I. INTRODUCTION

A. Nature of the research problem. Today approximately 200 million people worldwide are considered illicit drug or substance abusers. Approximately 5% of these people are between the ages of 15-64, and half of this age group use drugs regularly (UNODC, 2000; World Drug Report, 2006). An estimated 112,085,000 people in the United States over the age of 12 have reported using an illicit drug at least once in their lifetime (SAMHSA, 2005). In the state of Florida, 8% of those 12 year old and older used illicit drugs in the month prior to the National Survey on Drug Use and Health between 2004 and 2005 (SAMHSA, 2005). Substance abuse is a dominant societal concern, affecting not only substance abusers but also their families and communities. The estimated costs of this public health problem range upwards of $400 billion annually for the treatment of substance abuse and its co-morbid illnesses and complications (DHHS, 1999; SAMHSA, 2001). With the use of crack cocaine on the rise, especially in some urban communities (Healthy People 2000, 2010), approximately 4.6 million women of child-bearing age regularly use cocaine, resulting in nearly 750,000 drug-exposed births annually. The adverse effects of perinatal substance abuse are complex, including not only the physical and neurological impairment of the developing fetus and neonate, but also heightened maternal stress, hopelessness, and depression, as well as poor maternal-infant attachment and limited parenting effectiveness (Nicholson, 2000; Sterk, Elifson, & Theall, 2000; D’Apolito, 1998; Burns, 1997). Cost-effective interventions to enhance parenting effectiveness, which build upon natural components of early mother-infant interactions, may improve health outcomes of both substance-abusing mothers (SAMs) and their infants. One such intervention that has been used to counteract the effects of maternal drug use on newborn babies is infant massage (IM), which has been shown to improve the growth and development of premature and crack-exposed babies (Lindrea & Stainton, 2000; Field, 1998; Cigales, Field, Lundy, Cuadra & Hart, 1997), as well as term babies of depressed mothers (Field, Grizzle, Scafidi, Adams, Richardson, Kuhn, & Schanberg, 1996). However, IM has been applied primarily in hospital settings, focusing on infant outcomes.

B. Purpose, scope, and methods of the investigation. The purpose of this randomized, controlled study was to test the effects of blending IM into a systematically planned Parenting Enhancement Program (PEP) on maternal and infant health outcomes, as well as parent-child interaction among SAMs and their babies. The study utilized two levels of intervention: the blended IMPEP and the PEP. A third non-intervention group comprised a control (CON) arm. The study goals were as follows: 1) determine whether the IMPEP improves health outcomes of SAMs including parenting stress, hope, self-esteem, and depression at 6, 12, 24, and 48 weeks, and drug use recidivism at 24 and 48 weeks (MCH Issue # 8.1.12); 2) determine whether the IMEP improves infant health outcomes including growth (length, weight, head circumference), development (motor, mental, behavioral), and safety (home environment, emergency department visits, risk of unintentional injury and child abuse) at 6, 12, 24, and 48 weeks, immunization status at 12, 24, and 48 weeks (MCH Issue #3.2.3), and mother-infant interaction at 6, 12, 24, and 48 weeks. Due to high attrition rates by Week 24, limited data were collected at 24 and 48 weeks post-baseline. Thus, as recommended by the funding agency, the study period for each subject was completed at 12 weeks post-baseline.

II. REVIEW OF THE LITERATURE

Substance abusing mothers (SAMs) experience multiple risks to themselves and their unborn child (D’Apolito & Hepworth, 2000; SAMHSA, 1999; D’Apolito, 1998; Healthy People 2000, 2010; Hawley & Disney, 1992; Lester et al., 1991; Hadeed & Siegel, 1989). Mothers are at increased risk of acquiring HIV/AIDS and hepatitis from contaminated needles when injecting drugs and are vulnerable to mental health and social problems, including heightened parenting stress, depression, hopelessness, low self-esteem, and deviant maternal-infant attachment (Walton, Becker & Moss, 2001; Nicholson, 2000; Sterk, Elifson, & Theall, 2000; D’Apolito, 1998; Kelly, 1998; Burns, 1997; Gowen & Nebring, 1997; Abidin, 1996). The infant suffers from physical and psychological impairment when born drug-addicted. These factors comprise a major crisis confronting SAMs and are profoundly detrimental to developing parenting effectiveness.
A. Maternal Health

**Parenting Stress.** *Parenting stress* is defined as the mother’s perceived burden of feeling unduly pressured with infant care and the parenting role. Although the baby’s birth may give SAMs a powerful motive to undergo treatment and seek recovery, parenting can be especially difficult for SAMs who are stressed not only because of the need to care for their infants but also because they are simultaneously driven to satisfy the intense cravings created by their addiction (Gottwald and Thurman, 1994). In turn, however, parenting stress may be relieved by hope and improved self-esteem.

**Hope.** There is increasing interest in determining the significance of hope as a mediating factor in crisis. Irving and Seidner (1998) investigated the relationship between current hopeful thinking about goals and recovery from substance dependence in a sample of graduates of a residential program for substance-dependent homeless veterans. The findings revealed no differences in state hope before and after treatment. However, state hope was particularly correlated with abstinence from substance use, quality of life, and self-efficacy.

**Self-Esteem.** A great deal of existing research indicates that low self-esteem is the universal common denominator among people suffering from addiction to any mind-altering substances (Candito, 1996). Low self-esteem implies self-rejection, self-dissatisfaction, self-contempt, and a lack of self-respect. Earlier studies (Keegan, 1987) reported that low self-esteem either causes or contributes to neurosis, anxiety, defensiveness, and ultimately alcohol and drug abuse. Increasingly, research on the etiology of substance abuse among teenagers and teenage pregnancy reflects the importance of depression and low self-esteem as causative factors among adolescents.

**Depression.** According to the Department of Health and Human Services, more than one third of females using drugs have major depressive episodes. Depression increases the risk for alcohol and drug addiction (Kelley, 1998; Barnett and Duggan, 1995; Kelley, 1992). Maternal depression is further associated with a variety of problems in both parenting behaviors and infant health outcomes (Seifer & Dickstein, 1993; Field, 1992), including social, emotional, and cognitive deficits (Campbell, Cohn, & Meyers, 1995).

