ORIGINAL REPORT: PHASE IV RANDOMIZED CLINICAL TRIAL

Randomized Trial of Motivational Interviewing to Prevent Early Childhood Caries in Public Housing

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Abstract: Introduction: Caries experience among preschool-age children has remained relatively unchanged for the past 2 decades, despite recently documented decreases in untreated decay.

Objectives: In a community-based cluster-randomized controlled trial, a motivational interviewing (MI) intervention administered to primary caregivers was hypothesized to reduce caries increment over 2 y as compared with controls, among children aged 0 to 5 y at baseline living in public housing.

Methods: Public housing residents, who served as interventionists, were trained in MI with a focus on early childhood caries prevention. All 26 eligible public housing developments were randomized to either control (quarterly clinical examinations, fluoride varnish applications, toothbrush/toothpaste, and educational brochures) or intervention (same procedures as control plus MI counseling). Quarterly MI sessions

were delivered in English or Spanish over 2 y, audio recorded, and assessed for treatment fidelity. The primary outcome was the increment in dmfs (decayed, missing, and filled tooth surfaces) as assessed by clinical examination at baseline, 12 mo, and 24 mo. Secondary outcomes included caregiver oral health knowledge and child oral health behaviors (child toothbrushing and sugar-sweetened beverage intake). Baseline characteristics were compared between groups and adjusted for housing-site clusters. Longitudinal outcomes were analyzed with mixed models.

Results: A total of 1,065 children (49% female, 55% non-White, 61% Hispanic, 89% below poverty level, n = 686 control) and their caregivers were enrolled. During 2 y of follow-up, the mean dmfs increment increased in both groups; however, there were no statistically significant group differences at 24 mo or group $\times$ time interactions. The mean increase in

intervention caregivers' knowledge was significantly greater than that of control, $F(2, 1,593) = 3.48$, $P = 0.0310$, but there were no significant intervention effects on caregiver-reported child sugar-sweetened beverage intake or child toothbrushing.

Conclusion: MI counseling plus intensive caries prevention activities resulted in knowledge increases but did not improve oral health behaviors or caries increment (ClinicalTrials.gov NCT01205971).

Knowledge Transfer Statement:

When viewed in light of the findings from the companion Pine Ridge study and other recent MI studies, the results of this study suggest that when the complex disease of early childhood caries is addressed in high-risk populations, MI is not effective, and alternative approaches are warranted.

Keywords: oral health, dental caries, randomized controlled trial, health behavior, knowledge, prevention

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A supplemental appendix to this article is available online.

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Introduction

Caries experience among preschool-aged children has remained relatively unchanged for the past 2 decades, despite recently documented decreases in untreated decay (Dye et al. 2017). Effective preventive treatments for early childhood caries (ECC) are well known; yet, it continues to be the most common chronic disease of childhood, and there are marked disparities in caries experience, untreated decay, and access to dental care by race/ethnicity and income (Dye et al. 2017). Given the complex multifactorial determinants of ECC that exist on the individual, family, and community levels (Fisher-Owens et al. 2007; Lee and Divaris 2014), finding innovative strategies to reduce the prevalence and severity of this disease in high-risk populations is essential to reducing disparities. For young children, the role of the primary caregiver in reducing ECC risk is especially important (Albino and Tiwari 2016).

Public housing is a nationwide governmental model for housing the urban poor. Residents are mainly low-income minority females and, overall, have the worst health of almost any US population (Ruel et al. 2010; Harley et al. 2014). Public housing developments (PHDs) in the United States share similar infrastructure: they are typically centrally administered, financed by a housing authority, have local tenant task forces, and are commonly located near community health centers. PHDs offer the opportunity to efficiently access large numbers of families whose children are at high risk for ECC, and the PHD infrastructure can serve as a locus of action and intervention delivery by building on the existing social and structural environment (Hynes 2000).

Nationwide, >2 million people live in public housing, and children represent 37% of public housing residents (National Center for Health in Public Housing 2014). Fifty-eight percent of the heads of public housing households did not complete high school (Bader et al. 2004). The median household income in 2015 was \$13,984, substantially less than the national poverty level for a family of 3 at that time

(\$20,090). Fifty-two percent of public housing households are White, 44% Black, and 22% Hispanic (US Department of Housing and Urban Development 2017).

Motivational interviewing (MI) is a form of patient-centered counseling that utilizes strategies tailored to an individual's readiness to change. These strategies are designed to resolve ambivalence, increase motivation, and take steps toward enacting healthy behaviors (Miller and Rollnick 2002). MI has been applied successfully to a variety of health behaviors and in ethnically diverse populations, including substance abuse (Vasilaki et al. 2006), smoking (Borrelli et al. 2010; Brooks et al. 2017), diet (Armstrong et al. 2011), physical activity (Hardcastle et al. 2008), glycemic control (Channon et al. 2007), oral health (Weinstein et al. 2004, 2006), and medication adherence (Drymalski and Campbell 2009). Early MI studies aimed at ECC prevention were positive (Weinstein et al. 2004); however, more recent studies had mixed results (Gao et al. 2014; Albino and Tiwari 2016).

