CHAPTER 7
TREATMENT VISITS AND FOLLOW-UP

7.1. Purpose
The objective of the periodontal treatment is to eliminate as much periodontal infection and gingival inflammation as possible using conventional mechanical non-surgical scaling and root planing, mechanical debridement, oral prophylaxis and oral hygiene reinforcement.

7.2. Timing / Scheduling of the Treatment Visits
Eligible and enrolled participants will have been randomized to one of 2 groups, Group 1 will have prenatal treatment, and Group 2, the control group, will have post-partum Treatment. Both groups will receive the same treatment. All participants will receive post-partum recommendations for dental care follow-up.

Treatment visits for participants randomized to Group 1 should be scheduled and completed prior to 23\textsuperscript{8} weeks gestation. Since delivery for this group will generally take place within 20 weeks of the periodontal treatment, additional supportive maintenance visits are not planned.

Periodontal treatment for participants in Group 2 should be scheduled at the post-partum exam, and completed as soon as possible, preferably within four weeks of delivery.

Treatment visits will be scheduled as a 1.5-hour appointment. Treatment will normally be provided within one to two visits. If for some extenuating circumstance treatment cannot be completed within two visits up to 4 visits will be scheduled within a 2-week period to complete therapy. Scheduling of all treatment visits for Group 1, should be made with the possibility that additional visit(s) may be necessary to complete the treatment, and would have to be completed prior to 23\textsuperscript{8} weeks gestation.

7.3. Staffing
The MOTOR periodontal therapy procedure will be performed by a dental hygienist, periodontal resident, or periodontist under the supervision of the Enrollment Site’s Periodontal Investigator (PI). Therapists must be licensed and experienced.

The therapists must be knowledgeable about the maximum allowable doses for any local anesthetics used based on the participant’s weight, age and medical status, taking into special consideration safety during pregnancy.
7.3.1. Training and Monitoring

The Enrollment Periodontal Site PI will monitor the periodontal hygienist, periodontal resident or periodontist to ensure that all treatments are performed according to the study protocol, as specified in this documents. Treatment is a standard treatment (see Section 7.4.1).

7.4. Sequence of Procedures and Forms

The following procedures and data collection forms are required for treatment:

- **Periodontal Treatment**
  - Scaling and Root Planing
  - Oral Prophylaxis
  - Oral Hygiene Instructions
- **Treatment Visit Form (TVF)**

7.4.1 Scaling and Root Planing

Each participant will receive supra- and subgingival scaling and root planing using a combination of hand and ultrasonic instruments. All detectable non-mineralized and mineralized tooth and root accretions will be removed and the tooth roots clinically smoothed. An explorer used for calculus detection (i.e. 17, ODU 11/12).

Curetts and scalers may be used for hand instrumentation. Ultrasonic instrumentation will be accomplished using a Dentsply Cavitron SPS unit or similar ultrasonic instrument. Ultrasonic handpiece inserts will include Dentsply FSI slimline inserts or other similar instruments as appropriate.

Local anesthesia, using topical anesthetics, infiltration or regional nerve blocks, will be used as needed for patient comfort. The minimum dose required for adequate anesthesia should be used. Allowable topical anesthetics are 5% lidocaine, 20% benzocaine and 1% dyclonine HCL. Preferred injectable anesthetics include 2% lidocaine (e.g., Xylocaine) with 1:100,000 epinephrine; 4% prilocaine without a vasoconstrictor. The Food and Drug Administration (FDA) considers lidocaine and prilocaine as category B, i.e., relative safe drugs for use in pregnant women.

Supragingival or subgingival irrigation with antimicrobial agents (e.g., chlorhexidine) or the use of local or systemic Antibiotics are not allowed. (Recall that women who require antibiotic premedication prior to periodontal scaling are excluded from participating).

Acetaminophen (up to 625mg) may be administered for immediate post-operative discomfort as needed. No other analgesic agents should be used without prior consultation with the subject’s obstetrician.
7.4.2 Oral Prophylaxis

Randomized participants will receive full-mouth polishing with prophy paste and rubber cup at the conclusion of scaling and root planing procedures. Polishing should not be a substitute for the complete removal of calculus and through scaling and root planing. This supra and subgingival polish will remove any additional remaining plaque or stains from the teeth. Selection of an appropriate grit of the prophy paste is important. Care should be taken to use the finest grit necessary to remove the remaining plaque or stain.

7.4.3 Oral Hygiene Instructions

Instruction will be provided in the modified Bass sulcular method of tooth brushing. The therapist will review cleaning facial and lingual surfaces of both anterior and posterior teeth. After receiving these instructions, the participant will be asked to demonstrate this method of brushing, in her own mouth.