B. Infant Health

**Infant Growth and Development.** Babies of cocaine and heroin users typically suffer withdrawal symptoms after birth (Field, 1998; Gottwald & Thurman, 1994; Gittler & McPhearson, 1990; Chasnoff, Griffith, and MacGregor, 1989; Larson & Field, 1991). They tend to be withdrawn, non-responsive, irritable and difficult to console, with poor sleeping and feeding patterns (Mundal, VanderWeele, Berger, & Fitsimmons, 1991; Lewis, Bennett & Schneider, 1989). In turn, *in utero* drug exposure results in a lifetime of physical and mental problems for the child. The long-term impact of low-cost, early infant stimulation-parenting enhancement interventions on such deficits has yet to be determined.

**Infant Safety.** Studies have noted that genetic and environmental risks put children of SAMs at higher risk for various problems, such as abuse and neglect (Johnson & Leff, 1999; McMahon & Luthar, 1998; Tartar & Messich, 1997). Children of substance-abusing parents are three times more likely to be abused and four times more likely to be neglected than other children (NCASA, 1999; NIDA, 2000).

C. Maternal-Infant Attachment.

Bonding (Klaus and Kennell, 1982), the attachment that occurs naturally between mother and infant, may be thwarted by the mother’s substance abuse and associated risk factors, such as poverty, mental illness, and a lack of social support (Easterbrooks & Graham, 1999; Gowen & Nebring, 1997; Dittler, 1990). Substance abuse worsens attachment difficulties due to the mother’s guilt, poor self-image, and lack of parenting confidence, predisposing the infant to abuse, neglect, and abandonment (Barnet & Duggan, 1995; Mundal, VanDerWeele, Berger, & Fitsimmons, 1991).

D. Programs to Promote Maternal-Infant Health Outcomes

Effective treatment of maternal substance abuse is an alternative to expensive and prolonged hospital stays for drug-exposed infants. Studies have demonstrated positive effects of multidimensional treatment programs on SAMs (Gowen & Nebring, 1997; Malow, West, Corrigan, Pena, & Cunningham, 1994; & Chasnoff, 1989). Of particular interest in this study is the use of infant massage and parenting enhancement programs, which have been shown in several studies to be effective in establishing positive maternal-infant interactions and improved infant growth and development. However, these studies were focused only on either maternal or infant outcomes and did not evaluate mother-infant interactions. Also, methodological limitations, such as the lack of randomized samples and true experimental designs, limit the generalizability of these findings.

**Porter’s Parenting Enhancement Program (PEP)** (Porter, 1985) is a systematically planned client-centered, health-focused educational parenting program that builds upon the belief that parents are the primary caregivers and health resource for the family. The program, aimed at enhancing the parenting skills of high-risk mothers, covers such topics as infant health and illness, growth and development, infant and child safety, CPR, self-care, and relaxation. Several
adaptations of the PEP have been shown to improve infant growth and development. However, these studies lacked randomized samples and were limited to descriptive designs (Porter, 1984, 1985, 1987; Porter & Knicely, 1985; Porter, Youssef, Shaaban, & Ibrahim, 1992).

Infant Massage. IM first became popular in the United States in 1970 when introduced by McClure (1989). Studies have shown that massage therapy on premature infants results in enhanced maternal-infant bonding and weights (Field, 1998; Cigales et al., 1997; Field, Grizzle, Scafidi, Adams, Richardson, Kuhn, & Schanberg, 1996). The findings of three pilot studies on the efficacy of infant massage and its impact on maternal-infant attachment, parental stress, and hope suggest the potential use of IM as a prevention and intervention measure for SAMs and their infants (Porter, Cameron, Haran, Orukoton, and Williams-Welch, 2000; Porter, Groger, Moncher, Murillo, & Rubert, 1999; Porter, Kissel, & Sanchez-Bongo, 1995). IM blended into a systematically planned PEP holds promise to further enhance the parenting skills of at-risk mothers and, in turn, may promote maternal and infant health outcomes.

III. STUDY DESIGN AND METHODS
A. Study design
The study utilized a controlled three group experimental design with repeated measures over time (T1-T3) to compare the efficacy of two levels of intervention (IMPEP and PEP) among the 3 study groups, as well as pre-and post-intervention outcomes within each group (IMPEP, PEP, CON). Clusters of 3 to 7 SAM-infant pairs were randomized by lottery within each study site to assign similar numbers of subjects to a) the IMPEP intervention treatment group (those participating in the blended Infant Massage-Parenting Enhancement Program); b) the PEP intervention treatment group (those participating in only the Parenting Enhancement Program); and c) the CON control group (those not participating in either the IMPEP or PEP, but provided with the usual health care and social services available at their respective service agencies). Infant massage (IM) was taught only within the IMPEP intervention, which consisted of four weekly two-hour classes held in a protected meeting space within each study site. These psycho-educational sessions incorporated both demonstration and practice of IM techniques (McClure, 1989), group discussions, and question-and-answer periods focused on childcare practices. Mothers also learned simple games and songs to promote infant stimulation and maternal-infant communication during IM sessions. Four weekly PEP classes lasting one and a half hours each were similarly held at each study site, scheduled on alternate days as IMPEP sessions to reduce intervention-related communication among SAMs in different treatment groups. Data on maternal health outcomes (e.g., parental stress, self-esteem, depression, hope, recidivism), infant health outcomes (e.g., growth and development, home safety, immunization status), and maternal-infant interaction were collected at a pre-intervention baseline assessment (T1); a post intervention assessment at week 6 (T2), and at week 12 follow-up (T3). In addition, demographic data were collected on socioeconomic status (measured by annual income), ethnicity, age, education, and infant’s age at study admission. Data were collected via self-administered questionnaires, guided interviews, random urine drug screens, and infant developmental assessments.