The objective of this cluster-randomized controlled trial was to assess the 2-y effect of MI on caries increment in primary teeth, as delivered by trained public housing residents to caregivers of children aged 0 to 5 y living in PHDs. It was hypothesized that children living in PHDs randomized to the intervention group would experience reduced caries increment as compared with those randomized to the control group.

Methods

Ethics Review

The Institutional Review Board at the Boston University Medical Center approved this study (protocol H-27749). All participants provided written informed consent.

Study Design

A cluster-randomized design was used, with family-designated PHDs in the Greater Boston area as the randomized units ($n = 26$). All eligible PHDs (those that did not participate in pilot

testing) agreed to participate and were randomized into 2 treatment groups: control and intervention. Individuals were eligible if they were residents of the included PHDs, had no plans to move in the ensuing 24 mo, and were women in their third trimester of pregnancy or primary caregivers of a child <6 y old. If a caregiver had >1 child, the youngest child was enrolled in the study as the index child, in an effort to instill healthy behaviors before unhealthy ones were adopted. However, although not included in the primary analyses reported in this manuscript, other children in the target age range were enrolled, and they received fluoride varnish and oral health assessments. Residents were excluded if they were unable to communicate orally in English or Spanish, they were <15 y of age, or their youngest child had a condition associated with abnormal tooth development or a fluoride varnish allergy. Adverse events to fluoride varnish were actively monitored (Garcia et al. 2017). A total of 5,645 fluoride varnish applications were completed for 1,360 children. No adverse events were identified (Appendix). Recruitment was conducted on a rolling basis by PHD from January 2011 until March 2014, and follow-up continued until December 2016. Multiple recruitment strategies were used, but most caregiver-child dyads were recruited via door knocking (Tiwari et al. 2014). The intervention was administered at baseline and then quarterly for 2 y (up to 9 visits). Outcomes were measured at baseline and 12 and 24 mo.

Randomization

The statistician stratified the 26 PHDs based on size and racial/ethnic composition. Within the 6 strata, housing sites were block randomized to the intervention groups via a computer random number generator.

Blinding

Given the study design, participants, interventionists, and field staff collecting questionnaire data could not be blinded. However, the clinical examiners

collecting primary outcome data were blinded to group assignment.

Control

The control group received 1) on-site child clinical examinations to collect data on decayed, missing, or filled surfaces (dmfs), with a report on current oral health status and a dental referral list; 2) fluoride varnish (0.40-mL dose of 3M ESPE CavityShield 5% sodium fluoride varnish); 3) a toothbrush and toothpaste; and 4) written handouts about 1 of the 9 topics described below. A research assistant with no MI training distributed the handouts but did not discuss them with participants.

Intervention

The intervention group received everything that the control received, plus quarterly MI counseling. Oral health advocates (OHAs), the interventionists, delivered a maximum of 9 MI counseling sessions (30 min each) to participants in their homes over the 24-mo study period. OHAs were public housing residents themselves with a high school education who were trained in ECC prevention and MI delivery, as described below. Counseling sessions were conducted in English or Spanish. The intervention was adapted from previously successful MI interventions (Borrelli et al. 2010). Per standard MI practices (Rollnick et al. 1999), participants were presented with a menu of ECC prevention strategies to discuss with the OHA: bottle and sippy cup use; cleaning your child's mouth; drinking fluoridated water; good-bye bottle, hello sippy cup; healthy snacks, keeping germs away; lift the lip; sleep time routine; and visiting the dentist. Each topic included the same handout given to the control group, which helped guide the discussions. OHAs used MI skills (rapport building, open-ended questions, reflections, affirmations, etc.) and strategies ("typical day," pros and cons of behavior change, values identification, etc.; Rollnick et al. 1999). At the end of each session, behavior change goals relevant to the topic were collaboratively set, and potential

strategies to overcome barriers were discussed. At subsequent sessions, OHAs reviewed progress toward the goal set at the previous session and discussed additional strategies to overcome any challenges that were identified, before the participant picked a new topic.

