CLINICALTRIALS.GOV FINAL SUBMISSION PACKAGE

Study Protocol with Statistical Analysis Plan (SAP), Informed Consent Form (ICF), Research Instruments, Ethical Clearance, and TREND Checklist

Simulation-Based Education and Caregiving Ability Among Families of Stunted Children: A Nonrandomized Quasi-Experimental Study

Universitas Muhammadiyah Tasikmalaya

2026

FINAL STUDY PROTOCOL

ClinicalTrials.gov

Simulation-Based Education and Caregiving Ability Among Families of Stunted Children: A Nonrandomized Quasi-Experimental Study

1. Protocol Identification

This study protocol describes a nonrandomized quasi-experimental study evaluating simulation-based growth and development education among family caregivers of children with stunting. The protocol is prepared as a supporting document for ClinicalTrials.gov registration and ethical review.

The study evaluates whether adding simulation activities to a standardized educational module improves caregiver ability in caring for children with stunting. The protocol describes the background, objectives, design, intervention, outcome measures, data collection procedures, analysis plan, and ethical safeguards.

2. Protocol Version

This version represents the final protocol document prepared for submission. Any future modification affecting study procedures, participant safety, intervention, or outcome assessment should be documented as a protocol amendment.

3. Background and Scientific Rationale

Stunting is a condition of impaired growth associated with chronic nutritional deficiency, repeated infection, and inadequate stimulation. The intervention rationale is based on the need to strengthen caregiver capacity because family practices influence nutrition, stimulation, and monitoring of child development.

The intervention uses the Caregiving Module for Children with Stunting Aged 1–3 Years . The module contains information regarding stunting, nutrition, developmental stimulation, family roles, growth monitoring, and home care practices. Simulation is added to provide demonstration, practice opportunities, and feedback. The intervention module document identifies simulation activities including discussion, demonstration, caregiver practice, and feedback as core implementation components.

4. Objectives

Primary objective:

To evaluate the effect of simulation-based growth and development education on caregiver ability in caring for children with stunting.

Secondary objectives:

1. To compare caregiver cognitive ability between intervention and comparator groups.
2. To compare caregiver psychomotor caregiving ability between groups.
3. To assess the feasibility of simulation-based education in community settings.

5. Study Design

The study uses a nonrandomized quasi-experimental pretest-posttest control group design. Participants are assigned to:

1. Simulation-Based Education Group.
2. Module-Only Education Group.

The design does not use individual randomization. The comparison evaluates the additional contribution of simulation when both groups receive standardized educational information.

6. Study Population

The study population consists of family caregivers of children with stunting aged 1–3 years in the working area of Tamansari Public Health Center, Tasikmalaya, Indonesia.

The caregiver is selected because family members are directly involved in daily nutrition practices, developmental stimulation, and monitoring of child growth.

7. Eligibility Criteria Inclusion criteria:

1. Family caregiver of a child with stunting.
2. Primary caregiver responsible for daily child care.
3. Lives with the child.
4. Willing to participate and provide informed consent.
5. Able to complete study assessments.

Exclusion criteria:

1. Unable to participate in intervention sessions.
2. Unable to complete assessment procedures.
3. Withdraws consent during the study.

8. Arms and Interventions

The intervention is based on the Caregiving Module for Children with Stunting Aged 1–3 Years. The module covers nutrition care, infection prevention, developmental stimulation, and growth monitoring.

9. Outcome Measures

Primary outcomes are caregiver ability outcomes:

1. Cognitive ability measured using a 32-item questionnaire.
2. Psychomotor caregiving ability measured using a 20-item questionnaire.

The instruments assess caregiver knowledge and reported caregiving practices related to child growth and development stimulation.

10. Data Collection Procedures

Data collection includes participant characteristics, baseline assessment, intervention implementation, and post-intervention assessment.

Participant identities are replaced with research codes. Data are stored securely and accessed only by authorized research personnel.

11. Ethical Considerations

The study applies autonomy, beneficence, non-maleficence, and confidentiality principles. Participants receive research explanations before providing written informed consent. Participation is voluntary and withdrawal is permitted without consequences to health services.

12. ClinicalTrials.gov Structured Tables

12.1 Arms and Interventions

Arm	Intervention Name	Description
Experimental Arm	Simulation-Based Education	Standardized module plus simulation consisting of explanation, demonstration, caregiver practice, and feedback.
Comparator Arm	Module-Only Education	Standardized module without simulation activities.