B. Population Studied
Recovering substance-abusing mothers (SAMs) in southeast Florida comprised our target population. The ethnically diverse nature of this region was reflected in the demographic make-up of our sample, which included African-American/Black (including Haitian and Caribbean), Caucasian/White, Hispanic, Asian/Pacific Islander, and Native American participants.

C. Sample Selection
Our study sample consisted of 138 SAMs (51% of the desired sample size), recruited from 2 community agencies in Miami-Dade and Broward Counties, and their infants, aged 4-52 weeks on study admission. All SAMs registered in these sites were considered for study participation, regardless of age, race/ethnicity, marital status, religion, education, or income level. Inclusion criteria required that the mother: 1) speaks and comprehends English, Spanish, or Creole; 2) has an infant 12 months old or younger; 3) performs activities of daily living; 4) maintains attention/follows directions; and 5) willingly signs an informed consent. The sample had an 84% retention rate through week 12 post-baseline.

D. Instruments
The outcome variables were measured using a variety of tools described in Appendix IV, including the following: Parenting Stress Index/Short Form (PSI, Abidin, 1996), sphygmomanometer, and abdomen-to-hip size ratio (Kubzansky, Kawachi, & Sparrow, 1999) to measure both the psychosocial and physiologic dimensions of stress; the Herth Hope Scale (Herth, 1989), Rosenberg Self-Esteem Scale (Rosenberg, 1979; Corcoran & Fischer, 1987), and Beck Depression Inventory (Beck, 1978; Corcoran & Fischer, 1987) and other maternal mental health measures; random urine drug screens and the Time Line Follow Back (TLFB)—Alcohol, Drug, Cigarette, and Marijuana (Sobell & Sobell, 1995) to assess recidivism; Infant Detecto Beam weighing scale, metric tape measure, Bayley Scales of Infant Development (Bayley, 1993; Cowden, Sayers, & Torrey, 1998), Safety
Checklist, and Infant Immunization Chart to assess infant outcomes; the Maternal-Infant Attachment Scale (Muller (1994) and Mother-Infant Interaction Observation Checklist (derived from Ukeje, Bendersky, & Lewis, 2001) to evaluate the mother-infant relationship; and a Demographic Questionnaire. In addition to established validity and reliability indices in the literature, the instruments in this study were further tested for reliability with the current sample, i.e., the extent to which the instrument yielded consistent results over repeated observations (Cohen, 1998). Cronbach alpha is an accepted statistic for assessing reliability of a scale composed of multiple items and measures internal consistency by examining intercorrelations between scale items (Creswell, 2003). A Cronbach alpha value of 0.70 or more generally implies adequate reliability. The results in Table 1 indicate the instruments used in this study have excellent reliability.

IV. DETAILED FINDINGS

The main objectives of this study are as follows: 1) to determine whether a blended Infant Massage-Parenting Enhancement Program (IMPEP) improves recovering substance-abusing mothers’ (SAMs’) health outcomes in terms of parenting stress, hope, self-esteem, depression, and drug abstinence; 2) to determine whether the IMPEP improves the health outcomes of infants of recovering SAMs in terms of increased growth and development, improved immunization status, and greater child safety; 3) to determine whether the IMPEP improves mother-infant interaction and attachment.

A. Demographic Profile of the Study Sample

From the original data set tested for reliability, several participants were omitted from further analyses due to missing responses across required outcome measures. The final study sample consisted of 62 mother-infant dyads in the IMPEP group, 37 in the PEP group, and 39 in the CON group who, in addition to baseline, had at least one other post-intervention assessment at week 6 or week 12. Table 2 through Table 8 presents the demographic profile of the sample.

B. Descriptive Statistics

Table 9 summarizes the age distribution of the mothers in the sample as a whole, as well as within each study group. Tables 10 through 16 present descriptive statistics of continuous outcome variables for both mothers and infants by study group for each of the assessment periods. Table 10 shows the results for parenting stress, and systolic and diastolic blood pressures of participating mothers. Table 11 summarizes the results for abdominal girth measurements and waist-to-hip size ratios. Table 12 shows the results for levels of hope, self-esteem, and depression among the participating mothers. Tables 13 through 16 summarize the descriptive statistics for the infant measures, including age, growth and development, levels of maternal attachment and interaction, and maternal adherence to safety measures at home and in transit.

C. Results for the Research Hypotheses

Hypothesis 1. IMPEP SAMs will achieve lower stress indices than PEP SAMs, as reflected in higher scores on the Parenting Stress Index (PSI), lower waist-to-hip size ratios (abdominal fat distribution), and lower systolic and diastolic blood pressures (BP) at 6 and 12 weeks post-baseline. The results presented in Table 18, demonstrate a significant difference in PSI among the groups at week 12 post-baseline and in waist-to-hip ratio between the groups at week 6 post-baseline. Post-hoc Mann-Whitney U tests showed that at baseline systolic BP in the IMPEP group was significantly greater than in the CON group (adjusted z=2.350, p=.019), whereas PSI (adjusted z=2.100, p=.036) and diastolic BP (adjusted z=2.145, p=.032) were significantly greater for the PEP group than for the CON group. At week 6 post-baseline, systolic BP (adjusted z=2.375, p=.018) and waist-to-hip ratio (adjusted z=2.878, p=.004) were significantly greater in the IMPEP group than in the CON group. Moreover, waist-to-hip ratios for the IMPEP group were also significantly greater than for the PEP group (adjusted z=3.293, p=.001), whereas PSI was significantly greater for the PEP group than the CON group (adjusted z=2.390, p=.017). At week 12 post-baseline, PSI scores for both the IMPEP (adjusted z=3.409, p=.001) and PEP (adjusted z=2.816, p=.005) groups were significantly higher than for control subjects. Within individual groups, there was a significant increase in PSI among IMPEP mothers from T1 to T2 (adjusted z=2.893, p=.004) and T1 to T3.
(adjusted z=4.189, p<.001), as well as significant decreases in systolic BP (adjusted z=1.976, p=.048) and waist-to-hip ratios from T1 to T2 (adjusted z=3.114, p=.002). A significant decrease in diastolic BP from T1 to T2 (adjusted z=2.190, p=.029) was seen among PEP mothers, whereas the CON group showed a significant increase in systolic BP from both T1 to T2 (adjusted z=2.771, p=.006) and T1 to T3 (adjusted z=2.690, p=.007).

