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Impact of the Korea Early Childhood Home-visiting Intervention (KECHI) on child health and development and maternal health: a randomised controlled trial protocol

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ABSTRACT

Introduction

Randomised controlled trials (RCTs) of early childhood home visiting interventions have been conducted mainly in Western countries, whereas such trials have been limited in non-Western cultures, including Asia. In South Korea, a national home visit program (Korea Early Childhood Home-visitation Intervention, KECHI) was developed in 2020 and launched throughout the country. We designed a pragmatic RCT to evaluate the effectiveness of KECHI on child health and development and maternal health.

Methods and analysis

Eligible participants will be pregnant women at less than 37 weeks of gestation with risk factor scores of 2 or over, who are sufficiently fluent in Korean to read and answer the questionnaire written in Korean and live in districts where the KECHI service is available. Eight hundred participants will be recruited from the general community and through the District Public Health Centres. The participants will be randomised 1:1 to KECHI plus usual care or usual care. KECHI encompasses 25-29 home visits, group activities, and community service linkage. Participants will complete assessments at baseline (<37 weeks gestation), 6 weeks, 6 months, 12 months, 18 months, and 24 months postpartum. The six primary outcomes will be 1) home environment (assessed by Infant/Toddler Home Observation for Measurement of the Environment), 2) emergency department visits due to injuries, 3) child development (assessed using Korean Bayley Scales of Infant and Toddler Development-III), 4) breastfeeding duration, 5) maternal self-rated health, and 6) community service linkage.

Ethics and dissemination

This trial has received full ethical approval from the Institutional Review Board of the Seoul National University Hospital. Written consent will be obtained from the participants. The results will be reported at conferences, disseminated through peer-reviewed publications, and used by the Korean government to expand the KECHI service.

Trial registration number

NCT04749888

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ➔ This trial is one of the first large randomised controlled trials on the impact of maternal and early childhood nurse home visiting programs in non-Western countries.
- ➔ The results of this trial will provide pragmatic evidence for the maternal and early childhood nurse home visitation program (i.e., KECHI) in South Korea and they will aid in the expansion of KECHI across the country.
- ➔ The findings may not be generalisable to families participating in the real-world KECHI program where, due to relative shortages of nurses in certain districts, nurses provide the service selectively to more vulnerable families.

INTRODUCTION

Providing children with the best possible start in life is crucial for reducing the magnitude of socioeconomic inequalities in health.[1] Maternal and early childhood home visits have been proposed as an effective strategy to improve the health and development of disadvantaged children.[2 3] Randomised controlled trials (RCTs) of maternal and early childhood nurse home visitation programs have been conducted in many Western countries, including Australia,[4 5] Canada,[6] England,[7 8] Germany,[9 10] the Netherlands,[11 12] and the USA.[13-15] However, RCT evidence on the effectiveness of these programs is sparse in non-Western cultures.

In South Korea (hereafter, Korea), a maternal and early childhood home visit program has been implemented since 2013 in Seoul.[16 17] The Maternal and Early Childhood Sustained Home-visitation (MECSH) program[5 17] was introduced to the Seoul Health First Step Project (SHFSP), and associated nurse training programs have been established.[16] In 2019, the Korean government decided to expand early childhood nurse home visit services (the Early Life Health Management Program) nationally.[18 19] In 2020, a home visit program (Korea Early Childhood Home-visitation Intervention, KECHI) where nurses (with social workers) make multiple home visits to vulnerable families starting prenatally and continuing until the child reaches the age of 2 years, was developed and launched throughout the country.

Scientific evidence from RCTs will play a crucial role in expanding the availability of home visiting services and, ultimately, reducing socioeconomic inequalities in health. The overarching hypothesis of the trial is that children and mothers receiving the KECHI will have a significantly better home environment and child, maternal, and family outcomes than those receiving usual care.

Methods and analysis

Study design

A 2-arm parallel group, superiority, individually randomised controlled trial was designed to evaluate the effectiveness of the KECHI in improving child health and development and maternal health (Figure 1). This trial is closer to a pragmatic RCT than to an explanatory one in the pragmatic-explanatory continuum,[20] considering two important trial settings: 1) the interventions are offered by home visiting nurses employed in District Public Health Centres (DPHCs) for the KECHI, not by those who are hired and trained separately only for this trial; and 2) the eligibility criteria used for RCT screening are nearly identical to those used by home visiting nurses to determine the KECHI beneficiaries.

Study setting

The KECHI was designed for implementation in the catchment areas of DPHCs across Korea. As of 2022 (the start of active recruitment), the KECHI has been conducted in 64 districts (25 in Seoul and 39 outside Seoul) out of 257 districts across the country. Based on administrative support from the Seoul Metropolitan Government and the Ministry of Health and Welfare of Korea, the research team contacted the directors and managers of DPHCs. Before the first home visit made to the intervention group, nurses who deliver the intervention to participants via home visits (plus social workers in some districts) are trained for at least 320 hours. The Support Teams administer intensive training sessions and monitor the performance of nurses' home visits.

Participants

The study will involve 800 pregnant women living in districts where KECHI is available. Eligible participants are pregnant women who:

- Have risk factor scores of 2 or over at the time of screening,
- Are at less than 37 weeks of gestation,
- Can read and answer questionnaires in Korean.

Women will be excluded if they:

- Have experienced any critical event such as termination of pregnancy, stillbirth, or child death.
- Plan to move abroad or to other regions where KECHI is not available within the next 6 months.

Eligibility risk factors

Eligibility will be determined by using a questionnaire eliciting information 16 risk factors across four domains: sociodemographic variables, psychosocial variables, health and healthcare factors, and trauma experiences (Table 1). The questionnaire items on psychosocial variables and trauma experiences were modified from the SAFE START guideline in New South Wales, Australia.[21] Three risk factors (i.e., maternal age younger than 19 years old, single mother, low income) are rated 2 points, and the other 14 risk factors are rated 1 point. Thus, individuals' risk factor scores range from 0 to 19. A risk factor score of 2 or more will be necessary for study eligibility. The screening survey used in the trial is almost identical to the one that the Korean DHPCs use for pregnant women or mothers with young children to register for the home-visiting service, with the exception of postnatal-related items. In the real-world KECHI service, home-visiting nurses consider the vulnerability of families with risk scores of

2 and higher because the number of home-visiting nurses is insufficient to offer services to all potential KECHI recipients. However, due to ethical issues, this study will not attempt to prioritise especially vulnerable families.

Usual care

Both the intervention and control groups will be eligible to receive usually provided publicly funded health and social care services, including services from DPHCs. These services include postnatal care services (usually for 2 weeks), universally offered childhood health check-ups at paediatric clinics, and immunisation. In addition, many Korean women pay for and stay in specialised postpartum care centres called *sanhujoriwon* for 2 weeks after childbirth.[22] According to a recent report,[23] 81.2% of women giving births pay for *sanhujoriwon*. Thus, the control and intervention groups may have *sanhujoriwon* services (mostly non-public) for 2 weeks after childbirth and then return home and use postnatal care services (public) for 2 additional weeks. The intervention group will be those who participate in KECHI from pregnancy until their children reach the age of 24 months. The control group will not receive KECHI, but nurses may provide basic postnatal home visits (once within 8 weeks postpartum) if requested. Eligibility for basic home visits is decided when women apply for the service via the internet or telephone. Contamination may occur if social service networks refer families in the control group to the home-visiting nurses in KECHI at DPHCs or if nurses decide to transfer them to KECHI after the basic home visit. Therefore, in this clinical trial, KECHI nurses will be able to make home visits to the control group based on their re-evaluation of the family situations at the basic home visit. However, the research team expects that the magnitude of contamination would be minimal because referrals from social service networks are uncommon, and the number of families in the control group requesting basic home visits would be small.

Intervention

KECHI is a complex intervention involving a wide range of outcomes in various domains. It encompasses 25-29 home visits by trained nurses from the prenatal period until the child reaches the age of 2 years.[19] Although KECHI is based on the experience of implementing MESCH in Seoul, these programs differ in several aspects. First, considering s*anhujoriwon* utilisation in Korea,[23] flexible numbers of home visits during the first 8 weeks (4-8 visits) were applied, and one additional visit before 24 months postpartum was added. Second, the Korean version of the *Learning to Communicate* parent education book[24] used in MECSH was replaced by a newly developed parent education book titled *Jaramtong*, which covers the prenatal period and 12-24 months postpartum as well as issues on prenatal care, child development, postnatal child care, parent-child attachment, play, communication, safety, and goal-setting.[19] Furthermore, new protocols for KECHI were developed, including protocols for addressing perinatal depression and intimate partner violence. The contents of each home visit can be tailored to the mother's needs, skills, strengths, and capacities using parenting education materials.

Primary outcomes

The UK Medical Research Council guidance[25] recommends using multiple outcomes to evaluate the impact of complex interventions. As presented in Table 2, we will focus on six primary domains of outcomes: 1) home environment, 2) child safety, 3) child development, 4) child care, 5) maternal well-being, and 6) community support. The domains reflect the target outcomes potentially affected by KECHI. We selected one primary outcome for each domain: 1) Infant/Toddler Home Observation for Measurement of the Environment (IT-HOME),[26] 2) emergency department visits due to injuries, 3) Korean Bayley Scales of Infant and Toddler

Development-III (K-Bayley-III),[27] 4) breastfeeding duration, 5) maternal self-rated health, and 6) community service linkage.

The IT-HOME[26] comprises 45 items evaluating the quality and quantity of stimulation and support available to children in the home environment. The items are assessed by a combination of structured interviews and observations by trained research nurses. Emergency department visits due to injuries could be considered a proxy measure for child maltreatment[28] and are used as the primary outcome for the child safety domain. The K-Bayley-III[27] was chosen as a measure for the child development domain. It is an extensive standardised developmental assessment tool for diagnosing developmental delays in early childhood. Mothers and children aged 24 months will be invited to medical institutions and assessed by K-Bayley-III experts. For childcare, research nurses will ask about breastfeeding duration and child feeding practices at 6 weeks, 6 months, 12 months, and 24 months postpartum. Self-rated health is one of the most frequently used measures for adulthood health status in health and social research. It is a strong predictor of mortality in many populations,[29] as well as in Korean women.[30] Thus, maternal self-rated health was chosen as the primary outcome for maternal well-being and will be assessed in all six surveys (baseline, 6 weeks, 6 months, 12 months, 18 months, and 24 months) through a single question ("How would you rate your health these days?") with responses on a 5-point Likert scale, ranging from 1 (very good) to 5 (very bad). One of the core components of KECHI is sharing information on available community services. Thus, for the community support domain, participants will be asked about their utilisation of the most popular DPHC services and other popular publicly funded social services.

Secondary outcomes

The domains of the secondary outcomes include child safety, child development, childcare,

maternal well-being, community support, family well-being and parent-child interactions (Table 2).

The child safety domain includes the mother's safety knowledge and the child's emergency department visits and hospital admissions. The questionnaire testing mothers' safety knowledge contains five items from the Korean National Health Insurance Service's Infant Health Examination Questionnaire.[31] Emergency department visits and hospital admissions reported by mothers will be included as proxy markers for child safety.

The child development domain includes the Denver Developmental Screening Test II (DDST-II),[32] premature birth, and delayed growth. DDST-II compares a child's development to the developmental age ranges in the tool. Research nurses will be trained to administer the DDST-II three times, before surveys at 6 months, 12 months, and 24 months postpartum. Delayed growth will be determined based on the child's body weight and height at 6 months, 12 months, and 24 months postpartum. The child's height and head circumference will be measured by research nurses, while body weight will be reported by mothers.

The childcare domain includes knowledge of sudden infant death syndrome (SIDS) prevention, vaccination, national health check-ups, spousal participation in parenting, parenting-related household expenses, intention to have another child, and experience of delivery in the past 2 years. The questionnaire testing the mother's knowledge of SIDS contains five items from the Korean National Health Insurance Service's Infant Health Examination Questionnaire.[31] Vaccination will be assessed by completion of the Korean childhood immunisation schedule. National health check-ups will be assessed by asking whether the mother has visited a health centre or paediatrician for an infant health check-up (scheduled at 14-35 days, 4-6 months, 9-12 months, 18-24 months postpartum). Spousal participation in parenting will be measured by

a questionnaire containing 4 items from the Panel Study on Korean Children.[33] Parenting-related household expenses measure a household's expenditures for pregnancy, childbirth, and supplies needed to care for the child. Intention to have another child and experience of delivery in the past 2 years will be determined by the mother's report at 24 months postpartum.

We will obtain information on a wide range of maternal well-being indicators: maternal depression measured with Edinburgh Postnatal Depression Scale (EPDS),[34] Patient Health Questionnaire-9 (PHQ-9),[35] and Whooley & Arroll questions;[36 37] anxiety measured by Generalised Anxiety Disorder 2-item (GAD-2);[38] maternal tobacco use and alcohol consumption; delivery type; parenting distress measured by Being a Mother Scale 13-item (BaM-13);[39] intimate partner violence measured by the Hurt, Insult, Threaten, and Scream (HITS) tool;[40] and maternal body weight and height. The 10th item of the EPDS is on suicidal ideation, which will also be considered as a secondary outcome. Delivery type will be assessed by the mother's self-report when the child is 6 weeks old.

As a community support domain indicator, the social support questionnaire used in the Panel Study on Korean Children[33] will be measured at baseline, 6 months, 12 months, and 24 months postpartum.

The family well-being domain includes food insecurity, spousal intimacy, spousal tobacco use, and spousal alcohol consumption. Food insecurity will be assessed by asking about the family's level of limited access to adequate food over the past year. Spousal intimacy will be measured using the 4-item Revised-Kansas Marital Satisfaction Scale[41] modified by the Korea Institute of Child Care and Education.[33]

We will measure parent-child interactions observed in teaching episodes using the NCAST (Nursing Child Assessment Satellite Training)-PCI (Parent-Child Interaction) teaching scale[42]

when the child is 12 and 24 months old. The NCAST-PCI teaching scale is composed of 73 items measuring three aspects of the caregiver's behaviour and two aspects of the child's behaviour. For this trial, we will use the Korean version of the NCAST-PCI manuals and videos according to a licensing agreement with the University of Washington. We will train coders to independently assess teaching interaction videos obtained during the home-visits at 12 months and 24 months postpartum by research nurses. We will also train research nurses regarding obtaining the videos at home.

