ORIGINAL REPORT: PHASE IV RANDOMIZED CLINICAL TRIAL

Randomized Trial of Motivational Interviewing to Prevent Early Childhood Caries in American Indian Children

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Abstract: ***Introduction:*** *In a randomized controlled trial, the effectiveness of motivational interviewing (MI) combined with enhanced community services (MI + ECS) was compared with ECS alone for reducing dental caries in American Indian children on the Pine Ridge Reservation. The intervention was developed and delivered with extensive tribal collaboration.*

Methods: *A total 579 mother-newborn dyads were enrolled and randomized to the MI + ECS and ECS groups. They were followed for 36 mo. Four MI sessions were provided, the first shortly after childbirth and then 6, 12, and 18 mo later. Both groups were exposed to ECS, which included public service announcements through billboards and tribal radio, as well as broad distribution of brochures on behavioral risk factors for early childhood caries (ECC), toothbrushes, and toothpaste. MI impact was measured as decayed, missing, and filled tooth surfaces (dmfs). Secondary outcomes included decayed surfaces, caries prevalence, and maternal oral health knowledge and behaviors. Modified intention-to-treat analyses were conducted. Eighty-eight percent of mothers completed at least 3 of 4 MI sessions offered.*

Results: *After 3 y, dmfs was not significantly different for the 2 groups (MI + ECS = 10, ECS = 10.38, P = 0.68). In both groups, prevalence of caries experience was 7% to 9% after 1 y, 35% to 36% at 2 y, and 55% to 56% at 3 y. Mean knowledge scores increased by 5.0, 5.3, and 5.9 percentage points at years 1, 2, and 3 in the MI + ECS group and by 1.9, 3.3, and 5.0 percentage points in the ECS group (P = 0.03), respectively. Mean maternal oral health behavior scores were not statistically significantly different between the treatment arms.*

Conclusion: *In summary, the MI intervention appeared to improve maternal knowledge but had no effect on oral health behaviors or on the progression of ECC (ClinicalTrials.gov NCT01116726).*

Knowledge Transfer Statement: *The findings of this study suggest that motivational interviewing focusing on parental behaviors may not be as effective as previously hoped for slowing the development of childhood caries in some high-risk groups. Furthermore, social factors may be even more salient determinants of oral health than what we previously supposed, perhaps interfering with the capacity to benefit from behavioral strategies that have been*

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useful elsewhere. The improvement of children's oral health in high-risk populations characterized by poverty and multiple related life stresses may require more holistic approaches that address these formidable barriers.

Keywords: clinical trial, dental caries, oral health knowledge, oral health behavior, behavior change, dental public health

Introduction

We aimed to test the efficacy of motivational interviewing (MI) as a primary behavior change strategy for improving the oral health of children in an American Indian (AI) population at very high risk for early childhood caries (ECC). This approach has proven highly effective in addressing a variety of health challenges and has demonstrated promising results in a few studies focused on improvement of oral health (McNeil et al. 2017). We reasoned that addressing the problem of ECC as early as possible by working with mothers of newborns and by culturally adapting the implementation of the MI approach for use in an AI population would maximize the potential for a successful outcome.

The documented prevalence of ECC among AI children has been higher than that for other U.S. population groups for decades (Phipps et al. 2012). The Indian Health Service (IHS) surveillance study conducted in 2010 found that 62.3% of AI children aged 2 to 5 y had caries and 43.6% had untreated decay (Phipps et al. 2012). Variation among the 12 IHS administrative areas ranged from 38.9% of children in the Oklahoma City Area experiencing decay to 85.9% in the Navajo Area. There is also variation among tribal locations within areas. Children in the Great Plains Area (previously called the Aberdeen Area) were somewhat better off than the IHS average in 2010, with 61.1% experiencing decay and 40.7% having untreated decay. However, previous studies conducted by the Center for Native Oral Health Research and others showed caries experience and the percentage of children with untreated decay to be very high among children living on and near the Pine Ridge Reservation in South Dakota, a location within the Great Plains Area (Batliner et al. 2013; Warren et al. 2015).

The dental problems experienced on the Pine Ridge Reservation are exacerbated by the relative paucity of dental providers. Tribal residents can access dental care in only 3 locations on a reservation approximately the size of Connecticut—the dental clinic at the IHS hospital in the town of Pine Ridge and clinics in the towns of Kyle and Wamblee, 50 and 85 miles from Pine Ridge, respectively. The dentist:population ratio varies with IHS provider vacancies but usually exceeds 1:4,000 (U.S. Department of Health and Human Services 2017), as opposed to 1:1,600 across the United States (U.S. Department of Health and Human Services 2018). These factors led our investigative team to develop a targeted preventive intervention aimed at reducing ECC among children on Pine Ridge.

