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The Family Check-Up 4 Health: Study protocol of a randomized type II hybrid effectiveness–implementation trial in integrated primary care (the healthy communities 4 healthy students study)

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ABSTRACT

Background: Parenting interventions like the Family Check-Up have demonstrated effects on child physical and behavioral health outcomes. However, access to these programs is limited, particularly for populations experiencing health disparities. Primary care settings have become recognized as a potential delivery system in which these programs may be implemented at scale. The purpose of this trial is to test the effectiveness of the Family Check-Up 4 Health (FCU4Health) program, an adaptation of the FCU for primary care, and assess program implementation in an integrated primary care setting.

Methods: We will conduct a hybrid type 2 effectiveness-implementation trial in partnership with a primary care clinic in a low-income, majority Latino community. Families with 2- to 5-year-old children will be eligible to participate. Families will be randomized to receive the intervention (n = 130) or services as usual (n = 70) and will be assessed annually over three years. Outcomes are informed by the RE-AIM framework (i.e., reach, effectiveness, adoption, implementation, and maintenance). Effectiveness outcomes include child health behaviors (e.g., Dietary Screener Questionnaire), behavioral health (e.g., Strengths and Difficulties Questionnaire), and parenting (e.g., Proactive Parenting). Early stage implementation outcomes are also included (e.g., cost, acceptability, appropriateness, and feasibility). Effectiveness outcomes will be assessed via intent-to-treat (ITT) analyses. Implementation outcomes will be primarily descriptive with comparisons to prior trials of FCU4Health and the original FCU.

Projected outcomes: This trial will provide evidence related to the potential of integrated primary care settings to deliver evidence-based preventive interventions with a dual focus on behavioral and physical health.

1. Introduction

Parenting interventions have been shown to prevent an array of negative behavioral health outcomes for children [1,2]. Recent evidence has come to light that these interventions can improve child physical health as well [3,4]. Extensive research has confirmed a link between child health behaviors, like nutrition and physical activity, and later behavioral health outcomes [5–7]. A developmental cascade model [8] highlights how parenting behaviors linked to child behavior problems, such as permissive parenting or low parental involvement,

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also play a role in poor nutrition and physical inactivity, which can translate to obesity, chronic disease, and mortality for youth [9]. These findings indicate a clear connection between parenting, child physical health, and child behavioral health, and the potential for parenting interventions to improve all three.

Moreover, parenting interventions may serve as an effective strategy to reduce health disparities. An examination of patterns of health disparities suggest that particular racial/ethnic groups experience disparities in a range of behavioral and physical health outcomes, suggesting underlying root causes [10,11]. Mexican Americans have the highest prevalence rates of obesity in childhood and adolescence [12]. Ayala and Arredondo present an ecological review of the unique risk and protective factors related to Mexican American children's health [13]. Their nuanced review addresses complexities of ethnic differences and enculturation/acculturation to explain the immigrant paradox. For example, Familismo, a Mexican cultural value which centers the role of the family in all aspects of daily living, can support eating meals together and active family-focus free time [13,14]. Traditional gender roles, in which mothers are responsible for shopping and preparing fresh meals every day, are associated with more availability of fruits and vegetables in the home [13]. Residing in an ethnic enclave is associated with access to Providing food for children is an essential component of Latina mothers' identity, which brings joy and satisfaction [15]. Unfortunately, this can sometimes lead to permissive parenting, which is associated with poor nutrition and obesity [16–19], as well as child conduct problems [20,21]. In addition, more acculturated mothers have been found to be more knowledgeable about effective child feeding strategies [19]. Moreover, while parenting skills have a clear influence on child behavioral and physical health, it is also important to consider social determinants of health. Latino children, are disproportionately reside in low income neighborhoods with variable availability of fresh and nutritious food and limited access to safe areas for outdoor recreation [22–24]. Strategies that build on culturally-based strengths, while addressing social determinants of health, may be most effective in reducing disparities for Mexican American families.

To date, parenting interventions have not been delivered at sufficient scale to enable public health impact [2]. There is significant interest in primary care as a potential delivery system for parenting interventions [25,26]. The potential of parenting interventions to address both physical and behavioral health makes them very appealing to primary care settings, in particular to those with integrated behavioral health [26]. Although parenting interventions can be delivered in primary care, a number of barriers have hindered their success in this context and sustainability has not been achieved [25]. The sections that follow present a protocol of a type 2 hybrid effectiveness implementation trial an evidence-based parenting program adapted for primary care.

