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Abstract

Background: Modifiable health risk behaviors tend to co-occur, are transmitted intergenerationally, and contribute substantially to chronic disease burden and mortality in the US. These behaviors disproportionately affect populations experiencing low socioeconomic status and/or behavioral health conditions. Parent-focused multiple health behavior change

(MHBC) interventions have shown mixed results and often overlook parents' own health behaviors. Furthermore, few have linked intervention components to established theoretical constructs. This pilot study evaluated the reach, preliminary effectiveness, and feasibility of a novel, theoretically grounded, MHBC intervention – RAISE Families for Health – within a federally qualified integrated care clinic serving a predominantly Hispanic/Latine population.

Methods: We employed a mixed-methods effectiveness-implementation hybrid Type I design with a single pre/post arm. Participants were adult parents and caregivers recruited from the clinic and surrounding community in Denver, CO. The intervention comprised an eight-session virtual curriculum delivered by trained clinic staff in English or Spanish and in individual or group formats. Quantitative and qualitative data were evaluated using the RE-AIM framework.

Results: In total, 65 unique individuals (100% female; 62% Hispanic/Latine) participated in the RAISE program, and 75% attended at least 6/8 sessions. Participants demonstrated significant improvements during the RAISE program in average sleep duration (6.9 to 7.4 hours per night; p=.049, Cohen's d=.38), perceived food quality (6.2 to 7.1 on 10-pt scale; p=.042, d=.45), and increased confidence in ability to improve family's health (8.3 to 8.8 on 10-pt scale; p=.049, d=.39). No significant changes were found in levels of physical activity or perceived stress. Perceived importance and motivation remained high from pre to post intervention and did not change significantly. Thematic results extracted from participant focus groups highlight the importance of virtual delivery for increasing the program's reach, perceptions of social support created by the facilitator and other participants, and intentions to maintain healthy habits developed during the program.

Conclusions: This study demonstrated preliminary effectiveness, feasibility, and acceptability of a theory-driven, parent-focused MHBC intervention within an integrated care setting. These findings show promise for promoting health behavior change among underserved parents and caregivers and support further evaluation in larger controlled studies.

Keywords: Multiple health behavior change (MHBC); Parent-focused intervention; Integrated primary care; Chronic disease prevention; Hybrid effectiveness-implementation design; Information-Motivation-Behavioral Skills (IMB) model; Mixed methods; RE-AIM

Background

Noncommunicable diseases, also referred to as chronic diseases, accounted for an estimated 43 million deaths worldwide in 2021 [1]. In the United States, three in four adults live with at least one chronic condition, and more than half live with two or more [2]. Recent projections suggest that the prevalence of multimorbidity among U.S. adults aged 50 years and older will increase by 91% by 2050 [3]. The burden of chronic disease is strongly associated with modifiable health behaviors, including tobacco use, poor nutrition, inadequate physical activity, and insufficient sleep. Historically, tobacco use and poor diet/physical inactivity were considered the two leading preventable causes of death in the United States [4]. More recent analyses from the Global Burden of Disease Study suggest that metabolic risk factors- particularly high systolic blood pressure and fasting plasma glucose – now rank ahead of tobacco use as contributors to mortality in the US [5]. Interventions have targeted these risk behaviors individually; however, health risk behaviors often co-occur and interact synergistically, increasing vulnerability to

chronic disease [6-9]. For example, poor dietary habits may contribute to reduced energy and nutritional deficiencies, which can discourage physical activity and ultimately increase risk for metabolic and cardiovascular disease.

The distribution of health risk behaviors and associated chronic disease burden is not uniform across populations. Individuals with lower household incomes experience disproportionately higher rates of poor diet quality, type 2 diabetes, hypertension, overweight and obesity, physical inactivity, tobacco use disorder, and poorer tobacco treatment outcomes [10-12]. Similar patterns emerge during childhood and adolescence. Youth from lower socioeconomic status (SES) households are more likely to exhibit behavioral risk profiles characterized by inadequate physical activity, low fruit and vegetable consumption, and excessive screen time, all of which are associated with adverse health outcomes [13, 14]. Behavioral health challenges such as depression and suicidality are also consistently associated with poor dietary quality, physical inactivity, inadequate sleep, and tobacco use, suggesting that multiple health risk behaviors often cluster within vulnerable populations and contribute to widening health disparities [15-17].

The intergenerational transmission of health behaviors is well established, highlighting the family system as an important target for prevention and intervention efforts. Families play a central role in shaping children's tobacco use, dietary habits, physical activity patterns, and how they view themselves with respect to health and health behaviors [18-20]. Accordingly, family-based interventions have been identified as promising approaches for addressing childhood obesity, increasing physical activity, preventing smoking initiation, and improving family

functioning and cohesion [21-25]. Nevertheless, evidence regarding the effectiveness of family-based interventions remains mixed [26-28], and relatively few interventions have targeted multiple health behavior changes (MHBC) across behavioral domains such as nutrition, physical activity, sleep, and substance use. Primary care and integrated care settings offer substantial opportunities to deliver preventive interventions to underserved families; however, implementation of evidence-based MHBC programs within these settings remains limited. A recent systematic review of parent-based interventions targeting multiple health risk behaviors among parents and adolescents identified 36 randomized controlled trials (RCT) but found relatively little evidence regarding intervention effects on parents themselves [29]. Only a small number examined parent health behaviors, and no interventions targeted sleep among parents or adolescents. Among the limited studies assessing parent outcomes, improvements were observed primarily in dietary quality and physical activity, although findings were inconsistent across interventions. These gaps highlight the need for additional research evaluating comprehensive, family-based MHBC interventions that directly target parents' own health behaviors while examining implementation within real-world healthcare settings.

One framework with potential to guide MHBC interventions is the Information-Motivation-Behavioral Skills (IMB) model of health behavior change [30, 31]. Originally developed to explain HIV-related risk and prevention behaviors, the IMB model proposes that three constructs are essential for sustained behavior change: information, motivation, and behavioral skills. Individuals must possess accurate and actionable knowledge regarding health behaviors, be motivated to engage in those behaviors, and have the skills necessary to initiate and maintain

behavior change. The IMB model has since been applied successfully to a variety of chronic disease contexts, including diabetes self-management and cancer-related care and prevention [31, 32]. In addition, IMB constructs have demonstrated predictive validity across diverse health behaviors, including physical activity among adults with chronic disease, fruit and vegetable consumption among adolescents, medication adherence among older adults with multiple chronic conditions, and hepatitis B medication adherence among Asian American populations [33-36]. Despite this growing evidence base, relatively few interventions have systematically operationalized all three IMB constructs outside of HIV-related contexts, and even fewer have applied the model to interventions targeting multiple health risk behaviors simultaneously.

