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Acceptability, feasibility and pilot study of a culturally sensitive parental and caregiver, community-based intervention using participatory learning and action groups to optimise infant nutrition, feeding, and dental practices in children from South Asian families: NEON (Nurture Early for Optimal Nutrition)

Submission date	**Recruitment status**	[_] Prospectively registered
08/02/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/03/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/05/2024	Other	

Plain English summary of protocol

Background and study aims

In countries such as Bangladesh, India, and Nepal, women's group activities called Participatory Learning and Action (will be referred to as 'PLA') have been found to have beneficial effects on maternal and newborn health.

These approaches engage the community in their healthcare issues and encourage community members to identify and plan activities to prevent healthcare problems from arising. Poor nutrition during infancy can affect short-term and long-term health during childhood and adulthood. It can lead to problems such as obesity, heart disease and diabetes. Higher rates of these conditions have been found in the South Asian populations in the United Kingdom. Tower Hamlet, Newham, and Waltham Forest have some of the largest South Asian communities in the UK; these areas have been chosen for the study. High levels of obesity have been found in South Asian children in the UK, and they may also be at risk of nutrient deficiencies and poor oral health. What, when and how you feed and care for your child can impact the development of these conditions. Therefore, we would like to see if the women's group PLA cycle is suitable for the South Asian community in Tower Hamlet, Newham, and Waltham Forest using infant feeding, care, and dental hygiene practices as an exemplar.

Who can participate?

Mothers or female carers of infants aged less than 2 years old from the South Asian community in East London

What does the study involve?
The women's group Participatory Learning and Action (PLA) cycles. It is an iterative process led by multilingual facilitators who facilitate the participants through a four-stage cycle of identifying and prioritising contextual issues, designing strategies to address these issues and a post-implementation evaluation. Participants will attend a total of 7 sessions to discuss about infant feeding, care, and dental hygiene practices within their community.

What are the possible benefits and risks of participating?
The main benefit of taking part in this study is that they will have a chance to discuss issues around infant feeding, care and dental hygiene practices within their community and they may also learn some new information and from the experiences of others in the group. They will have the opportunity to get involved with the community in a participatory approach and to engage in a discussion around a topic that is important in the long-term health and wellbeing of children in their family and community. There is no risk with participating in this study that is greater than the risk that participants encounter in their normal lifestyles. The potential risk that participants could encounter some mental distress will be mitigated by making sure that no one during the workshops will embarrass, frighten, offend or harm participants.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
December 2019 to May 2023

Who is funding the study?
National Institute for Health Research (NIHR) Academy (UK).

Who is the main contact?
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Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
296259

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 50858, NIHR300020, IRAS 296259

Study information

Scientific Title
Nurture Early for Optimal Nutrition (NEON) pilot feasibility randomised controlled trial: community facilitator-led participatory learning and action (PLA) women's groups to improve infant feeding, care, and dental hygiene practices in South Asian infants aged <2 years in East London

Study objectives
The women's group participatory learning and action cycles will help to optimise infant feeding, care, and dental hygiene practices for infant less than 2 years old within the South Asian community in East London

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/12/2021, South West - Cornwall and Plymouth Research Ethics Committee (Bristol HRA Centre, Temple Quay House, 2 The Square, Temple Quay, Bristol BS1 6PN, UK; +44 207 104 8370; cornwallandplymouth.rec@hra.nhs.uk), ref: 21/SW/0142

Study design
Interventional pilot feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Infant feeding, care, and dental hygiene practices

Interventions
The Participatory Learning and Action (PLA) group cycle is an iterative process led by multilingual facilitators who facilitate the participants through a four-stage cycle of identifying and prioritising contextual issues, designing strategies to address these issues, implementing these strategies and a post-implementation evaluation. The PLA approach is a low-cost, community-based, culturally sensitive intervention that can be adapted from LMICs to HICs, to different population groups and topic areas (whilst making use of local community assets where possible).

