Full title of trial	Nurture Early for Optimal Nutrition (NEON) Protocol for a pilot feasibility cluster 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
Short title	Nurture Early for Optimal Nutrition (NEON) Pilot Feasibility Randomised Controlled Trial
Version and date of protocol	Version 2, 22/11/2021
Sponsor:	University College London (UCL) **Lead Sponsor** **Name:** Prof Andrew Hayward UCL Institute of Epidemiology & Healthcare Director **Organisation:** UCL Institute of Epidemiology and Health Care (IEHC) **Address:** Dept of Epidemiology and Public Health, UCL IEHC, 1-19 Torrington Pl, Fitzrovia, London WC1E 7HB **Email:** a.hayward@ucl.ac.uk **Telephone:** 0207 679 2000
Sponsor reference number:	142660
Funder (s):	**Organisation:** National Institute for Health Research Academy **Contact:** Tom Pratt **Address:** 21 Queen St, Leeds LS1 2TW, United Kingdom **Email:** Academy-awards@nihr.ac.uk **Telephone:** 0113 532 8410

IRAS Number:	**296259**
UCL Data Protection Number:	Z6364106/2021/06/195
Intervention:	NEON Women's Group Participatory Learning and Action (PLA) cycle
Chief investigator:	**Sponsor Representative**: **Sponsor Representative**: **Name:** Dr Logan Manikam, NIHR Advanced Fellow & Honorary Consultant in Public Health Medicine **Address:** Dept of Epidemiology and Public Health, UCL IEHC, 1-19 Torrington Pl, Fitzrovia, London WC1E 7HB **Email:** logan.manikam.10@ucl.ac.uk **Telephone:** +447949110711 UCLH/UCL Joint Research Office, 4th Floor, West 250 Euston Road London NW1 2PG

PROTOCOL VERSION HISTORY

Version Stage	Versions Number	Version Date	Protocol updated & finalised by;	Reasons for Update
Current	Draft Version 2.1	11/01/2022	Shereen Al Laham Research Assistant, UCL Institute of Epidemiology and Health Care	Deleted pregnant women as inclusion criteria after discussion with the core team about the feasibility of including them while we won't be able to collect their outcomes
Current	Draft Version 2	22/11/2021	Shereen Al Laham, Research Assistant, UCL Institute of Epidemiology and Health Care	Deleted one of the exclusion criteria: Having a known pre-diagnosed mental health disorder, including depression, drug or alcohol abuse (comment from the NHS REC)
Previous	Draft Version 1.2	02/08/2021	Shereen Al Laham, Research Assistant, UCL Institute of Epidemiology and Health Care	Incorporated the comments from the JRO about Data ref number
Previous	Draft Version 1.1	24/05/2021	Shereen Al Laham, Research Assistant, UCL Institute of Epidemiology and Health Care	

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the research investigation without the prior written consent of the Sponsor.

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor green light confirmed.

I (investigator) also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:

Signature:  **Date 26/ 05 /2021**

Print Name (in full): Dr Logan Manikam

Position: NIHR Advanced Fellow & Honorary Consultant in Public Health Medicine

On behalf of the Study Sponsor:

Signature:  **Date 26/05/2021**

Print Name (in full): Prof Andrew Hayward

Position: UCL Institute of Epidemiology & Healthcare Director

STUDY SUMMARY

IDENTIFIERS	
IRAS Number	296259
REC Reference No.	
Sponsor Reference No.	142600
Other research reference number(s) (if applicable)	UCL Data Protection number: Z6364106/2021/06/195 Funder Reference: NIHR300020
Full (Scientific) title	Nurture Early for Optimal Nutrition (NEON) Protocol for a pilot feasibility cluster 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
Health condition(s) or problem(s) studied	Infant feeding, care and dental hygiene practices
Study Type i.e. Cohort etc	Pilot Feasibility Cluster Randomised Controlled Trial
Aim(s):	The aim of this study is to evaluate the feasibility of conducting a full-scale definitive cluster randomised controlled trial comparing the Women's Group PLA Cycle to usual care among SA infants who are <2 years old at the time of recruitment in East London, to

	decide whether to proceed, to proceed with amendments, or not to proceed with the definitive trial.
Objectives:	**Primary objectives:** • To assess the feasibility of proceeding to a definitive trial against the predetermined Go/Stop criteria which includes participant recruitment and retention rates across the three trial arms, intervention support and acceptability • To assess the intervention fidelity and participants' adherence of the NEON intervention with SA participants and community facilitators • To assess the implementation of the online versus the face-to-face intervention arms **Secondary objectives** • To assess the feasibility of data collection of primary, secondary, and economic outcomes at the individual and cluster level • To establish optimal primary, secondary, economic outcomes and data collection procedures including completeness and acceptability for a definitive trial • To assess adequacy of blinding of participant recruitment and data collection • To assess the time needed to competently deliver both versions of the NEON intervention To assess the mean, standard deviation and intervention effect with 95% confidence interval of the primary outcome, child BMI z-score
Type of trial:	A 3-arm pilot feasibility single-blinded (participant recruitment and outcome assessment) multi-site cluster randomised controlled trial (RCT) among South Asians in 3 East London boroughs
Trial design and methods:	Randomisation will be at cluster level (borough ward level) with 1:1:1 allocation to 2 intervention and 1 control arms. 18 clusters in total (6 wards per borough) will be randomised to one of the 3 study arms. The three trial arms are face-to-face NEON Women's Group PLA cycle, online NEON Women's Group PLA cycle and control (i.e. usual care by health visiting teams). The interventions will be delivered by multilingual community facilitators for different South Asian ethnic/ language groups, first in TH, then in NH and finally in WF. To achieve the primary objectives, we will assess these primary outcome measures for the pilot feasibility RCT (i.e. quantitative and qualitative feasibility and process measures): • participant recruitment and retention rates across the three trial arms

	• intervention support, acceptability, fidelity • participants adherence To achieve the secondary objectives, we will assess these secondary outcome measures which relates to the *feasibility* of collecting proposed outcome measurements for the definitive trial. We will assess the response rates, completion rates, acceptability of these outcome measures and the adequacy of blinding during participant recruitment and data collection to establish optimal outcomes and data collection procedures. The proposed outcome measures for the definitive trial include individual-level, cluster-level and economic outcomes.
Trial duration per participant:	12 months from consent to last trial assessment
Key Study milestones	**Pre-trial:** Submission and approval of JRO sponsorship, NHS ethics, and data sharing agreement; registration of clinical trial and NIHR portfolio **Following trial commencement**: first community facilitator recruitment, first participant recruitment, running of first PLA cycle, follow-up of PLA participants, data analysis
Estimated total trial duration:	18 months from when first participant enrolled to last participant follow-up. Anticipated start date: 1 July 2021 (recruitment), 1 October 2021 (first PLA session). Anticipated end of study date: 8 January 2023 (defined as the last participant followed-up) or 31 May 2023 (defined as the completion of data analysis and write-up).
Planned trial sites:	Multi-site in London Boroughs of TH, Newham, and Waltham Forest: 6 wards in each borough with the highest proportion of the targeted South Asian groups (i.e. 18 sites in total).
Total number of participants planned:	384
Main inclusion/exclusion criteria:	For participation in women's group PLA cycle: Inclusion criteria • Mothers or female carers of an infant aged <24 months; • From the following Asian background: Indian, Pakistani, Sri Lankan, Bangladeshi; • Resident in a randomised study ward in the London Boroughs of TH, NH, WF Exclusion criteria • Participants <18 years old;

	• Anticipating moving out of the a priori defined geographical area before or after delivery; • Currently participating or having participated in another study within 4 weeks of the trial commencing
Statistical methodology and analysis:	We will use mixed-methods analysis to understand intervention and trial feasibility, acceptability and fidelity to participants and community facilitators alongside assessing equity impact and informing design of the definitive trial. Quantitative data analysis will involve descriptive summary measures with expressions of uncertainty using the 95% confidence interval, including the parameters for sample size calculation for the definitive trial. For the primary outcome measure of the definitive trial, child BMI z-score, we will additionally estimate the intervention effect with confidence intervals between each of the intervention arms versus the control arms. Quantitative findings will be complemented by a qualitative thematic framework analysis of the intervention implementation processes.
FUNDING & OTHER	
Funding	Funded via a National Institute for Health Research (NIHR) Advanced Fellowship (Ref: NIHR300020) **Organisation:** National Institute for Health Research Academy **Contact:** Tom Pratt **Address:** 21 Queen St, Leeds LS1 2TW, United Kingdom **Email:** Academy-awards@nihr.ac.uk **Telephone:** 0113 532 8410
Other support	N/A
STORAGE of SAMPLES / DATA (if applicable)	
Human tissue samples	N/A
Data collected / Storage	N/A
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Other relevant study personnel	N/A

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

OTHER: N/A

TRIAL PERSONNEL

See protocol cover page for Chief Investigator and Sponsor contact details.

Study Coordinator	Name: Dr Logan Manikam E-mail: logan.manikam.10@ucl.ac.uk Tel: 00447949110711 fax: n/a
Statistician	N/A
Central laboratories	N/A

Please refer to 'Key Study Contacts' in the Study Summary table above. The roles and responsibilities for the committees are detailed under the section 'Oversight Committees'.

KEY WORDS

Community-based intervention; infant; child health; nutrition; feeding practices; clinical trial

LIST OF ABBREVIATIONS

NIHR	National Institute of Health Research
CLAHRC	Collaborations for Leadership in Applied Health Research and Care
WCF	Women and Children First
CFP	Complementary feeding practice
WHO	World Health Organisation
PLA	Participatory Learning and Action
RCT	Randomised Controlled Trial
MARKS	Motivation Awareness Resources Knowledge and Skills
LMIC	Low- and middle-income countries
HIC	High Income Countries
SA	South Asian
UKPRP	United Kingdom Prevention Research Partnership
NIHR	National Institute of Health Research

TH	Tower Hamlets
NH	Newham
WF	Waltham Forest
HV	Health Visitors
CF	Community Facilitator
PPI	Participants and Public Involvement
UCL	University College London
UK	United Kingdom
NHS	National Health Services
ONS	Office for National Statistics
PIS	Participant information sheet
ASQ-3	Ages and stages questionnaire
DNSIYC	Diet and Nutrition Survey of Infants and Young Children
CEBQ	Children's Eating Behaviour Questionnaire
PEBQ	Parents Eating Behaviour Questionnaire
EIA	Equality Impact Assessment
DRVs	Dietary reference values
CI	Confidence Interval
ICCP	Intra-class correlation coefficient
GCPG	Good Clinical Practice Guidelines
MRC	Medical Research Council

GLOSSARY TABLE

Participatory Learn and Action (PLA) group	An iterative process led by multilingual facilitator who facilitates the participant through a four-stage systematic cycle of problem identification, identifying solutions, implementing solutions and participatory evaluation.
Community Researcher	A bilingual female community member who was previously involved in NEON's intervention development phase and who will now assist recruitment and research activities in the pilot feasibility RCT.
Community facilitators	A bilingual female community member who will deliver the NEON intervention to community members after attending the required training by an independent PLA consultant.
Community members	A group of people living in the same locality, and share common interests or similar identity, or the district or locality in which such groups live. In NEON the community members are mothers or female carers from South Asian origins living in London Boroughs of Tower Hamlets, Newham, or Waltham Forest.
Experts	In this study, experts refer to; Health visitors, dentists, dieticians, Bengali nutritional advocates, communication experts, GPs, and/or midwives
Feasibility	This refers to the consideration of all aspects of project/intervention including the availability of time, capacity, financial resources, and technical aspects to ascertain if the project/intervention can carry on.
Acceptability	This refers to determining how well an intervention will be received by the target population and the extent to which the new intervention meets the needs of the target population and organisational setting.

Contents

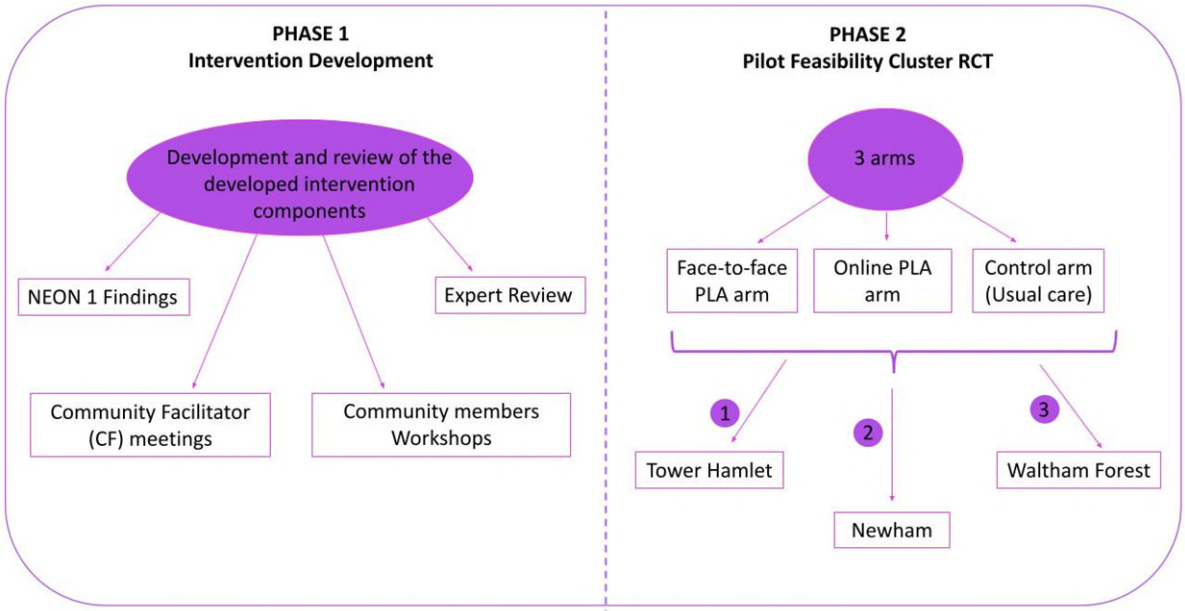
1. INTRODUCTION

The NEON programme aims to collaborate with South Asian (SA) families using the Participatory Learning and Action (PLA) approach to optimise infant feeding, care, and dental hygiene practices in SA infants aged <2 years in East London. The NEON programme to date is detailed in Figure 1 NEON phase 1 (NEON 1; funded by NIHR CLAHRC) focused on intervention development which consisted of a formative and feasibility phase.