2. Methods

2.1. Overview

The Family Check-Up 4 Health (FCU4Health) program was designed to support integrated child health by promoting parenting skills and improving access to resources to address health determinants in primary care settings [27,28]. The FCU4Health is an adaptation of the Family Check-Up (FCU), a family-centered preventive intervention designed to prevent child conduct problems and adolescent substance use [29] that has long-term collateral effects on health behaviors and obesity [3,4]. In partnership with a community advisory board, we expanded the FCU to explicitly target child health behaviors (in addition to behavioral health) and fit within primary care [26,27].

The FCU4Health was first tested in the Raising Healthy Children study, a randomized type 2 hybrid effectiveness-implementation trial [30] with 240 caregivers of children who were 6-to-12-years old, 75% Latino, and identified in primary care as having elevated BMI ($\geq$85th percentile for age and gender) [31]. Because we were working with children with elevated BMI, in this prior trial, we followed the US Preventive Services Task Force recommendation for intensive services obesity management (26–50 h) over a 6-month period; this was a requirement of the funder [32]. Preliminary evidence suggests that intervention families experienced improvements in parenting, parent mental health, and child behavioral and physical health outcomes [33,34]. For example, in accordance with our theoretical model, relative to the control condition, we found improvements in parenting at 3-months, which mediated program effects on self-regulation at 6-months, and internalizing and externalizing at 12-months [34]. Neither language nor ethnicity moderated these effects. Members of our advisory board recommended moving upstream to implement the FCU4-Health with younger children before negative health routines were established. In response, we developed the Healthy Communities 4 Healthy Students trial to test the preventive effects of the FCU4Health on child physical and behavioral health, when delivered via an annual health maintenance approach in an integrated primary care setting with families of 2-to-5-year olds.

2.2. Study design

To test the FCU4Health in the *Healthy Communities 4 Healthy Students* project, we will conduct a type 2 hybrid effectiveness implementation trial, which enables simultaneous evaluation of intervention effectiveness and implementation [35]. Outcome evaluation follows the RE-AIM framework: reach, effectiveness (parenting, child and family health behaviors, and child behavioral health), adoption, implementation (acceptability, cost, fidelity [26]), and maintenance [36]. Families will be recruited from a low-income, predominantly ethnic minority (50% Latino) community to the southwest of the metropolitan Phoenix area. Families (n = 200) will be assessed annually over three years. The FCU4Health will be delivered to families randomly assigned to the intervention condition using a health maintenance approach in which the family receives a “check-up” each year, followed by tailored follow-up support. All study procedures and materials are approved by Arizona State University's Institutional Review Board.

2.3. Recruitment and eligibility

Eligible families will be identified by organizations involved in an existing community partnership, made up of an integrated primary care-behavioral health clinic, local preschools, and a family resource center, which serves as a local hub for services such as WIC, SNAP, parent training, career counseling, housing, domestic violence services, and adult education. The partnership is facilitated by the local regional council of First Things First, a state agency that is funded by a tobacco tax to support early childhood development. Parents with a child aged 2-to-5 years (at study entry) and who understand English and/or Spanish well enough to complete the assessment will be eligible. No other eligibility criteria will be used to fit the universal focus of primary care settings as closely as possible. However, because families who receive support in these settings are primarily Latino, we expect to enroll at least 65% Latino families. We will monitor enrollment weekly and take corrective action if we find lower enrollment rates. Our center is well-known for its work with Latino families [37,38] and our team has extensive experience with culturally appropriate recruitment and retention strategies. Families will be referred to the study using a study flyer, a referral form acknowledging the families' interest in participating and ROI (Release of Information) and HIPAA release forms (as applicable) to document permission to share the families' contact information with study staff. Study staff will contact referred families in person or by phone to screen for eligibility and enroll them in the study.

