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Supporting the Implementation of a State Policy on Screening for Adverse Childhood Experiences (ACEs) in Federally Qualified Health Centers (FQHC).

Statistical Analysis Plan

NCT: 04916587

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Statistical Analysis Plan

Title of Study: Supporting the Implementation of a State Policy on Screening for Adverse Childhood Experiences (ACEs) in Federally Qualified Health Centers (FQHC)

NIMH Study ID Number: R21MH123835

Clinical Trial Number: NCT04916587

Sponsor: Study funded by the National Institute of Mental Health.

Principal Investigator: Monica Perez Jolles, PhD.

Summary and research objective(s):

Screenings for Adverse Childhood Experiences (ACEs) promote early identification of toxic stress and potential trauma, allowing for intervention and possible amelioration of detrimental effects of the ACEs. The state of California enacted a 2020 fee-for-service healthcare policy, ACEs Aware, reimbursing clinics for annual ACEs screenings during well-child visits, but did not provide guidance on screening implementation. This study aims to test the effectiveness and acceptability of a multifaceted implementation strategy for implementing ACEs screenings, in partnership with a Federally Qualified Health Center (FQHC) system in California that adopted the ACEs Aware policy in August of 2020.

The proposed strategy is comprised of personnel training (e.g., Trauma-informed care), integrated technology with a customized screening scoring and aligned service referral algorithm, team-based screening workflows, ongoing care team coaching, and peer support. Significant changes to the original study protocol were needed to accommodate the negative impact that the COVID-19 pandemic had in the partner FQHC system.

Hypotheses

1. **ACEs screenings**
    a. Clinics using implementation strategies will have higher rates of REACH of ACEs screenings compared to their screening rates before implementing the strategies.
    b. Clinics using implementation strategies will have higher rates of REACH of ACEs screenings than clinics screening for ACEs and as part of the state funded CALQIC project, without the implementation strategies.

c. Exploratory: Are there any differences between in the effectiveness of the implementation strategies in different sub-groups (such as race, ethnicity, age and gender)?

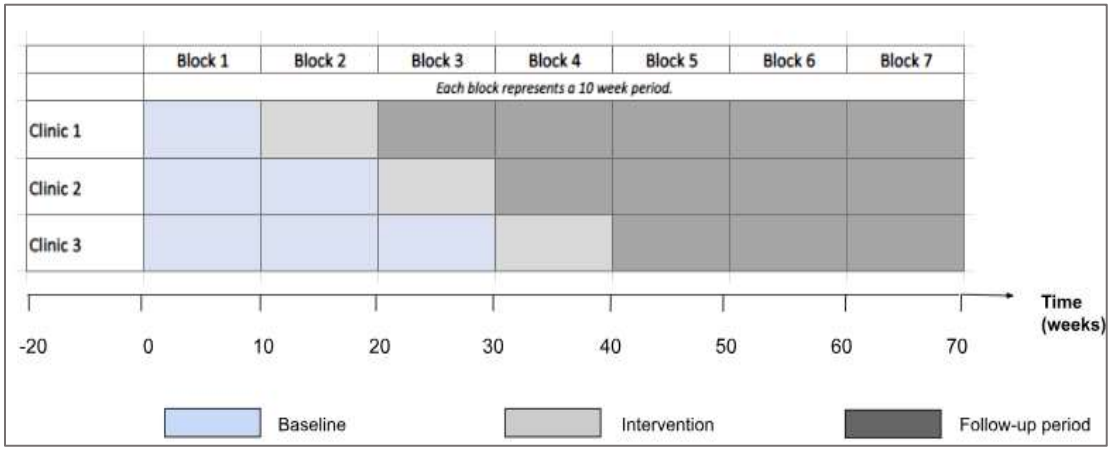
2. **Referrals to mental health services**
    a. Clinics using implementation strategies will have higher rates of mental health referrals compared to their referral rates before implementing the strategies.
    b. Clinics using implementation strategies will have higher rates of mental health referrals than clinics screening for ACEs and as part of the state funded CALQIC project, without the implementation strategies.
    c. Among children screened, ACEs screenings indicating medium and high risk will leading to mental health referrals at higher rates than screenings indicating low risk.
    d. Exploratory: Are there any differences between in the effect of the implementation strategies on referrals in different sub-groups (such as race, ethnicity, age and gender)?

3. **Implementation outcomes**
    a. Perceive feasibility, acceptability, and usefulness of the intervention will be sufficiently high (see Table 1).