OHA Training

The OHAs received 8 h of classroom instruction in ECC and caries prevention and demonstrated competence by obtaining 100% on a written test. Competence was assessed annually. OHAs also received training in the protocol and MI over the course of 4 wk (13 full- and half-day sessions) through didactics, demonstrations, role-plays, written exercises, and video. The lead MI trainer was a clinical psychologist certified in MI training. Acquisition of counseling skills was determined by role-plays and simulated participant sessions in which intervention delivery was scored according to a checklist of required intervention components. Proficiency was also assessed by the Motivational Interviewing Treatment Integrity (MITI; version 3.1.1) coding system, which is an objective verification of MI adherence (Moyers et al. 2010). Prior to engaging with study participants, an OHA needed to reach the MI proficiency level on the MITI with 3 consecutive pilot participants. OHAs who failed to meet minimum requirements for ECC or MI training received additional training until they reached the required threshold.

Measure of MI Dose and Treatment Fidelity

OHAs completed intervention checklists documenting the MI counseling components delivered during each session and the session length. The checklists were used to ensure that the counseling was delivered as intended and to obtain estimates of counseling "dose" and treatment "exposure."

All MI sessions were audio recorded, and treatment fidelity was maintained through adherence to best practice guidelines (Borrelli et al. 2005; Borrelli

2011). Internal validity was assessed by 3 methods. First, 20% of randomly chosen audio recordings were coded with MITI. Sessions were coded in the language in which they were recorded by coders fluent in Spanish or English. Twenty percent of the English-coded sessions (88 total) were double coded to assess coder reliability. For OHAs who drifted below proficiency on the MITI coding, 50% of recordings were listened to, and additional training exercises and supervision were provided. Weekly supervision with each OHA also occurred in which a randomly selected audio recording was listened to and feedback provided on MI and adherence to intervention components. OHAs were required to use the treatment manual to guide their intervention delivery, and this was verified through audio-recording review. Finally, the MI supervisor validated the intervention checklists while listening to the audio recording during MI supervision.

Study Measures

The primary outcome measure was increment in dmfs over 2 y, as assessed by clinical examination based on criteria adapted from Iowa Fluoride Study. Caries increment was defined as a tooth surface developing caries (d, f, or m due to caries) on a previously sound tooth surface. Two calibrated dental examiners who were blinded to group assignment conducted the clinical examinations (Warren et al. 2015). Calibration sessions were conducted annually, during which clinical examiners and gold standard examiners needed to attain a minimum tooth surface level agreement of Cohen's kappa statistic ≥ 0.75 (Warren et al. 2015). A visual caries assessment was conducted with an intraoral light but without air, probing, or radiographs. Each surface was scored as decayed, missing due to caries, filled, or sound. A tooth surface was counted as decayed when there was enamel cavitation. White spot lesions were considered sound. For teeth that had crowns or were missing due to caries, 4 surfaces were recorded as carious for anterior teeth and 5

surfaces for posterior teeth. If a tooth was lost from exfoliation, extraction, or trauma over the study period, the last dmfs scores were used for subsequent examinations.

Caregiver-reported measures were collected via an interviewer-administered questionnaire in either English or Spanish and included sociodemographics (education, income, insurance status, etc.), oral health knowledge, and oral health-related behaviors related to their children's toothbrushing or mouth cleaning for pre-dentate children and sugar-sweetened beverage intake, as well as motivation, importance, and self-efficacy as related to oral health-related behaviors. Details on these measures are reported elsewhere (Albino et al. 2017). Scores were calculated as percentage of correct answers (knowledge), percentage of responses agreeing with oral health recommendations (behavior), or mean of responses for specific oral health-related behaviors within each construct (motivation, importance, and self-efficacy).

Sample Size and Power Analysis

Power analyses assumed a sample size of 1,090 fully enrolled caregiver/index-child dyads from 26 PHDs, with an intra-PHD correlation of dmfs equal to 0.01 (based on preliminary data), 70% retention at 24 mo, and 2-tailed tests with alpha equal to 0.05. We also assumed a baseline prevalence of ECC ranging from 22% to 25.5% (Kressin et al. 2009) and an intervention effect corresponding to a 40% reduction in ECC (Weinstein et al. 2004; Kressin et al. 2009). The design obtained power of 80.7% and 87.3% for the base rates of 22% and 25.5%, respectively.

