Improving Dental Care and Oral Health in Children with ASD

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PROTOCOL SYNOPSIS

Study Title

Improving Dental Care and Oral Health in Children with ASD

Version Number

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Rationale for the Study

Participation in routine dental care is a significant unmet healthcare need for children with ASD (McKinney et al., 2014), who have excessive plaque, caries, and oral infections (DeMattei, Cuvo, & Maurizio, 2007). Multiple factors may hinder dental care for children with ASD, including challenges arising from autism-related symptoms (e.g., maladaptive behaviors, language delays, sensory sensitivities, and problems regulating affect and arousal; Isong et al., 2014; McKinney et al., 2014; Lai et al., 2012; Stein et al., 2014). Families with low socioeconomic status and racial/ethnic minority backgrounds face additional barriers and have increased risk for poor oral health (Isong et al., 2014; McKinney et al., 2014; Lai et al., 2012; Stein et al., 2014). The current proposal aims to apply multi-disciplinary, evidence-based approaches to address health disparities and improve dental outcomes for underserved children with ASD by remediating barriers that impede home daily hygiene and participation in routine dental examinations.

Interventions that enhance participation in dental care for underserved children with ASD have significant potential to improve long-term physical health through reduction of children's dental caries, periodontal disease, abscesses, and related problems. We will conduct a randomized controlled trial (RCT) to compare the efficacy of the established AIR-P Dental Toolkit to a combined regimen involving the Dental Toolkit and a parent-mediated behavioral intervention. Our combined intervention integrates strategies shown to be efficacious in improving adherence to dental care in low-income families (e.g., motivational interviewing; Weinstein et al., 2014) with evidence-based behavioral techniques designed to improve child compliance with dental procedures.

Study Design

This is a two-arm randomized controlled trial conducted at two sites. Owing to the nature of the intervention, families and interventionists cannot be blinded. All dental providers performing exams and raters coding observational data from dental visits will remain blinded in order to ensure that the dental office data are collected in a blinded fashion (with the exception of dental visit endpoints reported by families).

Study Aims and Hypotheses

This randomized controlled trial will compare the efficacy of the established AIR-P Dental Toolkit (control condition) to a combined regimen involving the Dental Toolkit and parent-mediated behavioral intervention (intervention condition) to address the following aims.

Aim 1

To improve child functional and behavioral compliance with home dental hygiene.

> *Hypothesis 1a (co-primary):* Relative to children randomized to the control condition, children randomized to the intervention condition will exhibit greater 6-month improvement in functional compliance with home dental hygiene as measured by twice-daily tooth brushing.
>
> *Hypothesis 1b (secondary):* Relative to children randomized to the control condition, children randomized to the intervention condition will exhibit greater 6-month improvement in behavioral compliance with home dental hygiene as measured by parent-reported behavior on the *Home Dental Experiences* questionnaire.

Aim 2

To improve child oral health.

> *Hypothesis 2 (co-primary): R*elative to children randomized to the control condition, children randomized to the intervention condition will exhibit greater 6-month improvement in oral health as measured by the *Visual Plaque Index* (VPI).

Aim 3

To reduce child anxiety and improve compliance with dental visits.

> *Hypothesis 3a-c (secondary):* Relative to children randomized to the control condition, children randomized to the intervention condition will exhibit greater 6-month improvement in: (a) dental anxiety during dental visits as measured by *Venham Anxiety Scale*, (b) behavioral compliance during dental visits as measured by *Venham Behavior Scale*,, and (c) completion of dental visit procedures as measured by dentist report on the *Dental Visit: Dentist Report* questionnaire.

Aim 4

To test for mediators of intervention outcome.

> *Hypothesis 4a-b (exploratory):* Treatment-dependent improvements in functional and behavioral compliance with home dental hygiene and in oral health will be associated with concurrent reductions in: (a) parenting stress as measured by *Family Impact Questionnaire*, and (b) perceived parenting competence as measured by the *Parenting Sense of Competence* scale modified to include the *Oral Health Self-Efficacy* measure.

Aim 5

To test for moderators of intervention outcome.

> *Hypothesis 5a-b (exploratory):* Treatment-dependent improvements in functional and behavioral compliance with home dental hygiene and in oral health will be greater in parents reporting a) less parenting stress as measured by the *Family Impact Questionnaire*, and (b) higher levels of perceived parenting competence as measured by the *Parenting Sense of Competence* scale modified to include the *Oral Health Self-Efficacy* measure.

Study Locations

Recruitment sites include the University of California-Irvine and Nationwide Children's Hospital (NCH), and the respective partner dental sites, Healthy Smiles of Orange County and the Johnstown Road program at NCH.

Number of Planned Subjects

The target sample size is 100 subjects. Approximately 118 will be randomized, with 71 expected at UCI and 47 expected at NCH, to allow for 15% attrition.

Study Population

English-speaking families of children ages 3 to 13:11 with a current diagnosis of ASD will be recruited from the regional area. Inclusion criteria also require parent-reported difficulty participating in dental care (described further below), confirmed absence of dental screening or exams within the previous 6 months, and underserved status as defined by Medicaid eligibility. We will confirm ASD diagnosis at the baseline assessment according to established criteria on the ADOS-2 and DSM-5 diagnostic checklist. We will exclude children who present with an acute dental condition requiring emergency treatment. We will also ask families to refrain from participating in any non-study adaptive behavior interventions or therapies focused on dental hygiene. We will also ask families to refrain from participating in any non-study dental screenings or exams for the duration of the present investigation.

Treatment Groups

We will conduct a randomized controlled trial (RCT) to compare the efficacy of the established AIR-P Dental Toolkit to a combined regimen involving the Dental Toolkit and a parent-mediated behavioral intervention. Our combined intervention integrates strategies shown to be efficacious in improving adherence to dental care in low-income families (e.g., motivational interviewing) with evidence-based behavioral techniques designed to improve child compliance with dental procedures.

All families will be provided with materials to facilitate dental hygiene over the course of the 6-month study period, including an electric toothbrush and a 6-month supply of toothbrush heads, fluoridated toothpaste, and flossers. We will also provide materials to assist with oral desensitization to dental office equipment (e.g., plastic mirror).

Families in both conditions will be asked to refrain from participating in non-study, routine dental screenings and exams for the duration of the study. Families will also be asked to refrain from participating in any non-study adaptive behavior or non-emergency dental interventions during the study period.

Duration of Treatment and Follow-up

Our parent-training intervention is comprised of 5 center-based sessions (CBS), 1 home coaching session, 1 dental office coaching session, and 4 phone booster sessions. We will also provide families with the option to add a second home coaching session between weeks 12 and 24.

The parent-training intervention timeline is outlined below:

Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8	Week 10	Week 13	Week 16	Week 21	Week 12-24
CBS 1	CBS 2	CBS 3	Home Coach	CBS 4	CBS 5	Dental Coach	Phone 1	Phone 2	Phone 3	Phone 4	Optional Home Coach

Intervention content emphasizes behavioral strategies shown to be efficacious in the treatment of children with ASD and existing strategies used clinically with neurotypical populations to address dental fear and maladaptive behaviors during dental exams. Sessions are designed to build skills in a hierarchical fashion in a way that is also dynamic and responsive to family needs.

Families will participate in two baseline visits. The initial baseline is comprised of a dental office visit and exam. The second baseline visit involves direct child testing, and parent interview and report measures. Children will receive two follow-up dental visits, a short-term follow-up at 3 months and a long-term follow-up at 6 months. For children in the intervention condition, data from the dental office visit at 3 months will be used

to further refine treatment efforts in the context of booster sessions leading up to the 6-month follow-up dental visit.

Glossary of Abbreviations

AIR-P	Autism Intervention Research Network on Physical Health
ASD	Autism Spectrum Disorder
ATN	Autism Treatment Network
CBS	Center-based sessions
CCC	Clinical Coordinating Center
DCC	Data Coordinating Center
DMFT	Decayed, missing, and filled teeth
eCRF	Electronic Case Report Form
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration
ICDAS	International Caries Detection and Assessment System
IQ	Intelligence Quotient
IRB	Institutional Review Board
ISAAC	Internet System for Assessing Autistic Children
MGH	Massachusetts General Hospital
NCH	Nationwide Children's Hospital
OHRP	Office of Human Research Protection
PHS	Public Health Services
PSI-4-SF	Parent Stress Index-4, Short Form
PSOC	Parenting Sense of Competence
RCT	Randomized Controlled Trial
SID	Study Identification Number
UCI	University of California Irvine

1. ETHICS/PROTECTION OF HUMAN SUBJECTS

1.1 *Institutional Review Board (IRB)*

This protocol and the informed consent documents (Appendix A) and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study. A signed consent form will be obtained from all parents or legal guardians participating in the study. Study procedures will be reviewed with child participants and assent will be obtained as appropriate. The written consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy of the consent form will be given to the subject, parent, or legal guardian, and this fact will be documented in the subject's record.

