Expensive helmets do not improve outcomes in healthy babies with positional skull flattening
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Babies who have skull deformation because they lie in the same position most of the time do not benefit from wearing a corrective helmet, finds research published today in BMJ.

There was no meaningful difference in skull shape at the age of two years between children treated with therapy helmet and those who received no active treatment. Both groups showed similar improvements although only a quarter made a full recovery to a normal head shape, according to the team of researchers based in The Netherlands.

Around one baby in five under the age of six months develops a skull deformation as a result of lying in the same position for long periods, a condition known as positional skull deformation or plagiocephaly. It has become more common since the launch of campaigns such as Back to Sleep, which encourage parents to lay their babies on their backs to sleep to reduce the risk of sudden infant death syndrome (SIDS).

Helmet therapy is a controversial treatment for this condition. It is not available on the NHS, meaning some parents opt to pay privately, with bills running to over £2,000. But it is commonly used in some countries – in the Netherlands, for example, 1 to 2% of all babies have helmet therapy.

There has been little previous research comparing helmet therapy with no active treatment so the researchers conducted the HEADS study – the first randomised trial to compare the long-term results of the two approaches.

They identified 84 healthy full-term babies who had a moderate or severe positional skull deformation – either plagiocephaly, where one side of the head becomes flattened and the ears can become misaligned, or brachycephaly, where the back of the head is flattened and the front of the skull may bulge.

Half the babies were randomly allocated to wear a rigid, custom-made, closely fitting helmet for 23 hours a day for a six-month period, starting at the age of six months. The other half had no treatment.

When the babies turned two years, detailed measurements of their head shape showed there was no significant difference in the degree of improvement in skull shape between the two groups. Some 25.6% of babies who had helmet therapy had a full recovery at two years of age, compared with 22.5% of those who had no treatment – again, not a significant difference.

All the parents whose babies wore a helmet reported side-effects. These included skin irritation (in 96% of babies), parents feeling hindered from cuddling their baby (77%), an unpleasant smell (76%), sweating (71%) and pain (33%).

The parents of both groups were generally satisfied with their child's head shape at two years of age – the average satisfaction score was 4.6 out of 5 among those whose babies had worn helmets compared with 4.4 among those whose babies had no treatment.

The researchers say more studies will be needed to confirm their findings but they conclude: 'Based on the effectiveness of helmet therapy, and the high prevalence of side-effects and high costs, we discourage the use of a helmet as a standard treatment for healthy infants with moderate to severe skull deformation.'

They point out that only a quarter of the babies in either group made a full recovery by the age of two years, meaning prevention is important. Previous
studies suggest laying a baby on its tummy while awake protects against positional skull deformities. Still, it remains vital for parents to continue laying babies on their backs to sleep to reduce the risk of SIDS.

Positional skull deformities can develop in the early months of life because a baby's skull is growing fast and the skull bones are still soft enough to change shape as a result of pressure.

In an accompanying editorial, Professor Brent Collett from the University of Washington School of Medicine, says "parents would want to know whether treatment would result in improvements above and beyond what would be expected by doing nothing at all."

He says that unfortunately this study suggests that helmets offer no treatment effect and as such there are several important next steps for future research.

He adds that it would be "of interest to learn whether children with the most severe PPB (positional plagiocephaly and brachycephaly), who were excluded from this trial, show meaningful improvement" and that additional work "incorporating behavioural and public health strategies to promote 'tummy time' and similar positioning strategies should be explored."
