

Harnessing Indonesia's Traditional Dairy Foods to Support Exclusive Breastfeeding: Protocol for a Multicentre Cluster Randomised Controlled Trial Study Protocol

Citrakesumasari Citrakesumasari

citrakesumasari@unhas.ac.id

Hasanuddin University

Zuhrah Taufiq

Universitas Negeri Padang

Lili Rohmawati

Universitas Sumatera Utara

Study protocol

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Abstract

Background: Exclusive breastfeeding is a key intervention for infant health, growth and development, as well as maternal health. Its continuation is influenced not only by breastfeeding knowledge and support but also by maternal dietary adequacy. Indonesia has culturally embedded, nutrient-dense traditional dairy foods, including dangke, dadiah and dali ni horbo, that may provide locally acceptable vehicles for maternal nutrition support. This study aims to evaluate an integrated intervention combining structured lactation and nutrition education with site-specific traditional dairy foods to support exclusive breastfeeding, maternal nutrient intake, breastfeeding knowledge and attitudes, and infant growth.

Methods: This prospective, open-label, multicentre cluster randomised controlled trial will be conducted in six service-area clusters across Enrekang Regency, South Sulawesi; Bukittinggi, West Sumatra; and Medan, North Sumatra, Indonesia. Clusters will be allocated to intervention or control conditions. Intervention clusters will receive structured lactation and nutrition education and counselling together with a site-specific traditional dairy food: dangke in Enrekang, dadiah in Bukittinggi, and dali ni horbo in Medan. Control clusters will receive routine maternal and infant health education without the study food. The active intervention will last 3 months, followed by monthly monitoring until infants reach 6 months of age. The primary outcome is exclusive breastfeeding at 3 months. Secondary outcomes include changes in maternal energy and macronutrient intake, breastfeeding and lactation-nutrition knowledge and attitudes, infant anthropometric Z-scores, intervention adherence, and continuation of exclusive breastfeeding to 6 months. Primary analyses will follow the intention-to-treat principle and use mixed-effects models or generalised estimating equations to account for clustering and repeated measurements.

Discussion: This protocol evaluates a culturally grounded model that integrates breastfeeding education with food-based maternal nutrition support across three Indonesian settings. The study is expected to provide evidence on the feasibility and potential effectiveness of a local-food-based intervention model for strengthening maternal nutrition support and exclusive breastfeeding. The study has received ethical approval from three institutions: Hasanuddin University (No. 2313/UN4.14.1/TP.01.02/2026), Universitas Negeri Padang (No. 100/KEPK-UNP/6/2026), and Universitas Sumatera Utara (No. 2605440-KEPK-USU).

Background

Breastfeeding is a high-impact intervention for child survival and development and for maternal health. The World Health Organization (WHO) recommends initiation of breastfeeding soon after birth, exclusive breastfeeding for the first 6 months, and continued breastfeeding with appropriate complementary feeding up to 2 years of age or beyond [1]. The 2025 Global Breastfeeding Scorecard and the 2026 global investment case indicate that progress has been made but remains insufficient, with substantial preventable health and economic losses when women do not receive adequate support to breastfeed [2, 3].

The benefits of breastfeeding extend beyond short-term nutrition. Large epidemiological syntheses associate breastfeeding with lower childhood infectious morbidity and improved long-term outcomes, while maternal benefits include lower risks of breast and ovarian cancer [4]. Scaling up effective breastfeeding protection, promotion and support requires coordinated action across health services, communities, families and policy environments [5].

Indonesia is simultaneously addressing gaps in breastfeeding and persistent child undernutrition. The latest national health profile provides current programme context for maternal and child nutrition, while the 2024 Indonesian Nutritional Status Survey reported a national stunting prevalence of 19.8%, down from 21.5% in 2023 [6, 7]. Improving nutrition throughout the first 1,000 days of life therefore requires attention to both infant feeding practices and maternal dietary adequacy.