Statistical Analyses

The data had a 3-level nested structure: PHDs, participants (index children or caregivers), and repeated assessments. Baseline characteristics were compared between intervention groups via chi-square and *t* tests that adjusted for PHD clusters. An intention-to-treat (ITT) mixed-effects marginalized zero-inflated overdispersed Poisson (MZIP)

model (Kassahun et al. 2014) fit to the baseline and 12- and 24-mo dmfs outcomes tested group, categorical time, and group $\times$ time effects. The group $\times$ time interaction was the primary test of intervention effects. Factor change coefficients are reported for modeled effects on dmfs counts. Mixed-effects linear models (motivation, importance, self-efficacy, oral health knowledge, and child sugar-sweetened beverage consumption) and a mixed effects logistic model (adequate child oral brushing/cleaning) were fit to caregiver-reported baseline through 24-mo outcomes testing ITT group, categorical time, and group $\times$ time effects. A per-protocol MZIP model of 24-mo dmfs outcomes compared control with the adherent intervention group, where intervention adherence was defined as completing ≥ 4 of the possible 5 MI sessions through the 12-mo visit. In addition, a per-protocol MZIP model of 24-mo dmfs outcomes compared adherent control with the adherent intervention group, where 1) intervention adherence was defined as completing ≥ 4 of the possible 5 MI sessions through the 12-mo visit and 6 of a possible 7 varnish applications through 21 mo of the study and 2) control adherence was defined as completing 6 of the 7 fluoride varnish applications by 21 mo. Candidate baseline modifiers of intervention effects on the dmfs and toothbrushing outcomes included race/ethnicity, poverty level, insurance, parental education, prior caries experience of child, acculturation, and parental motivation. Finally, mixed-effects dose-response models were fit to data from the intervention group only. In a dose-response MZIP model, 24-mo dmfs outcomes were regressed onto an indicator of cumulative MI dose as of the 12-mo visit. Also, dose-response mixed-effect models of caregiver-reported outcomes regressed 12- and 24-mo responses onto corresponding lagged, time-varying indicators of MI dose (i.e., MI dose through 9 and 21 mo for the 12- and 24-mo outcomes, respectively). Observed means are reported for all outcomes.

Results

A total of 1,065 dyads (379 intervention, 686 control) completed baseline activities and were enrolled in the study. Eighty-five percent of participants completed a 24-mo assessment (Figure). There were no significant differences between the groups in baseline characteristics (Table 1). Forty-two percent of the intervention participants attended at least 4 of the 5 MI visits in the first 12 mo (Table 2).

Fidelity of Intervention Delivery

Of 1,801 MI sessions completed, 552 were reviewed during weekly supervision sessions, and 439 (268 English and 179 Spanish) were MITI coded. Coders achieved good to excellent reliability with respect to the behavior count summary scores (percentage complex reflections, intraclass correlation coefficient [ICC] = 0.67; percentage open-ended questions, ICC = 0.75; reflection:question ratio, ICC = 0.93; percentage MI adherent, ICC = 0.63).

All average summary scores exceeded proficiency thresholds in both English and Spanish sessions. For English sessions, OHAs exceeded proficiency ratings for average global scores in 88.1% of sessions, percentage complex reflections in 82.5% of sessions, percentage open questions in 100% of sessions, reflection:question ratio in 89.6% of sessions, and percentage MI adherence in 94% of sessions. For Spanish sessions, OHAs exceeded proficiency ratings for average global scores in 92.4% of sessions, percentage complex reflections in 93.6% of sessions, percentage open questions in 98.8% of sessions, reflection:question ratio in 88.3% of sessions, and percentage MI adherence in 93.6% of sessions.

Primary Outcome dmfs Increment

There were no significant differences between the groups in dmfs at baseline (Table 3). Mean dmfs increased in both groups over the 2-y period: from 1.3 to 3.1 in intervention and from 1.6 to 3.1 in control. In ITT analyses, there were no statistically significant group differences

Figure. CONSORT (Consolidated Standards of Reporting Trials) diagram. FV, fluoride varnish; ITT, intention to treat; MI, motivational interviewing.

(continued)

Figure. (continued)