12.2 Outcome Measures

Outcome	Measure	Time Frame
Caregiver Cognitive Ability	32-item cognitive questionnaire	Baseline and post-intervention

Caregiver Psychomotor Ability	20-item psychomotor questionnaire	Baseline and post-intervention

12.3 Participant Flow

Stage	Description
Screening	Identification of eligible caregivers
Enrollment	Obtaining informed consent
Baseline	Initial questionnaire assessment
Intervention	Education according to assigned arm
Posttest	Outcome measurement after intervention

12.4 Schedule of Events

Procedure	Baseline	Intervention	Posttest
Eligibility assessment	X		
Informed consent	X		
Questionnaire assessment	X		X
Module education		X	
Simulation session		X	

13. Statistical Analysis Plan Summary

The analysis includes descriptive statistics and comparative analysis.

Participant characteristics are summarized using appropriate descriptive statistics. Baseline characteristics are evaluated to describe comparability between groups.

Cognitive outcome analysis uses ANCOVA with adjustment for baseline cognitive score and relevant covariates. Psychomotor outcome analysis uses robust linear regression with HC3 correction as specified in the research analysis plan.

The significance level is determined according to the approved statistical analysis plan.

14. Appendices

Appendices include:

1. Statistical Analysis Plan.
2. Informed Consent Form.
3. Participant Information Sheet.
4. Research instruments:
    a. Respondent characteristics questionnaire.
    b. 32-item cognitive ability questionnaire.

c. 20-item psychomotor ability questionnaire.

5. TREND checklist alignment.

The informed consent document explains study objectives, procedures, confidentiality protection, and voluntary participation. The research instruments assess caregiver knowledge and caregiving practices related to child growth and development.

Statistical Analysis Plan (SAP)
Simulation-Based Education and Caregiving Ability Among Families of Stunted Children:
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1. Analysis Population
The analysis population will include all participants who meet eligibility criteria, provide informed consent, complete baseline assessment, and participate in the study procedures. The primary analysis will use the intention-to-treat principle adapted for a nonrandomized quasi-experimental design. Participants will be analyzed according to their assigned intervention group.The final analysis population consists of caregivers who completed baseline and post-intervention assessments. The study includes 55 caregivers in the final analysis, consisting of 31 caregivers in the Simulation-Based Education Group and 24 caregivers in the Module-Only Education Group. Participants who withdraw or have incomplete primary outcome measurements will be documented with reasons for missing assessment.

2. Descriptive Analysis
Descriptive analysis will summarize participant characteristics, baseline measurements, and outcome distributions.
Categorical variables will be presented as frequencies and percentages. Continuous variables will be presented as mean and standard deviation for normally distributed data or median and interquartile range for non-normal distributions. Characteristics analyzed include caregiver demographics, child characteristics, baseline cognitive scores, and baseline psychomotor scores. Changes in outcome scores will be calculated as the difference between post-intervention and baseline measurements.

3. Baseline Comparison
Baseline comparison will assess comparability between intervention and comparator groups before intervention.
Categorical variables will be analyzed using Chi-square test or Fisher exact test. Continuous variables will be analyzed using independent t-test for normally distributed data or Mann-Whitney U test for non-normally distributed data. Baseline differences will be considered during adjusted analysis when clinically relevant.

4. Primary Outcome Analysis
The primary outcomes are caregiver cognitive ability and psychomotor caregiving ability. Cognitive ability is measured using a 32-item questionnaire. The primary analysis uses ANCOVA with post-intervention cognitive score as the dependent variable, intervention group as the independent variable,

and baseline cognitive score and relevant covariates as adjustment variables.Results will be reported as adjusted mean difference, 95% confidence interval, and p-value.

5. Secondary Outcome Analysis

Psychomotor caregiving ability is measured using a 20-item self-reported questionnaire. Because assumptions for conventional ANCOVA may not be fully satisfied, psychomotor outcomes will be analyzed using robust linear regression with HC3 correction. The model includes postintervention psychomotor score as dependent variable, intervention group as predictor, and baseline psychomotor score and relevant covariates as adjustment variables.Results will be presented as regression coefficient, robust standard error, 95% confidence interval, and p-value.

6. Model Assumptions

Statistical assumptions will be evaluated before analysis. ANCOVA assumptions include linearity, homogeneity of regression slopes, normality of residuals, and homogeneity of variance. Regression assumptions include linear relationships, absence of severe multicollinearity, evaluation of influential observations, and residual assessment.If assumptions are violated, appropriate robust analytical methods will be applied.

7. Missing Data Handling

Missing data will be evaluated based on completeness, reasons for missing values, and missing data patterns.

If missing data are minimal, complete-case analysis will be performed. Participants without postintervention primary outcome data will be reported in participant flow.If missing data are substantial, appropriate sensitivity analysis may be considered.

8. Significance Level

All statistical tests will use a two-sided significance level of $\alpha = 0.05$. Results will be interpreted using p-values, 95% confidence intervals, and effect estimates. Statistical significance will be considered together with clinical relevance and practical implications for caregiver education programs.