In Phase 2 which this protocol describes, we now move to testing of procedures, estimating recruitment and retention and determining sample size and study design for the subsequent full-scale definitive cluster RCT. Since the key driver of the intervention is communication and being culturally sensitive, we will target the most common South Asian ethnic/language groups in the three London boroughs of Tower Hamlets (TH), Newham (NH) and Waltham Forest (WF): the Indian Gujarati, Indian Punjabi, Bangladeshi Bengali & Sylheti, Pakistani Urdu and Sri Lankan Tamil. In each borough, 6 wards (clusters) with the densest South Asian population will be randomised in a 1:1:1 allocation ratio to 2 wards face-to-face PLA, 2 wards online PLA and 2 wards control (usual care). The PLA groups will be delivered by multilingual community facilitators (CFs) for each ethnic/ language group.

Traditional health services in the UK tends to provide unidirectional information based on guidelines and NHS recommendations to parents/carers on the optimal nutrition, care and dental hygiene practices for their children. This model of enabling community participation in the development and delivery of culturally sensitive interventions aligns with the NHS 10 Year Forward Plan that shifts the emphasis to the community to equitably optimize health outcomes.

Figure 1. NEON programme to date



2. BACKGROUND AND RATIONALE

The first 1,000 days of a child's life are an important period for both growth and brain development. There is mounting evidence that influences during pregnancy and infancy may alter lifetime risk of nutrition and dental related diseases [1]. Feeding practices developed during this period can therefore impact children's nutrition, growth, dental health and cognitive development, and may lead to heart disease, obesity, and diabetes in the long term [2].

Studies in the past have shown that Britain's minority ethnic population is mostly disadvantaged across a range of social and economic outcomes. These social and economic inequalities underpinned by ethnicity are fundamental causes of many ethnic inequalities in health in the UK [3]. Some of the widest differences have been observed to be in the South Asian (SA) population within which the Pakistani and to an even greater extent, the Bangladeshi communities stand out as more disadvantaged compared to other ethnicities such as Indians [4].

Systematic reviews of studies assessing complementary feeding practices (CFP), and the sociocultural beliefs that underpin them, in children <2 years old within South Asian (SA) families living in the UK were explored. Findings showed that despite the adoption of the World Health Organisation (WHO) Infant and Young Children Feeding Guidelines, substantial evidence of non-recommended complementary feeding practices are being followed [5-7]. Factors that affected these practices persisting after migration included bicultural issues or low acculturation levels and conflicting information among health professionals, extended family, and religious and community leaders. By contrast, barriers to engagement with WHO-recommended complementary feeding practices in SA countries included conflicts about the best use of mother's time, short birth intervals, and poverty.

Effective early life intervention tailored to infants and young children of different ethnic groups therefore has great potential to reduce the growth of short- & long-term conditions as well as lifetime inequalities but few of such interventions exist [8, 9]. Traditionally health services in the UK provide unidirectional information based on guidelines and NHS recommendations. Specific ethnic groups may be marginalised by this approach as most of the advice is not tailored to their cultural practices. Based on the Lakhanpaul et al. MARKS (Motivation Awareness Resources Knowledge and Skills) model [10], the current NHS standard practice also lacks the space to understand what motivates parents & is also unable to support families in skills development all of which are key to providing optimal infant feeding, care, and dental hygiene support. Considering the limited NHS resources and the NHS 10 Year Forward Plan which aims to shift the emphasis to the community, there is a need for low-cost community-based culturally sensitive interventions that utilise community assets.

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). Community mobilisation through facilitated Women's group PLA cycles have been recommended by the World Health Organisation (WHO) as a strategy to improve maternal and infant survival [11]. Evidence from a number of studies have shown positive effects of using a PLA approach. In a meta-analysis of seven cluster RCTs in Low- and Middle-income countries (LMICs), PLA was shown to have reduced maternal and neonatal mortality by 37% and 23% respectively [12]. An RCT and controlled before and after (CBA) study have also demonstrated PLA groups to reduce maternal depression, increase exclusive breastfeeding rates, and decrease under 5 morbidity [13]. Additionally, in a Mumbai based RCT, PLA groups achieved improvements in maternal practices and care-seeking behaviour [14]. Recognising that the PLA approach has been successful in LMIC and is recommended by the WHO, this approach was adopted for this study.

In NEON Phase 1, the NEON intervention was co-developed with SA community facilitators (now community researchers), community members, the research team and independent experts (i.e. health visitors, dentists, dieticians, Bengali nutritional advocates, GPs, and/or midwives) (Figure 1). This follows the MRC complex intervention framework starting from the use of best available evidence and appropriate theory during the Intervention Development phase. These key steps do not follow a linear sequence. This study also utilised all 4 areas of the theoretical adaptation framework for reverse innovation. This includes but is not limited to using formative research and prior trials as evidence-based factors for process of adaptation, to making micro adaptations to the intervention including adjusting language, literacy levels for materials used and using picture cards, face-to-face, and interactive learning delivery methods.

In Phase 2 which this 3-arm pilot feasibility RCT protocol describes, we will test the procedures, estimate recruitment and retention, determine sample size and study design for subsequent full-scale definitive cluster RCT, which will formally evaluate the effectives of this NEON intervention over usual care. Since all participants will be aware of the treatment they are receiving irrespective of their

intervention/control arm, blinding is limited to participant recruitment (to reduce recruitment bias) and outcome assessment (to reduce measurement bias).

3. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

Principal Research Question

What is the most acceptable, feasible and robust trial protocol to address the question "Can a co-adapted participatory learning & action (PLA) cycle targeted at South Asian community members optimise infant feeding, care and dental hygiene practices?"

PICO	
Population of Interest	SA (South Asian) mothers /carers (grandmothers or aunts) of infants <2 in London Boroughs of TH, WF & NH
Intervention	PLA (Participatory Learning and Action) cycle to optimise infant feeding, care, and dental hygiene practices
Control	Usual care
Outcome	Primary: individual Child BMI Z-score, secondary: child feeding behaviour, audio and video recorded child eating behaviours and parental feeding practices, 4-day food diary, parental feeding style, network information diffusion, child development, child dental caries, and GP healthcare utilisation, process outcomes, and economic outcomes.

(Richardson et al. 1995)

3.1 Primary Objective

- To assess the feasibility of proceeding to a definitive trial against the predetermined Go/Stop criteria which includes participant recruitment and retention rates across the three trial arms, intervention support and acceptability
- To assess the intervention fidelity and participants' adherence of the NEON intervention with SA community members in the London Boroughs of TH, NH, and WF and community facilitators
- To assess the implementation of the online versus the face-to-face intervention arms

3.2 Secondary Objective(s)

- To assess the feasibility of data collection of primary, secondary, and economic outcomes at the individual and cluster level

- To establish optimal primary/secondary/economic outcomes & data collection procedures including completeness and acceptability for a definitive trial for both individual and cluster level outcomes
- To assess adequacy of blinding of participant recruitment and data collection
- To assess the time needed to competently deliver both versions of the NEON intervention
- To assess the mean, standard deviation and intervention effect with 95% confidence interval of the primary outcome, child BMI z-score

3.3 Outcome measures/endpoints

The primary outcome for the pilot feasibility RCT would be a range of feasibility and process measures. The secondary outcomes include all the other proposed outcome measures for the definitive trial. Figure 2 shows the outcomes, outcome measures and the timing of data collection from baseline. This is equivalent to the "Schedule of Assessments" (Appendix A). Please see section on 'Statistical Considerations' for details of each measurement and their analysis plan.

Figure 2. Outcomes, Outcome Measures & Timing of Collection. Also in Appendix A.

Outcome	Outcome measures	Data collection	Timing				
			Baseline	Every two weeks (end of each PLA meeting)	14 weeks (end of PLA cycle)	6 months	12 months
Proposed primary individual-level outcome	Individual Child BMI z-score	RA, CRs	✓		✓	✓	
Proposed secondary individual-level outcome	Children feeding behaviour	RA, CRs	✓		✓	✓	
	Audio/Video recording of child eating behaviours and parental feeding practices	RA	✓		✓		
	4-day food diary	RA, CRs	✓		✓	✓	
	Parental feeding style	RA, CRs	✓		✓	✓	
	Network diffusion*	RA, CRs		✓		✓	
Proposed secondary cluster-level outcome	Development performance of children	RA, HRs	✓			✓	
	Level of dental caries	RA	✓			✓	
	GP healthcare utilisation	RA	✓			✓	
Process Outcome*	Participants Feedback Questionnaire	RA, CRs		✓	✓		
	Facilitator Report Form	RA, CRs		✓	✓		
	PLA cycle meeting register	RA, CRs		✓	✓		
	Direct observation	RA, CRs		✓	✓		
	Sustainability assessment	RA, CRs		✓	✓		
Economic Outcome	Cost tool	RA	✓			✓	
	Partner's time Questionnaire	RA					✓

Footnote: *for intervention arms only

4. TRIAL DESIGN

We will conduct a 3-arm pilot feasibility single-blinded (participant recruitment and outcome assessment) cluster randomised controlled trial (RCT) in 3 East London boroughs: first in Tower Hamlets (TH) then in Newham (NH) and finally in Waltham Forest (WF). Figure 3 shows the schematic diagram of overall trial design. Randomisation will be at cluster level (cluster defined as borough ward level) with 1:1:1 allocation to 2 intervention and 1 control arms. 18 clusters in total (6 per borough) will be randomised to receive one of the 3 study arms. Ward-level randomisation was chosen as a trade-off between minimising participant contamination between arms & ensuring maximum South Asian population representation across East London (i.e. different boroughs have different South Asian sub-groups).

The three arms are:

1. **Face-to-face** – The 14-week intervention will be delivered in-person in children /community centres in alignment with government coronavirus social distancing rules (Appendix B). Participants will have access to paper-based women's group PLA cycle resources.

2. **Online** – The 14-week intervention will be delivered virtually (e.g., using Zoom platform). Participants will have access to digital women's group PLA cycle intervention resources via the eRedbook app. Participants without internet access will be provided with a tablet with free internet.

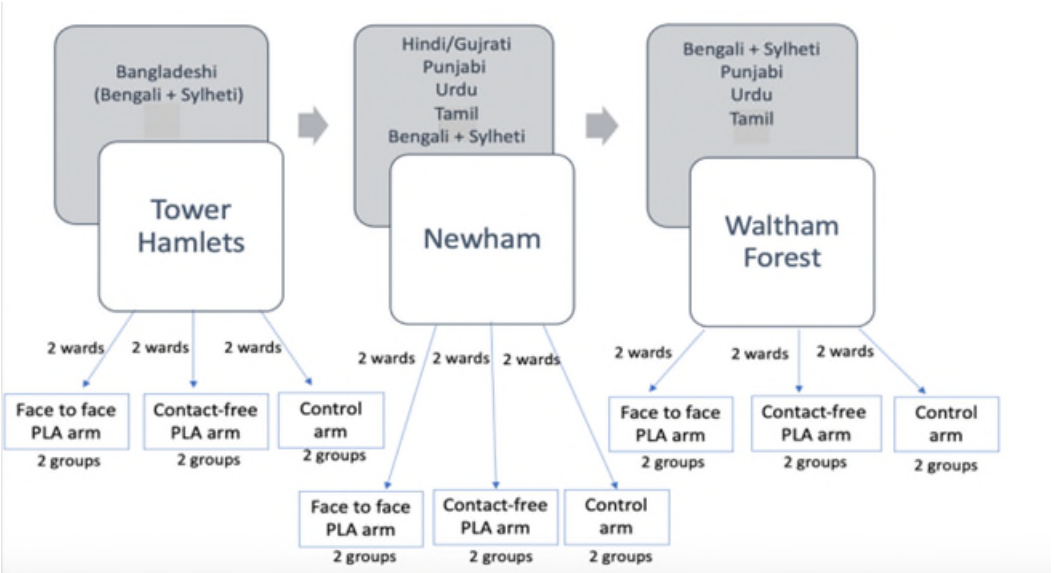
3. **Control** – Participants will receive usual care by health visiting teams in respective boroughs with no access to women's group PLA cycle resources.

The delivery of women's group PLA cycle in both intervention arms will be led by multilingual community facilitators (CFs) (Appendix C).

Data collection for intervention and control groups will take place at the same four time points;

1. 0 months (Baseline): Beginning of 1st PLA session
2. 3.5 months: Immediately post-intervention (end of Women's group PLA cycle)
3. 6 months
4. 12 months

Figure 3. Overview schematic detailing number of wards & PLA groups by East London boroughs



5. SAMPLING METHODS

Study Population

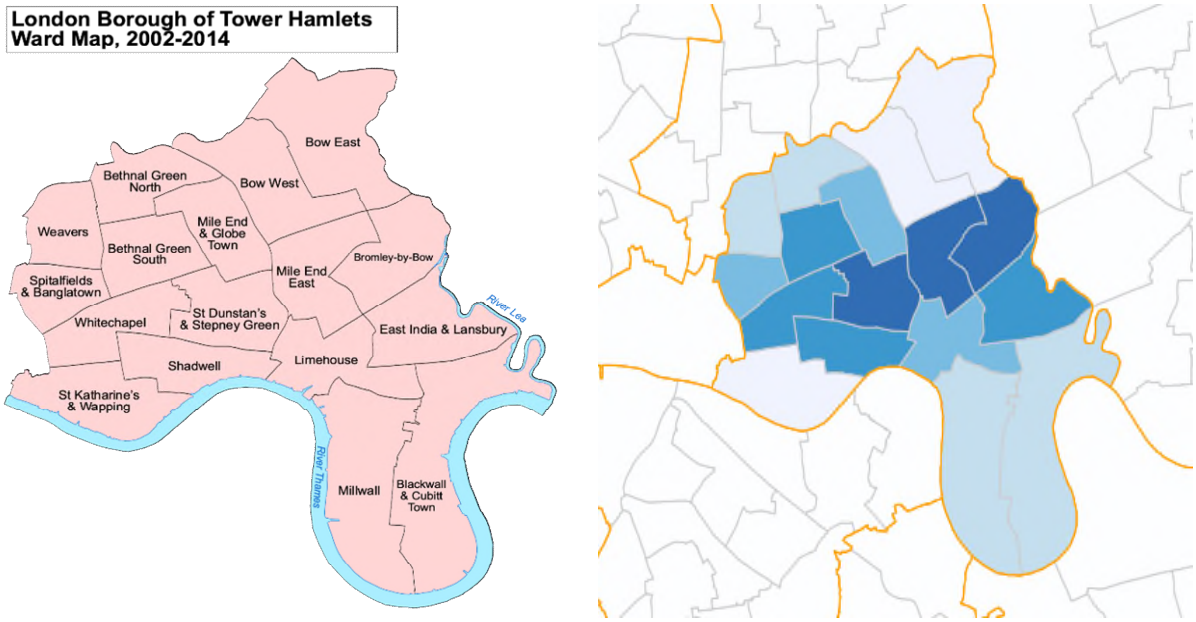
The target population are South Asian groups living in London Boroughs of TH, NH and WF. According to the 2011 Census, the most common South Asian ethnic/languages in these boroughs were Indian Gujarati, Indian Punjabi, Bangladeshi Bengali & Sylheti, Pakistani Urdu and Sri Lankan Tamil. The breakdown of ethnicities and languages present in the study boroughs are detailed below in 'Study Setting'.