9 Month Visit <i>Children</i> 107 (28.2% of 379) completed dental screening 107 (100% of 107) dentate 106 (28.0% of 379) completed FV application <i>Caregivers</i> 150 (39.6% of 379) completed MI session	9 Month Visit <i>Children</i> 275 (40.1% of 686) completed dental screening 275 (100% of 275) dentate 275 (40.1% of 686) completed FV application
12 Month Visit <i>Children</i> 201 (53.0% of 379) completed dental screening 199 (52.5% of 379) completed FV application <i>Caregivers</i> 228 (60.2% of 379) completed self-report survey 220 (58.0% of 379) completed MI session	12 Month Visit <i>Children</i> 434 (63.3% of 686) completed dental screening 432 (63.0% of 686) completed FV application <i>Caregivers</i> 492 (71.7% of 686) completed self-report survey
15 Month Visit <i>Children</i> 97 (25.6% of 379) completed dental screening 95 (25.1% of 379) completed FV application <i>Caregivers</i> 141 (37.2% of 379) completed MI session	15 Month Visit <i>Children</i> 232 (33.8% of 686) completed dental screening 231 (33.7% of 686) completed FV application
18 Month Visit <i>Children</i> 96 (25.3% of 379) completed dental screening 95 (25.1% of 379) completed FV application <i>Caregivers</i> 126 (33.2% of 379) completed MI session	18 Month Visit <i>Children</i> 191 (27.8% of 686) completed dental screening 191 (27.8% of 686) completed FV application
21 Month Visit <i>Children</i> 86 (22.7% of 379) completed dental screening 85 (22.4% of 379) completed FV application <i>Caregivers</i> 130 (34.3% of 379) completed MI session	21 Month Visit <i>Children</i> 211 (30.8% of 686) completed dental screening 210 (30.6% of 686) completed FV application
24 Month Visit <i>Children</i> 310 (81.8% of 379) completed dental screening 307 (81.0% of 379) completed FV application <i>Caregivers</i> 297 (78.4% of 379) completed self-report survey 246 (64.9% of 379) completed MI session	24 Month Visit <i>Children</i> 596 (86.9% of 686) completed dental screening 595 (86.7% of 686) completed FV application <i>Caregivers</i> 582 (84.8% of 686) completed self-report survey
Dyads included in analyses 379 (100%) with ≥ 1 child dental screening 379 (100%) with ≥ 1 caregiver survey	Dyads included in analyses 686 (100%) with ≥ 1 child dental screening 686 (100%) with ≥ 1 caregiver survey

Table 1.
Baseline Characteristics by Intervention Group.

Characteristic	Intervention (<i>n</i> = 379)		Control (<i>n</i> = 686)		<i>P</i> Value
	<i>n</i>	Mean (SE) or %	<i>n</i>	Mean (SE) or %	
Child age	379	2.8 (0.09)	686	2.8 (0.04)	0.8163
Child sex	379	50.7 male	686	51.0 male	0.8989
Child is Hispanic or Latino	377	66.1	686	59.3	0.1907
Ethnicity	248		401		0.1211
Puerto Rican	64	25.8	122	30.4	
Dominican	134	54.0	225	56.1	
Other ethnicity ^a	27	10.9	22	5.5	
>1 ethnicity	23	9.3	32	8.0	
Race	370		670		0.2597
White	171	46.2	301	44.9	
Black or African American	138	37.3	277	41.3	
Other race ^b	33	8.9	36	5.4	
More than one race	28	7.6	56	8.4	
Caries prevalence	377	20.0	685	22.2	0.3825
Couldn't get needed dental care past year	377	2.4	675	4.3	0.1700
How often are child's teeth brushed? ^c (for child ≥1 y old)	312	2.7 (0.03)	567	2.7 (0.03)	0.7480
How often are child's teeth and gums brushed or wiped? ^c (for child <1 y old)	63	1.6 (0.18)	111	1.3 (0.12)	0.1895
Fluoride toothpaste is usually used for brushing	294	84.7	547	87.0	0.2831
How often does child drink sweet/sugary drinks? ^d	377	2.0 (0.05)	682	2.1 (0.08)	0.3449
How long has it been since caregiver's last dental visit? ^e	376	1.5 (0.04)	676	1.5 (0.06)	0.7737
How often does caregiver need help when reading medical / dental / drug instructions / material? ^f	379	0.6 (0.07)	684	0.5 (0.04)	0.2144
Language caregiver usually reads and speaks	379		683		0.5075
Only Spanish	66	17.4	111	16.3	
Spanish better than English	77	20.3	109	16.0	
Both equally	70	18.5	118	17.3	
Only English	166	43.8	345	50.5	
Caregiver age	373	32.0 (0.32)	672	31.8 (0.46)	0.6315
Caregiver sex	378	97.9 female	683	98.5 female	0.4718

(continued)

Table 1.
(continued)

Characteristic	Intervention (<i>n</i> = 379)		Control (<i>n</i> = 686)		<i>P</i> Value
	<i>n</i>	Mean (SE) or %	<i>n</i>	Mean (SE) or %	
Caregiver education ^a	377	13.0 (0.1)	682	12.9 (0.2)	0.4617
Employment status	378		682		0.4803
Employed ≥32 h per week	62	16.4	109	16.0	
Employed <32 h per week	70	18.5	117	17.2	
Student	30	7.9	76	11.1	
Homemaker	84	22.2	154	22.6	
Disabled / on medical leave / retired	18	4.8	27	4.0	
Unemployed	114	30.2	199	29.2	
No. of children in household	378	2.2 (0.04)	681	2.2 (0.06)	0.5013
Years caregiver has lived in current residence	377	4.6 (0.8)	676	4.2 (0.3)	0.6804
Household income below \$xx,xxx ^b	356	86.5	634	90.2	0.3324

SAS PROC SURVEYMEANS clustering on study site for means and PROC SURVEYFREQ clustering on study site for percentages. *t* test was used for comparison of means and chi-square test for comparison of percentages.

