

DESCRIPTION: State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

Despite ongoing efforts to prevent maternal drinking during pregnancy, prenatal alcohol exposure continues to be the leading non-genetic cause of mental retardation. As the result of ongoing epidemiological studies in South Africa since 1999, the prevalence of fetal alcohol syndrome (FAS) in the Western Cape Region of South Africa has been found to range from 46 per 1000 to 75 per thousand among school children ages 5 to 9 years. These are the highest recorded rates in any general community in the world and are many times higher than prevalence estimates for the United States. Even though the need for developing intervention programs for alcohol-affected children has long been recognized, no systematic outcome studies of such intervention programs exist. Therefore, the current project aims to test the efficacy of three intervention methods in the remediation of specific behavioral and learning problems in alcohol-affected children in the Western Cape Province of South Africa. The specific aims of the multi-method study are: 1) To determine the degree to which cognitive control therapy improves academic skills and behavior in alcohol-exposed children; 2) To determine the degree to which family interventions improve academic skills and behavior of alcohol-exposed children; 3) To determine the degree to which specific linguistic and literacy training programs improve academic skills and behavior of alcohol-exposed children; 4) To determine the degree to which environmental modifications in the classroom (e.g. limited class size and structured teaching) improve academic skills and behavior in alcohol-exposed children; 5) To determine the degree to which combinations of above methods improve academic skills and behavior in alcohol-exposed children; 6) To assess the effects of 3 mediating variables (self-efficacy, attention, meta-cognitive skills) and 3 moderating variables (child's IQ, life stress, maternal education) on therapeutic outcomes.

One hundred and twenty children, ages 7 to 9 will be recruited through an epidemiological study currently being conducted in the Western Region of South Africa. Twenty children will be randomly assigned to one of six groups, four treatment groups (cognitive control therapy, family support, classroom modification, and linguistic and literacy training) and one alcohol-exposed control group and one typically developing control group. During the first phase of the project, all treatment and control-group children will be administered a comprehensive battery of tests consisting of a neuropsychological test battery, tests of academic achievement, selected speech/language tests, and a functional behavior assessment. The pre-testing will serve the following two distinct purposes: 1) to provide pretest data for each child in the research cohort and, 2) to identify current educational and behavioral issues for each child in the study. Following the pre-testing, each of the three proposed intervention methods will be administered once a week with children in each study group over a period of 18 months. In addition, each child in the study will be observed by a blinded observer 4 times in the prescribed time of intervention. After the 18-month intervention trial, the same testing battery will be administered as post-intervention measures. The pre-test and post-test performance of the children will be analyzed.

PERFORMANCE SITE(s) (organization, city, state)

The University of New Mexico, Albuquerque

The University of Cape Town, Rondebosch, South Africa

A town in the Western Cape Province of the Republic of South Africa

KEY PERSONNEL. See instructions. Use continuation pages as needed to provide the required information in the format shown below. Start with Principal Investigator. List all other key personnel in alphabetical order, last name first.

Name	Organization	Role on Project
Piyadasa Kodituwakku	The University of New Mexico	Principal Investigator
Wendy Kalberg	The University of New Mexico	Co-PI
Philip A. May	The University of New Mexico	Co-PI
Colleen M. Adnams	The University of Cape Town	Co-PI

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A. Specific Aims

Although considerable attention has been devoted to delineating neurobehavioral functioning of children with fetal alcohol spectrum disorders (FASD), relatively little is known about effective interventions for learning and behavioral problems in these children. The Institute of Medicine (IOM) report on fetal alcohol syndrome published in 1996 recommended: "Evaluation of effectiveness of educational interventions on children with FAS, ARND, and ARBD" (p.15). Despite this recommendation, no systematic study evaluating the effectiveness of intervention methods for children with FASD has yet been published.

Accordingly, the study of effectiveness of behavioral and pharmacological interventions is envisioned as a primary goal of the consortium. As Dr. Edward Riley points out, "While both physical and behavioral diagnosis is extremely important, an important goal of this RFA and this consortium is to provide a mechanism by which novel interventions can be tested". In line with this goal, the current proposal seeks to evaluate the effectiveness of four intervention methods on children with FASD from a community in South Africa. Two major motivators have led us to submit this intervention study as part of the consortium proposal. First, we expect that the intervention study will profit from the neurobehavioral studies proposed in the consortium, as identification of a profile of strengths and weaknesses in cognition constitutes an important step toward developing interventions. Similarly, the intervention study also can shed light on the cognitive architecture of children with FASD. Interventions aimed at certain deficits may effect improvements in other deficits, thus helping to identify primary (core) and secondary deficits. Second, the consortium will also afford an opportunity for cross-fertilization of information gathered through behavioral, neuroimaging, and basic science research. Researchers have found evidence of changes in brain activity associated with behavioral improvements produced by behavioral interventions. Accordingly, through the collaboration among researchers from neurobehavioral, neuroimaging, and basic science units, we will eventually be able to identify the neurobiological mechanisms underlying behavioral change in children with FASD, and eventually to develop effective intervention methods.

Thus, the broad, long-term aim of the current research is to develop effective interventions for behavioral and learning problems of children with FASD. Specific aims of the project are as follows:

- 1) To determine the degree to which cognitive control therapy improves academic skills and behavior in alcohol-exposed children.
- 2) To determine the degree to which family interventions improve academic skills and behavior of alcohol-exposed children.
- 3) To determine the degree to which linguistic and literacy training programs improve academic skills and behavior of alcohol-exposed children.
- 4) To determine the degree to which environmental modifications in the classroom (e.g. limited class size and structured teaching) improve academic skills and behavior in alcohol-exposed children.
- 5) To determine the degree to which combinations of above methods improve academic skills and behavior in alcohol-exposed children.
- 6) To assess the effects of three mediating variables (self-efficacy, attention, meta-cognitive skills) and three moderating variables (child's IQ, life stress, maternal education) on therapeutic outcomes.

B. Background and Significance

Even though the need for developing intervention programs for alcohol-affected children has long been recognized (Carmichael-Olson, Burgess, & Streissguth, 1992), no systematic outcome studies of such intervention programs exist. The curious lack of research on effective interventions to ameliorate behavioral and learning problems in children with FASD can be attributed to multiple factors. First, despite extensive literature on neurobehavioral functioning of children with FASD, there is no consensus among researchers on a behavioral phenotype of these children. As will be discussed below, designing effective treatment for a given disorder requires specifying central (core) and peripheral deficits associated with that disorder. Second, researchers with a specialty in intervention have not had access to large groups of well-diagnosed children with FASD let alone FAS. This has prevented researchers from designing outcome studies that employed rigorous scientific methodology. Third, there has been minimal exchange of ideas among educators, clinicians and basic scientists with regard to development of effective intervention programs.

The current collaborative initiative under the auspicious of the proposed consortium will provide an unprecedented environment for applying rigorous scientific methodology to evaluate intervention methods. Thanks to international collaboration, researchers now have access to large numbers of well-diagnosed children with FASD. Over the last five years, our research team has been working in a community in the Western Cape Province of South Africa where the prevalence estimates of fetal alcohol syndrome (FAS) range from 46 to 75 per thousand (May et al., 2000; and unpublished data). When other children from the fetal alcohol spectrum are included, the prevalence rates will be well over 100 per thousand. We have provided diagnostic research in three waves of effort in schools where the majority of children in one classroom were alcohol-affected. Therefore, we will be able to utilize group comparison methodology to evaluate intervention strategies in this community. The consortium will also provide a forum for clinicians and basic scientists to exchange ideas on interventions with a view to understanding the neurobiological mechanisms of behavioral change.

With the intention of collaborating with basic scientists in the development of intervention and treatment methods, we will first present a conceptual framework developed by Rapport (2001), which integrates behavioral and pharmacological approaches to the treatment of childhood disorders. We will then review the literature on behavioral and cognitive issues in children with FASD by way of providing a rationale for the selection of areas targeted for intervention. We will then proceed to present a rationale for choosing specific intervention methods for the current study. This will follow a description of hypothesized moderator and mediator variables. Finally, we will discuss the significance of this study.

B.1. Theory and Practice

Alan Kazdin, a renowned methodologist in therapy research, has underscored the importance of theory in outcome research (Kazdin, 2000). According to Kazdin (1999), the term *theory* refers to “an explanatory statement that is intended to account for, explain, and understand relations among variables, how they operate, and the processes involved” (p. 533). Thus, a critical element of a theory is that it specifies what variables mediate therapeutic outcomes under what conditions (moderators). Accordingly, theory-guided research is called explanatory research because this type of research seeks to explain what mechanisms or processes are involved in therapeutic change. Once the mechanisms

underlying the effects have been established, therapies can efficiently achieve outcomes through manipulating the mechanisms.