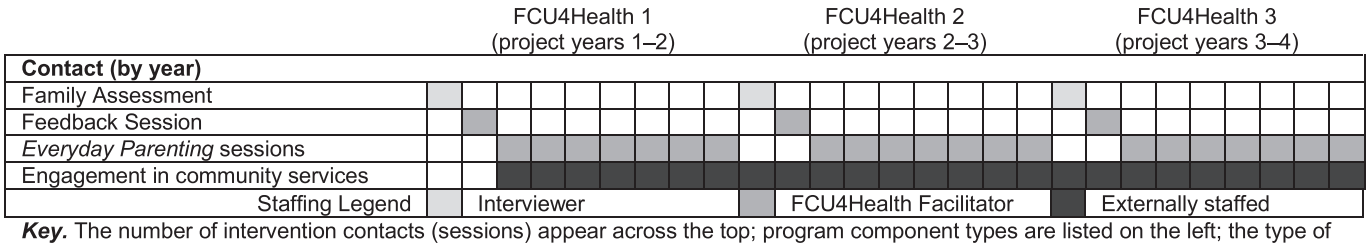

Fig. 1. FCU4Health program delivery strategy for an average family.

2.4. Assessments

Once enrolled, families will complete a comprehensive assessment (~90 min) with a study-employed interviewer who will obtain consent from the caregiver. The assessment uses a multi-agent battery of caregiver-reported questionnaires and a series of brief video-recorded family interaction tasks to evaluate the broad domains of family health behaviors, child health behaviors, family well-being and support, child adjustment, and family management and relationships (see Measures section below). All questionnaires will be completed in English or in Spanish by caregivers through a secure HIPAA compliant website accessed via a Wi-Fi enabled tablet. All measures have been validated in Spanish and interviewers conducting assessments with Spanish-speaking parents will be bilingual. The research coordinator who supervises the interviewer team is also bicultural and bilingual. Pencil-and-paper versions will also be available if needed. Family interaction tasks will be recorded using the tablet. Files are uploaded to a cloud based, HIPAA-compliant, password-protected portal for secure storage, viewing, and scoring. Families in both arms will be assessed once per year for three years and will receive reminders by phone, email, and postcard two weeks prior to each annual contact. Because of the COVID-19 restrictions, these assessments will be conducted by telephone, at least for the first wave of data collection. We will also collect claims data from each target child's healthplan to assess economic outcomes. Families will receive $50 for each annual assessment, $25 for release of insurance data, and children receive health-related gifts (e.g., ball, earbuds) valued at $10.

2.5. Randomization

After the baseline assessment, families will be randomized to either the FCU4Health (n = 130) or the comparison condition (n = 70) using a randomized-block design by ethnicity and gender. To estimate power, we used Optimal Design [39] and Monte Carlo simulations in Mplus [40]. The unbalanced design (n = 130 FCU4Health; 70 usual care) was chosen to maximize the ability to examine implementation of FCU4-Health with only moderate effect on statistical power [41]. SAS's pseudo random number generator will be used to randomize families to condition, blocking by child age, gender, and ethnicity. Values will be randomly generated to follow a uniform distribution with a minimum of 0 and a maximum of 1. We will use a cutoff of 0.35 on the random number generator to achieve the intended 65–35 split. The trial's quantitative methodologist will monitor randomization to ensure the appropriate split is achieved. To ensure masking of condition for the first assessment, the interviewer will follow a script revealing random assignment after the baseline assessment is completed. For subsequent assessments, families and providers will be aware of condition; interviewers are not told about condition, but may inadvertently become aware (e.g., if family tells them or if they remember from the baseline assessment). Comparison families will receive services as usual through the school, primary care, and family resource center, as well as a booklet of local resources created for the project. The intervention condition will receive these and the FCU4Health program.

2.6. Intervention

The components of FCU4Health mirror the core structure of the original FCU, with added content to target health behaviors. The FCU4Health consists of 1) a comprehensive assessment of the family environment, parenting skills, and child adjustment and health behaviors; 2) a feedback session which uses motivational interviewing strategies to engage families in making change to support child behavioral health; and 3) tailored follow-up services which include parent training modules and referrals to additional support services in the community. The norm-based data-driven approach and motivational interviewing strategies used in the original FCU and FCU4Health were originally inspired by Bill Miller's Drinker's Check-Up, in which clients completed a brief alcohol use screening measure, were provided feedback and motivational interviewing to engage them in care and reduce alcohol consumption [42]. However, this remains a relatively unique approach in family-based prevention and health promotion programs. Observational ratings of motivational interviewing skills have been linked with engagement and improvements in program outcomes in the FCU[43] and FCU4Health [44]. Considerable evidence documents the FCU and FCU4Health's clinical effectiveness and high rates of engagement among racial and ethnic minority families, including Latinos, African Americans, and Native Americans [34,45–50]. Rates of engagement in follow-up parenting sessions were higher for Spanish compared to English-speaking families in the FCU4Health [44].