Participants will also be instructed in using dental floss. Participants will be shown how to clean 1-2 mm subgingivally on proximal tooth surfaces and should demonstrate use of the floss in their own mouths. Participants will be instructed to floss once per day in the evening. Unwaxed floss, dental tape, yarn, interdental (proxy) brushes, mechanical flossing aids, or other mechanical interdental cleaning devices may be used if, in the therapists opinion, use of these products will facilitate daily cleaning.

7.4.4 Periodontal Treatment Form (DTF)

The data collection form DTF, is to be completed at all MOTOR treatment visits (for either randomized group), by the treating dental professional, documenting adherence to study protocol.

A DTF is to be completed at each treatment visit, regardless of the number of visits necessary. Forms are identified as visit 03 at the treatment visits for the prenatal group, and as visit 05 for treatments occurring post-partum. Sequence numbers will be used to indicate the multiple visits necessary to complete treatment. Refer to the DTF QXQ’s for specific instructions on completing this form.
7.5. Safety Issues Regarding Treatment Visits

Data on participant demographics, medical history, vital signs, medications and infections will have been collected as part of the patient chart for review by the treatment staff. Prior to treatment, good clinical practice requires current medical history and medication use to be queried, and vital signs monitored. This information should be recorded on the medical history forms that each center’s institution uses to evaluate treatment considerations in the clinical setting. This form is not considered study data, and does not replace any of the study data collection forms. It should be considered part of the patient’s study clinical chart and updated with each dental treatment or examination.

Participant adverse event monitoring, as well as overall study monitoring for safety and compliance occur throughout the study. Study procedures are in place for detecting, assessing, treating, and reporting any safety issues arising, see Chapter 10 of the MOTOR MOP.

7.5 Participant Follow-up Post Treatment

The study protocol does not include periodontal follow-up visits other than at the post partum visit. At the treatment visits, participants will have been given contact names and numbers if they experience any dental symptoms or concerns. An additional telephone or prenatal OB visit will be scheduled 2 weeks post treatment for those participants who receive the prenatal treatment. A list of Suggested Questions for Post-Treatment Telephone Follow-up is on the next page. All dental complaints and symptoms reported will be immediately followed-up by one of the dental staff members, OB concerns followed by the OB staff.

Participants will continue with their OB surveillance through parturition. Regular prenatal visits continue and become more frequent as a participant gets closer to their due date. MOTOR staff perform OB chart reviews on a weekly basis to note any adverse events or treatments provided (outside of the routine), or any missed or rescheduled visits that might indicate problems.
Suggested Questions for Post-Treatment Telephone Follow-up

The following questions are available for a telephone interview if the participant cannot return for the two week post treatment check for any dental symptoms or concerns.

During the telephone interview, questions 1 and 2 should be asked of all participants who completed dental therapy post-partum. If the answer to question 1 indicates that the participant may have had a problem, or if you receive a “Yes” to question 2, then questions 3 through 8 should be asked. If there is no indication of a problem you may stop after question 2.

If the participant has had a dental problem since therapy, she should be scheduled for a follow-up visit to evaluate her for a periodontal adverse event.

All participants:

1. How do your gums feel after your dental cleaning?  
   (If there is any indication of a problem, answer all questions)

2. Have you had any problems since your tooth cleaning?  
   Yes ➔ proceed to questions 3-8  
   No  
   Don’t Know ➔ proceed to questions 3-8

For Participants who have experienced a problem or answered “Yes” or “Don’t Know” to question two, continue with questions 3 through 8.

3. What dental problems have you had since your tooth cleaning?  
   (schedule a follow-up visit to evaluate for any periodontal AEs)

4. Are your gums tender?  
   Yes ➔ ➔ How long have they been tender?  
   No  
   Don’t Know ➔ (If only since the dental cleaning, schedule a follow-up visit to evaluate for any periodontal AEs)

5. Have your gums bled since the cleaning?  
   Yes ➔ schedule a follow-up visit to evaluate for any periodontal AEs  
   No  
   Don’t Know

6. Did you have bleeding gums before the cleaning?  
   Yes ➔ ➔ Has the bleeding increased since your tooth cleaning?  
   No  
   Don’t Know  
   (If yes, schedule a follow-up visit to evaluate for any periodontal AEs)

7. Are any of your gums swollen?  
   Yes ➔ schedule a follow-up visit to evaluate for any periodontal AEs  
   No  
   Don’t Know

8. What color would you say your gums are after your cleaning?  
   Red to Purplish ➔ schedule a follow-up visit to evaluate for any periodontal AEs  
   Red ➔ schedule a follow-up visit to evaluate for any periodontal AEs  
   Pink to Red ➔ schedule a follow-up visit to evaluate for any periodontal AEs  
   Pink  
   Pink to White