A conceptual framework can be distinguished from a theory in that the former does not specify moderator or mediator variables (Kazdin, 2001). Rather, a conceptual model focuses on variables that correlate with a problem (correlated antecedents or risk factors) and uses such correlations as rationale for choosing specific treatment. Thus, a choice of a specific treatment within a conceptual model is usually based on a hunch that “It makes sense” or “It is reasonable”.

In view of the lack of information on effective treatment for behavioral and learning problems in children with FASD, we propose to utilize a conceptual model of child psychopathology proposed by Rapport (2001) in the current research (See Figure 1).

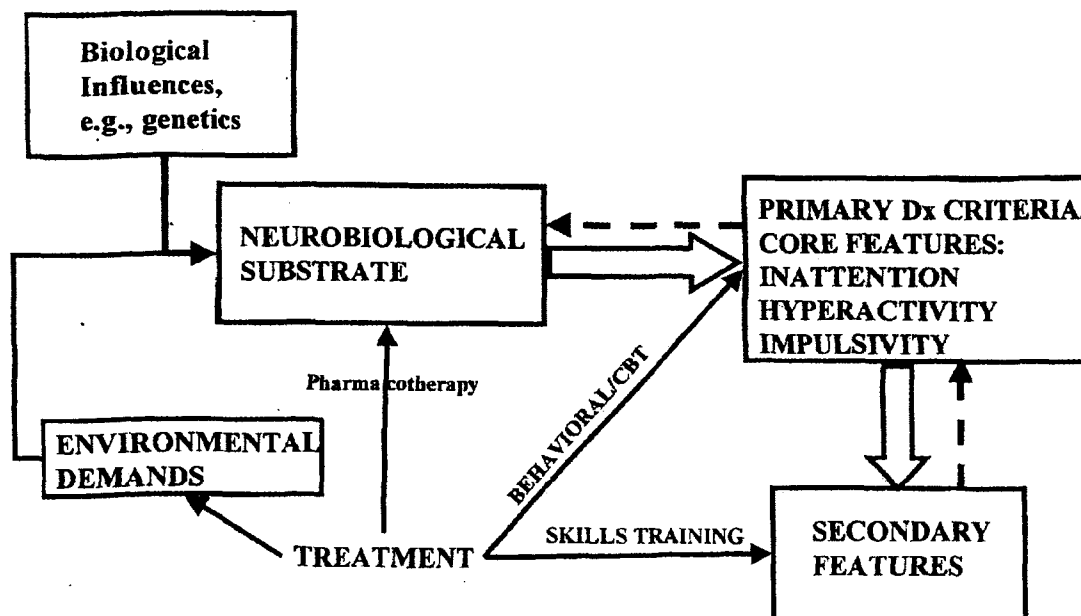


Figure 1. A conceptual model of child psychopathology.

From: Rapport, M.D., 2001.

In the Rapport model, a neurobiological substrate is hypothesized to underlie the core variables associated with a disorder. These core variables, in turn, lead to specific patterns of behavior. For example, there is evidence that dysfunction of the fronto-striatal dopaminergic and norenergic circuits results in core deficits in ADHD, which include inattention, hyperactivity, and impulsivity (Pennington, 2002). These core variables account for a range of behavioral problems seen in children with ADHD such as social deficits and academic problems. Rapport (2001) has proposed that this model has implications for designing treatment. That is, pharmacological agents targeting the neurobiological substrate influence both core and peripheral variables whereas interventions aimed at modifying peripheral variables produce effects with limited generalizability. There is now evidence, however, that behavioral interventions targeting core deficits of a disorder potentially can modify the neurobehavioral substrate (Schwartz, 1998). This model, however, provides a framework for integrating information on

the effects of modifying neurobehavioral substrates and core variables on learning and behavior of children with FASD.

B.2. Core and peripheral variables associated with FASD

Designing effective interventions requires delineation of core and peripheral variables in children with FASD. Streissguth and colleagues (1996) distinguished between those disabilities that reflect the CNS dysfunction inherent in the diagnosis and those with which a client is not born, labeling the two types as primary and secondary respectively. These authors classified intellectual deficits and deficient skills in academic and adaptive functioning as primary disabilities. Examples of secondary disabilities include mental health problems, disrupted school experience, trouble with the law, confinement, inappropriate sexual behavior, and alcohol/drug problems. However, deficient academic and adaptive skills may not be true primary disabilities in that they can be secondary to some other disabilities such as attention and memory problems. It is also known that deficits in academic and adaptive skills are associated with impoverished living conditions.

Dennis, Barnes and Hetherington (1999) have defined a core deficit associated with a developmental disorder as a deficit that is independent of generalized cognitive impairment (e.g. IQ). Researchers have found that children with FASD are impaired compared to controls in a range of abilities after controlling for intellectual ability. There is evidence that deficient performance of alcohol-exposed children on tests measuring components of attention is independent of their intellectual deficits. Researchers have obtained evidence that individuals with prenatal alcohol exposure are impaired in both cognition-based and emotion-related executive functioning (EF) (Kodituwakku, et. al., 2001). Children with prenatal alcohol exposure perform less competently than controls on tests of planning (Mattson et al., 1999, Kodituwakku et al, 1995), conceptual set shifting (Coles et al., 1997), verbal and non-verbal fluency (Schonfeld, Mattson, Lang, Delis, & Riley, 2001). Kodituwakku, May, Clericuzio, & Weers (2001) found that people with prenatal alcohol exposure (primarily FAS and ARND) were markedly impaired, relative to controls in emotion-related learning, as measured by visual discrimination reversal. Deficient performance on this test and a test of conceptual set shifting (Wisconsin Card Sorting Test) was found to be associated with parent-rated behavioral problems in the participants of the study.

In studies conducted in South Africa, we also found that children with full blown FAS were impaired in tasks that measured fundamental language skills (e.g. grammar comprehension and phonological working memory), visual construction, memory, and manual dexterity (Adnams, et al., 2001; and yet unpublished data). We also found that deficient performance of children with FAS on these tests was independent of their intellectual deficits. Therefore, it is reasonable to hypothesize that language, memory and attention deficits lead to poor academic performance of these children. Accordingly, in the current research we will treat attention, language, and memory as core variables and school performance and behavioral problems as peripheral variables.

B.3. Intervention methods

Referring to “best practices” in the area of mental retardation, Landesman and Ramey (1989) have recommended three principles that can be used to integrate theory and practice: metacognitive conveyance, ecological dominion, and environmental prevention. The principle of metacognitive conveyance holds that teaching children about the thinking process produces beneficial effects on

cognitive functioning. The second principle, ecological dominion, states that the social environment is an important determinant of behavior and competence of individuals with mental retardation. The third principle, targeted intervention, underscores the significance of implementing high-quality, theory-based programs targeted at high-risk groups. In accordance with these recommendations, we plan to employ two intervention methods designed to improve metacognitive skills and literacy (cognitive control and linguistic/literacy training). We also will implement two interventions targeted at two important ecosystems of the child: family and classroom environment.

Cognitive control therapy:

The primary goal of cognitive control therapy (CCT) is to develop the capacity of children for self-observation and self-regulation. We selected this therapy in view of the accumulating evidence that children with FASD are deficient in self-regulation, specifically in planning, maintenance of goal-directed behavior, and alteration of behavior in response to feedback and changing environmental demands (Kodituwakku et al., 1995; 2001).

Cognitive controls have been defined as the processes that determine how information is gathered and produced (Santostefano, 1985). Santostefano has identified five main cognitive controls, which have a hierarchical structure with processes characterizing cognitive behaviors in a young child at the bottom to those characterizing cognitive behaviors of an adolescent or adult at the top. These controls, from the bottom to top of the hierarchy, are as follows: body-ego-tempo regulation, focal attention, field articulation, leveling-sharpening, and equivalence range. The development within each of these controls follows a trajectory from “global- diffuse” to “differentiated-integrated”. Similarly, the developmental progression between controls follows the hierarchical order from simple to advanced.

The body-ego-tempo control concerns the manner in which an individual uses images or symbols to represent the body and body movement. A child delayed in body tempo control may produce the same tempo when asked to move slow and fast. The manner in which an individual surveys a field of information is the primary focus of the focal attention control. The level of sophistication within this level varies along two dimensions: the amount of information surveyed (small segments to large amounts) and speed (slow to fast). Field articulation refers to the capacity for selective attention; that is the ability to attend to relevant elements while ignoring irrelevant elements. Leveling-sharpening concerns the manner in which an individual forms images of information that change or remain stable over time and compares with present perception. This control is, thus, analogous to the neuropsychological construct of working memory. Equivalence range refers to the way in which information is grouped and categorized in terms of a concept or belief. There is an overlap between what is termed equivalence range and the neuropsychological constructs of extra and intra-dimensional set shifting.