The primary aim of the present pilot study was to evaluate RAISE Families for Health (RAISE), a novel MHBC intervention designed for parents and caregivers and grounded in the IMB framework. RAISE was implemented within a federally qualified integrated care clinic (ICC) in metropolitan Denver, Colorado, serving predominantly low-income Hispanic/Latine families. The program integrates prevention services within a comprehensive whole-health framework through health education, motivational engagement strategies, and skill-building activities. Program goals are to improve parents' own health behaviors which is known to have life-long impacts on children's health-related identities and increase parental efficacy to effect change within their families. By targeting parents and caregivers, the program seeks to disrupt the intergenerational transmission of poor health and chronic disease.

Given the clinic population, two secondary research questions were of particular interest. First, we examined whether RAISE engaged Hispanic/Latine parents at rates comparable to those of

non-Hispanic/Latine parents and whether intervention outcomes differed by ethnicity. Understanding equitable program reach and effectiveness is critical because Hispanic/Latine populations experience disproportionate barriers to preventive health services and behavioral healthcare [37, 38].

Second, we tested whether intervention outcomes differed according to participants' SES and the extent to which they are future-oriented. Health-promoting behaviors often require individuals to incur immediate costs—including expenditures of time, effort, money, or foregone gratification—in exchange for benefits that may not materialize until the future. Consequently, individual differences in future-oriented thinking may influence engagement in and maintenance of health behaviors. Future time perspective refers to the extent to which individuals consider and value future outcomes when making present-day decisions [39]. Greater future orientation has been associated with healthier dietary patterns, increased physical activity, improved sleep-related behaviors, and other health-promoting practices [40-43]. Importantly, future orientation also varies across socioeconomic contexts. Individuals experiencing socioeconomic disadvantage often demonstrate lower levels of future orientation, reduced optimism regarding future outcomes, and greater impulsivity—patterns that may represent adaptive responses to environmental uncertainty and resource scarcity [44]. However, these tendencies may also create additional barriers to initiating and sustaining health behavior change. Examining variation in intervention outcomes across SES and future time perspective may therefore provide important insights into how MHBC interventions can be tailored to reduce health disparities and improve effectiveness among underserved populations.

The objectives of this pilot study were to (1) evaluate the reach, feasibility, and preliminary effectiveness of RAISE Families for Health and (2) examine whether outcomes differed by ethnicity, SES, and future time perspective. Accordingly, we employed a mixed-methods effectiveness-implementation hybrid Type I design [45] and organized findings using the RE-AIM framework [46]. RE-AIM evaluates five dimensions of intervention impact—Reach, Effectiveness, Adoption, Implementation, and Maintenance—and has been widely applied in public health and health behavior change research [47]. Specific measures corresponding to each RE-AIM dimension are described below.

Methods

Setting. The study was conducted at a Federally Qualified Health Center (FQHC) – a nurse-operated ICC in metropolitan Denver, Colorado, currently recognized as a Level 1 Patient-Centered Medical Home. The ICC's mission is to provide comprehensive, integrated, and culturally responsive healthcare to communities with high concentrations of racial/ethnic minority and low-income families. Services include adult and pediatric primary care, behavioral health, dental care, maternity care, and pharmacy services. The ICC operates in a Medically Underserved Area, a Primary Care Health Professional Shortage Area (HPSA), and a Mental Health HPSA. Socioeconomic disadvantage is particularly pronounced; in 2017, approximately 84% of clinic patients lived below 200% of the federal poverty level.

Participants and Recruitment. Participants were adult parents and caregivers interested in improving their own health and the health of their families. Recruitment occurred through multiple channels. Clinic providers received information about the program during staff

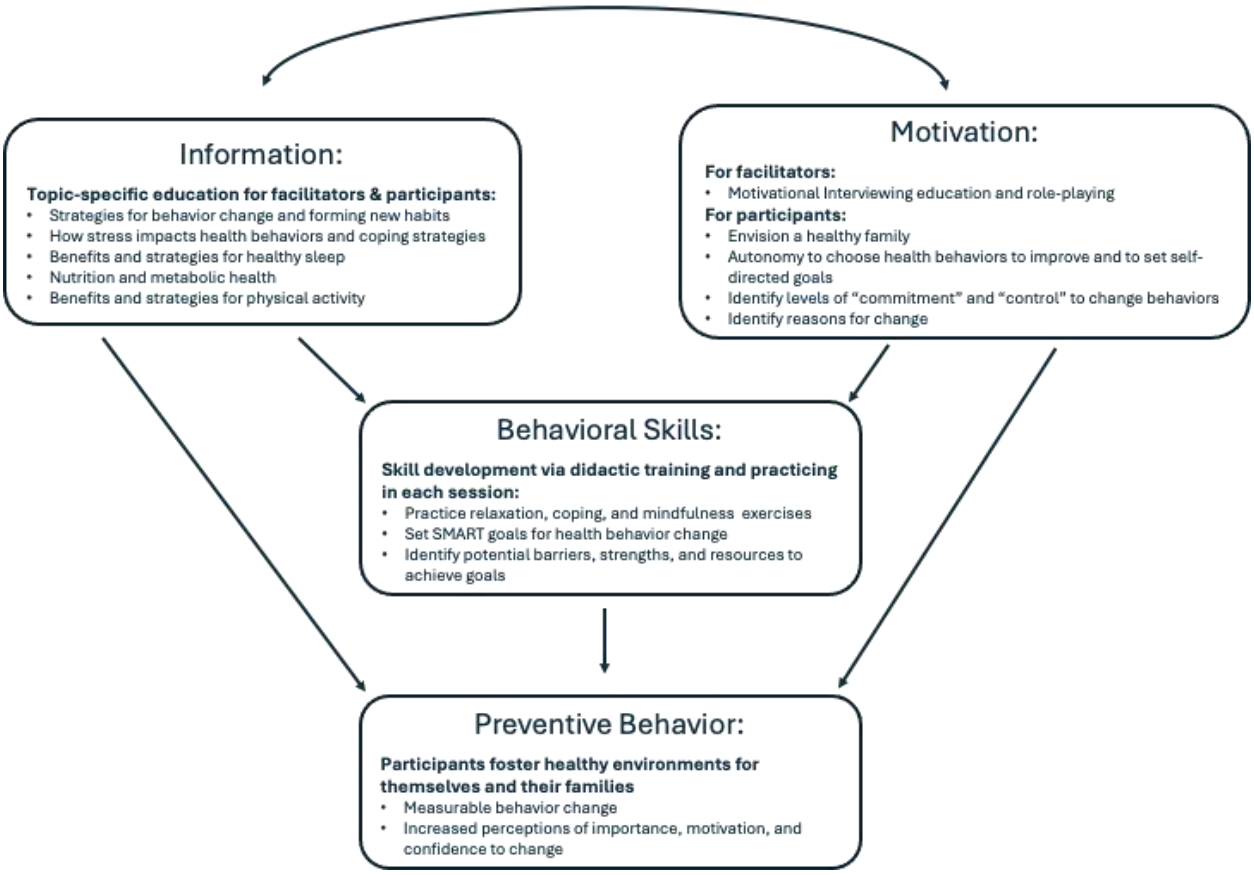
meetings and were provided referral materials and program flyers to distribute to patients. A RAISE facilitator personally contacted referred patients by telephone to discuss participation. Additional recruitment strategies included distribution of flyers throughout the clinic and community settings (e.g., schools, recreation centers, libraries), presentations to community organizations, and word-of-mouth referrals from community members and former participants. Participants were not required to be registered patients of the ICC to participate. Eligibility criteria included being at least 18 years of age, speaking English or Spanish, and having access to the internet. Participants received Target gift cards as incentives for participation ($20 for attending the first session and $10 for each subsequent session attended).