A 3-arm pilot feasibility randomised controlled trial (RCT) will be carried out in 3 boroughs of London. The randomisation will be at cluster level and individual level with 1:1:1 cluster level randomisation and allocation to the intervention and control arms. Cluster (ward-level) randomisation has been chosen to minimise the participant contamination to different intervention arms. Participants will be randomly allocated to either of 3 arms; the control, face-to-face or contact-free study arm:
1. The face-to-face arm – This is where our intervention (PLA cycle) will be delivered in person in children centres/community centres. The participants of this arm will have the access to the paper-based NEON intervention toolkit (the traditional way). The face-to-face arm will be carried out in alignment with government coronavirus social distancing rules for the duration these are in place.
2. The contact-free arm – This is where we will use the virtual platform (e.g., using Zoom software) to trial the intervention online. The participants of this arm will have the access to the digital NEON intervention toolkit via Eredbook©, and
3. The control arm – This is where participants will continue to receive the usual care provided in the target study boroughs with no intervention being utilised and no access to the NEON intervention toolkit.
All intervention arms will be led by multilingual PLA community facilitators (CFs). Participants who do not have digital access will be provided with tablet and internet access to be able to take part in the study for the contact-free arm.

For the intervention arms, we aim to run a minimum of 20 women's group PLA cycle (10 face-to-face PLA and 10 online PLA) and up to 32 Women's group PLA cycle (16 face-to-face PLA and 16 online PLA) across the 3 boroughs, starting from TH and subsequently to NH and then WF. Each PLA group will have 6-8 participants including mothers, pregnant women or carers (e.g., aunts or grandmothers). When we include participants in the control groups, we will recruit 288-384 participants in total. This sample size should be sufficient to estimate the feasibility outcome measures (eg. recruitment and retention rates) to the necessary degree of precision (please see section 'Sample size calculation').

Each PLA group will run over 14 weeks (1 session per 2 weeks) with a follow up time of 6 months for each PLA group participant. HVs, GP practice managers, and midwives' teams will be invited to selected sessions of the PLA intervention (1-2 sessions when requested by the participants) to provide evidence-based information where required. The intervention will be implemented in three boroughs in East London (TH, NH, and WF) and will identify one community/children's centre per ward in which to conduct the PLA sessions. This will occur sequentially in the three boroughs, rather than in parallel, i.e., the intervention will first be rolled out in TH, then in NH and finally in WF so that we may apply iterative learning to improve the process of delivering the interventions.

For the usual care arm, in all wards the HV team have regular mandatory postnatal visits for all families of new-borns and infants in TH, NH, and WF. These visits are immediately after birth, 6-8 weeks, 12-16 weeks, 1 year, and between 2 and 2 ½ years of age. Besides, one optional prenatal visit is conducted by HVs for pregnant women between 28 and 32 weeks of pregnancy. This is the usual standard of care.

Data collection for outcomes will take place at three time points in both intervention arms at baseline (beginning of 1st PLA session), immediately post-intervention (end of PLA cycle), and at 6-months follow-up. Participants in the control arm in each randomised ward will complete measures at the same time as participants in the intervention arm for that borough. The 3 arms will be therefore balanced in terms of outcome measures timing.

For the intervention arms, data collection for process outcomes will take place after each PLA-meeting sessions.

Intervention Type
Behavioural

Primary outcome(s)
Individual child BMI Z-Score - Infants' length/height, head circumference and weight and we will refer to the WHO 2006 growth standard to measure the BMI z-score - Baseline, 14 weeks, 6 months

Key secondary outcome(s))
1. Children feeding behaviour - will be measured using 6 of 8 domains adapted from the validated Children's Eating Behaviour Questionnaire (CEBQ) - Baseline, 14 weeks, 6 months
2. Parental feeding style - will be assessed with a validated self-reported Parental Feeding Style Questionnaire (PFSQ) - Baseline, 14 weeks, 6 months
3. Audio/Video recording of child eating behaviours and parental feeding practices - involves asking participants about the meal (e.g. name, ingredients) and creating annotations that link to behaviour codes identified from NEON formative study. Before-and-after audio/video recordings will be thematically analysed using Elan Software to measure intervention effect. -