Thus, CCT is designed to help an individual achieve skills in self-observation and self-regulation through fostering the development of his or her cognitive controls. Following a comprehensive assessment of cognitive controls the therapist presents the child with tasks designed to improve deficient controls. CCT has successfully been used with children with developmental disabilities in cross-cultural settings, because the procedures utilized in CCT are easily adaptable across different cultural settings. Professor Petra Engelbrecht of the University of Stellenbosch (South Africa), who is a consultant to the current research project, has used CCT with rural Tswana-speaking children in South Africa

(Engelbrecht, 1994). The participants of this study were 90 children in the age range 6-10, who showed inefficient learning strategies. An intensive course of CCT in conjunction with classroom activities was designed and teachers were trained to administer this program. The results showed that children demonstrated significant improvements in information processing and cognitive functioning. In a similar study also carried out South Africa, Du Preez (1991) found that children and adolescents with learning disabilities demonstrated improved skills in attention and meta-cognitive insight into their abilities following CCT.

Thus, CCT has proven to be a method of intervention that is easily adaptable for use in cross-cultural settings. Furthermore, given that CCT targets skills related to attention and self-regulation, areas of functioning markedly affected in children with FASD, it is an appropriate method of intervention for these children.

Linguistic and literacy training:

Although some researchers have failed to find significant delays in language development in alcohol-exposed children without dysmorphia (Greene et al., 1999), numerous researchers have found marked deficits in linguistic and intellectual aspects of verbal functions in children with substantial prenatal alcohol exposure. For example, researchers have found that children with substantial prenatal alcohol exposure are impaired in naming (Mattson & Riley, 1998), word comprehension (Conry, 1990), grammatical and semantic abilities (Becker et al., 1990), phonological processing (Carney & Chermak, 1991), and general verbal abilities (Adnams, et al. 2001). Adnams and colleagues found that the Speech and Hearing subtest on the Griffiths Scales of Mental Development highly discriminated between children with FAS in South Africa and controls matched with respect to age, gender, first language (Afrikaans), and SES (Adnams et al, 2001).

The significance of linguistic and literacy training in children with FASD is incontrovertible. There is overwhelming evidence that early linguistic environments of young children have long-term effects on their development and academic performance (Locke, Ginsborg, & Peers, 2002). Bryant et al. (1990) found that preschool children with fully developed phonological skills later became successful early readers. There is also evidence that children reared in poverty have poor spoken language skills. It is known that children with prenatal alcohol exposure grow up in poverty with limited language input. Researchers have found that language input is a robust predictor of vocabulary development in young children (Huttenlocher, 1998). Therefore, it is reasonable to conclude that literacy problems in alcohol-exposed children are partly related to adverse environmental conditions, a relationship mediated through delayed development of phonological skills. Therefore, in the current research we propose to target both phonological and literacy training.

As mentioned above, researchers have found that behavioral problems in children with FASD are associated with deficient executive functioning (Kodituwakku et al., 2001). Extending Vygotsky's developmental ideas to neuropsychology, Luria has cogently argued that self-regulation (analogous to executive function) is mediated by speech (Luria, 1962). Accordingly, it is reasonable to hypothesize that development of speech and language facilitates self-regulation.

Thus, we considered that linguistic and literacy training would contribute to improvements in academic performance and behavior.

Environmental modification:

Researchers have long recognized that learners profit from environmental modifications in the classroom. For example, school size has been shown to have a notable effect on achievement (Glass, Cahen, Smith, & Felby, 1982). Students in smaller classes tend to participate in more activities and feel a greater level of responsibility for their activities. We found that class size in schools in our research community in South Africa were very large, with teacher-student ratio being about 1 to 50. Therefore, reduction in class size is a necessary intervention in schools where environmental modification will be implemented.

As mentioned above, there is evidence that behavioral problems in children with FASD are associated with specific deficits in executive functioning (e.g. difficulties in modifying behavior in response to the changes in reinforcement contingencies). In other words, some behavioral problems in alcohol-affected children seem to result from deficient skills in working memory and response inhibition. Environmental modifications can be profitably used for reducing working memory demands and response inhibition. Some methods developed by the TEACCH program in North Carolina exemplify use of environmental modification to address issues related to executive function deficits in children with autism spectrum disorder. These modifications include changes in the seating arrangement, visual scheduling, and provision of head phones to address sensory hypersensitivities. We plan to utilize TEACCH methods for environmental modification in South African classrooms.

Family Interventions:

There is considerable evidence that the quality of the home environment is a determinant of cognitive and emotional functioning in children (Bradley & Caldwell, 1976, McLloyd, 1998). Children growing up in alcoholic families are often exposed to a range of adverse conditions including poverty, disruption of attachment, and violence. O'Connor and colleagues have obtained evidence that maternal quality of assistance mediates the effect of prenatal alcohol exposure on child cognitive functioning (O'Connor, Kogan, & Findlay, 1999).

In South Africa we have completed two detailed control studies of maternal risk factors for FAS. In these studies the lives of the mothers and children with FAS are quite disrupted and chaotic. Alcohol abuse is multi-generational and quite prevalent among entire extended families. The socio-economic status of the families of FAS children is much lower than that of the control families in this community, and unlike America, the children with FAS are much more likely to live with their biological mother and her family. Other confounding conditions are: significantly lower education of mothers of FAS children versus controls (4.4 vs. 6.1), lower income, more siblings, lower marriage rates, and continued drinking of the mothers of FAS children through their first children's grade years (80.6% vs. 45.2%) (Viljoen, Croxford, Gossage, Kodituwakku and May, 2002).

Accordingly, researchers and clinicians have utilized family interventions as means of improving behavior in children exposed to drugs and alcohol in utero. Butz et al., (2001) conducted a home-based nurse intervention study aimed at improving behavior of drug-exposed children, focusing on parenting education/skills and caregiver emotional support. The results showed that drug-exposed children in families that received treatment displayed fewer behavior problems than controls.

In South Africa, members of the Department of Health in the Western Cape are engaged in the promotion and implementation of a holistic model of community health and education. The model was developed by the World Health Organization (WHO) and is dedicated to the promotion of the concept that “Good health supports successful learning” and “Successful learning supports health” (WHO, 1996). The “Promoting Health Through Schools” model has been adopted in part to acknowledge and combat the residual societal effects of school segregation and discriminatory practices under the Apartheid era. The interventions proposed in this project will complement the Health Promoting Schools initiative. The various treatment methods will inform families and the community about the damage that can be done to a child exposed to alcohol prenatally. One legacy of Apartheid is disempowered parents with minimal school experience, and who contribute little to the education of their children. The interventions will also promote a better understanding of how to effectively intervene with these children for better educational outcomes. A group therapy format will be utilized in working with parents. Issues related to alcoholism, domestic violence, parental emotional functioning, and parenting will be addressed in these group therapy sessions.

B.4. Moderating and mediating variables

A specific goal of the current research is to elucidate the variables that moderate and mediate the effects of the above-mentioned therapies on academic performance and behavior of children with FASD. A *moderator* refers to a variable that influences the relationship between two or more variables. For example, if maternal education moderates the relationship between CCT and outcome variables, then one can expect that effects of the therapy will vary dependent on the level of maternal education. In the current research we will examine the effects of three potential moderators: child’s IQ, child’s life stressors, and maternal education. A *mediator* refers to the mechanism through which a variable produces a particular outcome. In the current research, we hypothesize that three variables—metacognitive skills, self-efficacy, and attention—operate as mediators.

First, given that children with higher intellectual ability tend to perform better on tests of scholastic achievement than those with lower intellectual ability, it is reasonable to hypothesize that the effects of some therapies (e.g. linguistic/literacy training and CCT) may vary based on the child’s intellectual ability. There is also evidence that life stress (e.g. alcoholism in the family, a parent losing a job, and domestic violence) is a robust predictor of behavioral problems in children. The majority of children in the community where the proposed research will be conducted are currently experiencing a multitude of stressors such as parents losing jobs, serious health issues in the family, moving from farms to urban settings, etc. Therefore, we will explore the possibility that life stressors may moderate the magnitude of therapeutic effects. Parent education, particularly maternal education, is also a potential moderator of the effects, given that educated parents tend to talk to children more and help with their homework more than uneducated parents. As mentioned above, our epidemiological studies conducted in South Africa have demonstrated that mothers of children with FAS are less educated than those of control children (Vijoen et al., 2002).