Sample size

We considered IT-HOME as a main outcome measure for sample size calculation. In our prior study,[43] the mean IT-HOME score for children at 6-24 months postpartum who received nurse home visitation services in Seoul was 32.5, and the standard deviation (SD) was 5.0. Since we expect to recruit participants from more diverse backgrounds, we anticipated approximately 10% larger variations in IT-HOME scores. Effect sizes of 0.25-0.3 SDs are considered meaningful and impactful at the population level,[44 45] so we set the difference in IT-HOME scores to 1.50. The probability of type I error (alpha) was set at 0.05 (2-tailed) and type II error (beta) was set at 0.10 (power = 90%). The presumption of 35% attrition for the primary outcome indicator at the 2-year follow-up, reflecting a rate slightly higher than that reported in other studies,[44] resulted in a sample size of 400 per group (800 total).

Recruitment

Participants will be recruited through in-person invitations at the maternal and child health departments of DPHCs, social media posts, and advertisements using mobile phone numbers of perinatal women registered in DPHCs.

Interested perinatal women will contact the study team and be screened for eligibility by a member of the research team. Trained research nurses will make a home visit for the baseline survey and obtain signed consent from study participation. Consent for linkage to secondary data (e.g., national health insurance data) and long-term follow-up will also be obtained. Subsequently, participants will be randomised.

Randomisation and allocation

Stratified randomisation stratified by parity and recruitment sites will be conducted to randomly assign participants to the control or intervention group at a 1:1 ratio using computer-generated random numbers. Research nurses will enrol participants and a research manager will informs nurses in DPHCs of the contact information of families needing interventions. Randomisation will be conducted using the Interactive Web Responsive System (IWRS) by the Medical Research Collaboration Center (MRCC) of Seoul National University Hospital (SNUH).

Blinding

As information on allocation is not withheld from participants, this study is an open trial. However, every effort will be made to maintain blinding of allocation status. The research management staff, KECHI nurses (for the intervention group), and study participants will be aware of the allocation results. However, the research nurses making postnatal outcome assessments will be blinded to the randomisation, and families will be asked not to disclose their group status during the surveys at home. The research nurses (outcome assessors) will only be notified of the survey schedules (6 weeks, 6 months, 12 months, and 24 months) of both groups. Independent assessments with blinding will be made for some outcome measures.

The NCAST-PCI teaching scale will be coded by independent coders, and the K-Bayley-III will be independently measured at medical institutions by K-Bayley-III experts. Statistical analysts will not be able to access the randomisation variable until all 2 years of data are collected.

Compensation

Participants will be compensated 30,000 Korean won (1,300 Korean won = 1 US dollar) for each survey (maximum compensation: 180,000 Korean won).

Patient and public involvement

Patients and/or the public are not involved in the design, conduct, reporting, or dissemination plans of this trial.

Data collection, data management, monitoring, and auditing

At four home visits (baseline, 6, 12, 24 months) and two phone interviews (6 weeks and 18 months), trained research nurses will collect data on primary and secondary outcomes. At 24 months, additionally, K-Bayley-III experts will administer the K-Bayley-Ⅲ at Seoul National University and Dong-A University. The home and lab visits will usually take 1.5 hours, and the phone calls will last for 5 minutes on average. For observational measures, research nurses will be trained by a developer for the IT-HOME and the Barnard Center at the University of Washington for the NCAST-PCI teaching scale, respectively, and only those who achieve an inter-rater reliability rate greater than 90% will administer observations and scoring. The quality and procedures of data collection will be regularly monitored by a research manager. All data collected will be reported in a written Complete Report Form (CRF) first, and then

research nurses will enter the data again in an electronic Complete Report Form (eCRF) created in the web-based Clinical Research and Trial management system (iCReaT, http://icreat.nih.go.kr). The iCReaT is developed and maintained by the Korea Disease Control and Prevention Agency (KDCA) and provides an effective platform for managing study protocols, participants, data entry, and data monitoring. Many clinical trials conducted in Korea use the iCReaT to develop their own eCRFs. Anyone who needs access to the iCReaT (e.g., research nurses or project managers) requires online training courses and should be certified by the KDCA. Although data collection and entry are conducted mainly by research nurses, the MRCC at SNUH is fully responsible for regular data management and analysis, in addition to the use of the IWRS (i.e., eCRF, web-based random assignment). The MRCC team consists of members responsible for random assignment, data management, and data analysis, and they work independently and collaboratively with the research team. From the initial stage of the trial, they developed the data management plan (DMP), web-based random assignment plan, data verification specification (DVS), eCRF complete guideline (CCG), and statistical analysis plan (SAP). Data validation of the eCRF will be completed up to twice a year using manual and system queries. All processes of the trial and data management will be audited by the funder and an external consulting group.

Statistical analysis plan

After database locking, the primary analyses will be conducted on an intention-to-treat (ITT) basis. For the six primary outcomes, analyses will be conducted with both data without missing information and data with multiple imputation (five times). For other outcomes, data without missing information will be analysed. After completion of the survey at 6 months postpartum, we will conduct an interim ITT analysis for selected outcomes (IT-HOME, emergency

department visit due to injury, breastfeeding duration, maternal self-rated health, knowledge on SIDS prevention, Denver-II, spousal participation in parenting, EPDS, PHQ-9, GAD-2, BaM-13, HITS, social support questionnaire, and the Revised-Kansas Marital Satisfaction Scale). A per-protocol analysis will also be conducted, in which participants will be excluded from the intervention arm of the trial if they did not have at least 13 KECHI nursing visits; any such participants will be included in the control group.

Regression analysis will be conducted to evaluate the effects of the intervention, and the results will be summarised using point estimates and their 95% confidence intervals. Analyses adjusted for parity and region (Seoul vs. non-Seoul) will also be presented. For repeatedly collected variables, interactions between allocation status and follow-up periods will be examined. Differences at each follow-up period (6 weeks, 6 months, 12 months, and 24 months) will be presented if the interactions are significant; otherwise, mean differences over the follow-up period will be estimated. Subgroup analyses stratified by parity, region, risk factor score (2 vs. ≥3), and EDPS score (<13 vs. ≥13) will be conducted. Considering the potential increase in alpha error by having six primary outcomes, we will interpret the overall effectiveness of the intervention by assessing the comprehensive analysis results and outcome-specific contents of KECHI.

Ethics and dissemination

The study protocol was reviewed and approved by the institutional review board of the Seoul National University Hospital (IRB No. C-1911-150-1083). The trial was initially registered at ClinicalTrials.gov (ClinicalTrials.gov identifier: NCT04749888) on February 11, 2021 and revised on May 5, 2022. The trial was scheduled to start on October 27, 2022, and is expected

to be completed by January 31, 2025. Participants consent for themselves and give parental permission for their babies. Participants are informed that their participation is voluntary and they can withdraw without penalty at any time and their decision does not impact their care in any way. The study results will be published in peer-reviewed journals and presented at scientific meetings. The results will be reported at conferences and in peer-reviewed publications and will be used by the Korean government for expanding the KECHI service.

Discussion

The effects of nurse home visitation interventions may vary among societies,[28 46] and effects detected in one country may not translate to another country.[46] For example, the RCT of the Family Nurse Partnership (FNP) program in England did not identify significant impacts on four primary endpoints (prenatal cigarette smoking at the end of pregnancy, birthweight of the baby, subsequent pregnancy, and emergency attendances and hospital admission) while the effects were significant for language and cognitive development.[7] The characteristics of population and existing home visitation services might have contributed to these findings.[7 28] In addition, while few effects of home visitation on healthcare utilisation, child health, and child accidents were found in trials conducted in England,[7] Germany,[47] and Ireland,[48] home visiting programs in the US appear to produce clear beneficial effects on those outcomes.[49 50] These discrepancies might also be attributed to differences in the public health insurance systems between Europe and US affecting disadvantaged mothers' access to comprehensive healthcare services for children. In this regard, Korea may provide a unique opportunity to understand the effects and mechanisms of maternal and early childhood home visitation. In Korea, while universal national health insurance is established (similar to the European

context), maternal early childhood home visiting services are underdeveloped (similar to the US context). A prior paper showed that maternal distress reported by Korean women with young children was very high compared to other countries.[51] This Korean situation may shed light on the difference in the discordant RCT findings from different countries on the effects of home visitation.

Although early childhood nurse home visits have a long history in many Western countries,[3] Korea has only a 10-year history of implementing maternal and early childhood nurse home visits as a component of public services. The SHFSP started only in 3 districts of Seoul in 2013 and expanded to all 25 districts in 2020. In 2020, the central government of Korea started to expand the service to other parts of Korea.[19] In this early stage of the national expansion of the intervention, this RCT may be instrumental in policy decision-making with respect to the speed of the national expansion and any potential modification of the service.

This trial has some limitations. Outcome reporting made by mothers may be affected by their perceptions and feelings. Although the research nurses making outcome measurements will be blinded to randomisation and families will be asked not to disclose their allocation status, breaches of blinding would be possible. However, the direct observation measures (IT-HOME) would mitigate the limitation of self-reports, and the independent assessments of the NCAST-PCI teaching scale and K-Bayley-III will be blinded. In addition, the findings may not be generalisable to the highly vulnerable families included in the real-world KECHI service, wherein nurses prioritise more vulnerable families due to a relative shortage of nurses. Subgroup analyses by EPDS scores and risk factor scores would provide information on the effect size in the real-world KECHI. Moreover, the findings may not generalise to families of multicultural mothers with communication challenges in Korean.

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Contributors

YHK, YMK, KJJ, SHC, JYL and HJC developed the grant proposal for this project. YHK, YMK, JHK, JY, and RO administratively led the project. YHK wrote the draft. The manuscript was revised based on comments from all authors. All authors read and approved the final manuscript.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication

Not applicable.

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Table 1. Risk factors used to determine eligibility and their descriptions

Risk factors	Descriptions
Sociodemographic risk factors	
Maternal young age*	Pregnant women aged 19 or less are scored 2 and pregnant women aged 20-23 are scored 1.
Single mother*	Single mothers are scored 2.
Low income*	Families receiving basic living security program or families whose household income is 50% or less of national median household income are scored 2.
Multicultural background	Born or raised abroad
Low education	Less than high school graduation
Disability	Physical disability, mental disability, or intellectual disability
Psychosocial risk factors	
Depression or suicidal ideation	Edinburgh Postnatal Depression Scale (EPDS, 10 items) ≥ 10 or EPDS 10th item (suicide ideation) ≥ 1
Anxiety	Generalized anxiety disorder 2-item ≥ 3
Recent major stressors	Have you ever experienced serious stress, change, or loss over the past 12 months such as financial problems, someone close to you dying, or any other serious worries? (yes)
Lack of instrumental or emotional support	Will you be able to get practical support with your baby? (no) or Do you have someone you are able to talk to about your feelings or worries? (no)
Past treatment history for emotional issues	Have you ever been treated for emotional issues? (yes)
Health and healthcare risk factors	
Delayed prenatal care	Start of obstetric care ≥ 20 weeks gestation
Smoking or alcohol consumption	Smoking during pregnancy or alcohol consumption twice per week during pregnancy
Multiple foetuses	Multiple foetuses
Risk factors of trauma experiences	
Childhood abuse experience or witnessing domestic violence	Have you ever been physically, emotionally, or sexually abused in your childhood? (yes) or Have you ever witnessed domestic violence during childhood or adolescence? (yes)
Intimate partner violence or need of assistance regarding domestic violence	Score of Hurt, Insult, Threaten, and Scream (HITS) questionnaires (4 items) ≥ 7 or Do you need any help for domestic violence? (yes)

*Except for these three risk factors, other risk factors are scored 1.

