

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt

Release Date: October 29, 2016

ClinicalTrials.gov ID: NCT02329431

Study Identification

Unique Protocol ID: 13-2106

Brief Title: Padres Efectivos (Parent Activation): Skills Latina Mothers Use to Get Healthcare for Their Children

Official Title: Padres Efectivos (Parent Activation): Skills Latina Mothers Use to Get Healthcare for Their Children

Secondary IDs:

Study Status

Record Verification: October 2016

Overall Status: Active, not recruiting

Study Start: August 2013

Primary Completion: July 2016 [Actual]

Study Completion: November 2016 [Anticipated]

Sponsor/Collaborators

Sponsor: University of North Carolina, Chapel Hill

Responsible Party: Principal Investigator

Investigator: Kathleen Thomas, PhD [kthomas]

Official Title: Fellow and Adjunct Associate Professor

Affiliation: University of North Carolina, Chapel Hill

Collaborators: University of North Carolina, Greensboro

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved

Approval Number: 13-2106

Board Name: Office of Human Research Ethics

Board Affiliation: University of North Carolina at Chapel Hill

Phone: 919-966-3113

Email: irb_questions@unc.edu

Data Monitoring?: No

Plan to Share IPD?: Undecided

Oversight Authorities: United States: Institutional Review Board

Study Description

Brief Summary: The goal of this study is to develop an intervention to teach activation skills to Latino parents who bring children for mental health services.

Detailed Description: Background:

Latinos are the largest and fastest growing minority population in the US; by 2050, 2 in 5 children will be Latino. Latino children are disproportionately affected by poverty and other factors associated with increased risk of psychiatric disorder. However, Latino children with mental health needs are half as likely to use services as children in white non-Latino families. Latino families are more likely to report problems getting services, lack of a usual source of care and a medical home, and dissatisfaction with the care they receive. Unmet mental health needs, in turn, are associated with poor outcomes over the lifespan, both economic and social. Assessing the comparative effectiveness of interventions to overcome these disparities is a major national health priority central to PCORI's mission and mandate.

Activation is a promising focus of research to eliminate disparities because it reflects a set of attitudes and skills that people can use to reduce disparities. Our work provides evidence that activation in Latino adults is associated with better quality health care and outcomes; and in African American parents with greater child mental health service use. There is need for further research on parent-focused interventions founded on culturally meaningful concepts to address these needs and disparities.

Objectives:

The long-term goal of this research is to improve the mental health care and outcomes of Latino children with mental health needs. The proposed study will examine the comparative effectiveness of an activation intervention for Latino families raising children with mental health needs by means of three aims:

Aim 1. To identify parent-reported facilitators of Latino child mental health service use amenable to change through parental activation
Aim 2. To test the comparative effectiveness of an adapted psycho-educational intervention to teach activation skills adapted for Latino mothers of children with mental health needs compared to a parent support group control
Aim 3. To enhance

the intervention, based on parent input and lessons learned from the first trial, and test its comparative effectiveness with a parent support group control

Methods:

Qualitative and quantitative data from Latino mothers who have a child with mental health needs (n=294) will be used in a difference-in-difference mixed effects approach to address these aims.

Projected Patient Outcomes:

The proposed study will provide evidence of the comparative effectiveness of an enhanced, culturally sensitive, advocacy skills intervention to build activation among Latino families and improve service use of their children with mental health needs compared to a preliminary adaptation of an existing intervention and to a usual care discussion group. Activation skills are a promising strategy to improve child mental health service use and to bridge cultural differences and disparities with wide-ranging impacts consistent with PCORI's research agenda.

