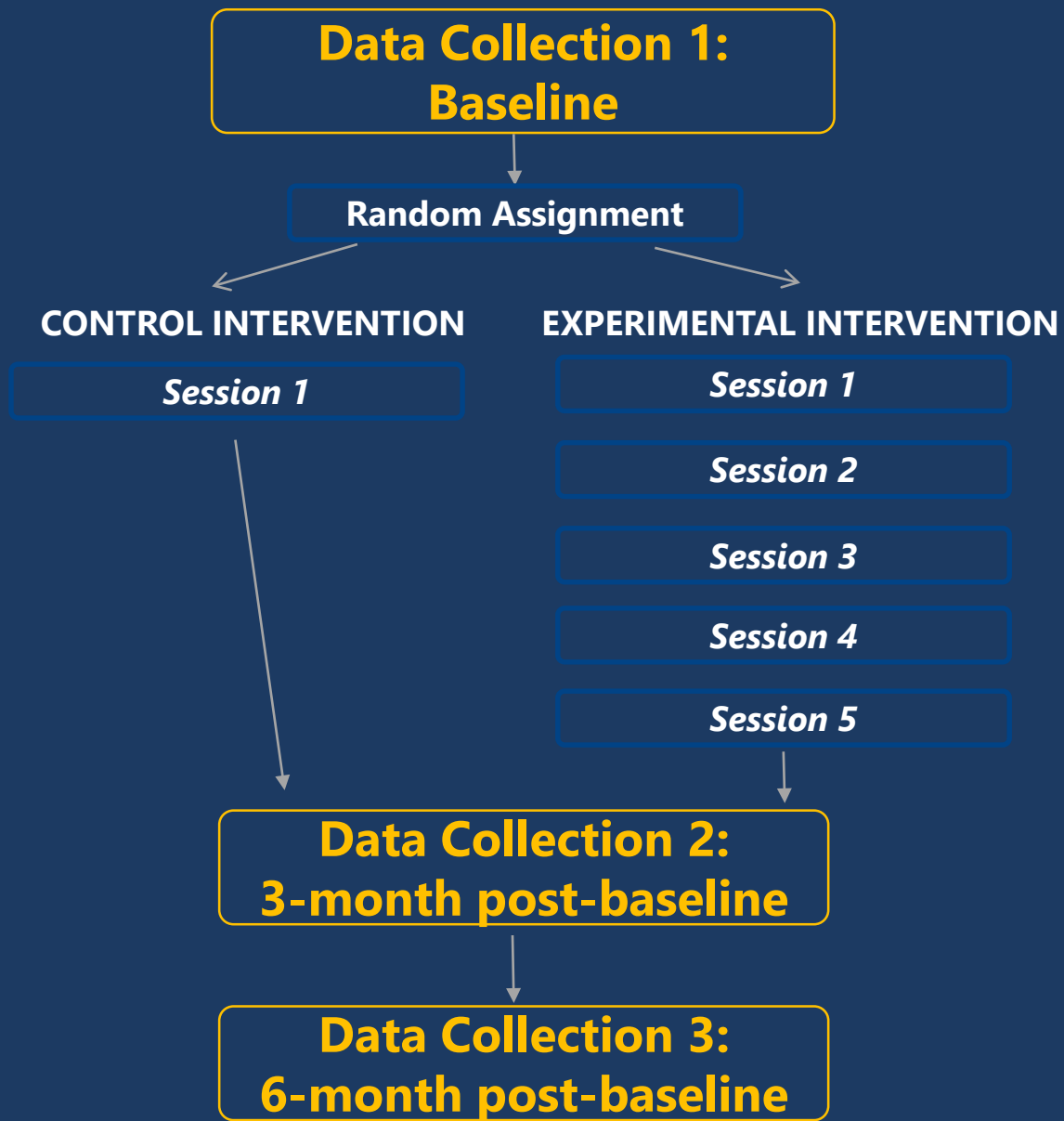
- NMSU's first clinical trial
- Testing a behavioral intervention culturally adapted for Hispanic women living in the U.S.-Mexico border region (Conexiones)
 - Comparing to a control intervention: Taking Time (NCI)
- Which is most effective in helping Hispanic mothers and their children to cope with her cancer?

How are Latina mothers enrolled?