Table 2. Assessment variables and associated assessment schedules

Assessment variables			Assessment time					
Domains		Outcomes	Baseline	6 weeks	6 Months	12 Months	18 Months	24 Months
Primary outcomes	Home environment	IT-HOME (Infant/Toddler Home Observation for Measurement of the Environment) (45 items)			X	X		X
	Child safety	Emergency department visits due to injuries		X	X	X		X
	Child development	K-Bayley-III (Korean Bayley Scales of Infant and Toddler Development-III)						X
	Childcare	Breastfeeding duration		X	X	X		X
	Maternal well-being	Maternal self-rated health	X	X	X	X	X	X
	Community support	Community service linkage	X			X		X
Secondary outcomes	Child safety	Safety knowledge (5 items)	X		X	X		X
		Emergency department visits		X	X	X		X
		Hospital admission		X	X	X		X
	Child development	Denver (Denver Developmental Screening Test) II			X	X		X
		Premature birth		X				
		Delayed growth			X	X		X
	Childcare	Knowledge of sudden infant death syndrome prevention (5 items)	X	X				
		Vaccination			X	X		X
		National health check-ups			X	X		X
		Spousal participation in parenting (4 item)			X	X		X
		Parenting related household expenses	X		X	X		X
		Intention to have another child						X
		Experience of delivery in the past 2 years						X
	Maternal well-being	EPDS (Edinburgh Postnatal Depression Scale) (10 items)	X		X	X		X

Assessment variables			Assessment time					
Domains		Outcomes	Baseline	6 weeks	6 Months	12 Months	18 Months	24 Months
		PHQ-9 (Patient Health Questionnaire-9) (9 items)	X		X	X		X
		Whooley & Arroll questions (3 items)		X			X	
		GAD-2 (Generalized Anxiety Disorder 2-item)	X		X	X		X
		Maternal tobacco use	X		X	X		X
		Maternal alcohol consumption	X		X	X		X
		Delivery type		X				
		Being a Mother Scale (BaM-13) (13 items)			X	X		X
		HITS (Hurt, Insult, Threaten, and Scream) (4 items)	X		X	X		X
		Maternal body weight	X	X	X	X		X
	Community support	Social support questionnaires (12 items)	X		X	X		X
	Family well-being	Food insecurity	X			X		X
		Revised-Kansas Marital Satisfaction Scale (4 items)	X		X	X		X
		Spousal tobacco use	X		X	X		X
		Spousal alcohol consumption	X		X	X		X
	Parent-child interactions	NCAST (Nursing Child Assessment Satellite training)-PCI (Parent-Child Interaction) teaching scale (73 items)				X		X

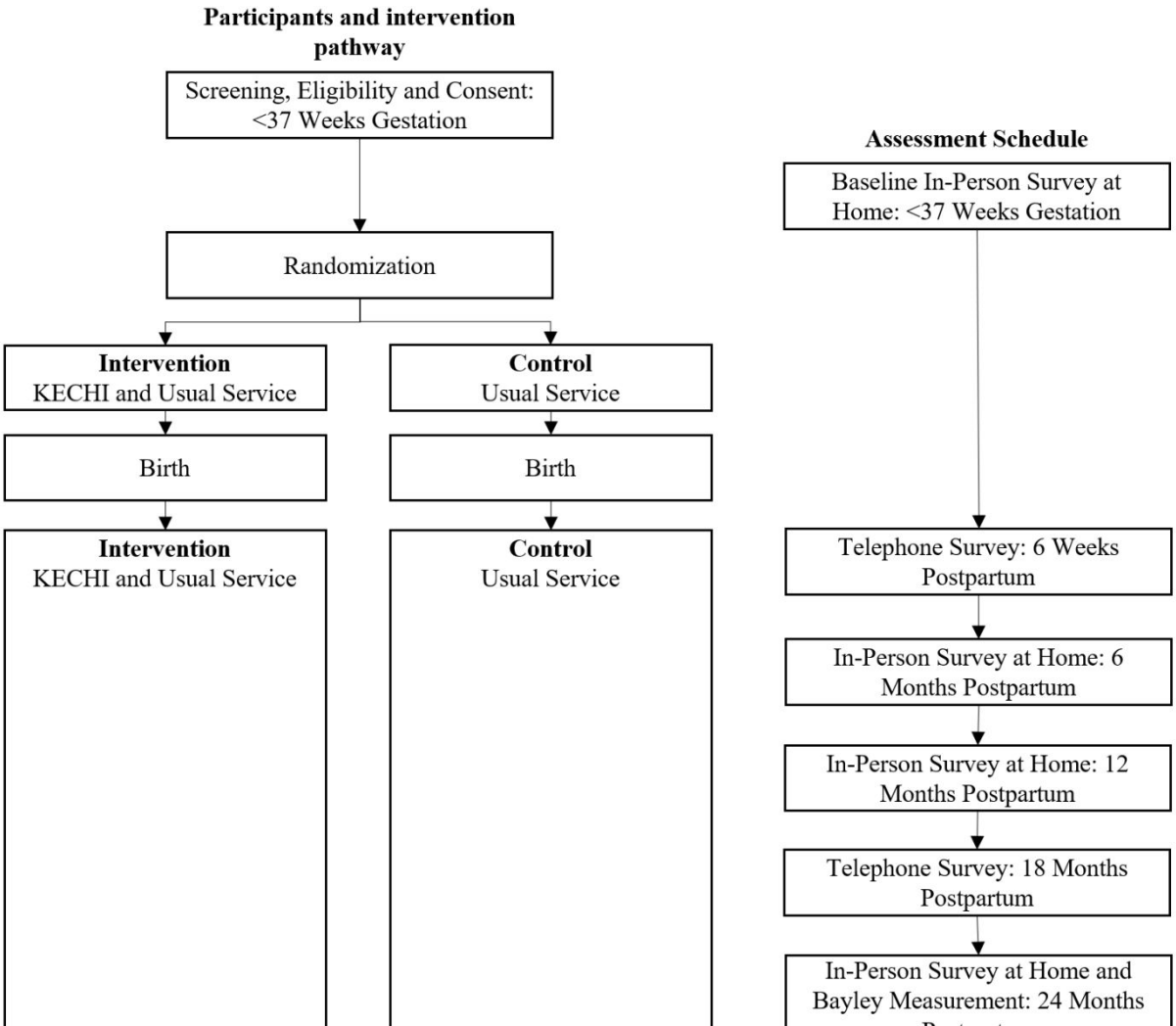

Figure 1. Study flow diagrams, showing the participants and intervention pathway and the assessment schedule

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	__1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	__3_____
	2b	All items from the World Health Organization Trial Registration Data Set	__NA_____
Protocol version	3	Date and version identifier	__NA_____
Funding	4	Sources and types of financial, material, and other support	__19-20_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	__1, 19_____
	5b	Name and contact information for the trial sponsor	__1_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	__19-20_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	__15_____

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6-7, 25
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	17
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7-8
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-12, 26-27
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	28

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13-14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13-14
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14-15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14-15

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___14-15_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___15-16_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	___16_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	___15-16_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___14-15_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___16_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___NA_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___15_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___3_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	___NA_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	___13_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	___13_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___NA_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___20_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	___15_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___NA_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	___17_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	___NA_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	___NA_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_Appendices 1, 2_
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	___NA_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Impact of the Korea Early Childhood Home-visiting Intervention (KECHI) on child health and development and maternal health: a randomised controlled trial protocol

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Impact of the Korea Early Childhood Home-visiting Intervention (KECHI) on child health and development and maternal health: a randomised controlled trial protocol

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ABSTRACT

Introduction

Randomised controlled trials (RCTs) of early childhood home visiting interventions have been conducted mainly in Western countries, whereas such trials have been limited in non-Western cultures, including Asia. In South Korea, a national home visit program (Korea Early Childhood Home-visitation Intervention, KECHI) was developed in 2020 and launched throughout the country. We designed a pragmatic RCT to evaluate the effectiveness of KECHI on child health and development and maternal health.

Methods and analysis

Eligible participants will be pregnant women at less than 37 weeks of gestation with risk factor scores of 2 or over, who are sufficiently fluent in Korean to read and answer the questionnaire written in Korean and live in districts where the KECHI services are available. Eight hundred participants will be recruited from the general community and through the District Public Health Centres. The participants will be randomised 1:1 to KECHI plus usual care or usual care. KECHI encompasses 25-29 home visits, group activities, and community service linkage. Participants will complete assessments at baseline (<37 weeks gestation), 6 weeks, 6 months, 12 months, 18 months, and 24 months postpartum. The six primary outcomes will be 1) home environment (assessed by Infant/Toddler Home Observation for Measurement of the Environment), 2) emergency department visits due to injuries, 3) child development (assessed using Korean Bayley Scales of Infant and Toddler Development-III), 4) breastfeeding duration, 5) maternal self-rated health, and 6) community service linkage.

Ethics and dissemination

This trial has received full ethical approval from the Institutional Review Board of the Seoul National University Hospital. Written consent will be obtained from the participants. The results will be reported at conferences, disseminated through peer-reviewed publications, and used by the Korean government to expand the KECHI services.

Trial registration number

NCT04749888

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ➔ This study is a 2-arm parallel group, superiority, individually randomised controlled trial designed to evaluate the effectiveness of the Korea Early Childhood Home-visiting Intervention (KECHI) in improving child health and development and maternal health.
- ➔ The results of this trial will provide pragmatic evidence for the maternal and early childhood nurse home visitation program (i.e., KECHI) in South Korea and they will aid in the expansion of KECHI across the country.
- ➔ The findings may not be generalisable to families participating in the real-world KECHI program where, due to relative shortages of nurses in certain districts, nurses provide the service selectively to more vulnerable families.

INTRODUCTION

Providing children with the best possible start in life is crucial for reducing the magnitude of socioeconomic inequalities in health.[1] Maternal and early childhood home visits have been proposed as an effective strategy to improve the health and development of disadvantaged children.[2 3] Randomised controlled trials (RCTs) of maternal and early childhood nurse home visitation programs have been conducted in many Western countries, including Australia,[4 5] Canada,[6] England,[7 8] Germany,[9 10] the Netherlands,[11 12] and the USA.[13-15] However, RCT evidence on the effectiveness of these programs is sparse in non-Western cultures.[16-18]

In South Korea (hereafter, Korea), a maternal and early childhood home visit program has been implemented since 2013 in Seoul.[19 20] The Maternal and Early Childhood Sustained Home-visitation (MECSH) program[5 20] was introduced to the Seoul Healthy First Step Project (SHFSP), and associated nurse training programs have been established.[19] In 2022, the Seoul Healthy First Step Project covered 18.7% of families with new born babies in Seoul.[21] In 2019, the Korean government decided to expand early childhood nurse home visit services (the Early Life Health Management Program) nationally.[22 23] In 2020, a home visit program (Korea Early Childhood Home-visitation Intervention, KECHI) where nurses (with social workers) make multiple home visits to vulnerable families starting prenatally and continuing until the child reaches the age of 2 years, was developed and launched throughout the country. The central government of Korea has announced a plan to make the Early Life Health Management Program available to all 257 districts in Korea in late 2020s.[23]

Scientific evidence from RCTs will play a crucial role in expanding the availability of home visiting services and, ultimately, reducing socioeconomic inequalities in health. The overarching hypothesis of the trial is that children and mothers receiving the KECHI will have

a significantly better home environment and child, maternal, and family outcomes than those receiving usual care.

Methods and analysis

Study design

A 2-arm parallel group, superiority, individually randomised controlled trial was designed to evaluate the effectiveness of the KECHI in improving child health and development and maternal health (Figure 1). This trial is closer to a pragmatic RCT than to an explanatory one in the pragmatic-explanatory continuum,[24] considering two important trial settings: 1) the interventions are offered by home-visiting nurses employed in District Public Health Centres (DPHCs) for the KECHI, not by those who are hired and trained separately only for this trial; and 2) the eligibility criteria used for RCT screening are nearly identical to those used by home-visiting nurses to determine the KECHI beneficiaries.

Study setting

The KECHI was designed for implementation in the catchment areas of DPHCs across Korea. As of 2022 (the start of active recruitment), the KECHI has been conducted in 64 districts (25 in Seoul and 39 outside Seoul) out of 257 districts across the country. Based on administrative support from the Seoul Metropolitan Government and the Ministry of Health and Welfare of Korea, the research team contacted the directors and managers of DPHCs. Before the first home visit made to the intervention group, nurses who deliver the intervention to participants via home visits (plus social workers in some districts) are trained for at least 320 hours. The

training program includes pregnancy and postpartum care, infant's health and care, early childhood growth and development, maternal mental health and associated care, counselling (especially for social workers), family partnership model training, mothers' group facilitator training, case conferences, and reflective practice.[23] The Support Teams of the Seoul Healthy First Step Project and the Early Life Health Management Program administer intensive training sessions and monitor the performance of nurses' home visits.

Participants

The study will involve 800 pregnant women living in districts where KECHI is available. Eligible participants are pregnant women who:

- Have risk factor scores of 2 or over at the time of screening,
- Are at less than 37 weeks of gestation,
- Can read and answer questionnaires in Korean.

Women will be excluded if they:

- Have experienced any critical event such as termination of pregnancy, stillbirth, or child death.
- Plan to move abroad or to other regions where KECHI is not available within the next 6 months.

Eligibility risk factors

Eligibility will be determined by using a questionnaire eliciting information 16 risk factors (age considered as 1 risk factor) across four domains: sociodemographic variables, psychosocial variables, health and healthcare factors, and trauma experiences (Table 1). The questionnaire items on psychosocial variables and trauma experiences were modified from the SAFE START guideline in New South Wales, Australia.[25] Three risk factors (i.e., maternal age younger than

19 years old, single mother, low income) are rated 2 points, and the other 14 risk factors are rated 1 point. Thus, individuals' risk factor scores range from 0 to 19. A risk factor score of 2 or more will be necessary for study eligibility. The screening survey used in the trial is almost identical to the one that the Korean DHPCs use for pregnant women or mothers with young children to register for the home-visiting service, with the exception of postnatal-related items. In the real-world KECHI services, home-visiting nurses consider the vulnerability of families with risk scores of 2 and higher and prioritise families because the number of home-visiting nurses is insufficient to offer services to all potential KECHI recipients at the catchment areas of DHPCs. However, in this trial, study participants (those with a risk factor score of 2 or more) who provided signed consent are randomly allocated to either intervention or control groups. The KECHI services should be provided based on the allocation status, not based on prioritisation of subjects by home-visiting nurses.

Usual care

Both the intervention and control groups will be eligible to receive public health and social care services that are usually offered to pregnant women or mothers with young children. For instance, these services include postnatal care services (usually for 2 weeks), childhood health check-ups that are universally offered at paediatric clinics, and immunisation. In addition, many Korean women pay for and stay in specialised postpartum care centres called *sanhujoriwon* for about 2 weeks after childbirth.[26] According to a recent report,[27] 81.2% of women giving births pay for *sanhujoriwon*. Thus, the control and intervention groups may have *sanhujoriwon* services (mostly non-public) for 2 weeks after childbirth and then return home and use postnatal care services (public) for additional 2 weeks. The intervention group will be those who participate in KECHI from pregnancy until their children reach the age of 24 months.

On the other hand, the control group will not receive KECHI, but nurses may provide basic postnatal home visits (once within 8 weeks postpartum) if requested. Eligibility for basic home visits is decided when women apply for the service in person, online, or over the telephone. Contamination may occur if nurses provide KECHI to the control group based on their evaluation of the family situations at the basic home visit. It is also possible that public social service networks could refer families in the control group to the home-visiting nurses in KECHI at DPHCs. However, the research team expects that the magnitude of contamination would be minimal because the number of families in the control group requesting basic home visits would be small and referrals from social service networks are uncommon.

