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Choosing Healthy Eating for Infant Health (CHErIsH) study: protocol for a feasibility study

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ABSTRACT

Introduction Childhood obesity is a public health challenge. There is evidence for associations between parents' feeding behaviours and childhood obesity risk. Primary care provides a unique opportunity for delivery of infant feeding interventions for childhood obesity prevention. Implementation strategies are needed to support infant feeding intervention delivery. The Choosing Healthy Eating for Infant Health (CHErIsH) intervention is a complex infant feeding intervention delivered at infant vaccination visits, alongside a healthcare professional (HCP)-level implementation strategy to support delivery.

Methods and analysis This protocol provides a description of a non-randomised feasibility study of an infant feeding intervention and implementation strategy, with an embedded process evaluation and economic evaluation. Intervention participants will be parents of infants aged ≤6 weeks at recruitment, attending a participating HCP in a primary care practice. The intervention will be delivered at the infant's 2, 4, 6, 12 and 13 month vaccination visits and involves brief verbal infant feeding messages and additional resources, including a leaflet, magnet, infant bib and sign-posting to an information website. The implementation strategy encompasses a local opinion leader, HCP training delivered prior to intervention delivery, electronic delivery prompts and additional resources, including a training manual, poster and support from the research team. An embedded mixed-methods process evaluation will examine the acceptability and feasibility of the intervention, the implementation strategy and study processes including data collection. Qualitative interviews will explore parent and HCP experiences and perspectives of delivery and receipt of the intervention and implementation strategy. Self-report surveys will examine fidelity of delivery and receipt, and acceptability, suitability and comprehensiveness of the intervention, implementation strategy and study processes. Data from electronic delivery prompts will also be collected to examine implementation of the intervention. A cost–outcome description will be conducted to measure costs of the intervention and the implementation strategy.

Ethics and dissemination This study received approval from the Clinical Research Ethics Committee of the Cork Teaching Hospitals. Study findings will be disseminated via peer-reviewed publications and conference presentations.

Strengths and limitations of this study

- This study provides a robust evidence base for future examination and implementation of the intervention and implementation strategy in primary care by utilising a comprehensive, multi-methods approach to examine feasibility, including an embedded process evaluation, of both a parent-level intervention and a healthcare professional-level implementation strategy.
- A significant strength of this study is the combination of evidence related to current infant feeding guidelines, implementation science and behavioural science to develop both a parent-level intervention and a healthcare professional-level implementation strategy.
- Inclusion of parent and practitioner involvement in the study design and the feasibility trial improves the quality and relevance of this research.
- A further strength is the inclusion of an economic assessment, a cost–outcome description, of the intervention and implementation strategy. While implementation process costs are identified as an important factor in implementation science, these costs are understudied and often overlooked.
- Recruitment and selection, and retention of participants is susceptible to recruitment bias at provider and patient levels.

INTRODUCTION

Childhood obesity tracks to adulthood[1 2] and is associated with increased risk of diabetes,[3 4] hypertension, coronary heart disease and stroke,[5–7] as well as long-term morbidity and premature mortality.[5 6 8] Though recent evidence suggests some stabilisation of childhood obesity rates,[9] global prevalence remains high.[10] In 2016, there were approximately 41 million children aged

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<5 years with obesity or overweight.[11] In Organisation for Economic Co-operation and Development countries, it is estimated that one in six children are living with overweight or obesity; in Ireland, this rises to one in four children.[12–14]

Evidence indicates that the period from pregnancy to 2 years of age is a critical window for development and prevention of childhood obesity.[15 16] Identified risk factors for childhood obesity within this time frame include maternal factors such as body mass index (BMI),[15 17] and infant birth weight and growth in infancy.[15 18 19] There is also evidence for an association between parents' modifiable feeding behaviours and childhood obesity risk.[20–24] Such behaviours include the initiation and duration of breast feeding,[25–27] inappropriate bottle use including prolonged use,[15 28] early introduction of solids[15 29 30] and the types, variety and sensory properties of foods fed to children.[31 32] Parental feeding behaviours are particularly important in infancy because of rapid developmental changes and concurrent developmental and feeding needs.[23 33] During this period, how parents feed their infant may impact on child weight outcomes via different mechanisms. More rapid weight gain among formula-fed infants[34–36] is associated with increased risk of childhood obesity[15 18 19]; conversely, breast feeding is associated with reduced risk of obesity.[25 37] The types of food fed during complementary feeding are also posited to stimulate gut microbiota changes that are associated with overweight.[38 39] Feeding behaviours such as responsive or non-responsive feeding may influence child obesity risk through development of child self-regulation of energy intake[20 21 38–40] and establishing future child eating behaviours.[15 38 41 42]

Parental feeding behaviours are influenced by multiple factors including demographic characteristics,[43–45] cost and time constraints[46 47] and information about infant feeding.[46 48 49] A recent qualitative evidence synthesis indicated that when parents are confused by conflicting infant feeding information they receive from multiple sources, this can lead to inappropriate feeding behaviours.[46] Currently, only 44% of women initiate breast feeding globally, and rates of exclusive breast feeding at 6 months are approximately 40%[50]; this is despite WHO recommendations to exclusively breast feed until 6 months of age, followed by the introduction of nutritionally adequate food, accompanied by breast feeding up to at least 2 years of age.[51] There is also evidence that a large proportion of children worldwide start solids before the recommended age.[52–54] In Ireland, approximately 60% of infants are breast fed, with 49% exclusively breast fed, at discharge from maternity hospital[55] and only 15% of infants are exclusively breast fed at 6 months[56]; 13.5% of infants regularly consume solids between 12 and 16 weeks in Ireland, while 47% of infants regularly consume solids before 5 months.[57] These figures are high despite national and international guidelines regarding infant feeding. For instance, in Ireland, programmes such as the National Healthy Childhood Programme (NHCP) and the Nurture Programme aim to provide guidance, advice and support for families during early childhood on topics including infant feeding. An important focus of these programmes is the use of existing healthcare contact points to provide support and advice, and improve consistency in information delivery by healthcare professionals (HCPs).