The FCU4Health will be delivered via a health maintenance approach (see Fig. 1) where the family has regular, repeated visits over time (once annually over three years). The advantages of repeated contact are that the intervention becomes adaptive in that data and response to the program inform ongoing intervention and the FCU4-Health Coordinator has multiple occasions to reinforce positive attempts to change while also addressing barriers and engaging the family. The FCU4Health Coordinator reviews the results of the assessment, compares them to established norms, and plots them on a Feedback Form. The Feedback Form is shared with families at a Motivational Interviewing-based Feedback Session to discuss the results of the assessment and plan for follow-up support [44]. The feedback form used to summarize the assessment for families was modified from that used in the original FCU to visually provide a clear link between parenting strategies and children's health behaviors and behavioral health. The first annual Feedback Session will begin with a discussion to understand: a) caregivers' perception of their needs; b) their child's physical and behavioral health; and c) the caregivers' motivation to change parenting practices in support of health behavior change. In the second and third annual sessions, the coordinator will begin by checking in with the family about their progress since the last meeting. Next, the coordinator will present the assessment results using the scored Child and Family Feedback Form. The coordinator will contextualize the norm-based results based on the interview with the family to better represent the current family strengths and accentuate areas in need of further support. The goals of this session will be to: a) share assessment findings with family members regarding strengths and challenges; b) engage in a motivation-enhancing discussion about promoting positive

changes; and c) provide a menu of resources and next steps to facilitate the family change process.

After the Feedback Session, the rest of the program is individually-tailored in content area and dosage [51] based on identified needs in the assessment. Families with identified needs related to parenting or child behavior will be offered parenting sessions. These sessions are derived from *Everyday Parenting* [52], a 12-module skills-based curriculum focusing on the three core areas of parenting: relationship quality, positive behavior support, and monitoring and limit setting. Coordinators will use these modules to work with caregivers on a specific behavior change goal, such as setting limits on screen time or positively rewarding children's healthy choices. In each module, the Coordinator will demonstrate the parenting skill, the caregiver will practice the skill in a roleplay with the Coordinator, the Coordinator and caregiver will discuss solutions for potential barriers, and the Coordinator will assign home practice to try the skill at home with the child(ren). At the following session, the Coordinator will review how the home practice went.

For families experiencing needs related to social determinants of health, the Coordinator will connect them with resources in the community. In collaboration with our partner agencies, the team of Coordinators will identify services in the community to address family needs, such as social services supporting housing, employment, and nutrition that are available at little or no cost to families. Coordinators will also ensure that families have health insurance coverage, a medical home, and access to specialty care if needed. The intent is to leverage existing services to support families and to test whether the motivational aspects of FCU4Health lead to higher engagement compared to families in usual care. If needed, Coordinators will teach families skills to find resources in the community (e.g., through Family Resource Centers or FindHelpPhx.org) and to overcome obstacles in accessing resources (e.g., best time of day to call/visit agencies, ensuring paperwork is complete) in the future.

2.7. Program delivery

The program will be delivered by FCU4Health coordinators, who are behavioral health consultants (typically with a Master's degree in behavioral health counseling or clinical social work) in either a) a local clinic with integrated behavioral health and primary care with existing staff trained in FCU4Health, or b) through home visitation by FCU4Health trained staff employed by the university for the study, as was done in a prior trial of FCU4Health [30]. This dual delivery strategy is an innovative feature of our study design that will allow us to achieve both our effectiveness and implementation aims. Approximately half of the Coordinators will be bicultural and families will be able to receive the intervention in their preferred language. In addition, the Implementation Coordinator, who is responsible for overseeing program delivery, is also bicultural and bilingual.

