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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 programme (Korea Early Childhood Home-visiting 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 <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 post partum. 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 two-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 programme (ie, 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 programme 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 home visitation programmes led by nursing professions 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 programmes is sparse in non-Western cultures, although RCTs of home vising programmes 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 programme has been implemented since 2013 in Seoul.[18 19] The Maternal and Early Childhood Sustained Home-visitation (MECSH) programme[5 19] was introduced to the Seoul Healthy First Step Project, and associated nurse training programmes 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 Programme) nationally.[21 22] In 2020, a home visit programme (Korea Early Childhood Home-visiting 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 Programme 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 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 two-arm parallel-group, superiority, individually randomised trial was designed to evaluate the effectiveness of 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 the District Public Health Centres (DPHCs) for 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

KECHI was designed for implementation in the catchment areas of DPHCs across Korea. As of 2022 (the start of active recruitment), 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 programme includes pregnancy and postpartum care, infant's health and care, early childhood growth and development, maternal mental health and associated care, psychological 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 Programme 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 <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 that assesses 16 risk factors (with 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 (ie, maternal age ≤19 years, single mother and 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 nurse home-visiting services, with the exception of postnatal-related items (eg, low birthweight). 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 in this trial should be provided according to 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

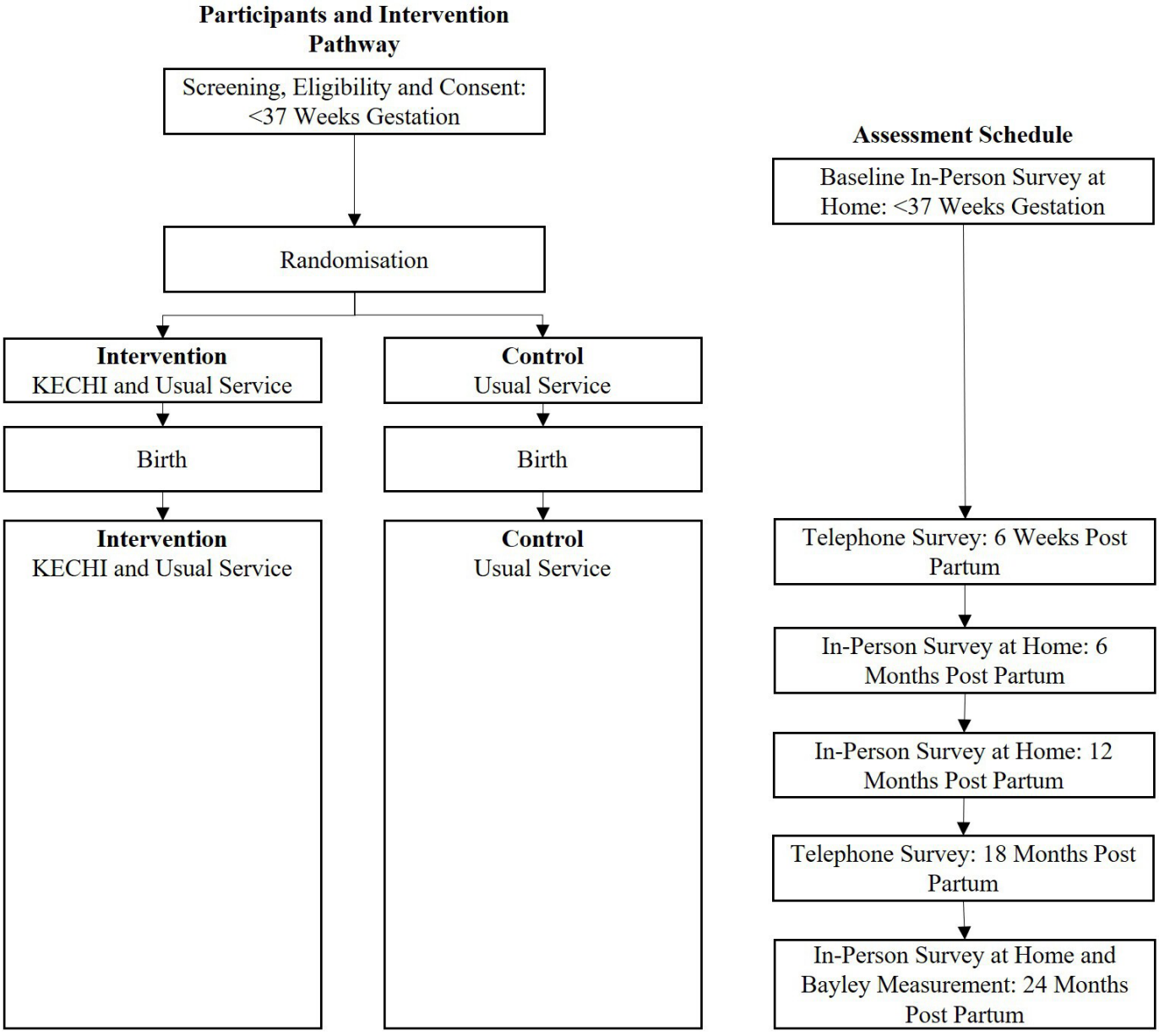

Figure 1 Study flow diagrams, showing the participants and intervention pathway and the assessment schedule. KECHI, Korea Early Childhood Home-visiting Intervention.

