

NEURODEVELOPMENT

Helmet therapy in infants with positional skull deformation: randomised controlled trial

Background

Prevalence of positional head deformities increased dramatically after the 1992 AAP recommendation to place infants in a supine position to avoid sudden infant death. Skull deformation is considered a cosmetic condition and is increasingly seen as a marker for developmental delays. Helmet therapy is a widely used treatment option in moderate to severe cases. Since conclusive evidence from randomised trials is lacking, the clinical benefit of helmet therapy compared with the natural course of skull deformation remains unknown. Van Wijk and coworkers tested helmet therapy in a randomised clinical trial.

Summary of results

The change score for both plagiocephaly and brachycephaly was equal between helmet therapy and natural course, with a mean difference of -0.2 (95% confidence interval -1.6 to 1.2 , $P=0.80$) and 0.2 (-1.7 to 2.2 , $P=0.81$), respectively. Full recovery was achieved in 10 of 39 (26%) participants in the helmet therapy group and 9 of 40 (23%) participants in the natural course group (odds ratio 1.2, 95% confidence interval 0.4 to 3.3, $P=0.74$). All parents reported one or more side effects.

Strength

The HEADS trial is the first study to provide evidence from a randomised controlled trial on the long term effectiveness of helmet therapy for skull deformation. Strengths of this study include the randomised allocation of treatment, nested design, high follow-up rates, use of various long term outcomes measures, and both plagiocephaly and brachycephaly being studied.

Limitations

Limitations of this study include the difference of severity of skull deformation at baseline between both arms of the trial, a low participation rate, limited generalisability of study results to specific subgroups of infants, and no assessment of daily wearing time of the helmet.

Practical conclusion

Based on the equal effectiveness of helmet therapy compared with the natural course, the high prevalence of side effects and the high costs of treatment, the authors discourage the use of helmet therapy as a standard treatment for healthy infants with moderate to severe skull deformation.

Renske M van Wijk et al., "Helmet Therapy in Infants with Positional Skull Deformation: Randomised Controlled Trial," *BMJ (Clinical Research Ed.)* 348 (2014): g2741.

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