Study Setting

The study will run in London Boroughs of TH, NH, and WF. According to a Mayor of London report in 2016 these boroughs are within 5% of the most deprived in England [15].

- **Tower Hamlets:** In TH, 41.1% are Asian/Asian British with British Bangladeshis comprising 32% of the entire population [16]. 3.2% Chinese, 2.7% Indian, 2.3% Other Asian and 1% Pakistani make up the remaining Asian ethnicities. Of the total TH population, 65.8% speak English, with the second biggest language group being Bengali, spoken by 18% of the TH population [17]. Figure 4 displays the Borough of TH and its subdivision in wards (left), as well as density (number of persons per hectare) of the Asian population in Tower Hamlet's wards (right; the darker the colour, the higher the density of Asian population) in 2011. 6 wards were identified based on the highest density of the Asian population in the borough, these are: Bromley-by-Bow, Mile End East, Bethnal Green South, St Dunstan's & Stepney Green, Shadwell, and Whitechapel.

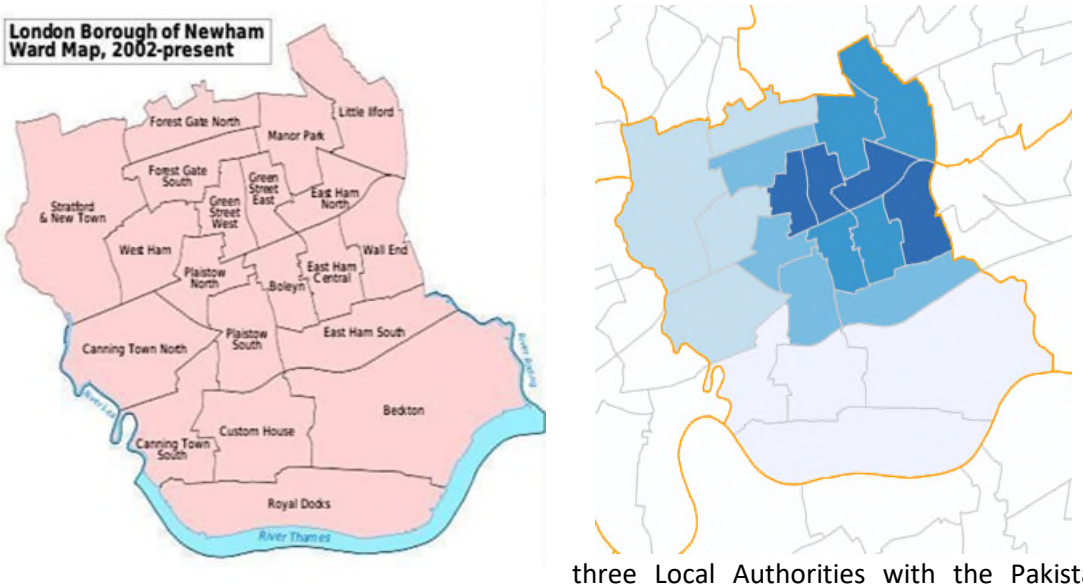
Figure 4. Division of London Borough of TH according to different SA ethnicities



- **Newham:** The NH Borough population has 43.5% who are Asian/Asian British. This is made up of 13.8% Indian, 12.1% Bangladeshi, 9.8% Pakistani, 6.5% Other Asian, 1.3% Chinese [18]. The predominant language is English, with the other spoken language represented at the following proportions: 7.4% Bengali, 4.4% Urdu, 3.3% Gujarati, 2.7% Lithuanian, 2.3% Tamil, 2.0% Polish, 1.8% Panjabi, 1.6% Romanian, 1.4% Portuguese [19]. Figure 5 displays NH and its associated wards (left) as well as density (number of persons per hectare) of the Asian population in NH's wards (right, the darker the colour, the higher the Asian population density in the respective ward) in 2011. The 6 wards with the highest density of the Asian population in the borough were selected: Green Street West, Green Street East, East Ham North, Wall End, East Ham Central, and Boleyn.

Figure 5. Division of London Borough of NH according to different SA ethnicities

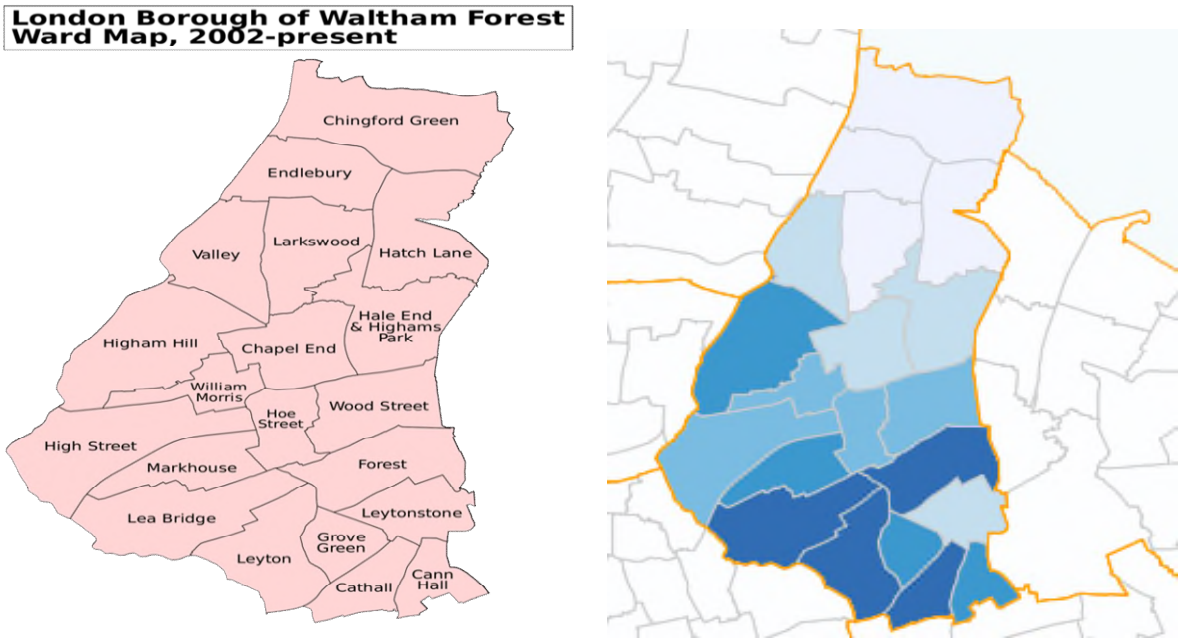
- **Waltham Forest:** With 21.1%, WF has proportionally the smallest Asian population out of the



three Local Authorities with the Pakistani

population most prevalent locally. The remaining percentage is comprised of Indian, Bangladeshi and other Asian populations [20]. The majority of the WF population speak English with the most common South Asian local languages being Urdu, Punjabi, Tamil, and Bengali, respectively [21]. Figure 6 presents WF and its associated wards (left) as well as density (number of persons per hectare) of the Asian population in NH's wards (right; the darker the colour, the higher the Asian population density) in 2011. The 6 wards displaying the highest density of the Asian population in the borough were selected: Forest, Lea Bridge, Markhouse, Leyton, Grove Green, and Cathall.

Figure 6. Division of London Borough of WF according to different SA ethnicities



5.1Inclusion criteria for participants

- Mothers or female carers of an infant aged <24 months;
- From the following Asian background: Indian, Pakistani, Sri Lankan, Bangladeshi;
- Resident in a randomised study ward in TH, NH and WF;
- Willing and able to provide written informed consent

5.2 Exclusion criteria for participants

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

To assess compliance with the inclusion and exclusion criteria, we will use the participant demographic questionnaire (Appendix D).

5.3 Eligibility criteria for study staff (community facilitators)

In order for study staff (CF) to be included in this study, they must fulfil all of the following criteria:

- Female
- Have at least one child, preferably <24 months

- From the South Asian community in TH, NH, or WF
- Able to read and write
- Fluent in speaking English and one of other local languages (Hindi, Bengali, Sylheti, Urdu, or Tamil)
- Understand social norms and values and the South Asian culture within the study boroughs
- Known to and respected by their local community
- Motivated to address issues related to infant growth and development
- Able to manage a group and have some leadership qualities

5.4 Recruitment of Individual Participants and Staff

Participant recruitment at a site will only commence when the trial has:

1. Been confirmed by the Sponsor (or it's delegated representative), and
2. Been issued with Confirmation of Capacity and Capability from the participating NHS site (i.e. TH GP Care Group CIC).

5.4.1 Recruitment of Participants

Due to the diversity of target population South Asians by ethnic/language group, multiple recruitment methods are needed to maximise recruitment reach for this study, it is likely that concentrating on one recruitment method will lead to low reach of recruitment efforts [22]. For instance, online recruitment solely might be ineffective due to digital poverty or digital exclusion whereby there are those who are not engaging effectively with the digital world and therefore at risk of being left behind from ease of access to information, services, and connecting with others, giving a rise in inequalities [23]. Many factors can cause digital poverty including low income, disability, language barrier, and lack of digital skills [23]. These factors can leave out many eligible participants, leading to a non-representative sample [23]. Therefore, it is crucial to use other mediums such as leveraging on existing social networks (snowballing), identifying and fostering collaborations with community leaders, and creating recruitment materials that clearly and succinctly describes the study aims of the study [24].

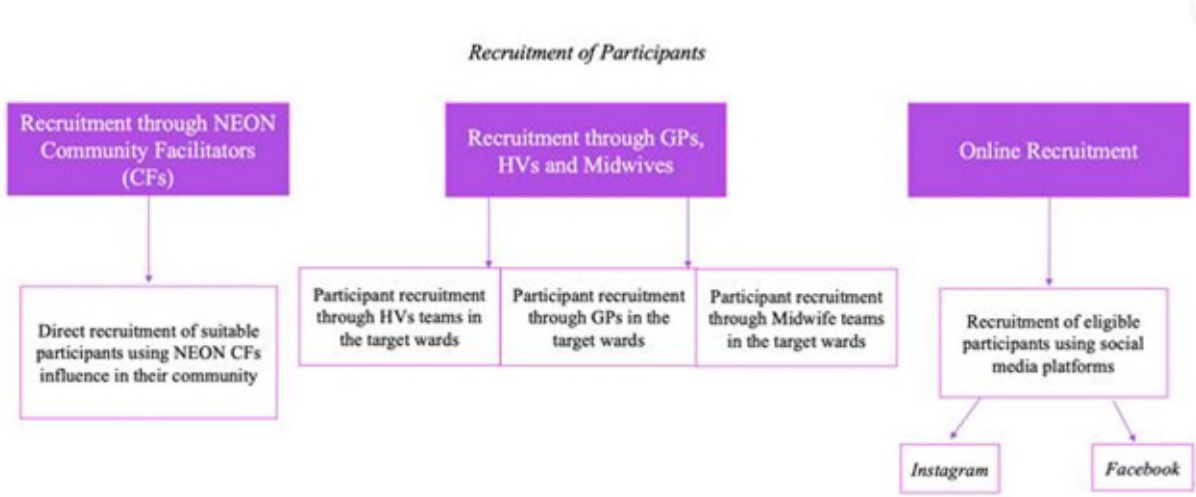
The recruitment of participants will follow three broad strategies as listed in Figure 7 with regular advice by our community researchers throughout to maximise reach. The RA will confirm eligibility of potential participants. The three strategies are:

1. **Recruitment through women's group PLA cycle CFs**: snowballing and the use of the PLA CFs network to invite eligible participants to take part of the study. The PLA CFs will share the study materials with their network and those who express interest will contact the RA to register in the study.
2. **Recruitment through HVs, GPs, and Midwifery teams:** In each of the identified study wards, Health Visitor (HV) teams, GP practice manager, and midwives' teams have been identified based on their geographical proximity to the selected study wards (Appendix E) illustrates the structure of HVs, GPs, and Midwifery teams in each borough). They will be contacted to aid the recruitment of the participants. Participant recruitment will be further complemented by HVs, GPs, and midwives' teams in the selected study wards in each borough. Study promotional materials (e.g., participants information sheets, posters) will be

made available to the HVs, GPs, and midwives in selected study wards to promote the study. All information material will be made available in English and other local languages of relevance to this study (Urdu, Bengali, Punjabi, Hindi and Tamil). The HVs, GPs, and midwifery teams will share the study materials with the eligible participants. Details of interested study participants will be given to the RA who will consent them into the study. Payments to HVs, GPs, and midwives will be supported by NHS support costs and decided with the relevant clinical lead (Appendix E).

3. **Online recruitment:** Online social media campaigns on Facebook and Instagram will be utilised to increase our study's reach and call out for eligible participants fulfilling our inclusion criteria. See Appendix F for examples of the advertisement materials that will be used in the recruitment. People who will be interested will contact the RA who will share more study materials with them and consent them into the study.

Figure 7. Three participant recruitment strategies in the randomised wards



To standardise the recruitment process as far as possible, will provide a script to aid recruitment. All recruiters will use the same participant information sheet (PIS) and other supporting materials. We will also provide training to standardise CF recruitment.

There is no monetary cost involved for participating in the study to the PLA CFs or participants. To make taking part in the study easier for participants, childcare will be provided at the local centre where the workshops are taking place if they need to bring their child with them. Light refreshments and snacks will also be provided during the meetings.

5.4.2 Recruitment of Staff

We will recruit the PLA CFs from the network of our community researchers and local stakeholders to facilitate the Women's group PLA cycle. Recruitment via community leaders/facilitators (CFs) is known

to be particularly useful for studies focused on underserved or traditionally hard-to-reach populations (e.g. low-income, racial/ethnic minority, older adults) [25]. According to NICE guidelines (2016), CFs are leaders/champions in their local community who with training and support help to improve the health and wellbeing of their families and communities. In line with NIHR's "INVOLVE" guideline on payment of fees and expenses, PLA CFs will be paid for their involvement in this study. PLA CF will receive £30 (in vouchers or payment) for each PLA meeting whether face-to-face or contact free arms. Additionally, each PLA CF will receive £5 (in vouchers or payment) to cover their travel costs for face-to-face arm. Further details in Appendix C.