HCPs are in a unique position to promote healthy and appropriate infant feeding to parents in early childhood due to increased frequency of contact from birth to 2 years.[58 59] A recent systematic review demonstrated potential benefits of HCP-delivered interventions, including improved infant feeding and reductions in some child weight outcomes.[58] While evidence for efficacy of intervention delivery in specific healthcare contexts is unclear,[58] vaccination visits in primary care provide an opportunity to integrate an early feeding intervention into routine healthcare. For instance, in Ireland, children are entitled to free vaccination services under the Childhood Immunisation Programme at 2, 4, 6, 12 and 13 months; uptake rates are approximately 93%.[60] Infant feeding information is not typically provided to parents at these vaccination visits, though infant feeding/nutrition interventions delivered in primary care have been found to be acceptable to parents and HCPs.[61 62]

Recent evidence indicates the importance of supportive trusting relationships between parents and HCPs to facilitate the successful implementation of such interventions.[63] There is also a need for clear and consistent guidelines and messages regarding infant feeding for both parents and HCPs[46] to ensure successful intervention delivery and receipt.[63] Furthermore, issues with HCP capacity (ie, time and resources) and clarity regarding HCP roles have been reported as important barriers to the implementation and delivery of infant feeding interventions.[63] Given the importance of support provision, clarity and consistency in HCP delivery of infant feeding information during an existing busy contact point in primary care (ie, the vaccination visit), there is a need to develop appropriate and feasible implementation strategies to support HCPs to deliver such interventions in real-life settings.

This feasibility study will therefore examine both a brief complex parent-level intervention and an implementation strategy targeting the HCPs who will deliver this intervention. The brief complex intervention targets parents to improve infant feeding behaviours in the ages of 2–13 months, and is delivered during primary care-based vaccination visits. The implementation strategy targets HCPs to support their delivery of this clinical intervention via training and additional resources. This feasibility study is not intended to function as a 'scale model' of a larger trial but will instead address uncertainties about feasibility of the intervention, the implementation strategy, economic evaluation and the overall study procedures as recommended by existing guidance on the development of complex interventions.[64 65]

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Aims

The primary aim of the Choosing Healthy Eating for Infant Health (CHErIsH) pilot feasibility study is to collect and examine data on the acceptability and feasibility of the delivery of a brief infant feeding intervention by HCPs to parents at child vaccination visits, and the strategy to support implementation of this intervention in primary care for HCPs. This will facilitate the refinement of the intervention and its implementation strategy, and inform the next step of the CHErIsH study, such as a definitive trial.

Specifically, the CHErIsH feasibility study will address the following research questions:

1. Are the intervention content, delivery and implementation procedures acceptable to parents who will receive the intervention, and HCPs who will deliver the intervention?
2. Are the data collection processes, including mode and duration of data collection and outcome measures used, acceptable to parents and HCPs?
3. Is the intervention feasible to deliver in primary care practice, in terms fidelity of delivery and receipt of the intervention?
4. Is the study feasible in terms of recruitment and retention procedures and data collection?
5. What are the costs associated with the intervention and its implementation strategy?

METHODS

Design

The CHErIsH study is a non-randomised feasibility study, including an embedded process evaluation and economic evaluation.

Patient and public involvement

One of the study co-investigators and co-authors (TH) is an HCP in primary care practice and was involved in the development of all aspects of the study. A CHErIsH patient and public involvement (PPI) group was established, comprising five mothers, including one grandmother, and three fathers, including one grandfather. The CHErIsH PPI group has advised on study design, measurement and study materials.

Participants

Primary healthcare centre providers

The intervention will be delivered in the Mallow Primary Healthcare Centre (MPHC) in Cork, Ireland. MPHC is a large primary care centre, which includes three separate primary care practices. MPHC has approximately 20 general practitioners (GPs) and 12 practice nurses (PNs), and a large nationally representative catchment population. Approximately, 450 infants are delivered by women attending MPHC per year. HCPs will be eligible for inclusion if they are involved in the delivery of routine infant vaccinations and can participate in training to deliver the intervention. In Ireland, routine vaccinations are typically delivered by PNs or GPs.

Parents

Parents or primary caregivers (herein referred to as 'parents') are eligible for inclusion if they meet the following criteria:

- Parent of an infant ≤6 weeks of age at study recruitment.
- Intends to attend a participating GP and/or PN in the primary care centre for child's vaccination visits.
- Is over 18 years of age.
- Can provide written informed consent to participate.

Recruitment

Healthcare professionals

All eligible HCPs will be invited to participate in the study, and all HCPs within each of the three MPHC practices need to consent and undergo training in order for the intervention to be delivered within that practice. Recruitment will be facilitated and supported by a local opinion leader[66] (TH), who is a GP based in MPHC. The local opinion leader will liaise with the manager of primary care centre and also identify an existing healthcare centre staff member as a designated onsite administrator. The primary care centre manager will facilitate recruitment of GPs and PNs by providing study information leaflets, invitation sheets and consent forms to all eligible GPs and PNs. On completion, consent forms will be returned to the designated onsite administrator and stored securely until collected by the research team. Alternatively, consent forms will be returned directly to a member of the CHErIsH research team in MPHC prior to commencing intervention training.

As part of the embedded process evaluation, GPs and PNs who consented to participate in the study will be contacted following intervention cessation and invited to participate in qualitative interviews. Purposive sampling will be used to identify HCPs with differing levels of reported acceptability and fidelity of delivery based on the quantitative data collected. It is expected that interviews will be conducted with an initial sample size of 10 HCPs, with a stopping criterion of an additional 5 HCP interviews conducted without development of additional topics or themes.[67]

See figure 1 for recruitment flowchart.

Parents

All parents of infants ≤6 weeks of age registered at the primary care centre, and who are scheduled to attend vaccination visits with a participating GP and/or PN, will be identified by the onsite study administrator. Two approaches to recruitment to the intervention will be used (see figure 1).

1. Remote recruitment

a. A letter of information and invitation, an informed consent form, and baseline questionnaire will be posted to all potential participants' home addresses from MPHC before the infant is 6 weeks of age.

b. Signed informed consent forms can be returned at the 2 or 6 week visit with the GP. Parents who have not