Study Design





Data Collection

Cecy Corona, BS
Annel Mena, BA

Primary Outcomes: Diagnosed Mother

Center for Epidemiological Studies-Depression (CES-D; Conerly et al, 2002)	Depressed mood
The State-Trait Anxiety Inventory (STAI, Spielberger & Rickman, 1991)	Anxiety
Parenting Skills (Lewis et al, 2006)	Skills to: <ul style="list-style-type: none">- elicit child's concerns- connect and assist child in coping
Family Peer Relationship Questionnaire (Lewis et al, 2006)	Skills to assist child in disclosing negative feelings and bad things
Parenting Self Efficacy (Lewis et al, 2006)	Confidence to help child and stay calm/manage

Primary Outcomes: Child

Child's Behavioral Checklist (Achenbach & Edelbrock, 1987) (reported by mother)

- Internalizing behavioral/emotional problems
- Externalizing behavioral/emotional problems
- Child Anxiety
- Child Depression



Data Collectors

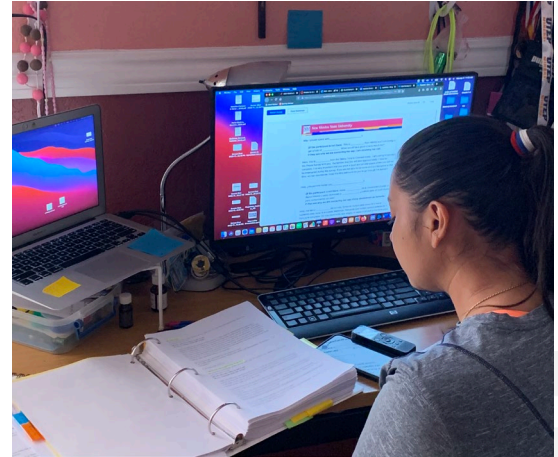
- Train before implementing surveys
- Edit and translate survey materials
 - Adapt for COVID-19 pandemic
 - Add survey items
 - Protocols
- Program all surveys into Qualtrics Survey Software
- Prepare for survey appointments
- Remain blinded to participant's intervention
- Follow protocols to address issues during surveys:
 - Domestic Violence, Socioeconomic Burdens, Suicide, Self-Harm
- Follow the “Taking Care of You” Protocol
- Prepare data for safe transmission to Fred Hutch/UW partners
- Quality control of data collection:
 - Review survey recordings (Performance Checklist)
 - Monitor correct survey delivery



Other roles

Cecy Corona & Annel Mena

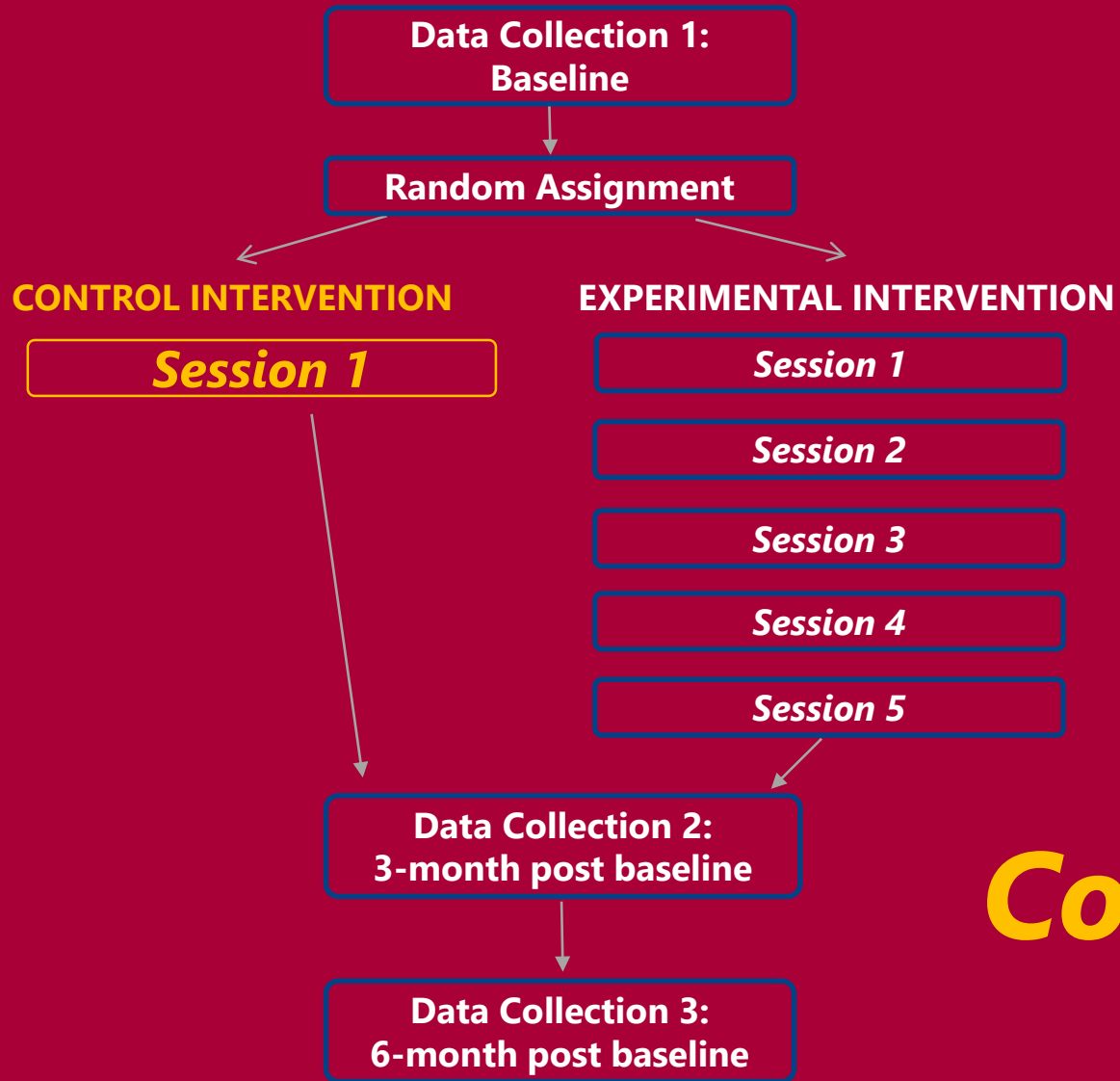
- Recruitment
 - Medical offices
 - Community agencies
- Research additional cancer resources