Originally developed as a behavioral technique for treating substance abuse (Miller et al. 1980), MI has been minimally tested in the context of oral health. MI-based oral health interventions for reducing dental caries in children were used in several minority populations across the world (Weinstein et al 2004; Harrison et al. 2012; Merrick et al. 2012; Plutzer et al. 2012; Gao et al. 2013; Wagner et al. 2014). These studies showed mixed results, with some reporting change in parental behavior (Ismail et al. 2011; Wagner et al. 2014) and others showing reduction in dental caries in children (Plutzer et al. 2012; Harrison et al. 2012; Wagner et al. 2014).

In this report, we describe findings regarding the effectiveness of MI to reduce caries occurrence and progression among AI children <3 y of age.

Methods

This trial was approved by the Oglala Sioux Tribal Research Review Board, the Aberdeen Area IHS Institutional Review Board, and the Colorado Multiple Institutional Review Board. Details of the trial design and protocol (Batliner et al. 2014) as well as caries assessment procedures (Warren et al. 2016) were previously published. Consequently, only salient features of the design and procedures are described here. The trial is registered at ClinicalTrials.gov (NCT01116726).

Trial Design and Implementation

The study described here was conducted on and near the Pine Ridge Reservation of the Oglala Sioux Tribe, the second-largest reservation in the United States. The randomized controlled trial was designed to determine whether a behavioral intervention with MI among AI mothers of newborns could achieve a greater reduction of caries experience for children in the first 3 y of life than would exposure to enhanced community services (ECS) alone. A total of 579 mother-newborn dyads were enrolled and randomized in a 1:1 ratio to MI + ECS versus ECS between July 2011 and March 2014. The last follow-up visit was completed in January 2017.

Study participants were enrolled at the several locations, such as Pine Ridge IHS hospital, powwows, health fairs, and local community events on the reservation and in Rapid City, South Dakota. Each participating adult was the mother or primary caregiver of a newborn AI child (up to 3 mo of age), between 15 and 65 y of age, able to understand and sign a consent form, and willing and able to follow study procedures and instructions. Hereafter, participants responsible for the children participating in the study are referred to as "mothers." Consent was obtained from the mother and a parent or guardian in the case where the mother was <18 y old. All newborns were AI and had no medical conditions expected to adversely affect the development of primary teeth. Compensation of $25 was given for each visit. The MI intervention consisted of 4 visits: the first shortly after childbirth and again when the child was 6, 12, and 18 mo old. Visits usually required 45 to 60

min for completion. Outcome data were collected at enrollment and when the child was 12, 24, and 36 mo of age.

Randomization

A stratified blocked randomization design employed a random number generator, with stratification based on the age of the mother. Randomly selected block sizes of 2 or 4 were used. Randomization was implemented by telephone between field staff enrolling the participants and a staff member at the University of Colorado Anschutz Medical Campus. Field staff obtained informed consent and enrolled participants prior to obtaining group assignments.

Blinding

Due to the nature of the intervention, providers and participants could not be masked in this trial. However, the licensed dental professionals, who collected primary outcome data through annual oral health screenings of the children, were blinded to group assignment.

MI Intervention

A culturally specific MI script was developed; a training manual was compiled; and interventionists received training before the MI intervention was used in the field. At each of the 4 MI visits in this study, the mother selected 2 topics to address from a list of 8 options: taking your child to the dentist, only water in sippy cup in bed, transition to cup by 1 y, offer nonsugary foods, germs cause cavities, protect with fluoride, clean mouth/brush 2 times daily, and take care of your own teeth. These topics were chosen by dental professionals experienced in working with the tribe; they conducted a preliminary assessment and informal interviews (Batliner et al. 2013) and incorporated input from a tribal advisory committee.

For the 2 topics chosen at each visit, the mother worked with the MI interventionist to discuss her ambivalence, concerns, or hesitations and to establish goals and a plan of action. In subsequent visits, the mother and interventionist discussed progress and obstacles and then amended goals and action plans, discussing new topics as needed. At a mother's request, the same topic could be repeated in a subsequent session, although at least 1 new topic was added in these cases.