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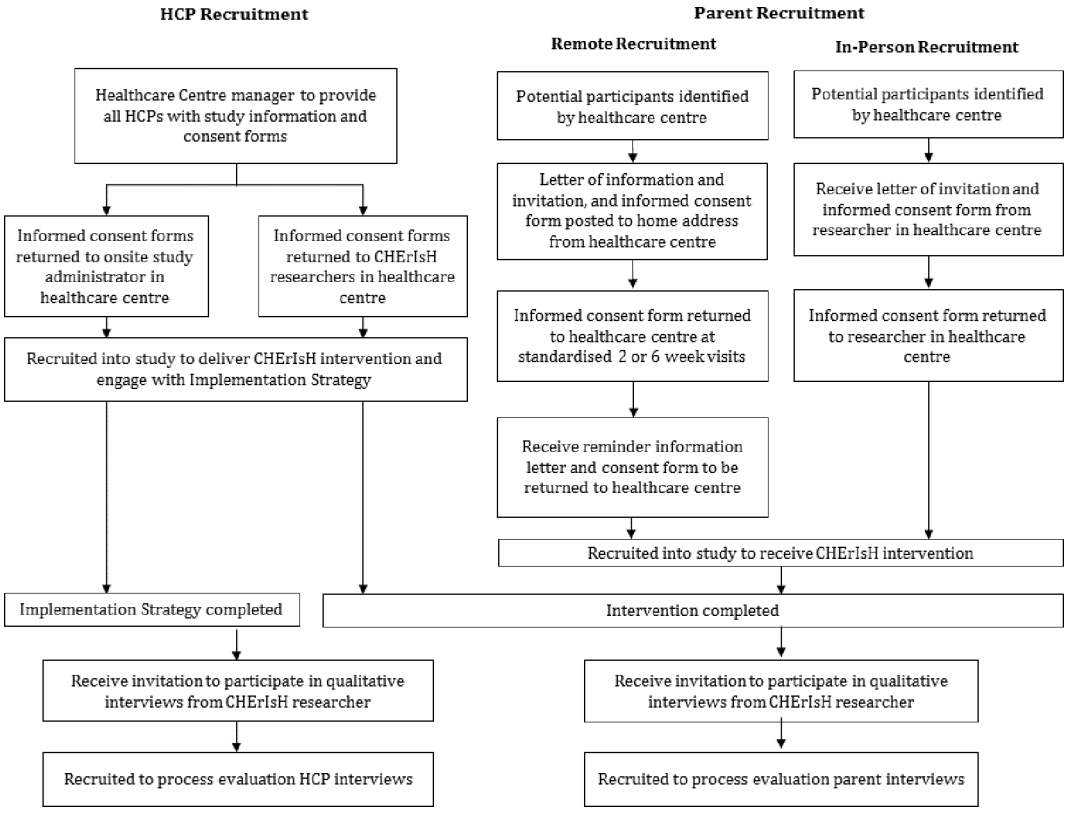


Figure 1 Approaches to HCP and parent recruitment. CHErIsH, Choosing Healthy Eating for Infant Health; HCP, healthcare professional.

returned their consent form within 2 weeks after receiving their recruitment letter will receive a reminder invitation and informed consent form from MPHC.

2. In-person recruitment

a. A CHErIsH researcher will be present in MPHC at times identified by the designated MPHC on-site administrator as suitable for participant recruitment.

b. Eligible parents attending MPHC will be provided with a letter of information and invitation, and an informed consent form by the CHErIsH researcher in MPHC.

c. Signed informed consent forms can be returned to the CHErIsH researcher in MPHC.

Recruitment posters and information leaflets will also be displayed in the MPHC waiting areas. It will be made clear to parents that they do not have to participate in study data collection but that all parents attending the healthcare centre will still receive brief infant feeding messages from their GP and/or PN. This is to minimise HCP burden for delineating between participating and non-participating parents during the vaccination visit. Also, parents routinely receive information on infant care including infant feeding in the first 2 years of life, and so this intervention will not pose any risk or additional burden.

Following intervention cessation, a sample of parents who consent to participate in the CHErIsH intervention will be invited to take part in a single semi-structured qualitative interview as part of the process evaluation. A purposive sampling approach will be used to select parents for interview based on data from study measures (eg, high and low socioeconomic status; parents who breast fed or formula fed). This will ensure maximum variation in the sample for interview in terms of demographic characteristics and study outcomes. As for HCP interviews, parent interviews will be conducted with an initial sample size of 15 parents, with a stopping criterion of an additional 5 parent interviews conducted without development of additional topics or themes.[67]

Intervention and implementation strategy

The CHErIsH study involves a brief complex intervention targeting parents to improve infant feeding behaviours in the ages of 2–13 months. The intervention will be delivered during routine vaccination visits, alongside an implementation strategy targeting HCPs to support the delivery of this intervention in primary care. The intervention and implementation strategy are described below; full details of the theory-based development of the intervention and implementation strategy are in preparation for publication.

Parent-level intervention

The intervention will be delivered to parents by PNs and/or GPs in MPHC at each of the vaccination visits, prior to administration of the vaccination. These vaccination visits take place at 2, 4, 6, 12 and 13 months (see figure 2). The intervention was developed based on the findings

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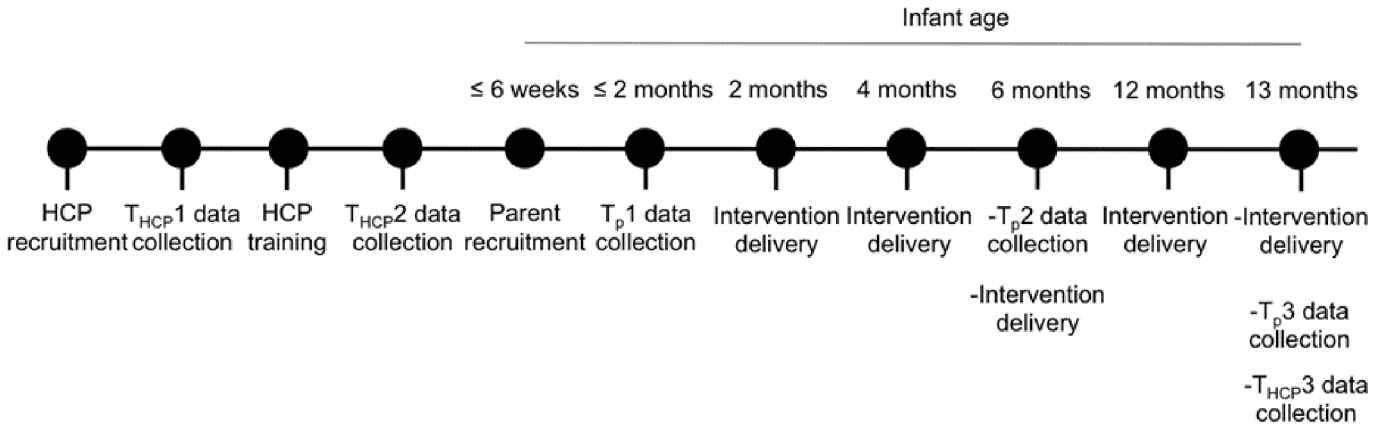


Figure 2 CHErIsH timeline including timing of intervention and implementation strategy delivery, and data collection for parents and healthcare professionals. CHErIsH, Choosing Healthy Eating for Infant Health; HCP, healthcare professional.