Baseline, 14 weeks
4. 4 day food diary - a self-reported, prospective, open-ended survey that collects detailed quantitative estimates of food consumption of infants between 4-18 months [6]. It assesses nutrient intake (e.g. total fat, total carbohydrate, salt, sugar) by comparing with age/sex-specific UK dietary reference values - Baseline, 14 weeks, 6 months
5. Network diffusion – measured by tracking the number of downloads using the eRedbook platform. Participants will also complete a questionnaire on the number of people they shared the material with, their family size, age, gender, relationship to the participant and platform used. -2 weeks, 4weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks, 14 weeks, 6 months
6. Equality impact assessment- An EIA tool will systematically assess likely effects of the intervention on people (e.g. with respect to disability, gender, ethnicity, age, sexual orientation, religion/belief etc.) - Baseline
7. Children's development performance- The Ages and Stages questionnaire (ASQ-3) include communication, gross motor, fine motor, problem-solving, and personal-social domains - baseline, 6 months
8. Level of dental caries - NHS dental services records for registered patients - baseline, 6 months
9. GP healthcare utilisation- participants' NHS medical records - baseline, 6 months

Economic outcomes:
10. Cost tool - a spreadsheet cost tool to capture the cost of the NEON pilot feasibility RCT - Baseline, 6 months
Partner's time questionnaire - A questionnaire will capture time spent for the delivery of NEON trial – 12 months

Process outcome:
11. Participants feedback - A structured feedback questionnaire with close- and open-ended questions will be administered through self-reported questionnaires, face-to-face or phone interviews - 2 weeks, 4weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks, 14 weeks
Facilitator Report- The PLA group facilitator report form will include close- and open-ended questions about the intervention delivery, participant engagement, fidelity, and general thoughts about the session from the facilitator's perspective -2 weeks, 4weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks, 14 weeks
12. PLA cycle meeting register- the meeting register to monitor participants' attendance at each meeting -2 weeks, 4weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks, 14 weeks
13. Direct observation- supervising the Women's group PLA cycle sessions to ensure consistency of sessions across all groups, and to complete a form after each PLA session digitally, which assesses whether the facilitator delivered the components of the sessions according to the manual at 1-4 scale -2 weeks, 4weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks, 14 weeks
14. Sustainability assessment- to use the sustainability assessment tool to self-assess group capacity against nine domains that are key in ensuring sustainability and empowerment of community groups. These domains are: participation, leadership, structures, problem assessment, resources mobilisation, ability to ask why, link to others, relationship with outside agents, and programme management -2 weeks, 4weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks, 14 weeks

Completion date
31/05/2023

Eligibility

Key inclusion criteria

Participants
1. Mothers or female carers of an infant aged <24 months (including pregnant women)
2. From the following Asian background: Indian, Pakistani, Sri Lankan, Bangladeshi
3. Resident in the London Boroughs of Tower Hamlets, Newham, Waltham Forest
4. Willing and able to provide written informed consent

Study staff (community facilitators)
1. Female
2. Have at least one child, preferably <24 months
3. From the South Asian community in TH, NH, or WF
4. Able to read and write
5. Fluent in speaking English and one of other local languages (Gujarati, Punjabi, Urdu, Tamil, Bengali or Sylheti)
6. Understand social norms and values and the South Asian culture within the study boroughs
7. Known to and respected by their local community
8. Motivated to address issues related to infant growth and development
9. Able to manage a group and have some leadership qualities

Participant type(s)
Patient, Population

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
261

Key exclusion criteria
1. Participants <18 years old
2. Anticipating moving out of the a priori defined geographical area before or after delivery
3. Currently participating or having participated in another study within 4 weeks of the trial commencing

Date of first enrolment
01/03/2022

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Tower Hamlets GP Care Group
1st Floor Beaumont House
London
United Kingdom
E1 4DG

Study participating centre
London Borough of Newham
Children's Health 0-19 & Headstart Service
London
United Kingdom
E16 2QU

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data supporting the findings of this study is available upon reasonable request from the corresponding author.
To guarantee confidentiality, participant data will be pseudonymised. Only pseudonymised quotes or data from audio/video recording may be published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/11/2023	01/12/2023	Yes	No
Basic results			20/05/2024	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.1	11/01/2022	28/02/2022	No	No