Cecy Corona

- Community Health Worker (CHW) liaison





Control Intervention

Clara Reyes, MPH
Adriana Hernandez, BA, BPH

Control Health Educator

- Training to deliver the control intervention
 - UW & NMSU mentors
 - Remain blind to experimental intervention
- Schedule education session in participant's preferred language (English & Spanish)
- Practice the education session with a Control Team Member
- Conduct education session with participant by telephone
- Follow protocols when issues arise during sessions:
 - Domestic Violence, Socioeconomic Burdens, Suicide, Self-Harm
- Recording reviewed for quality control

Taking Time to Connect

*A Study Comparing Education Programs for
Hispanic Mothers Diagnosed with Cancer*

TAKING TIME



Other roles

Adriena Hernandez

- Communications with community partners
 - Monthly newsletter providing study updates
 - Weekly social media posts to advertise the study
 - Monthly continuing education for CHWs recruiting for the study
- Cancer Resource Directory
- Recruitment

The image shows a screenshot of a newsletter titled "TAKING TIME TO CONNECT" dated January 14, 2021. The newsletter is a "MONTHLY STUDY NEWSLETTER" and features a quote from Miryam Granthon-Gerdine of the Latinas Researchers Network: "Every Latina is part of some sort of *familia*, so participating in clinical trials is supporting the health and well-being of all our families..." The newsletter also includes information about the clinical trial's focus on culturally appropriate interventions for Latina mothers and their children, and provides contact information for questions. A grid of 10 small photos shows participants in a video call. At the bottom, there are logos for the New Mexico State University Partnership for the Advancement of Cancer Research and social media handles for Facebook (@nmsucanceroutreach) and Instagram (@nmsucancer).

JANUARY 14, 2021

 **TAKING TIME TO CONNECT**

MONTHLY STUDY NEWSLETTER

"Every Latina is part of some sort of *familia*, so participating in clinical trials is supporting the health and well-being of all our families..." - Miryam Granthon-Gerdine of the Latinas Researchers Network

In cancer research, Latino participation in clinical trials is important to developing interventions and programs that are truly helpful to them.

The *Taking Time to Connect* clinical trial has prioritized developing a culturally appropriate intervention to support Latina mothers diagnosed with cancer and their children.

This clinical trial provides an opportunity to bring more effective interventions to the Latino and border communities.