1.2 *Ethical Conduct of Study*

This study will be conducted using good clinical practice (GCP), as delineated in *Guidance for Industry: E6 Good Clinical Practice Consolidated Guidance*, and according to the criteria specified in this study protocol. Before study initiation, the protocol and the informed consent documents will be reviewed and approved by an appropriate IRB/REB. Any amendments to the protocol or to the consent materials must also be approved by the AIR-P CCC, AIR-P DCC, and local IRB before they are implemented.

Compliance with 42 CFR Part 93, Public Health Service (PHS) Policies on Scientific Misconduct is implicit in the application for this proposal. The academic institutions participating in the ATN and this proposal have approved assurances and required renewals on file with the Office of Research Integrity (ORI) and compliance with these policies and procedures and the requirements of part 93 are in place. We understand and abide by the definitions of research misconduct per PHS policies (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results).

1.3 *Subject Information and Consent*

All laboratory specimens, evaluation forms, reports, video recordings, and other records that leave the site will be identified only by the Study Identification Number (SID) to maintain subject confidentiality. All records will be kept in a locked file cabinet. All computer entry and networking programs will be done using SIDs only. Clinical information will not be released without written permission of the subject, except as necessary for monitoring by IRB, HRSA, the OHRP, the sponsor, or the sponsor's designee.

1.4 *Subject Inclusion*

Inclusion of Females: There are no exclusionary criteria related to gender. However, since the ratio of males to females in autism is 4-5:1, we expect that there will be a preponderance of males in this sample of children with ASD. In addition, evidence suggests that mothers are often the primary caregivers for children with neurodevelopmental disorders. Consequently, we anticipate that participating caregivers will most often include mothers, but fathers who are in the role of primary caregiver will be included.

Inclusion of Minorities: Multi-site recruitment is expected to yield a sample reflective of the high degree of diversity that exists within our regional communities. In line with our stated objectives, we will also be exclusively recruiting families with Medicaid insurance.

Inclusion of Children: Children will be included in the proposed sample given the study emphasis on dental care for children with ASD. Inclusion criteria involve child age between 3 and 13:11 at study entry, current diagnosis of ASD (confirmed at baseline by the ADOS-2 and DSM-5 diagnostic checklist), parent-reported difficulty participating in dental care (described further below in screening), confirmed absence of dental screening or exams within the previous 6 months, and underserved status as defined by Medicaid eligibility. We will exclude children who present with an acute dental condition requiring emergency treatment and children currently taking medications that affect oral and gingival health such as chronic continuous steroids and anti-epileptic drugs (e.g., Dilantin, lamotrigine, vigabatrin, ethosuximide, topiramate, primidone). We will also ask families to refrain from participating in any non-study adaptive behavior interventions or therapies focused on dental hygiene or dental screenings/exams for the duration of the present investigation.

Importance of Knowledge to be Gained: Improved understanding of factors contributing to dental hygiene and oral health for children with ASD will contribute to enhanced care for this vulnerable population. Evidence supporting the efficacy of the parent-training intervention developed for this project would greatly enhance the intervention efforts given the relative paucity of systematic interventions designed to improve home dental care for families of children with ASD.

1.5 *Study Modification/Discontinuation*

The study may be modified or discontinued at any time by the IRB, HRSA, the sponsor, the OHRP, or other government agencies as part of their duties to ensure that research subjects are protected.

2. BACKGROUND

2.1 *Rationale*

Participation in routine dental care is a significant unmet healthcare need for children with ASD (McKinney et al., 2014), who have excessive plaque, caries, and oral infections (DeMattei, Cuvo, & Maurizio, 2007). Multiple factors may hinder dental care for children with ASD, including challenges arising from autism-related symptoms (e.g., maladaptive behaviors, language delays, sensory sensitivities, and problems regulating affect and arousal; Isong et al., 2014; McKinney et al., 2014; Lai et al., 2012; Stein et al., 2014). Families with low socioeconomic status and racial/ethnic minority backgrounds face additional barriers and have increased risk for poor oral health (Isong et al., 2014; McKinney et al., 2014; Lai et al., 2012; Stein et al., 2014). The current proposal aims to apply multi-disciplinary, evidence-based approaches to address health disparities and improve dental outcomes for underserved children with ASD by remediating barriers that impede home daily hygiene and participation in routine dental examinations.

Interventions that enhance participation in dental care for underserved children with ASD have significant potential to improve long-term physical health through reduction of children's dental caries, periodontal disease, abscesses, and related problems. We will conduct a randomized controlled trial (RCT) to compare the efficacy of the established AIR-P Dental Toolkit to a combined regimen involving the Dental Toolkit and a parent-mediated behavioral intervention. Our combined intervention integrates strategies shown to be efficacious in improving adherence to dental care in low-income families (e.g., motivational interviewing; Weinstein et al., 2014) with evidence-based behavioral techniques designed to improve child compliance with dental procedures.

Study inclusion criteria involve child age between 3 and 13:11 at study entry, current diagnosis of ASD (confirmed by ADOS-2 and DSM-5 diagnostic criteria at baseline), parent-reported difficulty participating in dental care (described further below in screening), confirmed absence of dental screening or exams within the previous 6 months, and underserved status as defined by Medicaid eligibility. We will exclude children with an acute dental condition requiring emergency treatment and children currently taking medications that affect oral and gingival health such as chronic continuous steroids and anti-epileptic drugs (e.g., Dilantin, lamotrigine, vigabatrin, ethosuximide, topiramate, primidone). We will also ask families to refrain from participating in any non-study adaptive behavior interventions or therapies focused on dental hygiene or dental office screenings/exams for the duration of the present investigation.

Our parent-training intervention includes 5 center-based sessions, 1 home coaching session, 1 dental office coaching session, and 4 phone booster sessions. We will provide families in the intervention condition with the option to

add a second home coaching session between the short- and long-term follow-up assessments. Intervention content emphasizes behavioral strategies shown to be efficacious in the treatment of children with ASD and existing strategies used clinically with neurotypical populations to address dental fear and maladaptive behaviors during dental exams. Sessions are designed to build skills in a hierarchical fashion in a way that is also dynamic and responsive to family needs.

Families will participate in two baseline visits. The initial baseline visit is comprised of a dental office visit and exam. The second baseline visit involves direct child testing and parent interview, and completion of any parent-report forms not finished at the initial dental visit. Children will receive two follow-up dental visits, a short-term follow-up at 3 months and a long-term follow-up at 6 months. For children in the intervention condition, data from the dental office visit at 3 months will be used to further refine treatment efforts in the context of booster sessions leading up to the 6-month follow-up dental visit.

The project intervention and follow-up timeline is outlined below:

CBS 1	CBS 2	CBS 3	Home Coach	CBS 4	CBS 5	Dental Coach	Phone 1	3mo Dental FU	Phone 2	Phone 3	Phone 4	6mo Dental FU
Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8	Week 10	Week 12	Week 13	Week 16	Week 21	Week 24

2.2 ***Risks and Benefits***

2.2.1 Risks

There is minimal risk anticipated in this study. Study procedures are consistent with standard clinical care.

Dental Visits

We plan to collect behavioral and oral health data for all participants in the context of routine preventative care dental visits at baseline and at a 6 month follow-up, and through a preventative dental screening at a 3-month follow-up. A standardized dental exam protocol will be implemented. This protocol will include use of metrics to document oral health based on extra- and intra-oral visual exam and associated procedures (e.g., see dental procedures below). Dentists will also complete additional routine procedures associated with preventative care, which will vary according to the clinical needs of each child and will not be dictated by the research study. Preventative dental visits often include prophylaxis, scaling, application of fluoride varnish, and radiographs. A range of behavioral procedures and medical supports are used to support pediatric dental patients with ASD during preventative dental visits, including pharmacological methods and protective stabilization. The

decision to use or not use behavioral procedures or medical supports will be determined at the sole discretion of the treating dentist based on clinical judgment and care needs. Following completion of the preventative dental exam, dentists will report on exam procedures, utilization of management techniques, child behavior, and general impressions. Risk associated with participation in the preventative dental exams is expected to be commensurate with risk associated with routine care.

An abbreviated dental visit will be implemented for all participants at 3 months in order to capture immediate treatment effects. This 3-month dental visit will consist of standardized visual exam procedures (completed at baseline at 6-months) as well as a routine preventative care. The nature and extent of preventative dental care at 3 months will be determined at the discretion of the treating dental provider according to the child's clinical needs. We anticipate that the 3-month visit will also serve to support desensitization to the dental office environment for all participants, as repeated visits to the dental office and related exposures are frequently recommended in caring for children with ASD.