2.8. Training & supervision model

To promote comparability, the FCU4Health Coordinators employed by the university will receive the same level of training and supervision as the clinic-based Coordinators. Training will include an online overview of the program and in-person training that focuses on roleplaying program delivery with feedback from FCU4Health Consultant. Training will also address culturally appropriate delivery of services to Latino families. Supervision will involve meeting with Coordinators prior to the Feedback Session to discuss the case conceptualization and potential follow-up services to suggest. The Coordinator and Consultant will meet again after the Feedback Session to discuss issues related to the fidelity of delivery, as rated by the COACH (see section on Fidelity below) [53]. Coordinators become certified after implementing two sessions with minimum acceptable fidelity. Group supervision to share resources and troubleshoot difficult issues will be held monthly.

2.9. Measures

Study measures are guided by the RE-AIM framework. Effectiveness outcomes will include parenting, health behaviors, and behavioral health. We will also include theoretical predictors of implementation outcomes, including provider and participant perceptions of appropriateness and acceptability, provider perceptions of feasibility, and cost [26,54].

Reach. Study enrollment and participation data will be used to evaluate the reach of the program. We will track the proportion of families who initiate services relative to those randomized to the FCU4Health condition and participation rates for each component of the intervention over the length of the trial. Using methods developed and tested in previous trials, the FCU4Health coordinators and other agency staff will track all family contacts and record the delivery location, travel time, family members, type of the contact, and content areas covered on the FCU4Health Activities Checklist [55]. Initiation and participation rates will be calculated for the overall sample and for each racial/ethnic group to determine equity in program access.

Effectiveness. Families participate in a comprehensive assessment, which includes the validated and normed measures (i.e., questionnaires and observational ratings) from the original FCU, plus additional measures related to health routines and outcomes. Questionnaires include two positive behavior support scales (proactive parenting [7 items], incentives and encouragement [4 items]) [56,57]; three relationship quality scales (parental warmth [5 items] [58], family conflict [4 items] [57], quality time [5 items]) [56]; monitoring (7 items); and limit setting (7 items) [56]. All measures have demonstrated convergent and predictive validity and internal consistency above 0.75. We will use the Family Interaction Task, a validated observational coding system to rate parent-child interactions [59,60]. The caregiver(s) and child will be video-recorded for 4–5 min while discussing three core topics (Health Goals; Limit Setting; Planning a Fun, Physically Active Activity for the Family). The recorded family interactions will be scored for relationship quality, positive behavior support, and monitoring and limit setting, as well as demonstrated knowledge of children's health behavior guidelines. A random sample of 20% of the interaction tasks will be double-coded in order to calculate reliability [61].

Caregivers will complete a 6-item version of the National Health and Nutrition Examination Survey's Dietary Screener Questionnaire (DSQ) to report the frequency a child made certain food (fruits, vegetables, fast food) and beverage (soda, 100% fruit juice, or sweetened fruit drinks, sports drinks, and energy drinks) choices during the past week on an 8-point scale (0 = *never*, 4 = *5–6 times per week*, 8 = *6 or more times per day*) [62]. The DSQ has been shown to be a low burden food recall screener [63]. The 27-item Family Health Behaviors Scale [64] will be used to assess health-promoting family behaviors, mealtime routines, and child and family physical activity habits. Parent ratings on this scale are sensitive to change, have been shown to predict child weight classification, and have good internal consistency ($\alpha > 0.83$), temporal stability ($\alpha = 0.86$), and invariance in diverse low-income families [64].

Caregivers will complete the conduct problems (e.g., often lose(s) temper), hyperactivity (e.g., is constantly fidgeting or squirming), emotional problems (e.g., is often unhappy, depressed, or sad), and prosocial behavior (e.g., is considerate of other people's feelings) subscales from the Strengths and Difficulties Questionnaire. Each 5-item subscale is rated a 3-point scale (0 = *not true*, 1 = *somewhat true*, 2 = *very true*).Caregivers will also complete 13 items (e.g., is able to resist laughing or smiling when it isn't appropriate) from the Children's Behavior Questionnaire [65], using a 5-point scale (1 = *almost always untrue*, 5 = *almost always true*).

Adoption. The partnering clinic is part of a network of clinics that includes five other brick and mortar integrated care sites, two mental health sites, and virtual care. We will calculate the proportion of sites and unique providers that adopt FCU4Health by the end of the trial.