As higher scores on the PSI indicate less stress, our findings demonstrated that parenting stress levels decreased significantly over the assessment periods for the IMPEP group but not for the PEP or CON groups. In addition, mothers in the IMPEP group were significantly less stressed than those in the CON group at week 6 and at week 12, while the PEP group was significantly less stressed than the CON group at week 12. Although waist-to-hip ratios decreased significantly for the IMPEP group from week 6 to week 12, waist-to-hip ratios for the IMPEP group were significantly greater than for the PEP and CON groups at week 6. Furthermore, while systolic BP in the IMPEP group was significantly greater than the CON group at baseline and at week 6, it decreased significantly from week 6 to week 12 within the IMPEP group itself. However, this difference was also noted at baseline and may have reflected a systematic bias in the study sample, despite randomization. Nonetheless, in contrast to control subjects, systolic BP decreased over time within the IMPEP group, suggesting a post-intervention benefit from the IMPEP. Thus, the hypothesis that IMPEP SAMs will achieve lower stress indices than PEP SAMs was supported by the data overall.

**Hypothesis 2.** IMPEP SAMs will achieve higher hope scores than PEP SAMs on the Herth Hope Scale (HHS) at 6 and 12 weeks post-baseline. The Kruskall-Wallis ANOVA results in Table 20 indicate no significant differences among or within groups, while post-hoc Mann-Whitney U tests also showed no significant changes in levels of hope across assessment periods or between the IMPEP and PEP study groups. Therefore the hypothesis that IMPEP SAMs will achieve higher hope scores than PEP SAMs on the HHS at 6 and 12 weeks post-baseline was not supported by the data.

**Hypothesis 3.** IMPEP SAMs will achieve higher self-esteem scores than PEP SAMs on the Rosenberg Self-Esteem Scale (RSE) at 6 and 12 weeks post-baseline. The Kruskall-Wallis ANOVA results in Table 21 indicate that there was a significant difference in self-esteem between the study groups at the week 6 and week 12 post-baseline assessments. In particular, post-hoc Mann-Whitney U tests showed that these results were influenced by the IMPEP and PEP levels of self-esteem being significantly greater than the CON group. However, there were no significant differences between the IMPEP and PEP groups at the baseline, week 6, or week 12 assessments. Therefore the hypothesis that IMPEP SAMs will achieve higher self-esteem scores than PEP SAMs on the RSE at 6 and 12 weeks post-baseline was not supported by the data.

**Hypothesis 4.** IMPEP SAMs will achieve lower depression scores than PEP SAMs on the Beck Depression Inventory (BDI) at 6 and 12 weeks post-baseline. The Kruskall-Wallis ANOVA results in Table 22 show that there was a significant difference in levels of depression among the study groups at the week 12 post-baseline assessment, as well as significant differences within the IMPEP and PEP groups over time. In particular, post-hoc testing indicated the IMPEP group of mothers had significantly lower levels of depression than the PEP group at week 12 (adjusted z=2.588; p=.010). Furthermore, the analyses showed that levels of depression in the IMPEP group were significantly lower at week 6 compared to baseline (adjusted z=3.852; p=.000), at week 12 compared to baseline (adjusted z=5.872; p=.000), and at week 12 compared to week 6 (adjusted z=2.082; p=.037). The PEP group of mothers also showed a significant decrease in levels of depression at week 12 compared to baseline (adjusted z=3.025; p=.002). Therefore, the hypothesis that IMPEP SAMs will achieve lower depression scores than PEP SAMs on the BDI at 6 and 12 weeks post-baseline was supported.

**Hypothesis 5.** IMPEP SAMs will achieve higher drug abstinence levels and demonstrate lower drug use and recidivism rates than PEP SAMs, using the Time Line Follow Back (TLFB), as well as objectively though urine drug screens at 6 and 12 weeks post-baseline. The Kruskall-Wallis ANOVA test (presented in Table 23) with post-hoc Mann-Whitney U Tests were used to compare ranked differences among and within group values for non-normally distributed ordinal variables characterizing drug use, revealing a significant difference among the study groups at week 12 regarding when street drugs were last used. Post-hoc Mann-Whitney U tests revealed the proportion of mothers who had stopped using drugs in the IMPEP group was greater than that in the CON group at the week 12 assessment (adjusted z=2.434; p=.015). However, there were no significant differences between the IMPEP and PEP groups. Of note, in urine drug screens, all participating SAMs had negative test results across all testing periods. Thus, the hypothesis that IMPEP SAMs will achieve higher drug abstinence levels and demonstrate less drug use than PEP SAMs was not supported by the data.