Given the nature and needs of the target population, we anticipate that some children may experience behavioral challenges or anxiety in the context of the dental visits. Accompanying parents may also experience negative emotion in the context of observing the dental exams and screening. Parents will be asked to report on their experiences getting to the dental office and during the dental visit in order to enhance scientific understanding and improve supports available to families during dental office visits. Families will be reminded that they can discontinue participation in any aspect of the dental visit or terminate the dental visit at any time. This will not disqualify families from continuing participation in the larger study. Families can also withdraw from study participation should a child experience a need for emergency dental treatment at any point during the investigation.

Completion of Baseline Testing and Questionnaires

Families will participate in a baseline assessment, which involves direct child testing, parent interviews, and parent completion of questionnaires. These procedures are consistent with standard psychological assessment practices. However, it is possible that participating in routine testing may activate frustration or negative emotion for children. Parents may also experience some mild negative emotion when reporting on their children's behavior, skills, and experiences at baseline and again at the 3- and 6-month follow-up assessments. Risks are expected to be minimal.

Combined Intervention Condition: Parent-Training

The current project involves a randomized controlled trial of a parent-training intervention to enhance home dental care and improve oral health

outcomes for underserved children with ASD. To serve our unique population, the manualized parent-training program builds upon and integrates established evidence-based techniques designed to: 1) engage families with underserved status in the treatment process, 2) enhance dental experiences for children with neurotypical development and high levels of dental fear, and 3) behaviorally support children with autism spectrum disorder.

Our parent-training intervention is based upon established standards of clinical care. It is possible that the process of engaging in treatment sessions and associated homework activities may activate some mild negative emotion or frustration for parents. Procedures for addressing parental discomfort, frustration, dissatisfaction, and disengagement are embedded within the motivational interviewing and cognitive-reframing approaches included in our intervention approach. Given that we plan to recruit families of children experiencing difficulty with dental care, we anticipate that children may resist engaging in dental hygiene and that this may be difficult for some families. Our intervention is explicitly targeted to alleviate behavioral challenges associated with dental hygiene and we have included center-based, home coaching, and phone booster sessions to provide multiple avenues of support for families.

Management of Adverse Events and Unanticipated Problems
The research team will manage adverse events and unanticipated problems by following HIPAA rules and regulations and being well versed in safety procedures. We will also provide all families with access to a 24-hour phone number to call in the event of clinical need. Following study completion, families will be encouraged to contact the project main phone number should questions or concerns arise.

2.2.2 Benefits

Interventions that enhance participation in dental care for underserved children with ASD have significant potential to improve long-term physical health through reduction of children's dental caries, periodontal disease, abscesses, and related problems. Given the paucity of research on interventions targeting home dental care, the current investigation will greatly enhance scientific understanding while also contributing directly to needs of underserved families.

More specifically, all participants in the study will receive an electric toothbrush and a 6-month supply of toothbrush heads, fluoridated toothpaste, and flossers. We will also provide materials to assist with oral desensitization to dental office equipment (i.e., plastic mirror). Participants

will also receive monetary compensation for completion of the study protocol.

3. OBJECTIVES

3.1 *Study Objectives*

3.1.1 Primary Objectives

To conduct a randomized controlled trial comparing the efficacy of the established AIR-P Dental Toolkit to a combined regimen involving the Dental Toolkit and parent-mediated behavioral intervention.:

Aim 1. To improve child functional and behavioral compliance with home dental hygiene

Aim 2. To Improve oral health.

Aim 3. To reduce anxiety and improve compliance with dental visits.

3.1.2 Secondary Objective (Exploratory)

Aim 4. To examine mediators of intervention effects

Aim 5: To examine moderators of intervention effects.

3.2 **Study Outcome Measures**

3.2.1 Primary outcomes

Aim 1. Hypothesis 1a: Frequency of successful (twice-daily) tooth brushing completed at home during the past week will be derived from parent report to item 3 on the *Home Dental Experiences* questionnaire.

Aim 1. Hypothesis 1b: Parent report of occurence and severity of behavior problems during home dental hygiene during the past week will be derived from parent report to items 10, 11, and 12 on the *Home Dental Experiences* questionnaire. Analysis will examine the degree to which individual items detect treatment effects as well as an aggregate composite of these three items (items will be standardized and composited, if internal consistency is appropriate, e.g., alpha > .70).

Aim 2. Hypothesis 2: Dentist reported child oral health will be examined according to the Visual Plaque Index score (primary) and secondary measures of DMFT/deft score (caries risk) and the Löe & Silness index score (gingival health). Given that each measure

indexes a different aspect of oral health, we will consider VPI, DMFT/deft, and Löe & Silness as separate endpoints.

Aim 3. Hypothesis 3a: Child anxiety rated from the videotaped dental visit by blinded observers using the Venham Anxiety Scale.

Hypothesis 3b: Child behavioral compliance rated from the videotaped dental visit by blinded observers using the Venham Behavior Scale (primary). We will examine the Venham Anxiety and Behavior Scales separately, but we anticipate that it might be appropriate to create a composite based upon an average of the two scales, as has been calculated in prior research (e.g., Isong et al. 2014). Dentist reported child challenging behavior will be examined as a secondary endpoint and will be calculated based upon a composite average of items 5 and 6 (behavior severity ratings) on the *Dentist Visit: Dentist Report* form. Dentist-reported challenging behavior will also be examined based upon the dentist's rating on item 9b and on item 10 (the Frankl Behavior Rating Scale) of the *Dentist Visit: Dentist Report* form.

Hypothesis 3c: Dentist report of completed exam procedures (primary) will be examined based upon total number of attempted and completed exam procedures (item 5 on the *Dentist Visit: Dentist Report* form). Dentist rated adequacy of dental visit (secondary) will be examined based upon item 9c on the *Dentist Visit: Dentist Report* form).

3.2.2 Secondary outcomes

Aim 4. Hypothesis 4a-b *(exploratory):* (a) Parent reported parenting stress as measured by the negative impact scale score on the *Family Impact Questionnaire*, and (b) Parent reported perceived parenting competence as measured by the self-efficacy scale scores on the *Parenting Sense of Competence* (PSOC) scale and the *Oral Health Self-Efficacy* (OHSE) measure. The PSOC and OHSE measures will initially be examined separately, but will be composited (following standardization of variables) should alpha values (> .70) indicate that this is an appropriate strategy.

Aim 5. Hypothesis 5a-b *(exploratory):* (a) Parent reported parenting stress as measured by the negative impact scale score on the *Family Impact Questionnaire*, and (b) Parent reported perceived parenting competence as measured by the self-efficacy scale score on the *Parenting Sense of Competence* (PSOC) scale and the *Oral Health Self-Efficacy* (OHSE) measure. The PSOC and OHSE measures will initially be examined separately, but will be

composited (following standardization of variables) should alpha values (> .70) indicate that this is an appropriate strategy.

4. STUDY DESIGN

4.1 *Overall Study Design and Plan*

4.1.1 Year 1 Activities

Year 1 Activity 1 Refining the Intervention. Behavioral techniques designed to permit oral care may increase cooperation with dental exams, but it is not clear that these approaches improve dental health, nor whether vulnerable and underserved families find such techniques useful in improving care at home. During year 1, we have focused on refining and manualizing our parent-mediated behavioral intervention. To ensure understanding of facilitators and barriers to participating in routine dental care and dental exams, particularly for underserved families, we will conduct two focus groups (one per site) to gather information directly from parent and community stakeholders (focus group procedures have been approved by MGH under a separate protocol: 2016P000560).

Year 1 Activity 2: Developing Training Videos. Utilizing information gathered from our focus groups, existing toolkits, and prior research on video modeling for children with ASD, we have developed open-source videos. The culturally-competent video resources will complement the previously developed Dental Toolkit and will provide information as well as point-of-view and third person modeling of home dental care and participation in dental exams.

Year 1 Activity 3: Manualizing the Parent-Training Intervention. Our parent-training intervention includes 5 center-based sessions, 1 home coaching session, 1 dental office coaching session, and 4 phone booster sessions. We will provide families in the intervention condition with the option to add a second home coaching session between the short- and long-term follow-up assessments. Intervention content emphasizes behavioral strategies shown to be efficacious in the treatment of children with ASD and existing strategies used clinically with neurotypical populations to address dental fear and maladaptive behaviors during dental exams. Intervention targets and delivery will be informed by focus group data and information regarding past history and current child presentation (see *Study Measures*). Sessions are designed to build skills in a hierarchical fashion in a way that is also dynamic and responsive to family needs.