INFORMED CONSENT FORM

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Simulation-Based Education and Caregiving Ability Among Families of Stunted Children: A Nonrandomized Quasi-Experimental Study

Universitas Muhammadiyah Tasikmalaya 2026

1. Invitation to Participate

You are invited to participate in a research study entitled “Simulation-Based Education and Caregiving Ability Among Families of Stunted Children: A Nonrandomized Quasi-Experimental Study.”

This research is conducted by researchers from the Faculty of Health Sciences, Universitas Muhammadiyah Tasikmalaya. The purpose of this study is to evaluate the effect of growth and development education using a simulation model on the ability of families to care for children with stunting.

2. Purpose of the Study

The purpose of this study is to determine whether simulation-based growth and development education improves caregiver knowledge and caregiving ability for children with stunting.

3. Study Procedures

If you agree to participate, you will be asked to complete questionnaires regarding caregiver characteristics, child characteristics, knowledge about child growth and development, and caregiving practices.

Participants will receive educational activities according to the study group. The intervention group will receive a module combined with simulation activities consisting of explanation, demonstration, practice, observation, and feedback. The comparison group will receive the educational module without simulation.

4. Risks and Discomforts

This study involves minimal risk. Possible inconvenience may include the time required to complete questionnaires and participate in educational sessions.

5. Benefits

Participants may gain additional knowledge and skills regarding child growth, developmental stimulation, and caregiving practices.

6. Confidentiality

All information collected during the study will be kept confidential. Participant identity will be replaced with a research code. Only authorized research team members will access the data.

7. Voluntary Participation

Participation is voluntary. You may refuse or withdraw from the study at any time without affecting your access to health services.

8. Questions and Contact Information

If you have questions about this research, you may contact the researchers:
Nia Restiana, Neni Solihat

Faculty of Health Sciences, Universitas Muhammadiyah Tasikmalaya Phone: 081322958323

9. Consent Statement

I have read and understood the information provided in this consent form. I have had the opportunity to ask questions and receive satisfactory answers. I voluntarily agree to participate in this study.

Participant Name:

_____

Signature:

_____

Date:

_____

Researcher Statement

The researcher confirms that the participant has received adequate explanation regarding the study objectives, procedures, benefits, risks, confidentiality, and voluntary participation.

APPENDIX: RESEARCH INSTRUMENTS

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Appendix 1. Respondent Characteristics Questionnaire (Questionnaire A) Instructions:

1. Read each question carefully.
2. Complete the information in the provided fields.
3. For multiple-choice questions, select the answer according to your condition.

No	Variable	Response
1	Respondent initials	_____
2	Age	_____ years
3	Occupation	Working / Not working
4	Highest education level	Elementary School / Junior High School / Senior High School / Higher Education / No formal education
5	Income	_____
6	Child initials	_____
7	Child age	_____
8	Birth order	_____
9	Gestational age at birth	_____

10	Birth weight	_____
11	Birth length	_____
12	Current weight	_____
13	Current height	_____

Appendix 2. Family Cognitive Ability Questionnaire (32 Items)

Instruction: Put a check mark (√) in the answer column considered correct. Each statement has one answer.

No	Statement	True	False
1	Growth and development stimulation is performed at children's educational facilities (kindergarten).	□	□
2	Children begin scribbling and drawing squares at certain developmental stages.	□	□
3	Children are given developmental stimulation so they can function healthily.	□	□
4	Children can learn development from their environment.	□	□
5	Children can stand on one leg and jump.	□	□
6	Children are not yet able to throw and catch a ball.	□	□
7	Children are able to walk.	□	□
8	Children cannot understand instructions given.	□	□
9	Children prefer watching and listening rather than imitating activities.	□	□

10	Children should not yet be taught writing because they may scribble on walls.	□	□
11	Children are able to pronounce two syllables.	□	□

12	Children like to imitate activities performed by other people.	□	□
13	Children only use sign language.	□	□
14	Children are able to understand instructions.	□	□
15	Children need a safe and protected play environment.	□	□
16	Children should not play outside because they may become naughty.	□	□
17	Children are given opportunities to bathe independently.	□	□
18	Children are fed during meals.	□	□
19	Children are invited to play and recognize their surrounding environment.	□	□
20	Children should only play inside the house to make supervision easier.	□	□
21	Children like to perform activities independently.	□	□

22	Children are always helped when wearing clothes.	□	□
23	Children understand explanations given to them.	□	□
24	Children should be scolded when they make mistakes.	□	□
25	Children enjoy playing with their own toys.	□	□
26	Children imagine with their toys.	□	□
27	Children enjoy playing with peers.	□	□
28	Interaction with peers helps children develop	□	□
	communication abilities.		
29	Children learn to communicate with peers.	□	□
30	Children do not understand how to introduce themselves to others.	□	□
31	Children are given praise to increase selfconfidence.	□	□
32	Children are taught fear using words such as 'Watch out' or 'Don't'.	□	□

Appendix 3. Family Psychomotor Ability Questionnaire (20 Items) Instruction:
Mark the response according to activities performed with your child

1. Never: The activity is never performed.
2. Rarely: The activity is performed once a day.
3. Often: The activity is performed 2–3 times a day.
4. Always: The activity is performed more than 3 times a day.