**Hypothesis 6.** IMPEP SAMs will achieve higher smoking cessation levels and demonstrate lower smoking rates than PEP SAMs, using the TLFB at 6 and 12 weeks post-baseline. There were 11 smokers in the sample, 3 of whom were chain smokers. Two out of the 6 smokers in the IMPEP group, and 2 out of the 5 in the PEP group stopped smoking by the week 12 assessment period. None of the 5 smokers in the CON group reported having stopped smoking at the week 6 or week 12 post baseline assessment. Given the small proportion of smokers in the overall sample, inferential statistics were not done for this outcome.
Hypothesis 7. Infants of IMPEP SAMs will achieve greater growth rates than infants of PEP SAMs, as reflected in length, weight, and head circumference measures, with a decreased tendency to decline along standardized pediatric growth curves at 6 and 12 weeks post-baseline. The Kruskal-Wallis ANOVA test results shown in Table 25 reveal many significant differences, particularly within individual groups over time. Differences among groups were significant for weight and head circumference, with post-hoc Mann-Whitney U tests indicating infants in the IMPEP group had significantly greater weights (adjusted \( z=3.471; p<.001 \)) and head circumferences (adjusted \( z=4.456; p<.000 \)) than infants in the PEP group at week 6. In addition, IMPEP infants had greater head circumferences (adjusted \( z=2.271; p<.023 \)) than PEP infants at week 12. Furthermore, IMPEP infants demonstrated significant within group increases in length, weight, and head circumference from baseline to week 6 (adjusted \( z=2.679; p<.007 \), adjusted \( z=5.352; p<.001 \), and adjusted \( z=7.307; p<.001 \), respectively) and baseline to week 12 (adjusted \( z=4.386; p<.001 \), adjusted \( z=5.167; p<.001 \), and adjusted \( z=7.039; p<.001 \), respectively), and in length from week 6 to week 12 (adjusted \( z=2.091; p<.037 \)). PEP infants showed significant growth in length and head circumference from baseline to week 6 (adjusted \( z=2.155; p<.031 \) and adjusted \( z=2.978; p<.003 \), respectively), and in length, weight and head circumference from baseline to week 12 (adjusted \( z=3.098; p<.002 \), adjusted \( z=3.766; p<.001 \), and adjusted \( z=4.465; p<.001 \), respectively). Similarly, from week 6 to week 12, PEP infants had a significant increase in weight (adjusted \( z=3.332; p<.001 \)). Of note, the CON group also showed significant growth in weight and head circumference from baseline to week 6, and in height, weight and head circumference from baseline to week 12, although they demonstrated no significant increases in these growth measures from week 6 to week 12. Therefore, the hypothesis that Infants of IMPEP SAMs in the IMPEP group will achieve greater growth rates than infants in the PEP group was supported by the data.

Hypothesis 8. Infants of IMPEP SAMs will display more advanced development than infants of PEP SAMs, as reflected in overall motor, mental, and behavioral ratings on the Bayley Scales of Infant Development (BSID) at 6 and 12 weeks post-baseline. The results of the Kruskal-Wallis ANOVA are presented in Table 27. These tests revealed many significant differences, particularly within the groups over time for all three BSID subscales, as well as significant differences among the study groups for behavioral rating at week 6 and motor development at week 12. In particular, post-hoc Mann-Whitney U tests indicated among group differences were most attributed to the IMPEP infants having significantly greater motor development than the CON group at week 12 and significantly greater behavior ratings at week 6. However, the differences between IMPEP and PEP infants did not reach statistical significance for any of the BSID subscales at follow-up. In contrast, the PEP infants had significantly greater mental development at baseline than the IMPEP infants (adjusted \( z=2.140; p<.032 \)). Nonetheless, the IMPEP infants showed significant changes in motor and mental development and behavior rating across both follow-up assessments, compared to baseline. More specifically, at week 6, significant improvements were noted for infants of IMPEP mothers in motor development (adjusted \( z=3.287; p<.001 \)), mental development (adjusted \( z=5.875; p<.001 \)), and behavior rating (adjusted \( z=6.631; p<.001 \)). Similarly, at week 12, significant improvements were noted compared to baseline in motor development (adjusted \( z=6.111; p<.001 \)), mental development (adjusted \( z=3.549; p<.001 \)), and behavior rating (adjusted \( z=3.110; p<.002 \)). At week 12 compared to week 6, while there was further improvement in motor development (adjusted \( z=3.182; p<.001 \)) in the IMPEP group, there was a significant decline in mental development (adjusted \( z=2.721; p<.007 \)) and behavior rating (adjusted \( z=4.357; p<.001 \)). Infants of PEP mothers demonstrated significant improvement in behavior rating at week 6 compared to baseline, in motor development and behavior rating at week 12 compared to baseline, and in mental development at week 12 compared to week 6. Therefore the hypothesis that infants of IMPEP SAMs will display more advanced development than infants of PEP SAMs at week 6 and week 12 post-baseline was not supported by between group comparisons.

Hypothesis 9. Infants of IMPEP SAMs will display better immunization status than infants of PEP SAMs, as reflected in greater adherence to the American Academy of Pediatrics (AAP) childhood immunization guidelines at 6 and 12 weeks post-baseline. All infants in the study were fully up-to-date on their immunizations, per AAP guidelines. Thus, no group differences were seen. Given that the study period was only 12 weeks long, during which time all mother-infant pairs lived in a residential treatment facility, the close monitoring of immunization status by program staff may have contributed to this lack of treatment effect.

Hypothesis 10. Infants of IMPEP SAMs will achieve greater child safety status than infants of PEP SAMs, as reflected by self-report on the Home and Safety Checklist and Infant Supervision tool at 6 and 12 weeks post-baseline. The Kruskal-Wallis ANOVA results presented in Table 28 indicate significant differences were found in infant supervision among groups at baseline and at week 6. Differences in infant supervision were also observed in the IMPEP group over time. However, no treatment effect was observed with regard to home safety practices. In particular, post-hoc Mann-Whitney U tests showed the IMPEP group of mothers displayed greater adherence to home and infant safety practices than mothers in the CON group at baseline (adjusted \( z=2.681; p<.007 \)) and at week 6 (adjusted \( z=2.698; p<.007 \)), again potentially reflecting a systematic bias in the study sample that was not eliminated through randomization. Of note, the IMPEP group had a significant decline in home safety adherence at week 12 compared to baseline, but no
other significant findings emerged. Therefore, the hypothesis that infants of IMPEP SAMs will achieve greater child safety status than infants of PEP SAMs at 6 and 12 weeks post-baseline was partially supported by the data.  