of our preparatory work[46 58 63 68–70] and was guided by the Behaviour Change Wheel,[71] a systematic behaviour change intervention development framework, to understand, identify and specify intervention functions, content and implementation options. Specific behaviour change techniques (BCTs) identified in our preparatory work were also included, following the Behaviour Change Technique Taxonomy V1.[72] The theoretical underpinning of the intervention is based on The Theory of Planned Behaviour[73] (TPB), Responsive Feeding,[20] Social Cognitive Theory[74] (SCT) and Family Systems Theory[75] (FST). Following the TPB, parents' attitudes, perceived behavioural control and norms about infant feeding may influence their feeding behaviours.[76 77] Responsive Feeding emerges from responsive parenting and involves appropriate, prompt and consistent feeding interactions and responses to child hunger and satiety cues,[20 39 40] which can influence children's self-regulation of energy intake. SCT is the most commonly applied theory in infant feeding interventions to prevent childhood obesity,[78] and adopts a broader view of feeding that encompasses personal, behavioural and environmental factors. FST views the family as a system in which each part of the system affects the others in an interconnected manner; as such, parenting practices occur that can impact all family function, including child behavioural and health outcomes, which can in turn influence the family system.[79] Any behavioural changes related to infant feeding must be acceptable to the existing structures such that they do not upset the stability of the family system.[70]

As such, this intervention consists of (1) verbally delivered prespecified infant feeding messages and (2) provision of additional infant feeding resources including an information leaflet, a magnet, an infant bib and access to an informational website.

Verbal infant feeding messages

Verbal messages delivered at each vaccination visit are outlined in table 1. These messages have been developed in consultation with the Irish Health Service Executive (HSE) NHCP and the Nurture Programme to ensure consistency with Irish national strategies. Messages are timed to coincide with vaccination visits and provide infant feeding information and support. As outlined in table 1, messages focus on appropriate milk feeding and establishing complementary feeding and solid food introduction in relation to timing and practical guidance around processes of feeding. There is a focus on positive and enjoyable aspects of feeding based on parental reports of the importance of this aspect for their feeding experiences.[43] The feeding environment is also addressed, as is sleep in relation to not using feeding to promote sleep.

Additional resources

Parents will be provided with a single-standard information leaflet at vaccination visits. This leaflet restates the brief infant feeding messages in table 1 and includes signposting to the Irish HSE NHCP Child Health website (www.mychild.ie). This website has been designed by the NHCP to provide empirically based childcare information, including infant feeding information and managing emotional aspects of childcare. Parents will be provided with a CHErIsH study fridge magnet containing the key infant feeding messages and sign-posting to the Child Health website, and a CHErIsH infant bib that will also sign-post to the Child Health website.

Healthcare professional-level implementation strategy

The HCP-level implementation strategy is a multi-faceted implementation strategy[80] and aims to ensure that HCPs are provided with the supports necessary to deliver the intervention as intended. The selection of strategy components within the HCP-level implementation strategy was based on the findings of our preparatory work,[46 58 63 70] and guided by the Behaviour Change Wheel framework.[71] The multi-faceted strategy will consist of (1) use of a local opinion leader, (2) incentivised HCP training, (3) distribution of supporting HCP resources and educational materials, (4) electronic delivery prompts for HCPs, (5) awareness raising across all HCPs within the clinical practice and local primary care community and (6) regular

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Table 1 Infant feeding messages to be delivered at vaccination visits

Time point	Infant feeding messages
2 months	► Breast milk or a first infant formula provides all the nutrition your baby needs until they are 26 weeks / 6 months old* ► The earliest you should consider introducing solid food to your baby's diet is at least 17 weeks old but ideally wait until as close to 26 weeks as possible ► Your baby gives you signals when they are hungry or full, like putting his/her hands to his/her mouth when hungry or turning away or falling asleep when full or not hungry. Crying does not always mean your baby is hungry
4 months	► Breast milk or a first infant formula provides all the nutrition your baby needs until they are 26 weeks / 6 months old ► The earliest you should consider introducing solid food to your baby's diet is at least 17 weeks old but ideally wait until as close to 26 weeks as possible, even if your baby seems more hungry at this stage or you would like to introduce solids to help your baby sleep ► When your baby is 26 weeks old, start introducing solids once per day. Start with one teaspoon and gradually increase at each meal. Offer the first food with breast or formula milk. Once your baby is eating 6 teaspoons of solids at one meal, introduce a second meal per day† ► Introduce new foods one at a time to allow your baby get used to the taste and texture† ► Your baby gives you signals when they are hungry or full, like putting his/her hands to his/her mouth when hungry or turning away or falling asleep when full or not hungry. Crying does not always mean your baby is hungry
6 months	► Breast feeding continues to be important from 6 months, as other foods are introduced, for up to the first 2 years and beyond* ► If not breast fed, your baby should remain on a First infant milk, there is no need to move to a 'number 2' or 'follow on' infant formula. ► It is important to not delay introduction of solids beyond 26 weeks or 6 months ► Start by introducing solids once per day. Start with one teaspoon and gradually increase at each meal. Offer the first food with breast or formula milk. Once your baby is eating 6 teaspoons of solids at one meal, introduce a second meal per day† ► Introduce new foods one at a time to allow your baby get used to the taste and texture† ► Progress through the stages and consistencies, and include fruits and vegetables at each stage‡ ► Teaching your child to eat and helping them learn new tastes can be fun ► Your child is getting better at letting you know when they are hungry or full, so continue to watch for and respond to their signals. For example, if your child signals that they are full, you should not try and get them to finish the meal
12 months	► Breast feeding continues to be important for up to the first 2 years and beyond* ► Meals should be eaten without distractions such as televisions and mobile phones ► If you are/were formula feeding, your baby should now have full fat cow's milk, your baby no longer needs infant formula milk§ ► Your child is getting better at letting you know when they are hungry or full, so continue to watch for and respond to their signals. For example, if your child signals that they are full, you should not try and get them to finish the meal
13 months	► Breast feeding continues to be important for up to the first 2 years and beyond* ► Eating together as a family is enjoyable and good for your child ► Meals should be eaten without distractions such as televisions and mobile phones ► If you are/were formula feeding, your baby should now have full fat cow's milk, your baby no longer needs infant formula milk§ ► Your child is getting better at letting you know when they are hungry or full, so continue to watch for and respond to their signals. For example, if your child signals that they are full, you should not try and get them to finish the meal

*Message only delivered to parents of infants currently being breast fed.
†Message delivered to parents who have not yet begun introducing solids.
‡Message not delivered if parents are using baby-led weaning approach.
§Only delivered to healthy child.