Landesman and Ramey (1989) proposed that teaching children how to think, metacognition, would improve their cognitive performance. Extending this proposal to therapy research, our second hypothesis is that the effects of some therapies operate through improvement of metacognitive skills. As noted above, CCT underscores the importance of teaching children metacognitive strategies. An alternative

hypothesis is that motivational beliefs operate as a mediating variable. There is a growing literature on self-efficacy as a mechanism contributing to academic achievement and amelioration of behavioral problems (Bandura, Barbaranelli, Caprara, & Pastorelli, 1996). Bandura et al. found that perceived self-regulator efficacy was related to academic achievement both directly and indirectly through adherence to self-sanctions for detrimental conduct that can interfere with academic pursuits. Thirdly, we hypothesize that improvement in attention and response inhibitory capacities contribute to positive outcomes in academic functioning and behavior.

B.5. Significance

The significance of comparing the effectiveness of four intervention strategies to ameliorate behavioral and academic problems in children with FASD is obvious. As noted above, no systematic reviews or meta-analyses evaluating outcome studies with children with FASD have yet been published. Faced with the lack of information on evidence-based therapies, teachers and parents have resorted to using methods that have been developed for other disabilities such as ADHD. The current research seeks not only to evaluate the effectiveness of therapies, but also to examine the variables that may moderate and mediate therapeutic effects. The study of moderators and mediators are critically important for developing new strategies to ameliorate academic and behavioral problems in children with FASD. The results of the current study may also shed light on core and peripheral deficits in children with FASD. For example, the results will help to evaluate the relative significance of language and metacognition in terms of the magnitude of outcomes produced by a comparison of effect size of therapeutic outcomes produced by linguistic/literacy training and CCT.

C. Preliminary Studies

As neurobehavior team for to the NIAAA –funded epidemiology projects on fetal alcohol syndrome in South Africa (Philip A. May, Ph.D., PI), our research team has been working in the proposed research community in the Western Cape Province of South Africa over the past 5 years. We have established collaborative relationships with school principals, local and regional administrators and school psychologists, and two universities (University of Cape Town and Stellenbosch University). Through these collaborative relationships, we have completed a number of studies aimed at defining a behavioral phenotype in children with FAS. Furthermore, our research team conducted a pilot study of the effectiveness of CCT in the remediation of behavioral and learning problems in children with FAS (Riley, Mattson, Li, Jacobson, Coles, Kodituwakku, Adnams and Korkman, 2003). Two collaborators on the current research (Mr. Rubin Adams, a school psychologist from the community and Ms. Pharyn Sorour, a speech pathologist from the University of Cape Town) have also completed pilot studies aimed at examining the effectiveness of parent intervention/environmental modification and speech and literacy therapy, respectively, in ameliorating behavioral and learning issues in children with FASD.

First, we will outline a number of neurobehavioral studies to highlight the fact that we have extensive experience in the assessment of neurobehavioral abilities in children from the research community. The studies outlined below also illustrate that we have been successful in creatively adapting neuropsychological instruments for assessment of cognitive abilities in children with minimal exposure to modern tools of test administration such as computers and tape recorders. Then, we will present the pilot data from the studies in which the effectiveness of proposed intervention methods was explored.

Neurobehavioral Studies:

The first study conducted by our team in South Africa aimed to assess patterns of cognitive-motor development in children with FAS (Adnams et al., 2001). Thirty-four children with FAS and 34 age (FAS mean age=6.99 years; control mean age=7.12 years), gender, and ethnicity-matched controls participated. The Griffiths Mental Developmental Scales were utilized to assess cognitive-motor development. As Figure 1 shows, four Griffiths scales highly discriminated the FAS group from controls: Hearing and Speech (language), Eye-Hand Coordination (fine-motor), Performance (pattern construction), and Practical Reasoning. In sharp contrast, no significant group differences were found on the Gross Motor and Personal-Social (simple adaptive skills) scales. It should be noted that the scales that highly discriminated between the two groups involve a higher-level of intellectual skills.

In a subsequent study, we utilized the Lhermitte-Signoret memory tests to contrast the ability of children with FAS to encode materials of varying complexity. The test consists of two parts: spatial and logical. In the spatial condition, the participants were required to learn the locations of nine line-drawn objects. The logical memory condition involved learning a logical pattern of colored geometric shapes. The participants were 64 children diagnosed with FAS and 63 age, gender, and ethnicity-matched controls. The results showed that the FAS group performed as competently as the control group in the spatial memory condition [$F(1,122) = 3.11, p = .08$], but that the former performed markedly worse than the latter in the logical memory condition [$F(1,122) = 7.32, p < .01$]. Similarly, on a test of recognition memory span, the FAS group displayed relatively intact recognition memory, but impaired free recall of information.

To assess phonological working memory in children with FAS, we constructed a test of nonword repetition similar to that developed by Gathercole et al. (1994). Included in the test were 40 nonwords, 10 each containing two, three, four, or five syllables. The phoneme sequences in each word conformed to phonotactic rules of Afrikaans. The child was asked to repeat each word after the examiner. Thus, this test required holding increasing numbers of syllables in working memory. The results showed that children with FAS ($N=61$) were markedly deficient in the ability to repeat nonwords compared to age, sex, and ethnicity matched controls, [$F(1,119) = 8.191, p = .005$].

Intervention studies:

Cognitive Control Therapy

As mentioned, CCT has been utilized to teach self-observation and self-regulation to children with developmental disabilities. In view of the success of CCT with rural South African children, we conducted a pilot study to determine its effectiveness in ameliorating behavioral and learning problems in children with FAS. Participants of this study were 10 primary school learners with FAS in the proposed study community. They were identified from a group of 64 children diagnosed with FAS in wave II of our previous FAS epidemiology studies. Pretest-posttest controlled intervention was utilized. Two of the community's 13 primary schools were randomly selected for participation. The children were randomly assigned to either an experimental (intervention) group within one classroom at one school ($n=5$) or a control within one classroom at the other school ($n=5$). The intervention and control groups were matched for age, first language, SES, grade, and locality of school. The results showed significant changes in behavior. Pre-intervention behavior in the intervention group was rated by

teachers as worse (a higher Personal Behaviors Checklist (PBCL) score) than the control group. After intervention, there was a marked improvement in the rated behavior of the intervention group, but there was no change in the control group. The mean post-intervention behavior score for the intervention group was comparable to that on non-FAS control children in a previous study.

Although there was no significant difference in the post-intervention neuropsychological test scores between the two groups, there was a trend toward functionality. In the intervention group, therapists noted qualitative improvements in the children's self-efficacy, motivation, cooperation, self-confidence, and emotionality. Teacher and school reports showed improvements in general school achievement, attitude toward learning, writing, self-confidence, and self-activity.

CCT resulted in some qualitative and quantitative neurobehavioral gains in children with FAS. The improvement in classroom and adaptive behavior is significant, as behavior problems in children with FAS may be associated with poor social outcome and lifelong negative sequelae that are independent of IQ. Because there was a greater extent of environmental deprivation in the intervention group, the intervention may have been influenced. Because of this, intervention in children with FAS should be at multiple levels and should address home and environmental factors. For this reason, the proposed project will focus one of the intervention methods on the family system and environment as well as in the classroom.

Speech/Language Intervention:

The aim of this project was to provide small group speech therapy with the intervention group to assist with improved literacy and language competence, including improved skills in pragmatic aspects of language (the use of language for social communication).

An intervention program was developed to improve the literacy skills of 22 school-aged children with FAS (9.0 - 12 years) and 22 non-FAS controls who were matched with regard to age, and literacy performance. The FAS children presented with severe literacy problems and had shown very little progress in the school system in the past three years of schooling. The intervention program focused on the development of basic phonological awareness skills (rhyme, segmentation, blending, and phoneme manipulation), letter knowledge and memory, and the direct instruction of early reading and writing skills. The program was conducted over a 16-week period where each child participated in small groups for 2 hours per week in training. The instruction of every component of the program began with teaching of pre-requisite skills needed to acquire particular components. The intervention was constructed into three main parts: The early part focused mainly on letter knowledge training and the training of pre-requisite skills. The second part of the intervention focused on consolidating the pre-requisite skills through the medium of culturally appropriate stories graded in terms of difficulty. The last part of the intervention focused mainly on reading and spelling speed and accuracy, while incorporating and consolidating more complex aspects of the intervention. The differences between the pre and post literacy intervention program results indicated a reduction in the deficit in auditory analysis and synthesis as well a single word reading and spelling performance between FAS and non-FAS controls. The means and standard deviations (across the sample of 22 FAS and Controls) of the percent improvements from the pre-test score to the post-test score on the literacy assessment measures are shown in table 2 below.