Intervention

KECHI is a complex intervention involving a wide range of outcomes in various domains. It has five goals: (1) improving transition to mothers' and parents' roles, (2) improving mothers' and families' health and wellbeing, (3) improving child health and development, (4) developing and promoting families' aspiration for the future, (5) strengthening social support networks.[23] KECHI encompasses 25-29 home visits by trained nurses from the prenatal period until the child reaches the age of 2 years.[23] Home-visiting nurses are expected to apply family partnership model, child-centred approach, and strength-based approach in their home visitation. Although KECHI is based on the experience of implementing MESCH in Seoul, these programs differ in several aspects. First, considering s*anhujoriwon* utilisation in Korea,[27] flexible numbers of home visits during the first 8 weeks (4-8 visits) were applied, and one additional visit before 24 months postpartum was added. The visit schedule of KECHI is presented in Table 2. Second, the Korean version of the *Learning to Communicate* parent education book (which covers 0-12 months postpartum)[28] used in MECSH was replaced by a

newly developed parent education book titled *Jaramtong*, which covers the prenatal period (*Jaramtong* 1, 120 pages), 0-6 months postpartum (*Jaramtong* 2, 162 pages) and 6-24 months postpartum (*Jaramtong* 3, 132 pages) as well as issues on prenatal care, child development, postnatal child care, parent-child attachment, play, communication, safety, and goal-setting.[23] The *Jaramtong* book contains sessions for activities (e.g., family shield activities to understand family strength, sharing housework with partner, activities to strengthen parent-child attachment, goal setting activities) which are usually initiated by home-visiting nurses. A total of 20 leaflets are also developed and used for the KECHI services: breastfeeding, home safety, crying (3 leaflets), sudden infant death syndrome prevention, maternal depression (3 leaflets), child abuse, home without any violence, intimate partner violence (2 leaflets), smoking, alcohol drinking, birth control, companion dogs, first aid in early childhood (2 leaflets), partner relationships. Home-visiting nurses use the KECHI manual containing period-specific goals of home visitation, potential lists of services, lists of assessments, and expected outcomes.[23] Furthermore, new protocols for KECHI were developed, including protocols for addressing perinatal depression and intimate partner violence. The contents of each home visit can be tailored to the mother's needs, skills, strengths, and capacities using parenting education materials. Social workers in some DPHCs are included as a service team member. Social workers should co-visit home with nurses in the 2nd or 3rd visits of the KECHI visitation schedule and should assess social welfare needs of families. Social workers have two major roles: instrumental support (referrals to community services) and psychosocial support (clinical psychological counselling service).[23] For psychosocial support, social workers obtain additional training programs provided by the Support Teams.

Primary outcomes

The UK Medical Research Council guidance[29] recommends using multiple outcomes to evaluate the impact of complex interventions. As presented in Table 3, we will focus on six primary domains of outcomes: 1) home environment, 2) child safety, 3) child development, 4) child care, 5) maternal well-being, and 6) community support. The domains reflect the target outcomes potentially affected by KECHI. We selected one primary outcome for each domain: 1) Infant/Toddler Home Observation for Measurement of the Environment (IT-HOME),[30] 2) emergency department visits due to injuries, 3) Korean Bayley Scales of Infant and Toddler Development-III (K-Bayley-III),[31] 4) breastfeeding duration, 5) maternal self-rated health, and 6) community service linkage.

The IT-HOME[30] comprises 45 items evaluating the quality and quantity of stimulation and support available to children in the home environment. The items are assessed by a combination of structured interviews and observations by trained research nurses during their home visits at 6, 12, and 24 months postpartum. Emergency department visits due to injuries could be considered a proxy measure for child maltreatment[32] and are used as the primary outcome for the child safety domain. Parents report their children's hospital utilisation, including the number of emergency department visits and reasons of the utilisation such as injuries and diseases at four time points: 6 weeks postpartum and 6, 12, and 24 months postpartum. The K-Bayley-III[31] was chosen as a measure for the child development domain. It is an extensive standardised developmental assessment tool for diagnosing developmental delays in early childhood. Mothers and children aged 24 months will be invited to medical institutions and assessed by K-Bayley-III experts. For childcare, parents report their feeding practices, specifically breastfeeding duration and types of foods provided when their children were 6 weeks, 6 months, 12 months, and 24 months old. Self-rated health is one of the most frequently used measures for adulthood health status in health and social research. It is a strong predictor

of mortality in many populations,[33] as well as in Korean women.[34] Thus, we chose maternal self-rated health as the primary outcome for assessing maternal well-being and it will be evaluated at six survey time points from baseline to 24 months. Mothers answer a single question ("How would you rate your health these days?") on a 5-point Likert scale, ranging from 1 (very good) to 5 (very bad). One of the core components of KECHI is sharing information on community services available for mothers and their families. Thus, for the community support domain, participants will be asked about their utilisation of the most popular DPHC services and other popular publicly funded social services. These community services include public services for nutritional support, breastfeeding, medical expense assistance, smoking cessation, mental health, counseling, childcare support, and support for multicultural families and the disabled.

Secondary outcomes

The secondary outcomes pertain to 7 domains: child safety, child development, childcare, maternal well-being, community support, family well-being and parent-child interactions (Table 3).

The child safety domain includes the mother's safety knowledge and the child's emergency department visits and hospital admissions. The questionnaire testing mothers' safety knowledge contains five items from the Korean National Health Insurance Service's Infant Health Examination Questionnaire.[35] Mothers report a total number of emergency department visits and hospital admissions as one of the proxy markers for child safety, which is different from the primary outcome measure of child's emergency department visits especially due to injuries.

The child development domain includes the Denver Developmental Screening Test II (DDST-

II),[36] premature birth, and delayed growth. DDST-II compares a child's development to the developmental age ranges in the tool. Research nurses will be trained to administer the DDST-II at three times including 6 months, 12 months, and 24 months postpartum periods. Delayed growth will be determined based on the child's body weight and height at 6 months, 12 months, and 24 months postpartum. Research nurses measure child's weight, height, and head circumference, and parents' report on these anthropometric outcomes can be used when actual measurement is not available during the home visits.

The childcare domain includes knowledge of sudden infant death syndrome (SIDS) prevention, vaccination, national health check-ups, spousal participation in parenting, parenting-related household expenses, intention to have another child, and experience of delivery in the past 2 years. The questionnaire testing the mother's knowledge of SIDS contains five items from the Korean National Health Insurance Service's Infant Health Examination Questionnaire.[35] Vaccination will be assessed by completion of the Korean childhood immunisation schedule. National health check-ups will be assessed by asking whether the mother has visited a health centre or paediatrician for an infant health check-up (scheduled at 14-35 days, 4-6 months, 9-12 months, 18-24 months postpartum). Spousal participation in parenting will be measured by a questionnaire containing 4 items from the Panel Study on Korean Children.[37] Parenting-related household expenses measure a household's expenditures for pregnancy, childbirth, and supplies needed to care for the child. Intention to have another child and experience of delivery in the past 2 years will be determined by the mother's report at 24 months postpartum.

We will obtain information on a wide range of maternal well-being indicators: maternal depression measured by the Edinburgh Postnatal Depression Scale (EPDS),[38] Patient Health Questionnaire-9 (PHQ-9),[39] and Whooley & Arroll questions;[40 41] anxiety measured by the

Generalised Anxiety Disorder 2-item (GAD-2);[42] maternal tobacco use and alcohol consumption; delivery type; parenting distress measured by the Being a Mother Scale 13-item (BaM-13);[43] intimate partner violence measured by the Hurt, Insult, Threaten, and Scream (HITS) tool;[44] and maternal body weight and height for mother's body mass index. Maternal suicidal ideation, the 10th item of the EPDS, will also be considered as a secondary outcome in addition to the total score of the EPDS. Delivery type (i.e., vaginal delivery, planned C-section, or emergency C-section) will be assessed by the mother's self-report when the child is 6 weeks old.

As a community support domain indicator, the social support questionnaire was adopted from the Panel Study on Korean Children[37] to assess the level of social support mothers recognise at baseline, 6 months, 12 months, and 24 months postpartum.

The family well-being domain includes food insecurity, spousal intimacy, spousal tobacco use, and spousal alcohol consumption. Food insecurity will be assessed by asking about the family's level of limited access to adequate food over the past year. Spousal intimacy will be measured using the 4-item Revised-Kansas Marital Satisfaction Scale[45] modified by the Korea Institute of Child Care and Education.[37]

The NCAST (Nursing Child Assessment Satellite Training)-PCI (Parent-Child Interaction) teaching scale is an observational measure of parent-child interactions.[46] The NCAST-PCI teaching scale is composed of 73 items measuring three aspects of the caregiver's behaviours and two aspects of the child's behaviours during the semi-structured teaching episode. In this trial, the NCAST-PCI teaching is conducted when research nurses visit home at 12- and 24-month follow-up. During the home visit, the parent will be given a list of tasks (e.g., stacking 2 blocks, draw a line on a paper using a crayon) and asked to choose one that has a slightly

above their child's current developmental level. Research nurses who participated in a recording training then hand over toys associated with the task and videotape the parent-child interaction. Once the home visit is completed, trained coders independently assess the quality of parent-child interactions by observing mother and children's verbal and nonverbal interactions. In the training and coding processes, we will use the Korean version of the NCAST-PCI manuals and videos, translated under a license agreement with the Barnard Center at the University of Washington.

Sample size

We considered IT-HOME as a main outcome measure for sample size calculation. In our prior study,[47] the mean IT-HOME score for children at 6-24 months postpartum who received nurse home visitation services in Seoul was 32.5, and the standard deviation (SD) was 5.0. Since we expect to recruit participants from more diverse backgrounds, we anticipated approximately 10% larger variations in IT-HOME scores. Effect sizes of 0.25-0.3 SDs are considered meaningful and impactful at the population level,[48 49] so we set the difference in IT-HOME scores between intervention and control groups to 1.50. The probability of type I error (alpha) was set at 0.05 (2-tailed) and type II error (beta) was set at 0.10 (power = 90%). The presumption of 35% attrition for the primary outcome indicator at the 2-year follow-up, reflecting a rate slightly higher than that reported in other studies,[48] resulted in a sample size of 400 per group (800 total).

Recruitment

Participants will be recruited through in-person invitations at the maternal and child health departments of DPHCs, social media posts, and advertisements using mobile phone numbers

of perinatal women registered in DPHCs.

Interested perinatal women will contact the study team and be screened for eligibility by a member of the research team. Trained research nurses will make a home visit to conduct the baseline survey and obtain signed consent to participate in the study. Consent will be also obtained for linkage to secondary data (e.g., national health insurance data) and long-term follow-up. Subsequently, participants will be randomised.

Randomisation and allocation

Stratified randomisation stratified by parity and recruitment sites (DPHCs) will be conducted to randomly assign participants to the control or intervention group at a 1:1 ratio using computer-generated random numbers. Research nurses will enrol participants and a research manager will inform home-visiting nurses in DPHCs of the contact information of families needing interventions. Randomisation will be conducted using the Interactive Web Responsive System (IWRS) created by the Medical Research Collaboration Center (MRCC) of Seoul National University Hospital (SNUH).

Blinding

As information on allocation is not withheld from participants, this study is an open trial. However, every effort will be made to maintain blinding of allocation status. The research management staff, KECHI nurses (for the intervention group), and study participants will be aware of the allocation results. However, the research nurses making postnatal outcome assessments will be blinded to the randomisation, and families will be asked not to disclose their group status during the surveys at home. The research nurses (outcome assessors) will only be notified of the follow-up survey schedules (6 weeks, 6 months, 12 months, and 24

months) of both groups. It is important to note that some outcome measures (i.e., NCAST-PCI teaching scale and K-Bayley-III) will be assessed by independent researchers other than research nurses. The NCAST-PCI teaching scale will be coded by independent coders, and the K-Bayley-III will be independently measured at medical institutions by K-Bayley-III experts. Statistical analysts will not be able to access the randomisation variable until all 2 years of data are collected.

Compensation

Participants will be compensated 30,000 Korean won (1,300 Korean won = 1 US dollar) for each survey (maximum compensation: 180,000 Korean won). In addition, they are paid 10,000-30,000 Korean won for the travel cost of visiting the medical institutions for the K-Bayley-III assessment.

Patient and public involvement

Patients and/or the public are not involved in the design, conduct, reporting, or dissemination plans of this trial.

Data collection, data management, monitoring, and auditing

At four home visits (baseline, 6, 12, 24 months) and two phone interviews (6 weeks and 18 months), trained research nurses will collect data on primary and secondary outcomes. At 24 months, additionally, K-Bayley-III experts will administer the K-Bayley-Ⅲ at Seoul National University and Dong-A University. The home and lab visits will usually take 1.5 hours, and the phone surveys will last for 5 minutes on average. For observational measures, research nurses will be trained by a developer for the IT-HOME and the Barnard Center at the University

of Washington for the NCAST-PCI teaching scale, respectively, and only those who achieve an inter-rater reliability rate greater than 90% will administer observations and scoring. The quality and procedures of data collection will be regularly monitored by a research manager. All data collected will be reported in a written Complete Report Form (CRF) first, and then research nurses will enter the data again in an electronic Complete Report Form (eCRF) created in the web-based Clinical Research and Trial management system (iCReaT, http://icreat.nih.go.kr). The iCReaT is developed and maintained by the Korea Disease Control and Prevention Agency (KDCA) and provides an effective platform for managing study protocols, participants, data entry, and data monitoring. Many clinical trials conducted in Korea use the iCReaT to develop their own eCRFs. Anyone who needs access to the iCReaT (e.g., research nurses or project managers) requires online training courses and should be certified by the KDCA. Although data collection and entry are conducted mainly by research nurses, the MRCC at SNUH is fully responsible for regular data management and analysis, in addition to the use of the IWRS (i.e., eCRF, web-based random assignment). The MRCC team consists of members responsible for random assignment, data management, and data analysis, and they work independently and collaboratively with the research team. From the initial stage of the trial, they developed the data management plan (DMP), web-based random assignment plan, data verification specification (DVS), eCRF complete guideline (CCG), and statistical analysis plan (SAP). Data validation of the eCRF will be completed up to twice a year using manual and system queries. All processes of the trial and data management will be audited by the funder and an external consulting group.