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communication with the CHErIsH study team and provision of local technical assistance.

Use of a local opinion leader

The local opinion leader (TH) is GP based in MPHC in a senior leadership role. In addition to facilitating recruitment, the local opinion leader will play an important role in liaising with HCP staff from all three clinics including other senior decision-making staff as well as the staff who will be required to deliver the intervention and influencing their participation.

Incentivised HCP training

All eligible HCPs will be invited to attend the CHErIsH HCP training. Accredited continuing professional development (CPD) points will be offered as an incentive for participation to maximise attendance and engagement. Training involves two 40–60 min group-based sessions occurring during pre-existing primary care centre lunchtime CPD meetings. As these existing meetings are also typically attended by other HCPs, including public health nurses (PHNs) and community dieticians, training sessions will be open to all HCPs for inclusivity and also to promote consistency in feeding messages. Additional training may be conducted to accommodate GPs and PNs, if requested. The HCP training will be delivered by a CHErIsH study researcher in conjunction with a dietician member of the NHCP Nurture programme team with expertise in infant nutrition and primary care practice. Training will be standardised using PowerPoint slides and the HCP training manual, pre-developed by the study team with input from the HSE to ensure consistency with NHCP/Nurture national strategies and will address the following:

- Information on and rationale for the CHErIsH study and its aims.
- Information on current national feeding guidelines and recommendations.
- Information on feeding issues including, for example, how to start introducing solids.
- Introduction and overview of the parent-level intervention.
- Training in delivery of intervention content and materials.
- Overview of study procedures and protocol and requirements from participating HCPs.

Distribution of supporting HCP resources and educational materials

HCP educational materials and supporting resources that have been developed by the study team with input from the NHCP/Nurture programme team to ensure consistency with HSE national strategies will be distributed to HCPs during the training. These resources consist of a HCP training manual, a CHErIsH poster to be put in rooms where vaccinations take place, and sign-posting to further training and resources for HCPs regarding infant feeding. In addition, HCPs will also be provided with the parent resources (ie, information leaflets, magnets and bibs and sign-posting to NHCP website).

Electronic delivery prompts for HCPs

Electronic delivery prompts via existing electronic systems in the primary care centre will be used as a reminder to prompt HCPs to deliver the intervention, and to record delivery of the intervention. Prompts will be automatically programmed to appear at the start of each vaccination visit, and will ask HCPs to click whether the intervention components (ie, brief messages, leaflet, infant bib and magnet) were delivered or not.

Awareness-raising across all HCPs

To raise awareness of the study and thus potentially mitigate inconsistency of infant feeding messages across all HCPs,[46] study information leaflets will also be provided to PHNs and community dieticians working within the geographical remit of the primary care centre by CHErIsH study team via the local opinion leader and primary care centre manager. To avoid contamination, it will be clarified that only GPs and PNs will deliver intervention components in MPCH and that information provided serves the purpose of promoting awareness about the intervention should any participating parents wish to discuss it with them.

Regular communication with the CHErIsH study team and provision of local technical assistance

To promote adherence to the intervention and to deliver assistance in case of implementation issues, HCPs will be informed and encouraged to contact the onsite study administrator if any issues related to the implementation of the intervention are encountered. The research team will initiate bi-weekly phone calls with the onsite study administrator so that any issues can be reported, documented and addressed.

Process evaluation

A process evaluation will be conducted using a comprehensive mixed-methods approach, informed by the National Institute of Health's Behaviour Change Consortium[81] treatment fidelity guidelines in conjunction with the Medical Research Council guidance for process evaluation of complex interventions.[64] This involves assessing fidelity of implementation and any potential adaptations, hypothesised mechanisms of action and contextual influences, ensuring that fidelity is considered across five specific fidelity domains[81]: (1) design, (2) training, (3) delivery, (4) receipt and (5) enactment.

The process evaluation will provide a better understanding of the intervention and implementation processes, ensuring confidence in the validity of feasibility study outcomes and informing a future definitive intervention. Quantitative and qualitative parent and HCP data will be integrated to ensure a comprehensive, multi-perspective approach to exploring the intervention process (see table 2).

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Table 2 Process evaluation outline

Process evaluation component	Specific component to be assessed	Data source
Fidelity	► Fidelity of delivery and receipt of parent-level intervention ► Fidelity of enactment of parent-level behaviours ► Fidelity of delivery and receipt of HCP-level implementation strategy ► Fidelity of enactment of HCP-level implementation strategy	► Parent qualitative interviews ► Parent questionnaire ► Parent fidelity checklist ► Fidelity checklist for HCP training ► Audio recordings of HCP training ► HCP delivery fidelity checklists ► Electronic prompt data ► Phone logs ► HCP qualitative interviews
Mechanisms of change	► Parent knowledge and understanding of infant feeding ► Parent self-efficacy ► Parent stress and health-related quality of life ► HCP knowledge and awareness of infant feeding recommendations ► HCP attitudes towards infant feeding	► Parent questionnaire ► Parent qualitative interviews ► HCP questionnaire ► HCP qualitative interviews
Contextual influences	► Influences on delivery and receipt of parent-level intervention ► Influences on delivery and receipt of HCP-level implementation strategy	► HCP qualitative interviews ► Parent qualitative interviews

HCP, healthcare professional.

Qualitative data collection

Qualitative data will be collected from parents and HCPs using semi-structured interviews following intervention completion; these will be conducted in person, where possible, or by phone. Interviews will be conducted to explore intervention implementation and further explore intervention feasibility and reasons for any issues with the intervention or implementation strategy.

Parent interviews

Interviews will explore parents' experiences and perspectives of the CHErIsH intervention and study procedures, whether they received the intervention as intended and any perceived contextual influences on intervention receipt. It is anticipated that interviews will be conducted in an iterative manner until no new themes or topics are developed.[67]

HCP interviews

Interviews will follow a semi-structured guide to explore HCPs' perspectives and experiences of the CHErIsH intervention, implementation strategy, research procedures and the overall feasibility and acceptability of the study. Fidelity of intervention delivery will be investigated by exploring whether the intervention was delivered as planned or whether adaptations to the intervention were made during delivery, including elaborating on reasons for any adaptations. Beliefs about the quality of intervention delivery, capacity and resource needs to deliver the intervention, identification of additional training needs and contextual influences on intervention implementation will be explored.