CBS 1	CBS 2	CBS 3	Home Coach	CBS 4	CBS 5	Dental Coach	Phone 1	3mo Dental FU	Phone 2	Phone 3	Phone 4	6mo Dental FU
Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8	Week 10	Week 12	Week 13	Week 16	Week 21	Week 24

A summary of planned parent-training sessions is included below:

- Week 1: Introduction and Treatment Overview
- Week 2: Tooth Brushing Part 1
- Week 3: Tooth Brushing Part 2
- Week 4: Home Coaching
- Week 5: Tooth Brushing Part 3, Flossing, and Dietary Considerations
- Week 6: Preparing for the Dental Office Visit
- Week 8: Dental Office Coaching
- Week 10: Phone Booster 1
- Weeks 13 - 21: Phone Boosters 2 – 4 (Optional Home Coaching 2)

Year 1 Activity 4: Measurement Development and Pilot Testing. We have developed tools to assess treatment fidelity, including clinician adherence to the manualized program and indicators of parent and child participation in training. We have also developed a measure to evaluate parent and child adherence with home dental hygiene, and frequency of home hygiene, through adaptation of existing tools that assess parental confidence in managing child behaviors during everyday tasks (*Parenting Tasks Checklist*) and frequency and intensity of child non-adherence in routine situations (*Home Situations Questionnaire-PDD*). Research assistants, blind to study hypotheses, will be trained to reliability on behavioral coding systems used to evaluate child anxiety and behavioral compliance in the context of videotaped dental exams. We will pilot the newly developed and adapted measures, dental exam procedures, and components of the manualized treatment with 4 families (2 per site) prior to initiating the full randomized controlled trial.

4.1.2 Years 2-3.5

Years 2 – 3.5: Randomized Controlled Trial (Aim 1). During years 2 through 3.5, we will focus on participant recruitment, administration of the intervention, and data collection.

4.1.3 Years 3.5-4

Year 3.5-4: *analysis, write-up, and planning for future investigations.* During the last 6 months of the project, we will finalize all observational coding and data processing, complete data analysis and write up. We anticipate that this research will lead to multiple manuscripts and provide a critical foundation for future research focused on testing the efficacy of specific components for the parent-mediated intervention

4.2 *Study Enrollment Procedures*

4.2.1 Recruitment of Subjects

We will recruit English-speaking families who meet the stated inclusion criteria. Our focus on English-speaking families stems from the need to first establish treatment efficacy prior to considering appropriate adaptations for non-English speaking families. In addition, we will recruit families with Medicaid insurance only given our funding mandate to address underserved populations.

Recruitment sites include the University of California-Irvine and Nationwide Children's Hospital (NCH), and the respective partner dental sites, Healthy Smiles of Orange County and the NCH Johnstown Road program and the NCH dental clinics. Recruitment materials will be shared with families through several mechanisms: through postings in the recruitment site waiting rooms, by providers following visits, and through contact with our Family Advisory Committee. Recruitment materials will include the contact information for the site coordinator. Families will be encouraged to contact project staff to obtain study information. Families will also have the option to release contact information to the study team to enable project staff to contact potential participants directly. Participants already consented for enrollment in ATN registry or in site patient database registries, and who have consented to future contact, may be contacted via telephone (staff making the contact will read the study recruitment flyer) and/or will be mailed or emailed study recruitment materials. Study team members will also review patient medical records to identify potential eligible participants. Patient contact information will be extracted from the medical record in order to facilitate patient contact. Study team members will coordinate with patient providers to approach patients about study participation. Study information will also be listed on clinicaltrials.gov.

The number of randomized subjects is expected to be 118, with 71 expected at UCI and 47 expected at NCH.

Project coordinators will maintain a screening log at each site in order to facilitate recruitment efforts and to document: 1) referral source, 2) the total number of interested families, 3) the number of interested families meeting inclusion criteria and reasons for ineligibility, and 4) the proportion of families meeting inclusion criteria who consent to study participation and reasons for nonparticipation of eligible families. Data will be evaluated within and across recruitment sites, and will be reviewed on bi-weekly project calls to enhance and streamline recruitment efforts.

4.2.2 Consent and Assent

Written (signed) informed consent will be obtained from participants. Families will be provided with a copy of the informed consent form in person or via mail or email at least one week in advance of the baseline dental visit. At the baseline dental visit, project staff will provide an overview of the study and will review the Informed Consent form with each family individually in order to verify understanding of study procedures and to provide the family with an opportunity to ask questions. Project team members will also remind families that: 1) study activities are independent from any other clinical care or services received at the respective study site, 2) study procedures are completely voluntary, and 3) families can decline participation in any aspect of the study and/or can discontinue study participation at any time.

Parents will consent to participation. However, project staff will also review study procedures with participating children. Assent procedures will be implemented as appropriate for children over the age of 7 years. Staff members will read the assent form to children who are unable to read the assent form independently. For children that have difficulty understanding the assent form, the staff member will explain why the child is being asked to participate and what the study will involve (i.e., the nature of his/her likely experience). If the consenting staff member determines that a child is unable to understand these aspects of the assent process, assent will be waived.

4.3 ***Study Duration***

Study duration is 6 months. Families will participate in a baseline evaluation and a dental exam. Follow-up dental exams will occur at 3 months and again at 6 months post-baseline.

4.4 ***Protocol Adherence***

Therapist Adherence and Fidelity. Fidelity procedures will be implemented to ensure therapist adherence to the manualized parent-training intervention. These procedures will include: 1) therapist completion of a fidelity checklist following each treatment session, and 2) a weekly clinical case conference to provide supervision and discuss active cases.

Dentist Adherence and Fidelity. Fidelity procedures will be implemented to ensure dentist adherence to the standardized dental exam protocol. These procedures will include dentist report on completion of exam procedures at each visit and documentation of special circumstances. Procedures will also be

employed to establish fidelity in dentists' ratings on oral health measures, including use of standardized training procedures and assessment of reliability on study measures.

5. STUDY ENROLLMENT AND WITHDRAWAL

5.1 *Number of Study Subjects*

The number of randomized subjects is expected to be 118, with 71 expected at UCI and 47 expected at NCH.

5.2 *Inclusion and Exclusion Criteria*

5.2.1 Subject Inclusion Criteria

1. English-speaking families of children between ages 3-13:11 at study entry
2. Current community diagnosis of ASD confirmed by ADOS-2 and DSM-5 diagnostic checklist at baseline
3. Parent-reported difficulty with participating in dental care, indexed by endorsement of a "Yes" response to either of the two study screening questions:

    - Does your child have problems brushing his/her teeth at least twice a day for two minutes (either independently or with help)? Y/N

    - Does your child have problems going to the dentist? Y/N

4. Absence of dental screening or exams within the previous 6 months
5. Underserved status (Medicaid insurance)

5.2.2 Subject exclusion criteria

1. Ongoing or planned participation in non-study adaptive behavior interventions or therapies focused on dental care
2. Children who present with an acute dental condition requiring emergency treatment
3. Medications that affect oral and gingival health such as chronic continuous steroids and anti-epileptic drugs (Dilantin, lamotrigine, vigabatrin, ethosuximide, topiramate, primidone).

5.3 *Treatment Assignment Procedures*

5.3.1 Randomization procedures

Subjects will be randomized according to a computer-generated, permuted-block randomization schedule that assigns subjects equally (1:1) to the intervention and control arms. Randomization will be stratified by clinical center (UCI and NCH).

Subjects will be randomized after the following events have occurred: eligibility is verified, written consent is obtained, and the baseline assessments have been completed. The randomization assignments will be provided by the AIR-P DCC.

5.3.2 Reasons for withdrawal

Participation will be voluntary. Participants will not be withdrawn from the study unless they request to discontinue participation or they require emergency dental treatment.

5.3.3 Handling of withdrawals

Data from withdrawn participants will be stored with data from participants who complete the study. No further data will be collected from participants who have withdrawn, and participant decisions to withdraw will be noted in the data collection system.

6. STUDY INTERVENTIONS

6.1 *Interventions, Administration and Duration*

Families will be randomized one of two conditions:

1. AIR-P Dental Toolkit only
2. Combined intervention characterized by provision of the AIR-P Dental Toolkit and a manualized parent-training intervention

The parent-training intervention includes 5 center-based sessions (at the UCI Center for Autism or the NCH clinic, respectively), 1 home coaching session, 1 dental office coaching session (at the UCI/NCH dental site), and 4 phone booster sessions. We will provide families in the intervention condition with the option to add a second home coaching session between the short- and long-term follow-up assessments.

Families will participate in two baseline visits. The initial baseline is comprised of a dental office visit and exam. The second baseline visit involves direct child testing, as well as parent interview and report measures. Children will receive two follow-up dental visits, a short-term follow-up at 3 months and a long-term

follow-up at 6 months. For children in the intervention condition, data from the dental office visit at 3 months will be used to further refine treatment efforts in the context of booster sessions leading up to the 6-month follow-up dental exam.