MI Training

The MI interventionists were local people, living on the reservation or nearby, and were required to have a college degree (BA, BS), preferably in psychology, human services, health education, nursing, or social work, as well as job experience involving contact with the public. Each interventionist completed 2 d of training, which included the following: study of MI materials prepared by a Native MI expert (Venner et al. 2006), learning fundamental communication skills for working as partners in personal behavior change, and practicing specific MI techniques for helping mothers strengthen their motivation to improve oral health behaviors. During training, MI providers conducted 5 audio-recorded practice sessions with mothers for review and feedback by the MI intervention director and an MI consultant. Interactive feedback sessions were conducted 2 times per month with each interventionist for the first 6 mo and then monthly for the study duration.

Treatment Fidelity

All MI sessions were audio recorded and treatment fidelity monitored, with appropriate feedback aimed at maintaining fidelity. Ongoing monitoring included a review of a randomly selected sample of sessions (20%) and completion of the Motivational Interviewing Treatment Integrity 3.1.1 instrument (Moyers et al. 2016) for those sessions. For purposes of monitoring interrater reliability, half of the random sample of sessions were rated a second time with the instrument by the MI consultant. Feedback on the audited sessions focused on adherence to the spirit of the MI model and competence in the use of MI. Details of the intervention and results of the MI fidelity study were recently published (Wilson et al. 2018).

Enhanced Community Services

ECS included public service announcements broadcast on the tribal radio station, billboards, and broad distribution of brochures focused on behavioral risk factors for ECC and oral health topics covered in the MI sessions. Each participant received oral health brochures targeting the age of her infant, as well as toothbrushes and toothpaste for all family members. Participants in the MI arm also received ECS. The tribal research review board had expressed strong preference for a study design that would provide some benefits for all participants, and this was the primary reason for the ECS condition rather than a no-intervention control.

Outcome Measures

The primary outcome was the dmfs measure of decayed, missing, or filled primary tooth surfaces, measured at months 12, 24, and 36, by calibrated dental examiners masked to group assignment (Warren et al. 2015). Inspection was visual, without x-rays or probing. Tooth surfaces were counted as decayed when there was missing tooth structure. During calibration events, study examiners and the gold standard examiner did not demonstrate significant and consistent agreement regarding white spot lesions. Therefore, white spot lesions were not considered indicators of disease in this outcome article. For teeth missing due to trauma or exfoliation, any prior dmfs measures for those teeth were carried forward. Hence, the longitudinal data indicated cumulative disease burden. For teeth crowned or missing due to caries, 4 surfaces were scored as decayed for anterior teeth and 5 for posterior teeth. Annual calibration meetings were held with volunteer children; minimum tooth surface-level agreement between each calibrated examiner and the gold standard examiner was a Cohen's kappa ≥0.75 (Warren et al. 2015).

Secondary outcome measures included longitudinal assessments of decayed surfaces (ds) and caries prevalence assessed at months 12, 24, and 36, as well as validated survey items assessing mothers' oral health knowledge (16 items) and parental oral health behaviors (13 items) at baseline and 12, 24, and 36 mo (Wilson et al. 2018). Scores were calculated as percentage of correct answers (knowledge) or recommended oral health behaviors to which parents reported adhering (behavior).

Sample Size and Statistical Power

Based on the IHS 1999 national dental survey of the AI population (United States Department of Health and Human Services and IHS 2002), the mean dmfs was 10.05 (SD = 16.27) at age 2 y and 12.22 (SD = 19.17) at age 3 y. Assuming a repeated measures analysis with dmfs measured at 3 time points, an intraclass correlation of 0.50, a 40% reduction in mean dmfs due to the MI intervention, 90% statistical power ($\alpha = 0.05$, 2-sided test), and an 80% retention rate, we determined that a total sample size of 540 mothers and newborns in the 2 treatment arms (270 per arm) was needed. The final target sample size was set at 600 to allow for unanticipated deviations from statistical assumptions.