^aOther ethnicity includes Cuban/Cuban American, Mexican, Mexican American, Central American, South American, other Latin American, and other Hispanic/Latino/Spanish.

^bOther race includes Native Hawaiian / other Pacific Islander, American Indian / Alaska Native, Asian, and other single race.

^c0 = never, 1 = sometimes but not every day, 2 = 1×/day, 3 = 2×/day, 4 = >2×/day.

^d0 = rarely/never, 1 = at least 1×/week but not every day, 2 = 1×/day, 3 = 2×/day, 4 = 3×/day, 5 = 4×/day, 6 = ≥5×/day.

^e1 = within the past year (1 to 12 mo ago), 2 = >1 y but <2 y ago, 3 = >2 y but <5 y, 4 = ≥5 y ago.

^f0 = never, 1 = rarely, 2 = sometimes, 3 = often, 4 = always.

^gCaregiver education measured as “highest grade completed.” Grades 0 to 12, 13 = GED, 14 = some vocation/technical school, 15 = vocational/technical certificate, 16 = some college (no degree), 17 = college degree 18 = graduate/advanced.

^hFor family household size: 1 = \$10,830, 2 = \$14,570, 3 = \$18,310, 4 = \$22,050, 5 = \$25,790, 6 = \$29,530, 7 = \$33,270, 8 = \$37,010 (+\$3,740 per additional family member in household).

in dmfs increment at 24 mo, $F(2, 1,063) < 1$, $P = .535$. Both per-protocol models and the dose-response model showed similar nonsignificant results.

Caregiver Self-reported Motivation, Importance, and Self-efficacy

Caregivers reported high motivation, importance, and self-efficacy at baseline in intervention and control (Table 4). There were no significant group × time interaction effects on motivation, importance, or self-efficacy. Small but significant group-averaged main effects of time were observed for all 3 constructs between baseline and 12 mo: motivation +0.08 points, $P = 0.0005$; importance +0.05 points, $P = 0.0021$;

and self-efficacy +0.14 points, $P < 0.0001$. Between 12 and 24 mo, there were no significant effects of time, but the small gains made in the first 12 mo persisted.

Caregiver Knowledge

At baseline, there was no significant difference between the mean knowledge scores for the intervention and control groups. By 24 mo, knowledge scores increased by 6.8 percentage points in the intervention group versus 4.6 points in the control group, a statistically significant group × time interaction effect, $F(2, 1,593) = 3.48$, $P = 0.0310$ (Table 4).

Caregiver Self-reported Sugar-Sweetened Beverage Intake and Child Toothbrushing

Caregivers' report of their children's sugar-sweetened beverage intake showed no significant difference at baseline between intervention (1.98) and control (2.08). There was no significant group × time interaction effect. Overall, there was a small significant group-averaged increase in sugar-sweetened beverage intake from baseline to 12 mo, +0.14 points, $t = 2.09$, $P = 0.036$, and a nonsignificant increase of +0.06 points from 12 to 24 mo, $t = 0.85$, $P = 0.3957$ (Table 4).

At baseline, 57.8% of the caregivers in the control and 56.8% in intervention reported brushing their child's teeth

Table 2.
Participant Adherence to the Motivational Interviewing Intervention.

Characteristic	<i>n</i>	%
Visits completed out of 5 ^a		
1	70	18.5
2	72	19.0
3	76	20.1
4	89	23.5
5	72	19.0
Topic discussed		
Bottle and sippy cup use	35	9.2
Cleaning your child's mouth	168	44.3
Drinking fluoridated water	179	47.2
Good-bye bottle, hello sippy cup	70	18.5
Healthy snacks	179	47.2
Keeping germs away	151	39.8
Lift the lip	136	35.9
Sleep time routine	142	37.5
Visiting the dentist	76	20.1
No module chosen	4	1.1

^aMean number of visits: 2.9 (*n* = 379).

Table 3.
Comparison of dmfs Count (Primary Outcome) over Time in the Control versus Intervention Groups.

Time	Sample Size, <i>n</i>		dmfs Count, ^a Mean (SD)	
	Control	Intervention	Control	Intervention
Baseline	685	377	1.6 (5.6)	1.3 (4.6)
12 mo	434	201	1.8 (5.5)	1.5 (5.5)
24 mo	596	310	3.1 (8.1)	3.1 (8.0)

dmfs, decayed, missing, and filled tooth surfaces.