Study design:

Changes to the original study design were needed to accommodate the negative impact that the COVID-19 pandemic had in the partner FQHC system. We conducted a stepped-wedge design (SWD) trial with three sites, with data collection divided into 7 10-week intervals. Study sites remained in the intervention phase for multiple intervals to allow additional data to be collected. In addition to the 3 study sites, 2 additional sites from the same health system served as comparison sites, implementing ACEs screenings without the support of the implementation strategies. See Figure 1 for the SWD schedule.

Figure 1. Stepped-wedge schedule for the ACEs pilot study.



Study sites and patient eligibility:

The study statistician originally selected five clinics from a pool of 16 clinics providing family medicine, pediatric, or primary care for children ages 0 to 5 years old and across five regions to maximize variation (e.g., clinic characteristics such as resources and size). Clinics were located in urban, suburban, rural, and frontier communities. The study PI and FQHC champions invited the identified clinics via email to an informational video session to introduce the study and provided study informational materials to the clinic manager.

Once the pilot study started, two randomly selected clinics were not able to participate - one clinic closed and one clinic lost their pediatrician leading ACEs screenings. Due to extremely high staff turnover at the clinics and among FQHC leadership, additional clinics selected were not able to participate in this research study. Thus, from the three clinics that finished the stepped wedge schedule, one was randomly selected and two clinics joined based on their capacity to participate in a research study at that time.

Eligible children were those aged 0-5, on public insurance, attending a wellness visit with the participating clinician.

Data sources:

Data for the primary outcomes, including reach of ACEs screenings and mental health referral rates, was obtained via the electronic medical record (EMR) at the partner health system. Additional data for secondary analyses was collected using REDCap among intervention patients only, including the PSC scores and ACEs screening results. See Figures 2 and 3 for the Consort tables.

Figure 2. CONSORT table for the study pilot study – Electronic Medical Records Data.

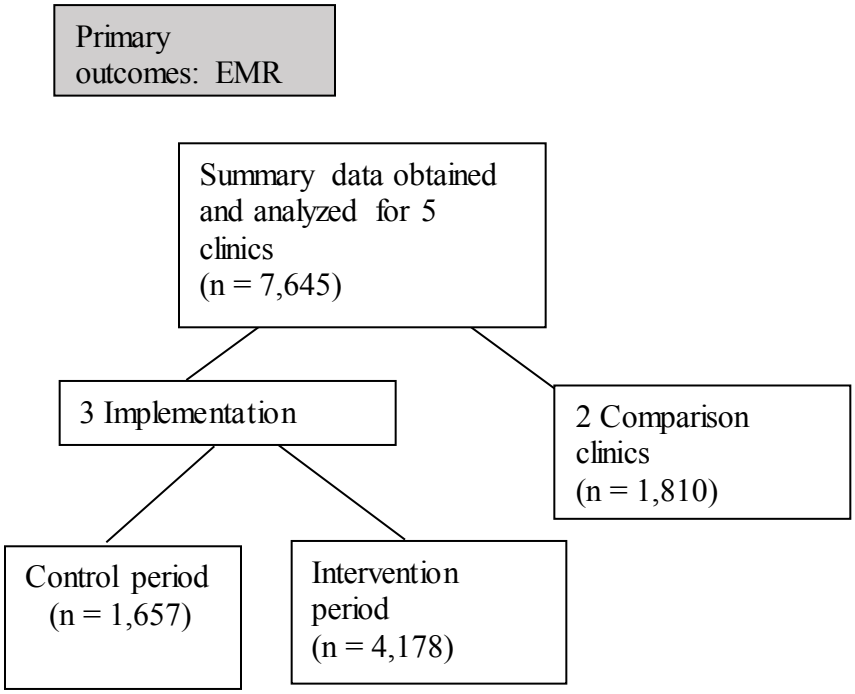


Figure 3. CONSORT table for sub-sample of data – REDCap system.