Ethics approval and consent to participate. This research was reviewed by the University of Colorado's Multiple Institutional Review Board (COMIRB) and was determined to meet criteria for exemption under Category 4 (secondary research) according to the Revised Common Rule (45 CFR 46.104); Protocol Reference #19-1085. Per 45 CFR 46, Category 4 studies are "secondary research for which consent is not required."

Intervention. RAISE Families for Health (RAISE) was developed in 2018 to address the intergenerational transmission of health risk behaviors and chronic disease among underserved populations. Grounded in the IMB model of health behavior change, the program seeks to help parents and caregivers envision and achieve healthier lifestyles for themselves and their families. The curriculum addresses multiple health behaviors associated with chronic disease prevention, including stress management, tobacco-free living, healthy sleep, nutrition, and

physical activity. RAISE facilitators complete a standardized two-day training covering the evidence base for each content area, as well as motivational interviewing and behavior change strategies. Facilitators receive a detailed manual containing session guides, participant handouts, and implementation instructions, as well as in-person training in curriculum delivery. The intervention consists of an eight-session curriculum that can be delivered in English or Spanish, in person or virtually, and in either group or individual formats. Figure 1 illustrates how specific RAISE components align with the information, motivation, and behavioral skills constructs of the IMB model.

Figure 1. Mapping of RAISE Components to the Information-Motivation-Behavioral Skills Model



Procedure. Clinic staff training occurred across three days in June and July 2019 and included 12 hours of didactic instruction covering program content and motivational interviewing strategies. Selected staff members completed an additional four-hour training focused on curriculum facilitation. Participant-facing RAISE sessions were conducted between March 2020 and August 2021. A total of 136 sessions were delivered during the study period. Because COVID-19-related clinic closures occurred during the week of program launch, only the first session was conducted in person. All subsequent sessions were delivered virtually via Zoom. Of the 136 sessions, 58 (43%) were conducted individually and the remainder were delivered in a group format.

Evaluation Strategy. The RE-AIM framework guided study design, measure selection, data collection, and reporting [46, 47]. RE-AIM evaluates five dimensions of intervention impact: Reach, Effectiveness, Adoption, Implementation, and Maintenance. Given the single-site nature of the study and the clinic's commitment to allocating staff time to intervention delivery, adoption outcomes were considered of secondary importance relative to other RE-AIM dimensions. Quantitative and qualitative data were collected to evaluate RE-AIM domains. Quantitative and qualitative data sources included participant surveys and focus groups. Participants received a $10 gift card for completing a post-program feedback survey and a $30 gift card for participating in a focus group.

Qualitative Data Collection. Two focus groups were conducted by a member of the study team via Zoom following program completion. Both groups were conducted in Spanish, as all participants who volunteered for focus groups were Spanish-speaking or bilingual. Focus groups followed a semi-structured interview guide developed for this study (see Supplementary File A) and included opportunities for probing and follow-up questions. Discussion topics included recruitment, perceptions of the program, implementation logistics, and perceived successes and challenges. Sessions lasted approximately 60–90 minutes. Focus group participants provided verbal consent for audio and video recording. Recordings were translated from Spanish to English and transcribed verbatim by bilingual study personnel. A second bilingual researcher independently reviewed all transcripts for accuracy.

RE-AIM Measures

Reach: Reach was assessed through participant enrollment, demographic characteristics (including race/ethnicity and language preference), referral-to-enrollment conversion rates, and comparison of participant demographics with those of the broader clinic population. Baseline health indicators were also collected using validated measures (Perceived Stress Scale [PSS]; [48]) and/or study-specific assessments. Qualitative findings related to recruitment and participation are also reported.

Effectiveness: At the beginning of each session, participants completed a Personal Progress Form assessing health behaviors and readiness-to-change. The Personal Progress Form consisted of shortened (i.e. single-item) versions of baseline assessments and included:

- **Sleep:** Average hours of sleep per night during the previous week
- **Physical activity:** Average daily physical activity during the previous week (none, 0–30 minutes, 31–60 minutes, >60 minutes)
- **Stress:** Perceived stress during the previous week rated on a 0–10 scale (0 = Not at all stressed, and 10 = Extremely stressed)
- **Nutrition:** Perceived quality of family nutrition during the previous week rated on a 0–10 scale (0 = Very poor quality [e.g., highly processed, fast food, high sugar] and 10 = Very good quality [e.g., minimally processed, fresh foods])
- **Tobacco use:** Average daily use of cigarettes, tobacco products, or vaping products (none, 1–5, 6–10, 11–20, ≥21).