For more information about the *Taking Time to Connect* clinical trial for Latinas visit cancer.nmsu.edu/ttcpilot.html

STUDY ELIGIBILITY CRITERIA:

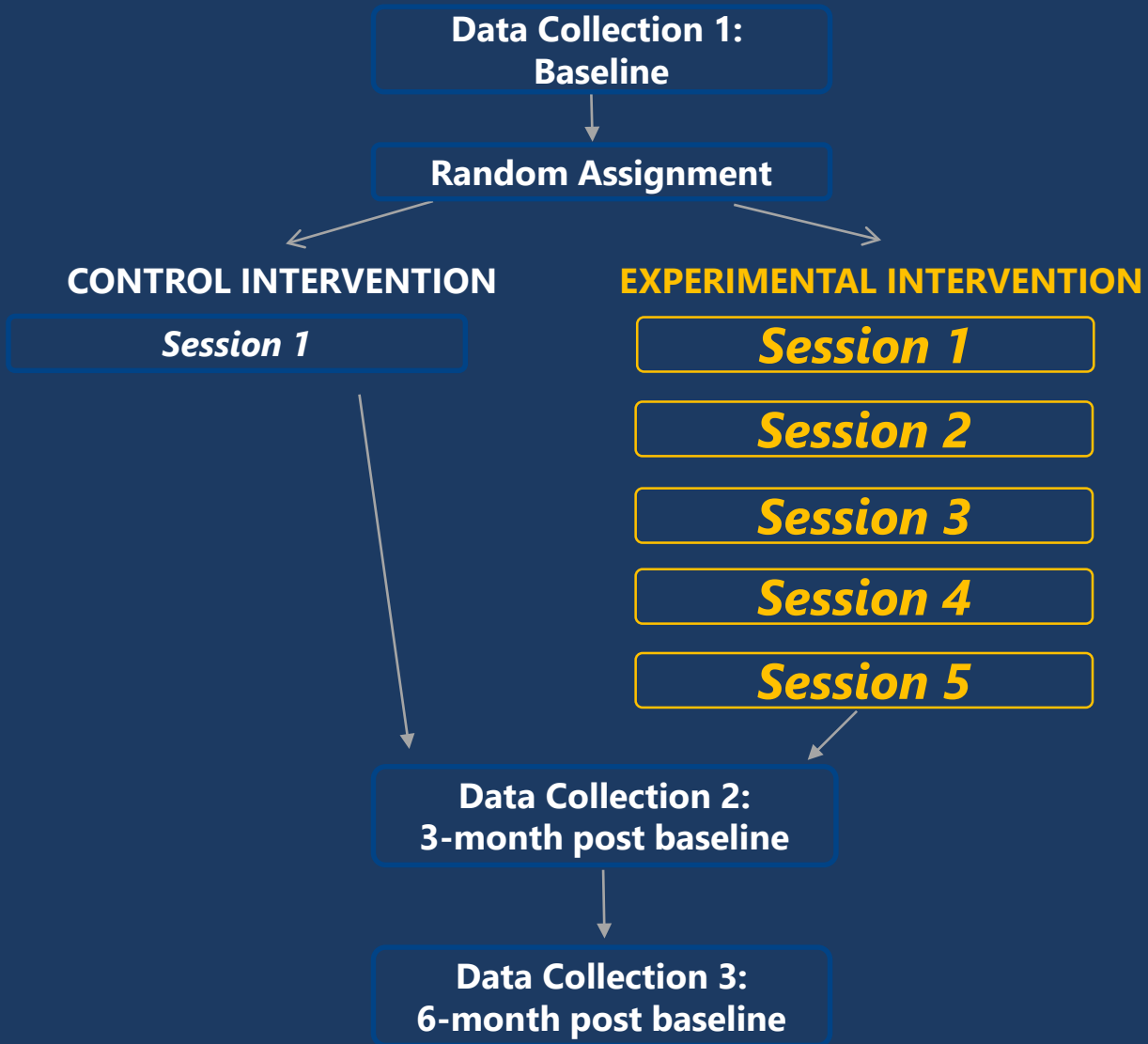
- Latina or Hispanic mother
- Diagnosed with cancer in the past 2 years
- Has an early stage cancer (stage 0, I, II, or III)
- Has a child 5 to 17 years old
- Child must know about the mother's cancer
- Lives in NM or TX

Participants Still Needed
134

QUESTIONS?
Clara Reyes, 575-646-5883
Rebecca Palacios, 915-274-6206

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Instagram: @nmsucancer

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Experimental Intervention

Rebecca Palacios, PhD

Isela Garcia, MPH

Lily Marquez, BS

Leidi Collazos, BS

Experimental Health Educators

- Training to deliver culturally adapted intervention to the participants
 - Mentors at NMSU and University of Washington
 - Months of practice
 - Learning to deliver an interactive, scripted program in English and Spanish
- Remaining blind to the control intervention
- Following study protocols
 - Domestic Violence, Socioeconomic Burdens, Suicide, Self-Harm
 - Protection of:
 - Study outcomes
 - Wellbeing of participants
- Quality Control of Intervention Delivery (Performance Checklist)
- Training junior and senior health educators