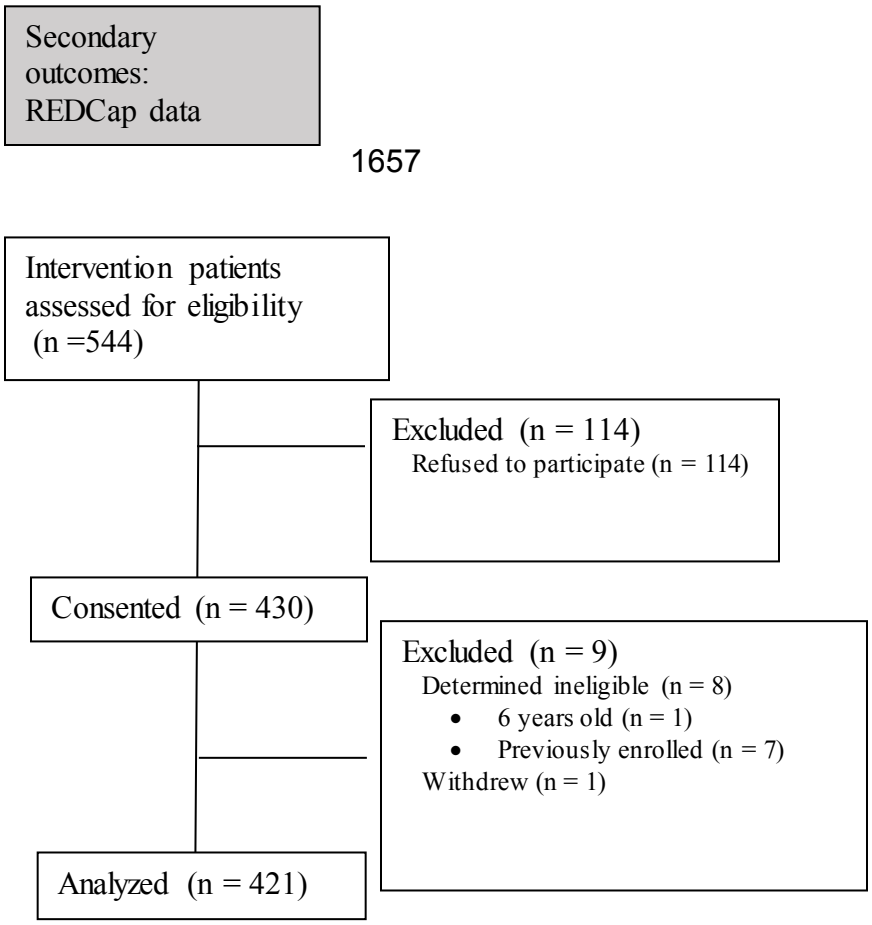


Table 1. Description of measures		
Eligibility criteria: Clinic eligibility is defined by: provision of services for child patients ages 0-5 years old. Child eligibility is defined by: ages 0-5 years; attending the selected clinic for a wellness visit during the 10-week trial period. **Exclusion criteria:** Clinics not providing pediatric care (family medicine, pediatric, primary care). Children older than age 5; not active per EMR system.		
Measure	**Description/psychometrics**	**Source**
ACEs Screening		
PEARLS[1] screening (ages 0-11)	Caregiver-reported tool (17-items) designed to identify exposure to childhood adversity and stress factors that may lead to toxic stress and negative health outcomes. Number of endorsed events are summed up (0-4+) to identify risk level for toxic stress and potential symptomatology. English/Spanish	Caregiver
ACEs associated health conditions[2]	State-sponsored list with 25 ACEs associated health conditions for children ages 0 – 5.[2] Physical conditions include asthma, allergies, unexplained somatic symptoms such as headaches. Mental health related conditions (over 10) include aggression, depression, ADHD, and anxiety	EMR system
Clinical screening tools	BPSC: 12-item screening measuring children's psychosocial functioning validated for children 0-18 months. Assesses irritability, inflexibility and difficulty with routines.[3] Designed for children 0-18 months; three subscales of four items each. Parents answer questions by selecting one of three responses: "not at all" = 0, "somewhat" = 1, "very much" = 2. Any summed score of 3+ on any of the three subscales indicates that a child is "at risk and needs further evaluation." Scores 0-2 indicates child "appears to meet expectations." Cronbach's alpha adequate for subscales (α =0.75 to 0.83). PPSC: 18-item screening for measurement of children's psychosocial functioning; validated for children ages 18-60 months. Assesses externalizing, internalizing, attention problems, and parenting challenges.[3] Parents select responses as: "not at all"=0; "somewhat"=1; "very much"=2. A score of 9+ indicates children is "at risk and needs further evaluation." α =0.92.	**Caregiver**
FIM[4]	Self-reported 4-item instrument to evaluate feasibility of implementation efforts. 4-pt Likert scale; average score of	Staff, manager