^a $R^2(2, 1,063) < 1$, $P = .5351$ for the test of group $\times$ time interaction.

at least twice a day. There was no significant group $\times$ time interaction effect, but overall, there were relatively large and significant group-averaged increases in adequate toothbrushing from baseline to 12 mo (odds ratio = 2.76; 95% CI, 2.19 to 3.48; $P < .0001$) and a

further increase from 12 to 24 mo (odds ratio = 1.39; 95% CI, 1.06 to 1.82; $P = 0.018$; Table 4).

Discussion

Despite adequate power, high intervention fidelity, and an 85%

retention rate, results showed that the MI intervention had no effect on the primary outcome. Specifically, neither the ITT nor the per-protocol analysis revealed significant differences in dmfs increment between intervention and control children at 12 or 24 mo. There were, however, significant group differences in caregiver knowledge at 24 mo favoring the intervention group, but the intervention was not associated with significant group differences in child toothbrushing and sugar-sweetened beverage intake.

It is well known that while health education can lead to increased knowledge, it does not generally lead to behavior change. In contrast, MI counseling has been shown to be effective in eliciting change in a variety of health behaviors. Consistent with the tenets of social cognitive theory (Bandura 1988) and the transtheoretical model of change, MI engages patients at their level of readiness to change and is designed to enhance their motivation to change behaviors (Miller and Rollnick 1991; Miller and Rollnick 2002). Using MI in the oral health field is relatively new, but a few studies aimed to change caregiver behaviors, such as child-feeding practices, oral hygiene, and dental visit attendance, in an attempt to improve child oral health (Gao et al. 2013). In a case-cohort study, Wagner et al. (2014) showed a change in caregiver behaviors of toothbrushing with fluoride toothpaste and fluoride salt use as well as a reduction in caries increment. However, randomized controlled trials in this area have reported mixed results. In the first MI study focused on ECC, Weinstein et al. (2004) showed a reduction in the number of new decayed surfaces in children but in a later study (Weinstein 2012) showed increased caries preventive behaviors among caregivers but no effect on dmfs. Ismail et al. (2011) demonstrated improved caregiver oral health behaviors related to ECC risk reduction, such as bedtime brushing and checking the child for "precavities," but found no group differences in number of new untreated caries lesions. Harrison et al. (2012)

Table 4.

Comparison of Importance, Self-efficacy, Motivation, Knowledge, and Oral Health Behaviors (SSB Intake and Child Toothbrushing) over Time in the Control versus Intervention Groups.

	Sample Size		Importance ^a			
Time	Control	Intervention	Control		Intervention	
Baseline	683	379	4.9 (0.3)		4.9 (0.3)	
12 mo	490	227	4.9 (0.3)		4.9 (0.2)	
24 mo	581	296	4.9 (0.3)		4.9 (0.2)	
			Self-efficacy ^b			
Baseline	683	379	4.6 (0.5)		4.5 (0.5)	
12 mo	490	227	4.7 (0.5)		4.7 (0.4)	
24 mo	581	296	4.7 (0.5)		4.7 (0.4)	
			Motivation ^c			
Baseline	683	379	4.8 (0.4)		4.8 (0.4)	
12 mo	490	227	4.8 (0.4)		4.9 (0.3)	
24 mo	581	296	4.8 (0.3)		4.9 (0.3)	
			Knowledge ^d			
Baseline	685	379	70.9 (10.3)		70.6 (10.1)	
12 mo	492	228	73.7 (9.2)		75.1 (8.3)	
24 mo	581	297	75.5 (9.0)		77.3 (7.9)	
			SSB Intake ^e			
Baseline	682	377	2.1 (1.7)		2.0 (1.7)	
12 mo	492	228	2.2 (1.7)		2.2 (1.6)	
24 mo	582	296	2.3 (1.6)		2.1 (1.6)	
			Toothbrushing ^f <i>n</i> (%)			
			<2×/d	≥2×/d	<2×/d	≥2×/d
Baseline	678	375	286 (42.2)	392 (57.8)	162 (43.2)	213 (56.8)
12 mo	491	228	110 (22.4)	381 (77.6)	46 (20.2)	182 (79.8)
24 mo	581	296	106 (18.2)	475 (81.8)	43 (14.5)	253 (85.5)

Values are presented as mean (SD) unless noted otherwise. Knowledge, SSB, and toothbrushing are secondary outcomes.

SSB, sugar-sweetened beverage.

^a $F(2, 1,587) < 1.0, P = 0.5306$.

^b $F(2, 1,587) < 1.0, P = 0.6885$.

^c $F(2, 1,587) = 1.48, P = 0.2272$.

^d $F(2, 1,593) = 3.48, P = 0.0310$.

^e $F(2, 1,589) < 1.0, P = 0.4266$.

^f $F(2, 1,583) = 1.51, P = 0.2217$.

found no difference in caries increment but did find that children of caregivers receiving MI had less severe decay.

