



# ECHO

Environmental influences  
on Child Health Outcomes

A program supported by the NIH

## Study Summary

### ***“Eat, Sleep, Console” approach shown to be more effective in caring for newborns with neonatal opioid withdrawal syndrome***

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#### Who sponsored this study?

This clinical trial is a collaboration between the [National Institutes of Health \(NIH\) Environmental influences on Child Health Outcomes \(ECHO\) Program](#) and the [NIH’s Eunice Kennedy Shriver Institute of Child Health and Human Development \(NICHD\)](#), funded through the [NIH Helping to End Addiction Long-term® Initiative \(HEAL\)](#).

#### What were the study results?

Researchers found that the “Eat, Sleep, Console” (ESC) care approach is more effective for the treatment of infants with neonatal opioid withdrawal syndrome (NOWS) than usual approaches to care. ESC focuses on care without the use of medications, and includes holding, swaddling, and rocking the baby in a quiet, calm environment.

In this clinical trial, infants cared for with ESC were medically ready for discharge after an average of 8.2 days, whereas infants cared for with usual approaches were medically ready for discharge after 14.9 days. That means that babies were, on average, able to go home 6.7 days sooner. Newborns cared for with ESC were also 63% less likely to receive medication as part of their treatment (19.5% in the ESC group received opioid therapy, compared to 52% in the Finnegan Neonatal Abstinence Scoring Tool [FNAST] group). Safety outcomes at three months of age were similar between both groups.

#### What was the study’s impact?

Newborns exposed to opioids before birth may develop symptoms of NOWS. These symptoms may include tremors, excessive crying and irritability, and problems with sleeping and feeding. In the United States, at least one newborn is diagnosed with NOWS every 24 minutes. There has not previously been strong evidence to support a standard approach to the care of babies with NOWS, and medical care for these babies has varied widely across hospitals.

This study gives hospitals an evidence-based approach to care for babies with NOWS. Compared with usual care using traditional scoring approaches, the ESC care approach substantially shortens the time infants spend in the hospital. The ESC approach has also been shown as safe as usual care approaches after discharge through early infancy.

## Why was this study needed?

Hospitals have different approaches for caring for these babies. They often use FNAST to assess newborns with NOWS. The FNAST is an extensive scoring system that assesses signs of withdrawal in more than 20 areas. Concerns have been raised about its subjectivity and overestimation of the need for opioid medication.

The ESC care approach was developed about eight years ago and is growing in popularity in some nurseries, but this method had not previously been rigorously tested. ESC assessments are centered on an infant's ability to eat, sleep and be consoled without the introduction of medications, and this approach keeps mother and baby together, empowering families to play a larger role in the care of their infants. However, the widespread adoption of ESC without solid evidence of its effectiveness and safety has raised concerns about potentially undertreating infants or discharging them too early. This study tested the extent to which ESC might be a better way to care for babies with NOWS.

## Who was involved?

The study examined the hospital outcomes of a diverse group of 1,305 opioid-exposed infants from 26 hospitals across the U.S. The study is part of the [Advancing Clinical Trials in Neonatal Opioid Withdrawal](#) (ACT NOW) Collaborative, which brings together two existing pediatric research networks: the [NICHD Neonatal Research Network](#) and the ECHO Program's [Institutional Development Award \(IDeA\) States Pediatric Clinical Trials Network \(ISPCTN\)](#).

## What happened during the study?

The researchers randomized 26 hospitals to transition from FNAST-based care to the ESC care approach at different times. They then evaluated each method based on how soon infants were ready to leave the hospital and whether infants were treated with opioid medication to manage their symptoms.

Footnote: Results reported here are for a single study. Other or future studies may provide new information or different results. You should not make changes to your healthcare without first consulting your healthcare professional.

## What happens next?

The researchers will continue to follow up with a subset of the participating infants for two more years to see if the ESC approach has any effect on infant and family well-being.

## Where can I learn more?

Access the full journal article, titled "Eat, sleep, console approach versus usual care for neonatal opioid withdrawal," in the [New England Journal of Medicine](#).

Learn more about this clinical trial and the NIH Helping to End Addiction Long-term® Initiative on the NIH HEAL Initiative® [website](#).

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