Conditions

Conditions: Mental Disorders

Keywords: child mental health, mental health services, Latino families

Study Design

Study Type: Interventional

Primary Purpose: Health Services

Research Study Phase: N/A

Intervention Model: Parallel

Assignment Number of Arms: 2

Masking: Double Blind (Subject, Caregiver, Investigator)

Allocation: Randomized

Endpoint Classification: N/A

Enrollment: 302 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: activation curriculum Psycho-social curriculum teaching activation skills	Behavioral: activation curriculum psychosocial activation curriculum
Active Comparator: support group	Behavioral: support group

Arms	Assigned Interventions
Parent-directed support group	parent directed support group

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- For children:
 - seeking services at target clinic
 - maximum age 22 years
- For caregivers:
 - Latino ethnicity
 - bringing child for services to target clinic
 - able to attend a weekly class for 4 weeks
 - able to give informed consent

Exclusion Criteria:

- For children:
 - not living with potential participant caregiver
- For caregiver:
 - not living with target child
 - evidence of emergency mental health needs

Contacts/Locations

Study Officials: Kathleen C Thomas, PhD

Study Principal Investigator
UNC Chapel Hill

Locations: **United States, North Carolina**

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Recruitment was from a Spanish-language mental health clinic, November 2013 through August, 2015
Pre-Assignment Details	Evaluation criteria were focal child not living with potential participant and evidence of urgent parent mental health needs

Reporting Groups

	Description
Activation Curriculum	Psycho-social curriculum teaching activation skills activation curriculum: psychosocial activation curriculum
Support Group	Parent-directed support group support group: parent directed support group

Overall Study

	Activation Curriculum	Support Group
Started	92	89
Baseline Interview	87	85
Completed	72	76
Not Completed	20	13
Lost to Follow-up	20	13

Baseline Characteristics

Baseline Analysis Population Description
Completed a baseline interview

Reporting Groups

	Description
Activation Curriculum	Psycho-social curriculum teaching activation skills activation curriculum: psychosocial activation curriculum
Support Group	Parent-directed support group support group: parent directed support group

Baseline Measures

		Activation Curriculum	Support Group	Total
Overall Number of Participants		87	85	172
Age, Continuous Mean (Standard Deviation) Unit of years measure:	Number Analyzed	87 participants	85 participants	172 participants
		35.3 (6.9)	36.4 (6.3)	35.8 (6.6)
Gender, Male/Female Measure Count of Type: Participants Unit of participants measure:	Number Analyzed	87 participants	85 participants	172 participants
	Female	84 96.55%	84 98.82%	168 97.67%
	Male	3 3.45%	1 1.18%	4 2.33%
Ethnicity (NIH/OMB) Measure Count of Type: Participants Unit of participants measure:	Number Analyzed	87 participants	85 participants	172 participants
	Hispanic or Latino	87 100%	85 100%	172 100%
	Not Hispanic or Latino	0 0%	0 0%	0 0%
	Unknown or Not Reported	0 0%	0 0%	0 0%

		Activation Curriculum	Support Group	Total
Race (NIH/OMB) Measure Count of Type: Participants Unit of participants measure:	Number Analyzed	87 participants	85 participants	172 participants
	American Indian or Alaska Native	0 0%	0 0%	0 0%
	Asian	0 0%	0 0%	0 0%
	Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%
	Black or African American	0 0%	0 0%	0 0%
	White	87 100%	85 100%	172 100%
	More than one race	0 0%	0 0%	0 0%
	Unknown or Not Reported	0 0%	0 0%	0 0%
Region of Enrollment Measure Number Type: Unit of participants measure:	Number Analyzed	87 participants	85 participants	172 participants
United States	87	85	172	
Medicaid coverage [1] Measure Count of Type: Participants Unit of participants measure:	Number Analyzed	87 participants	85 participants	172 participants
		62 71.26%	62 72.94%	124 72.09%
		[1] Measure Description: Target child covered by Medicaid		

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Parent Activation
Measure Description	self-report patient activation measure
Time Frame	up to 3 months
Safety Issue?	No

Analysis Population Description
Completed a baseline interview

Reporting Groups

	Description
Activation Curriculum	Psycho-social curriculum teaching activation skills activation curriculum: psychosocial activation curriculum
Support Group	Parent-directed support group support group: parent directed support group

Measured Values

	Activation Curriculum	Support Group
Number of Participants Analyzed	87	85
Parent Activation Mean (Standard Deviation) Unit of measure: participants		
patient activation measure 1-month	88.08 (12.13)	84.73 (12.65)
patient activation measure 3-months	92.75 (10.52)	91.63 (11.13)