HV, GP and midwives are identified and recruited by our study partners at each study ward.

5.5 Sample Size

The key driver of the Women's group PLA cycle in the NEON programme is communication and being culturally sensitive to all ethnicities. The choice of the ethnic/language groups has been made based on the ONS Census 2011 [26] and input of the NEON community facilitators expressing that as much as language is important for communication, people's practices are embedded in different ethnicities. Therefore, both language and ethnic groupings are important. As such, the sample size for this pilot feasibility trial will partly depend on the coverage of the specific ethnic/ language groups.

With reference to Figure 3 above, we have identified the main ethnic/language groups for each borough (detailed information in section 'Study Population'): 1 group in TH (Bangladeshi/ Bengali & Sylleti group); 4 groups in NH (Indian/Gujrati, Indian/Punjabi, Pakistani/Urdu, and Sri Lankan/Tamil); 3 groups in WF (Indian/Punjabi, Pakistani/Urdu, Sri Lankan/Tamil). In each borough, 1 Women's group PLA cycle will run per ethnic/language group per ward. As an example, in TH, there will be 2 face-to-face Bangladeshi/ Bengali & Sylheti PLA groups (1 per ward), 2 groups of Bangladeshi/ Bengali & Sylheti online PLA group (1 per ward), and 2 Bangladeshi/ Bengali & Sylheti control groups (1 per ward). This will be the same for each ethnic/language group in NH and WF. The more the ethnic/ language group in the borough, the more the intervention and control groups. Table 1 shows a detailed breakdown of the number of PLA and control groups by ethnic/ language groups and by borough.

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 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').

Table 1: Layout of PLA groups and participant numbers by ethnicity/language groups and by borough

	East London	**Total**

Ethnicity	Indian		Pakistani	Sri Lankan	Bangladeshi			
Language	**Gujarati**	**Punjabi**	**Urdu**	**Tamil**	**Bengali & Sylheti**	**Tower Hamlets**	**Newham**	**Waltham Forest**
Face to Face PLA Arm	2 groups; 12-16 participants	4 groups; 24-32 participants	4 groups; 24-32 participants	4 groups; 24-32 participants	2 groups; 12-16 participants	2 groups; 12-16 participants	8 groups; 48-64 participants	6 groups; 36-48 participants
Online PLA Arm	2 groups; 12-16 participants	4 groups; 24-32 participants	4 groups; 24-32 participants	4 groups; 24-32 participants	2 groups; 12-16 participants	2 groups; 12-16 participants	8 groups; 48-64 participants	6 groups; 36-48 participants
Control Arm	12-16 participants	24-32 participants	24-32 participants	24-32 participants	12-16 participants	12-16 participants	48-64 participants	36-48 participants
Total participant numbers (6-8 per group)	36-48 in total	72-96 in total	72-96 in total	72-96 in total	36-48 in total	36-48 in total	144-192 in total	108-144 in total

5.5 Informed Consent

It is the responsibility of the Investigator, or a person delegated by the Investigator to obtain written informed consent from each participant prior to participation in the trial, following adequate explanation of the aims, methods, anticipated benefits and potential hazards of the trial.

The person taking consent will be suitably qualified and experienced, and will have been delegated this duty by the CI/ PI on the Staff Signature and Delegation of Tasks.

The participant information sheet and informed consent form must contain the HRA's GDPR recommended wording. This can be found on the HRA website:

Prior to agreeing to participate in the study, participants will be provided with a participant information sheet (PIS) (Appendix G), detailing the rationale behind the study, what the study entails, information regarding data collection and handling, as well as issues around confidentiality and data protection and storage. The PIS will be provided to participants either in written form or verbally by our community facilitators, HVs, GPs, or Midwifery teams. A translation of the PIS in the participants' respective native language (written and/or verbally by our community facilitators) will be made available to allow for informed consent. The interested participants will then contact the RA or the community researchers to consent in writing or verbally. The consent form will include consent for participation for themselves and for their child, publications, audio/video recording of the PLA cycle sessions, access to medical records (linkage to the GP records), and to be contacted for other studies in the future. All participants will be informed by the RA or the community researchers in the language they are familiar with, both verbally and/or in writing, that their participation is entirely voluntary and that they can freely withdraw from the study at any time without reason and without prejudicing their further treatment or usual care. Data and samples collected up to the point of withdrawal can only be used after withdrawal if the participant has consented for this. Any intention to utilise such data

should be outlined in the consent form. They will be advised that all their data are going to be pseudonymised, securely stored, and analysed for publication. Participants will be given the opportunity to discuss and ask questions about the study, as well as adequate time for consideration by the participant before taking part. Consent will be sought at least 24 hours after being given the study documentation.

Participants will be required to provide either written consent (Appendix H) prior to their participation in the PLA sessions or Audio recorded consent provided verbally before/at the beginning of the 1st PLA session by the community researchers. Audio consent is a recognised approach approved by HRA and MHRA as there might be eligible participants willing to participate who are unable to physically sign a paper or electronic document and so may provide consent orally [27]. In those instances where it is not possible to capture written consent in paper form, we will consider alternative methods such ticking an opt-in box via an online survey platform, responding to an email requesting consent, or answering yes to a clear oral consent request which is captured via a digital audio-recording. Participants who do not offer formal consent will be subject to study exclusion.

No trial procedures, including the collection of identifiable participant data (unless the study has prior approval from the Confidentiality Advisory Group (CAG) and the Research Ethics Committee (REC)), will be conducted prior to the participant giving consent by signing the Consent form. Consent will not denote enrolment into trial. A copy of the signed Informed Consent form will be given to the participant when possible. The original signed form will be retained in the Investigator Site File. It will be recorded when participants choose to take part in the trial.

The PIS and consent form will be reviewed and updated if necessary throughout the trial (e.g. where new safety information becomes available) and participants will be re-consented as appropriate. Where a participant is required to re-consent or new information is required to be provided to a participant, it will be ensured that this is done in a timely manner.

For the participant who has initially given consent, but subsequently loses capacity to consent during the study, the participant and all identifiable data collected would be withdrawn from the study. Data that is not identifiable to the research team may be retained.

6. PRODUCT/INTERVENTIONS

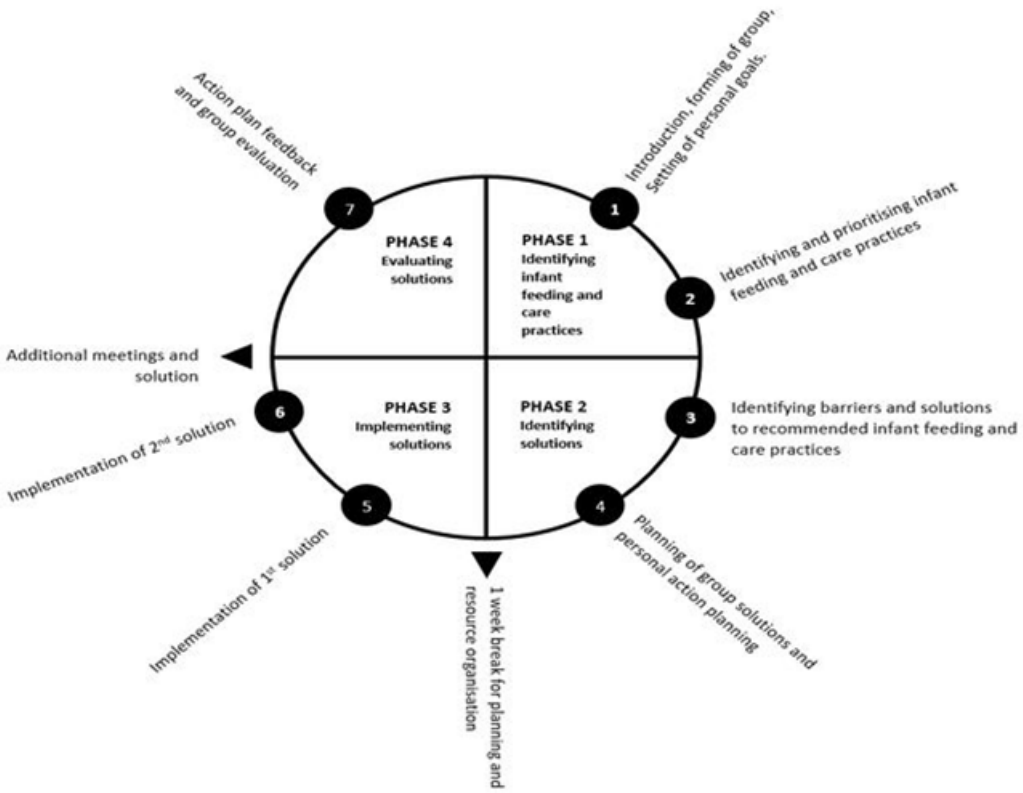
6.1 Name and description of intervention under investigation.

6.1.1 Intervention arms

There are 2 versions of the co-adapted women's group PLA cycle being trialed in this study, i.e. (1) face-to-face or (2) virtually (online), tailored to ethnic/language groups as described above. 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. The aim of each session is illustrated in Figure 8 below. A detailed description about the Women's group PLA cycle sessions and objectives of each session can be found in Appendix I. To reduce study contamination, we will not allow recruited participants to switch wards (i.e. switch arms) after knowing their allocation.

Figure 8. NEON Women's Group PLA Cycle

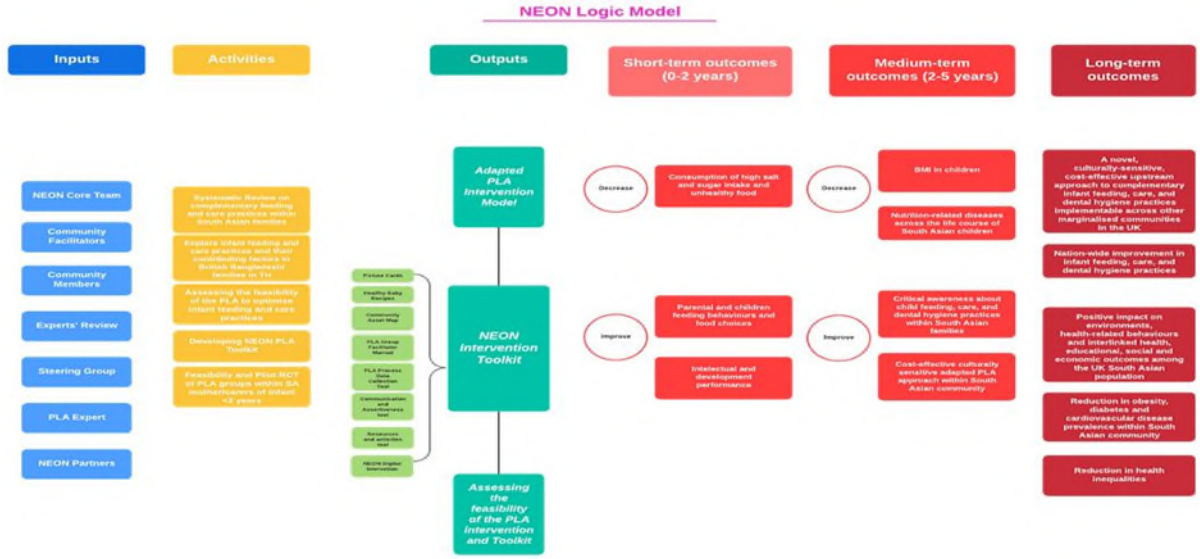


We have collaboratively developed a culturally sensitive intervention toolkit consisting of:

1. PLA group facilitator manual
2. Picture cards detailing recommended and non-recommended infant feeding, care and dental hygiene practices with facilitators/barriers to uptake and how to address them
3. Healthy baby food recipes
4. Participatory community asset maps (e.g., identifying low-cost fruit and vegetable shops play areas)
5. List of resources and services supporting infant feeding, care and dental hygiene practices.

A detailed description of each component can be found in Appendix J. A graphical depiction that shows the relationship between these activities and resources and the intended effects can be found in Figure 9 Logic Model. For participants randomised to the online arm, all elements of our intervention toolkit will be made available online using the eRedbook platform (Appendix J). The participants in the online intervention arm will be able to review the NEON intervention toolkit and receive information related to the NEON programme via the app/website at their convenience, irrespective of time and place. To reduce study contamination, we will not allow recruited participants to switch wards (i.e. switch arms) after knowing their allocation.

Figure 9. Logic model for NEON phase 2 pilot feasibility trial



6.1.2 Control group (Usual Care)

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. Other initiatives and resources that are available in each of the study boroughs are listed in the NEON list of resources and activities tool (Appendix J). This is the usual standard of care.

7. TRIAL PROCEDURES

7.1 Pre-intervention assessments

The recruiters and the RA will screen potential participants before consent according to standardised recruiter scripts which assesses the inclusion/ exclusion criteria. Further screening will be aided with the Participant Demographic Questionnaire (Appendix D). The screening process will not involve any routine assessments, physical examination, medical history or concomitant medication but instead rely on self-identification for the trial-specific inclusion/ exclusion criteria.

All pre-intervention procedures to assess baseline measures will be carried out as specified in the schedule of assessments (Appendix A).

7.2 Randomisation Procedures

Consent and screening do not necessarily constitute enrolment. Participants are considered to be enrolled into the trial following: screening to confirm eligibility, consent, completion of the randomisation process, baseline assessment and allocation of the participant trial number.

Random Allocation at the Cluster Level

As described in section 'Study Setting', in each borough, the 6 identified wards will be randomly allocated in 1:1:1 allocation to 2 wards face-to-face women's group PLA cycle intervention, 2 wards to online women's group PLA cycle intervention, and 2 wards will act as controls. The randomisation will be undertaken by the RA on cluster level, not individual level, using Research Randomizer software [28] for the 18 wards stratified by borough. The RA will hold the randomisation list.

Ward-level randomisation will occur before staff (CF) and participant recruitment detailed in section 'Recruitment of Community Facilitators and Individual Participants'. Once sufficient numbers of participants are recruited in an ethnic/language group then that Women's group PLA cycle can start. GPs will be informed of participants' registration when required.