Statistical Analyses

The primary analysis of the trial was conducted according to the intention-to-treat principle. We call the analysis "modified intention to treat" because a small percentage of the mother-child dyads were dropped after randomization. Baseline group characteristics were compared with *t* tests for continuous variables and chi-square tests for categorical variables. Comparisons of changes in dmfs and ds over time between the MI + ECS and ECS-only groups utilized a mixed-effects, marginalized, zero-inflated, overdispersed Poisson model fit to the longitudinal outcomes (Kassahun et al. 2014). Comparisons of changes in dmfs and ds prevalence over time between the treatment arms were similarly performed with a mixed-effects binomial model. Group differences in baseline through 36-mo assessments of maternal oral health knowledge and behavior were tested with linear mixed-effects models, which were used to accommodate intrachild correlation of the repeated outcome responses. Preliminary models found that inclusion versus exclusion of a covariate for mother's age did not alter the substantive results, so we opted to report on the simpler model. Preliminary models for dmfs and ds outcomes included the natural log of the observed number of tooth surfaces as a modeled covariate. The effect of that variable was nonsignificant for both models, so that covariate was dropped and the models refit. For all longitudinal analyses, the primary test of MI effect was based on the group × categorical time interaction. In addition, simple group comparisons at each assessment, as well as group comparisons that averaged outcomes across all follow-up assessments, were conducted. All analyses were conducted with SAS 9.4.

Results

The Figure presents the CONSORT (Consolidated Standards of Reporting Trials) diagram for the study, enumerating participants screened, enrolled, randomized, and followed at each interval. A total of 579 dyads (290 MI + ECS, 289 ECS) completed the baseline activities, and 84% completed the 36-mo assessment. Table 1 presents baseline characteristics of the MI + ECS and ECS groups. Mother and child characteristics were well balanced between the treatment groups.

MI Adherence

Well over 80% of mothers completed primary and secondary data collection activities at each study visit (Fig.). Intervention adherence was also excellent (Table 2). Eighty-eight percent of participants completed at least 3 of the 4 MI visits. The mean number of MI visits completed was 3.5 (SD = 0.8). The length of the MI visits was generally around 30 min, with the average length decreasing from 33.9 min at baseline to 29.3 min at 18 mo. Over the course of the intervention, 85% to 98% of the participating mothers addressed each topic related to mothers taking care of their children's teeth. The only topic that had low coverage was mothers taking care of their own teeth, discussed by 70% of participating mothers. Participant satisfaction with the MI visits was very high (generally >4.9 on a 5-point scale). Participant engagement—the MI interventionists' rating of how well the mother was engaged in the MI session—was also quite high (4.75 to 4.86 on a 5-point scale).

Primary Outcomes

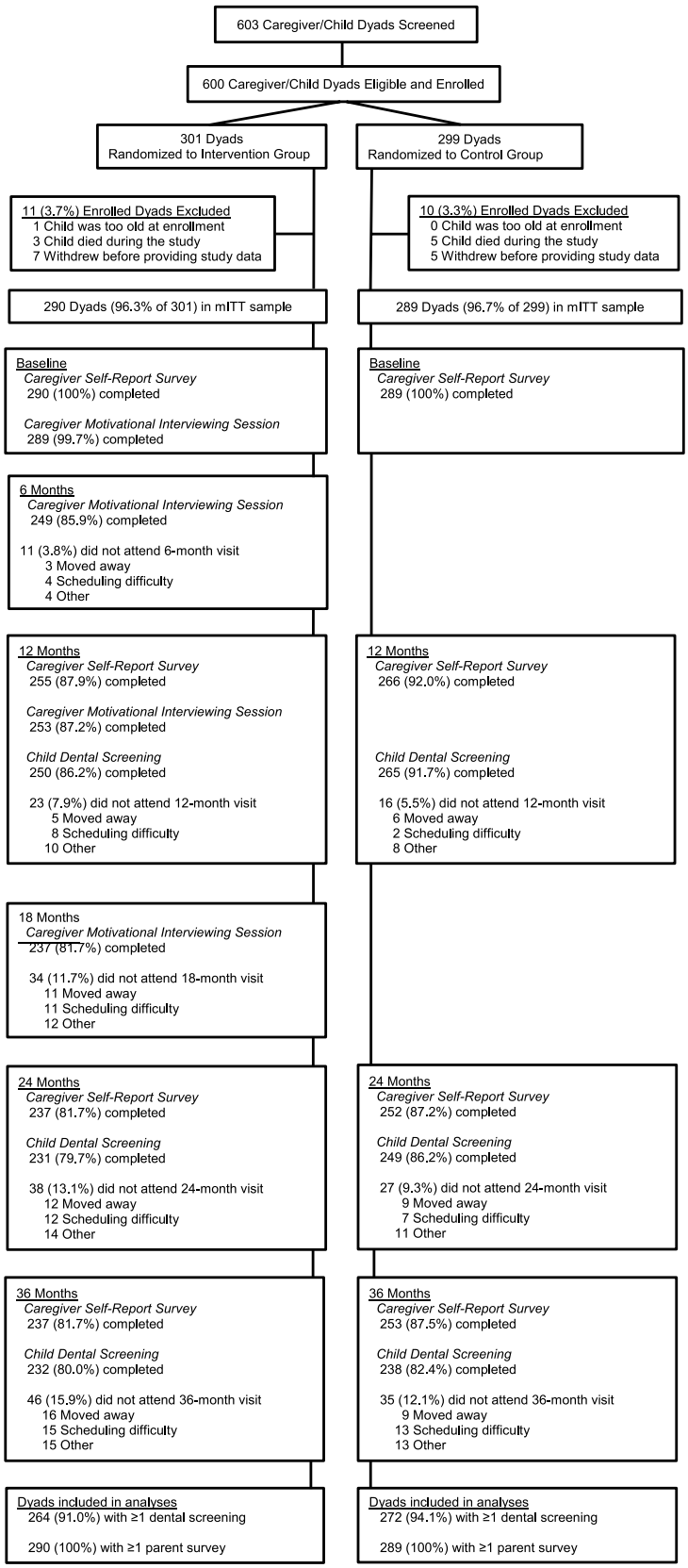
Table 3 presents mean dmfs and ds at 12, 24, and 36 mo for the MI + ECS and ECS groups. In both groups, mean dmfs was about 0.4 at year 1, increasing to about 4 at 24 mo and 10 at 36 mo. There were no statistically significant differences in changes in dmfs over time ($P = 0.72$) or in time-averaged dmfs levels between the groups ($P = 0.70$). In both groups, ds was about 0.4 at year 1, 2.7 to 2.9 at year 2, and 3.2 to 4.1 at year 3. There were no statistically significant group differences for change in ds over time ($P = 0.67$) or time-averaged ds ($P = 0.38$).