Statistical analysis plan

After database locking, the primary analyses will be conducted on an intention-to-treat (ITT)

basis. For the six primary outcomes, analyses will be conducted with both data without missing information and data with multiple imputation (five times). For other outcomes, data without missing information will be analysed. After completion of the survey at 6 months postpartum, we will conduct an interim ITT analysis for selected 14 outcomes (IT-HOME, emergency department visit due to injury, breastfeeding duration, maternal self-rated health, knowledge on SIDS prevention, Denver-II, spousal participation in parenting, EPDS, PHQ-9, GAD-2, BaM-13, HITS, social support questionnaire, and the Revised-Kansas Marital Satisfaction Scale). A per-protocol analysis after completion of 24 month assessment will also be conducted, in which participants will be excluded from the intervention arm of the trial if they did not have at least 13 KECHI nursing visits; any such participants will be included in the control group. Regression analysis will be conducted to evaluate the effects of the intervention, and the results will be summarised using point estimates and their 95% confidence intervals. Clustering of study subjects at the recruitment sites (DPHCs) will be considered in the analysis. Analyses adjusted for parity and region (Seoul vs. non-Seoul) will also be presented. For repeatedly collected variables, interactions between allocation status and follow-up periods will be examined. Differences at each follow-up period (6 weeks, 6 months, 12 months, and 24 months) will be presented if the interactions are significant; otherwise, mean differences over the follow-up period will be estimated. Subgroup analyses stratified by parity, region, risk factor score (2 vs. ≥3), and EDPS score (<13 vs. ≥13) will be conducted. Considering the potential increase in alpha error by having six primary outcomes, we will interpret the overall effectiveness of the intervention by assessing the comprehensive analysis results and outcome-specific contents of KECHI.

Ethics and dissemination

The study protocol was reviewed and approved by the institutional review board of the Seoul National University Hospital (IRB No. C-1911-150-1083). The trial was initially registered at ClinicalTrials.gov (ClinicalTrials.gov identifier: NCT04749888) on February 11, 2021 and revised on May 5, 2022 and March 24, 2024. The trial was scheduled to start on October 27, 2021, and is expected to be completed by February 15, 2025. Participants consent for themselves and give parental permission for their babies. Participants are informed that their participation is voluntary and they can withdraw without penalty at any time and their decision does not impact their care in any way. The study results will be published in peer-reviewed journals and presented at scientific meetings. The results will be reported at conferences and in peer-reviewed publications and will be used by the Korean government for expanding the KECHI services.

Discussion

The effects of nurse home visitation interventions may vary among societies,[32 50] and effects detected in one country may not translate to another country.[50] For example, the RCT of the Family Nurse Partnership (FNP) program in England did not identify significant impacts on four primary endpoints (prenatal cigarette smoking at the end of pregnancy, birthweight of the baby, subsequent pregnancy, and emergency attendances and hospital admission) while the effects were significant for language and cognitive development.[7] The characteristics of population and existing home visitation services might have contributed to these findings.[7 32] In addition, while few effects of home visitation on healthcare utilisation, child health, and

child accidents were found in trials conducted in England,[7] Germany,[51] and Ireland,[52] home visiting programs in the US appear to produce clear beneficial effects on those outcomes.[53 54] These discrepancies might also be attributed to differences in the public health insurance systems between Europe and US affecting disadvantaged mothers' access to comprehensive healthcare services for children. In this regard, Korea may provide a unique opportunity to understand the effects and mechanisms of maternal and early childhood home visitation. In Korea, while universal national health insurance is established (similar to the European context), maternal early childhood home visiting services are underdeveloped (similar to the US context). A prior paper showed that maternal distress reported by Korean women with young children was very high compared to other countries.[55] This Korean situation may shed light on the difference in the discordant RCT findings from different countries on the effects of home visitation.

Although early childhood nurse home visits have a long history in many Western countries,[3] Korea has only a 10-year history of implementing maternal and early childhood nurse home visits as a component of public services. The SHFSP started only in 3 districts of Seoul in 2013 and expanded to all 25 districts in 2020. In 2020, the central government of Korea started to expand the service to other parts of Korea.[23] In this early stage of the national expansion of the intervention, this RCT may be instrumental in policy decision-making with respect to the speed of the national expansion and any potential modification of the service.

This trial has some limitations. Outcome reporting made by mothers may be affected by their perceptions and feelings. Although the research nurses making outcome measurements will be blinded to randomisation and families will be asked not to disclose their allocation status, breaches of blinding would be possible. However, the direct observation measures (IT-HOME)

would mitigate the limitation of self-reports, and the independent assessments of the NCAST-PCI teaching scale and K-Bayley-III will ensure blinding. In addition, the findings may not be generalisable to the highly vulnerable families included in the real-world KECHI services, wherein nurses prioritise more vulnerable families due to a relative shortage of nurses. Subgroup analyses by EPDS scores and risk factor scores would provide information on the effect size in the real-world KECHI. Moreover, the findings may not generalise to families of multicultural mothers with communication challenges in Korean.

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Contributors

YHK, YMK, KJJ, SHC, JYL and HJC developed the grant proposal for this project. YHK, YMK, JHK, JY, and RO administratively led the project. YHK wrote the draft. The manuscript was revised based on comments from all authors. All authors read and approved the final manuscript.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication

Not applicable.

Data availability statement

Raw data with a codebook will be available for sharing once core data are published and data sharing agreements are formalized through the Patient-Centered Clinical Research Coordinating Center (PACEN), Korea.

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Table 1. Risk factors used to determine eligibility and their descriptions

Risk factors	Descriptions
Sociodemographic risk factors	
Maternal young age*	Pregnant women aged 19 or less are scored 2 and pregnant women aged 20-23 are scored 1.
Single mother*	Single mothers are scored 2.
Low income*	Families receiving basic living security program or families whose household income is 50% or less of national median household income are scored 2.
Multicultural background	Born or raised abroad
Low education	Less than high school graduation
Disability	Physical disability, mental disability, or intellectual disability
Psychosocial risk factors	
Depression or suicidal ideation	Edinburgh Postnatal Depression Scale (EPDS, 10 items) ≥ 10 or EPDS 10th item (suicide ideation) ≥ 1
Anxiety	Generalized anxiety disorder 2-item ≥ 3
Recent major stressors	Have you ever experienced serious stress, change, or loss over the past 12 months such as financial problems, someone close to you dying, or any other serious worries? (yes)
Lack of instrumental or emotional support	Will you be able to get practical support with your baby? (no) or Do you have someone you are able to talk to about your feelings or worries? (no)
Past treatment history for emotional issues	Have you ever been treated for emotional issues? (yes)
Health and healthcare risk factors	
Delayed prenatal care	Start of obstetric care ≥ 20 weeks gestation
Smoking or alcohol consumption	Smoking during pregnancy or alcohol consumption twice per week during pregnancy
Multiple foetuses	Multiple foetuses
Risk factors of trauma experiences	
Childhood abuse experience or witnessing domestic violence	Have you ever been physically, emotionally, or sexually abused in your childhood? (yes) or Have you ever witnessed domestic violence during childhood or adolescence? (yes)
Intimate partner violence or need of assistance regarding domestic violence	Score of Hurt, Insult, Threaten, and Scream (HITS) questionnaires (4 items) ≥ 7 or Do you need any help for domestic violence? (yes)

*Except for these three risk factors, other risk factors are scored 1.

Table 2. Home visitation schedules of the Korea Early Childhood Home-visiting Intervention (KECHI)

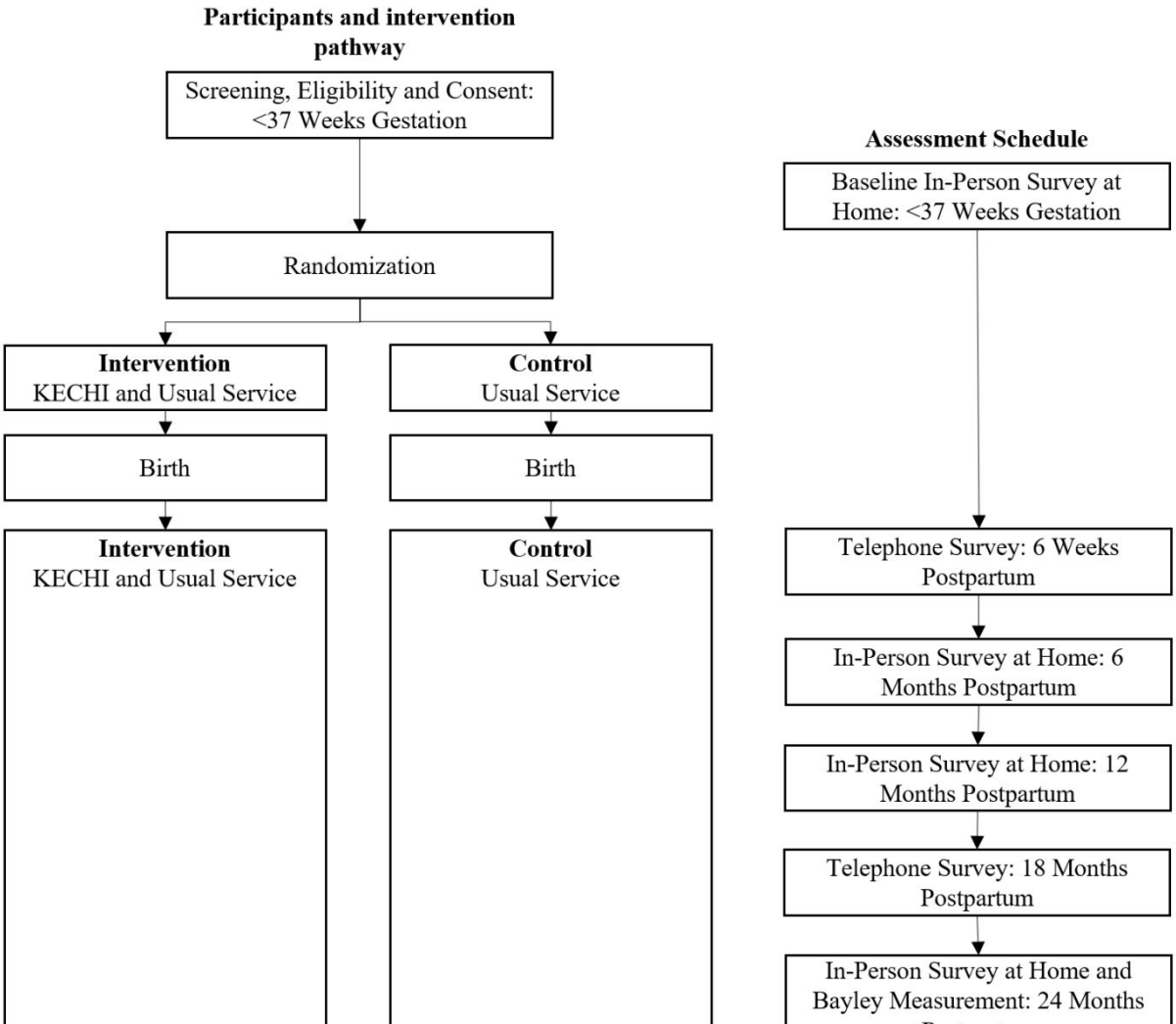
Period (child age)	Frequency of visits	No. of visits (additional visits are possible)
Before birth		3
1-8 weeks (56 days) postpartum	Weekly	4-8 (depends on the use of postpartum care facility)
9-14 weeks (100 days) postpartum	Fortnightly	3
15-26 weeks (6 months) postpartum	3-weekly	4
27-52 weeks (12 months) postpartum	6-weekly	4
53-104 weeks (24 months) postpartum	Bimonthly	6 + 1 (1 visit for ending)

Table 3. Assessment variables and associated assessment schedules

Assessment variables			Assessment time					
Domains		Outcomes	Baseline	6 weeks	6 Months	12 Months	18 Months	24 Months
Primary outcomes	Home environment	IT-HOME (Infant/Toddler Home Observation for Measurement of the Environment) (45 items)			X	X		X
	Child safety	Emergency department visits due to injuries		X	X	X		X
	Child development	K-Bayley-III (Korean Bayley Scales of Infant and Toddler Development-III)						X
	Childcare	Breastfeeding duration		X	X	X		X
	Maternal well-being	Maternal self-rated health	X	X	X	X	X	X
	Community support	Community service linkage	X			X		X
Secondary outcomes	Child safety	Safety knowledge (5 items)	X		X	X		X
		Emergency department visits		X	X	X		X
		Hospital admission		X	X	X		X
	Child development	Denver (Denver Developmental Screening Test) II			X	X		X
		Premature birth		X				
		Delayed growth			X	X		X
	Childcare	Knowledge of sudden infant death syndrome prevention (5 items)	X		X			
		Vaccination			X	X		X
		National health check-ups			X	X		X
		Spousal participation in parenting (4 item)			X	X		X
		Parenting related household expenses	X		X	X		X
		Intention to have another child						X
		Experience of delivery in the past 2 years						X
	Maternal well-being	EPDS (Edinburgh Postnatal Depression Scale) (10 items) including suicide ideation (10th item)	X		X	X		X

Assessment variables			Assessment time					
Domains		Outcomes	Baseline	6 weeks	6 Months	12 Months	18 Months	24 Months
		PHQ-9 (Patient Health Questionnaire-9) (9 items)	X		X	X		X
		Whooley & Arroll questions (3 items)		X			X	
		GAD-2 (Generalized Anxiety Disorder 2-item)	X		X	X		X
		Maternal tobacco use	X		X	X		X
		Maternal alcohol consumption	X		X	X		X
		Delivery type		X				
		Being a Mother Scale (BaM-13) (13 items)			X	X		X
		HITS (Hurt, Insult, Threaten, and Scream) (4 items)	X		X	X		X
		Maternal body weight	X	X	X	X		X
	Community support	Social support questionnaires (12 items)	X		X	X		X
	Family well-being	Food insecurity	X			X		X
		Revised-Kansas Marital Satisfaction Scale (4 items)	X		X	X		X
		Spousal tobacco use	X		X	X		X
		Spousal alcohol consumption	X		X	X		X
	Parent-child interactions	NCAST (Nursing Child Assessment Satellite training)-PCI (Parent-Child Interaction) teaching scale (73 items)				X		X