Allocation concealment at the time of participant recruitment

To reduce recruitment bias, staff (CF who help as recruiters, GP, HV, midwives team) will not be aware of the treatment allocation of the clusters (i.e. ward) at the time of participant recruitment. After recruitment has been completed for that ethnic/ language group in the borough, then only will the RA will reveal ward allocation to CF and participants via text or email that lists postcodes under different trial arms, since this is necessary for CFs to deliver the interventions to the participants in intervention arms. After recruitment, the RA will reach out to all participants in intervention and control wards to arrange for baseline assessment by either RA or community researchers (CRs) and provide the participant ID. Participants in intervention wards will then be contacted by their CF and sent details of their PLA group sessions by email or text message. We will check with CF recruiters whether they were in fact unblinded in a debrief.

Though all participants and staff delivering the intervention (CFs) will be aware of the treatment they are receiving irrespective of their intervention/control arm, outcome measurement blinding will occur for CRs.

7.3 Baseline and Intervention Procedures

7.3.1 Baseline data

Please refer to Appendix A 'Schedule of Assessments' for the baseline data that needs to be collected. Please refer to sections 'Secondary outcomes' for details of the baseline measurements.

7.3.2 Intervention Procedures

Please refer to section 'Name and description of intervention under investigation' for details of the NEON Women's Group PLA Cycle intervention. A detailed description about the Women's group PLA cycle sessions and objectives of each session can be found in Appendix I.

7.4 Subsequent assessments and procedures

Please refer to Appendix A 'Schedule of Assessments' for the subsequent assessments.

7.5 Discontinuation/withdrawal of participants

In consenting to participate in the trial, participants are consenting to intervention, assessments, follow-up and data access and collection.

It is always within the remit of the physician responsible for a patient to withdraw the patient from a trial (or certain aspects of the trial) for appropriate medical reasons, adverse events or new information gained about an intervention. A participant may be withdrawn from trial whenever continued participation is no longer in the participant's best interests, but the reasons for doing so must be recorded. Reasons for discontinuing the trial may include those stated in the 'exclusion criteria':

- moving out of the a priori defined geographical area before or after delivery
- participants withdrawing consent
- persistent non-compliance to protocol requirements

The decision to withdraw a participant from treatment will be recorded.

7.6 Definition of End of Trial

The expected duration of the trial is 18 months from recruitment of the first participant.
The end of trial is the date of the last follow-up of the last participant.

8. FINANCE AND SUPPLY OF EQUIPMENT

The research costs for the study have been funded by the National Institute for Health Research (NIHR) Academy (Reference: NIHR300020), £805,854 (Dec.2019 – May.2023). All equipment required will be funded on the grant.

The authors declare that there are no competing interests

9. DATA MANAGEMENT

7.7 Confidentiality

The study is compliant with the requirements of the General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All Investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller of the NEON study and therefore all personal data gathered during the NEON study will be stored in alignment with UCL's governance policies regarding research and information; the UCL Data Protection Officer can be contacted at data-protection@ucl.ac.uk.

The Data Management portion of the NEON Steering and Data Management team has been formed to uphold the responsibility for the safety monitoring role when necessary given the nature and expected duration of the NEON RCT.

UCL is the data processor. The study will be collecting the following personal data: NHS Medical records, the study outcome measures, demographic questionnaire. Please see Section 'Data Handling' for details.

The participant's initials, date of birth and trial identification number, will be used for identification and this will be clearly explained to the participant in the Participant information sheet. Participant consent for this will be sought.

7.8 Data collection tools and source document identification

Data will be collected from sites on a range of validated and trial-specific data collection tools.

Source data are contained in source documents and must be accurately transcribed to trial-specific data collection tools. Examples of source documents are medical records which include laboratory and other clinical reports etc.

A source document list will be implemented prior to the start of the trial to identify:

- which data is to be recorded directly onto the trial-specific data collection tools;
- which data is recorded firstly into source documents, such as medical notes, and then transcribed into the trial-specific data collection tools; and

- which data is not to be recorded in the trial-specific data collection tools but only recorded in source documents, e.g. participant questionnaires.

It is the responsibility of the investigator to ensure the accuracy of all data entered. The delegation log will identify all those personnel with responsibilities for data collection and handling, including those who have access to the trial database.

For data collection and handling, we will use RedCap electronic data management system [29]. Academic use of RedCap is provided free of charge. Individual participants' data and consent will be recorded and outcome will be tracked using the RedCap system. The RA can assign data permissions to individuals such as the ability to view personally identifiable information (PII) and access to other modules such as file exports and repositories. Furthermore, data exports to data analysis softwares such as R and STATA are straightforward, and the existence of a RedCap API allows for more flexible data import and export.

7.9 Completing Case Report Forms (CRF)

N/A.

The CRF will not be used in this trial. Instead, a range of validated and trial-specific data collection tools will be used (please refer to the Appendices).

Any adverse events/safety concerns will be captured in the Participant Feedback Questionnaire (Appendix K) and Facilitator Report form (Appendix L), which will then be reported to the steering and safety monitoring team.

7.10 Data Handling

In this study, participants' data outlined in Section 3.3 'outcome measures/ endpoints' will be collected from participants in accordance with the participants consent form and participants information sheet attached to this protocol.

UCL will act as the data controller of all data for the study. The study partners: TH GP Care Group, London Borough of NH Council, WF Council, will process, store and dispose of the aforementioned data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 2018 and any amendments thereto.

Personal data (e.g. contact details) will be password protected and stored separately from the trial data on a secure UCL computer. All participant data will be pseudonymised and stored on an encrypted password protected computer, or UCL S: Drive accessible only to study staff and authorised personnel in line with best practice as recommended by UCL Research and Information Governance policies. Recordings of the discussions will be kept for research purposes, as they may be required as a reference for the research team to refer to at a later stage of the NEON programme, in which it will be kept in the UCL S: Drive.

Data sharing agreement will be in place between UCL and the study partners (TH GP Care Group, London Borough of NH Council, WF Council) to access the participant medical data on the EMIS and RIO databases. The data sharing agreement will be signed by both parties (UCL and partners) after reviewing the study protocol and the participants consent to access their medical records. The study partners will be asked to send reports of the participants' medical records to the RA upon request.

Personal data and audio/video recordings of the child eating behaviours and parental feeding practices will be stored for 3 years after the end of the study and then destroyed. All research data generated by the study and audio/video recordings of the PLA sessions will be stored for 20 years after the end of the study. The Steering & Data Management team will meet every 3 months to review Go/stop criteria.

These data will not be transferred to any party not identified in this protocol and are not to be processed and/or transferred other than in accordance with the participants' consent. Direct access to the data will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections, in line with participant consent.

Table 2 shows the data flow diagram to map out the organisational relationship and flow of identifiable and pseudonymised data between the different organisations and collaborators.

Table 2: Data flow for NEON pilot feasibility cluster RCT

Data Type	Data Life Cycle (Data collection and handling using RedCap electronic data management system*)			
	Collection of primary data/ Transfer of secondary data	**Retention**	**Use**	**Destruction**
1. Participant enrolment/ registration data (e.g. consent and contact details)	The research assistant (RA) or community researcher (CR) will collect participants' contact detail and consent through three recruitment strategies: (1) referral form community facilitators; (2) referral from GP, health visitors and midwives, (3) online recruitment.	Pseudonymised data saved to encrypted password protected computer, UCL S: Drive or stored separately in a locked filing cabinet at UCL. Personal data will be password protected and stored separately from the trial data on a secure UCL computer.	These files will be only be accessible by the research team and authorised personnel The transfer of any information between the research team will be through the UCL S: Drive and there will be no sharing of the data by sending emails between the research team.	Personal data and audio/video recordings of the child eating behaviours and parental feeding practices will be stored for 3 years after the end of the study and then destroyed. All research data generated by the study and audio/video recording of the PLA sessions will be stored for 20 years after the end of the study.
2. Primary data (e.g. study records, audio/video recording of PLA meeting sessions, anthropometric measurements, questionnaires, transcripts etc. as part of planned outcome assessment)	Participants' data will be collected by the community facilitators and collated by the RA/ CRs, or collected directly by the RA/ CRs.			
3. Secondary cluster-level data (routinely collected NHS medical data, as part of planned outcome assessment)	Data sharing agreement will be in place between UCL and the study partners (Tower Hamlets GP Care Group, London Borough of Newham Council, Waltham Forest Council) to access the participant medical data on the EMIS and RIO databases. The data sharing agreement will be signed by both parties (UCL and partners) after reviewing the study protocol and the participants consent to access their medical records. The study partners will be asked to send reports of the participants' medical records to the research assistant (RA) upon request. The RA will access these reports at each organisation or the study partners will share the pseudonymised data upon request.**	Pseudonymised data saved to the UCL S: Drive.		

Footnote: *The RA can assign data permissions to individuals such as the ability to view personally identifiable information (PII) and access to other modules such as file exports and repositories. This research is in the UK, East London. No international data transfer will take place.

**Depending on the data sharing agreement, this may involve authorised trial personnel to be on-site to access identifiable patient medical records in order to link them to participants' trial ID and pseudonymising them before saving to the UCL S:Drive.

9.5 Personal Data breaches

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer data-protection@ucl.ac.uk, and to the Sponsor via the UCL JRO research incident reporting form (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their Trust incident reporting mechanisms, and will document this within their TMF/ISFs.

10.STATISTICAL CONSIDERATIONS

Please refer to Appendix A 'Schedule of Assessments' for a summary of outcomes, outcome measures and timing of data collection.

10.1 Primary outcome

Feasibility and process measures

To address the **primary objectives** of assessing feasibility of proceeding to a definitive trial, we will collect both quantitative and qualitative data required to assess the predetermined Go/Stop criteria (Table 3). These measurements include participant recruitment and retention rates across the three trial arms, intervention support and acceptability. Retention rates will be assessed in relation to the percentage of Women's Group PLA sessions attended and the percentage reporting the primary outcome measure, BMI Z-score. Additionally, intervention fidelity and participants adherence will also be measured. We will collect these data using **study records** and a **series of process measurements**, including participants' feedback (Appendix K), facilitator's feedback (Appendix L), PLA cycle meeting register, direct observation of intervention delivery and CF performance, and sustainability assessment (Appendix M)**.**

Table 3: Progression rules (Go/ Stop criteria) for the definitive trial

Definite Go	**Definite Stop**
>=50% of eligible participants consenting to pilot feasibility study	<40% of eligible participants consenting to pilot feasibility trial
>=80% of mothers attend >=60% of planned sessions in the intervention arm.	<20% of mothers attend >=60% of sessions as planned in each intervention arm
Retention of >=70% of consented participants for primary outcome data collection	Retention of <50% of participants at 12 months

High intervention support with respect to content, frequency, duration, and quality	Low support of Intervention Procedures
Intervention is perceived as acceptable	Intervention perceived as unacceptable

Footnote: The study will have to meet the Definite Go criteria in order for the study to be feasible and to be able to proceed. However, if any one of the Definite Stop criteria is met then the study stops. The 'Go/Stop' indicates that it is either feasible or not feasible to proceed to a definitive trial. The progression rules have been approved by the steering and data management team. Should any of the progression rules not be met, assessments and adjustments of the NEON pilot feasibility RCT will be negotiated before proceeding to a definitive trial.

Study Records

We will record an enrolment log for all participants who meet the eligibility criteria, the total number of participants enrolled, reasons for non-participation and number of participants followed-up on primary outcome data. We will keep pre-screen failure logs for those who meet the inclusion criteria but were unable to be enrolled, with reasons. We will also record the date on how many people responded to adverts/invitations. Audio/video recordings of the PLA sessions will be collected using secured Dictaphone, video cameras, CCTV, and/or audio/video recording of the Zoom PLA meeting online.

Process outcome measures

The following process measures will be collected by the RA and/or CRs, either digitally or in a paper format, and stored in the UCL S: Drive and/or UCL cabinets.

Participants' feedback (Appendix K): A structured feedback questionnaire with close- and open-ended questions will be administered through self-reported questionnaires, face-to-face or phone interviews by our independent observers. This will capture issues related to recruitment, retention, acceptability, fidelity, reach (diversity), measures, and contaminations. At the last women's group PLA session, the CRs will additionally gather participants' views about the intervention, how it differs from the usual care, and explore areas of improvement.

Facilitators' feedback (Appendix L): 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. This will be collected by the RA from the CFs after each PLA session.

PLA cycle meeting register: The CF will be provided with sufficient copies of the meeting register to monitor participants' attendance at each meeting. This will be filled and sent to the RA after the end of each PLA session.

Direct observation of intervention delivery and CF performance: The CRs will be supervising the Women's group PLA cycle sessions to ensure consistency of sessions across all groups. The CRs

were the facilitators from the previous phase (Intervention Development phase) who have prior experience working in NEON study. The independent observers will 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 (i.e. 1 = no elements of the programme delivered; 2 = some elements of the programme, others missed or inserted; 3 = majority elements of the programme delivered; 4 = all elements of the programme delivered as per handbook). We will also include open-ended questions of the observer's thoughts or feelings about the sessions. This information will only be accessible to the RA and authorised research staff.

Sustainability assessment (Appendix M): The CRs will 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.

Each domain will be rated on a scale of 1 (poor performance) to 4 (excellent performance) during the last PLA session (7th session) to reflect on their group performance during the intervention.

Once all groups are assessed, an average score for all PLA groups in each ethnic/language group should be worked out (sum of the numbers divided by the total number of values in the set).

The scores will be plotted on a radar/spiderweb chart by the RA to visually represent which domains need to be improved and which are being performed well. The assessment can be done a few months into cycle implementation and repeated periodically.

10.2 Secondary outcome(s)

Outcome Measures for the Definitive Trial

To address the secondary objectives related to outcome data being evaluated for use in the definitive trial, we will collect a range of proposed primary, secondary and economic outcome measures at individual and cluster level. We will assess the response, completion rates and acceptability of these outcome measures and the adequacy of blinding during data collection.

These outcome measures are summarised in Appendix A 'Schedule of Assessments'. The process measures have also been included here to show the timing of data collection. As described in the logic model (Figure 9), the intervention is envisaged to have short (<2 years), medium (2-5 years) & long-term outcomes but for the purposes of this trial, the follow up time period is capped at 1 year or children up to 3 years of age, whichever is later. Although our intervention acts on the individual level, we anticipate that awareness of good infant feeding and dental hygiene practices would diffuse throughout their network in the medium to long-term (Figure 9). While we do not expect to see changes in cluster-level outcomes in a short time scale, we would like to carry out the process of collecting cluster-level outcomes in this pilot feasibility study.