Table 1 Improvement on Literacy Assessment Measures (means and standard deviations) from Pre to Post Test (n=22 FAS, 22 controls)

Phonological Awareness and Early Literacy Test (PAELT)	SUBTESTS		Name of test	Mean % improvement		SD (Diffs)	
				FAS	Control	FAS	Control
B: SEGMENTATION	B1	First sounds	PAELT**	11.9	6.3	14.7	10.7
	B2	*Last sounds	PAELT**	11.4	0.6	17.6	6.1
	B3	*All sounds	PAELT**	15.5	8.9	12.8	10.2
C: BLENDING	C1	* Blending	PAELT**	15.5	13.4	18.3	14.8
D: MANIPULATION	D1	***Auditory analysis	Pendulum medium ***	22.7	1.4	23.0	9.1
	D2	***Auditory synthesis**	Pendulum medium ***	22.1	1.8	23.5	11.7
F: READING	F1	***Single words	Essi***	16.2	14.5	7.0	6.4.
	F2	One minute read. test	One minute read.test ***	51.4		20.5	
G: SPELLING	G1	Single words (ESSI)***	ESSI	14.3	12.3	7.6	6.2
	H1	Short-term memory***	Pendulum ***medium				

* Non Standardized tests included across pre and post literacy tests

***Standardized tests included across all 3 assessments

** Phonological Awareness and Early Literacy Test (PAELT)

Parent Intervention and School Environmental Modification:

Families in the proposed research community are primarily of lower socio-economic status (SES) and the literacy in families is generally at the basic level. Many parents of children in this community believe that the schools hold the primary responsibility for the scholastic progress of their children. Many parents do not see themselves as part of the process. Information on positive parenting and child development is limited in the community, and parenting skills have been passed down from one generation to the other with little formal parent skill training. However, parents want what is best for their children. One of the collaborators of the current research project (Rubin Adams) began training parents in basic parenting skills, with the goal of enhancing the home environment and making it more conducive for learning and achievement. Group meetings for parents of children with FAS were convened in 2001. A psychologist and a school psychologist from the community conducted the group sessions. Small groups of approximately ten parents were formed. After establishing rapport, active

teaching strategies were used to share information on the following topics: listening for feelings, building self-esteem, problem-solving skills and the family meetings (their value and how to conduct one), general child development.

The children of the families in the parent support groups were also provided classroom accommodations in their neighborhood school. The following school accommodations were made: limited classroom size, more access to one-on-one instruction. The performance and school-placement of those children was tracked over the course of the school year when the interventions took place. In general, the children whose families and school participated in the interventions made good progress, and approximately one third of the children were moved into a mainstream placement at the end of the school year. The following three graphs show preliminary data that was generated throughout that school year. Table 2 reflects the performance of the children at the initial school year assessment. The mid-year progress of the students is shown in Table 3 and the school placement decisions for the following school year are shown in Table 4.

**Newton Primary School – 2001
Progress After Parent Support and Environmental
Interventions**

Table 2: Performance of intervention subjects at initial evaluation

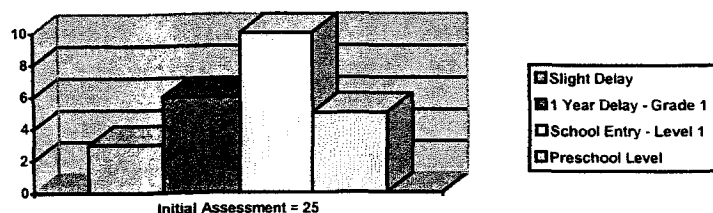


Table 3. Mid-Year Progress of Children enrolled in the pilot study

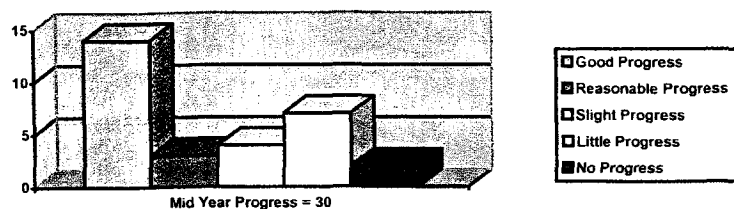
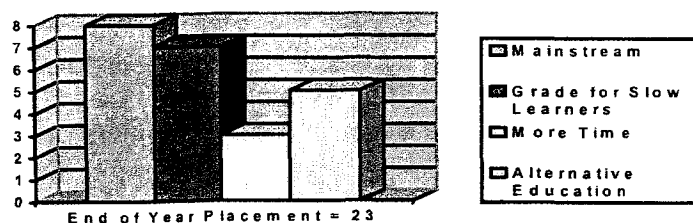


Table 4. End of the Year Placement decision for pilot study group



Thus, preliminary data show that CCT, linguistic/literacy training, classroom environmental modification, and parent training are all potentially effective methods in amelioration of behavioral and other aspects of learning problems in children with FASD.

D. Research Design and Methods

D.1 Overview of research design

Specific aims 1-5 of the current research project concern testing the effectiveness of four intervention methods and specific combinations of these interventions. Our plan is to administer individual therapies in the first phase of the study and then to evaluate combined effects in the second phase. Two of the proposed interventions (CCT and linguistic/literacy training) involve working directly with the child to improve specific skills, such as metacognition and phonological awareness. The remaining two intervention methods aim to improve two ecosystems (family and school environment) that directly impact the child's behavior and learning. Therefore, in the second phase we plan to contrast the effects of three combinations (Specific aim 5): interventions focused on the child, interventions focused on the ecosystems, and combinations of interventions from child-focused and ecosystem-focused. Specific aim 6 concerns evaluating the variables that may potentially mediate and moderate the therapeutic effects.

We propose to draw potential participants from among a group of children with FASD identified in the last wave of screening conducted in 2002 (see the next section for details on screening). We plan to assign 100 children with FASD to the following five groups: 1.) CCT (n=20); 2.) linguistic/literacy (n=20); 3.) family intervention (n=20); 4.) environmental modification (n=20) and 5.) one wait list control group (n=20). In addition, a normal control group (n=20) will be selected from among age peers who do not have a history of prenatal alcohol exposure or developmental delay. Given that children in this community live in relatively impoverished conditions, the latter group will serve as a local "standard" of normal development. Considering the fact that the potential subjects are in 12 schools, which vary in size and geographic location (rural vs. urban), we plan to use a strategy akin to randomized blocks assignment. That is, from the group of 100 FASD children, we will form ten groups of children, each comprised of 10 children with similar characteristics; we will then randomly assign the 10 groups to the 5 intervention groups.

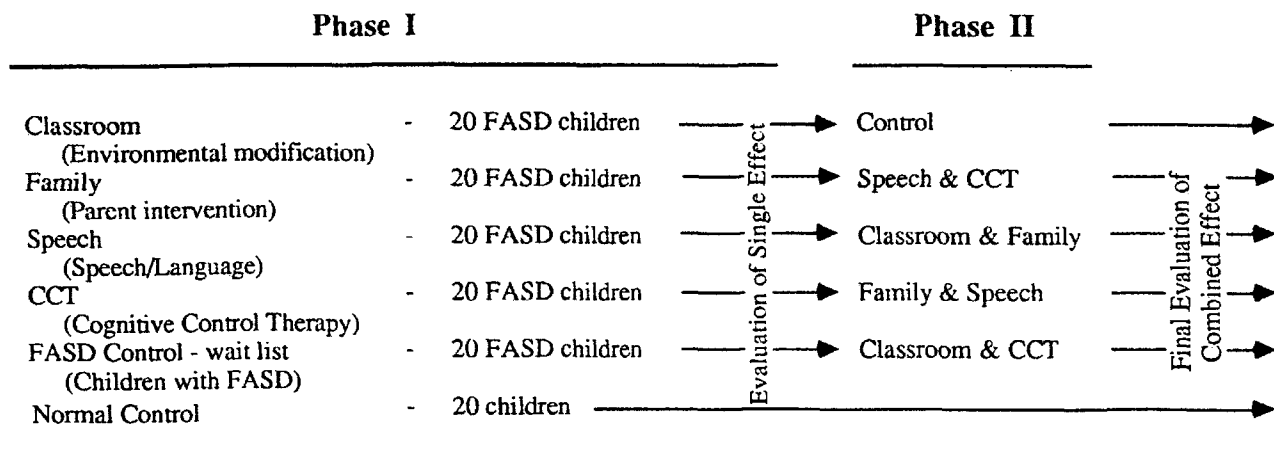
After completing the first phase of intervention (from March 2005 to July 2006), we will collect post-intervention data and then begin the second phase during which we will administer combined treatments. A number of reasons motivated us to institute a second phase: First, participants are unable to maintain interest in a given therapy for more than 12 to 18 months; second, benefits from a given therapy will reach a plateau after a certain time period; and finally, this will allow us to collect pilot data on the combined effects of therapies. The disadvantage of instituting the second phase is that the above considerations constrain the random assignment of the groups. That is, the combination of family intervention and another intervention will not be appropriate for those who received family intervention during the first phase. Therefore, group assignments and combination of interventions in the second phase will be determined based on the following considerations: theoretical interest of combinations, whether group received a component of the combination in the first phase, and ethical considerations (wait list controls will be offered interventions). Accordingly, in the second phase, the group that receives family intervention will be offered the combination of speech therapy and CCT; the group that

receives speech therapy will be offered the combination of classroom modifications and family interventions; the group receiving CCT will be offered the combination of family intervention and speech therapy; and the control group will be offered the combination of classroom modifications and CCT. Finally, the group receiving classroom modifications will continue to receive classroom modifications as this intervention can be continued without reaching a satiation point. The last group will serve as controls for those receiving combined interventions. Figure 2 graphically shows the timeline of these interventions.