A systematic review and meta-analysis of pregnant and lactating women in Indonesia and Malaysia found frequent inadequacy of energy, macronutrient and micronutrient intakes [8]. Human milk is biologically resilient, but maternal diet can influence selected milk components, particularly fatty-acid profiles and some vitamins and minerals; evidence for total protein, lactose and milk volume is more heterogeneous [9-11]. A meta-analysis of dietary patterns likewise suggests that human milk fat is more responsive to maternal diet than protein or lactose [12].

Maternal lifestyle and nutritional status may also shape bioactive and metabolic characteristics of human milk, although causal evidence remains incomplete and methods vary substantially across studies [13]. Observational work has associated dietary patterns rich in minimally processed foods with higher antioxidant capacity of human milk, supporting the rationale for testing food-based approaches rather than focusing on single nutrients alone [14].

Behavioural support is equally important. Theory-based breastfeeding education can improve maternal self-efficacy and exclusive breastfeeding, and multicomponent educational and supportive programmes may sustain breastfeeding during the first 6 months [15, 16]. Updated evidence also indicates that breastfeeding support interventions can increase exclusive breastfeeding up to 6 months [17]. Community and lay support and family-centred strategies may provide additional benefit when they are sustained and adapted to context [18, 19]. Evidence from Indonesia has identified maternal knowledge as an important correlate of exclusive breastfeeding, while recent work in West Sumatra highlights the role of cultural beliefs and community norms in infant-feeding decisions [20, 21].

Rationale for integrating local foods

Indonesia has a range of culturally embedded dairy foods that may serve as acceptable vehicles for additional maternal energy and protein. Dangke is a traditional cheese from Enrekang with high nutritional value and a strong local identity; recent reviews emphasise its protein content, lactic-acid bacteria and the need for standardised, safe production [22, 23]. Dadiah (also known as dadih) is a

traditional fermented buffalo-milk food from West Sumatra with probiotic potential and a growing evidence base for product development [24, 25].

Dadiah-based products contain measurable energy, protein, minerals and viable lactic-acid bacteria, and supplementation research suggests biologically plausible effects on maternal-infant microbiota and secretory immunoglobulin A pathways, although these findings do not in themselves establish improved breastfeeding outcomes [26]. In North Sumatra, dali ni horbo is a buffalo-milk food with cultural and nutritional relevance; recent analyses describe its nutrient-rich profile and identify protein and lactic-acid bacteria as potential functional-food attributes [27, 28].

The novelty of this protocol is not a claim that any of these local foods is a proven galactagogue. Rather, the trial tests whether an integrated package comprising strengthened maternal dietary support plus structured breastfeeding education can improve maternal nutrient intake and exclusive breastfeeding in real-world Indonesian communities. This framing is consistent with current evidence supporting breastfeeding counselling and maternal dietary adequacy, while recognising that evidence remains insufficient to conclude that a single food directly increases milk volume or exclusive breastfeeding [9, 17].

Methods/design

This manuscript has been structured in accordance with SPIRIT 2025 principles for randomised trial protocols, the CONSORT 2025 framework for transparent reporting, the cluster-trial extension where applicable, and TIDieR guidance for intervention description [29-32].

Study design

This study is a prospective, open-label, multicentre cluster randomised controlled trial with pre-intervention and post-intervention assessments. It will be conducted in six service-area clusters across three research centres: Enrekang Regency, South Sulawesi; Bukittinggi, West Sumatra; and Medan, North Sumatra. Clusters, rather than individual mothers, will be randomised to reduce contamination between participants exposed to the education and food components. The unit of analysis is the mother-infant dyad. Intervention clusters will receive a site-specific traditional dairy food: dangke in Enrekang, dadih in Bukittinggi, and dali ni horbo in Medan. The active intervention will last 3 months, followed by monthly monitoring until infants reach 6 months of age.

