Commentary: Methodological Issues in Clinical Research

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Intervention techniques for infant sleep problems have been a fruitful research area. Most research has consistently documented significant improvements in most infants following interventions ranging from short-term behavioral intervention (Mindell, this issue) to psychodynamic treatments (Daws, 1989). These encouraging results, however, leave questions yet to be resolved. If most interventions are very effective, what are their actual curative factors? What are the essential elements in treating infant sleep problems and which technique-specific components are redundant or irrelevant? These basic clinical questions could be resolved by (a) outcome research based on methodology that compares the results of various groups receiving interventions that vary only by the specific element under inquiry (e.g., clinical sessions versus phone interventions) or (b) process research that addresses the influence of specific elements of interventions, for example, the impact of addressing family issues in behavioral interventions (see Shirk and Russell, 1996, for a review of these methodological issues).

The search for the essential components of these interventions may lead to the conclusion that most modes of interventions are effective and that there are common elements (overt or covert) to all effective intervention methods (e.g., emotional support to the weary parents, or introducing the concept that infants need to learn self-soothing). However, it is also possible that each method intervenes at a different level (e.g., parent-infant dyad versus family system), and thus each method has its own pathways for change (Stern, 1995). For instance, a psychodynamic intervention may focus on alleviating parental separation anxiety from the infant, which will be followed by a greater capacity of the parent to behaviorally set limits and change bedtime behavior and eventually solve the child’s sleep problem. A behavioral intervention, on the other hand, which is directly focused on setting limits, may eventually lead to alleviated parental separation anxiety or increased tolerance to it (Sadeh & Anders, 1993).

Another important methodological issue is the necessity to employ objective sleep assessment methods in clinical research. Sleep disturbances, such as night-wakings, can now be documented with relatively nonintrusive methods (see Thomas & Acebo, 1995, for a review). This is a real asset to clinical research, which often only assesses subjective complaints. It has been repeatedly documented that parents are good reporters of their infant sleep schedule, but when it comes to sleep quality measures (e.g., number of night-wakings, duration of night-wakings) parents are very poor reporters because they can only report what comes to their awareness, usually when the infant signals and calls their attention (Sadeh, 1994; 1996). Furthermore, it has been demonstrated that when parents are asked to report their infant’s night-wakings on a daily basis (the common research practice in this area), they often lose motivation or energy to do so (Sadeh, 1994; 1996). The result might be that fewer and fewer night-wakings are being reported with time progression due to this attrition process. Needless to say, such a pattern can lead to artificial or exaggerated positive intervention effects. In addition to this specific risk for error, some of the most interesting questions cannot be answered without...
employing objective measures. For instance, even the basic question of what really changes during successful intervention cannot be fully understood. Do infants learn to sleep through the night without any night-wakings or do they learn not to signal and soothe themselves back to sleep when they do wake? The underlying process that leads to successful intervention for sleep problems and the use of objective measures to assess sleep outcomes are two important areas for future research.

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References