- **Readiness-to-change:** Ratings of importance, motivation, and confidence related to improving family health (0–10 scales; 0 = Strongly Disagree and 10 = Strongly Agree).

Moderators: Future time perspective and future orientation were assessed at baseline using complementary measures. The 10-item Future Time Perspective Scale measures the extent to which individuals perceive their future as expansive versus limited, with responses rated from 1 ("very untrue") to 7 ("very true") [49]. The 5-item Time Perspective subscale of the Future Orientation Scale assesses the tendency to consider future consequences during decision making [50]. Higher scores reflected greater future orientation. A dichotomous proxy variable was created for SES. “Low SES” was defined as having reported one or more of the following: housing insecurity, food insecurity, or no one in the household having completed a high school level education. All others who supplied this information were placed in the alternative SES category.

A total of 42 participants completed at least two Personal Progress Forms and were included in analyses examining change over time. Program satisfaction was assessed using an anonymous online post-program survey consisting of four Likert-scale items evaluating overall satisfaction and perceived utility. Qualitative findings related to perceived outcomes are also presented.

Adoption: Adoption was assessed by the number of staff members completing RAISE training, the number completing additional curriculum facilitation training, and the number of staff who facilitated the RAISE curriculum.

Implementation: Implementation outcomes included participant attendance and intervention delivery format (individual vs. group). Facilitator fidelity to the core curriculum was assessed using a structured checklist completed after each session. Checklist items evaluated logistical preparation, completion of required session activities, delivery of key educational content, and use of participant engagement strategies. To allow facilitators time to gain experience with the curriculum, fidelity monitoring was initiated after completion of at least two full curriculum cycles. Qualitative findings related to feasibility, acceptability, and implementation processes are also presented.

Maintenance: Maintenance was assessed qualitatively through participant focus groups exploring sustained behavior changes among participants.

Data Analysis

Quantitative. To evaluate changes in health behaviors and readiness-to-change outcomes, participants' responses at their first session were compared with responses from the final session they attended using paired *t*-tests. Effect sizes were calculated using Cohen's d. Although all participants completed a Personal Progress Form during their first session, the number of sessions attended varied across participants. Consequently, the final observation represented each participant's last available assessment and may have occurred prior to completion of the full eight-session curriculum. Analyses therefore reflect within-person change

from program entry to last observed participation. To account for multiple comparisons across the seven pre–post outcomes, p-values were adjusted using the Benjamini–Hochberg false discovery rate (FDR) procedure [51]. All quantitative analyses were conducted using IBM SPSS Statistics v31.

Qualitative. Data were analyzed using a combination of deductive and inductive thematic analysis. Prior to coding, the research team developed a preliminary codebook based on the interview guide and study objectives. The codebook included anticipated codes and operational definitions to support coding consistency. Focus group data were analyzed independently of one another and by two separate researchers. Each researcher first reviewed transcripts multiple times to become familiar with the data. During coding, emergent codes were identified, defined, and incorporated into each codebook as needed. Following independent coding, researchers met to compare coding decisions, resolve discrepancies through discussion, and finalize the coding framework. Codes were subsequently organized into broader themes. Researchers reviewed all coded excerpts, identified patterns across participants, and iteratively refined candidate themes. Final themes were defined and named through consensus among the analytic team. Each theme was then assigned to the component of the RE-AIM framework it best aligned with. The research team was not employed by the clinic implementing RAISE but collaborated with the clinic during program implementation. This familiarity with the intervention may have influenced development of the interview guides and interpretation of qualitative findings. Researchers had no prior relationships with focus group participants before data collection.

Results

REACH

In total, 65 unique individuals participated in the RAISE program during the study period. As noted, RAISE participants were recruited via multiple routes and one of the largest sources of referrals was through the ICC healthcare providers. Out of 84 provider referrals throughout 2020 and 2021, 41 individuals participated in at least one RAISE session for a 49% conversion rate. Overall, 75% of participants completed at least six of the eight-session curriculum (mean no. sessions attended = 6.2). Table 1 presents the demographic and descriptive statistics for the sample of participants who provided evaluation data (n = 42). Participants were female (100%) and over half identified as Hispanic/Latine (62%), with an equal proportion participating in Spanish-language sessions (57%). Among those reporting education (n=29), educational attainment varied, with the largest proportion reporting less than a high school education (31%), followed by GED/high school diploma (21%), some college (21%), and college degree (21%), while a smaller percentage reported community or technical college training (7%).

Table 1. Demographics and Baseline Health Characteristics

	n/$\bar{x}$	%/St. Dev
Female (n=42)	42	100.0
Latine (n=41)	26	61.9
Spanish Language (n=41)	24	57.1
*Food Insecure (n=29)	8	27.5

**Housing Insecure (n=30)	7	23.3
Education (n=29)		
Less than high school	9	31.0
GED or high school diploma	6	20.7
Community or technical college	2	6.9
Some college	6	20.7
College graduate (Bachelor's degree)	6	20.7
Tobacco Use (n=42)	4	9.5
Hours of Sleep on Weekdays (n=27)		
Doesn't get recommended hrs	16	59.3
Gets recommended hrs	11	40.7
Hours of Sleep on Weekends (n=26)		
Does not get recommended hrs	14	53.8
Gets recommended hrs	12	46.2
Sleep Quality (n=27)		
Excellent	3	11.1
Good	13	48.1
Fair	7	25.9
Poor	4	14.8
Physically Active (n=32; hours per week)		
Less than 1 hour	7	21.9
1–3 hours	8	25.0

3–5 hours	8	25.0
5–10 hours	6	18.8
Over 10 hours	3	9.4
Time Sitting (n=32; hours per day)		
Less than 1 hour	6	18.8
1–3 hours	11	34.4
3–5 hours	9	28.1
5–10 hours	5	15.6
More than 10 hours	1	3.1
Perceived Stress Categorical Scores (n=28)		
0-13 "Low"	13	46.5
14-26 "Moderate"	15	53.5
27-40 "High"	0	0.0
Perceived Stress Score Average (n=28; range 0-40)	13.8	5.4
Reported Health (n=29; range 1-10)	7.1	1.52
Individual Overall Diet (n=29; range 1-10)	6.34	1.8
Family Overall Diet (n=29, range 1-10)	6.34	1.9

*Participants were considered food insecure if they answered 'yes' to "in the past 12 months we worried whether our food would run out before we got money to buy more" or "Within the past 12 months the food we bought just didn't last and we didn't have money to get more"

**Participants were considered housing insecure if they answered 'no' to "In the past two months, have you been living in stable housing that you own, rent, or stay in as part of a household?" or if they answered 'yes' to "Are you worried or concerned that in the next two months you may NOT have stable housing that you own, rent, or stay in as part of a household?"