The project intervention and follow-up timeline is outlined below:

CBS 1	CBS 2	CBS 3	Home Coach	CBS 4	CBS 5	Dental Coach	Phone 1	3mo Dental FU	Phone 2	Phone 3	Phone 4	6mo Dental FU
Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8	Week 10	Week 12	Week 13	Week 16	Week 21	Week 24

Therapists providing the parent-training intervention will have a background in behavioral techniques and intervention. Study therapists will include doctoral-level psychologists, master's level clinicians with relevant licensure and/or BCBA certification, and/or graduate students in a doctoral psychology training program.

Licensed dentists providing the participant exams will have a relevant background in pediatrics.

6.2 *Handling of Study Interventions*

Standardized training on all study procedures, measures, and protocols will be implemented across research sites, and fidelity will be monitored through established procedures and through biweekly project calls. Dentists will be blinded to study intervention condition in order to ensure the integrity of oral health outcome reporting.

6.3 *Concomitant Interventions*

6.3.1 Required Interventions

Families in the combined treatment condition will participate in a 10-week intervention, comprised of 5 center-based sessions, 1 home coaching session, 1 dental office coaching session, and 1 phone booster session. Following the 3-month follow-up assessment, families will receive an additional 3 booster sessions and an optional second home coaching session.

6.3.2 Prohibited Interventions

Families will be asked to refrain from participating in non-study adaptive behavior interventions or therapies focused on dental care. We will also ask

families to refrain from participating in any non-study dental screenings or exams for the duration of the present investigation.

6.4 *Adherence Assessment*

Treatment attendance will be documented and will include data regarding number of missed and rescheduled sessions (and associated reasons). Tracking will also include parent completion of assigned treatment activities and homework. Families in both conditions will be asked to complete questionnaires inquiring about the frequency and nature of home dental hygiene, which will also function as an adherence assessment for families in the treatment group. Similarly, questions regarding fidelity to the dental exam protocol are incorporated in the dentist's report of examinations as a measure of adherence.

All families will be provided with materials to facilitate dental hygiene over the course of the 6-month study period, including an electric toothbrush and a 6-month supply of toothbrush heads, fluoridated toothpaste, and flossers. We will also provide materials to assist with oral desensitization to dental office equipment (i.e., plastic mirror).

7. STUDY SCHEDULE

Targeted Treatment Windows

Baseline Dental Visit	Baseline Testing	Parent Training Session 1	3mo Dental Exam	6mo Dental Exam
Within 6mo of Screening	Within 4 weeks of Baseline Dental Visit	Within 4 weeks of Baseline Testing	3mo from Baseline Dental Exam (±4 - 6 weeks)	6mo from Baseline Dental Exam (±4 - 6 weeks)

7.1 *Screening Visit*

Screening

Project staff will contact interested families to screen for eligibility. Project staff will confirm the following inclusion criteria: English language fluency, child age (3 – 13:11), child community diagnosis of ASD, absence of a need for emergency dental treatment for the child, absence of dental screenings or exams within the previous six months, and Medicaid eligibility. Project staff will confirm that the child is not currently taking medications that affect oral and gingival health, including chronic continuous steroids and anti-epileptic medications. The staff member will also ask parents two questions to related to the child's experiences with dental care; a "Yes" response to either question will be considered to meet the study inclusion criterion related to child difficulty participating in dental care:

1. Does your child have problems brushing his/her teeth at least twice a day for two minutes (either independently or with help)? Y/N

2. Does your child have problems going to the dentist? Y/N

Participants will be scheduled for the preliminary baseline assessment within 6 months of eligibility screening.

7.1.1 Screen Failures

Project coordinators will maintain a screening log at each site in order to document screen failures, including the reasons for ineligibility. Families will be provided with relevant clinical resources and follow-up as needed.

7.2 *Baseline Visit*

Families will participate in two baseline visits. The initial baseline is comprised of a dental office visit and exam. The second baseline clinic visit involves direct child testing, and parent interview and report measures. In the event that a family does not complete all questionnaire forms at the initial baseline visit, the family will be given the opportunity to complete the forms at home and return the data at the clinic visit. Any questionnaires that remain incomplete will be re-administered at the clinic visit.

7.3 *Follow-up Visit*

Families will participate in two follow-up dental visits: a short-term follow-up at 3-months post-baseline and a long-term follow-up at 6-months post-baseline. Both follow-up visits will include standardized measures of oral health based upon a visual exam and preventative care procedures. The follow-up visits will also include parent completion of questionnaires. For children in the combined intervention condition, data from the dental office visit at 3 months will be used to further refine treatment efforts in the context of booster sessions and/or home coaching leading up to the 6-month follow-up dental visit.

7.4 *Protocol Deviations*

Project coordinators will maintain a log at each site in order to document protocol deviations and special circumstances. Clinical considerations will be addressed in weekly clinical case conference calls and other project management or procedural issues will be addressed through biweekly project calls and related contacts.

7.5 *Missed visits and Procedures*

Project staff will document missed treatment and dental visits, including the number of missed and rescheduled sessions (and associated reasons). Effort will be made to reschedule missed visits within two weeks of the original target date. Clinical considerations will be addressed in weekly clinical case conference calls and other project management or procedural issues will be addressed through biweekly project calls and related contacts.

8. CLINICAL ASSESSMENTS AND OUTCOME MEASURES

8.1 *Pre-Randomization Evaluations*

Baseline Dental Visit

The baseline dental visit will involve completion of an established protocol, which adheres to standards of routine clinical care. The dental visit will be videotaped to allow for later, blinded, observational coding of child anxiety and behavior during the dental exam.

The standardized dental protocol will include use of metrics to document oral health based on an extra- and intra-oral visual exam and associated procedures. Dentists will complete three standardized oral health measures during the visual exam: the DMFT/deft, the Visual Plaque Index (VPI) Quigley-Hein modified Turesky Index, and the modified Löe & Silness Gingival Index. Dentists will also complete additional routine procedures associated with preventative care, which will vary according to the clinical needs of each child and will not be dictated by the research study. Preventative dental visits often include prophylaxis, scaling, application of fluoride varnish, and radiographs. A range of behavioral procedures and medical supports are used to support pediatric dental patients with ASD during preventative dental visits, including pharmacological methods and protective stabilization. The decision to use or not use behavioral procedures or medical supports will be determined at the sole discretion of the treating dentist based on clinical judgment and care needs. Following completion of the preventative dental visit, dentists will be asked to report on exam procedures, utilization of medical and behavioral techniques, child behavior, and general impressions.

Domain	Measure
Dental Experiences & Oral Health	1. *Dental Visit: Dentist Report*: Includes the following standardized indices of oral health based upon visual intra-oral inspection and associated procedures: 1) DMFT/deft, 2) Visual Plaque Index Quigley-Hein modified Turesky Index, 3) modified Löe & Silness Gingival Index 2. *Dental Visit: Parent Report*

Child Behavior During Dental Exam	3. *Venham Scales-Anxiety Scale* (attached; coded from videotape) 4. *Venham Scales-Behavior Scale* (attached; coded from videotape)

Parent-Report Measures

Domain	Measure
Demographic / Family Information Questionnaire	1. A demographic questionnaire will be used to gather information regarding age, gender, race/ethnicity, parent/caregiver relationship to the child, marital status, level of education, family income, and child comorbid diagnoses, medication history/current medications, and intervention history/current services.
Family Resources	2. *Family Resource Scale* (FRS): to assess family access to resources and level of strain.
Dental Experiences	3. *Dental Visit History* 4. *Home Dental Experiences*
Child Behavior Problems	*5. Child Behavior Checklist* *6. Home Situations Questionnaire-PDD*
Parenting Perspectives	7. *Parenting Sense of Competence Scale (PSOC)* with *Oral Health Self-Efficacy (OHSE)* 8. *Family Impact Questionnaire* (FIQ)

Baseline Clinic Visit

The baseline clinic visit will involve direct child testing, parent interview, and parent completion of questionnaire measures not finished at the baseline dental visit.