Primary individual-level outcome

Individual child BMI z-score: Child growth patterns will be measured using BMI z-scores. During the baseline, at the end of the women's group PLA cycle, and 6 months from baseline (after the women's group PLA cycle has ended), the CRs will measure physical measurements (e.g. length/height, weight, and head circumference) for all participant's infant. CRs will input this data onto electronic platforms, with participant ID being automatically linked to maintain blinding.

The RA will use this data to measure the child BMI z-score using the WHO 2006 growth standard [2]. We will use age- and gender-adjusted length or height (m)/weight (kg)^2 and other related information to provide a comparison on the cluster level. All data will be stored in the UCL S: Drive.

Secondary outcome measures

Secondary individual-level outcomes

Children's feeding behaviour (Appendix N): Children's eating behaviour will be measured by the Children's Eating Behaviour Questionnaire (CEBQ), a validated questionnaire that is rated by parents to assess eating behaviour in children.[7, 8, 30]. It was suggested that 6 of these 8 domains are considered suitable for infants [8, 30]. The questionnaire examines behaviour across eight domains, i.e. (1) food responsiveness, (2) enjoyment of food, (3) emotional overeating, (4) desire to drink, (5) satiety responsiveness, (6) slowness in eating, (7) emotional undereating, and (8) food fussiness [7]. It was claimed that the risk of obesity could be linked with external eating, emotional overeating, and food fussiness [7]. Therefore, this questionnaire helps to capture these behaviours to reduce the risk of obesity in the future. In this study, we will adapt the 6 domains to measure the infant feeding behaviours. The PLA CFs will provide this questionnaire to the participants at baseline (at the beginning of the first PLA session), and at the end of the Women's group PLA cycle in each borough either digitally or in paper format. The RA will provide the questionnaire to the participants 6 months from baseline (after the women's group PLA cycle has ended). The paper format will be posted to the RA.

Infant feeding behaviours at baseline, post Women's group PLA cycle, and at 6 months follow-up will be summarised overall, by arm, and by time-point. 95% Cis will be constructed for differences in questionnaire outcomes between control and intervention arms. All digital data will be stored in the UCL S: Drive and/or UCL cabinets.

Audio/Video recording of child eating behaviours and parental feeding practices: In addition to the CEBQ and PFSQ, we will assess child eating behaviours and parental feeding practices using audio/video recording. This method was used in Fogel et al.'s paper where they used video recordings to study the parental feeding practices and children's oral processing behaviours [31]. This will be done by:

1. Identifying the behaviour codes from the NEON formative study [32]. The behaviour codes will include: early and late introduction of semi and solid foods, forced feeding, unregulated portioning, top-up feeding, distraction feeding,

preferences for milk and sweet foods, chasing fussy eaters, prolonged hand and spoon feeding, prolonged bottle feeding.

2. The CR overseeing the audio/video recording. To standardise the audio/video recording for all participants, we will ask participants of the face-to-face arm at the beginning of the second session to feed their child in front of audio/video recording camera (using a camera or the CCTV in the room where applicable), where we will ask them to provide the infant meal at the beginning of the session. For the online arm, we will similarly ask the participants to position themselves in front of the mobile/laptop camera and to provide the infant meal while we are recording the meeting using Zoom software recording.

3. We will repeat this at the end of the 7th session to assess before and after child eating behaviours and parental feeding practices for both intervention arms.

4. For each participant during the recording we will ask them about the meal they are serving for their infant (e.g., the name of the meal and the ingredients in that meal). Using Elan software [33], we will add the audio/video recordings and analyse the eating behaviours and feeding practices. The audio/video recording will be analysed using Elan software, where we will add the audio/video recordings and analyse the eating behaviours and feeding practices starting one month into the PLA intervention. Annotation will be created thereafter and will be linked to the behaviours codes we identified. We will then identify the key themes using thematic qualitative analysis for the before and after audio/video recordings, where we will be able to measure the effect of the intervention on the eating behaviours and feeding practices.

Network diffusion (Appendix O): This study will measure social diffusion of study materials between participants and their communities using 1) the "eRedbook platform", where the CRs will track the number of downloads of the study materials after the PLA ends and after 6 months for each borough, and 2) a digital or paper-based questionnaire to be completed by PLA participants including questions on the number of people they shared the material with, their relation to the participant, the platform they used, their family size, and their age and gender. The PLA CFs will provide this questionnaire to the participants at the baseline (at the beginning of the first PLA session) and at the end of each PLA session after, in digital format. The CR will provide the questionnaire to the participants 6 months after the end of the PLA intervention. All digital data will be stored in the UCL S: Drive and/or UCL cabinets. In TH, 92% of residents have access to the internet in their homes [34]. This was, however, found to be strongly related to age and disability. In those over 60, 54% confirmed internet access, with disabled residents also displaying lower access levels (67%). Also, social grades seemed to influence access to the internet, with households from social grades (DE) (typically lower income households) exhibiting relatively low levels with 77% access rate as opposed to 99% in households from social grades (AB) (typically higher income households). 91% of NH households identified have access to the internet, either inside or outside their home, in a recent household survey [35]. This demonstrates an increase of five percentage points (from 86%) since 2015. Like in TH, digital exclusion was found to be more prevalent amongst NH's more vulnerable residents. 30% of those with a disability and 37% of over 65-year-olds reported no access to the internet, compared to only 1% for residents between 16-34. Whilst there remains a disparity between the young vs. the old, it is necessary to note that also the

proportion of those aged 65 and over who do not have internet access has fallen by 22 percentage points since 2015 (59% to 37%). With similar figures in WF, this highlights high digital literacy among young residents compared to elderly and disabled people in our target boroughs.

Equality impact Assessment (Appendix P): We will measure the equality impact of this pilot feasibility RCT through the RA using the Equality Impact Assessment (EIA) tool described in Appendix P with our study partners in each borough to assess priority areas and highlight any missing data. This will be collected at the start of the women's group PLA cycle in each borough from our study partners and stored in the UCL S: Drive.
The Equality Impact Assessment (EIA) is a tool used to meet requirements of the equality duties and also identify active steps and approaches to promote equality. By carrying out the EIA one needs to systematically assess the likely effects of policies on people specifically in respect to disability, gender and racial equality, and other wider equality areas. These could include age, sexual orientation, religion/belief.

We want to use the EIA tool in NEON Pilot feasibility RCT to identify opportunities to further promote equality that have been missed, could be better used, and to look for negative or adverse impacts that can either be removed or mitigated where possible. If any of the negative or adverse impacts can lead to unlawful discrimination, they must be removed. The Pilot feasibility RCT should reflect the diversity of the target population making sure there is equal access to all but also recognising that providing the same service in the same way to everyone can sometimes create disadvantage. Due to the diversity of the target population/groups (ethnicity, language, location, age) the intervention needs to meet the differing needs, accommodate differences and diversity, and address any existing disadvantage. We will make use of demographic data from participants and ONS census data of TH, NH and WF. By having this information about the local communities, we can then compare them to our participants to ensure we have equal representation from demographics including religion/belief, age, race, and even disability.

Child food intake (Appendix Q): We will then measure the outcome of children's food intake using a 4-day food diary, originally used as part of the Diet and Nutrition Survey of Infants and Young Children (DNSIYC). It provides detailed information and quantitative estimates of the food consumption and nutrient intake of infants between 4 to 18 months [6]. The food diary [7] is a prospective, open-ended survey method collecting data about the foods and beverages consumed over a previously specified period of time. It is completed over four consecutive days and will be self-reported by parents. The appendix displays the food diary form which will be used as part of our study. This diary will allow insight into the total fat, total carbohydrate, and salt intake. Misreporting and under or overestimating the infrequently consumed foods are two main issues related to this survey and should be considered when interpreting the finding. The PLA CFs will provide this food diary to the participants at the baseline (at the beginning of the first PLA session), and at the end of the Women's group PLA cycle in each borough either digitally or in a paper format. The RA will provide the questionnaire at 6 months follow-up. The paper format will be posted to the RA and all the digital and paper-based data will be stored in the UCL S: Drive and/or UCL cabinets.

The food diary will assess the food intake (total fat, total carbohydrate, salt and sugar) by comparing intake with age/sex-specific UK dietary reference values (DRVs) [36]. After collecting the 4-days food diary, the dietary data will be presented based on age group (e.g. 4 to 6 months, 7 to 9 months, 12 to 18 months).

Parental Feeding Style (Appendix R): The outcome of parents' feeding behaviours will be assessed with Parental Feeding Style Questionnaires (PFSQ), developed based on clinical and experimental literature on these behaviours. It includes four scales: (1) emotional feeding, (2) instrumental feeding, (3) encouragement to eat, and (4) control overeating [37]. This is a self-reported validated questionnaire that has been used in an RCT to evaluate the outcomes of an early intervention started in infancy that promote protective feeding practices [31]. The PLA CFs will provide this questionnaire to the participants at the baseline (at the beginning of the first PLA session), and at the end of the Women's group PLA cycle in each borough either digitally or in a paper format. The RA will provide the questionnaire to the participants at 6 months follow-up. The paper format will be posted to the RA and all the digital and paper-based data will be stored in the UCL S: Drive and/or UCL cabinets.

Secondary cluster-level outcomes

Development performance of children (Appendix S): The developmental outcomes of children studied will be measured with the Ages and Stages questionnaire ASQ-3 [5], which has been identified as best satisfying the requirements for a population measure in a systematic review of all available child development screening tools. This questionnaire helps to assess the development performance of children through different main domain scores: communication, gross motor, fine motor, problem-solving, and personal-social [5]. There are 3 forms of this questionnaire based on the age of the child (24 months, 27 months, 30 months). The HVs will be using this questionnaire during their mandated visits. Other relevant data is also collected about gestational age, gender, postcode, ethnicity and mother's date of birth, child's date of birth, date of completion of ASQ, as well as which questionnaire was used (24/27/30 months). The resulting data is stored in the EMIS database in TH and RIO database in NH, and WF. The RA will extract the participants' data from the relevant databases in each study borough at the baseline (at the beginning of the first PLA session) and at 6 months follow-up. All data will be stored in the UCL S: Drive.

GP healthcare utilisation: The outcome of GP healthcare utilisation will be measured through routinely collected data that will be available in the participants' medical record data. It will allow us to identify the times that participants utilised the GP healthcare services. The RA will extract the participants data from the relevant databases in each study borough and/or the study partners in each borough will send participants data in a report when requested by the RA at the baseline (at the beginning of the first PLA session) and at 6 months follow-up. All data will be stored in the UCL S: Drive.

Level of dental caries: Children's dental health will be measured using their level of dental caries, which is routinely collected data through NHS dental services for registered patients beginning at the age of 6 months and approximately every half year following an initial visit [28]. This will be extracted by the RA for applicable practices at two timepoints: the beginning of the first PLA session (baseline), and at 6 months follow-up and will contain dental examination results from routine check-ups describing the presence of caries, as well as other signs of tooth decay [38]. Electronic data capture will be used to obtain this information after ethical approval (i.e. participant consent for researchers to access linked medical records) and the integration of data management systems [39]. This data will be stored in the UCL S: Drive.

Economic outcomes measures

Cost tool: The cost of the programme will be captured using a cost tool, which will include the cost of the NEON Intervention Development Phase and the Pilot feasibility RCT phase. The cost is a spreadsheet that includes different domains, which will be populated every 6 months.

The RA will insert the cost of the programme and participants in the cost tool once at the end of the intervention development phase and every 6 months after during the pilot feasibility RCT.

Partners' time used (Appendix T): To capture the cost of time at the delivery level, our partners in each borough (Ms Jenny Gilmour, Ms Kelley Webb-Martin, Ms Carol Irish, Mr Mfon Archibong, Ms Corinne Clarkson, Ms Mary Marsh, Ms Daley Delceta, Ms Amanda Nutkins) need to complete a questionnaire about the time they have spent on the NEON programme and/or any associated programmes. This questionnaire will include questions to capture the cost of the staff time (Appendix T). The RA will send the questionnaire to the aforementioned partners once at the end of the second year of the study. The data will be stored in the UCL S: Drive for analysis.

10.3 Sample size calculation

For the primary outcomes of this pilot feasibility trial, assuming that we will achieve a recruitment or retention rate of 80%, the intended sample size of n=384 would enable us to be 85% confident that the true population recruitment or retention rate will fall between 0.76% to 0.84% (i.e. precision of 0.04). This was estimated using a geometric mean cluster size of 16 participants across the 18 clusters (i.e. wards), cluster size coefficient of variation (COV) of 0.7 and an Intra-Cluster Correlation Coefficient (ICC) of 0.02.

Data from the pilot feasibility trial will be subsequently be used to refine estimates for power or samples size calculation for the definitive trial.

10.4 Planned recruitment rate

In each borough, the estimated recruitment period for staff (CFs) and participants are 2 months and 3 months respectively. Across the whole trial, the estimated recruitment period for CFs and participants would be 6 months and 9 months in total.

This pilot feasibility trial intends to assess more accurately the time required for recruitment through the three recruitment strategies in section on 'Recruitment', to inform the design and conduct of a future definitive trial.

10.5 Randomisation methods

Please refer to section on 'Randomisation Procedures' above.

10.6 Statistical analysis

Overall, we will use mixed-methods to understand intervention and trial feasibility, acceptability and fidelity to participants and community facilitators alongside assessing equity impact and informing design of the definitive trial. Quantitative data analysis will involve descriptive summary measures with expressions of uncertainty using the 95% confidence interval, including the parameters for sample size calculation for the definitive trial. For the primary outcome measure of the definitive trial, child BMI z-score, we will additionally estimate the intervention effect with confidence intervals between each of the intervention arms versus the control arms. Quantitative findings will be complemented by a qualitative thematic framework analysis of the intervention implementation processes. Data collection will be blinded to allocation.

