

# The Family Check-Up for Health (FCU4Health): A Family-Centered Health Maintenance Approach to Improve Nutrition and Prevent Obesity in Early Childhood

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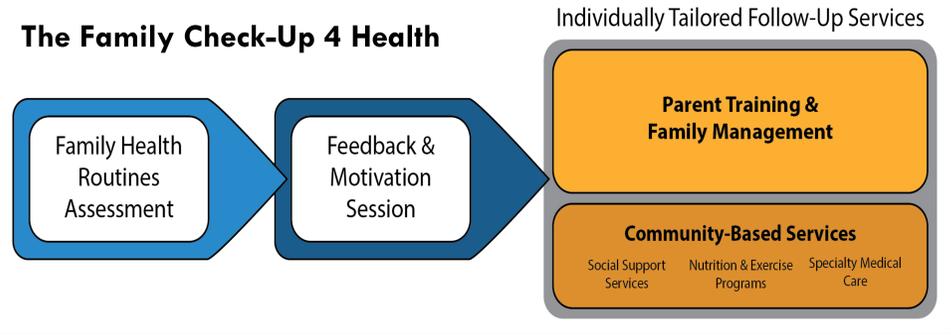
## Introduction

- Obesity is an epidemic in the United States that begins very early in life and disproportionately impacts Latino, African American, and American Indian children (Ogden et al. 2017)
- Family-based interventions are best practice for prevention and management of obesity in early to late childhood (e.g., Whitlock et al. 2014), yet they have not been widely adopted and sustained in the US healthcare system (Smith, St. George, & Prado, 2017)
- Improved obesity rates and BMI trajectories were identified in two completed randomized trials of the Family Check-Up (Smith et al. 2015; Van Ryzin & Nowicka, 2013), an evidence-based program designed to address conduct problems and substance use (Dishion et al. 2008)
- To achieve a population-level impact on reducing rates of childhood obesity, research is needed on ways to implement evidence-based programs in communities and systems of care that reach the families in greatest need and at greatest risk for health disparities
- We adapted the Family Check-Up to address pediatric obesity and health behaviors in the primary care setting. The new program, called the Family Check-Up 4 Health (FCU4Health; Smith, Berkel, et al., 2018a), is currently being tested in primary care with 6-12 year old patients with elevated BMI in an ongoing randomized trial (Smith, Berkel, et al. 2018b)
- In the current study, we are testing the FCU4Health as a prevention model in coordination with multiple systems: a preschool, an integrated primary care/behavioral health clinic, and a family resource center
- This study will evaluate the effectiveness and implementation of the FCU4Health delivered in primarily, Latino families low-income community to prevention obesity in children ages 2 to 5 years of age. A health maintenance model is used for repeated assessment and intervention across a 3-year period.

## Method

### Participants & Procedures

- Children ages 2 to 5 years of any weight/BMI recruited for inclusion in the study from schools, community resource center, and an integrated primary care/behavioral health clinic in low-income community in Maricopa Country, Arizona.
- Recruitment materials are distributed to the caregiver(s) of eligible children through partnership with the school and the community resource center. In-person recruitment occurred in the healthcare clinic (by providers) and the resource center (by study staff).
- Upon consenting to participate, families are assessed in the home using validated surveys and semi-structured family interaction tasks (FIT). See Table for primary process and outcome measures.
- Randomization occurs at the end of the assessment. Families randomized to the FCU4Health arm (n=120), compared to services as usual (n=80), are then offered the program (see Figure below).



## Trial Design

- Efficacy/Effectiveness-Implementation Hybrid Type I Trial design** (Curran et al. 2012). Simultaneous evaluation of the effectiveness of the FCU4Health to improve dietary practices and nutritional intake in service of preventing obesity and of its implementation in an underserved community with health disparities in childhood obesity rates.
- Allocation:** Effectiveness trials often result in limited power to examine associations between implementation and program outcomes. As a result, we used an unbalanced design (120 FCU4Health/80 control) to provide more power to test these associations.
- Health maintenance approach.** Similar to a prior trial of the original FCU (Dishion et al. 2008), families randomized to the intervention arm will be offered the FCU4Health feedback and motivation session and the individually-tailored follow-up services yearly over three years, resulting in regular and repeated contact with families and thus multiple opportunities for the family to engage in the program and for the facilitator to monitor progress and emerging challenges and intervene in the right amount at the right time.
- Evaluation.** All families in the trial are assessed yearly on the outcomes listed in the table below.
- Training and monitoring FCU4Health delivery.** FCU4Health facilitators receive formal in-person and e-learning based training in the program followed by individual and group consultation during delivery. Fidelity to the program is monitored by rating feedback sessions using the validated COACH rating system (e.g., Smith et al., 2013)

	YEAR 1		YEAR 2				YEAR 3				YEAR 4				YEAR 5				
	Q1-3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Recruitment																			
Assessments		W1				W2				W3				W4					
FCU4Health		FB1		Services		FB2		Services		FB3		Services							

Note. W = Assessment Wave; FB = FCU4Health Feedback Session.