Baseline health behavior characteristics. Most participants who provided data related to sleep patterns (n = 26) reported not getting the recommended hours of sleep on either weekdays (59%) or weekends (54%). Among participants with sleep quality data (n=27), most reported good or fair sleep quality, with 48% rating their sleep as good and 26% as fair. Smaller proportions reported excellent sleep (11%) or poor sleep (15%). Physical activity levels were relatively evenly distributed, with participants reporting less than 1 hour (22%), 1-3 hours (25%), 3-5 hours (25%), and 5-10 hours (19%) of activity per week, while fewer reported over 10 hours (9%). Sedentary behavior varied, with the largest proportion reporting 1-3 hours of daily sitting time (34%), followed by 3-5 hours (28%) and less than 1 hour (19%). Food insecurity was operationalized as an affirmative ('yes') response to either of the two items assessing concerns about food running out or food not lasting due to financial constraints within the past 12 months. Among participants with data (n=29), 28% indicated experiencing food insecurity. Perceived stress levels (n=28) were primarily in the moderate range (54%), with the remainder in the low range (47%) and none in the high range. The mean PSS score was 13.8 (SD=5.4). Participants reported moderate overall perceived health (M=7.1, SD=1.52), with average diet ratings of 6.34 (SD=1.8; SD=1.9) for both individual and family diet. Four participants (10%) disclosed tobacco use at the beginning of their participation in the program.

Did RAISE reach Hispanic/Latine participants at the same rate as non-Hispanic/Latine participants? As noted above, 62% of participants identified as Hispanic/Latine, and 57% attended sessions facilitated in Spanish. In the year before the project began, the ICC reported that 63% of their patient population identified as Hispanic/Latine, and 40% were best served in

a language other than English. These results indicate that the percentage of participants in the RAISE program identifying as Hispanic/Latine are reflective of the broader patient population. A higher percentage of the sample preferred sessions facilitated in Spanish, compared to the overall percentage of Spanish-preferred speakers at the ICC.

Qualitatively, participants discussed cultural norms that may have affected the program's reach, including gender roles in the family. In addition, participants said facilitating the program virtually made it easier for them to attend sessions (Table 2).

Table 2. REACH qualitative themes and illustrative quotes

Theme	**Example Quotes**
Virtual implementation made scheduling around other family commitments (e.g., school) easier	*"I am also very grateful that we were able to do it online because I would have not been able to participate if it was in person because of my work schedule."* *"I also really like it online because I was able to just be at the comfort of my home, like I didn't have to worry about getting ready or being showered or dressed, and I also liked that my daughters were here with me, like they were doing their own thing while I was in class and we would just not have to leave the house."*

Men may be more difficult to reach because women are typically the primary family caregiver to care for the family and because men are expected to work as a primary responsibility	*"Since young we are thought that women are supposed to educate, take care of the children, clean the house, stay home and men are thought to provide and work. I think that pattern continues right, like men are just supposed to work and provide money, home, food, and clothes… I do think that the woman does play a very important role because we are the ones that tell our children, eat this and eat that because it is good for that, so we play a very important role in the health of our families and that is true that men can take a part of this role and get involved more… I mean it would be incredible to see it."*

EFFECTIVENESS

Table 3 presents within-participant, self-reported changes in health behaviors and "readiness-to-change" measures from the first session to the final session attended. Paired t-tests indicated significant improvements over the course of the RAISE program in several domains of health behavior. Average sleep duration increased significantly from 6.85 to 7.35 hours per night (FDR-adjusted p=.049, Cohen's d=.38). Perceived food quality also improved significantly, increasing from 6.19 to 7.14 (FDR-adjusted p=.042, d=.45). Of the four participants who disclosed tobacco use at baseline, one successfully quit tobacco and two others started on nicotine replacement therapy (NRT), one of whom reduced from 6-10 cigarettes per week to 1-2 cigarettes per week.

In addition, participants reported significantly increased confidence in their ability to improve family health (8.28 to 8.82; FDR-adjusted p=.049, d=.39). Changes in perceived stress were not statistically significant, though mean stress scores decreased from 6.00 to 5.43, reflecting movement in the expected direction. Similarly, no statistically significant change was observed for physical activity, however mean scores increased, as expected. Participants' ratings of the importance of improving family health and motivation to engage in healthy behaviors remained high and did not change significantly over time.

Table 3. First and Last Session Differences

	n	Min	Max	1st Session	Last Session	Sig.
Sleep Hours Per Night[1]	40	2	10	6.85	7.35	**.049**
Perceived Stress[2]	42	1	10	6.00	5.43	.284
Food Quality[2]	42	1	10	6.19	7.14	**.042**
Physical Activity[3]	42	0	3	1.55	1.88	.191
Family Health Improvement: Important[2]	39	5	10	9.31	9.33	.921
Family Health Improvement: Motivated[2]	39	3	10	8.90	8.92	.921
Family Health Improvement: Confident[2]	39	3	10	8.28	8.82	**.049**

All tests were paired t-tests; p-value corrections were done via Benjamini–Hochberg False Discovery Rate; 1=Hours per night, 2=Likert Scale from 1-10, 3=Likert Scale from 0-4

Exploratory: Did intervention outcomes vary as a function of participant characteristics? To examine this question, we calculated change scores for each outcome by subtracting

participants' first-session values from their final-session values. Independent samples t-tests were then used to compare mean change scores by ethnicity (Hispanic/Latine vs. non-Hispanic/Latine) and SES (low vs. high SES). Because future orientation and future time perspective were measured continuously, Pearson correlations were used to examine associations between these measures and changes in outcome variables. Across these analyses, few statistically significant differences emerged. Non-Hispanic/Latine participants and those in the relatively higher SES group reported greater increases in confidence to improve family health compared to Hispanic/Latine participants (p=.010) and those in the lower SES group (p=.048). As well, self-reported changes in food quality were positively correlated with participants' future time perspective (p=.033). No other subgroup differences reached statistical significance.