Figure 1. Study flow diagrams, showing the participants and intervention pathway and the assessment schedule



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	__1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	__3_____
	2b	All items from the World Health Organization Trial Registration Data Set	__NA_____
Protocol version	3	Date and version identifier	__NA_____
Funding	4	Sources and types of financial, material, and other support	__21-22_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	__1, 21_____
	5b	Name and contact information for the trial sponsor	__1_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	__21-22_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	__16-17_____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	___4-5_____
	6b	Explanation for choice of comparators	___4_____
Objectives	7	Specific objectives or hypotheses	___4-5_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	___5_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	___5-6_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	___6-7, 28____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	___8-9_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	___18_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	___NA_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	___7-8_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	___10-14, 30-31_
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	___32_____

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	___14_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___14-15_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	___15_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	___15_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	___15_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	___15-16_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___15-16_____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	___16-17_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	___16-17_____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___16-17_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___17-18_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	___18_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	___18_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___16-17_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___18_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___NA_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___19_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___3_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	___NA_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	___15_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	___15_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___NA_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___22_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	___17_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___NA_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	___19_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	___NA_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	___NA_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_Appendices 1, 2_
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	___NA_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Impact of the Korea Early Childhood Home-visiting Intervention (KECHI) on child health and development and maternal health: a randomised controlled trial protocol

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Impact of the Korea Early Childhood Home-visiting Intervention (KECHI) on child health and development and maternal health: a randomised controlled trial protocol

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ABSTRACT

Introduction

Randomised controlled trials (RCTs) of early childhood home visiting interventions led by nurses have been conducted mainly in Western countries, whereas such trials have been limited in non-Western cultures, including Asia. In South Korea, a national nurse home visit program (Korea Early Childhood Home-visitation Intervention, KECHI) was developed in 2020 and launched throughout the country. We designed a pragmatic RCT to evaluate the effectiveness of KECHI on child health and development and maternal health.

Methods and analysis

Eligible participants will be pregnant women at less than 37 weeks of gestation with risk factor scores of 2 or over, who are sufficiently fluent in Korean to read and answer the questionnaire written in Korean and live in districts where the KECHI services are available. Eight hundred participants will be recruited from the general community and through the District Public Health Centres. The participants will be randomised 1:1 to KECHI plus usual care or usual care. KECHI encompasses 25-29 home visits, group activities, and community service linkage. Participants will complete assessments at baseline (<37 weeks gestation), 6 weeks, 6 months, 12 months, 18 months, and 24 months postpartum. The six primary outcomes will be 1) home environment (assessed by Infant/Toddler Home Observation for Measurement of the Environment), 2) emergency department visits due to injuries, 3) child development (assessed using Korean Bayley Scales of Infant and Toddler Development-III), 4) breastfeeding duration, 5) maternal self-rated health, and 6) community service linkage.

Ethics and dissemination

This trial has received full ethical approval from the Institutional Review Board of the Seoul National University Hospital. Written consent will be obtained from the participants. The results will be reported at conferences, disseminated through peer-reviewed publications, and used by the Korean government to expand the KECHI services.

Trial registration number

NCT04749888

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ➔ This study is a 2-arm parallel group, superiority, individually randomised controlled trial designed to evaluate the effectiveness of the Korea Early Childhood Home-visiting Intervention (KECHI) in improving child health and development and maternal health.
- ➔ The results of this trial will provide pragmatic evidence for the maternal and early childhood nurse home visitation program (i.e., KECHI) in South Korea and they will aid in the expansion of KECHI across the country.
- ➔ The findings may not be generalisable to families participating in the real-world KECHI program where, due to relative shortages of nurses in certain districts, nurses provide the service selectively to more vulnerable families.

INTRODUCTION

Providing children with the best possible start in life is crucial for reducing the magnitude of socioeconomic inequalities in health.[1] Maternal and early childhood home visits have been proposed as an effective strategy to improve the health and development of disadvantaged children.[2 3] Randomised controlled trials (RCTs) of maternal and early childhood nurse home visitation programs have been conducted in many Western countries, including Australia,[4 5] Canada,[6] England,[7 8] Germany,[9 10] the Netherlands,[11 12] and the USA.[13-15] However, RCT evidence on the effectiveness of the nurse-led early childhood home visiting programs is sparse in non-Western cultures, although RCTs of home vising programs led by non-professionals have been conducted in non-Western low- and middle-income countries.[16 17]

In South Korea (hereafter, Korea), a maternal and early childhood nurse home visit program has been implemented since 2013 in Seoul.[18 19] The Maternal and Early Childhood Sustained Home-visitation (MECSH) program[5 19] was introduced to the Seoul Healthy First Step Project , and associated nurse training programs have been established.[18] In 2022, the Seoul Healthy First Step Project covered 18.7% of families with new born babies in Seoul.[20] In 2019, the Korean government decided to expand early childhood nurse home visit services (the Early Life Health Management Program) nationally.[21 22] In 2020, a home visit program (Korea Early Childhood Home-visitation Intervention, KECHI) where nurses (with social workers) make multiple home visits to vulnerable families starting prenatally and continuing until the child reaches the age of 2 years, was developed and launched throughout the country. The central government of Korea has announced a plan to make the Early Life Health Management Program available to all 257 districts in Korea in late 2020s.[22]

Scientific evidence from RCTs will play a crucial role in expanding the availability of home

visiting services and, ultimately, reducing socioeconomic inequalities in health. The overarching hypothesis of the trial is that children and mothers receiving the KECHI will have a significantly better home environment and child, maternal, and family outcomes than those receiving usual care.

Methods and analysis

Study design

A 2-arm parallel group, superiority, individually randomised controlled trial was designed to evaluate the effectiveness of the KECHI in improving child health and development and maternal health (Figure 1). This trial is closer to a pragmatic RCT than to an explanatory one in the pragmatic-explanatory continuum,[23] considering two important trial settings: 1) the interventions are offered by home-visiting nurses employed in District Public Health Centres (DPHCs) for the KECHI, not by those who are hired and trained separately only for this trial; and 2) the eligibility criteria used for RCT screening are nearly identical to those used by home-visiting nurses to determine the KECHI beneficiaries.

Study setting

The KECHI was designed for implementation in the catchment areas of DPHCs across Korea. As of 2022 (the start of active recruitment), the KECHI has been conducted in 64 districts (25 in Seoul and 39 outside Seoul) out of 257 districts across the country. Based on administrative support from the Seoul Metropolitan Government and the Ministry of Health and Welfare of Korea, the research team contacted the directors and managers of DPHCs. Before the first home

visit made to the intervention group, nurses who deliver the intervention to participants via home visits (plus social workers in some districts) are trained for at least 320 hours. The training program includes pregnancy and postpartum care, infant's health and care, early childhood growth and development, maternal mental health and associated care, counselling (especially for social workers), family partnership model training, mothers' group facilitator training, case conferences, and reflective practice.[22] The Support Teams of the Seoul Healthy First Step Project and the Early Life Health Management Program administer intensive training sessions and monitor the performance of nurses' home visits.

Participants

The study will involve 800 pregnant women living in districts where KECHI is available. Eligible participants are pregnant women who:

- Have risk factor scores of 2 or over at the time of screening,
- Are at less than 37 weeks of gestation,
- Can read and answer questionnaires in Korean.

Women will be excluded if they:

- Have experienced any critical event such as termination of pregnancy, stillbirth, or child death.
- Plan to move abroad or to other regions where KECHI is not available within the next 6 months.

Eligibility risk factors

Eligibility will be determined by using a questionnaire eliciting information 16 risk factors (age considered as 1 risk factor) across four domains: sociodemographic variables, psychosocial variables, health and healthcare factors, and trauma experiences (Table 1). The questionnaire

items on psychosocial variables and trauma experiences were modified from the SAFE START guideline in New South Wales, Australia.[24] Three risk factors (i.e., maternal age younger than 19 years old, single mother, low income) are rated 2 points, and the other 14 risk factors are rated 1 point. Thus, individuals' risk factor scores range from 0 to 19. A risk factor score of 2 or more will be necessary for study eligibility. The screening survey used in the trial is almost identical to the one that the Korean DHPCs use for pregnant women or mothers with young children to register for the home-visiting service, with the exception of postnatal-related items. In the real-world KECHI services, home-visiting nurses consider the vulnerability of families with risk scores of 2 and higher and prioritise families because the number of home-visiting nurses is insufficient to offer services to all potential KECHI recipients at the catchment areas of DHPCs. However, in this trial, study participants (those with a risk factor score of 2 or more) who provided signed consent are randomly allocated to either intervention or control groups. The KECHI services should be provided based on the allocation status, not based on prioritisation of subjects by home-visiting nurses.

Usual care

Both the intervention and control groups will be eligible to receive public health and social care services that are usually offered to pregnant women or mothers with young children. For instance, these services include postnatal care services (usually for 2 weeks), childhood health check-ups that are universally offered at paediatric clinics, and immunisation. In addition, many Korean women pay for and stay in specialised postpartum care centres called *sanhujoriwon* for about 2 weeks after childbirth.[25] According to a recent report,[26] 81.2% of women giving births pay for *sanhujoriwon*. Thus, the control and intervention groups may have *sanhujoriwon* services (mostly non-public) for 2 weeks after childbirth and then return home

and use postnatal care services (public) for additional 2 weeks. The intervention group will be those who participate in KECHI from pregnancy until their children reach the age of 24 months. On the other hand, the control group will not receive KECHI, but nurses may provide basic postnatal home visits (once within 8 weeks postpartum) if requested. Eligibility for basic home visits is decided when women apply for the service in person, online, or over the telephone. Contamination may occur if nurses provide KECHI to the control group based on their evaluation of the family situations at the basic home visit. It is also possible that public social service networks could refer families in the control group to the home-visiting nurses in KECHI at DPHCs. However, the research team expects that the magnitude of contamination would be minimal because the number of families in the control group requesting basic home visits would be small and referrals from social service networks are uncommon.

Intervention

KECHI is a complex intervention involving a wide range of outcomes in various domains. It has five goals: (1) improving transition to mothers' and parents' roles, (2) improving mothers' and families' health and wellbeing, (3) improving child health and development, (4) developing and promoting families' aspiration for the future, (5) strengthening social support networks.[22] KECHI encompasses 25-29 home visits by trained nurses from the prenatal period until the child reaches the age of 2 years.[22] Home-visiting nurses are expected to apply family partnership model, child-centred approach, and strength-based approach in their home visitation. Prior Korean papers presented nurses' competencies, nursing practices addressing complex and difficult issues (e.g., domestic violence), and mothers' experiences associated with prenatal and early childhood sustained nurse home visitation services.[27-29] Although KECHI is based on the experience of implementing MESCH in Seoul, these programs differ

in several aspects. First, considering s*anhujoriwon* utilisation in Korea,[26] flexible numbers of home visits during the first 8 weeks (4-8 visits) were applied, and one additional visit before 24 months postpartum was added. The visit schedule of KECHI is presented in Table 2. Objectives of home visits, frequency of home visits, lists of assessment tools, remarks and cautions for home visits, lists of topics covered, expected outcomes stratified by the periods (e.g., before birth, 1-8 weeks postpartum, 9-14 weeks postpartum) are documented in the KECHI manual used by nurses and social workers.[22] Second, the Korean version of the *Learning to Communicate* parent education book (which covers 0-12 months postpartum)[30] used in MECSH was replaced by a newly developed parent education book titled *Jaramtong*, which covers the prenatal period (*Jaramtong* 1, 120 pages), 0-6 months postpartum (*Jaramtong* 2, 162 pages) and 6-24 months postpartum (*Jaramtong* 3, 132 pages) as well as issues on prenatal care, child development, postnatal child care, parent-child attachment, play, communication, safety, and goal-setting.[22] The *Jaramtong* book contains sessions for activities (e.g., family shield activities to understand family strength, sharing housework with partner, activities to strengthen parent-child attachment, goal setting activities) which are usually initiated by home-visiting nurses. A total of 20 leaflets are also developed and used for the KECHI services: breastfeeding, home safety, crying (3 leaflets), sudden infant death syndrome prevention, maternal depression (3 leaflets), child abuse, home without any violence, intimate partner violence (2 leaflets), smoking, alcohol drinking, birth control, companion dogs, first aid in early childhood (2 leaflets), partner relationships. Furthermore, new protocols for KECHI were developed, including protocols for addressing perinatal depression and intimate partner violence.[22] The contents of each home visit can be tailored to the mother's needs, skills, strengths, and capacities. Although social workers' activities are part of the KECHI services,[22] only some DPHCs have social workers as a service team member. According to the KECHI

manual,[22] social workers should co-visit home with nurses in the 2nd or 3rd visits of the KECHI visitation schedule and should assess social welfare needs of families. Social workers have two major roles: instrumental support (referrals to community services) and psychosocial support (clinical psychological counselling service).[22] For psychosocial support, social workers obtain additional training programs provided by the Support Teams.

Database systems monitoring home visits have been established by the Seoul metropolitan government (for the Seoul Healthy First Step Project) and the central Korean government (for the Early Life Health Management Program). Nurses and social workers are government employees and should input their activities on the nature of home visits (personal identifiers, date of the visit, mode of home visits, gestational weeks or babies' age in weeks, contents delivered in the home visits, service duration) at the completion of each home visit through the database systems. Antenatal and postnatal electronic checklists are used to record activities completed in the home visit. The checklists contained topics within nine antenatal and nine postnatal domains which could be dealt during the home visit. Antenatal domains included parentcraft, pregnant women's wellbeing, family members' wellbeing, safety, planning and goal setting, referrals, tools, and *Jaramtong* materials. Postnatal domains included children's wellbeing, caregivers' wellbeing, caregivers' mental health, family members' wellbeing, safety, planning and goal setting, referrals, tools, and *Jaramtong* materials. Except for *Jaramtong* materials (29 antenatal items and 96 postnatal items) which are inputted in the database systems with unique material numbers, there were 39 items in the antenatal checklist and 52 items in the postnatal checklist, which is similar to the checklists used in the prior study on the right@home randomized controlled trial.[31] The Support Teams of the program can monitor the home visits via the database systems. Once a year the Support Teams provide home-visiting nurses with a performance report of each nurse's activities (no. of visits, satisfaction survey results). In addition to regular case reviews (monthly led by the Support Teams

and weekly in the service team of each DPHC) and clinical supervision, this database system based performance report for each nurse is used as a quality control measure.