Self-report data collection

Parent self-report

To examine intervention receipt, parents will complete a brief self-developed Likert-style fidelity checklist at middle and end of the intervention assessing intervention components received (eg, 'Did you receive a leaflet about infant feeding?'). An open-ended question will ask parents for their thoughts or comments on the acceptability, suitability and comprehensiveness of the study and intervention procedures, and how these might be improved.

HCP self-report

To examine fidelity of intervention delivery, a brief Likert-style fidelity checklist will be completed by HCPs following intervention cessation. A set of three previously validated questionnaires[82] will be used to assess the acceptability, appropriateness and feasibility of the parent-level intervention (following intervention cessation), study procedures (following study cessation) and the CHErIsH training and supporting resources for HCPs (following delivery of HCP training). These are the Acceptability of Intervention Measure, Intervention Appropriateness Measure and Feasibility of Intervention Measure.[82] HCPs will also be able to provide additional comments using open-ended self-developed questions that will ask if HCPs have further thoughts or comments on the fidelity,

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acceptability, suitability and/or comprehensiveness of the study and intervention procedures, and how these might be improved. At the end of the study, HCPs will also be asked about the usefulness of the CHErIsH implementation strategy for supporting the intervention delivery. HCPs will rate how much they agree that the implementation strategy was useful on a 5-point scale from 'completely agree' to 'completely disagree'.

CHErIsH researcher self-report

A quantitative self-report checklist will be used by the members of the CHErIsH team delivering the HCP-level training to enhance and assess the fidelity of delivery of each component of the HCP training. The self-report checklist will be reviewed by the CHErIsH researcher and Nurture programme member delivering the CHErIsH HCP-level training prior to training delivery and completed following training delivery. This will be supplemented with direct observation data completed by an independent observer from the CHErIsH team during the training, and by audio recordings of the training. Audio recordings will be independently coded by two members of the research team to identify presence or absence of intended HCP training components and BCTs. The duration of the training sessions will also be recorded.

Electronic data

Data from the MPHC electronic prompt systems will also be used to record HCP self-reported delivery of the specific intervention components.

Evaluation of reach and recruitment

Data will be collected on the number of invitations sent to HCPs and parents, the number of acceptances to participate and the number of refusals. Attrition of parents and HCPs will be documented at each data collection time point. Levels of missing data in returned questionnaires will be recorded.

Health economics evaluation

A cost–outcome description will be undertaken, which is the most appropriate analytic approach in a non-randomised feasibility trial. This analysis will measure costs and outcomes of the CHErIsH intervention and its implementation. Following recommended steps in undertaking economic evaluations,[83 84] this analysis will be conducted in four stages.

Define the analysis assumptions

Following the Health Information Quality Authority guidelines, this analysis will assume a healthcare perspective.[85] The base year for all analyses will be 2017 representing the most recent year for which cost data are available.

Measure healthcare resources for each cost

Resources used will be identified in relation to multiple components involved in the delivery of the intervention and implementation strategy. Costs incurred and cost savings arising as a consequence of the intervention and implementation strategy will also be identified. This will include all time and resources expended, and costs borne by MPHC including the training and time spent by HCPs and administrative staff involved in the study. Other costs examined will include healthcare resource use related to infant feeding using the Client Service Receipt Inventory[86] measure completed by parents.

Measure outcomes associated with each cost

Health-related quality of life of the primary caregiver will be evaluated using the standardised validated EQ-5D-5L[87] and ICE- CAP[88] self-report surveys.

Conduct a sensitivity analysis

This analysis will repeat comparisons between resources and outcomes with different assumptions to examine what happens to the total cost of each activity if the underlying costs of the resources that are used are changed.

Quantitative data collection of intervention outcome measures

Quantitative data from participating parents and HCPs will be collected using questionnaires completed by hand, online or by phone. A multimodal approach to data collection has been adopted to maximise questionnaire response rates and reduce participant burden among two populations (parents of infants and HCPs) who have demanding existing schedules and lives. For parents, T_p1 data will be collected at study entry, prior to their infant's 2 month vaccination visit (baseline); T_p2 data will be collected from parents by the infant's 6 month vaccination visit; T_p3 data will be collected following the infant's 13 month vaccination visit. Parents will receive email or text message reminders to complete T_p2 or T_p3 questionnaires. For HCPs, $T_{HCP}1$ data will be collected prior to training (baseline); $T_{HCP}2$ data will be collected immediately after the training and $T_{HCP}3$ data will be collected 11 months after intervention commencement. See figure 2 for timing of data collection.

Parent and child data collection

Self-report questionnaire

Data on parent and child characteristics, feeding practices and styles, dietary intake, child health service use, child feeding preferences, knowledge and self-efficacy and parent psychological quality of life will be collected (see table 3). Infant feeding outcomes have been informed by the infant feeding core outcome set for obesity prevention interventions.[68]

Parent information

Age, gender, relationship to child, number of children (including ages), ethnic/cultural background, relationship status, education level, employment, medical card status, any time taken off work due to infant feeding issues, and any medications (either prescription or over-the-counter) taken in the previous 6 months.

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Table 3 CHErIsH parent and child outcome measures and time points

Outcome	Measure	T_p1	T_p2	T_p3
Parent demographic information	Self-report items and medical records.	✓	✓	✓
Infant characteristics	Self-report items and medical records.	✓	✓	✓
Feeding practices	Self-report items about breast feeding, formula feeding, complementary feeding and feeding environment.	✓	✓	✓
Child dietary intake	Parent rating of frequency of child consumption of prespecified foods.		✓	✓
Child feeding preferences	Parent report of child liking of foods included in the dietary intake report by indicating 'yes', 'no' or 'never tried' (adapted version of the approach of Denney-Wilson *et al*.[72 89])		✓	✓
Infant feeding styles	The restrictive, pressuring and responsive subscales of the Infant Feeding Styles Questionnaire.[73]	✓	✓	✓
Knowledge and self-efficacy	The self-efficacy subscale of Maternal Knowledge and Self-Efficacy scale.[74]	✓	✓	✓
Infant feeding-related healthcare costs	Adapted Client Resource Use Questionnaire.[75] Parents will also be asked about feeding-related HCP engagement and child medicine use.	✓	✓	✓
Parent HRQoL	The standardised EQ-5D-5L[76] and the ICE-CAP.[77]	✓	✓	✓
Parent stress	The perceived Stress Scale.[78]	✓	✓	✓
Parent intervention feedback	Open-ended question on parental thoughts about acceptability, suitability and comprehensiveness of study and intervention procedures.		✓	✓
Fidelity checklist	Self-report checklist of intervention receipt and enactment.		✓	✓
Infant biomarker samples	Infant urine and stool samples.	✓	✓	✓
Parental biomarker samples	Parental saliva samples and breast milk samples*	✓	✓	✓

T_p1, baseline, prior to infant's 2 month vaccination visit; T_p2, by the infant's 6 month vaccination visit; T_p3, at infant's 13 month vaccination visit.
*Sample collected only from breastfeeding mothers.
CHErIsH, Choosing Healthy Eating for Infant Health; HCP, healthcare professional; HRQoL, health-related quality of life.