Program Satisfaction. Eighteen participants completed a post-program feedback survey. Of those, most reported that they "Strongly Agreed" or "Agreed" with the following statements: "I'm glad I participated in RAISE"- 100%; "As a result of this program, I'm motivated to make healthy changes" – 94%; "My family will benefit because I participated" – 78%; and "I would recommend this program to my friends or family" – 89%.

In focus group interviews, RAISE participants frequently described the progress they made towards their goals, skills they learned, changes they notice in their families, and the connections they made as a result of RAISE sessions (Table 4).

425 **Table 4. EFFECTIVENESS qualitative themes and illustrative quotes**

Theme	**Example Quotes**
Participants made progress towards their goals	*"I came to the group to change my health habits, to improve my sleep habits – to sleep better – and honestly for me it has gone great."*
RAISE taught useful skills, including information on smoking, its dangers, and how to talk to others about it	*"No one in my family smokes, but I just thought it was important to teach the dangers of smoking to my children. But yes, I want to continue teaching them this even though these classes are over. I want to continue to implement these changes because for me and my family. They have been really helpful. Sometimes I go outside and work out for up to two hours. I really like it. I feel so great and with eating healthier as well … I plan to continue with these goals for the rest of my life while I can."*
RAISE benefited families by encouraging conversations about healthy habits, stress management skills, coming together more, and making healthy changes	*"I'm also a single mother, and I have a son here. It's only him and I. Now I talk to him more, I feel de-stressed, I sleep more, we are learning to eat more vegetables, fruits. And like the lady said … [I] learned to control stress and breathing techniques, all of that has helped me a lot."*

RAISE provided a foundation of knowledge to help form healthy habits and educate others	*"I think it is important for us to continue informing ourselves because things keep on changing every day. We as moms are very important because we are the ones that cook for our children, and so we need to find ways and tricks in order to feed them healthy and educate them about toxic things in the community like cigarettes, which are very popular now, and well after that is also alcohol. But overall making healthier life choices in order to live a pleasant life."*
While some participants already knew each other, RAISE created communities among participants that contributed to success	*"I liked the group because I was creating an exercise plan with a group member outside of the group meeting, and I started to connect with her."*
Family-wide improvements to physical activity, sleep, nutrition, stress, and tobacco use	*"My daughter … fell in a stress episode. She was hospitalized in December in a crisis clinic because of everything COVID and being stuck at home. So, I showed her the breathing technique, I was helping her relax, and now she has more control of it. I think overall it has helped my whole family because, when stressed … well for me personally, it has me in a bad mood almost all of the time … I got home and had to cook and clean and this and that*

	… but now not anymore, I get home and [my kids] help me. It has helped me a lot."

ADOPTION

Eleven staff members participated in 12 hours of didactic training related to topic areas as well as motivational interviewing strategies for health behavior change. Four of these staff members additionally completed a 4-hour training on facilitating the RAISE curriculum for parents and caregivers. Due to the onset of the pandemic coinciding with the launch of RAISE sessions, subsequent challenges at the ICC such as staff furlough, and competing priorities for remaining staff, only a single facilitator of those initially trained was available to facilitate sessions.

IMPLEMENTATION

Implementation outcomes were assessed through participant attendance, intervention delivery format, and facilitator fidelity monitoring. Due to COVID-19-related clinic closures occurring immediately after program launch, all sessions except the first were delivered virtually via Zoom. Despite this transition, implementation was feasible and participant engagement remained high. Participants attended an average of 6.2 sessions, and 75% completed at least six of the eight curriculum sessions. Seven participants (17%) completed the curricula individually with a facilitator, whereas the majority (83%) completed the curricula in a group-based format.

The small number of individuals participating on an individual basis precluded an examination of whether delivery format differentially influenced intervention outcomes.

Facilitator fidelity was assessed using a structured self-report checklist following each of 15 sessions. The checklist evaluated logistical preparation, completion of required session activities, delivery of key educational messages, and participant engagement strategies. Fidelity was high across domains. The facilitators reported completing 91% of required session activities (64 of 70 activities) and delivering all core educational messages either “mostly” or “completely.” Specifically, 84% of key messages (38/45) were reported as delivered “completely”, with the remaining messages delivered “mostly”. The facilitator also consistently reported implementing participant engagement strategies, indicating “strong agreement” that she “elicited participants’ own ideas” (12 of 15 sessions), “encouraged participation from all attendees” (10 of 15 sessions), and “fostered a supportive atmosphere” (12 of 15 sessions).

Qualitative findings further supported the feasibility and acceptability of implementation. Participants described the program as engaging, supportive, and relevant to their families’ needs. Focus group participants were thankful for the facilitators, often saying the facilitators were helpful, trusting, and led sessions with expertise (Table 5).

Table 5. IMPLEMENTATION qualitative themes and illustrative quotes

Theme	**Example Quotes**

Virtual implementation made it easier to join due to scheduling, but some participants needed help logging onto the software and some would like to attend in-person	*"I liked it because, well, I am a single mother and I have to work. And so … one comes home from work and they don't want to go out, and zoom gave me the opportunity to learn and continue working."* *"I struggled for like 3 weeks to get in our meeting using the codes … but … now I am good at it."*
Participants' desire to become healthier was more motivating than incentives offered for completing the program	*"I liked it a lot because I suffered because I smoked a lot and a lot of stress and a lot depression, and a lot of problem in my home, with my son. I liked it a lot and now I feel good and truthfully, it has helped me a lot and it wasn't because of the gift card; it had just helped, and this is why I joined today because I want to continue in the program."*
Virtual implementation created supportive communities among participants	*"I really enjoyed it because we were able to create a community even if it was through a screen. I was able to meet people that have similar thoughts as me and well that no longer makes you feel alone because it helps you realize that other people also think like you."*
Facilitators expertly leading the program with compassion,	*"Thank you to [the facilitator] because she has always talked to us with the truth, and it has all been really helpful, and I liked it a lot."*

connection, and trust helped participants succeed.	*"I really appreciated these classes and the connections; they were really beautiful to me and I want to thank … [the facilitator] for making this happen"*

MAINTENANCE

Qualitative data indicated a desire among participants to continue applying the habits and skills RAISE taught them following participation in the intervention. Participants also suggested topic areas for future program refinements (Table 7).