Trained testers who are blinded to group membership will collect pretest and posttest data. Furthermore, we will collect a range of outcome data, including teacher ratings, classroom observations, neuropsychological test data, and school grades. These data will be collected at baseline, at a mid point during intervention, and at post-intervention.

Accordingly, the proposed design is a between group design with multiple repeated measures.

Figure 2. Methodological Design and Sampling Framework of South African Intervention Study



South Africa 030413-01

Participants:

Potential participants in the current research will be 120 children from a community in the Western Cape Province of South Africa. One hundred of these children will be from among a group diagnosed as having FASD in 2002, the majority of whom will be FAS or Partial FAS. Twenty normal controls will be selected from among age peers in the same classrooms.

The community where the study will be conducted is in the wine-producing region of the Western Cape Province in South Africa. According to the 1996 Census of Population in the Republic of South Africa, this community had a population of 45225 (35364 urban and 9861 rural), made up primarily of people classified as Coloured. The majority of potential participants are children of farm workers, who live in impoverished conditions.

The methodology for determining FAS in this community is described in detail by May and colleagues (May et al., 2000). While 3 waves of screening for FAS have been completed in this community since 1997, the targeted group for intervention was screened in 2002. Using an active case ascertainment methodology, all first grade students from 12 schools (N = 869) were screened for growth retardation. Those children who were at or below the 10th percentile in head circumference or in height and weight (N = 447) were referred for a full dysmorphology evaluation. To establish reliability of diagnosis, each child was evaluated by a minimum of two experienced clinical geneticists/dysmorphologists. Based on morphology data, a preliminary diagnosis of FAS or that of "deferred" has been assigned to 108 children. Brief neuropsychological examinations and maternal interviews are currently in progress and a case conference to determine final diagnoses has been scheduled for September of 2003. Based on experience in two previous waves of research in this community, we expect that 60 to 70 of the 108 children will receive diagnosis of FAS following the case conference. Furthermore, randomly selected community controls have been selected for the epidemiology study. If the maternal interviews of these control children's mothers reveal that some of these controls are substantially exposed to alcohol, they will not participate in this educational intervention study. The children who finally receive an FASD diagnosis will be potential candidates for the current intervention study as we are focusing on children in the spectrum. We expect that there will be about 130 children with FASD, found in the epidemiology study and, therefore, we are confident that we will be able to recruit the targeted number of children (100) for the current study.

Children with a history of head trauma with loss of consciousness, seizure disorder, severe psychiatric disorder, or severe mental retardation will be excluded. The normal control group will meet two additional exclusionary criteria: 1.) history of prenatal exposure to moderate or heavy amounts of alcohol or other drugs; and 2.) history of learning disability or developmental delay.

D.2. Procedure

As noted above, this project will be closely coordinated with the neurobehavioral study also proposed in this consortium, and will be conducted concurrently. The starting date of the educational intervention study will officially be October of 2004. The potential participants will first be recruited to take part in the neurobehavioral study, which is expected to start in September of 2003. This will allow us to collect some data pertinent to establishing a baseline for intervention and determining eligibility (e.g. intellectual ability, emotional functioning, and various cognitive skills). We will also have access to detailed data on demographics, measures of care giving and home environment, and exposure history (quantity, frequency and variability of maternal drinking and estimated peak BAC) of the potential participants, which are being obtained through maternal interviews. Thus, we will have relevant data to determine the eligibility of potential participants prior to beginning of the intervention study. Our bi-national team will contact the parents of potential subjects and invite them to participate in the intervention study. We will also seek the assent of the child to participate. Having obtained informed consent from the parents and assent of the child we will assign children with FASD to one of the 5 groups as described above. The normal control group will be selected from the 12 schools using the eligibility criteria listed above. Concurrently with recruitment, we will train classroom observers and test administrators. Ninety percent inter-observer agreement will be used as the learning criterion for classroom observers. Then the following pretests will be administered to the five FASD groups and normal controls.

Pretests:

Cognitive Control Battery (Santostefano, 1988).

This test consists of subtests designed to formally assess cognitive control abilities, such as focal attention, sustained attention, working memory, and concept formation. The test data will be utilized to tailor appropriate intervention procedures for the group receiving CCT. Selective subtests from the test will be administered to the participants receiving other therapies and to the two control groups to determine if other therapies will have an effect on cognitive control abilities.

Linguistic and literacy tests:

A battery of tests will be administered to assess linguistic and literacy skills in the participants. The linguistic battery will include tests measuring receptive syntax, receptive semantic, semantic conceptualization, narrative discourse, phonology, and oral motor function. The literacy battery will include tests measuring auditory analysis, auditory synthesis, auditory memory, reading, and spelling. Those assigned to the linguistic/literacy training will be administered the full battery and those receiving other therapies and controls will be administered selected subtests.

Children's Depression Scale (Kovacs, 1992).

The Afrikaans version of this short questionnaire will be administered to assess subjective symptoms of depression in the participants. We will also utilize supplementary pictorial materials to explain the items.

Test of Variables of Attention (TOVA; Greenberg, 1993)

A test included in the neurobehavioral study, the TOVA will be re-administered before interventions. The TOVA is a computerized continuous performance test that assesses processing abilities in both the visual and auditory modalities. Attention and impulse control are measured in the following three areas: inattention scored by omissions, impulse control scored by commissions, and response time variability.

Children's Perceived Self-Efficacy Scale (Bandura, Barbaranelli, Caprara, & Pastorelli, 1996)

This 37-item scale is designed to assess self-efficacy beliefs representing 7 domains of functioning: enlisting social resources, academic achievement, self-regulated learning, extracurricular activities, self-regulatory efficacy, meeting other's expectation, and self-assertive efficacy. We have used this scale previously with children in South Africa, and have found it to be a relevant and valuable measure.

Metacognition (Kreutzer, Leonard, & Flavell, 1975). The items used by Kreutzer et al. to study metamemory in children will be adapted for use in South Africa. The examiner presents short stories about memory to the child and asks questions to test the child's knowledge of memory. This test may prove to be useful, as children with FASD tend to have diminished self-awareness.

Functional Behavioral Assessment -Behavior Assessment System for Children BASC (Reynolds, C.R. & Kamphaus, R.W., 1992)

Functional behavior assessment involves gathering information on antecedents, behaviors, and consequences in order to determine the function of behavior. Once the function of behavior is determined, this information is used for a design to reduce problem behaviors or to facilitate positive behaviors. In the current research we plan to utilize functional behavior analysis to gather the requisite information for designing environmental modifications in the classroom.

Parent and teacher rated questionnaires:

Two short questionnaires will be utilized to assess teacher and parent-rated behaviors: Parent/Teacher Disruptive Behavior Rating Scale (Pelham, 2002) and the Personal Behavior Checklist-36 (Streissguth et al. 1998). The Parent/Teacher Disruptive Behavior Scale consists of 45 items tapping ADHD, conduct disorder, and oppositional/defiant disorder. The PBCL-36 contains 36 items designed to assess common behavioral problems seen in children with FASD.

Classroom Behaviors (Wood, Murdock, & Cronin, 2002):

The raters will observe the following on-task academic behaviors during a class period: 1.) being in one's chair or otherwise appropriately out of seat; 2.) using materials appropriately (not throwing, breaking); 3.) working on the assigned task; 4.) following the teacher's directions; 5.) participating in class discussions (not screaming or yelling when called upon by teacher); 6.) paying attention (keeping eyes focused); 7.) starting assignments as soon as the teacher finishes instructions; 8.) asking for teacher assistance if needed; 9.) accepting teacher feedback appropriately; and 10.) not talking to or touching other students or their materials unless directed by the teacher. These behaviors are marked 'yes' as they occur.

The following instruments will be administered to the parents:

Beck Depression Inventory (Beck, 1996).

This commonly used instrument contains 21 items, which are rated on a 4-point scale.