In both groups, prevalence of caries (dmfs > 0) was about 7% to 9% at year 1, increasing to 35% to 36% at year 2 and 55% to 56% at year 3 (Appendix Table). There was no significant difference in the increases in prevalence between the groups ($P = 0.67$). In both groups, active decay experience (ds > 0) was about 7% to 9% at year 1, 30% to 33% at year 2, and 41% to 42% at year 3. There was no significant group difference in prevalence of active decay increase ($P = 0.91$).

Oral Health Knowledge and Behavior

Table 4 shows that mothers' baseline oral health knowledge was moderately high in both groups (MI, 76.2%; ECS, 75.1%). Mean knowledge scores

Figure. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. mITT, modified intention to treat.



increased by 5.0, 5.3, and 5.9 percentage points at years 1, 2, and 3 in the MI + ECS group and by 1.9, 3.3, and 5.0 in the ECS group ($P = 0.03$), respectively. Oral health knowledge was significantly higher in the MI group at 12 mo ($P = 0.0006$) and 24 mo ($P = 0.006$), but the groups no longer significantly differed at 36 mo. Mothers' self-reported oral health behavior scores at baseline were 67.9% for the MI + ECS group and 68.3% for the ECS group. Mean oral health behavior scores decreased over time in both groups ($P = 0.86$; Table 4).

Discussion

The modified intention-to-treat analysis demonstrated no significant difference in the dmfs scores of children in the MI + ECS and ECS groups at 12, 24, or 36 mo, indicating that the intervention did not produce a significant effect. Mean values for dmfs at 36 mo for the MI + ECS and ECS cohorts (10.00 and 10.38, respectively) were very close to the mean value of 9.6 found in a sample of children aged 36 mo examined on the Pine Ridge Reservation in 2014 by Warren et al. The retention rate for the study was high, at >80% for every planned encounter. Eighty-eight percent of participants completed at least 3 of the 4 MI visits. Participating mothers completed an average of 3.5 of the 4 planned MI visits, and the topics related to taking care of their children's teeth were covered by 85% to 97% of the mothers. Participant satisfaction and engagement scores were very high. No per-protocol analyses were conducted, since these high participation rates indicated that the results would have been essentially the same as those from our modified intention-to-treat analysis.

The goal of MI is for individuals to initiate change in an effort to improve negative outcomes related to targeted behavior. In this study and others that used MI interventions to reduce ECC, MI was used with mothers of targeted children to provide support for initiating behavior changes that would positively affect the oral health of these children. In the context of earlier studies of MI in

Table 1.
Baseline Caregiver and Child Characteristics in the MI and ECS Randomized Groups.