Child Direct Testing & Structured Parent Interview

Domain	Measure
Intellectual Functioning	1. *Stanford-Binet Intelligence Scales, 5th Edition*
ASD Diagnosis	2. *Autism Diagnostic Observation Schedule-2* 3. *DSM-5 Diagnostic Checklist*
Child Adaptive Behavior	*9. Vineland Adaptive Behavior Scales-3, Interview form*

8.2 *3-Month Follow-Up Evaluation*

The 3-month dental visit will include completion of the standardized dental protocol administered at baseline, including use of metrics to document oral health based on an extra- and intra-oral visual exam and associated procedures. Dentists will repeat the same three standardized oral health measures during the 3-month visual exam: the DMFT/deft, the Visual Plaque Index (VPI) Quigley-Hein modified Turesky Index, and the modified Löe & Silness Gingival Index. Dentists will also complete routine preventative care, the nature and extent of which will be determined solely by the treating dentist according to the child's clinical needs. Following completion of the 3-month dental visit, dentists will be asked to report on exam procedures, utilization of medical and behavioral techniques, child behavior, and general impressions. The dental visit will again be videotaped to allow for later, blinded, observational coding of child anxiety and behavior during the dental visit.

Domain	Measure
Dental Experiences & Oral Health	1. *Home Dental Experiences* *2. Dental Visit: Dentist Report* *3. Dental Visit: Parent Report* 4. *Venham Scales-Anxiety Scale* 5. *Venham Scales-Behavior Scale*
Child Behavior Problems	*6. Home Situations Questionnaire-PDD*
Parenting Perspectives	7. *Parenting Sense of Competence Scale (PSOC)* with *Oral Health Self-Efficacy (OHSE)* *8. Family Impact Questionnaire (FIQ)*
Child Services Update	*9. Child Services Update*
Treatment Fidelity/Satisfaction	*10. Treatment Fidelity & Satisfaction*

We will also gather information related to any change in child services since baseline (medication and exogenous treatment/therapy). We will also assess treatment/protocol fidelity across both conditions and satisfaction within the treatment condition.

8.3 *6-Month Follow-Up Evaluation*

The 6-month follow-up evaluation will repeat baseline data collection for parent report questionnaires and data collected at the dental office visit.

Domain	Measure
Dental Experiences & Oral Health	1. *Home Dental Experiences* *2. Dental Exam Report—Dentist Version* *3. Dental Visit: Parent Report* 4. *Venham Scales-Anxiety Scale* 5. *Venham Scales-Behavior Scale*
Child Behavior	*6. Home Situations Questionnaire-PDD*

Problems	
Parenting Perspectives	7. *Parenting Sense of Competence Scale (PSOC)* with *Oral Health Self-Efficacy (OHSE)* 8. *Family Impact Questionnaire (FIQ)*
Child Services Update	9. *Child Services Update*
Treatment Fidelity/Satisfaction	10. *Treatment Fidelity & Satisfaction*

We will also gather information related to any change in child services since 3-month follow-up (medication and exogenous treatment/therapy). We will also assess treatment/protocol fidelity across both conditions and treatment satisfaction within the combined intervention condition.

8.4 ***Additional Measures***

8.4.1 **Baseline Measures**

Measures that are collected only at baseline include measures designed to facilitate sample characterization and potential methodological control, including demographics, financial resources/strain (FRS), and child developmental functioning and symptomatology (SB-5, VABS-III, ADOS-2, DSM-5 Checklist, CBCL).

Selected variables from these measures may be used as follows: as covariates or moderators in statistical models; in an exploratory fashion to characterize the study population; to identify subgroups and/or baseline predictors of efficacy.

Demographic / Family Information Questionnaire	1. A demographic questionnaire will be used to gather information regarding age, gender, race/ethnicity, parent/caregiver relationship to the child, marital status, level of education, employment status, family income, and family history of medical and psychiatric diagnoses, child comorbid diagnoses, age at diagnosis/diagnoses, diagnosing provider, medication history/current medications, intervention history/current services, and school placement.
Family Resources / Strain	2. *Family Resource Scale* (FRS)
Child Behavior Problems	*3. Child Behavior Checklist*
Child Adaptive Behavior	*4. Vineland Adaptive Behavior Scales-3, Interview Form*
Intellectual Functioning	*5. Stanford-Binet Intelligence Scales, 5th Edition*
ASD Diagnosis	*6. Autism Diagnostic Observation Schedule-2* *7. DSM-5 Diagnostic Checklist*

8.4.2 **Dental Exam History**

A Dental Exam History Form will be administered to assess previous dental experiences and outcomes in order to characterize the study population and to facilitate comparability with prior research. In addition, selected variables may be used as covariates in statistical models or used in an exploratory fashion to identify subgroups and/or baseline predictors of efficacy.

Dental Experiences	1. *Dental Exam History*

8.4.3 **Dental Visit Report**

Dentists will report on the use and effectiveness of certain management strategies during the exam, which will be used in supporting analyses of child behavior (Aim 3).

Parents will also report on the experience of getting to the dental office and completing the dental visit. These measures will be used in supporting analyses of child compliance with dental care (Aims 1 and 3) and in examination of intervention effect on parental stress and confidence surrounding dental exams (Aim 4: exploratory analysis).

Dental Experiences & Oral Health	*1. Dental Exam Report—Dentist Version* 2. *Dental Exam Experience—Parent Report*

8.4.4 **Parent-Reported Child Behavior**

Standardized measures of child internalizing and externalizing behavior problems (CBCL) and child behavioral compliance in the home environment (HSQ-PDD) will be employed to characterize the study population at baseline. The HSQ-PDD will also be administered at 3- and 6-month follow-up visits to serve as a validity check for novel study measures of behavioral compliance with dental care, and to examine generalization of intervention effects. The CBCL and the HSQ-PDD have both been used to document behavioral pathology in children with ASD. The HSQ-PDD has shown particular promise as an instrument sensitive to change in the context of behavioral parent training.

Child Behavior Problems	*1. Child Behavior Checklist* *2. Home Situations Questionnaire-PDD*

8.6.1. Family Environment and Parenting Factors

Aspects of the family environment, particularly parenting stress and perceived parenting self-competence have been found to influence treatment outcome in behavioral parent training programs. We will consider these factors in the context of the current investigation. We will also examine change in parenting perspectives at 3- and 6-month post-baseline.

Parenting Perspectives	1. *Parenting Sense of Competence Scale (PSOC)* 2. *Family Impact Questionnaire* (FIQ)

8.5 ***Special Instructions and Definitions of Evaluations***

8.5.1 Informed Consent

Written (signed) informed consent will be obtained from participants. Families will be provided with a copy of the informed consent form in person or via mail or email at least one week in advance of the baseline dental visit. At the baseline dental visit, project staff will provide an overview of the study and will review the Informed Consent form with each family individually in order to verify understanding of study procedures and to provide the family with an opportunity to ask questions. Project team members will also remind families that: 1) study activities are independent from any other clinical care or services received at the respective study site, 2) study procedures are completely voluntary, and 3) families can decline participation in any aspect of the study and/or can discontinue study participation at any time.

Parents will consent to participation. However, project staff will also review study procedures with participating children. Assent procedures will be implemented as appropriate for children over the age of 7 years. Staff members will read the assent form to children who are unable to read the assent form independently. For children that have difficulty understanding the assent form, the staff member will explain why the child is being asked to participate and what the study will involve (i.e., the nature of his/her likely experience). If the consenting staff member determines that a child is unable to understand these aspects of the assent process, assent will be waived.

8.5.2 Adherence Assessments

Therapist Adherence and Fidelity. Fidelity procedures will be implemented to ensure therapist adherence to the manualized parent-training intervention. These procedures will include: 1) therapist completion of a fidelity checklist following each treatment session, and 2) a weekly clinical case conference to provide supervision and discuss active cases.

Dentist Adherence and Fidelity. Fidelity procedures will be implemented to ensure dentist adherence to the standardized dental visit protocol. These procedures will include dentist report on completion of exam procedures at each visit and documentation of special circumstances. Procedures will also be employed to establish fidelity in dentists' ratings on oral health measures, including use of standardized training procedures and assessment of reliability on study measures.

Family Treatment Adherence: We will assess parents' perceptions regarding participation in treatment at the outset of the initial session in order to inform our motivational intervention approach (*Parent Motivation Inventory*; see Appendix). In addition, treatment attendance will be documented and will include data regarding number of missed and rescheduled sessions (and associated reasons). Tracking will also include parent completion of assigned treatment activities and homework. Families in both conditions will be asked to complete questionnaires inquiring about the frequency and nature of home dental hygiene, which will also function as an adherence assessment for families in the treatment group.

All families will be provided with materials to facilitate dental hygiene over the course of the 6-month study period, including an electric toothbrush and a 6-month supply of toothbrush heads, fluoridated toothpaste, and flossers.

9. MANAGEMENT OF ADVERSE EXPERIENCES

The research team will manage adverse events and unanticipated problems by following HIPAA rules and regulations, being well versed in safety procedures, and following established safety protocols. We will provide all families with a 24-hour phone number to call in the event of clinical need.