The parents participating in family intervention will also be administered three other short instruments: Conflict Tactics Scale (Straus, Hamby, McCoy, & Sugarman, 1996), Alcohol Use Disorders Identification Test (AUDIT; Barber et al. 1993) and the Test for the Reception of Grammar (Bishop, 1989). The Conflict Tactics Scale measures how couples resolve issues in the family including violence. The AUDIT is a 10-item rating scale used to measure alcoholism, which is widely used throughout the world. The TROG is a test of grammar comprehension that has been used with children and adults in South Africa. This test provides an accurate estimate of verbal ability.

Interventions:

We will institute interventions immediately after completing pretests (see the timeline in Figure 2).

Specific aim 1: To determine the degree to which cognitive control therapy improves academic skills and behavior in alcohol-exposed children.

As noted above, the primary goal of cognitive control therapy (CCT) is to develop the capacity of children for self-observation and self-regulation. There is indeed evidence that children with FASD display deficiencies in self-regulation, specifically in planning, maintenance of goal-directed behavior, and alteration of behavior in response to feedback and changing environmental demands (Kodituwakku et al., 1995; 2001).

In the current research, cognitive control training sessions in Afrikaans will be conducted by trained therapists from the University of Stellenbosch under the supervision of Professor Engelbrecht, who is an internationally known expert in the use of these methods in educational settings. First, each child's pre-intervention level of cognitive control ability is determined based on the performance on the Cognitive Control Test Battery. Then the child is systematically presented with exercises designed for facilitating the development of cognitive control competencies within and between the levels of a developmental hierarchy. These tasks are analogous to those used in neuropsychological assessments to assess focal and sustained attention, working memory and concept formation. Thus, we hypothesize that the effect of CCT on behavior and school performance operates through improving attention skills and executive control.

Weekly therapy sessions are conducted in small groups in the first phase. Therapy sessions in the second phase will be held bi-weekly.

Specific Aim 2: To determine the degree to which linguistic and literacy training improve academic skills and behavior in alcohol-exposed children.

It has been well documented that children living in impoverished conditions have poor phonological skills, which in turn lead to deficits in literacy. Pilot data collected by Ms. Pharyn Sorour, a collaborator of the current research project, show that children with FASD reared in poverty display greater deficits in phonological skills and literacy because of the combined effects of poverty and alcohol-related CNS damage. Given that literacy is critical for academic success, the importance of interventions aimed at improving phonological awareness and literacy in these children is obvious.

Ms. Pharyn Sorour, a speech and language pathologist from the University of Cape Town, will conduct the linguistic/literacy training intervention, also in the Afrikaans language. Ms. Sorour and her research assistants will provide small group therapy for children with FASD. This program will consist of 28 sessions of speech and language therapy followed by 28 sessions of phonological awareness and early literacy (PAEL) program. These therapy sessions will be individualized based on pretest data.

Specific Aim 3: To determine the degree to which family interventions improve academic skills and behavior in alcohol-exposed children.

There is a vast literature showing that life stressors in the family environment negatively impact academic functioning and behavior in children. Therefore, the primary objective of the family intervention is to help parents create an environment conducive to learning, which in the case of the South African families of FAS children is greatly needed (Viljoen et al, 2002).

The participants in family interventions are the parents of children with FASD. A typical session will consist of a number of steps. First, the parents will identify problem areas that are significant for them. Then the group members participate in an activity that serves as an icebreaker. The next step, called providing context, is to introduce a topic for the group. This followed by practicing specific skills such as listening for feelings, building self-esteem, family meetings, and problem solving. In the next step, the participants reflect on issues and the session. At the end, each group member sets at least one goal for the week.

Specific Aim 4. To determine the degree to which environmental modifications in the classroom (e.g. limited class size and structured teaching) improve academic skills and behavior in alcohol-exposed children.

Environmental modification in the classroom has proven to be an effective way of facilitating the learning of children with specific disabilities. For example, the TEAACH program in North Carolina has used various environmental modifications to facilitate learning in children with autism. The rationale of this approach is that the child's environment plays a critical role in determining his or her learning and behavior. Through manipulating the environment, the child's behavior can be managed and learning can be facilitated.

The first step in setting up environmental modifications in a classroom is conducting a functional behavior assessment. The purpose of a functional behavior analysis is to determine the function of a targeted behavior. This is accomplished through identifying antecedents and consequences of a behavior. For example, a child with FASD may engage in behaviors such as tapping the chair or touching the child sitting next to him. These behaviors may serve the purpose of increasing the arousal level. These problems can be easily addressed by having the child do a task in the class that involves moving around. A child with working memory problems can be provided with visual cues. In South Africa, an environmental variable that hampers the child's learning is the large classroom size. Therefore, additional environmental modification that will be implemented will be reducing the class size for the children participating in environmental modification intervention.

Specific aim 5: To determine the degree to which combinations of the above methods improve academic skills and behavior in alcohol-exposed children.

There is a consensus among researchers that learning and behavior are determined by multiple factors. Therefore, it is reasonable to hypothesize that a combination of interventions may produce better results than one intervention alone.

Therefore, we plan to test the effectiveness of some specific combinations in the second phase of the study. These combinations include speech therapy and CCT, classroom modification and family intervention, family intervention and speech therapy, and classroom modification and CCT. The wait list control group will receive the last combination. Those children who received classroom intervention will continue to receive classroom intervention and thus, they will serve as controls in this phase. In view of limited resources, speech therapy, family interventions, and CCT will each be provided only on alternate weeks.

Specific Aim 6: To assess the effects of three mediating variables (self-efficacy, attention, meta-cognitive skills) and 3 moderating variables (child's IQ, life stress, maternal education) on therapeutic outcomes.

Baron & Kenny (1986) have reasoned that one can speak of a mediating relationship among variables only when one has demonstrated the following three relationships: 1. between the independent and the mediator variables; 2. between the mediator and dependent variables; and 3. between the independent and dependent variables. It is reasonable to expect that the above interventions will selectively improve metacognition, language, self-efficacy beliefs, and attention in children. There is evidence in the literature that these variables influence the behavior and school performance. Specific aims 1-5 are to test the association between interventions and outcome variables. Therefore, it is reasonable to hypothesize that self-efficacy, attention, and metacognitive skills mediate therapeutic effects. If a variable mediates a relationship, the relationship should be markedly reduced or eliminated when the effect of the mediating variable is co-varied out. Isolation of mechanisms that contribute to therapeutic outcomes will help researchers to develop new therapies by directly targeting those mechanisms. A moderating variable affects the magnitude of an effect. Therefore, knowing moderators will also help maximize the therapeutic effect of an intervention.

Mid-intervention assessment:

The following procedures will be utilized in the mid-intervention assessment of children: TOVA, Self-Efficacy Beliefs Scale, Metacognition, and Children's Depression Scale. In addition classroom observations and school grades will be collected.

The Beck Depression Inventory, Conflict Tactics Scale, and Audit will be re-administered to the parents in the mid-intervention assessment.

Posttests:

All standardized and non-standardized procedures listed above will be administered in the post-intervention assessment, with the exception of the TROG. The TROG will be administered to the parents only at baseline.

The Second Phase:

The same procedures will be repeated in the second phase of interventions.

D.3. Data analyses

Specific aims 1-5 concern testing the effectiveness of four therapies and that of specific combinations of these interventions. We will first examine the effectiveness of each intervention. With regard to the effectiveness of individual interventions, we will focus on the following three questions:

1. Is the intervention method clinically significant?
2. Is the intervention method producing results that are statistically significant?
3. What is the specific effect size (ES) of the therapeutic gain(s)?

Three primary dependent measures will be used in these analyses: parent/teacher ratings of behavior, classroom behavior, and scholastic achievement scores (literacy scores gathered at pre and post testing). To determine if there is a statistically significant difference, a series of ANCOVAs will be performed comparing differences between intervention and wait list groups (FASD children not involved in interventions – FASD controls) on the averages of mid and post intervention data treating pretest data as covariates. The same method will be used to determine clinically significant differences, except that scores from the normal control group will be utilized in comparisons. We will compute effect size ratios (Effect size for the intervention group compared to that for that of the control group) using the following method (Rappaport, Kyong-Mee Chung, & Isaacs, 2001): The post-assessment mean is subtracted from the pre-assessment mean and divided by the pretreatment standard deviation for the treated and control group separately to obtain an estimate of ES for the each group. Then, the ES ratio is calculated by dividing the treatment group ES by the control group ES. This ratio shows the magnitude of change in the treatment group relative to the control group.

The above statistical procedures will be used to test the effects of combined interventions, as well. In these tests, the group that receives one intervention will be compared with those receiving two interventions. Furthermore, we will determine the clinical significance of the effects by comparing the treatment group to the normal control group.

In view of the fact that a washout of the effects of a behavioral intervention does not typically occur upon the termination of the intervention, we expect that the groups will be unequal at the beginning of phase two interventions. We will handle this issue statistically; that is, by performing an analysis of covariance to analyze the data from the second phase of interventions. In this analysis, we will analyze phase two posttest data using phase one posttest data as covariates.