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 post partum) if requested. Eligibility for basic home visits is determined when women apply for the service in person, online or by 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 services 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.

Table 1 Risk factors used to determine eligibility and their descriptions

Risk factors	Descriptions
Sociodemographic risk factors	
Maternal young age*	Pregnant women aged 19 years or less are scored 2 and pregnant women aged 20–23 years are scored 1.
Single mother*	Single mothers are scored 2.
Low income*	Families receiving basic living security programme 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	EPDS, 10 items ≥ 10 or EPDS 10th item (suicide ideation) ≥1.
Anxiety	Generalised 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)
Previous 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 fetuses	Multiple fetuses.
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 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.
EPDS, Edinburgh Postnatal Depression Scale.

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 well-being, (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 (eg, 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 programmes differ in several aspects. First, considering *sanhujoriwon* 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 post partum 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

Table 2 Home visitation schedules of the Korea Early Childhood Home-visiting Intervention

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

cautions for home visits, lists of topics covered, expected outcomes stratified by the periods (eg, before birth, 1–8 weeks post partum, 9–14 weeks post partum) 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 post partum)[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 post partum (*Jaramtong* 2, 162 pages) and 6–24 months post partum (*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 (eg, 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, baby 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 (equality wheel and power/control wheel). 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 a few 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 second or third 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 programmes 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 Programme). 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 well-being, family members' well-being, safety, planning and goal setting, referrals, tools and *Jaramtong* materials. Postnatal domains included children's well-being, caregivers' well-being, caregivers' mental health, family members' well-being, 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 RCT.[31] The Support Teams of the programmes can monitor the home visits via the database systems. Once a year the Support Teams provide each home-visiting nurse 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

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	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	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 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 items)			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	Edinburgh Postnatal Depression Scale (10 items) including suicide ideation (10th item)	X		X	X		X
		Patient Health Questionnaire-9 (9 items)	X		X	X		X
		Whooley and Arroll questions (3 items)		X			X	
		Generalised 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 (13 items)			X	X		X
		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

Continued

Table 3 Continued

Assessment variables		Assessment time					
Domains	Outcomes	Baseline	6 Weeks	6 Months	12 Months	18 Months	24 Months
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	Nursing Child Assessment Satellite Training Parent-Child Interaction Teaching Scale (73 items)				X		X

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-visit assessments at 6, 12 and 24 months post partum. 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 post partum and 6, 12 and 24 months post partum. 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 aged 6 weeks, 6 months, 12 months and 24 months. 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 (eg, maternal depression) and social well-being (eg, 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, counselling, childcare support and support for multicultural families and the disabled.

Secondary outcomes

The secondary outcomes pertain to seven 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 with 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 post partum. 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-visit assessments.

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 prevention 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 post partum). Spousal participation in parenting will be measured by a questionnaire containing four 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 post partum.

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 and 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 (ie, vaginal delivery, planned caesarean section (C-section) or emergency C-section) will be assessed by the mother's self-report when the child is 6 weeks of age.

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 post partum.

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 Nursing Child Assessment Satellite Training (NCAST)-Parent-Child Interaction (PCI) 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-month and 24-month follow-up. During the home visit assessment, the parent will be given a list of tasks (eg, stacking two blocks, draw a line on a paper using a crayon) and asked to choose one that is 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 assessment is completed, trained coders independently assess the quality of parent-child interactions by observing both verbal and non-verbal interactions between the mother and child. 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 Centre 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 post partum who received nurse home visitation services in Seoul was 32.5, and the 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 (two-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 (eg, 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 Centre (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 (ie, NCAST-PCI teaching scale and K-Bayley-III) will be assessed by independent assessors 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 in both intervention and control groups will be compensated 30 000 Korean won (1300 Korean won=US$1) 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-visit assessments (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 min on average. For observational measures, research nurses will be trained by a developer for the Korean version of IT-HOME and the Barnard Centre at the University of Washington for the NCAST-PCI teaching scale, respectively, and only those who achieve an inter-rater reliability rate ≥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 CRF (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 (eg, 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 (ie, 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, web-based random assignment plan, data verification specification, eCRF complete guideline and statistical analysis plan. 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 post partum, 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% CIs. Clustering of study subjects at the recruitment sites (DPHCs) will be considered in the analysis. Analyses adjusted for parity 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 post partum, 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 (eg, Denver-II) are expected to be greater in later phases of assessment (ie, 24 months post partum) since gaps in children's developmental trajectories usually became larger. Subgroup analyses stratified by parity, region (Seoul vs non-Seoul), education (high school or less vs college or over), risk factor score (2 vs ≥3) and EDPS score (<13 vs ≥13) at baseline 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 11 February 2021 and revised on 5 May 2022 and 24 March 2024. The trial was scheduled to start on 27 October 2021, and is expected to be completed by 15 February 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 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 programme in England did not identify significant impacts on four primary end points (prenatal cigarette smoking at the end of pregnancy, birth weight of the baby, subsequent pregnancy and emergency attendances and hospital admission), while significant effects were found 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 programmes in the USA 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 the USA 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 nurse 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 with 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 Seoul Healthy First Step Project 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, where nurses prioritise more vulnerable families due to a relative shortage of staff. Subgroup analyses by EPDS scores and risk factor scores would provide information on the effect size in the real-world KECHI programme. Moreover, the findings may not generalise to families with multicultural mothers who face communication challenges in Korean.

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