Hypothesis 11. IMPEP SAM-infant pairs will display greater interactive attachment than PEP SAM-infant pairs, as reflected in lower scores on the Maternal-Infant Attachment (MIA) scale and higher scores on the Maternal-Infant Interaction Observation Checklist (MIIO) at 6 and 12 weeks post-baseline. As shown in Table 29, these outcome variables were also not normally distributed. Thus, results of the non-parametric Kruskall-Wallis ANOVA test are shown in Table 30, which revealed the only significant finding for MIA was among the study groups at baseline. On the other hand, there were significant differences in MIIO among the groups at baseline and week 12, as well as within each study group over time. Post-hoc Mann-Whitney U Tests indicated the IMPEP group of mothers displayed significantly greater attachment but less interaction with their infants at baseline compared to the CON group (adjusted z=2.332; p=.020, and adjusted z=2.482; p=.013, respectively), while the PEP group showed significantly greater interaction with their infants than the CON group (adjusted z=2.278; p=.023). However, the IMPEP mothers showed significantly greater attachment to their infants at week 6 (adjusted z=2.279; p=.023) and at week 12 (adjusted z=2.589; p=.010) than control mothers. In addition, as a group the IMPEP mothers had a significant increase in MIIO at week 6 compared to baseline (adjusted z=2.961; p=.003), which further improved at week 12 (adjusted z=3.873; p<.001 compared to week 6; adjusted z=5.982; p<.001 compared to baseline). PEP mothers also showed a significant improvement in interaction with their infants; however, no significant differences emerged between the IMPEP and PEP groups in MIA or MIIO. Therefore the hypothesis that IMPEP SAM-infant pairs will display greater interactive attachment than PEP SAM-infant pairs at 6 and 12 weeks post-baseline was not supported by the data.

D. Additional Analyses
Further exploratory investigations were conducted to determine whether baseline variables including socio-economic status (measured by annual income), education, age, ethnicity, and infant age at study admission (collected via the demographic questionnaire) were related to outcome variables. Given that these data did not meet the assumption of normality, non-parametric Spearman Rho correlation tests were used, with results are presented in Table 31. Significant positive correlations were noted between annual income and both maternal self-esteem (RSE) and infant behavior rating on the BSID, the motor and behavior subscales of the BSID, number of children and home safety adherence, and infant age with both BSID behavior rating and home safety adherence. Moreover, annual income was inversely correlated with maternal diastolic BP.

V. DISCUSSION AND INTERPRETATION OF FINDINGS: COMPARISON WITH OTHER STUDIES

Parenting Stress. Our findings demonstrated that SAMs across study groups had high levels of stress, corroborating findings of earlier studies (Kelly, 1992, 1998; Thurman, 1994; Barnet & Duggan, 1995). However, the results further revealed a significant reduction in parenting stress among IMPEP SAMs, as compared to SAMs in the PEP and CON groups, providing evidence of the value added effect of integrating infant massage into parenting enhancement programs. Defined as the mother’s perceived burden of feeling unduly pressured with infant care and the parenting role, parenting stress increases the risk for drug-addiction and threatens healthy maternal-infant interaction. Although the birth of a child may serve as a powerful motivation to undergo addiction treatment, parenting can be especially difficult for SAMs who must additionally contend with the intense cravings created by their addiction (Gottwald & Thurman, 1994; Barnet & Duggan, 1995). In turn, maternal drug use in the presence of stressful environmental conditions interferes with effective parenting. As exposure to negative environmental risk factors increases, SAMs typically become overwhelmed and have little time for parenting (Kettinger, Nair, & Schuler, 2000; Black, Nair, & Knight, 1994). Our study supports the use of the IMPEP intervention as a means of reducing SAMs’ parenting stress.

Hope. In contrast, our findings did not lend support for the effectiveness of the IMPEP in improving SAMs level of hope. Earlier studies reported that state hope was particularly correlated with abstinence from substance use and quality of life, as well as self-efficacy (Herth, 1989; Hershey, 1997; Irving & Snider, 1998). In addition, hope is viewed as an energizing factor that can empower recovering SAMs to become better parents and role models for their children through the sharing of their own experiences (Spencer & Davidson, 1997). Those findings were not corroborated by our data, which showed no significant changes in levels of hope within study groups over time or among study groups at post-baseline assessments. Hope may be mediated by attitudes, perceived norms, and perceived behavioral control. Efforts to prevent substance use or improve maternal-infant health outcomes may be more effective if interventions address these global intra-personal factors.

Self-Esteem. Our findings also did not demonstrate that the IMPEP could raise SAMs’ level of self-esteem compared to the PEP intervention, although self-esteem was higher in the IMPEP and PEP groups than in the CON group. However, this difference was likely influenced by higher self-esteem levels at baseline. A great deal of existing research indicates that low self-
esteem is the universal common denominator among people suffering from addiction to any mind-altering substances (Candito, 1996). Similarly, Carvajal (1998) reported that optimism, hope, and self-esteem are determinants of avoiding substance use. Our study did not confirm those findings. However, the present findings on self-esteem are inconclusive, due to the apparent sample bias as noted above.

**Depression.** While several investigators have reported a variety of demographic and psychosocial risk factors as being associated with maternal substance abuse, including depression, parenting stress, poverty, and poor social support (Gowen & Nebrig 1997; Kelly 1998; Kettinger, Nair, & Schuler, 2000), there is general agreement that SAMs are prone to depression, particularly when compounded by poor socioeconomic status. Depression diminishes the quality of mother-child interaction by interfering with the ability of the mother to relate to her infant and for the infant to form a secure attachment to the mother (Josefsson, Berg, Nordin, & Sydsjo, 2001). Our study did not corroborate certain demographic associations, as neither age nor educational level correlated with degree of depression among SAMs. It has been reported that depression is most prevalent among women of childbearing age (Barnet et al., 1995; Desai & Jann, 2000; Marcus et al., 2003). Although the median age of our sample was 28 years, our data reflect only minimal depression among SAMs, even though these mothers were largely at or below poverty level (86%). It is possible that the variety and availability of social and rehabilitative services provided to our study population by both public and private agencies have enabled these mothers to acquire better problem solving skills and develop improved coping strategies, possibly counteracting depressive influences. For instance, given the structured nature of their rehabilitation program, the mother-infant pairs in our sample had lived in residential treatment facilities for 3 to 6 months, potentially providing stable social support and a sense of family belongingness—factors that can counter tendencies toward depression (Murata, 1995). Nonetheless, the IMPEP was effective in reducing levels of depression among mothers at post-intervention assessments, providing support for the value-added effects of infant massage in reducing SAMs’ level of depression.