Fidelity. We will observationally assess fidelity using the valid and reliable COACH rating system, which was developed and validated for the FCU [43,66,67], and was associated with engagement in the original FCU4Health trial [44]. The COACH comprises five dimensions of observable in-session coordinator skills: **C**onceptual accuracy; **O**bservant and responsive to the families' contexts and needs; **A**ctively structures session to optimize effectiveness; **C**arefully teaches and provides corrective feedback; **H**ope and motivation are generated. Each dimension contains exemplars (prescribed behaviors) and non-exemplars (proscribed behaviors) and is rated on a 9-point scale of *competent adherence* to the program: 1–3 (*needs work*); 4–6 (*competent work*); 7–9 (*excellent work*). Interrater reliability has been good in previous studies (≥0.73) [67]. We will code the first FCU4Health feedback session of every family (N = 130) and then a subset of 80 families will be randomly selected at study entry, balanced by coordinator, for coding the second and third feedback sessions (N = 160 more) to assess drift over the course of the 3-year trial.

Maintenance. In the RE-AIM framework, maintenance can refer to both the individual participant level and the setting level (i.e., sustainment) [68]. At the individual level, we will conduct growth curve analyses to determine the maintenance of effects on parenting, child health behaviors, and child behavioral health. At the setting level, we will examine fidelity over the three feedbacks sessions of the trial (as described above), and, at the end of the trial, clinic stakeholders will answer five items in each of 8 domains (e.g., Funding Stability, Organizational Capacity) of the Program Sustainability Assessment Tool [69]. Items such as "The program has sustained funding" are rated on a 7-point Likert scale (1 = *little or no extent*, 7 = *a very great extent*). This measure has good internal consistency (α = 0.88) [69].

Caregiver acceptability and appropriateness. We will assess caregiver acceptability and appropriateness using interview and survey methods. The FCU4Health Caregiver Acceptability Interview, designed for and used in our prior studies, consists of eleven open-ended questions pertaining to the relevance of the program components to the family's goals, the acceptability of the program and its components, and the barriers and facilitators of participation. Among families in the FCU4Health arm, an estimated 25% will be randomly selected and interviewed by study staff via phone. This number was selected to be inclusive across demographic categories (e.g., race/ethnicity, language, gender, family structure) and program goals (e.g., parenting, community resources), and achieve saturation. All of the families in the FCU4Health arm will provide feedback on acceptability and appropriateness through the Treatment Acceptability Rating Form-Revised Short [70], adapted for FCU4Health. The scale consists of ten items (e.g., "How likely is FCU4Health to make permanent improvements in your child's health behaviors?") rated on a seven-point Likert scale (1 = *not at all*, 7 = *very*). The original scale had high internal consistency (α = 0.92) [70].

Provider acceptability, appropriateness, and feasibility. We will assess provider acceptability through a brief battery of questionnaires concerning acceptability of training, program costs, and the delivery of each component of the program. The battery will comprise select subscales of the Annual Survey of Evidence-Based Programs [71], a measure which has been published extensively and has good internal consistency (α > 0.75). The battery will be electronically administered to stakeholders involved in the delivery of the program at two points in the project: six months into FCU4Health delivery in the implementation phase of the project and when all intervention families complete the FCU4Health. Provider appropriateness and feasibility is assessed with the FCU4Health Stakeholder Survey, which comprises eleven open-ended questions, adapted from the Treatment Acceptability Rating Form, related to the relevance of the FCU4Health, barriers and facilitators of the delivery of the FCU4Health program, and feasibility of this program from the perspective of stakeholders.

Cost. Cost capture methods [72] will be used to carefully track installation and delivery costs of the FCU4Health throughout the project period. All staff involved with the study will complete weekly surveys reporting on the number of hours they spent on different categories of activities. These will be used to prospectively separate costs associated with implementation from those specifically related to research (e.g., interviewer training) and those related to program delivery (e.g., supervision meetings). The FCU4Health Activities Checklist, described above, will also capture information about program staff involved in each component of FCU4Health implementation and the number of hours spent on each activity [55]. We will use budget information for non-salary costs associated with research (e.g., participant reimbursement, data analysis software), start-up (e.g., manuals), and ongoing costs (e.g., consultation with FCU4Health developers, technical assistance, travel for home visitation).