The interrelated issues of the study population diversity, the multifactorial nature of ECC, and the impact of the social determinants of health on dental caries may underlie why MI studies focused on ECC reduction had mixed results. It may be that individuals with the highest ECC risk, who also tend to experience issues such as food insecurity, unemployment, and unsafe neighborhoods, are less able to prioritize oral health behavior change in the face of these challenges; therefore, MI focused on ECC prevention is less effective. Another possible factor is the complexity of ECC. In contrast to many of the behaviors where MI has been successful, the number of caregiver behaviors related to ECC may make the application of MI more challenging. Another difference between ECC and these other fields is that the caregiver receives the intervention but the benefit is intended for the child. However, a recent meta-analysis of family interventions found that MI was successful in reducing child body mass index and improving behaviors related to child health (Borrelli et al. 2015). Finally, gaining a true understanding MI effectiveness is compounded by differences in MI dose as well as the intensity of services provided to the control group in the various studies.

Despite its strengths, this study had limitations, including only fair participant adherence to the MI protocol. Less than half (42%) of the intervention participants attended at least 4 of the 5 MI visits in the first 12 mo. Additionally, although all eligible PHDs were randomized, 1 development underwent reconstruction after randomization, so we were unable to recruit from it, and 1 development did not allow door-to-door recruitment. Both developments were randomized to the intervention arm, which limited the available sample in the first case and the recruitment efforts in the second. Since these 2 sites were among the largest of intervention sites,

it created an imbalance in the number of participants in the intervention and control groups. However, the statistical model accommodated for the imbalance, and the impact on the analysis was a modest reduction in statistical power.

Unlike previous MI studies focused on caries prevention among children, MI was tested against screening and referral, written informational handouts, and quarterly fluoride varnish application. The addition of MI to this rigorous set of preventive services had no additional benefit. This study was also one of the first to utilize laypersons, public housing residents with a high school diploma, to deliver MI. The OHAs were successfully trained in MI and delivered the intervention with good fidelity, so the interventionists' background and training were unlikely contributing factors. This is supported by the fact that a trial focused on smoking cessation in Boston Public Housing also used laypersons as MI interventionists and found that the MI increased utilization of treatment programs and smoking abstinence among public housing residents (Brooks et al. 2017).

An MI trial to prevent ECC that targeted American Indian children on the Pine Ridge Reservation was implemented concurrently with this study (Batliner et al. 2018). The 2 studies used comparable MI interventions and questionnaires to assess oral health knowledge and behavior. The clinical examiners collecting the primary outcome data for each study used the same methods and criteria and calibration procedures, but the Pine Ridge study followed the children for 36 mo and did not apply fluoride. Both trials had large sample sizes and were well controlled with high fidelity and good participant retention, yet neither study demonstrated a reduction in ECC.

Summary

Despite its rigor, the MI intervention had no effect on caries increment among young children living in public housing during 24 mo of follow-up. The

intervention did, however, significantly improve oral health-related knowledge in the intervention group versus the control group. However, that knowledge increase did not translate into significant group differences in oral health-related behaviors. Given this and that the intervention was modeled on behavior change, it is not surprising that there was no change in caries increment. This outcome, especially when viewed in light of the Pine Ridge results and other recent MI studies, suggests that while MI may still have promise when applied to other age groups or oral conditions, when addressing the complex disease of ECC, especially in high-risk populations, a different approach is warranted. The field may need to take a multipronged approach. Effecting change on the family level may take more intensive strategies focused on a single targeted behavior, but to date, single-behavior changes have not readily translated into reduced ECC. Those strategies likely will need to be complemented by interventions on community-level upstream factors, which may show the greatest promise for an effective approach to reduce ECC. However, this is challenging and will require innovative interdisciplinary interventions.

Author Contributions

M.M. Henshaw, B. Borrelli, contributed to conception, design, data acquisition, analysis, and interpretation, drafted and critically revised the manuscript; S.E. Gregorich, contributed to conception, design, data analysis, and interpretation, drafted and critically revised the manuscript; B. Heaton, R.I. Garcia, contributed to conception, design, and data interpretation, critically revised the manuscript; E.M. Tooley, contributed to data acquisition, analysis, and interpretation, critically revised the manuscript; W. Santo, contributed to conception, design, and data analysis, critically revised the manuscript; N.F. Cheng, contributed to data analysis and interpretation, critically revised the manuscript; M. Rasmussen, contributed to data acquisition, critically revised the manuscript; S. Helman, contributed

to design and data acquisition, critically revised the manuscript; S. Shain, contributed to data interpretation, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

Acknowledgments

Research reported in this publication was supported by the National Institute of Dental and Craniofacial Research of the National Institutes of Health (U54DE019275 and U54DE019285). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

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