Table 7. MAINTENANCE qualitative themes and illustrative quotes

Theme	**Example Quotes**
Participants felt motivated to continue applying program skills and setting goals after program conclusion	*"I want to continue to work on all of the goals that I have set for myself in the beginning of this group. I have several goals, but the ones that are more [interesting] to me [are] eating healthier and working out."* *"I plan to continue with these goals for the rest of my life while I can."*

Participants desire a focus on marijuana, as that is a larger concern than tobacco	*"Tobacco is not used in my home but like [participant] said I also think it would be important of we talked about Marijuana next time because our children are more informed about it than we are."*

Discussion

The purpose of this pilot study was to evaluate the preliminary effectiveness, feasibility, and implementation of RAISE Families for Health**,** a novel family-based MHBC intervention delivered within an FQHC. Quantitative findings demonstrated significant improvements in sleep duration, dietary quality, and participants' confidence to improve their families' health over the eight-week intervention. Although the present study was not designed to formally test mediation, the observed increase in participants' confidence to improve their families' health is consistent with the behavioral skills component of the IMB model and suggests one potential pathway through which RAISE may facilitate behavior change. Changes in physical activity, perceived stress, and readiness-related constructs (importance and motivation) did not reach statistical significance, however mean scores improved in the expected direction across all outcomes. Possibly, dietary changes and sleep hygiene behaviors may require fewer environmental, cognitive, and physical resources and less sustained time commitment than increasing physical activity, particularly among parents of young children with limited financial resources and competing caregiving responsibilities. Baseline responses to items assessing the importance of, and motivation to improve family health were already very high (approaching or greater than 9.0 on a 1-10 scale) and slightly higher than reported confidence to improve family health. This is unsurprising, as

this study would have attracted individuals who were motivated to improve their family's health and those who considered it important. Possibly, lack of change on these dimensions reflects a ceiling effect. Alternatively, the study may have lacked sufficient statistical power to detect changes in physical activity, importance, or motivation.

Although only four participants reported tobacco use at baseline, three demonstrated meaningful progress toward cessation, including complete abstinence, substantial reduction in tobacco use with NRT, or initiation of NRT. While the small number of tobacco users precluded formal statistical analysis, these findings suggest that the intervention may support tobacco treatment engagement alongside improvements in other health behaviors. Future studies might explore whether RAISE participation is associated with other substance-related outcomes, as well.

Exploratory subgroup analyses revealed few differences in intervention outcomes across ethnicity, SES, or measures of future orientation. Because these analyses were underpowered, they should be interpreted cautiously. Nevertheless, the absence of clear subgroup differences provides preliminary evidence that RAISE may be beneficial across diverse populations without requiring extensive adaptation. Confirmation of these findings will require adequately powered trials specifically designed to examine treatment heterogeneity.

Implementation findings further support the feasibility and acceptability of RAISE within an integrated primary care setting. Recruitment, referral-to-enrollment conversion, participant

attendance, and facilitator fidelity all met or exceeded expectations for a pilot implementation. Moreover, the ethnic distribution of intervention participants closely reflected that of the clinic population, suggesting that the program was successful in reaching the intended community rather than a narrowly selected subset of patients. Notably, nearly the entire intervention was delivered virtually because of the COVID-19 pandemic. Despite this unexpected transition, participants described virtual delivery as increasing access to those who would not otherwise have participated. At the same time, implementation required flexibility and extra accommodations to address technology-related challenges experienced by some participants. These findings suggest that hybrid or virtual delivery models may represent a viable strategy for expanding access to family-based preventive interventions in underserved communities.

A recent systematic review identified 36 RCTs evaluating parent-based MHBC programs; however, only nine examined parents' own health behaviors [29]. Among those, intervention effects were generally limited to parent improvements in dietary behaviors, physical activity, or weight-related outcomes, and findings were mixed across studies [52-54]. Notably, the review did not identify any interventions that targeted or evaluated sleep among parents or children, despite growing recognition that inadequate sleep frequently co-occurs with poor diet, physical inactivity, and other chronic disease risk behaviors. Parental interventions designed to address substance use typically focused on parent-child communication, family functioning, and parenting practices, and although one study reported reduced parent alcohol use [55], none reported on parental tobacco use outcomes.

The current study extends this literature in several important ways. First, unlike many previous family-based interventions that primarily sought to influence youth behaviors by changing parenting practices or family functioning, RAISE directly targeted parents' own health behaviors while equipping them with the knowledge, motivation, and behavioral skills needed to create healthier home environments for their families. Second, RAISE addressed a broader constellation of health behaviors – including sleep, nutrition, physical activity, stress management, and tobacco use – within a single intervention. The significant improvements observed in sleep duration and dietary quality complement previous findings regarding dietary behavior while providing preliminary evidence that sleep may be a feasible target within family-based MHBC interventions. As healthy sleep is increasingly recognized as a fundamental determinant of chronic disease risk and interacts closely with diet, physical activity, and mental health, incorporating sleep into comprehensive MHBC interventions may enhance their public health impact [56, 57]. The current study also raises the possibility that RAISE may support tobacco-related change among parents, which previous parent-focused MHBC interventions did not examine.

Finally, our implementation findings complement those reported in previous parent-based interventions [29]. The systematic review concluded that programs incorporating social support and flexible engagement strategies were generally associated with greater parent engagement and more favorable outcomes. Similarly, qualitative findings from the present study suggest that participants valued the supportive relationships developed with the facilitator and other parents, while the flexible virtual delivery model reduced barriers related to transportation,

childcare, and competing family responsibilities. These findings suggest that accessibility and social connectedness may be important mechanisms supporting engagement in family-based MHBC interventions, particularly among medically underserved populations receiving care in ICCs.