Primary outcomes

The UK Medical Research Council guidance[32] recommends using multiple outcomes to evaluate the impact of complex interventions. As presented in Table 3, we will focus on six primary domains of outcomes: 1) home environment, 2) child safety, 3) child development, 4) child care, 5) maternal well-being, and 6) community support. The domains reflect the target outcomes potentially affected by KECHI. We selected one primary outcome for each domain: 1) Infant/Toddler Home Observation for Measurement of the Environment (IT-HOME),[33] 2) emergency department visits due to injuries, 3) Korean Bayley Scales of Infant and Toddler Development-III (K-Bayley-III),[34] 4) breastfeeding duration, 5) maternal self-rated health, and 6) community service linkage.

The IT-HOME[33] comprises 45 items evaluating the quality and quantity of stimulation and support available to children in the home environment. The items are assessed by a combination of structured interviews and observations by trained research nurses during their home visits at 6, 12, and 24 months postpartum. Emergency department visits due to injuries could be considered a proxy measure for child maltreatment[35] and are used as the primary outcome for the child safety domain. Parents report their children's hospital utilisation, including the number of emergency department visits and reasons of the utilisation such as injuries and diseases at four time points: 6 weeks postpartum and 6, 12, and 24 months postpartum. The K-Bayley-III[34] was chosen as a measure for the child development domain. It is an extensive standardised developmental assessment tool for diagnosing developmental delays in early childhood. Mothers and children aged 24 months will be invited to medical institutions and

assessed by K-Bayley-III experts. For childcare, parents report their feeding practices, specifically breastfeeding duration and types of foods provided when their children were 6 weeks, 6 months, 12 months, and 24 months old. Self-rated health is one of the most frequently used measures for adulthood health status in health and social research. It is a strong predictor of mortality in many populations,[36] as well as in Korean women.[37] Thus, we chose maternal self-rated health as the primary outcome for assessing maternal well-being and it will be evaluated at six survey time points from baseline to 24 months. Mothers answer a single question ("How would you rate your health these days?") on a 5-point Likert scale, ranging from 1 (very good) to 5 (very bad). Prior studies showed that, among Korean mothers participating in the prenatal and early childhood nurse home visiting services, social support (instrumental and emotional support) was an important factor for maternal mental health (e.g., maternal depression) and social wellbeing (e.g., intimate partner violence).[38-40] Linkage to community services may provide mothers (often socially isolated) with opportunities to strengthen social support for them and their young children. Sharing information on community services available for mothers and their families is one of the core components of KECHI. Thus, for the community support domain, participants will be asked about their utilisation of the most popular DPHC services and other popular publicly funded social services. These community services include public services for nutritional support, breastfeeding, medical expense assistance, smoking cessation, mental health, counseling, childcare support, and support for multicultural families and the disabled.

Secondary outcomes

The secondary outcomes pertain to 7 domains: child safety, child development, childcare, maternal well-being, community support, family well-being and parent-child interactions (Table 3).

The child safety domain includes the mother's safety knowledge and the child's emergency department visits and hospital admissions. The questionnaire testing mothers' safety knowledge contains five items from the Korean National Health Insurance Service's Infant Health Examination Questionnaire.[41] Mothers report a total number of emergency department visits and hospital admissions as one of the proxy markers for child safety, which is different from the primary outcome measure of child's emergency department visits especially due to injuries.

The child development domain includes the Denver Developmental Screening Test II (DDST-II),[42] premature birth, and delayed growth. DDST-II compares a child's development to the developmental age ranges in the tool. Research nurses will be trained to administer the DDST-II at three times including 6 months, 12 months, and 24 months postpartum periods. Delayed growth will be determined based on the child's body weight and height at 6 months, 12 months, and 24 months postpartum. Research nurses measure child's weight, height, and head circumference, and parents' report on these anthropometric outcomes can be used when actual measurement is not available during the home visits.

The childcare domain includes knowledge of sudden infant death syndrome (SIDS) prevention, vaccination, national health check-ups, spousal participation in parenting, parenting-related household expenses, intention to have another child, and experience of delivery in the past 2 years. The questionnaire testing the mother's knowledge of SIDS contains five items from the Korean National Health Insurance Service's Infant Health Examination Questionnaire.[41] Vaccination will be assessed by completion of the Korean childhood immunisation schedule. National health check-ups will be assessed by asking whether the mother has visited a health centre or paediatrician for an infant health check-up (scheduled at 14-35 days, 4-6 months, 9-12 months, 18-24 months postpartum). Spousal participation in parenting will be measured by

a questionnaire containing 4 items from the Panel Study on Korean Children.[43] Parenting-related household expenses measure a household's expenditures for pregnancy, childbirth, and supplies needed to care for the child. Intention to have another child and experience of delivery in the past 2 years will be determined by the mother's report at 24 months postpartum.

We will obtain information on a wide range of maternal well-being indicators: maternal depression measured by the Edinburgh Postnatal Depression Scale (EPDS),[44] Patient Health Questionnaire-9 (PHQ-9),[45] and Whooley & Arroll questions;[46 47] anxiety measured by the Generalised Anxiety Disorder 2-item (GAD-2);[48] maternal tobacco use and alcohol consumption; delivery type; parenting distress measured by the Being a Mother Scale 13-item (BaM-13);[49] intimate partner violence measured by the Hurt, Insult, Threaten, and Scream (HITS) tool;[50] and maternal body weight and height for mother's body mass index. Maternal suicidal ideation, the 10th item of the EPDS, will also be considered as a secondary outcome in addition to the total score of the EPDS. Delivery type (i.e., vaginal delivery, planned C-section, or emergency C-section) will be assessed by the mother's self-report when the child is 6 weeks old.

As a community support domain indicator, the social support questionnaire was adopted from the Panel Study on Korean Children[43] to assess the level of social support mothers recognise at baseline, 6 months, 12 months, and 24 months postpartum.

The family well-being domain includes food insecurity, spousal intimacy, spousal tobacco use, and spousal alcohol consumption. Food insecurity will be assessed by asking about the family's level of limited access to adequate food over the past year. Spousal intimacy will be measured using the 4-item Revised-Kansas Marital Satisfaction Scale[51] modified by the Korea Institute of Child Care and Education.[43]

The NCAST (Nursing Child Assessment Satellite Training)-PCI (Parent-Child Interaction) teaching scale is an observational measure of parent-child interactions.[52] The NCAST-PCI teaching scale is composed of 73 items measuring three aspects of the caregiver's behaviours and two aspects of the child's behaviours during the semi-structured teaching episode. In this trial, the NCAST-PCI teaching is conducted when research nurses visit home at 12- and 24-month follow-up. During the home visit, the parent will be given a list of tasks (e.g., stacking 2 blocks, draw a line on a paper using a crayon) and asked to choose one that has a slightly above their child's current developmental level. Research nurses who participated in a recording training then hand over toys associated with the task and videotape the parent-child interaction. Once the home visit is completed, trained coders independently assess the quality of parent-child interactions by observing mother and children's verbal and nonverbal interactions. In the training and coding processes, we will use the Korean version of the NCAST-PCI manuals and videos, translated under a license agreement with the Barnard Center at the University of Washington.

Sample size

We considered IT-HOME as a main outcome measure for sample size calculation. In our prior study,[53] the mean IT-HOME score for children at 6-24 months postpartum who received nurse home visitation services in Seoul was 32.5, and the standard deviation (SD) was 5.0. Since we expect to recruit participants from more diverse backgrounds, we anticipated approximately 10% larger variations in IT-HOME scores. Effect sizes of 0.25-0.3 SDs are considered meaningful and impactful at the population level,[54 55] so we set the difference in IT-HOME scores between intervention and control groups to 1.50. The probability of type I error (alpha) was set at 0.05 (2-tailed) and type II error (beta) was set at 0.10 (power = 90%). The presumption of 35%

attrition for the primary outcome indicator at the 2-year follow-up, reflecting a rate slightly higher than that reported in other studies,[54] resulted in a sample size of 400 per group (800 total).

Recruitment

Participants will be recruited through in-person invitations at the maternal and child health departments of DPHCs, social media posts, and advertisements using mobile phone numbers of perinatal women registered in DPHCs.

Interested perinatal women will contact the study team and be screened for eligibility by a member of the research team. Trained research nurses will make a home visit to conduct the baseline survey and obtain signed consent to participate in the study. Consent will be also obtained for linkage to secondary data (e.g., national health insurance data) and long-term follow-up. Subsequently, participants will be randomised.

Randomisation and allocation

Stratified randomisation stratified by parity and recruitment sites (DPHCs) will be conducted to randomly assign participants to the control or intervention group at a 1:1 ratio using computer-generated random numbers. Research nurses will enrol participants and a research manager will inform home-visiting nurses in DPHCs of the contact information of families needing interventions. Randomisation will be conducted using the Interactive Web Responsive System (IWRS) created by the Medical Research Collaboration Center (MRCC) of Seoul National University Hospital (SNUH).

Blinding

As information on allocation is not withheld from participants, this study is an open trial. However, every effort will be made to maintain blinding of allocation status. The research management staff, KECHI nurses (for the intervention group), and study participants will be aware of the allocation results. However, the research nurses making postnatal outcome assessments will be blinded to the randomisation, and families will be asked not to disclose their group status during the surveys at home. The research nurses (outcome assessors) will only be notified of the follow-up survey schedules (6 weeks, 6 months, 12 months, and 24 months) of both groups. It is important to note that some outcome measures (i.e., NCAST-PCI teaching scale and K-Bayley-III) will be assessed by independent researchers other than research nurses. The NCAST-PCI teaching scale will be coded by independent coders, and the K-Bayley-III will be independently measured at medical institutions by K-Bayley-III experts. Statistical analysts will not be able to access the randomisation variable until all 2 years of data are collected.

Compensation

Participants will be compensated 30,000 Korean won (1,300 Korean won = 1 US dollar) for each survey (maximum compensation: 180,000 Korean won). In addition, they are paid 10,000-30,000 Korean won for the travel cost of visiting the medical institutions for the K-Bayley-III assessment.

Patient and public involvement

Patients and/or the public are not involved in the design, conduct, reporting, or dissemination plans of this trial.

Data collection, data management, monitoring, and auditing

At four home visits (baseline, 6, 12, 24 months) and two phone interviews (6 weeks and 18 months), trained research nurses will collect data on primary and secondary outcomes. At 24 months, additionally, K-Bayley-III experts will administer the K-Bayley-Ⅲ at Seoul National University and Dong-A University. The home and lab visits will usually take 1.5 hours, and the phone surveys will last for 5 minutes on average. For observational measures, research nurses will be trained by a developer for the IT-HOME and the Barnard Center at the University of Washington for the NCAST-PCI teaching scale, respectively, and only those who achieve an inter-rater reliability rate greater than 90% will administer observations and scoring. The quality and procedures of data collection will be regularly monitored by a research manager. All data collected will be reported in a written Complete Report Form (CRF) first, and then research nurses will enter the data again in an electronic Complete Report Form (eCRF) created in the web-based Clinical Research and Trial management system (iCReaT, http://icreat.nih.go.kr). The iCReaT is developed and maintained by the Korea Disease Control and Prevention Agency (KDCA) and provides an effective platform for managing study protocols, participants, data entry, and data monitoring. Many clinical trials conducted in Korea use the iCReaT to develop their own eCRFs. Anyone who needs access to the iCReaT (e.g., research nurses or project managers) requires online training courses and should be certified by the KDCA. Although data collection and entry are conducted mainly by research nurses, the MRCC at SNUH is fully responsible for regular data management and analysis, in addition to the use of the IWRS (i.e., eCRF, web-based random assignment). The MRCC team consists of members responsible for random assignment, data management, and data analysis, and they work independently and collaboratively with the research team. From the initial stage of the

trial, they developed the data management plan (DMP), web-based random assignment plan, data verification specification (DVS), eCRF complete guideline (CCG), and statistical analysis plan (SAP). Data validation of the eCRF will be completed up to twice a year using manual and system queries. All processes of the trial and data management will be audited by the funder and an external consulting group.

Statistical analysis plan

After database locking, the primary analyses will be conducted on an intention-to-treat (ITT) basis. For the six primary outcomes, analyses will be conducted with both data without missing information and data with multiple imputation (five times). For other outcomes, data without missing information will be analysed. After completion of the survey at 6 months postpartum, we will conduct an interim ITT analysis for selected 14 outcomes (IT-HOME, breastfeeding duration, maternal self-rated health, knowledge on SIDS prevention, Denver-II, spousal participation in parenting, EPDS, suicide ideation, PHQ-9, GAD-2, BaM-13, HITS, social support questionnaire, and the Revised-Kansas Marital Satisfaction Scale). A per-protocol analysis after completion of 24 month assessment will also be conducted, in which participants will be excluded from the intervention arm of the trial if they did not have at least 13 KECHI nursing visits; any such participants will be included in the control group.

