World Health Organization

The WHO BRANCH Trial

(Breastfeeding counselling and management of growth faltering in infants aged under six months in Asia and Africa. An individually randomised trial)

Date

12th February 2025

Contact

Dr. Karen Edmond, Scientist, Newborn and Child Health and Development Unit, World Health Organization, is leading trial activities. Contact details: Karen Edmond, edmondk@who.int, phone +41 22 791 21 11

Title

BRANCH – Breastfeeding counselling and management of growth faltering in infants aged under six months in Asia and Africa. An individually randomised trial

Aims and objectives

The overall aim of this study is to determine, in infants who meet study criteria for growth faltering, the effect of intensive breastfeeding counselling and support (IBFCS) plus nutritional milk supplementation (NMS) compared with IBFCS alone on mortality, morbidity and growth at 6 completed months in low resource settings in South Asia and Sub-Saharan Africa.

The primary objective is to determine the effect of NMS on wasting free survival (alive without wasting [weight for length standard deviation score [WFL z score] < - 2 standard deviations [sd]) at 6 completed months of age.

The secondary objectives are: (i) To determine the effect of nutritional supplementation on common childhood morbidities, underweight, wasting and stunting outcomes; (ii) To determine the effect of nutritional supplementation on the primary outcome in subgroups based on birth weight and gestational age at birth (term appropriate for gestational age [AGA], preterm AGA, term small for gestational age [SGA], preterm SGA); (iii) To optimize breastfeeding support for vulnerable newborns and infants with growth faltering in low resource settings in South Asia and Sub-Saharan Africa; (iv) To develop operational guidance on breastfeeding and intensive lactation support that can be used across low and middle income countries

Design, recruitment and follow up

This is a multi-centre, parallel-group, individually-randomized, non-blinded, controlled trial implemented in seven countries: three in Asia (Bangladesh, India and Pakistan) and four in Africa (Ethiopia, Nigeria, Tanzania and Uganda).

11,000 infants greater than or equal to 28 weeks gestation are enrolled and individually randomised at 7 to <14 days of age. All infants receive IBFCS. Trained field workers follow up 1-2 weekly at the infant's home to collect growth and outcome data. When infants meet study criteria for growth faltering, all infants receive a clinical assessment. Intervention infants receive IBFCS plus NMS (prescribed quantities of term infant formula that meets Codex alimentarius standards calculated to meet the needs for catch up growth). The comparison group receives IBFCS alone. 1-2 weekly growth monitoring continues and final outcome data (mortality, wasting) are measured in all infants at 6 completed months.

Intervention group = IBFCS and NMS; Comparator group = IBFCS alone

Programmatic implications

The most important intervention to prevent and manage growth faltering in the first 6 months remains promotion and support of exclusive breastfeeding, including responsive feeding, intensive lactation management when required, and care for infant and maternal health and nutrition.

However, despite support for breastfeeding, some infants 'fail to thrive' or falter in growth in the first 6 months of life. Reasons include: chronic infections and disease, insufficient neurodevelopmental stimulation, lack of responsive caregiving, and poor maternal health and wellbeing.

There are WHO guidelines for the management of moderate and severe acute malnutrition in the first six months of life. However, there are no WHO guidelines for early intervention and management of growth faltering over this period. The optimal treatment for growth faltering in infants aged under six months remains unknown and there have been no intervention studies that have examined this issue. It is unclear if the provision of a nutritional milk supplement (NMS) has any benefit for a mother-infant dyad who are already receiving intensive breastfeeding counselling and support and if any benefits would outweigh the risks of infectious disease and metabolic imbalances from: diminishing breastfeeding, contamination of the NMS, unsafe water, and over and under dilution of feeds in real world low resource settings. Evaluation of interventions to manage growth faltering in the first six months after birth was one of the highest priority research questions identified during an informal WHO consultation in January 2019.

A breastfeeding-led nutritional strategy for managing growth faltering, and learning how to implement it, will have important benefits in reducing vulnerability and increasing resilience of infants, and thus will help them survive and thrive. Learning how to effectively deliver quality breastfeeding and support for the general population and especially for high risk young infants such as those with low birth weight is also essential for scale up into existing health systems.

Timeline

Infants are enrolled over a period of 18 months and followed up until they reach six months of age.

Geographic location

Bangladesh, Ethiopia, India, Nigeria, Pakistan, Tanzania, Uganda

Principal investigators

Bangladesh - Salahuddin Ahmed, Projahnmo Research Foundation, Dhaka, Bangladesh, Abdullah H. Baqui, Johns Hopkins Bloomberg School of Public Health, Baltimore, USA; Rukhsana Haider, Training & Assistance for Health & Nutrition Foundation (TAHN), Bangladesh
Ethiopia - Yemane Berhane, Addis Continental Institute of Public Health, Addis Ababa, Ethiopia; Wafaie Fawzi, Harvard T.H. Chan School of Public Health, Boston, USA
India - Nita Bhandari. Society for Applied Studies, New Delhi, India
Nigeria - Ebunoluwa Adejuyigbe, Obafemi Awolowo University, Ile-Ife, Nigeria
Pakistan - Fyezah Jehan, Aga Khan University, Karachi, Pakistan; Muhammad Imran Nisar, Aga Khan University, Karachi, Pakistan
Tanzania - Sunil Sazawal, Center for Public Health Kinetics (Global), New Delhi, India and Zanzibar
Uganda - Grace Ndeezi, Makerere University, Kampala, Uganda

Main external funders

Bill and Melinda Gates Foundation

For further information please contact | **Karen Edmond**
edmondk@who.int

Coordinator / sponsor	The trial is coordinated and sponsored by the World Health Organization (WHO) Newborn and Child Health and Development Unit (NBC)
Additional documents	Clinical trial registry. Australian and New Zealand Clinical Trial Registry (ANZ CTR) CTRN12624000704594 Trial protocol. WHO Ethical Review Committee number WHO ERC.0003754 . Also available on request. Statistical analysis plan. WHO BRANCH-TCU. Also available on request

For further information please contact | **Karen Edmond**
edmondk@who.int