10.6.1 Summary of baseline data and flow of participants

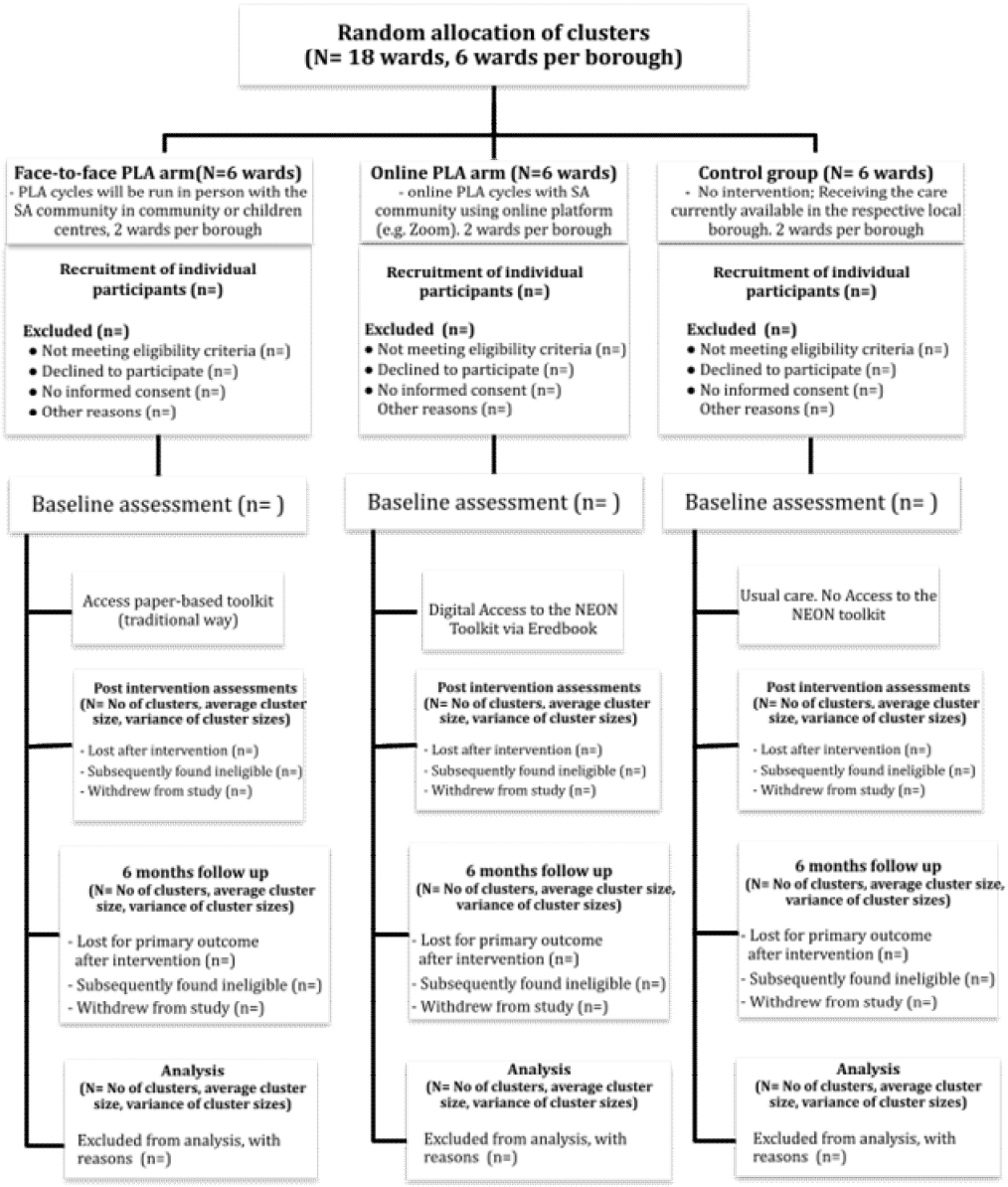
Sample Characteristics

Participant demographic questionnaire (Appendix D) will be utilised to collect demographic and socio-economic data. These include gender, ethnicity, number of children, employment status, income, age, and level of education. Each participant will be provided an ID.

Participants' demographic characteristics, stratified by trial arm will be summarised using mean and standard deviation for continuous variables and number with percentages for categorical variables. At baseline, we will check for potential recruitment bias. As those recruited later might be more likely to be recruited unblinded, we will compare later recruits across different arms. Participant characteristics by trial arm will also be informative in investigating factors associated with missing data.

Figure 10 shows the participant flow diagram.

Figure 10 Overview of the NEON pilot feasibility RCT design, recruitment and participant flow



10.6.2 Primary outcome analysis

Feasibility and process measures

Overall across the three trial arms, quantitative data related to recruitment and retention rates will be summarised descriptively using the frequency, percentages and 95% confidence intervals (CI). These include a summary of the screening, eligibility, consent and randomisation/ registration processes, with a breakdown of the numbers of participants involved in each ethnic/language group in each borough. We will pay special attention to any differential recruitment or retention rates (both in relation to Women's Group PLA sessions attended and the reporting of primary outcome, BMI z-score) across the intervention and control arms, as there is a risk that those in the control arm may be less keen to participate or remain in the study. We will compare the participant characteristics across the trial arms at different time points to check for any systematic differences due to differential drop-out.

For the two intervention arms, we will additionally conduct a mixed-methods implementation evaluation of the intervention support, acceptability, fidelity, participants adherence and time taken to competently deliver both interventions. Since it is likely that some features of each delivery mode (i.e. face-to-face or online) will be particularly salient, the findings of both intervention arms will be used to explore whether it would be better to adapt the intervention to a blended approach in the definitive trial.

Descriptive statistics will be reported for the quantitative data collected in the participants feedback questionnaire, facilitator report form, PLA cycle meeting register, direct observation checklists and sustainability assessment. These include information on the number of exercises completed in a meeting and so on.

Qualitative data from the same sources as above will be analysed thematically using a framework analysis to provide insights into participant's motivation for engagement, expectations and experiences of the programme, intervention acceptability, barriers to implementation, and suggestions for improvement. Using this a priori framework will help to systematically organise large volumes of qualitative data, while allowing flexibility in capturing emerging themes. Attention will be paid to negative, or 'deviant', cases to inform interpretation.

Quantitative and qualitative data will be analysed concurrently at multiple time points throughout the pilot feasibility trial. This is to identify any early problems that are rectified as the trial progresses.

These results will be collectively assessed against the go/stop criteria at the end of this pilot feasibility trial.

10.6.3 Secondary outcome analysis

Outcome measures for the definitive trial

Feasibility of collecting the outcome measures

For the descriptive analysis of quantitative data, continuous variables will be summarised using means, standard deviations (SD) and 95% CI; categorical variables will be summarised using frequency, percentages and 95% CI.

To assess the completeness of outcome data, the levels of missing self-reported outcome data, both at the individual item level and for entire outcome measures will be reported overall, by time-point and by intervention arms. We will also report the difference and its 95% CI for follow-up rates between the intervention arms and control arm to identify any large differences between the arms.

The acceptability of outcome measures and adequacy of blinding for participant recruitment and data collection would have been captured by the analysis of process measures.

Intervention effect for the primary outcome measure (BMI z-score)

We will also estimate the intervention effect with confidence intervals in the primary outcome measure (BMI z-score) between each intervention arm versus the control arm respectively. This will be conditioned upon comparable recruitment and retention rates across the trial arms such that recruitment bias is low, and that the feasibility trial protocol was sufficiently adhered to. We

will pay particular attention to the method to pool the outcome data across infants of different ages, depending on the age breakdown of the sample.

Sample size and power calculation for the definitive trial

Data from the pilot feasibility trial will be used to refine estimates for power calculation. The pilot feasibility trial will be able to determine the smallest difference of clinical importance; this will be done through multiple testing of the several key endpoints that have been outlined in this protocol (primary outcomes). From this, we will be able to establish the primary outcome that has the highest degree of clinical relevance for the individuals in the trial. We will also report the intraclass correlation coefficient (ICC). This will allow us to conduct the power calculation sample size needed in the larger trial.

The pilot feasibility trial will also assist in determining the clinically justifiable power-significance level or probability of "false positive" (type I error) results that is scientifically acceptable. Additionally, from the pilot feasibility trial we will also be able to establish whether we need to adjust for the calculated sample size for the expected level of non-compliance/ drop-in and drop-outs.

Economic evaluation

Economic evaluation will be conducted from a provider and user perspective exploring the direct cost of the intervention which includes time and resources spent on the training and participation of community facilitators. Additionally, the direct and indirect costs to participants (users) including their time and resources spent participating in the intervention will be explored. Data on the overall household consumption of participants and the costs of seeking care for children will be collected. Findings and data from this evaluation will allow for an estimation of total cost, average annual cost, cost-effectiveness analysis, and equity impact analysis. Overall, we will make a comparison between the three arms.

10.6.4 Sensitivity and other planned analyses

The Steering & Data Management team will meet every 3 months to review Go/stop criteria (Table 3).

Decision-making process: implications for progression from pilot feasibility to definitive trial

The end result of the pilot feasibility study will be one of the following:

1. Stop: the definitive trial is not feasible
2. Continue, with modification to the protocol: the definitive trial would be feasible with modifications
3. Continue without modifications, but monitor closely: the definitive trial would be feasible without modifications but with close monitoring
4. Continue without modifications: the definitive study will be feasible as is.

After applying the Go/Stop criteria, should the pilot feasibility trial be able to progress to the definitive trial, we will systematically and rigorously assess areas of improvement using a structured discussion. We could refer to A process for Decision-making after Pilot and feasibility Trials (ADePT)[40], which is a three-step process—deciding the type of problem, the identification of all solutions, and a systematic appraisal of these solutions—that will help to make the best use of findings from a pilot feasibility trial to inform subsequent decisions regarding a follow-on trial.

11.ASSESSMENT AND MANAGEMENT OF RISK

The table below summarise the risks and mitigation strategies:

Intervention	Potential risk	Risk Management
NEON Intervention	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 is that participants could encounter some mental distress.	This will be mitigated by making sure that no one during the workshops will embarrass, frighten, offend or harm participants.
NEON Intervention – Face-to-face Trial Arm	PLA cycle meeting sessions and meeting of the participants could possibly pose a risk due to the current pandemic environment around COVID-19 or physical injuries during commuting.	All meetings will occur in line with the government guidance. If we are able to run this arm, we will maintain social distance of 2 meters, or 1 meter with risk mitigation (face mask) where 2 meters is not viable. Using floor signage will help people maintain social distancing. Furthermore, meetings will be conducted in a contact-free manner, i.e. by avoiding transmission such the sharing of pens, documents, and other objects, the provision of hand sanitisers, and holding these meetings outdoors or in a well-ventilated room wherever possible. Meetings will be scheduled at varying times between 10.30am-3:30pm outside school run hours, rush hours, or based on participants' preferences.

12.RECORDING AND REPORTING OF ADVERSE EVENTS

12.1 Definitions

Term	Definition

Adverse Event (AE)	Any untoward medical occurrence in a patient or trial participant, which does not necessarily have a causal relationship with the intervention involved.
Serious Adverse Event (SAE).	Any adverse event that: • results in death, • is life-threatening*, • requires hospitalisation or prolongation of existing hospitalisation**, • results in persistent or significant disability or incapacity, or • consists of a congenital anomaly or birth defect. • Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences
* A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.	

12.2 Assessments of Adverse Events

N/A

12.2.1 Severity

N/A

12.2.2 Causality

N/A

12.2.3 Expectedness

N/A

12.2.4 Recording of Adverse Events

N/A

12.3 Procedures for recording and reporting Serious Adverse Events (SAEs)

N/A

12.4 Managing serious adverse events across research sites (if applicable)

N/A

12.5 Serious Adverse Events (SAEs) that do not require reporting (if applicable)

N/A

12.6 Incidental Findings in Research

N/A

12.7 Unblinding (if applicable)

N/A

12.8 Reporting Urgent Safety Measures

If any urgent safety measures are taken the CI/ PI shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice in the form of a substantial amendment to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

12.9 Protocol Deviations and Violations

The Sponsor will be notified immediately of any protocol violations during the trial conduct phase by completion of the online JRO Research Incident Reporting Form: https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo. All protocol violations must be recorded on the Protocol Violation Log and filed in the site file.

Protocol deviations are **minor** unintended departures from the expected conduct of the study protocol/SOPs, which **does not impact** the participants' safety or compromises the integrity of the study data. An example of a typical protocol deviation would be when a participant from the face-to-face intervention arm arriving at the wrong meeting venue (e.g. another children/ community centre) or at the wrong time. This would be recorded in the meeting register. Another example would be a

study visit date being outside the window defined in the protocol. These protocol deviations do not need to be reported to the Sponsor, but should be recorded in the Protocol Deviation Log and filed in the site file.

12.10 NHS Serious Incidents and Near Misses (if applicable)

N/A

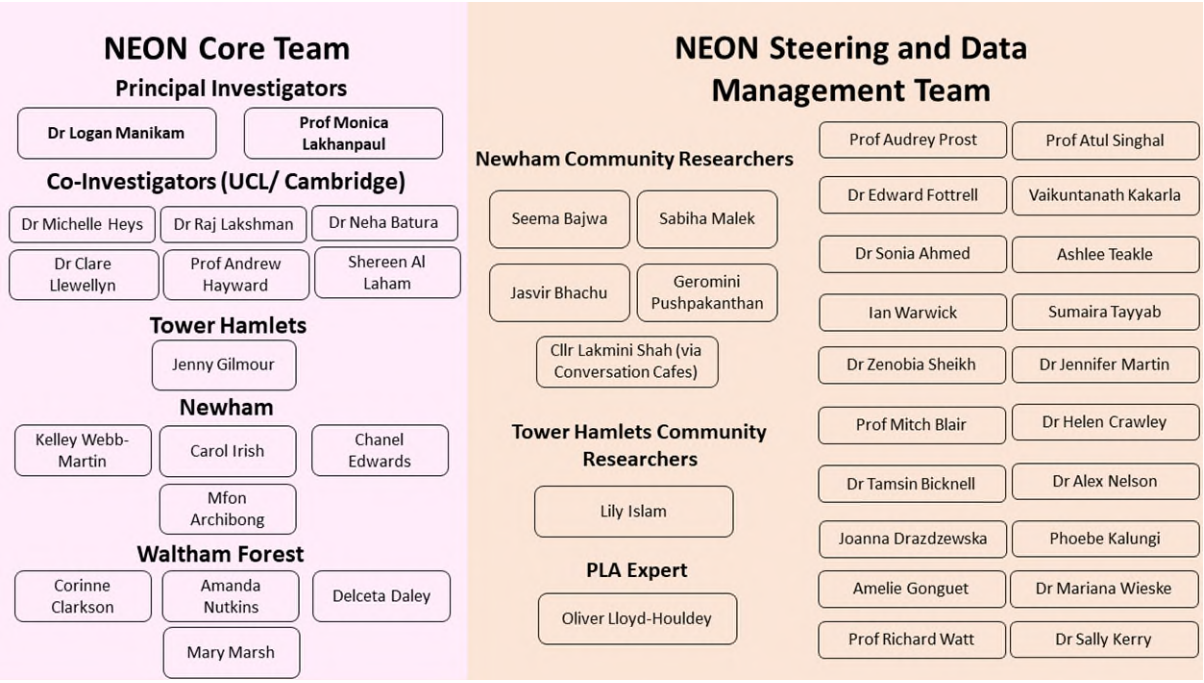
12.11 Complaints from research participants

In the first instance, research participant complaints (patients or health volunteers) will be reported to the CI/PI to investigate, as documented in the participant information sheet(s), and to the Sponsor via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy. For participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures were undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS and the Sponsor where necessary.