**Recidivism.** Our data showed that 2 PEP and 5 Control SAMs had a relapse and were incarcerated again, with their infants being once again placed into foster care. Frequency of drug use was significantly reduced. However, mounting outbursts of aggressive behavior resulted in the untimely discharge of 7 other study participants (1 IMPEP, 2 PEP, 5 Control) from the recovery center.

**Infant Growth and Development.** There is an emerging body of literature indicating the positive effects of touch, massage, and similar interventions on immune system responses and their subsequent benefits on medical and psychological variables (Kemeny & Gruenewald, 2000). The positive impact of infant massage has also been shown to extend to high-risk and drug exposed pre-term infants with neurological deficits and developmental delays (Field, 1998). Massage therapy on infants has resulted in enhanced maternal-infant bonding, increased communication, weight gain, improved digestion, increased alertness and awareness, greater infant relaxation, improved sleep patterns, and decreased hospital stays (Field, 1998; Cigales et al., 1997). Other studies revealed that the infants receiving massage therapy cried less, improved in sociability, exhibited a more soothing temperament, and produced less urinary catecholamine stress hormones (Field, Grizzle, Scafidi, Adams, Richardson, Kuhn, & Schanberg, 1996). Our findings further corroborated these earlier studies, as infants of IMPEP SAMs showed greater gains in length, weight, and head circumference at Week 6 and Week 12 post-baseline, as compared to the growth gains of PEP and CON infants. As expected, significant growth gains over time were seen within each study group, indicating that growth was not stunted in these infants as a whole. However, our findings reflect the value added effects of infant massage blended into a parenting enhancement program.

**Infant Safety.** Recent statistics indicate intentional and unintentional injuries are the leading cause of death among infants in the United States, accounting for almost half of all fatal childhood injuries (Jain, Khoshnood, Lee, & Concato, 2001). Children of substance-abusing parents are three times more likely to be abused and four times more likely to be neglected than other children (NIDA, 2001). They are at higher risk for accidental injuries (Field, 1998), fall, burns, and poisoning (Gilbert, El-Bassel, & Schilling, 1997; Gowen & Nebrig, 1997). Seatbelt non-use or misuse and the likelihood of not having a car seat have been identified as the primary cause of vehicular child passenger injuries (Taft et al. 1999; Kamerling, 2002; Chung et al., 2004). Thus, infant safety is of paramount concern in children of SAMs as the physiologic and behavioral effects of maternal substance abuse on the neonate complicate the care of these infants (D’Apolito & Hepworth, 2001; Conway & Kennedy, 2003). Our data revealed significant differences between study groups at baseline and week 6, as IMPEP SAMs were found to be more adherent to home safety practices than the CON group. However, IMPEP SAMs showed a significant decline in adherence to safety practices at week 12. Home and infant safety practices among SAMs may be influenced more by environmental factors than personal maternal attributes. The direct relationship between degree of home safety and extent of infant supervision indicates that as SAMs become more attentive to home safety measures, they increase infant safety practices as well. Moreover, as reflected in consistent seatbelt use for self, SAMs’ personal safety practices appear tied to both home environmental safety measures and improved infant care and supervision practices, including safety in transit. This may imply an interconnectedness of SAMs toward their infants, as they increasingly view personal safety practices as applying to the mother-infant dyad.
Mother-Infant Attachment and Interaction. Substance abuse worsens attachment difficulty due to the mother’s guilt, poor self-image, and lack of parenting confidence, predisposing the infant to abuse, neglect, and abandonment (Barnet & Duggan, 1995; Mundal, VanDerWeele, Berger, & Fitsimmons, 1991). Our data support previous studies, which demonstrated that massage therapy on infants results in enhanced maternal-infant bonding and increased communication (Field, 1998; Cigales et al., 1997). Our findings indicated IMPEP mothers achieved significantly greater attachment to their infants at week 6 and week 12 than mothers in the CON group. Moreover, IMPEP mothers significantly improved in interaction with their infants at both follow-up assessments. PEP SAMs also showed a significant improvement in interaction with their infants over time. Although both IMPEP and PEP mothers displayed greater attachment and interaction with their infants than control subjects, the two intervention groups did not differ, thus suggesting that IM did not provide value-added effects on these outcomes beyond the PEP itself. Nonetheless, our findings corroborate previous studies with respect to the positive impact of touch and infant massage, reinforcing the value of systematically planned parenting enhancement programs.

Demographic Correlates. Although our exploratory bivariate analyses cannot confirm causal relationships, this study revealed several significant correlations between key demographic variables and outcome measures. In summary, higher annual incomes were associated with greater maternal self-esteem and infant behavior ratings on the BSID. Similarly, a higher maternal education level was associated with greater infant motor development and BSID behavior ratings. Greater maternal age was similarly associated with increased BSID behavior ratings, as well as greater adherence to home and infant safety practices. Moreover, number of children was also positively correlated with greater infant safety, thus possibly reflecting learned behaviors accumulated over time.

A. Conclusion
Overall our findings demonstrate the positive value-added effects of a blended Infant Massage-Parenting Enhancement Program, particularly in terms of reducing parenting stress and maternal depression, as well as maintaining greater levels of abstinence from illicit drug use. Infants participating in the IMPEP group also achieved greater physical growth rates and improvements in motor development and behavior ratings. Infant supervision also improved in the IMPEP, although IM did not appear to enhance maternal-infant interactive attachment beyond the level achieved by the PEP itself.

B. Explanation of Study Limitations
Lack of Institutional Support. Initially, we projected a cohort of 27 mother-infant dyads would be recruited every four months. However, despite securing cooperative agreements with several well-established community-based rehabilitation agencies in southeast Florida, this recruitment goal was not met, as internal staff resources for intra-agency subject recruitment were often lacking.