2.10. Data analysis

Intent-to-treat (ITT) analyses will be applied using data from all participants who are randomly assigned to the two conditions. We expect the attrition rate across waves to be 10–15% based on retention rates for local studies with highly mobile, hard to track samples. We will use full information maximum likelihood to adjust for missing data, perform sensitivity analyses to check the nonresponse mechanism, and attrition analyses to detect differential rates by sociodemographic variables that may pose a threat to the validity or the equity of the findings. When missingness is not ignorable, we will use complex models to obtain parameter estimates (e.g., Diggle-Kenward selection model or pattern-mixture model). We will data reduction techniques (confirmatory factor analysis, weighted regression scores) by creating multi-indicator multi-informant construct variables when applicable. These techniques improve measurement properties and result in fewer contrasts to reduce Type I error. Before data analysis, we will test the psychometric properties (i.e., distribution, reliability) of the measures and invariance using nested multiple-group confirmatory factor analyses.

Data concerning implementation of FCU4Health will be largely descriptive with comparisons to rates or means from previous FCU/FCU4Health studies. ANCOVA will be used to compare caregiver satisfaction and acceptability between the trial arms (FCU4Health and services as usual). Concerning fidelity, mean scores will be compared in this study to those from past studies in which it was found that fidelity to the FCU predicts improvements in parenting skills and child behaviors [44,66,67,73].

An ingredients-based *cost analysis* (commonly referred to as a budget impact analysis) procedure will be employed to estimate FCU4Health start-up and continued implementation costs from various perspectives, such as the implementing site [74]. Using an activity-based costing approach, with data from a Cost Capture survey administered to appropriate, internal team and clinical site members, will allow us to value activities both locally and from national data sources, providing estimates relevant for scale up in Phoenix and in other pediatric care systems. Activities include further tailoring existing/developing new clinical and training materials for FCU4Health; participating in meetings and communication relevant to FCU4Health clinical components/training/delivery; and staffing for delivery takes and developing technology and other infrastructure takes to support FCU4Health. Second, a multi-perspective *cost benefit analysis* will be undertaken to capture the potential impact of the FCU4Health on different key stakeholders (i.e., clinic, family, insurer). The fiscal models will be structured to estimate monetary benefits associated with program effects. For significant program effects on the outcome measures, we will calculate the total benefit as a function of the size of the effect (Q) and the price per unit (P) for each year, y: represented as By = Qy x Py. Overall effects across years will be adjusted using a discount rate. To avoid overlap or 'double counting' benefits, we will employ a weighted average approach. While point estimates often represent the bottom line for such an evaluation (e.g., a return-on-investment), a confidence