Parent-Training Intervention
Procedures for addressing parental discomfort, frustration, dissatisfaction, and disengagement are embedded within the motivational interviewing and cognitive-reframing approaches included in our intervention approach. Given that we plan to recruit families of children experiencing difficulty with dental care, we anticipate that children may resist engaging in dental hygiene and that this may be difficult for some families. Our intervention is explicitly targeted to alleviate behavioral challenges associated with dental hygiene and we have included center-based, home coaching, and phone booster sessions to provide multiple avenues of support for families.

Dental Exams
We plan to collect behavioral and oral health data through dental visits at baseline, 3 months, and 6-months post-baseline. Minimal risk is expected in connection with use of standardized visual exam procedures and provision of routine dental care.

Given the nature and needs of the target population, we anticipate that some children may experience behavioral challenges or anxiety in the context of the dental visit.

Accompanying parents may also experience negative emotion in the context of observing the dental visit. Any adverse events experienced during the dental office visit will be documented and reported. Families will also be reminded that they can discontinue participation in any aspect of the dental visit or terminate the dental visit at any time. This will not disqualify families from continuing participation in the larger study.

Families will be encouraged to contact the project main phone number should questions or concerns arise after study completion.

10. STATISTICAL ANALYSIS PLAN

10.1 *Statistical Considerations*

10.1.1 Data Analysis

Standard summary statistics for all study measures will be prepared. The analysis will be intent-to-treat.

Aim 1: Improved Home Dental Hygiene

The frequency of successful tooth-brushing occuring at home during the past week (hypothesis 1a) and the severity of problem behavior associated with this activity (hypothesis 1b) will be assessed through repeated measures regression models allowing for a shared group mean at baseline and separate group means at each of the 3 and 6-month follow-up times (unstructured mean model at 3 and 6 months). For frequency of tooth-brushing, a log-linear generalized estimating equations (GEE) or random effects model allowing for overdispersion will be used. Additional fixed baseline covariates may include age, site and IQ and other key measures. The primary significance test will compare the treatment groups at 6-months.

Supporting analyses of in-home dental practices will look at group differences in these endpoints at 3 months and the overall time trend. Behavior problems may be classified and modeled through a generalized linear model (GEE or random effects logit model); similarly tooth brushing may also be analyzed through a standard linear repeated measures model (identity link). Additional analyses may include tests of group differences at 3 and 6 months in supporting endpoints such as flossing and specific behavioral problems (primarily through Wilcoxon and chi-square tests).

Aim 2: Improved Oral Health

Dentist report of the VPI score (hypothesis 2) at baseline, 3 months and 6 months will be modeled in , a linear repeated measures model as described above. An unstructured covariance matrix will be used, and the primary significance test is again the group difference at 6 months. Supporting analyses of this endpoint will look at group differences at 3 months and the overall time trend. The VPI may also be classified and modeled through a generalized linear model (GEE or random effects logit model). Tests of group differences at 3 and 6 months in supporting oral health endpoints such as the DMFT/deft and Loe & Silness index may be performed through regression models or Wilcoxon tests.

Aim 3: Reduced Anxiety and Improved Compliance with Dental Visit

Repeated measures models as described for the VPI will be used to analyze the *Venham Anxiety and Behavior Rating Scales* (hypotheses 3a and 3b) and the dentist's report of completion (hypothesis 3c), with the primary test of group difference occuring at the 6 month timepoint. Wilcoxon tests may also be used.

Wilcoxon tests, logistic regression and/or chi-square tests, and graphical/tabular presentations will be used to assess group differences in the supporting child behavior endpoints (dentist and parent report) and the supporting exam completion endpoints at 3 and 6 months. Generalized log-linear GEE or random effects models may be used to analyze exam completion rates.

Aims 4 and 5: Treatment Moderators and Mediators (Exploratory)

The effect of the intervention on parenting stress and competence scales at 3 and 6 months will be assessed through repeated measures models as described for VPI. Once group differences in these endpoints and on the primary outcomes are established, parenting stress and competence will be explored as mediators of the intervention effect on home hygiene and oral health measures. Similarly, tests of stress and competence as moderators of intervention effect will be incorporated through interaction terms in the regression models of the primary outcomes..

10.1.2 Sample Size and Accrual

Assuming a balanced 15% attrition rate, at least 30% correlation between baseline and follow-up estimates, and two-tailed testing at alpha = 0.025 to accommodate two co-primary outcomes (tooth-brushing and VPI), a sample size of 100 allows us to detect an effect size of 0.6 with 80% power.

10.2 *Missing Data*

Repeated measures models allows for missingness in the outcome at baseline or follow-up.

11. DATA COLLECTION, MANAGEMENT, AND MONITORING

11.1 *Role of Data Management*

11.1.1 Web-Based Data Collection and Management System

Data collection will occur via StudyTRAX, a web-based data entry system to allow easy access to enrollment 24 hours a day, seven days a week, and the Internet System for Assessing Autistic Children (ISAAC) system for copyrighted assessments. Upon enrollment, a form submission schedule is generated for each subject, and displayed as a grid of forms by study visit that permits direct access to each eCRF for data entry. As data are entered, they are validated through range and within-form consistency checks.

11.1.2 Certification in the Use of Web-Based Data Entry System

The DCC will provide training and certification of study staff in the use of the data entry system. Once certified, users are permitted to enter data into the production system. Access is password controlled. Certification for use of the web-based data entry system will be completed via individual practicum assessment.

11.1.3 Data Entry and Checks

Data for individual participants will be recorded on electronic case report forms (eCRF) in an electronic data capture system. All participants screened for the study, including the screen failures, must be entered into the system. The EDC will reflect participant status (screen failure, enrolled, early termination, completed) at each phase during the course of the study. Participants will not be identified on the eCRFs by name or initials. Each participant will be assigned a study identification number.

Clinical data processing and management will be employed based on the procedures developed in conjunction with the AIR-P DCC. All of the data entered into the electronic data capture system will be checked for valid values and ranges, between-item logical consistency, and within-subject variation.

11.1.4 Quality Assurance

Prior to the initiation of the study the AIR-P CCC, AIR-P DCC, the investigators and their study coordinators will discuss the protocol, performance of study procedures, safety reporting requirements, electronic data capture system training and eCRF completion and simulation of study procedures, as applicable. Study staff that are responsible for the collection and submission of the study data will be required to pass eCRF training for certification prior to use of the production system for submission of the data. The study Manual of Procedures will be reviewed during training for site personnel and should be utilized to reference key details regarding study processes.

After completion of the entry process, computer logic checks or Integrity reports will be executed to assess data inconsistencies (e.g., inconsistent study dates or out of range laboratory values). A response to these reports is required from site personnel by the defined report date. In addition, data modifications to the data field(s) must be made in the electronic data capture system which tracks the audit history of all data entered and modified.

11.2 *Data Handling and Record Keeping*

11.2.1 Confidentiality

Raw data will be stored in locked cabinets in a locked office at each site. All evaluation forms, reports and other records that leave a site will be identified only by the Study Identification Number (SID) to maintain participant confidentiality. De-identified data will be submitted to a central, password-protected database provided by the DCC. The key connecting participants to their SID will be secured in a locked cabinet at each site. All computer entry and networking programs will be done using SIDs only. Data forms will only be identified by SID. The database will not contain any personal identifiers other than study identification number and date of birth.

11.2.2 Retention of records

Sites will comply with their individual IRB’s policies for retention of records.

11.2.3 Publications

Publication of the results of this trial will be governed by the policies and procedures developed by the ATN Scientific Review Committee. Any presentation, abstract, or manuscript will be made available for review by the sponsor and HRSA prior to submission

Year 3.5 - 4: analysis, write-up, and planning for future investigations. During the last 6 months of the project, we will finalize all observational coding and data processing, complete data analysis and write up. We anticipate that this research will lead to multiple manuscripts and provide a critical foundation for future research focused on testing the efficacy of specific components of the parent-mediated intervention.

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APPENDIX A

UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Improving Participation in Dental Care and Oral Health Outcomes for Underserved Children with ASD

You and your child are being asked to participate in a research study. Participation is completely voluntary. Your participation will not affect any clinical care you receive. You may decide to stop participation at any time. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

In the instance of parental permission, "You" refers to "Your child."

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STUDY LOCATION(S): University of California Irvine, Healthy Smiles for Kids of Orange County, California State University, Fullerton

STUDY SPONSOR(S): Autism Intervention Research Network on Physical Health

WHY IS THIS RESEARCH STUDY BEING DONE?

This is a study to compare the efficacy of an established dental toolkit and a combined program involving the dental toolkit and parent-mediated behavioral intervention on improving home dental hygiene and oral health for children with autism spectrum disorder.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 60 participants will take part in the research at UCI. A total of 100 participants will be asked to participate across all study sites.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?

Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements

You can participate in this study if your child:

1. Is between age 3 years and 13 years, eleven months at study entry
2. Has a current diagnosis of ASD
3. Has not received dental screening or dental exams within the previous 6 months
4. Is not currently participating in or planning to participate in any non-study adaptive behavior intervention or therapies focused on dental care
5. Has underserved status (Medicaid insurance)

Exclusion Requirements

You cannot participate in this study if your child:

1. Has an acute dental condition requiring emergency treatment
2. Is currently taking medications that affect oral and gingival health such as chronic continuous steroids and anti-epileptic medications

HOW LONG WILL THE STUDY GO ON?

The study includes 4 visits (1 initial clinic visit and 3 dental office visits) over a period of 6 months. The combined intervention takes place over 10 weeks and includes follow-up phone sessions and an optional follow-up session at home.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?

Before you can participate in the main part of the study...

You will need to have "screening" exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include:

- **Verification of study eligibility**
- **Answering questions about your child's experience with dental care**
- **Direct testing of your child to confirm ASD diagnosis**

Verifying study eligibility will occur through an initial screening and through participation in two baseline visits, one at the Health Smiles dental clinic and one at the UCI Center for Autism and Neurodevelopmental Disorders. These visits include the following:

1. Baseline Dental Exam

- *Your child will have a dental exam to assess oral health and to rule out the need for emergency dental treatment. The exam will use visual inspection and standard dental procedures.*
- *Behavioral procedures and medical supports are routinely used during pediatric dental exams for children with ASD. The use of any behavioral procedure or medical support will be clinically determined at the discretion of the treating dentist, and will not be dictated or influenced by this research study. Some procedures may require a separate clinical consent. You may decide not to consent to these procedures. This will not affect your participation in this study.*
- *You will complete a questionnaire about your child's experiences and behavior during the dental exam.*
- *The dental exam will be videotaped to allow researchers to observe your child's behavior.*
- *You will complete questionnaires related to: demographic information, your child's past dental history, your child's experiences with dental care at home and at the dental office, as well as your child's current behaviors and sensory experiences. We will also ask you to complete questionnaires so that we can better understand your experience as a parent.*

2. Baseline Clinic Visit

- *Your child will receive direct testing to confirm ASD diagnosis and assess intellectual functioning.*
- *You will also be asked to complete an interview to help researchers better understand your child's everyday experiences and needs.*

During the main part of the study...

If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include…

3. Intervention

- *All participants in the study will receive the AIR-P dental toolkit*
- *If you are randomly assigned the combined intervention you will participate in:*
  - *5 sessions at the UCI Center for Autism*
  - *1 home coaching session*
  - *1 session at the UCI dental site*
  - *4 booster sessions by telephone*
  - *1 optional booster session at home*

4. Three and Six Month Follow-up Sessions

- *Your child will have a dental exam to assess oral health. The exam will use visual inspection and standard dental procedures.*
- *Behavioral procedures and medical supports are routinely used during pediatric dental exams for children with ASD. The use of any behavioral procedure or medical support will be clinically determined at the discretion of the treating dentist, and will not be dictated or influenced by this research study. Some procedures may require a separate clinical consent. You may decide not to consent to these procedures. This will not affect your participation in this study.*
- *The dental exam will be videotaped to allow researchers to observe your child's behavior.*
- *You will complete questionnaires related to your child's experiences and behaviors during the dental exam.*
- *We will also ask you to complete questionnaires related to your child's home dental behavior, your child's general behaviors, and your child's sensory experiences as well as questionnaires that will help us to better understand your experience as a parent.*

You will be asked not to participate in any non-study dental exams or screenings for the duration of the study except as needed in the case of an emergency.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

This study involves minimal risk. There is a risk of loss of privacy. During data collection, identifying information (name, contact information) is obtained. This creates a risk of breach of confidentiality if this information inadvertently became public.

Participants in the combined intervention may experience some frustration or negative emotion related to the training sessions and homework activities that are part of the intervention. The intervention is designed to adequately identify and address these emotions.

You may become upset or uncomfortable when answering questions about your child's behaviors. You do not have to answer any questions that make you uncomfortable and are invited to discuss any concerns with the research team using a 24-hour phone line that will be provided.

You may experience frustration when trying to get your child to engage in at-home dental behaviors.
You may also experience negative emotion when observing your child's dental exam. Your child may experience increased anxiety or behavioral challenges as part of the visit. You may decide to terminate the dental visit at any time.

You should talk to the research team about any concerns you have while taking part in the study.

ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY?

This study will help researchers learn more about the effect of a parent-mediated behavioral intervention on oral health outcomes for children with autism spectrum disorder and it is hoped that this information will help in the treatment of future patients with autism spectrum disorder who experience difficulty with home dental hygiene and visits to the dentist.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:

- Getting no treatment
- Getting standard treatment for your condition without being in a study.
- Getting a different experimental treatment/taking part in another study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

All participants in the study will receive an electric toothbrush and a 6-month supply of toothbrush heads, fluoridated toothpaste, and flossers. We will also provide materials to assist with oral desensitization to dental office equipment (i.e., plastic mirror). Families will receive a brief written summary of results from child testing completed at baseline. We will also provide childcare for families participating in the parent-training intervention.

In addition, participants will receive compensation in the form of gift cards for completion of the study protocol. Families participating in the parent-mediated intervention will receive up to $500.00 in compensation over 6 months of study participation. Families participating in the comparison condition will receive up to $300.00 in compensation over 6 months of study participation. Differences in compensation are based upon the required time and commitment for study participation.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you for participation in this study.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

For example, in the event that your child experiences a need for emergency dental treatment, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare.

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request in writing.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data

Some identifiable information collected about you will be kept with the research data. We will minimize collection of personally identifiable information. However, we will collect some information such as date of birth in order to calculate precisely the age of participating children and family members.

Data Storage

Research data will be maintained in paper format in a secure location at UCI. Only authorized individuals will have access to it. Research data will also be stored electronically on a secure computer/network in an encrypted file.

Research data will also be stored electronically on a password-protected database managed by the Massachusetts General Hospital Data Coordinating Center. Only authorized individuals will have access to it.

The video recordings that can identify you will also be stored in a secure location. The recordings will be retained with the other research data.

Data Retention

The researchers intend to keep the research data indefinitely.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized personnel at UCI, Healthy Smiles for Kids of Orange County, and California State University, Fullerton, as well as the study sponsor, the Massachusetts General Hospital clinical coordinating center and data coordinating center and regulatory entities may have access to your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be released or disclosed by these entities without your separate written consent, except as specifically required by law. Publications and/or presentations resulting from this study will not include identifiable information about you.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy

ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 5171 California Avenue, Suite 150, Irvine, CA 92697.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center or our partner dental site, Healthy Smiles for Kids of Orange County.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

Subject Signature	**Date**
Printed Name of Subject	
Legally Authorized Representative/Guardian Signature	***Date***
Printed Name of Legally Authorized Representative/Guardian	***Relationship to Subject***
Legally Authorized Representative/Guardian Signature	***Date***
Printed Name of Legally Authorized Representative/Guardian	***Relationship to Subject***
Signature of Person Obtaining Informed Consent *(Individual must be listed on Page 1 of this consent)*	**Date**

Printed Name of Person Obtaining Informed Consent ***A witness signature is required on this consent form only if: (Researchers: check which one applies)***

☐Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____

Witness Signature **Date**

(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____

Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 5171 California Avenue, Suite 150, Irvine, CA 92697.

APPENDIX B

Evaluation	Screening	Baseline Dental Visit	Baseline Clinic Visit	3-Month Follow-up	6-Month Follow-up
Informed Consent		X			
Verification of Eligibility	X	X			
Simplified 2 item screening questions	X				
Stanford-Binet Intelligence Scales – 5th Edition			X		
ADOS-2			X		
DSM-5 Checklist			X		
Demographic/Family Information Questionnaire		X			
Child Services Update				X	X
FRS		X			
Dental Exam History		X			
Home Dental Experiences		X		X	X
Child Behavior Checklist		X			

Home Situations Questionnaire-PDD		X		X	X
Evaluation	**Screening**	**Baseline Dental Visit**	**Baseline Clinic Visit**	**3-Month Follow-up**	**6-Month Follow-up**
Vineland Adaptive Behavior Scales-3, Interview			X		
PSOC		X		X	X
FIQ		X		X	X
Dental Exam Report-Dentist Version (includes DMFT, Visual plaque index, Gingival Index)		X		X	X
Dental Exam Report-Parent Version		X		X	X
Venham Scales-Anxiety Scale			X	X	X
Venham Scales-Behavior Scale			X	X	X
Videotape dental exam (for later observational coding)			X	X	X
Parent Motivation Inventory (PMI – intervention only; administered at initial treatment session)					