Variable	MI + ECS (*n* = 290)		ECS (*n* = 289)		
	n	Mean (SD) or %	*n*	Mean (SD) or %	*P* Value
Caregiver					
Age, y[a]	290	28.2 (15.2)	289	27.5 (13.7)	0.57
Female	290	97.9	289	96.5	0.31
Caregiver: mother	289	96.9	287	95.8	0.49
Household income[b]	218	3.0 (2.3)	221	3.0 (2.4)	0.87
Years of education[c]	290	12.8 (2.8)	289	12.6 (2.9)	0.34
No. children in household[d]	272	3.3 (2.0)	264	3.1 (1.8)	0.33
Oral health status[e]	287	3.3 (1.1)	276	3.4 (1.1)	0.54
Oral health knowledge score[f]	290	76.2 (12.5)	289	75.1 (13.4)	0.29
Oral health behavior score[g]	289	67.9 (22.5)	289	68.3 (20.0)	0.84
Child					
Age, mo[h]	290	0.62 (0.89)	289	0.73 (0.91)	0.12
Female	290	47.9	289	54.3	0.12
Oral health status[i]	231	1.6 (0.8)	226	1.6 (0.9)	0.78
Dental insurance other than Indian Health Service	256	50.4	247	44.9	0.22
Ever had teeth checked by dentist or other care provider?[j]	261	3.8	255	4.3	0.76
How often is child's teeth and gums brushed or wiped?[k]	254	2.1 (1.2)	253	2.2 (1.3)	0.62
How often does child eat sweet/ sugary foods?[l]	227	0.20 (0.69)	211	0.23 (0.78)	0.67
How often does child drink sweet/ sugary drinks?[l]	228	0.17 (0.63)	209	0.21 (0.77)	0.52

Chi-square test was used for percentages and *t* test for continuous variables.
ECS, enhanced community service; MI, motivational interviewing.
[a]Age = 90 recoded to missing value.
[b]Income level: 0 = no income, 1 = <1,000, 2 = 1,000 to 4,999, 3 = 5,000 to 9,999, 4 = 10,000 to 14,999, 5 = 15,000 to 19,999, 6 = 20,000 to 29,999, 7 = 30,000 to 39,999, 8 = 40,000 to 49,999, 9 = 50,000 to 74999, 10 = 75,000 to 9,9999, 11 = ≥100,000 (don't know, skip = missing).
[c]0 to 12 = grade, 13 = GED, 14 = some vocation, 15 = vocation, 16 = some college, 17 = college, 18 = graduate/advanced (don't know, skip = missing).
[d]Skip = missing.
[e]Caregiver rating of own oral health: 1 = excellent, 5 = poor (don't know, skip = missing).
[f]Knowledge score: percentage correct answers based on responses to 16 questions.
[g]Behavior score: percentage correct (adherent) based on responses to 8 questions.
[h]Age in months at enrollment (rounded to nearest month).
[i]Caregiver rating of child's oral health: 1 = excellent, 5 = poor (don't know, skip = missing).
[j]Missing or skipped = missing, don't know = no.
[k]0 = never, 1 = sometimes but not every day, 2 = 1×/day, 3 = 2×/day, 4 = more than 2×/day.
[l]0 = 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 or more.

oral health, this use of MI with mothers, rather than the children themselves, represents a "1 person removed" process that could dilute the effectiveness of the intervention, as compared with direct use of MI for altering an individual's behavior. Of course, the children with whom we were working were too young to participate in the MI interventions directly. In a recent study conducted with adolescents, where the participants received MI to alter their own behavior, MI proved more effective than other health education strategies in eliciting positive changes in adolescents' oral health behaviors and in preventing dental caries (Wu et al. 2017). Unfortunately, ECC begins very early in AI children, and waiting until they are old enough to participate directly is unlikely to prove effective.

MI has proved more successful in other health areas, such as substance abuse and smoking cessation (Brooks et al. 2017). We speculate that issues of perceived severity, barriers, and consequences of the problem may play a role in these responses. Furthermore, psychosocial factors—such as oral health locus of control, sense of coherence, stress, and fatalistic attitudes—could be underlying factors that influence the participant's response to a behavior change intervention such as MI (Albino et al. 2018). These factors may offer valid explanations why MI interventions are not successful in one group or condition but work for another. A full analysis of the success of MI in these other areas is not possible here, although a recent book by McNeil et al. (2017) provides a good beginning for this consideration. It must be noted that this use of MI could be perceived as more "structured" than recommended by the developers of the approach (Miller and Rollnick 2012). Indeed, given the need to standardize the intervention as much as possible in the context of a clinical trial, an MI script was provided to give guidance in implementing the intervention. In keeping with the spirit of MI, however, interventionists were encouraged to modify the script as needed to meet the

Table 2.
Participant Adherence to and Engagement in the MI Intervention.