Study population

Eligible participants are breastfeeding women with a healthy singleton infant recruited at approximately 0-1 month postpartum in participating service areas. Inclusion criteria are residence in or access to the study cluster, willingness to consume the assigned local food where applicable, ability to complete study

assessments, and provision of written informed consent. Mothers or infants with medical conditions likely to materially affect breastfeeding or nutritional assessment will be excluded. Withdrawal, loss to follow-up or failure to receive the intervention will be documented without removing participants from the primary intention-to-treat analysis unless consent for use of data is withdrawn. **Detailed inclusion and exclusion criteria are presented in Table 2.**

Screening and enrolment

Potential participants will be identified through participating maternal and child health services and community networks. Trained field staff will verify eligibility, explain the study, obtain written informed consent, and collect baseline sociodemographic, breastfeeding, dietary and anthropometric data. Recruitment logs will record the numbers screened, excluded and enrolled by cluster for reporting in a CONSORT-style flow diagram [30, 31]. **The schedule of enrolment, intervention, monitoring, and outcome assessment is summarised in Table 1.**

Table 1. Participant timeline

Study activity	Baseline	Intervention	Month 3	Month 6
Eligibility/consent	X			
Cluster allocation	X			
Knowledge and attitudes	X	Monitoring	X	
24-h recall/FFQ	X	Monitoring	X	
Maternal nutrition	X	Monitoring	X	
Infant anthropometry	X	Monthly	X	X
Exclusive breastfeeding	X	Monthly	X	X
Adherence/fidelity		Weekly/monthly	X	

Note: Month 3 is the primary endpoint for exclusive breastfeeding; month 6 is the follow-up endpoint for continuation of exclusive breastfeeding and infant growth.

Table 2. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Breastfeeding woman with an infant aged approximately 0-1 month	Maternal condition that materially limits breastfeeding or study-food intake
Healthy singleton infant	Infant condition that materially affects feeding or growth assessment
Able to participate in cluster follow-up	Contraindication or allergy to the relevant study food
Written informed consent	Investigator judges participation to be unsafe or infeasible

Note: Eligibility criteria will be applied consistently across centres, with site-specific adaptations for relevant food-safety considerations.

Study procedures

The trial has three operational phases. First, preparation will include cross-centre protocol harmonisation, enumerator training, instrument validation, participant screening and baseline measurement. Second, during the intervention phase, structured education and site-specific local foods will be provided in intervention clusters, with monitoring of adherence and exclusive breastfeeding. Third, endline assessment will repeat behavioural, dietary and anthropometric measurements. A harmonised manual of procedures will be used across all centres.

Randomisation and allocation

Six service-area clusters will represent intervention and control conditions across the three research centres. Cluster allocation will be generated by an investigator or statistician who is not involved in recruitment, using a reproducible computer-generated random sequence. Allocation will be stratified by research centre so that each centre contributes both intervention and control clusters. Allocation concealment will be maintained until cluster eligibility and initial recruitment procedures have been completed, thereby reducing the risk of selection bias [29, 31].

Intervention delivery

The intervention comprises two coordinated components: (1) structured lactation and nutrition education and counselling delivered using a standard module and culturally adapted communication; and (2) a locally specific dairy food. Education is planned approximately every 2 weeks for about 60 minutes during the 3-month active intervention, with reinforcement during monitoring contacts. Behaviour-change content will cover maternal nutrient needs, exclusive breastfeeding, practical breastfeeding skills, dietary planning, problem solving and use of locally available foods. Intervention

specification follows TIDieR principles for rationale, materials, procedures, provider, dose, schedule and fidelity [32].

In Enrekang, the study food is dangke. The protocol specifies approximately 170 g/day, providing about 331 kcal and 23.8 g protein based on the cited composition; this dose was selected to approximate the additional energy and protein needs during the first 6 months of lactation. Indonesian dietary reference values specify approximately 330 additional kcal/day and 20 g additional protein/day for breastfeeding women during the first 6 months [33]. The composition and safety of each batch will be documented because traditional dangke production can vary [23]. In Bukittinggi, the study food is dadiah, whereas in Medan it is dali ni horbo. Both foods will be prepared using standardised production, storage and safety procedures appropriate to the characteristics of each product. [The daily dose and nutrient contribution of dadiah and dali ni horbo should be specified from the approved product protocols before submission.]