Variable Client Census. Contrary to what was projected based on pre-initiation site data, the client census at each study site was highly variable, negatively impacting our ability to recruit mother-infant pairs at our projected level.

Climatic Natural Disasters. Locating our study in the south Florida region meant efficient program implementation was subject to unpredictable natural forces—namely, climatic disasters including Hurricanes Wilma and Katrina, which negatively impacted subject recruitment and retention near the end of Project Year II. For nearly three months, study implementation and recruitment was placed on hold due to weather-related conditions, which affected both the physical facilities and agency staffing at our study sites. In some instances, daily operations of the rehabilitation centers were disrupted due to the evacuation of clients to safer locations further inland, leading to unavoidable set backs in our recruitment timeline and overall research progression.

Retention Problems. Kendall & Sugarman (1997) reported that subject attrition may be reduced in behavioral interventions when therapies are manualized, time-limited, and provided free of charge. We initially anticipated no more than 25% attrition, which is at the upper end of rates achieved by Kendall & Sugarman (1997). Hansten et al. (2000) indicated a retention rate of at least 70% is required to obtain valid findings in longitudinal studies of substance abuse treatment samples. Our overall retention rate in the IMPEP study was 78% by week 12. We conducted a thorough analysis of those subjects who left the study prematurely. Of the initial 170 consenting SAMs, 37 mothers failed to complete the study, resulting in an attrition rate of 22%. Subject loss steadily increased over the course of the study period for several reasons: lack of a reliable address following discharge from the residential rehabilitation program (n = 11); discharge from the rehabilitation agency due to mounting aggressive or disruptive behavior (n = 7); incarceration due to addiction relapse (n = 7); failure to make-up missed classes or complete scheduled data collection sessions (n = 7); inability to continue participation due to a prolonged hospital stay for the baby (n = 3); death due to drug overdose (n = 2).

Cross-Group Contamination. To facilitate consistent attendance at IMPEP and PEP sessions, classes were scheduled on-site within the participating addiction treatment center on different days. However, this practice created the potential for participants from different treatment groups (IMPEP, PEP, or CON) to discuss their varied experiences with
one another, in turn, biasing results due to cross-contamination among treatment groups. Many of these women resided in close quarters within the same residential treatment facility, while others maintained mutual friendships prior to their study involvement and were important sources of support for one another. However, although preliminary observations indicated IMPEP mothers were enthusiastic and conversant about their infant massage experiences, we felt the true impact of the IMPEP was unlikely to stem solely from second-hand discussions of parental training activities or IM techniques in the absence of individualized skills training and group practice exercises reinforced by feedback from facilitators and peers. Nevertheless, the exchange of information among IMPEP, PEP, and CON subjects would be expected to reduce group differences and result in a more conservative evaluation of the IMPEP’s efficacy, as opposed to inflating Type I error and overestimating its significance for positive change.

**Conflicting Schedules.** Participating SAMs often felt they had insufficient time to speak casually within the group and share life experiences. Allowing participants to socialize and engage one another has the potential to promote a sense of group belonging and foster the natural development of social support systems. However, study participants were often forced to rush from IMPEP or PEP sessions in order to catch public buses or transportation services home. Alternatively, some mothers would habitually arrive late due to preceding classes or inconsistent transportation to the study site. Interestingly, both PEP and CON groups had significantly higher attrition rates than the IMPEP group.

**Lessons Learned.** Many of these challenges were difficult to predict and prepare for at the outset of the study. In efforts to increase subject recruitment, we negotiated for 2 additional study sites, but the agency approval process was cumbersome and became counterproductive. Thus, we made several modifications to our original experimental protocol to maximize recruitment and retention of a culturally diverse sample of mother-infant pairs, while maintaining the rigor of a randomized, controlled experimental design. These included incorporating block randomization, flexible class scheduling to accommodate the often disorganized lifestyle of this population, and securing home addresses and telephone numbers of two additional contact persons for each SAM. Allowing for such flexibility within a research protocol is a necessary compromise when working with difficult to access populations with historically high attrition levels, such as substance-abusing women—and especially new mothers. The overall 78% participant retention rate is a testament to the ongoing efforts of the project staff toward creating a welcoming and supportive environment for these women.

C. **Possible application of findings to actual MCH health care delivery**

The potential impact of the IMPEP is high with respect to parent-child health promotion and holds great promise for expanding the knowledge base of family preservation and health enhancement among high-risk populations. Infant massage holds great potential for promoting mother-infant bonding, as mothers engaged in IM are likely to gain confidence in applying specific massage strokes, be encouraged to assess their infant’s body signals and respond appropriately, and ultimately become empowered to help their babies release discomfort. Nurse educators, public health professionals, maternal-child health practitioners, and substance abuse service providers may use data from this study to design client-tailored parenting programs, blending IM as both a health promotion intervention and therapeutic tool.

**D. Policy Implications.** Our study findings add to the existing database to promote evidence-based practice in addiction treatment programs and expand the existing scientific knowledge regarding maternal-child health and well-being. The incorporation of psychomotor activity in the form of infant massage into parenting enhancement programs can promote the quality of mother-infant interactions and potentially improve maternal and infant health outcomes. Thus, incorporation of these findings into maternal-child health policy development merits attention.

E. **Suggestions for Further Research.** Building on the positive outcomes of the present study, while remaining cognizant of the methodological challenges described above, we hope to conduct a six-year follow-up study on the present sample of mother-infant pairs to determine whether outcome differences among the IMPEP, PEP, and CON groups persist over several years. Similar to the cross-cultural application of the PEP, the IMPEP model should be replicated in other addiction treatment settings to validate its effects and establish the generalizability of our findings within different cultural contexts in the larger global community. Based on our present findings, which demonstrated a high number of SAMs to be overweight and hypertensive, intervention studies to promote physical activity and improve dietary practices among low-income, multi-ethnic, and multi-cultural mothers should be pursued. In fact, a pilot study addressing this health problem is now under IRB review and will soon be implemented at Florida International University. It is projected that an RO1 research grant proposal for this study will be submitted to either the NIH or private foundations for potential funding.