MI Characteristic	Participants, *n*	Mean (SD) or %
No. of MI visits completed out of 4		
0	1	0.3
1	12	4.1
2	23	7.9
3	46	15.9
4	208	71.7
No. of visits	290	3.5 (0.8)
Length of visits, min		
Baseline	288	33.9 (9.0)
6 mo	248	32.7 (11.9)
12 mo	251	29.0 (9.4)
18 mo	237	29.3 (13.4)
All visits	1,024	31.3 (11.1)
Participants who discussed each topic		
Take child to dentist	280	96.6
Only water in sippy cup in bed	278	95.9
Transition to cup by 1 y	286	98.6
Offer nonsugary foods	275	94.8
Germs cause cavities	279	96.2
Protect with fluoride	261	90.0
Clean mouth/brush 2 times daily	247	85.2
Take care of your own teeth	203	70.0
Score for participant satisfaction		
Baseline	283	4.9 (0.3)
6 mo	247	5.0 (0.3)
12 mo	248	5.0 (9.2)
18 mo	236	5.0 (0.2)
All visits	1,014	4.9 (0.3)
Score for participant engagement		
Baseline	283	4.8 (9.6)
6 mo	248	4.9 (0.5)
12 mo	249	4.9 (0.5)
18 mo	235	4.9 (0.4)
All visits	1,015	4.8 (0.5)

MI, motivational interviewing.

Table 3.
Comparison of dmfs (Main Outcome) and ds (Secondary Outcome) over Time in the MI and ECS Groups.

Time	Dyads, *n*		dmfs[a]		ds[b]	
	MI + ECS	ECS	MI + ECS	ECS	MI + ECS	ECS
Baseline	290	289				
12 mo	250	265	0.4 (1.7)	0.5 (2.0)	0.4 (1.7)	0.4 (1.0)
24 mo	231	249	3.8 (8.3)	4.0 (8.6)	2.7 (6.6)	2.0 (6.7)
36 mo	232	238	10.0 (16.0)	10.4 (16.2)	3.2 (5.9)	4.1 (7.9)

Modified intention-to-treat analysis ($n = 579$). Values are presented as mean (SD).
ECS, enhanced community service; MI, motivational interviewing.
[a]*P* values: 0.72, group × time interaction with 2 degrees of freedom; 0.70, time-averaged group difference.
[b]*P* values: 0.67, group × time interaction with 2 degrees of freedom; 0.38, time-averaged group difference.

Table 4.
Comparison of Oral Health Knowledge and Behavior of Caregivers over Time in the MI and ECS Groups.

Time	Oral Health Knowledge[a]				Oral Health Behavior[b]			
	Dyad, *n*		Mean (SD)		Dyad, *n*		Mean (SD)	
	MI + ECS	ECS	MI + ECS	ECS	MI + ECS	ECS	MI + ECS	ECS
Baseline	290	289	76.2 (12.5)	75.1 (13.4)	289	289	67.9 (22.5)	68.3 (20.0)
12 mo	253	265	81.2 (12.2)	77.0 (12.7)	252	265	60.6 (18.5)	59.5 (18.4)
24 mo	237	250	81.5 (13.4)	78.4 (12.8)	237	251	53.3 (19.2)	51.7 (20.7)
36 mo	237	251	82.1 (13.9)	80.1 (12.8)	237	252	53.0 (19.9)	51.3 (20.0)

Modified intention-to-treat analysis ($n = 579$). Knowledge (16 items) and behavior (13 items) scores were calculated as the percentage of correct/appropriate responses.
ECS, enhanced community service; MI, motivational interviewing.
[a]$P = 0.03$ for the group × time interaction with 3 degrees of freedom.
[b]$P = 0.86$ for the group × time interaction with 3 degrees of freedom

needs and directions set by participants. Nonetheless, this attempt to standardize human interactions could have limited the effectiveness of the MI intervention, which depends on the development of a supportive relationship of the interventionist vis-à-vis the participant.