Control condition

Control clusters will receive general maternal and infant health education consistent with local routine services and will not receive the trial local-food supplement. To minimise contamination, the trial-specific lactation and nutrition module and study foods will not be distributed to control clusters during the active intervention. Any external nutrition or breastfeeding support received will be recorded as a co-intervention. **The sequence of study activities for intervention and control clusters is summarised in Table 3.**

Blinding

Blinding of participants and intervention providers is not feasible because the foods and educational activities are directly recognisable. Where operationally possible, field teams measuring infant anthropometry will be different from staff delivering the food and education. The analysis dataset will use coded treatment groups so that the statistician can perform the prespecified analyses without participant identifiers. These procedures are intended to reduce potential measurement and analysis bias [30].

Table 3. Intervention flow

Stage	Intervention clusters	Control clusters
Baseline	Consent + questionnaire + diet + anthropometry	Consent + questionnaire + diet + anthropometry
Allocation	Cluster assignment	Cluster assignment
Months 0-3	Lactation-nutrition education + local food	Routine/general maternal-infant health education
Monitoring	Food adherence + education attendance + exclusive breastfeeding	Exclusive breastfeeding + co-interventions
Month 3	Primary exclusive breastfeeding endpoint + repeat measures	Primary exclusive breastfeeding endpoint + repeat measures
Month 6	Follow-up of exclusive breastfeeding continuation/growth	Follow-up of exclusive breastfeeding continuation/growth

Note: Month-6 follow-up will assess continuation of exclusive breastfeeding and infant growth after the 3-month active intervention period.

Food standardisation and safety

Local foods will be prepared under harmonised hygiene and storage procedures, with lot or batch documentation and organoleptic acceptability checks before use. This is particularly important for traditional fermented products because microbial communities and nutrient composition may vary according to raw materials, fermentation and handling [23-25]. The dadiyah literature supports its potential as a nutrient-dense fermented food but also underlines the need for controlled processing and product specification [26, 34]. Dali ni horbo likewise requires standardised preparation when used as a research intervention [28].

Data collection

All centres will use harmonised case-report forms and a shared data dictionary. Baseline data will include maternal age, education, occupation, parity, nutritional status, infant birthweight, breastfeeding history, knowledge and attitudes, energy and macronutrient intake, and infant anthropometry. Follow-up will capture intervention exposure, adherence, breastfeeding status, dietary intake and growth. Data will be entered into a password-protected database with range checks, audit trails and regular cross-centre quality review.

Variables and measurements

Maternal diet will be assessed using repeated 24-hour dietary recalls supported by a food-frequency questionnaire (FFQ). Because self-reported dietary methods are vulnerable to day-to-day variation and

recall error, interviewer training, standard portion aids and repeated measurement are important. Energy, protein, fat and carbohydrate intake will be calculated using a prespecified food-composition database. Interpretation will refer to Indonesian recommended dietary allowances [33] and the documented high prevalence of nutrient inadequacy among lactating women in Indonesia and Malaysia [8].

Breastfeeding knowledge and attitudes will be assessed using a structured questionnaire validated before study implementation. Current evidence indicates that education and supportive interventions can improve self-efficacy and exclusive breastfeeding, although effects vary according to content, intensity, setting and provider; the questionnaire should therefore capture both knowledge and practical determinants relevant to the intervention [15, 16, 18].

Infant weight and recumbent length will be measured using calibrated digital infant scales and length boards with standardised duplicate measurements. Weight-for-age, length-for-age and weight-for-length Z-scores will be calculated using WHO child-growth standards. The source protocol specifies WHO Anthro for computation. Maternal nutritional status will be assessed using body mass index, where appropriate, and mid-upper arm circumference, interpreted alongside dietary intake rather than as a direct proxy for human milk adequacy [11, 13].

Data monitoring

The coordinating centre at Hasanuddin University will oversee protocol harmonisation, enumerator training, central data management and inter-site quality control. Site teams will regularly review recruitment, missing data, adherence, protocol deviations, adverse reactions to study foods and data completeness. Any serious adverse event plausibly related to a study food will be reported promptly to the responsible ethics committee and principal investigator.