	4+ shows ACEs policy and implementation strategy perceived as feasible. Good internal consistency (α=0.89). Test-retest reliability r=0.88.	provider
AIM[4]	Self-reported 4-item instrument to evaluate acceptability of ACEs policy and implementation efforts. 4-pt Likert scale; average score of 4+ shows acceptability. Good internal consistency (α=0.83). Test-retest reliability r=0.83.	Staff manager provider
Fidelity	The implementation coach will use a checklist to observe the screening staff/providers at each clinic (once in week 5 of each 10-week trial period) to assess adherence to screening protocols and competence of performance. She will identify deviations/concerns and provide immediate feedback. We expect at least 67% fidelity (number of endorsed deviations / all items in the checklist) based on a previous study[5] The coach will also document adaptations and emerging challenges and report back to the PI and TIC workgroup. Form will be developed by PI & Aarons. Observation checklists/ audits are effective strategies to improve fidelity of performance.[6]	Implem coach
Reach	Measured as a proportion = number of eligible visits in a 10-week period divided by the number of PEARLS and clinical (BPSC/PPSC) screenings. Expect between 80%-92% of eligible children will be screened as threshold; based on pediatric screening studies in primary care.[7,8]	EMR system
Mental health referrals	Number of mental health referrals (behavioral analysis, behavioral health, care coordinator, care management, child development/development center or social work) divided by the total # of eligible children in a 10-week trial period. expect 11.4% increased referral rate based on a similar study[9] and using current referral rate of 3.8% to inform this threshold [per i2itracks report	EMR system
Changes in BPSC/PPSC	Mean score differences from eligible child visits in each 10-week period. Compare those means in pre vs post implementation periods. No threshold as we will test a two-tail hypothesis for this measure given mixed evidence on the impact of screening policies on access to care and clinical outcomes.[10,11] Even if a positive effect is not found, this information is still valuable for implementation and leadership.	EMR system

Implementation leadership (ILS)[12]	12-item scale with four subscales measuring proactive leadership, knowledgeable leadership, supportive leadership, and perseverant leadership. Reliability for the total scale is strong (α=0.98). An average score of 4+ used as threshold**;** 5-point Likert scale (not at all-very great extent). Subscale score is based on the mean score for the items; total score is the mean of the subscale scores[12];	Staff provider
Implementation climate[13]	6-item scale measuring the strategic climate for the implementation of interventions. The average interrater agreement: r*wg (J) = 0.76 for the group referenced scale. Items are rated on a 5-item Likert scale (completely disagree-completely agree). Average score of 4+ as threshold[13]	Staff provider
Covariates		
Child characteristic	Variables include sex, self-identified race and ethnicity, age, language of preference for health care receipt, born in the USA. Note: EMR system does not report data on caregivers of child patients	EMR system

Statistical analysis:

Descriptive statistics will used to describe the sample of children and clinics. The sample will be described using counts and percentages, and treatment groups will be compared using chi-squared tests. We will calculate risk differences with confidence limits for each of our three groups of interest- the study clinics during the control period, study clinics during the intervention period, and the control clinics. For subgroup analyses exploring differences by child demographics, we will calculate risk differences within those subgroups (age, gender, race, and ethnicity).

The reach variable (proportions screened) will be analyzed using binary regression (a generalized linear model, specifying a binomially-distributed dependent variable and identity link function). Modified Poisson regression with robust variance estimation[14] will used to analyze mental health referrals to estimate adjusted risk differences. Both models will compare the intervention and control arms as the primary independent variable of interest. Possible covariates will include child's sex, age category (<18 months, 18-60 months), child's race (white, black, other/unknown), child's ethnicity (Latino, not Latino, unknown/not reported), language of preference, and study site; covariates will be included in their adjustment changes the intervention regression coefficient by more than 15%.

Models comparing the intervention and comparison clinics will be adjusted for the child's race and for the study site. Missingness in demographic data will be handled by including an 'unknown or not reported' category. Survey data will be analyzed using aggregated intra-class correlations (ICC) to assess within-group agreement, whether clinic care teams shared perceptions of readiness for change during the preparation phase, and implementation climate and leadership. ICC is the variance proportion attributed to care teams.[15] Higher scores in these measures reflect higher organizational support for the translation of a new clinical practice into practice.[16] An agreement of 0.70 or higher reflects an organizational measure.[17]

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