2. Secondary Outcome Measure:

Measure Title	Caregiver Depression
Measure Description	patient health questionnaire, 8 items, scored 0-27
Time Frame	baseline, 1 and 3 months

Safety Issue?	No
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Analysis Population Description
Completed a baseline interview

Reporting Groups

	Description
Activation Curriculum	Psycho-social curriculum teaching activation skills activation curriculum: psychosocial activation curriculum
Support Group	Parent-directed support group support group: parent directed support group

Measured Values

	Activation Curriculum	Support Group
Number of Participants Analyzed	87	85
Caregiver Depression Mean (Standard Deviation) Unit of measure: participants		
patient health questionnaire-8 1-month	4.63 (5.91)	3.49 (4.34)
patient health questionnaire-8 3-months	3.89 (4.63)	3.47 (4.43)

3. Secondary Outcome Measure:

Measure Title	Caregiver Stress
Measure Description	parental stress scale, 17 items, scored 0-75
Time Frame	baseline, 1 and 3 months
Safety Issue?	No

Analysis Population Description
Completed a baseline interview

Reporting Groups

	Description
Activation Curriculum	Psycho-social curriculum teaching activation skills activation curriculum: psychosocial activation curriculum
Support Group	Parent-directed support group support group: parent directed support group

Measured Values

	Activation Curriculum	Support Group
Number of Participants Analyzed	87	85
Caregiver Stress Mean (Standard Deviation) Unit of measure: participants		
parental stress scale 1-month	28.51 (7.63)	29.97 (6.90)
parental stress scale 3-months	26.68 (6.69)	27.25 (6.61)

4. Secondary Outcome Measure:

Measure Title	Parent Activation, Qualitative
Measure Description	qualitative assessment from audio-taped parent-provider conversation
Time Frame	1 month
Safety Issue?	No

Analysis Population Description

Completed baseline interview and had an audio-recorded visit

Reporting Groups

	Description
Activation Curriculum	Psycho-social curriculum teaching activation skills activation curriculum: psychosocial activation curriculum
Support Group	Parent-directed support group support group: parent directed support group

Measured Values

	Activation Curriculum	Support Group
Number of Participants Analyzed	55	63
Parent Activation, Qualitative Measure Type: Count of Participants Unit of measure: participants		
parent disagreed with therapist	4	5
parent mentioned speaking with child's teacher	16	16

5. Secondary Outcome Measure:

Measure Title	Child Visit Attendance Over 4 Months
Measure Description	number of scheduled visits that were attended
Time Frame	baseline to 4-month follow-up
Safety Issue?	No

Analysis Population Description

Target child with any scheduled clinic visits

Reporting Groups

	Description
Activation Curriculum	Psycho-social curriculum teaching activation skills activation curriculum: psychosocial activation curriculum
Support Group	Parent-directed support group support group: parent directed support group

Measured Values

	Activation Curriculum	Support Group
Number of Participants Analyzed	87	84
Child Visit Attendance Over 4 Months Mean (Standard Deviation) Unit of measure: participants	4.2 (2.8)	4.0 (2.8)

6. Secondary Outcome Measure:

Measure Title	Child Visit No-shows Over 4 Months
Measure Description	number of scheduled visits that were missed
Time Frame	baseline to 4-month follow-up
Safety Issue?	No

Analysis Population Description

Target child with any scheduled visits

Reporting Groups

	Description
Activation Curriculum	Psycho-social curriculum teaching activation skills activation curriculum: psychosocial activation curriculum
Support Group	Parent-directed support group support group: parent directed support group

Measured Values

	Activation Curriculum	Support Group
Number of Participants Analyzed	87	84
Child Visit No-shows Over 4 Months Mean (Standard Deviation) Unit of measure: participants	0.7 (0.9)	0.6 (1.0)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Activation Curriculum	Psycho-social curriculum teaching activation skills activation curriculum: psychosocial activation curriculum
Support Group	Parent-directed support group support group: parent directed support group

Serious Adverse Events

	Activation Curriculum	Support Group
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/92 (0%)	0/89 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Activation Curriculum	Support Group
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/92 (0%)	0/89 (0%)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Kathleen Thomas
Organization: UNC Chapel Hill
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