Primary outcome

The primary outcome is exclusive breastfeeding at 3 months, defined as the infant receiving breast milk without other foods or liquids except oral rehydration solution, drops or syrups of vitamins, minerals or medicines, consistent with WHO definitions [1]. Status will be assessed through a standardised maternal interview covering current and interval feeding, and deviations will be recorded prospectively during monthly monitoring. The primary estimand is the effect of assignment to the integrated intervention on the probability of exclusive breastfeeding at 3 months under an intention-to-treat strategy.

Secondary outcomes

- Change from baseline to month 3 in maternal daily energy, protein, fat and carbohydrate intake.
- Change in breastfeeding and lactation-nutrition knowledge and attitude scores.

- Infant weight-for-age, length-for-age and weight-for-length Z-scores at follow-up.
- Intervention adherence, defined as the proportion of prescribed local-food servings consumed and education sessions attended.
- Continuation of exclusive breastfeeding at month 6.

These outcomes reflect two complementary pathways: behavioural support may increase breastfeeding continuation, whereas dietary support may improve maternal nutrient adequacy [8, 17]. The trial is not designed to claim that improved maternal intake necessarily changes all human-milk macronutrients, because recent systematic reviews show heterogeneous and nutrient-specific effects [9, 10, 12].

Exploratory outcomes

Exploratory analyses will examine intervention effects according to centre or local-food context, maternal baseline nutritional status, parity and infant birthweight. Food-specific contrasts will be interpreted cautiously because food type is structurally linked to geographic centre; centre-by-treatment interaction estimates therefore reflect the whole local intervention context rather than an isolated biochemical effect of the food. Qualitative notes on acceptability, barriers and facilitators may be summarised descriptively if collected.

Fidelity assessment

Fidelity will be assessed using distribution and consumption logs, returned portions where feasible, weekly or monthly contact records, education attendance, and protocol-deviation logs. A priori, adherence of at least 80% of planned food consumption is the operational target specified in the source protocol. Education fidelity will include session completion, duration and coverage of core content. TIDieR-consistent reporting will document planned and actual dose, tailoring and modifications [32].

Sample size and power calculation

[To be completed from the approved trial protocol before submission. The source manuscript provided for translation does not state the target sample size or power calculation; these details have therefore not been invented.]

Statistical analysis plan

A detailed statistical analysis plan will be finalised before unblinding of coded group labels. Descriptive statistics will summarise recruitment, baseline characteristics and adherence by study arm and centre. Continuous variables will be reported as mean (standard deviation) or median (interquartile range), depending on distribution; categorical variables will be reported as counts and percentages. Baseline

significance testing will not be used to determine whether randomisation was successful; clinically important imbalances will instead be considered in adjusted sensitivity analyses [30].

Analysis of primary, secondary and exploratory outcomes

The primary analysis will follow intention-to-treat principles. Because randomisation occurs at cluster level and measurements are repeated, the main inferential analyses will use mixed-effects models or generalised estimating equations with centre and cluster structure represented explicitly. This approach is intended to account for intracluster correlation and within-participant correlation across repeated measurements [30, 31].

Primary outcome analysis

Exclusive breastfeeding at 3 months will be analysed using mixed-effects logistic regression with treatment arm as the principal fixed effect, centre as a fixed stratification factor and cluster as a random intercept. If model convergence is unstable because only six clusters are included, a prespecified small-sample alternative, such as cluster-level analysis or a bias-corrected marginal model, will be used. Effect estimates will be reported as adjusted odds ratios and, where feasible, marginal risk differences or risk ratios with 95% confidence intervals.

Secondary outcome analysis

Repeated continuous outcomes, including nutrient intake, knowledge, attitudes and infant Z-scores, will be analysed using linear mixed-effects models containing treatment, time and treatment-by-time interaction, with participant-level repeated measures and cluster structure specified as appropriate. Skewed outcomes will be transformed or modelled using an alternative distribution. Binary secondary outcomes will be analysed using mixed-effects logistic or marginal models. Centre-specific treatment estimates will be exploratory and accompanied by interaction terms rather than separate significance tests.