Although behavioral pathways are critical in reducing ECC, they are only a part of the larger schema that connects upstream factors to these more proximal factors. Low socioeconomic status, parental employment, education, and neighborhood and community factors are significantly associated with greater risk of ECC (De Fonseca 2017). Adherence to preventive recommendations is also low among children of low-income families (De Fonseca and Avenetti 2017). Inverse case law is a concept that may provide some explanation why the MI intervention was not effective in this AI population. This concept suggests "that individuals and groups who are in minor need of an intervention may benefit more from it than those who are in major need" (Watt 2002). Those who are in greater need of an intervention may not have recognized the challenges or may not have resources—personal, economic, or social—that allow them to recognize and address the health issues (Albino et al. 2017).

In discussing factors associated with ECC in high-risk children, Petti (2010) described how social determinants of health, parental psychosocial stress, and fatalism can influence the relationships reflected in the concept of inverse case law. The AI community living on the Pine Ridge Reservation faces extreme socioeconomic inequalities, unemployment, high levels of substance abuse, and other issues creating psychosocial distress, and it is understandable that these demands may be prioritized above even the important health needs within a family (Castor et al. 2006). The best intentions for positive oral health behaviors can be forgotten when other basic needs are not reliably met. Future strategies may be

more successful when they address the full spectrum of family needs, providing programs and interventions that acknowledge the broader life context and circumstances of people within these communities (Albino and Tiwari 2016).

Another MI trial that was conducted with public housing residents in Boston (ClinicalTrial.gov NCT01205971) in parallel with this study and with a comparable MI intervention, the same outcome measures, and the same statistical analysis also reported no positive effects for the intervention. Differences in the 2 trials included the use of a control group, the age of the children, the geographic location, and the setting of the trials. Both this trial and the trial conducted in Boston had large sample sizes and were well controlled and implemented, yet neither study proved effective for the high-risk populations that were involved.

Strengths of this study included a large sample size, excellent adherence to protocol, and ≥80% attendance at every planned encounter. The fidelity of the intervention was carefully monitored and successfully managed. Meaningful community participation occurred throughout the study. All study communications were developed jointly by study staff and community members, and retention strategies were formulated with involvement from community members. In addition, the trial was monitored by a Data and Safety Monitoring Board that comprised an external body of reviewers.

The MI intervention was developed in collaboration with 4 Native experts who carefully tailored the intervention along the lines of previously successful uses in AI populations. A manual was written for using MI with Native communities and included materials on, but not limited to, values of spirituality, community, and cultural identity. MI was consistent with the cultural values of AI people by emphasizing listening, learning, and guiding, rather than directing. MI techniques respect the sovereignty and self-determination of the individual and the tribe (Tomlin et al. 2014): they encourage the client's reflection on ambivalence related to behavior change, explore behavior change options, and then support setting goals and developing action plans through discussion with the interventionist. The manual was used as a guide by the interventionists, and care was taken to ensure that the spirit of MI always guided choices and that the approach was not overly structured in a way that would have limited responses and results (Batliner et al. 2014).

Summary

The study was carefully implemented, yielding strong participation and retention, yet there was no significant difference in oral health outcomes between the MS + ECS and ECS groups in dmfs at any time point. Although the intervention was successful in improving the oral health knowledge of participating mothers at the 12- and 24-mo time points, this difference did not continue to 36 mo. Oral health behavior did not differ across treatment arms. The discouraging results of this work suggest that addressing the oral health disparities of AI children—and perhaps those of other high-risk groups as well—may require considerably higher levels of effort and perhaps entirely new approaches altogether. We believe that it will be necessary to consider more carefully the demands of the overall social, psychological, and environmental contexts within which AI parents must address oral health challenges for their children. This suggests a more holistic approach to designing interventions that embed attention to oral health within larger parenting and health issues, taking into account and possibly utilizing the personal, family, and community resources that are available for support.

Author Contributions

J. Albino, T.S. Batliner, W.G. Henderson, contributed to conception, design, data acquisition, analysis, and interpretation, drafted and critically revised the manuscript; T. Tiwari, contributed to design, data acquisition, analysis, and interpretation, drafted and critically revised the manuscript; A.R. Wilson, contributed to data acquisition, critically revised the manuscript; S.E. Gregorich, M.M. Harper, contributed to data analysis and interpretation, critically revised the manuscript; K.A. Fehringer, A.G. Brega, E. Swyers, T. Zacher, K. Plunkett, W. Santo, M. Rasmussen, N.F. Cheng, S. Shain, contributed to data acquisition, analysis, and interpretation, critically revised the manuscript; S.M. Manson, contributed to conception and design, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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