A recent randomized controlled trial, funded by the National Institute of Health, was done at Penn State University.[6] 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 ½ 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.[8] 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

1. McRury JM, Zolotor JM. A randomized, controlled trial of a behavioral intervention to reduce crying among infants. J Am Board Fam Med 2010;23:315–22.
2. Karp HN. The happiest baby on the block: the new way to calm crying and help your baby sleep longer. Available at www.happiestbaby.com. Accessed 21 July 2010.
3. Karp HN The happiest baby on the block: the new way to calm crying and help your baby sleep longer. New York, NY: Bantam Dell; 2002.
4. Karp HN. The "fourth trimester": a framework and strategy for understanding and resolving colic. Contemporary Peds 2001;21:92–114.
5. Adler M. Promoting maternal child health by teaching parents to calm fussy infants at the Boulder, Colorado, Department of Health. Presented at the CityMatCH Urban Leadership Conference, Denver, CO, August 26–28, 2007.
6. Paul IM, Birch L. Pediatric The relationship between infant feeding, sleeping, and weight gain. Presented at the Ambulatory Society Meeting, Baltimore, MD, May 4, 2009.
7. UA Evaluation Research and Development Team. SEABHS: Data Summary of Happiest Baby on the Block Retrospective Post-Test Surveys: FY: 2007–2008. Available at http://www.thehappiestbaby.org/thbe-univ-az-study-2008.pdf. Accessed 21 July 2010.
8. Barr RG, Rivara FP, Barr M, et al. Effectiveness of educational materials designed to change knowledge and behaviors regarding crying and shaken-baby syndrome in mothers of newborns: a randomized, controlled trial. Pediatrics 2009; 123:972–80.

doi: 10.3122/jabfm.2010.05.100139

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[1] in response to the recent randomized controlled trial of The Happiest Baby on the Block (THB) video techniques,[2] a proprietary program which he has designed.[3]

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 maong 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

challenge of nonadherence. In the real world, people who pick up a copy of THB book or video either read it/watch it or not, and the either use it or not. Given that the program's website reports that more than 350,000 copies have been sold,[3] it seems time to test the effectiveness of a limited intervention. It is plausible that training educators to work with families may be more useful. We are impressed that more than 2000 certified educators have been trained. We hope that this technique is rigorously evaluated.

We applaud the ongoing research of THB techniques. None of the citations provided by Dr. Karp are available in the peer-reviewed literature. The Department of Public Health program has an extended abstract available.[4] This is a small intervention that serves as an add-on to an existing home visiting program. There is no appropriate comparison group. It is likely that the babies in the intervention group started to cry less as they aged (like all babies) and their parents gained confidence in parenting as they gained experience. Dr. Karp's claim of an "immediate, dramatic, and continuing improvement in ability to calm a crying infant" is not supported by available study documentation, and the methods used for measurement are not reported. There are no available details regarding the randomized controlled trial that was funded by the National Institute of Health.

The University of Arizona survey is only available at the THB website. The education and analytic methods are poorly described. This report presents the response of parents in classroom settings who were given a survey of questions before and after implementation of the techniques that was designed to illicit positive change from the material presented.[5]

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

1. Karp HN. Re: a randomized, controlled trial of a behavioral intervention to reduce crying among infants. J Am Board Fam Med 2010;23:689–90.
2. McRury JM, Zolotor AJ. A randomized, controlled trial of a behavioral intervention to reduce crying among infants. J Am Board Fam Med 2010;23:315–22.
3. Karp H. The happiest baby. Available at http://www.happiestbaby.com. Accessed 5 July 2010.
4. Adler M. Promoting maternal child health by teaching parents to calm fussy, crying infants. Presented at the CityMatCH Urban Leadership Conference, Denver, CO, 28 Aug 2007.
5. UA Evaluation Research and Development Team. SEABHS: Data summary of the happiest baby on the block retrospective post-test surveys: FY: 2007–2008. Available at http://www.happiestbaby.com/wp-content/uploads/files/THBE_Univ_AZ_study_2008.pdf. Accessed 5 July 2010.

doi: 10.3122/jabfm.2010.05.100158