

## Summary of findings

### **“A follow up study of a program to promote mothers’ ability to communicate with their very-low-birthweight infant”**

Feeley et al.

September 13, 2006

This follow up study sought to answer the following questions:

***Is a follow up assessment of the PMAC program acceptable to mothers of VLBW infants when the infants are 6 months old?*** We examined to what extent we are able to enrol eligible mothers in the follow up study at 6 months. We calculated the percentage of mothers who agreed to participate, of the total number who were eligible to participate in the follow-up study. 24 mothers began the program and of these 24 mothers, 20 (83%) completed the 6 month follow up assessment. Four mothers withdrew from the study after starting the program, but they withdrew from the earlier phase of the study (they did not complete the 1.5 month follow up). Of the four women who withdrew, two women had returned to work or school and no longer had time to participate. 100% (20/20) of the mothers who were eligible for the 6 month assessment took part in the assessment. This evidence suggests that the 6 month follow assessment phase of this study is very acceptable to mothers.

***Is it feasible to conduct an assessment of both mother and infant outcomes when the infants are 6 months old?*** To assess the feasibility of this follow up study we also examined adherence to the planned methods of data collection by computing the percentage of measures completed as planned for each study measure administered at the 6 month assessment (i.e., ***STAI, PBS, EAS, PPQ and Bayley***). We found that we were able to obtain 100% of the data for the 20 mothers who remained in the study at the 6 month follow up. All 20 mothers who participated completed all of the measures, and we were able to obtain developmental assessments on all 20 infants. We also found that our research staff were readily able to administer the questionnaires to mothers and assess infant development in one home visit. This was done by having the psychologist assess the infant’s development, while the research assistant administered the

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questionnaires to the mother. With this format, the visits were about 60 minutes long, thus very feasible and cost-effective.

#### ***Is it feasible to use the EAS to assess mother-infant interaction in VLBW infant-mother dyads when the infants are 6 months old?***

We examined monthly team meeting minutes to determine what methodological and logistical difficulties were encountered. It has been relatively easy to videotape mother-infant interaction in the home at 6 months of age. There were only two logistic problems that arose during the observations. We found that: 1) it was important to place the infant in an infant seat for the interaction observation in order to be able to see the infant’s face when scoring the videotape, and 2) at times when videotaping in the home other persons would come into the room. In this case, the RA was instructed to stop the filming and recommence once the person left the room.

The scoring of the interaction data with the EAS is still under-way. Nonetheless at this time we can conclude that it is feasible to use the EAS. The major methodological issue that has arisen is that we have noted that relatively little interactive behaviour on the infants’ part, and that we have seen limited variability in the infant scores on the measure for this reason. Although the EAS has been used with 6 month old full term infants, its use with 6 month preterm may be more limited for this reason. Based on these findings, we have decided to use another measure of mother infant interaction in our up-coming randomized controlled trial. This new measure we think will be better suited to preterm infants at 6 months of age, as it has been used with full-term newborns and includes infant behaviours that will be exhibited by preterms at 6 months (i.e.; eye movements).

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#### ***What effect does the intervention program have on mother’s anxiety, beliefs about their parenting competence and post-traumatic stress?***

The sample size for this study is small and insufficient to allow statistical analyses. Nonetheless we did conduct exploratory analyses to determine if the intervention appears to have a positive longer-term effect on: 1) mother’s anxiety (***State-Trait Anxiety Inventory (STAI)***), and 2) post-traumatic stress symptoms (***Postpartum Post-traumatic stress Questionnaire (PPQ)***). We expected that participation in the intervention program would decrease both mothers’ anxiety & post-traumatic stress.

To do so, we examined the percentage of mothers whose scores improved from pre-intervention to the ***6-month*** post-intervention assessment, and we also considered the change in the percentage of mothers who scored in the clinical range on a measure from pre- to post-intervention.

#### **Anxiety**

We found that 15 of the 21 mothers (71%) anxiety scores decreased by more than 7 points from pre-to immediately post intervention (1.5 months of age). A decrease of more than 7 points on the STAI is believed to be clinically significant. Furthermore, 6/18 (33%) mothers anxiety decreased by more than 7 points from the 1.5 month post intervention assessment to the 6 month follow up assessment. Thus a large percentage of the mothers who participated experienced a clinical meaningful decrease in their anxiety level from pre-intervention to post-intervention and again from the 1.5 months post-intervention assessment to the 6 month post-intervention assessment.

A standardized score on the STAI of greater than 60 is considered to be in the clinical range and indicative of high anxiety. 53% of the mothers (18/34) were found to be highly anxious pre-intervention and 0% at 1.5 months. However, at the 6 month

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follow up one mother was found to be highly anxious (1/19). These findings also indicate that maternal anxiety decreased over time.

#### **Post-traumatic stress**

On the measure of PTS that we used in this study a score of > or equal to 6 is considered to reflect post-traumatic stress disorder. We found that 61% of the mothers (20/30) scored in the clinical range on the PPQ pre-intervention, 33% (7/21) at 1.5 months and 26% (5/19) at 6 months.

From pre-intervention to the post intervention assessment at 1.5 months, 6/13 (46%) mothers who scored in the clinical range at pre-intervention, no longer were in the clinical range. From the 1.5 month assessment to the 6 month post assessment, 5/8 (63%) mothers who scored in the clinical range at 1.5 months were no longer in the clinical range at 6 months. These results suggest that mothers’ post-traumatic stress symptoms decreased from pre-to post-intervention.

It is very important to note that as this pilot study did not include a control group, it is impossible to determine whether these decreases in maternal anxiety and post-traumatic stress symptoms is a result of the intervention program, and not just a reflection of change that would occur with time after the infant’s birth.

#### **Summary**

The results of this follow-up phase of our pilot study indicated that the study design for the 6 month follow up is very feasible. We were able to retain all of the mothers in the 6 month follow up who were eligible to participate. Mothers found the home visiting and data collection format to be acceptable. Thus, we have incorporated this phase into the design of our current RCT funded by CIHR 2006-2010.