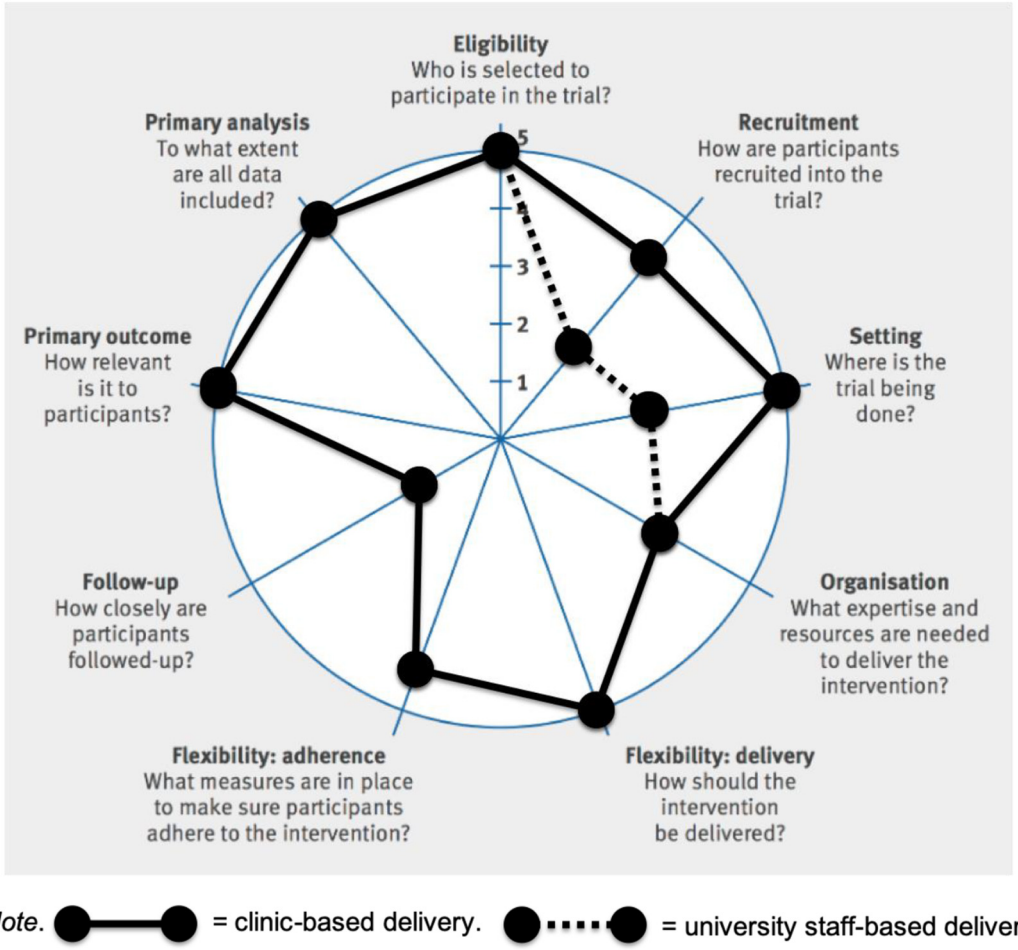

Fig. 2. Summary of the study design using the PRECIS-2 mapping.

interval is more appropriate when model assumptions vary. In addition to representing the variation that might be expected due to sampling, we will also consider a range of estimates due to anticipated variation in program characteristics determined through sensitivity analyses that incorporate different values of model input that might feasibly occur.

3. Discussion

The *Healthy Communities 4 Healthy Students* project of the FCU4Health program received support from the National Institute of Food and Agriculture (NIFA), Agriculture and Food Research Initiative (AFRI)'s Childhood Obesity Prevention Challenge Area. The stated aim of this Challenge Area is to end child obesity in the U.S. In previous years, this challenge sought to target early (FY 2011) and mid-to-late (FY 2012) adolescence, in alignment with the developmental periods experiencing the highest rates of childhood obesity. In FY 2016, the target age range was expanded down to two years to reflect data suggesting that early prevention is focused on addressing health behaviors, particularly for children at risk for health disparities, is more effective than later treatment.

Efforts to address public health problems must include a focus on effectiveness of interventions and factors related to uptake. Given the positive effects of the original FCU, the FCU4Health is likely to improve family health behaviors and prevent obesity. It is also likely to maintain its positive effects on behavioral health outcomes. From our perspective, the most important lesson to be learned as a result of this trial is whether and how a family-centered health promotion/parenting program like the FCU4Health may continue to be implemented in a primary care setting, which is an area with limited empirical data in the literature [75]. The trial is innovative in its combination of strategies to answer both effectiveness and implementation questions. To summarize the study's explanatory versus pragmatic design decisions, we applied the pragmatic–explanatory continuum indicator summary, version 2 (PRECIS-2) [76]. Each PRECIS-2 domain is rated on a scale of 1 to 5, with 5 representing the most pragmatic or similar to regular care. The co-developers of FCU4Health and PIs of the study rated the domains independently and then discussed each to come up with a consensus rating (see Fig. 2).

The first PRECIS-2 domain is eligibility. Recognizing physicians' aversion to limitations on who can participate in the first trial, the only exclusion for the current trial is the age of the child and the availability of a caregiver to participate. The recruitment and setting domains are given two scores because of the two approaches being used. Recruitment will be either done at the clinic by providers (more pragmatic) or by study staff (less pragmatic) Similarly, families can receive services from clinic providers (more pragmatic) or university-based providers (less pragmatic, although this is mitigated by using the same structure for training and supervision). Organization is rated at the midpoint because the expertise and resources needed to deliver most program components are similar to regular care, while the requirement for preparation time goes beyond regular care. Flexibility of program delivery and family adherence are rated as most pragmatic given the individually tailored nature of FCU4Health. Follow-up is rated at the midpoint because participants will be compensated for providing data. Primary outcomes are rated as pragmatic because child health behaviors and behavioral health are very relevant for caregivers and healthcare providers [26]. Finally, using intent-to-treat analysis is a pragmatic approach because all participant data are included in the

study results. In sum, these design choices should result in findings that are useful for program stakeholders in making decisions with respect to the implementation of the program should FCU4Health demonstrate effectiveness at improving parenting and child health behaviors and preventing obesity and behavioral health problems.

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