Regression analysis will be conducted to evaluate the effects of the intervention, and the results will be summarised using point estimates and their 95% confidence intervals. Clustering of study subjects at the recruitment sites (DPHCs) will be considered in the analysis. Analyses adjusted for parity and region (Seoul vs. non-Seoul) will also be presented. For repeatedly collected variables, interactions between allocation status and follow-up periods will be examined. Differences at each follow-up period (6 weeks, 6 months, 12 months, and 24 months)

will be presented if the interactions are significant; otherwise, mean differences over the follow-up period will be estimated. Our interpretation on the interaction of the time point and the allocation group may vary with outcomes and time points. For example, if the difference in maternal self-rated health between intervention and control groups were greater at 6 months postpartum, the difference should be interpreted with the frequent visits during the first 6 months and nurses' postnatal support (see KECHI visit schedules at Table 2). Meanwhile, the differences in measures related to child development (e.g., Denver-II) are expected to be greater in later phases of assessment (i.e., 24 months postpartum) since gaps in children's developmental trajectories usually became larger. Subgroup analyses stratified by parity, region, education (high school or less vs. college or over), risk factor score (2 vs. ≥3), and EDPS score (<13 vs. ≥13) will be conducted. We will also examine if the outcomes associated with social workers' activities (especially for community service linkage) vary with the presence of social workers in the service teams. Considering the potential increase in alpha error by having six primary outcomes, we will interpret the overall effectiveness of the intervention by assessing the comprehensive analysis results and outcome-specific contents of KECHI.

Ethics and dissemination

The study protocol was reviewed and approved by the institutional review board of the Seoul National University Hospital (IRB No. C-1911-150-1083). The trial was initially registered at ClinicalTrials.gov (ClinicalTrials.gov identifier: NCT04749888) on February 11, 2021 and revised on May 5, 2022 and March 24, 2024. The trial was scheduled to start on October 27, 2021, and is expected to be completed by February 15, 2025. Participants consent for themselves and give parental permission for their babies. Participants are informed that their

participation is voluntary and they can withdraw without penalty at any time and their decision does not impact their care in any way. The study results will be published in peer-reviewed journals and presented at scientific meetings. The results will be reported at conferences and in peer-reviewed publications and will be used by the Korean government for expanding the KECHI services.

Discussion

The effects of nurse home visitation interventions may vary among societies,[35 56] and effects detected in one country may not translate to another country.[56] For example, the RCT of the Family Nurse Partnership (FNP) program in England did not identify significant impacts on four primary endpoints (prenatal cigarette smoking at the end of pregnancy, birthweight of the baby, subsequent pregnancy, and emergency attendances and hospital admission) while the effects were significant for language and cognitive development.[7] The characteristics of population and existing home visitation services might have contributed to these findings.[7 35] In addition, while few effects of home visitation on healthcare utilisation, child health, and child accidents were found in trials conducted in England,[7] Germany,[57] and Ireland,[58] home visiting programs in the US appear to produce clear beneficial effects on those outcomes.[59 60] These discrepancies might also be attributed to differences in the public health insurance systems between Europe and US affecting disadvantaged mothers' access to comprehensive healthcare services for children. In this regard, Korea may provide a unique opportunity to understand the effects and mechanisms of maternal and early childhood home visitation. In Korea, while universal national health insurance is established (similar to the European context), maternal early childhood home visiting services are underdeveloped (similar to the

US context). A prior paper showed that maternal distress reported by Korean women with young children was very high compared to other countries.[61] This Korean situation may shed light on the difference in the discordant RCT findings from different countries on the effects of home visitation.

Although early childhood nurse home visits have a long history in many Western countries,[3] Korea has only a 10-year history of implementing maternal and early childhood nurse home visits as a component of public services. The SHFSP started only in 3 districts of Seoul in 2013 and expanded to all 25 districts in 2020. In 2020, the central government of Korea started to expand the service to other parts of Korea.[22] In this early stage of the national expansion of the intervention, this RCT may be instrumental in policy decision-making with respect to the speed of the national expansion and any potential modification of the service.

This trial has some limitations. Outcome reporting made by mothers may be affected by their perceptions and feelings. Although the research nurses making outcome measurements will be blinded to randomisation and families will be asked not to disclose their allocation status, breaches of blinding would be possible. However, the direct observation measures (IT-HOME) would mitigate the limitation of self-reports, and the independent assessments of the NCAST-PCI teaching scale and K-Bayley-III will ensure blinding. In addition, the findings may not be generalisable to the highly vulnerable families included in the real-world KECHI services, wherein nurses prioritise more vulnerable families due to a relative shortage of nurses. Subgroup analyses by EPDS scores and risk factor scores would provide information on the effect size in the real-world KECHI. Moreover, the findings may not generalise to families of multicultural mothers with communication challenges in Korean.

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Contributors

YHK, YMK, KJJ, SHC, JYL and HJC developed the grant proposal for this project. YHK, YMK, JHK, JY, and RO administratively led the project. YHK wrote the draft. The manuscript was revised based on comments from all authors. All authors read and approved the final manuscript. YHK is responsible for the overall content as guarantor.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication

Not applicable.

Data availability statement

Raw data with a codebook will be available for sharing once core data are published and data sharing agreements are formalized through the Patient-Centered Clinical Research Coordinating Center (PACEN), Korea.

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distress experienced by South Korean women with young children. *PLoS One* 2022;17(9):e0274016.

Table 1. Risk factors used to determine eligibility and their descriptions

Risk factors	Descriptions
Sociodemographic risk factors	
Maternal young age*	Pregnant women aged 19 or less are scored 2 and pregnant women aged 20-23 are scored 1.
Single mother*	Single mothers are scored 2.
Low income*	Families receiving basic living security program or families whose household income is 50% or less of national median household income are scored 2.
Multicultural background	Born or raised abroad
Low education	Less than high school graduation
Disability	Physical disability, mental disability, or intellectual disability
Psychosocial risk factors	
Depression or suicidal ideation	Edinburgh Postnatal Depression Scale (EPDS, 10 items) ≥ 10 or EPDS 10th item (suicide ideation) ≥ 1
Anxiety	Generalized anxiety disorder 2-item ≥ 3
Recent major stressors	Have you ever experienced serious stress, change, or loss over the past 12 months such as financial problems, someone close to you dying, or any other serious worries? (yes)
Lack of instrumental or emotional support	Will you be able to get practical support with your baby? (no) or Do you have someone you are able to talk to about your feelings or worries? (no)
Past treatment history for emotional issues	Have you ever been treated for emotional issues? (yes)
Health and healthcare risk factors	
Delayed prenatal care	Start of obstetric care ≥ 20 weeks gestation
Smoking or alcohol consumption	Smoking during pregnancy or alcohol consumption twice per week during pregnancy
Multiple foetuses	Multiple foetuses
Risk factors of trauma experiences	
Childhood abuse experience or witnessing domestic violence	Have you ever been physically, emotionally, or sexually abused in your childhood? (yes) or Have you ever witnessed domestic violence during childhood or adolescence? (yes)
Intimate partner violence or need of assistance regarding domestic violence	Score of Hurt, Insult, Threaten, and Scream (HITS) questionnaires (4 items) ≥ 7 or Do you need any help for domestic violence? (yes)

*Except for these three risk factors, other risk factors are scored 1.

Table 2. Home visitation schedules of the Korea Early Childhood Home-visiting Intervention (KECHI)

Period (child age)	Frequency of visits	No. of visits (additional visits are possible)
Before birth		3
1-8 weeks (56 days) postpartum	Weekly	4-8 (depends on the use of postpartum care facility)
9-14 weeks (100 days) postpartum	Fortnightly	3
15-26 weeks (6 months) postpartum	3-weekly	4
27-52 weeks (12 months) postpartum	6-weekly	4
53-104 weeks (24 months) postpartum	Bimonthly	6 + 1 (1 visit for ending)

Table 3. Assessment variables and associated assessment schedules

Assessment variables			Assessment time					
Domains		Outcomes	Baseline	6 weeks	6 Months	12 Months	18 Months	24 Months
Primary outcomes	Home environment	IT-HOME (Infant/Toddler Home Observation for Measurement of the Environment) (45 items)			X	X		X
	Child safety	Emergency department visits due to injuries		X	X	X		X
	Child development	K-Bayley-III (Korean Bayley Scales of Infant and Toddler Development-III)						X
	Childcare	Breastfeeding duration		X	X	X		X
	Maternal well-being	Maternal self-rated health	X	X	X	X	X	X
	Community support	Community service linkage	X			X		X
Secondary outcomes	Child safety	Safety knowledge (5 items)	X		X	X		X
		Emergency department visits		X	X	X		X
		Hospital admission		X	X	X		X
	Child development	Denver (Denver Developmental Screening Test) II			X	X		X
		Premature birth		X				
		Delayed growth			X	X		X
	Childcare	Knowledge of sudden infant death syndrome prevention (5 items)	X		X			
		Vaccination			X	X		X
		National health check-ups			X	X		X
		Spousal participation in parenting (4 item)			X	X		X
		Parenting related household expenses	X		X	X		X
		Intention to have another child						X
		Experience of delivery in the past 2 years						X
	Maternal well-being	EPDS (Edinburgh Postnatal Depression Scale) (10 items) including suicide ideation (10th item)	X		X	X		X

Assessment variables			Assessment time					
Domains		Outcomes	Baseline	6 weeks	6 Months	12 Months	18 Months	24 Months
		PHQ-9 (Patient Health Questionnaire-9) (9 items)	X		X	X		X
		Whooley & Arroll questions (3 items)		X			X	
		GAD-2 (Generalized Anxiety Disorder 2-item)	X		X	X		X
		Maternal tobacco use	X		X	X		X
		Maternal alcohol consumption	X		X	X		X
		Delivery type		X				
		Being a Mother Scale (BaM-13) (13 items)			X	X		X
		HITS (Hurt, Insult, Threaten, and Scream) (4 items)	X		X	X		X
		Maternal body weight	X	X	X	X		X
	Community support	Social support questionnaires (12 items)	X		X	X		X
	Family well-being	Food insecurity	X			X		X
		Revised-Kansas Marital Satisfaction Scale (4 items)	X		X	X		X
		Spousal tobacco use	X		X	X		X
		Spousal alcohol consumption	X		X	X		X
	Parent-child interactions	NCAST (Nursing Child Assessment Satellite training)-PCI (Parent-Child Interaction) teaching scale (73 items)				X		X

Figure 1. Study flow diagrams, showing the participants and intervention pathway and the assessment schedule

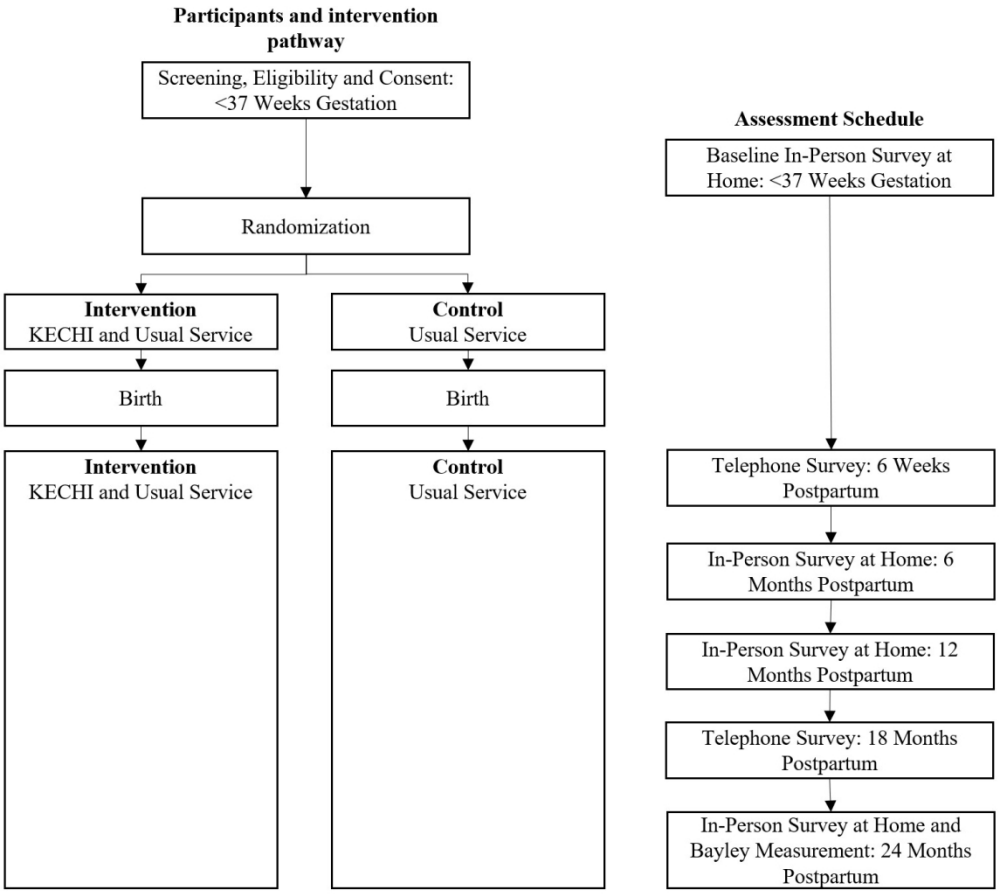

Figure 1. Study flow diagrams, showing the participants and intervention pathway and the assessment schedule

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	__1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	__3_____
	2b	All items from the World Health Organization Trial Registration Data Set	__NA_____
Protocol version	3	Date and version identifier	__NA_____
Funding	4	Sources and types of financial, material, and other support	__23_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	__1, 23_____
	5b	Name and contact information for the trial sponsor	__1_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	__23_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	__18-19_____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	___4-5_____
	6b	Explanation for choice of comparators	___4_____
Objectives	7	Specific objectives or hypotheses	___4-5_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	___5_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	___5-6_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	___6-7, 31____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	___8-11_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	___19_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	___NA_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	___7-8_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	___11-15, 33-34_
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	___35, Fig. 1___

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	___15-16_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___16_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	___16_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	___16_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	___16_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	___17_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___17_____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	___18-19_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	___18-19_____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___18-19_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___19-20_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	___20_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	___19-20_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___18-19_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___19_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___NA_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___19_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___3, 20-21____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	___NA_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	___16_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	___16_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___NA_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___23_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	___18, 19_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___NA_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	___20, 21_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	___NA_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	___NA_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_Appendices 1, 2_
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	___NA_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.