Infant information

Child's date of birth, gender, birth weight and gestational age; childcare arrangements.

Feeding practices

Parents will provide information about breast feeding and/or formula feeding, intended and/or actual age of introduction of solids, whether child self-feeds (baby-led weaning), type of food fed to child and feeding environment (use of tablets or television when feeding).

Dietary intake

Child dietary intake will be assessed by asking parents to rate how often their child eats foods including baby cereal, fruits, vegetables, meat, fish, bread, dairy, fast foods, sweets or treats, cow's milk, fizzy drinks or other drinks. Responses will be recorded on a 7-point scale from 'never' to 'once a day or more'.

Child feeding preferences

Parental perceptions of child feeding preferences will be measured by asking parents 'Does your child usually like this food' in relation to each of the foods included in the Dietary Intake question, and will rate responses as 'yes', 'no' or 'never tried'.[89]

Infant feeding styles

Parent's infant feeding styles related to infants and toddlers will be measured using the restrictive, pressuring and responsive subscales of the Infant Feeding Styles Questionnaire.[90] These subscales include 43 items in total; seven items are asked only at T_p2 and T_p3 as they relate to feeding behaviours for older children. Internal consistency of the three subscales of the Infant Feeding Styles Questionnaire range from r=0.75 to r=0.92.[90]

Maternal knowledge and self-efficacy

The self-efficacy subscale of Maternal Knowledge and Self-Efficacy scale is a 7-item scale assessing self-efficacy for infant feeding, which has an internal consistency of r=0.94.[91] Two additional items assess breastfeeding self-efficacy. Three items assessing parents' knowledge of appropriate timing of introduction of solids, and hunger and satiety cues will be included.

Infant feeding-related healthcare costs

Parents will be asked if they have engaged with different HCPs (eg, GP, lactation consultant, dietician) for issues related to feeding. Adapting the Client Resource Use Questionnaire,[92] parents will be asked to state the

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number of visits and provide a brief description of these visits (eg, whether visits were covered by health insurance or medical card, or were paid for directly by the parent). Parents will also be asked if their child has taken any medicines for feeding-related issues, including the dose and duration.

Parents health-related quality of life

Parent health-related quality-adjusted life years will be measured using the standardised EQ-5D-5L[87] and the ICE-CAP.[88] The EQ-5D-5L is a 25-item questionnaire, consisting of five domains containing 5 items each. The ICE-CAP is a 20-item questionnaire, consisting of five domains containing 4 items each.

Parenting stress

Stress will be measured using the Perceived Stress Scale.[93] This is a 10-item scale with items rated from 0 (never) to 4 (very often). Items assess how often parents have felt stressed in the last month. This scale has been found to have an internal consistency coefficient of r=0.89 among parents at 4 months postpartum.[94]

Child anthropometric outcomes

Child weight and length data will be extracted from medical records from the healthcare practice and from information provided by PHNs to the healthcare practice, corresponding to the infant's weight as measured at the routine 2 week and 6 week GP visits, and the 3 month and 9–11 month PHN visit. WHO weight-for-length (WFL) z-scores and BMI z-scores will be calculated at each time point following published standards.[95] Weight gain over time will also be calculated as change in WFL and BMI z-scores between time points. Body composition will not be assessed in this feasibility study despite its inclusion in the standardised core outcome set for infant feeding interventions[68] due to resource constraints.

Biomarkers

Half of all potential participants will be invited to provide maternal and infant biomarker samples during the study. These participants will be randomly assigned, using a random number generator, to receive information at recruitment about collection of biomarker samples and will be invited to collect the samples. If participants consent to participate, they will be sent collection materials prior to each collection time point and instructions on collection of the samples as described below. Participants can opt not to collect samples and still participate in all other aspects of the study.

Infant urine and stool samples will be collected at T_p1, T_p2 and T_p3 (see table 3).

- Infant urine samples will be collected using Sterisets Urine collection packs by placing the urine collection pad over the area where the infant passes urine. The pad will be checked at 10 min intervals for 30 min until the pad is wet (if the pad is not wet at 30 min a new pad will be inserted).
- Infant stool samples will be collected by mothers from the infant's nappy and a one teaspoon volume of the stool sample will be transferred to a provided stool sample collection container.

Parental saliva and breast milk samples will be collected at T_p1, T_p2 and T_p3 as follows:

- Parental saliva samples will be collected using a Salimetrics saliva swab and storage tube. Samples will be collected by placing the swabs in the mouth until saturated immediately on waking, 30 min after waking and 45 min after waking.
- A breast milk sample will also be collected from participating breastfeeding mothers, by asking the mother to express the equivalent of a teaspoon volume of breast milk (by hand or using a breast pump).

All samples will be stored by parents in the provided storage containers and refrigerated until returned to MPHC. All sample collection materials will be clearly labelled with the following: study name, participant number, date of birth, sample type, date of collection. All maternal and infant samples will be stored in a refrigerator in the primary care centre until collected by a member of the study team and transferred to a −80°C freezer in the APC Microbiome Ireland Clinical Laboratory in University College Cork. The purpose of the collection of infant urine and stool, and maternal saliva and breast milk, is to examine feasibility and costs of sample collection and storage. As such, samples will not be assayed and examined for the purposes of the current feasibility trial.

Healthcare professional data collection

Self-report questionnaire

Data will be collected from GPs and PNs involved in delivering the intervention using a self-report questionnaire as outlined below and in table 4.

Demographic information

Data will be collected on age, gender, profession, years qualified, years working in primary care and previous professional or personal experience with infant feeding.

Attitudes towards and knowledge of infant feeding

An adapted version of the Allcutt and Sweeney survey[96] will be used to assess knowledge and attitudes towards infant feeding, including breast feeding, formula feeding and solid food introduction.