### Primary Process and Outcome Measures

<b>Nutrition.</b> The Dietary Screener Questionnaire (DSQ) is a 26-item measure that assesses the frequency of consumption in the past month of fruits and vegetables, dairy/calcium, added sugars, whole grains/fiber, red meat, and processed meat. The DSQ has been used in NHANES since 2009-2010 and scoring algorithms were developed to calibrate DSQ results with data obtained via 24-hour recall.	Respondent: Caregivers (n=180) Frequency: Annual X3 (n=720)
<b>Physical Activity.</b> The Children's Physical Activity Questionnaire is a brief questionnaire that asks caregivers to report on the frequency and time their child spent engaged in different physical and leisure activities over the past week. It has shown adequate test-retest reliability (.55-.68) across different levels of physical activity intensity with highest correlations for moderate physical activity.	Same as above
<b>Family Health Behaviors.</b> The 27-item Family Health Behaviors Scale 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 ( $\alpha > .83$ ), temporal stability ( $\alpha = .86$ ), and invariance in diverse low-income families.	Same as above
<b>Parenting and Family Management Skills.</b> Surveys include two positive behavior support scales (proactive parenting [7 items], incentives and encouragement [4 items]); three relationship quality scales (parenting warmth [5 items], family conflict [4 items], quality time [5 items]); and scales on monitoring (7 items) and limit setting skills (7 items). All of these measures have been used in previous research and have demonstrated convergent and predictive validity and internal consistency above 0.75.	Same as above
We use the Family Interaction Task, a validated observational coding system to rate interactions. A random sample of 20% of the interaction tasks will be double-coded in order to calculate reliability.	Respondent: rating Frequency: Annual X3 (n=720)
<b>Engagement in Community-Based Services.</b> Caregivers report service engagement each year on a survey developed for and being validated in our current CDC-funded trial. Each year, we assess the type of services (e.g., cooking classes, recreation programs, SNAP benefits), families needed, sought, and whether they were successful in accessing the service. For those services the family does access, the survey asks caregivers to report on the amount (number of hours) they engaged in each over the prior year.	Respondent: Caregivers (n=180) Frequency: Annual X3 (n=720)
<b>Caregiver satisfaction and acceptability.</b> Caregivers will be administered the 9-item (4-point scale) FCU Caregiver Service Satisfaction Survey and three subscales (15 items total rated on a 5-point scale) from the Parent Experience of Assessment Survey to assess satisfaction with services. Both measures have good internal consistency ( $\alpha > .75$ ). The Treatment Acceptability Rating Form-Revised Short consists of 10 items rated on a 7-point Likert scale. Internal consistency is high ( $\alpha = .92$ ).	Respondent: Caregivers (n=400) Frequency: Annual (n=1200 total)
<b>Agency acceptability and appropriateness.</b> Agency stakeholders (n=40) will be administered two questionnaires electronically: 1) subscales of the Annual Survey of Evidence-Based Programs concerning acceptability of training, program costs, and the delivery of the program (internal consistency $> .75$ ); and 2) the FCU4Health Stakeholder Survey to assess the relevance, perceived fit, and compatibility of the program and barriers/facilitators to delivery (11 items rated on a 5-point scale).	Respondent: Stakeholders (n=40) Frequency: Twice (end of Y1, end of Y4) (n=80 total)
<b>Fidelity.</b> We will assess fidelity to the FCU4Health using the COACH, a valid, reliable, peer-reviewed observational rating system comprised of 5 dimensions of in-session coordinator skills that are rated on a 9-point scale: 1-3 (needs work); 4-6 (competent work); 7-9 (excellent work) that accounts for the degree to which prescribed behaviors are observed and how well they were applied. This procedure is referred to as competent adherence in the literature. Interrater reliability has been good in previous studies ( $\geq .73$ ).	Respondent: video Frequency: n=75 total Respondent: rating Frequency: 25/year
<b>Costs.</b> Cost capture methods will be used to carefully track installation and delivery costs of the FCU4Health. Facilitators, CHWs, and study staff will report the number of hours spent on relevant activities (see Family Participation measure below). Electronic budgets will track program spending and be used to prospectively separate costs associated with implementation from those specifically related to research (e.g., data analysis software), start-up (e.g., training, assessment materials), and ongoing costs (e.g., technical assistance, fidelity monitoring, case consultation).	Respondent: FCU4Health staff and implementation team Frequency: Weekly in Y1-Y4

## Public Health Impact

- Designs combining the characteristics of effectiveness trials, while simultaneously evaluating implementation, could speed translation of promising programs.
- This trial will test the feasibility of implementing the FCU4Health across multiple health and community-based service systems. Cost of implementation and cost-effectiveness outcomes are of high relevance.
- The health maintenance model could prove to be a key characteristic in slowing the childhood obesity epidemic compared to other intervention delivery approaches and, if successful, are well-aligned with the routine contact of the primary healthcare and school systems, which could support implementation.
- To appreciably move the needle on obesity rates in childhood, family-based approaches the improve nutrition and dietary practices early in life, before obesity is present, are desperately needed.

### Selected References

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