13.OVERSIGHT COMMITTEES

Figure 11 shows the composition of the NEON Core Team (trial management group) and the NEON Steering and Data Management Team:

Figure 11 Members of NEON oversight committees.



13.1 Trial Management Group (TMG)

The TMG will include the Chief Investigator and trial staff. The TMG will be responsible for overseeing the trial. The group will meet regularly every 3 months and will send updates to PIs. The TMG will review recruitment figures, SAEs and substantial amendments to the protocol prior to submission to the REC. All PIs will be kept informed of substantial amendments through their nominated responsible individuals.

NEON Core Team

The Trial Management Group is internally referred to NEON Core Team.

This team consists of Principal Investigators, Co-Investigators, sponsor, and borough partners has been formed which has been meeting bimonthly since the start of this NEON study in December 2019, and will meet during the phase 2 Pilot feasibility RCT every 3 months. Key Study Contact details of committee members are detailed under "Study Summary".

13.2 Other committees

Key Study Contact details of the **NEON Steering & Data Management Team members** are detailed under "Study Summary". This team also consists of a PLA expert and SA community facilitators who helped in the development of the NEON toolkit during Phase 1 Intervention Development, and selected SA community facilitators are now part of the research team as independent observers during phase 2 Pilot feasibility RCT. The independent observers will run research activities to ensure the consistency of the intervention delivery during this phase. Queen Mary University of London Pragmatic Clinical Trials Unit (QMUL PCTU) has also been involved in reviewing the protocol and providing methodological advice, and will continue to provide oversight during the pilot feasibility RCT.

NEON Steering & Data Management Team

The role of the Trial Steering Committee (TSC) is to provide overall supervision of the trial. The TSC will review the recommendations of the Data Monitoring Committee (DMC) and, on consideration of this information, recommend any appropriate amendments/actions for the trial as necessary. The TSC acts on behalf of the funder and Sponsor.

The role of the DMC is to provide advice on data and safety aspects of the trial but where not all members are independent. Meetings of the Committee will be held every 3 months to review interim analyses, or as necessary to address any issues.

The NEON Steering & Data Management Team has been formed to supervise and provide oversight for 2 Pilot feasibility RCT, ensuring it is in accordance with all relevant regulations as well as the principles of good clinical practice. The Steering team will (1) agree to the trial protocol and will facilitate any necessary protocol amendments, should they arise in the process of conducting the study; (2) hold an advisory role, aiding in project management governance and providing independent expert advice from an outside perspective, (3) will be key in monitoring the progress of the study, (4) ensuring that adequate deadlines are set and met, (5) Monitoring and advising the 'NEON' Core Team on strategic decisions in light of new evidence, stemming either directly from the

'NEON' study or from other sources, and (6) to ensure a successful delivery of the 'NEON' project, the steering team will meet with the Core team biannually and report on the study's progress to the NEON Core Team. The PI and other members of the core team will attend all necessary Steering Committee meetings and report on the study progress.

The Data Management portion of this team has been formed to uphold the responsibility for the safety monitoring role when necessary given the nature and expected duration of the NEON RCT.

The Steering & Data Management team will meet every 3 months to review Go/stop criteria.

14. REGULATORY REVIEW AND PATIENT AND PUBLIC INVOLVEMENT

14.3 Regulatory Review

The Sponsor will ensure that the trial protocol, participant information sheet, consent form, GP letter and submitted supporting documents have been approved by the appropriate research ethics committee, prior to any participant recruitment. The protocol, all other supporting documents including and agreed amendments, will be documented and submitted for ethical and regulatory approval as required. Amendments will not be implemented prior to receipt of the required approval(s).

The study was deemed to require regulatory approval from the following bodies: UCL Ethics approval and HRA Approval. This study will be conducted in line with the ethical framework set out by the NHS Health Research Authority and according to Good Clinical Practice (GCP) principles. The study design includes measures to safeguard the wellbeing and dignity of participants, as detailed below, and all staff and procedures will comply with the Data Protection Act 2018 and the EU General Data Protection Regulation. Before the start of the study, a favourable opinion will be sought from a REC for the study protocol, informed consent forms and other relevant documents e.g., topic guides.

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that the appropriate regulatory approvals have been issued.

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor, REC and HRA will be retained. The Chief Investigator will notify the Sponsor and REC of the end of the study.

It is the Chief Investigator's responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Sponsor and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

Within 90 days after the end of the trial, the CI will ensure that the main REC is notified that the trial has finished. If the trial is terminated prematurely, those reports will be made within 15 days after the end of the trial.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the Sponsor and to the REC and HRA.

14.4 Peer Review

The Sponsor considers the procedure for obtaining funding from (NIHR Academy) to be of sufficient rigour and independence to be considered an adequate peer review.

14.5 Patient and public involvement (PPI)

This NEON project has a strong ethos of stakeholder engagement from inception. The research has been co-designed with community facilitators to ensure that the research questions are relevant and important to participants and families, and to ensure that the study design is feasible and acceptable to them. CFs have been involved in all stages of developing and evaluating the intervention. 5 CFs who were part of the Intervention Development phase (each representing a different East London South Asian have since been recruited as Community Researchers (CRs)/Co-Investigators. Their role will be to;

- Support the development of the study protocol, information sheets and ethics application, ensuring any documents that are intended for participants and families are clear, appropriate and sensitively worded.
- Assist in developing topic guides and questionnaires to ensure topics covered are important and relevant to South Asian community members.
- Develop strategies to troubleshoot any problems e.g., with recruitment.
- Assist in data analysis, in particular in the latter stages of analysis when considering how key findings relate to one another and interpreting findings into recommendations for practice which are attainable and appropriate.
- Contribute to writing of academic papers, in particular reviewing and revising drafts.
- Develop plain language summaries and assist in dissemination activities (e.g., website updates, workshops)

15 MONITORING AND AUDITING

A trial specific oversight and monitoring plan will be established for studies. The trial will be monitored in accordance with the agreed plan. The degree of monitoring will be proportionate to the risks

associated with the trial. Risk will be assessed on an ongoing basis by the Chief Investigator, and adjustments made accordingly (in conjunction with the Sponsor).

Please refer to NEON Steering & Data Management Team for planned monitoring activities under 'Other Committees' section. The team will meet every 3 months to review the Go/ Stop criteria (Table 3).

The Chief Investigator will be responsible for the day-to-day monitoring and management of the study. The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the Sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

The UCLH/UCL Joint Research Office, on behalf of UCL as Sponsor, will conduct random audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the UK Policy Framework for Health and Social Care Research, and in accordance with the Sponsor's monitoring and audit policies and procedures.

16 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files.

Training of the PLA Community Facilitators

The PLA CFs will receive a training course face-to-face/online running. The training will run at the beginning of pilot feasibility RCT phase prior to the commencement of the women's group PLA cycles.

17 INSURANCE AND INDEMNITY

University College London (UCL) holds insurance against claims from participants for harm caused by their participation in this clinical study as this study is a clinical intervention study/trial where an inclusion criterion is pregnancy. An insurance form will have been completed when applying to the UCL Research Ethics Committee for ethical approval. The Joint UCL and UCLH Research office (JRO) will administer the insurance form on behalf of UCL.

Participants may be able to claim compensation if they can prove that UCL has been negligent. This trial will not be carried out in a hospital; we will only involve GP, HV and midwives as staff but will not use any hospital venues. The intervention will take place either in community/ children centres or online.

Participants may also be able to claim compensation for injury caused by participation in this clinical study without the need to prove negligence on the part of UCL or another party. Participants who sustain injury and wish to make a claim for compensation should be advised to do so in writing in the

first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

Additionally, UCL does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity.

18 RECORD KEEPING AND ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the Trial Master File at UCL S:Drive for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Trial Master File will be archived at UCL, in accordance with the UCL Retentions Schedule. It will be archived for a minimum of 5 years from the study end, and no longer than 20 years from study end.

NB: UCL do not archive student projects and therefore, the length of storage is not subject to the standard Sponsor requirements.

19 INTELLECTUAL PROPERTY

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol, the study data and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used independently of the study by each participating site, shall belong to UCL. All intellectual property rights deriving or arising from the material or any derivations of the material provided to UCL by the participating site shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, it agrees hereby to effectively assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL.

Each participating site agrees to, at the request and expense of UCL execute all such documents and do all acts necessary to fully vest the IPR in UCL.

Nothing in this section shall be construed so as to prevent or hinder the participating site from using know-how gained during the performance of the study in the furtherance of its normal activities of providing or commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual

property right of UCL or its funder. This does not permit the disclosure of any of the results of the study, all of which remain confidential.

20 PUBLICATION AND DISSEMINATION

All proposed publications will be discussed with and reviewed by the Sponsor prior to publishing other than those presented at scientific forums/meetings. Resulting publications and/or abstracts will be emailed to the JRO.

Dissemination of study findings will include:

- Peer reviewed publications in high impact factor journals (e.g., BMJ Open, Health Expectations) [anticipated 3-5 publications]. Members of the research team and the five community members on the steering (advisory) team will be invited to contribute to confirming analysis, write-up and authorship. Authorship guidelines will be followed, and paper will be presented on behalf of the NEON team.
- Presenting findings at national and international conferences.
- Workshops (2-3 per year) to present key findings and recommendations to commissioners and staff at relevant organisations (e.g., Tower Hamlet GP Care Group CIC, London Borough of NH), NEON community facilitators and social, print and broadcast media.

In order to ensure the findings reach a wide audience including parents, professionals and lay groups, the following dissemination activities will also take place:

- Regular updates about study progress on websites (e.g. UCL and NIHR) and via newsletters of patient groups to inform patients and wider population about study findings (e.g. Channel S);
- Presentations at lay-person meetings (e.g. community centres, children centres) to ensure widespread dissemination and through the NIHR CLAHRC network (e.g. Messages to Partners);
- Development of plain language summaries for each academic paper to be disseminated through community groups and social media and videos on YouTube.

21 TIMELINE

Figure 12. Timeline – Gantt Chart for NEON Pilot feasibility RCT.

	Start Date	End Date	Timeline
NEON 2 - Phase 2 Pilot Feasibiltiy RCT	5/2/2021	5/31/2023	
JRO sponsorship, CT registration, and NIHR po	5/2/2021	6/30/2021	
NHS ethics submission and approval	5/2/2021	6/30/2021	
Data sharing agreement DRAFT	5/2/2021	6/30/2021	
Data sharing agreement negotiation/sign-off	5/2/2021	6/30/2021	
PLA CFs recruitment in TH	7/1/2021	8/31/2021	
PLA participants recruitment in TH	7/1/2021	9/30/2021	
Running PLA cycle in TH	10/1/2021	1/7/2022	
Follow-up of PLA participants in TH	4/4/2022	10/1/2022	
PLA CFs recruitment in NH	10/1/2021	11/30/2021	
PLA participants recruitment in NH	10/1/2021	1/7/2022	
Running PLA cycle in NH	1/8/2022	4/16/2022	
Follow-up of PLA participants in NH	7/8/2022	1/8/2023	
PLA CFs recruitment in WF	1/8/2022	3/8/2022	
PLA participants recruitment in WF	1/8/2022	4/16/2022	
Running PLA cycle in WF	4/17/2022	7/23/2022	
Follow-up of PLA participants in WF	10/16/2022	1/8/2023	
Data Analysis	1/7/2022	2/28/2023	
Economic Evaluation	10/1/2022	2/28/2023	
Writing up	3/1/2023	5/31/2023	

Footnote: Dates (mm/dd/yyyy)

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23 APPENDICES

23.1APPENDICE 1: Schedule of Assessments

	Screening (Pre-treatment assessment)	Intervention phase					Final visit
Visit No:	1	2	3	4	5	6	8
	Day – X to Day -X	Day 1	Day 7	Day 14	Day 21	Day 28	Day 42/ Early Discontinuation visit
Window of flexibility for timing of visits:			e.g. +/- 2 days	e.g.+/- 2 days	E.g..+/- 3 days	e.g.+/- 3 days	e.g.+/- 3 days
Informed Consent	X						
Medical History	X						
Physical Examination							
Vital Signs							
Eligibility confirmation	X	X					
Add ALL Protocol Assessments including intervention, bloods/urine, ECGs, scans, c as applicable both trial specific and routine (include separate row for each assessment)							
Randomisation	X						
Adverse Events review	X	X	X	X	X	X	X
Concomitant Medication review (if applicable)	X	X	X	X	X	X	X

23.2 APPENDICE 2: Associated Documents

Document Name	Document Version	Document Date
Appendix A – Schedule of Assessments	1.0	20/05/2021
Appendix B - COVID-19 Government Meeting Guidelines (Face-to-Face)	1.0	20/05/2021
Appendix C - PLA community facilitators	1.0	20/05/2021
Appendix D - Participant demographics questionnaire	1.0	20/05/2021
Appendix E - HVs, GPs, Midwifery teams structure	1.0	20/05/2021
Appendix F - Advertisement materials	1.0	20/05/2021
Appendix G - Participants Information Sheet	1.0	20/05/2021
Appendix H- Consent Form	1.0	20/05/2021
Appendix I - PLA Meeting Objectives	1.0	20/05/2021
Appendix J - PLA Toolkit	1.0	20/05/2021
Appendix K - Participants Feedback Questionnaire	1.0	20/05/2021
Appendix L - Facilitator Report Form	1.0	20/05/2021
Appendix M - Sustainability assessment	1.0	20/05/2021
Appendix N- Children Feeding Behaviour*	1.0	28/09/2021
Appendix O- Network diffusion	1.0	18/09/2021
Appendix P- Equality Impact Assessment	1.0	20/05/2021
Appendix Q - 4-day Food Diary*	1.0	28/09/2021
Appendix R - Parental Feeding Style*	1.0	28/09/2021
Appendix S - Development performance of children – (ASQ-3) *	1.0	28/09/2021
Appendix T- Staff time questionnaire	1.0	20/05/2021