The study had several strengths. First, the hybrid effectiveness/implementation design generated essential information about RAISE outcomes *in the context of a real-world application*. Obtaining simultaneous knowledge about intervention effectiveness and implementation factors is fundamental for decreasing the length of time from clinical innovation to broad service adoption and for increasing the likelihood that a novel clinical innovation will make it into general usage at all [58]. RAISE was implemented with high fidelity and remained feasible to deliver despite substantial disruptions associated with the COVID-19 pandemic. This programmatic flexibility bolsters the potential of RAISE to scale successfully while maintaining effectiveness. Second, mixed-methods data revealed complementary support for the intervention's reach, effectiveness, adoption, implementation, and maintenance. Quantitative outcomes related to health behavior changes mirror qualitative, participant-reported experiences of the program along with facilitator and leadership observations. Importantly, qualitative data yielded additional insights not captured by numerical data. For example, barriers related to competing staffing priorities, virtual implementation, and sex and gender considerations point to opportunities for evaluating future program refinements. Another strength is the intervention's explicit grounding in the IMB model. Although the IMB framework has demonstrated utility across numerous health behaviors, relatively few family-based

interventions have operationalized all three constructs within a comprehensive MHBC program. Grounding RAISE in an established behavioral theory strengthens both its conceptual foundation and its potential for replication. This study also benefited from the ICC's "research-ready" capabilities and staff experience partnering with academic institutions, integrating evidence-based interventions into clinical workflows, and collecting data. These attributes, combined with high facilitator-reported fidelity to the core RAISE components, helped to ensure that the current study tested the effectiveness of RAISE *as it was intended to be delivered*. This was especially important, given this is the first study to examine this novel MHBC intervention. Finally, the study focused on a medically underserved population that is often underrepresented in behavioral intervention research. Reach was further extended to community members (i.e. non-registered patients) who may not have otherwise accessed ICC services. Demonstrating feasibility and preliminary effectiveness within a federally qualified ICC serving predominantly Hispanic/Latine and low-income families increases the potential public health relevance of the intervention.

Despite these strengths, several limitations should be considered when interpreting the findings. First, this was a single-arm pilot study without a comparison group or long-term follow-up. Consequently, factors other than the intervention (e.g., pandemic-related disruptions) may have contributed to the observed changes in health behaviors, and the durability of these changes cannot be determined. Furthermore, because RAISE integrates multiple behavioral strategies delivered simultaneously, the present study cannot identify which intervention components or IMB constructs were primarily responsible for the observed outcomes. Also, the

relatively small sample size limited statistical power, increasing the risk of Type II error and rendering subgroup analyses exploratory. Accordingly, findings from these analyses should be interpreted cautiously and require replication in larger, adequately powered studies. Future research should evaluate RAISE in a fully powered, multi-site randomized controlled trial with longer-term follow-up. Larger samples would also permit more rigorous examination of potential moderators, including age, sex, baseline health risk, SES, future orientation, and other social determinants of health, along with delivery methods (e.g., in person vs. virtual). Mediation analyses would determine whether improvements in information, motivation, and behavioral skills explain intervention effects.

The study's generalizability is also limited. The intervention was implemented within a single ICC that had substantial experience partnering with researchers and implementing evidence-based programs. As a result, implementation outcomes may not generalize to clinics with fewer organizational resources or less experience adopting new interventions. In addition, COVID-19-related staffing challenges resulted in all RAISE sessions being delivered by a single facilitator. Intervention outcomes may therefore differ when implemented by facilitators with different educational backgrounds, professional experience, or facilitation styles. Finally, because all participants were women, the findings may not generalize to fathers, male caregivers, or more gender-diverse caregiver populations. This limitation aligns with the existing literature describing parent-focused MHBC interventions; most parent samples in the systematic review were mother-only or majority mothers, and no study targeted fathers or other male caregivers

[29]. Future studies should examine implementation across diverse healthcare settings and facilitators, and work to include fathers and other male caregivers.

Data collected for this study were self-report, which raises the possibility of recall bias or social desirability effects. However, participants reported health behaviors each week for up to eight weeks, reducing the likelihood that systematic change over time could have resulted from either of these biases. Nevertheless, future studies should incorporate objective measures of health behaviors and clinical outcomes where feasible. In addition, incomplete data collection introduced the possibility of attrition bias if participants who provided follow-up data differed systematically from those who did not. Of the 65 participants enrolled, 42 submitted data to examine change over time. Importantly, missing outcome data did not necessarily reflect program attrition; some participants completed the full intervention but did not return all assessment materials, whereas others completed follow-up assessments despite attending fewer than eight sessions.

Conclusions

This study tested whether a theory-driven, family-based MHBC intervention can be implemented successfully within an FQHC serving medically underserved families. Results indicate RAISE is acceptable to the intended participants and feasible to implement in an integrated-care setting using a flexible delivery model. The study provides preliminary evidence of improvements in multiple health behaviors within the target population.

List of Abbreviations

false discovery rate (FDR)

Federally Qualified Health Center (FQHC)

Health Professional Shortage Area (HPSA)

Information-Motivation-Behavioral Skills (IMB)

integrated care clinic (ICC)

multiple health behavior change (MHBC)

nicotine replacement therapy (NRT)

Perceived Stress Scale (PSS)

RAISE Families for Health (RAISE)

randomized controlled trials (RCT)

reach, effectiveness, adoption, implementation, maintenance (RE-AIM)

socioeconomic status (SES)

Declarations

Ethics approval and consent to participate. This research was reviewed by the Colorado Multiple Institutional Review Board (COMIRB) and was determined to meet criteria for exemption under Category 4 (secondary research) according to the Revised Common Rule (45 CFR 46.104); Protocol Reference #19-1085. Per 45 CFR 46, Category 4 studies are “secondary research for which consent is not required.”

Clinical Trial Number: Not applicable

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Authors' contributions: "CGA led the project conception and development of the intervention, funding acquisition, study design, data collection and analysis, and manuscript preparation; TM led the collection and analysis of focus group data and contributed to manuscript preparation; ZG co-led quantitative data analysis and manuscript preparation; LAM collected, translated, and assisted with analysis of participant focus group data; CWM co-led intervention development; ER contributed to manuscript development and review; CDM co-led funding acquisition and contributed to manuscript preparation and review. All authors read and approved the final manuscript."

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AI: A University-approved large language model (LLM) was used to improve the clarity, conciseness, and organization of the manuscript. All suggested edits were reviewed by the first author and were accepted, modified, or rejected based on the authors' judgment.

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Supplementary Files

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