

Progress Report

A. Specific Aims

The specific aims of the study remain as they were presented in the proposal. They are as follows:

AIM 1. To establish prevalence rates for individual preschool anxiety disorders in pediatric primary care settings according to the DSM-IV criteria, by age, sex and ethnicity (African American vs. White).

AIM 2. To establish rates of comorbidity among the anxiety disorders (*homotypic* comorbidity).

AIM 3. To establish rates of comorbidity between the anxiety disorders and other disorders (*heterotypic* comorbidity).

AIM 4. To establish clinical cutpoints for identifying abnormal levels of anxiety-related behavior for symptoms that may be particularly common in preschoolers, who are not otherwise disordered.

AIM 5. To evaluate the match between service need and service use (including medication).

AIM 6. To establish the concurrent validity of parent-report preschool anxiety disorders. Aim 6a. In the interviewed sample (N=929) syndrome validators will include parent-report of: (1) psychosocial disability, (2) adverse impact of child's symptoms on family functioning, (3) increased parental stress and dysfunction in the parent-child relationship, (4) high parental neuroticism, and (5) increased parental anxiety and depressive symptoms. Aim 6b. In the nested case-control sample (N=250 + 250) syndrome validators will include (1) teacher/caregiver reports of behavioral/emotional disturbance, (2) deficits in social competence and peer relationships reported by teachers/caregivers and parents, (3) parental histories of depressive and anxiety disorders (4) observed fear, anxiety, and/or distress in anxiety-provoking observational protocols, (5) observed patterns of parent-child interactions characterized by increased maternal anxiety and intrusiveness.

AIM 7. To determine the relationships between DSM-IV anxiety diagnoses and the broad temperament constructs of negative affectivity and effortful control (including capacities for attention shifting and response inhibition); the temperament sub-domains of fear, shyness, and sociability; and the extreme temperament type of behavioral inhibition.

AIM 8. To use statistical methods, such as latent class analysis, to identify "natural classes" of individuals with particular patterns of anxiety-related symptomatology. AIM 9. To lay the foundation for a study of the outcomes of preschool anxiety disorders.

B. Studies and Results

The study protocol remains unchanged from the original proposal, with two exceptions that were reported in year 1:

Addition of gaze-tracking measures: Since the proposal was written we have obtained facilities for collecting gaze-tracking data in our lab. In the service of Aim 6b (validation of parent-reported anxiety disorders), we have added a 10-minute computerized passive viewing task with stimuli of varied emotional valence, to assess differences in gaze patterns between non-anxious children and those with various anxiety disorders. This addition has been approved by the Duke IRB.

Deletion of the screen for pervasive developmental disorders (PDDs): Our initial experience with the only available age-appropriate screen for PDDs indicated that, in this population, it was vastly over-sensitive; flagging many children who, on record review, and in interviews with parents, clearly were not suffering from a PDD. Since PDDs afflict fewer than 1% of the pediatric population (and most will already have been identified by ages 2-5), we concluded that it would be better to include those with unidentified PDDs in the assessment protocol, since that would provide a much better method for their identification. We continue to exclude those with already identified PDDs.

Recruitment and assessment progress during year 4 and across the study period as a whole: As shown in our inclusion enrollment report, and our triannual progress reports, we have now moved

slightly ahead of our recruitment targets. Those reports are entirely based on the numbers of children who have completed the interview component of the study, so here we provide further details of recruitment at various levels of the study:

As of 04/14/2010 over the course of the study so far we have screened 3097 children, of whom 1035 have screened positive or screened negative and been randomly assigned to be included in the interview phase of the study. Of these, 810 (of 929 to be collected by then end of the study) have been interviewed. 805 of these interviews have been checked and entered into our database. 34.6% (N=279) of these have had anxiety disorders, which is somewhat more than the 25% we predicted in the proposal. We have also completed 480 lab assessments out of 500 that we ultimately expect to collect.

Results: Since we have not yet come to the end of our projected data collection period, it is too early for us to be able to address the primary goals of the study, or present any results from it.

C. Significance

Anxiety disorders are probably among the most commonly observed psychiatric conditions in preschoolers, but, to date, there have been no adequately-sized studies of these conditions in this age-group. This study is the first large-scale attempt to demonstrate that preschool anxiety disorders are both common, disabling, and rarely treated in pediatric practice. If the eventual findings do indicate that anxiety disorders can be validly diagnosed in this age group, it would suggest that there is enormous unmet need for services for these children. In relation to Aim 4, we will also establish clinically useful information about when pediatricians and other child service providers should regard anxiety symptoms as lying outside the realm of normal developmental variation.

D. Plans

During the next fiscal period we plan to complete screening, interviewing and lab assessments as outlined in the proposal.

This application does not include a trial which requires registration in ClinicalTrials.gov.

E. Publications

None

F. Project-Generated Resources

None

Total Enrollment Report: Number of Subjects Enrolled to Date (Cumulative) By Ethnicity and Race

Ethnic Category	Females	Males	Unknown or not reported	Total
Hispanic or Latino	58	46		104
Not Hispanic or Latino	391	423		814
Unknown (Individuals not reporting ethnicity)	1233	1293		2526
Ethnic Category: Total All Subjects*	1682	1762		3444

Racial Categories	Females	Males	Unknown or not reported	Total
American Indian/ Alaska Native	2	0		2
Asian	10	14		24
Native Hawaiian or Other Pacific Islander	1	0		1
Black or African American	180	215		395
White	209	197		406
More than one race	45	42		87
Unknown or not reported	1235	1294		2529
Racial Categories: Total of All Subjects*	1682	1762		3444