No	Activity	Never	Rarely	Often	Always

1	Teaching children to observe and imitate activities performed by other people.	□	□	□	□
2	Teaching children to walk.	□	□	□	□
3	Teaching children to throw and catch a ball.	□	□	□	□
4	Teaching children to pronounce two syllables.	□	□	□	□
5	Inviting children to play outside the house.	□	□	□	□

6	Dressing children after bathing.	□	□	□	□
7	Teaching children to perform activities independently, such as combing hair.	□	□	□	□
8	Giving instructions for children to take an object.	□	□	□	□

9	Protecting children from dangerous objects around them.	□	□	□	□
10	Giving children opportunities to bathe independently.	□	□	□	□
11	Teaching children to play with their own toys.	□	□	□	□
12	Teaching children to follow instructions such as sitting when asked.	□	□	□	□
13	Scolding children when they make mistakes.	□	□	□	□
14	Teaching children to stand on one leg and jump.	□	□	□	□
15	Inviting children to play with peers.	□	□	□	□
16	Inviting children to	□	□	□	□
	communicate with peers.				

17	Teaching children to recognize other people or friends.	□	□	□	□
18	Giving praise when children complete tasks well.	□	□	□	□
19	Using fear words such as 'Watch out' or 'Don't' so children obey.	□	□	□	□
20	Inviting children to play throwing a ball.	□	□	□	□

Appendix 4. Instrument Scoring Procedure Cognitive Ability Scoring:

1. Correct answer = 1
2. Incorrect answer = 0

Total score is calculated from all 32 items.

Psychomotor Ability Scoring:

1. Never = 1
2. Rarely = 2
3. Often = 3
4. Always = 4

Assessment time points:

Baseline assessment before intervention.

Post-intervention assessment after completion of intervention.

Appendix 5. Instrument Reliability Reported reliability:

Cognitive questionnaire Cronbach's alpha = 0.934.

Psychomotor questionnaire Cronbach's alpha = 0.966.

Appendix 6. Instrument Administration Procedure

The instruments are administered by trained research team members during baseline and postintervention assessments. Participant identities are replaced with research codes. Data are stored securely and accessed only by authorized research personnel.

Appendix: Ethical Clearance

Ethical approval was obtained from the Health Research Ethics Committee of the Faculty of Nursing and Health Sciences, Universitas Muhammadiyah Semarang.

Ethical Clearance Number: 001/KE/05/2026 Approval Date: 21 May 2026.

The committee confirmed that the research proposal fulfilled ethical requirements and recommended implementation according to the principles of the Declaration of Helsinki and national health research ethics guidelines.

Appendix: TREND Statement Checklist

TREND Statement Checklist (Author Completed Version)

Manuscript: Simulation-Based Education and Caregiving Ability Among Families of Stunted Children: A Nonrandomized Quasi-Experimental Study

Guideline: TREND Statement

Section	Item	Reported	Page/Location
Title and Abstract	1	Yes	Abstract p.1
Introduction Background	2	Yes	Introduction p.1-2
Participants	3	Yes	Methods p.2-3
Interventions	4	Yes	Methods p.3
Objectives	5	Yes	Introduction p.2
Outcomes	6	Yes	Methods p.3
Sample Size	7	Yes	Methods p.3
Assignment Method	8	Yes	Methods p.3
Blinding	9	Yes	Methods p.3
Unit of Analysis	10	Yes	Methods p.3
Statistical Methods	11	Yes	Methods p.3-4
Participant Flow	12	Yes	Results p.4

Recruitment	13	Yes	Methods p.2
Baseline Data	14	Yes	Results p.4-5
Baseline Equivalence	15	Yes	Results p.5
Numbers Analyzed	16	Yes	Results p.4
Outcomes and Estimation	17	Yes	Results p.6
Ancillary Analyses	18	Yes	Results p.5-6
Adverse Events	19	Yes	Methods p.4
Interpretation	20	Yes	Discussion p.6-8
Generalizability	21	Yes	Discussion p.7-8
Overall Evidence	22	Yes	Conclusion p.8

Author statement: The authors confirm that this manuscript has been prepared according to the TREND Statement for transparent reporting of nonrandomized evaluations.

Protocol Version: Version 1.1 Final Revised Version
Document Date: 07 August 2026
Revision Notes: Updated for ClinicalTrials.gov PRS submission. Document metadata revised. Informed consent and supporting documents reviewed.