A recent randomized controlled trial, funded by the National Institute of Health, was done at Penn State University. Nurses taught THB techniques to breastfeeding mothers and gave each a THB DVD, a white noise compact disc, and a swaddling blanket. Intervention babies slept an extra \( \frac{1}{2} \) to 1 hour per night (\( P < .05 \)).

A University of Arizona survey (n = 225) showed THB classes significantly boosted parental reports of self-efficacy (\( P < .001 \)). Before the class, 40\% of expectant parents reported moderate, marked insecurity about being able to calm their baby’s crying. After the class that dropped to 0.5%.\(^7\)

Today, more than 2000 certified educators teach THB techniques in hospitals and clinics across the United States (including more than 1000 educators in the departments of health of Pennsylvania, Minnesota, Wyoming, Connecticut, and Massachusetts and in numerous regional shaken baby prevention programs). Another 2000 educators are currently in training.

The need to discover an effective intervention to reduce infant crying is especially pressing in light of the recent failure of the highly promoted anti-Shaken Baby Syndrome intervention, Period of PURPLE Crying.\(^6\) In a large randomized controlled trial, babies whose parents were taught PURPLE reported a 10\% increase in irritability. That is of great concern because crying is a primary risk factor for Shaken Baby Syndrome.

Although McRury and Zolotor’s\(^1\) study is seriously flawed, other well-designed studies are being planned and conducted to evaluate THB techniques. Hopefully they will yield sufficient information to allow further evaluation of this approach.

Simple, scalable, inexpensive interventions that can reduce infant crying are urgently needed to spare human suffering and reduce the billions of dollars of expenditures resulting from the numerous serious health risks that this stressful experience can trigger.

Harvey N. Karp, MD
University of Southern California School of Medicine
Los Angeles
dr.karp@thehappiestbaby.com

Conflict of Interest: The author developed The Happiest Baby video and profits from the sale of books and DVDs.

References

The above letter was referred to the author of the article in question, who offers the following reply.

Response: Re: A Randomized, Controlled Trial of a Behavioral Intervention to Reduce Crying among Infants

To the Editor: We appreciate the thoughtful letter written by Dr. Karp in response to the recent randomized controlled trial of The Happiest Baby on the Block (THB) video techniques, a proprietary program which he has designed.\(^1\)

We find his critiques mostly fair and fully acknowledged in our publication. Early trials of new interventions are often small and subject to the risk of a type II error. However, small trials can help identify unforeseen consequences and determine the appropriate sample size for larger trials. The only significant finding of the article was that mothers in the intervention group reported more stress at 12 weeks compared with parents in the control group (\( P = .01 \)).\(^2\) There was a tendency toward more crying by the babies in the intervention group at every time point (ie, \( P = .04 \) at 8 weeks), but this did not reach our a priori level of statistical significance.\(^2\) Given that this study showed more crying at every time point among babies whose mothers received the THB video intervention, these findings are not useful for supporting a larger trial of THB techniques as delivered.

A drop out rate of 30\% is a concern, but not out of the ordinary. We did compare participants that remained to those that dropped out and found little important difference.

We are puzzled by Dr. Karp’s concern about contamination. We did not advise mothers in the control group to swaddle their babies. Many mothers in both groups reported the use of swaddling, bouncing, swinging, and pacifiers to calm their babies. It is possible that an intervention such as THB technique will be of little use if such behaviors are either culturally normative or hard wired.

We appreciate Dr. Karp’s concern about the lack of “use” of the intervention. This is akin to the ever-present...
In short, although we agree with most of the limitations presented by Dr. Karp, we believe that our study and the peer-reviewed publication in this journal represent a significant addition to the quality of literature available to assess the effectiveness of the THB program. We look forward to future, rigorous, peer-reviewed studies of the THB program.

Jonna M. McRury, MD
Department of Pediatrics, University of Toledo, Toledo, OH
jmcrury@aol.com

Adam J. Zolotor, MD, MPH
Department of Family Medicine, University of North Carolina at Chapel Hill, Chapel Hill

References
doi: 10.3122/jabfm.2010.05.100158