Analysis

Qualitative analysis

All interviews with HCPs and parents will be transcribed verbatim, and interview transcripts will be entered into the NVivo qualitative analysis software programme to facilitate data management, coding and retrieval. Data will be analysed using thematic analysis following the guidelines of Braun and Clarke.[97] As such, all data will initially be open coded; open codes will then be analysed to generate themes and subthemes, which will be revised and refined through an inductive and iterative process. Analytic rigour will be maintained using the criteria of

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Table 4 CHErIsH HCP outcome measures and time points

Outcome	Measure	$T_{HCP}1$	$T_{HCP}2$	$T_{HCP}3$
Provider demographics	Self-report items	✓		
Attitudes towards and knowledge of infant feeding	Adapted version of Allcutt and Sweeney[81 96] knowledge, practice and attitudes of HCPs towards solid food introduction survey	✓	✓	✓
Feedback on CHErIsH HCP training and resources	Open-ended question and the AIM, IAM and FIM[82]		✓	
Usefulness of HCP training	Self-report item			✓
Feedback on CHErIsH parent-level intervention and study procedures	Open-ended questions and the AIM, IAM and FIM[82]			✓
Fidelity of intervention delivery	Self-report checklist Electronic prompt delivery records			✓

AIM, Acceptability of Intervention Measure; CHErIsH, Choosing Healthy Eating for Infant Health; FIM, Feasibility of Intervention Measure; HCP, healthcare professional; IAM; Intervention Appropriateness Measure.

credibility, audibility, confirmability and applicability. Qualitative data will be then integrated with quantitative data as part of the process evaluation, using a triangulation approach through the use of meta-matrices.[98 99]

Quantitative analysis

A study database for all self-report and anthropometric data will be created using SPSS Data Collection V.7 software. Descriptive summaries will be generated for HCP and parent outcomes and demographic variables. Means and SD will be calculated for continuous variables, frequencies will be calculated for categorical variables. Distributions of HCP and parent outcomes and variables, and potential outliers, will be examined. Data on recruitment, attrition, questionnaire response rates for parents and HCPs will similarly be descriptively summarised. Attrition and questionnaire response rates will also be descriptively examined in terms of parent demographics, including age, gender, relationship status, education and employment for parents. HCP age, gender, profession, number of years working in primary care and previous experience with infant feeding will also be examined in terms of HCP questionnaire response rates. Levels of missing data in returned questionnaires will be examined to evaluate feasibility and acceptability of data collection.

DISCUSSION

The aim of this feasibility study is to examine the acceptability and feasibility of an infant feeding intervention delivered by HCPs to parents at child vaccination visits in primary care, and the implementation strategy supporting delivery of this intervention. Developing and implementing interventions to prevent childhood obesity is a public health priority.[16] The implementation and integration of childhood obesity prevention strategies into existing service structures have also been highlighted as research priorities.[100] HCPs are uniquely placed to deliver interventions targeting parents' modifiable infant feeding behaviours to reduce child obesity risk.[58 59] Incorporating intervention components related to responsive feeding practices, and information about breast and formula feeding, introduction of solids and child dietary intake enables examination of a comprehensive intervention based on robust evidence[46 58–70] and feeding guidelines.[21 51]

While previous research indicates that implementation of interventions in primary care is acceptable to HCPs and parents,[61 62] issues around parent–HCP relationships and HCP capacity may influence the success of these interventions.[63] The use of existing HCP contact points, which has been identified as a useful strategy by national programmes such as the NHCP, provides a unique opportunity to overcome some of these potential issues in implementation and delivery. This approach will enable the first examination of a comprehensive implementation strategy for HCPs to deliver the infant feeding intervention in practice, which will provide unique insights to inform future implementation strategies for child health in primary care. A further strength is the inclusion of a health economic assessment of the implementation strategy in the form of a cost–outcome description. While implementation process costs are identified as an important factor in implementation science theories and frameworks,[101 102] these costs are understudied and often overlooked.[103 104] Robust assessments of implementation costs are necessary to facilitate translation from research into practice.[105] Overall findings relating to the feasibility and acceptability of the intervention and implementation strategy will inform the next steps of the CHErIsH study. If the project is successful, this is expected to involve evaluating the effects of the intervention in a definitive trial incorporating a comprehensive health economic evaluation. Findings from this feasibility study will also inform the feasibility of conducting an economic evaluation of CHErIsH in terms of the feasibility of capturing cost and outcome data in this population.

This feasibility study also has a number of potential limitations. There is potential for selection bias of

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participant recruitment and retention; however, a multimodal approach involving remote and in-person recruitment will be taken during the recruitment phase in an attempt to minimise this. Similarly, completion of study questionnaires can be completed by phone, in person or online, in an attempt to minimise retention. A further potential challenge is that parents of young infants may value information from other individuals, such as family and friends, over HCP-delivered information.[46] Potential measurement issues relate to the use of parental and HCP self-report, which could be subject to recall and self-report biases.[106] Self-report assessment of fidelity of the intervention will be supplemented by data from the electronic prompt system in the primary care system, and qualitative and quantitative findings from parent and HCP stakeholders will be integrated using a triangulation approach to further ensure confidence in our findings.

The long-term aim of the CHErIsH study is to contribute to the prevention of childhood obesity through appropriate infant feeding via an effective intervention delivered at primary care vaccination visits. Implementation and delivery of clear consistent infant feeding messages in routine primary care will address an important component of childhood obesity risk,[20–24] which can be further implemented in multicomponent, national and international approaches to childhood obesity prevention. This feasibility study is the first examination of an infant feeding intervention, and HCP implementation strategy, to prevent childhood obesity delivered by HCPs at infant vaccination visits in a primary care practice.

ETHICS AND DISSEMINATION

Ethical approval was obtained for this feasibility study from the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC), University College Cork. The CHErIsH study will be conducted in accordance with the principals of good clinical practice (GCP) and all site personnel have undergone training in GCP. The protocol and any amendments have been, and will be in the future, reviewed by the CREC and the Clinical Research Facility-Cork. Final results of this study will be disseminated in a peer-review journal, at relevant conferences, seminars and research meetings.

Trial status

Participant recruitment for this feasibility study will begin in January 2019.

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Contributors KM-S contributed to study design and development, and wrote the first draft of the paper and revised the paper with critical input from all authors. ET contributed to study design and development, and contributed to writing and revising the paper at all stages. MQ contributed to study design and development, and contributed to writing the first draft of the paper. CF, KON, TGD, MH, CK, JMcS and CS contributed to study design and development, and critically revised the manuscript. PMK, MB, CHa, JMH, ED, CHe, TH and SMcH contributed to the inception of the study and secured research funding, with PMK as project lead, and also contributed to study design and development, and critically revised the manuscript. All authors read, commented on and approved the final manuscript.

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