Handling of intercurrent events

Intercurrent events include introduction of infant formula or complementary feeds, maternal or infant illness, temporary discontinuation of study food, transfer out of the cluster, and receipt of external nutrition programmes. For the primary exclusive-breastfeeding estimand, introduction of non-permitted feeds before the month-3 assessment will constitute non-exclusive breastfeeding rather than missingness. Other events will be documented and handled according to a prespecified treatment-policy strategy unless consent is withdrawn.

Discussion

This protocol tests a pragmatic public-health proposition: breastfeeding support may be strengthened when behavioural education is combined with culturally familiar dietary support for breastfeeding women. The intervention deliberately integrates two modifiable domains. First, structured education and follow-up target knowledge, self-efficacy, practical breastfeeding skills and sustained support, pathways supported by systematic reviews and recent trial syntheses [15–19]. Second, local-food supplementation targets maternal dietary adequacy, an important issue in Indonesia and Malaysia [8].

The study is also culturally grounded. Dangke, dadiah and dali ni horbo are not interchangeable products, but each is embedded in a regional food tradition and provides a locally meaningful vehicle for nutrient support [23, 24, 27]. This may improve acceptability and future scalability compared with externally sourced supplements. The protocol deliberately avoids asserting that these foods have already been proven to increase milk production or exclusive breastfeeding. Current evidence on human milk indicates that maternal diet can alter selected nutrients and bioactive characteristics, whereas effects on total milk volume and many macronutrients remain inconsistent [9–12].

Dangke, dadiah and dali ni horbo have strong nutritional and cultural relevance in their respective study settings. Nutrient-composition studies show meaningful energy, protein, mineral and viable lactic-acid bacterial content in dadiah-based products, while supplementation research suggests potential effects on maternal-infant microbiota and secretory immunoglobulin A [26, 34, 35]. These findings support biological plausibility and product development, but the principal clinical outcome in this trial remains exclusive breastfeeding practice. Dangke and dali ni horbo likewise require rigorous standardisation before broader health claims are made [22, 28].

Several limitations should be considered. The trial includes only six clusters, which limits degrees of freedom for cluster-level inference and creates a risk of imbalance despite randomisation. The local food is also inherently linked to geographic centre, which means centre-specific intervention effects cannot be interpreted as isolated food effects. Participant and intervention-provider blinding is not feasible, and dietary intake and breastfeeding status rely in part on self-report.

Despite these limitations, the multicentre design may provide important evidence on the feasibility and potential clinical value of a culturally contextualised, integrated intervention model. If effective, the model could inform larger, adequately powered trials and policy discussions on nutritional support for breastfeeding women while preserving the central role of breastfeeding counselling and community support [3, 5].

Declarations

Ethics approval and consent to participate

This study has received ethical approval from three institutions: Hasanuddin University (No. 2313/UN4.14.1/TP.01.02/2026), Universitas Negeri Padang (No. 100/KEPK-UNP/6/2026), and Universitas Sumatera Utara (No. 2605440-KEPK-USU). All eligible participants will receive verbal and written information regarding the study objectives, procedures, potential risks and benefits, data confidentiality, and their right to withdraw. Written informed consent will be obtained from all participating mothers before enrolment and prior to any study-related procedures, including consent for their infant's participation in study assessments. Where applicable, written permission will be obtained from the infant's parent or legal guardian. Participation will be entirely voluntary, and withdrawal from the study will not affect access to routine health services.

Consent for publication

Not applicable. This manuscript is a study protocol and does not contain identifiable participant-level data, photographs, images or personal information.

Availability of data and materials

No participant-level dataset has been generated or analysed for this protocol manuscript. Data will be generated during implementation of the trial. Following study completion, de-identified data may be made available in accordance with the approved protocol, ethical requirements, institutional policies and applicable data-sharing regulations. Data-sharing procedures will be described in the final study report and subsequent publications.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

C, ZT and LR contributed to the conception and design of the study. All authors and local research teams contribute to site implementation and data acquisition. The statistical analysis plan, manuscript drafting

and critical revision will be finalised according to the authors' actual contributions before final submission.

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