There exists the possibility that some therapies produce specific effects that may not be reflected in the above dependent measures. For example, the effects of CCT may be greater on tasks that are assessed by the Cognitive Control Test Battery. Similarly, the effects of linguistic/literacy training may be limited to language abilities. In order to explore this possibility, we will conduct further pre-post analyses on language measures and cognitive control measures.

We will further explore the effects of parent data (depression, alcoholism, domestic violence) on the relationship between family interventions and dependent variables by means of a regression analysis.

Analyses pertaining to Specific Aim 6 will focus on evaluating mediators and moderators of therapeutic effects. We hypothesize that metacognition, attention, and self-efficacy mediate the effects of interventions. Similarly, there is a possibility that the effects of therapy may be moderated by a number of variables such as maternal depression and the child's IQ. We will test mediating and moderating relationship effects on the association between intervention and dependent variables in a series of multiple regression analysis. A test of the mediation effect involves testing the association between the dependent and independent variables controlling for the mediator. We will test the moderating effects by creating interaction terms (group x moderator) and testing them in multiple regression analyses.

D.4. Pitfalls and alternatives

We have paid heed to a number of issues that may threaten the internal and external validity of the results. One issue concerns the maintenance of interest in therapy, especially in the parents. Burdened by many domestic problems, the parents may not be motivated to attend group therapy sessions in the evenings. Therefore, we plan to provide transportation and other incentives. In the pilot study conducted by Mr. Adams, these incentives markedly reduced the attrition rate. In view of the lack of resources in the community, certain classroom interventions (reduction of classroom size) may be challenging. However, we have begun communication with the regional department of education and school principals to address this issue. In one pilot study (Adams), classroom interventions were successfully conducted in one school. Given that there will be a number of test administrators and observers, there is a possibility of tester or observer effect. In order to minimize error introduced by tester, we will standardize test administration and provide extensive training to testers and observers.

D.5. Power analysis

Data were available from three pilot studies of intervention strategies proposed in the current study, which were used as a basis of the power analyses to determine adequate sample size. Pertinent to Specific aim 1, a yet unpublished pilot study conducted by Adnams, et al (2001; and data not yet published), indicated that children with FAS who received cognitive control therapy demonstrated marked reduction in behavior problems in comparison to controls. Pre and post means for the intervention group were 21.4 and 7.6, as measured by the Personal Behavior Checklist, and those for the control group with FAS were 14.8 and 15.45. The effect size of this result is .72, which is in the moderate to large range. The projected sample size of 20 subjects per group would result in a power of .80 for detecting such a difference. Ms. Sorour has conducted a study of speech therapy with FAS in children in a pre-post design. The results of this study showed significant improvements in some areas of speech and language. The effect sizes derived from these data range from .3 (spelling, short term memory) to 1.3 (manipulation, auditory analysis). Therefore, the projected sample size of 20 will be adequate to detect the changes in a range of abilities in the domain of speech and language. Mr. Adams has completed a study of family intervention and classroom modification. The results of this study showed that a significant number of participants moved from special education to the mainstream because of the progress they made in academic skills. Therefore, the projected number of subjects per group will be adequate to detect the effects of interventions proposed in this study.

D.6. Future directions

This multiple method intervention project will be the first of its kind to systematically and empirically evaluate the effectiveness of specific intervention philosophies and methodologies with a large sample of FASD children, most of whom will be FAS, Partial FAS, or on the severe side of the rest of the FASD spectrum. The information gained from this complex and ambitious intervention study will inform the educational systems in South Africa as well as the United States regarding potentially effective treatment and school intervention methods. In addition, future intervention trials can be promulgated using the most promising rehabilitative techniques discovered through this study. Collaboration with basic science and neuroimaging core projects is also expected in the future. As positive outcomes of this intervention study are realized, it is expected that, in future studies,

neuroimaging pre-intervention and post-intervention might elucidate any neuro-pathway gains in children who are receiving functionally beneficial remediation.

E. Human Subjects

The proposed research will involve 120 children, 100 with FASD and 20 controls, ranging in age from 6 to 9. We expect that children will include relatively equal numbers of males and females. The study children will be made up of children of mixed ethnic heritage, so-called 'coloured'. The family intervention group will be comprised of parents of the affected children. There will be 20 families selected for the family intervention portion of the study. The majority of potential participants in this research project will be from lower socio-economic levels. Included in the FASD group will be the children who display a continuum of dysmorphia (ranging from severe to none) and who have a confirmed prenatal alcohol exposure. The FASD and control group will be comparable with respect to age, sex, SES and ethnic background. Children with a history of head trauma with loss of consciousness, seizure disorder, severe psychiatric disorder, or severe mental retardation will be excluded. The normal control group will meet two additional exclusionary criteria: 1. history of prenatal exposure to moderate or heavy amounts of alcohol or other drugs; and 2. history of learning disability or developmental delay. We will collect data pertaining to cognitive ability, language development, and behavior through standardized neurobehavioral tests.

Protection of Human Subjects

All procedures used in this study have been submitted for approval by the two Institutional Review Boards at The University of New Mexico; The UNM Main Campus and UNM Medical School. In addition, this research protocol has been submitted for approval by the University of Cape Town (South Africa) Medical Ethics Committee.

Human subjects are protected by using standard and conservative educational and medical procedures and protocol in the testing and treatment of children and the protection of privileged educational and medical information. Testing of subjects and implementation of services, both children and adults, will be carried out under strict patient confidentiality protocols. All research program personnel will conform to these protocols. All test and research data will be kept in locked cabinets and in secure areas. Case numbers will be assigned to the participants and these case numbers, without any personal identifiers, will be used to analyze data and disseminate the results of the study.

Risks to the Subjects

Risks to the research subjects include emotional stress that can be caused by test-taking and loss of privacy. In order to reduce fatigue during the testing and treatment, participants will be given frequent breaks when needed and refreshments. In addition, there can be emotional stress related to intervention activities, again because of lack of privacy and increased personal scrutiny.

Adequacy of Protection Against Risks

In this study, a social worker in the community or the child's classroom teacher will explain the study to the parents of potential participants because a significant number of parents have limited education. Consent of the parents and assent of the study children (if over age 7) will be obtained. The proposed research protocol and consent/assent forms are currently being reviewed by The University of New Mexico IRB committees; Main campus and Medical school. The project is also currently being reviewed the The Medical Ethics Committee at The University of Cape Town, South Africa.

Potential Benefits

Children involved in the research study will receive interventions that will potentially benefit their school performance and learning outcomes. In addition, the parents involved in the study will potentially benefit from increased information and education regarding parenting skills.

Importance of Knowledge to be Gained

The knowledge gained from this intervention trial will hopefully, increase the general understanding of the types of interventions that will be most advantageous for children who were alcohol exposed prenatally. This knowledge will then be shared for use with other alcohol-exposed individuals.

Inclusion of Minorities

The children in this study will be South African school children, primarily of mixed ethnic heritage, so-called 'coloured'. The family intervention group will be comprised of parents of the affected children. The majority of potential participants in this research project will be from lower socio-economic levels.

Inclusion of Children

The study will include 120 children, 100 of whom were prenatally exposed to alcohol and 20 of whom were not. Children were selected for this study, as the intent of the study is to intervene with FASD children early in their school-careers to investigate the methods that will lead to the best learning outcomes. In addition, it is known that early intervention with children who have FASD improves outcomes and prevents secondary disabilities in this population.

Inclusion of Women

Women will be included in this study as the mothers of the target children. These women will be included along with their male partners to receive family interventions. The parent dyads will receive potentially beneficial information for improved parenting abilities.

Targeted/Planned Enrollment Table**This report format should NOT be used for data collection from study participants.****Study Title:** Multi-Method Intervention Study of FASD in South Africa**Total Planned Enrollment:** 120

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	60	60	120
Not Hispanic or Latino	60	60	120
Ethnic Category: Total of All Subjects*	120	120	240
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	60	60	120
White			
Racial Categories: Total of All Subjects*	60	60	120

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

F. Verebrate Animals

G. Literature Cited

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H. Consortium/Contractual Arrangements

The most important collaborators in this project are the designated investigators at The University of Cape Town (UCT), UCT administrators, and UCT ethics board. Their specific units of administration will monitor the budgetary and administrative aspects of this project. Other key personnel will participate from the local school district where this project will be implemented. This includes the group of principals representing the target schools. Those individuals and agencies are tied to this project through administrative agreements, letters of commitment, and letters of support.

I. Consultants

The key personnel on the project will be UNM employees or UCT employees. Collaboration with designated UCT employees as well as professionals from the local school district being targeted will be vital to the success of this project. The proposed investigators at UNM and UCT have a long track record in successful collaborations.