Taking Time to Connect

*A Study Comparing Education Programs for
Hispanic Mothers Diagnosed with Cancer*

CONEXIONES



Study Coordinator: Clara Reyes
575-646-5883



BE BOLD. Shape the Future.
New Mexico State University
cancer.nmsu.edu

Other roles

Lily Marquez

- Recruitment
- Social media
- Transcription

Taking Time to Connect

Clinical Trial for Latina Mothers Diagnosed with Cancer

Participate in an education program for Latina mothers diagnosed with cancer. Education sessions are entirely by phone making it safe to participate during this pandemic. We can schedule all sessions at times convenient for you.



Leidi Collazos

- Back-translation
- Search for cancer-related services

Directory of Cancer Services

San Antonio, TX

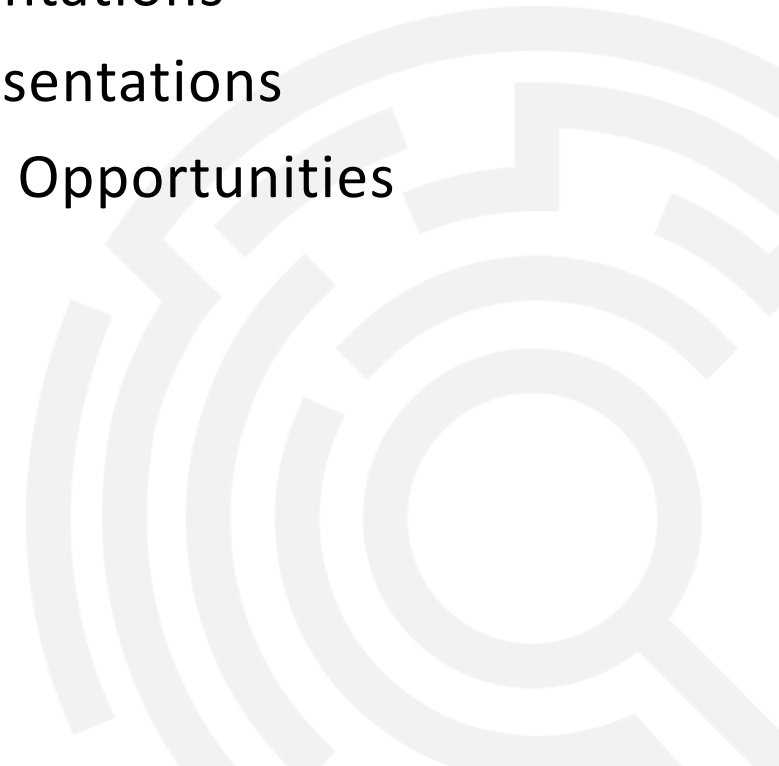
New Mexico State University
Public Health Sciences

Updated 3/30/2021

Public Health Research Professional Development

Developing skills we'll use after we graduate

- IRB & Maestro
- CITI Trainings:
 - Social and Behavioral Research
 - Good Clinical Practice (GCP)
 - HIPAA
- Inductive Coding Training
- Qualtrics Survey Software
- Atlas.ti Qualitative Data Analysis Software
- SPSS Statistics Software
- Thesis
- Publications
- Oral Presentations
- Poster Presentations
- Internship Opportunities




What the TTTC RCT means to me

- Clara Reyes, MPH, Program Manager
- Adriena Hernandez, BA, BPH, Health Educator
- Isela Garcia, MPH, Health Educator
- Lily Marquez, BS, Health Educator
- Leidi Collazos, Health Educator
- Cecy Corona, BS, Data Collector
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Thank you!


Dr. Rebecca Palacios

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 <https://cancer.nmsu.edu/ttcpilot.html>

Clara Reyes, MPH

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 <https://cancer.nmsu.edu/ttcpilot.html>



How do we recruit Latina mothers diagnosed with cancer?

- **Our staff**
 - Telephone Recruitment
 - Medical Providers
- **Medical Recruitment Sites**
 - Memorial Medical Cancer Center
 - The Hospitals of Providence
 - UMC El Paso
 - Texas Tech
- **NMDOH**
 - Office of Border Health
- **Community Health Workers**
- **Cancer Support Organizations**
 - CARE Las Cruces
 - Cancer Support of Luna & Deming
 - Chia's Silver Lining
 - Comadre a Comadre
 - Elsa's Hope
 - Rio Grande Cancer Foundation
- **Social Media**

