

NOurishing Start for Health (NOSH)

Submission date 11/02/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/03/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/05/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Breastfeeding helps prevent disease and promote the health of both mum and baby. However, breastfeeding rates in the UK are among the lowest worldwide. The impact of offering financial support to mums for breastfeeding is a new area. This study aims to test the impact of offering financial support in the form of shopping vouchers in areas with low 6-8 week breastfeeding rates. It is hoped that the scheme will increase the numbers of mums who breastfeed and how long they breastfeed for.

Who can participate?

Neighbourhoods in South Yorkshire and Derbyshire where less than 2 babies out of 5 are breastfed when they are 6-8 weeks old are eligible to participate. Mums are eligible for the scheme if they have babies born between 01/09/2014 and 01/09/2015.

What does the study involve?

Neighbourhoods in South Yorkshire and Derbyshire are randomly allocated to either offer the scheme (shopping vouchers) to mums with new babies, or to not offer the scheme. Changes in neighbourhood breastfeeding rates are measured.

What are the possible benefits and risks of participating?

Mums who are in the study neighbourhoods where the scheme is offered have the opportunity to participate in the scheme. By taking part in this study there are no risks of physical injury or psychological harm or distress to mums or their partners or healthcare providers involved in helping deliver the scheme.

Where is the study run from?

The study is being run by researchers at the University of Sheffield (SchARR). They are working with researchers at Brunel University and the University of Dundee (UK)

When is the study starting and how long is it expected to run for?

July 2014 to July 2016

Who is funding the study?

Medical Research Council (MRC) (UK)

Who is the main contact?

Dr Clare Relton

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Study website

<http://www.shef.ac.uk/scharr/sections/ph/research/breastmilk>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

V1.1

Study information

Scientific Title

The clinical and cost effectiveness of a financial incentive scheme to improve 6-8 week breastfeeding in neighbourhoods with low breastfeeding rates (cluster randomised controlled trial with pre-trial feasibility stage).

Acronym

NOSH

Study objectives

The offer of a structured financial incentive to mums living in areas with low breastfeeding rates will increase the proportion of babies being breastfed at 6-8 weeks.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS Research Ethics Committee, 26/07/2013, ref: 13/WM/0299

Study design

Parallel cluster randomised controlled trial (RCT) with a mixed methods process and context evaluation and a pre-trial feasibility stage

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Other

Participant information sheet

<http://www.noshvouchers.org/#!about-nosh/cjg9>

Health condition(s) or problem(s) studied

Neighbourhood levels of breastfeeding at 6-8 weeks

Interventions

Neighbourhoods in South Yorkshire and Derbyshire will be randomly assigned to one of two conditions:

1. Neighbourhoods offer NOSH scheme to new mums
2. Neighbourhoods do not offer NOSH scheme to new mums

A neighbourhood level behaviour change intervention in the form of the offer of a structured financial incentive (shopping vouchers each worth £40 x 5) for mums which is designed to increase breastfeeding rates at 6-8 weeks in neighbourhoods with low breastfeeding rates.

Duration of follow up is 12 months (as the primary outcome measure will be the change in neighbourhood level 6-8 week breastfeeding rate from the baseline (previous 12 months breastfeeding) rate).

Intervention Type

Behavioural

Primary outcome measure

Change in neighbourhood level 6-8 week breastfeeding rate from the baseline (previous 12 months breastfeeding) rate

Secondary outcome measures

Area level

1. Duration of breastfeeding (BF), BF intention, BF initiation, BF at discharge, BF at 3/12, BF at 6

/12 (any BF vs exclusive BF where available)

2. Hospital visits: in-patient days, out-patient visits

3. Conditions: SIDs, coeliac, otitis media, necrotizing enterocolitis (NEC)

Individual level

1. Healthcare providers/ commissioners/ funders/policy makers views on the intervention and the completeness and accuracy of 6-8 week BF data

2. Eligible mums in study neighbourhoods - their Health Related Quality of life (as measured by EQ-5D), Life satisfaction score and their awareness of the intervention (NOSH Scheme) and their views on & experience of the intervention

3. Eligible babies in study neighbourhoods: the incidence of infections (ear, chest, GI), eczema, constipation.

4. Delivery of the intervention: Number of enquiries, applications, claims, concerns

Overall study start date

01/07/2014

Completion date

01/07/2016

Eligibility

Key inclusion criteria

All neighbourhoods in Chesterfield, Rotherham and Sheffield which report mean 6-8 week breastfeeding rates of $\leq 40\%$ in the previous four quarters

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

956 babies per group (1,912 in total)

Key exclusion criteria

All neighbourhoods in Chesterfield, Rotherham and Sheffield which report mean 6-8 week breastfeeding rates greater than 40% in the previous four quarters

Date of first enrolment

01/07/2014

Date of final enrolment

01/07/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Sheffield

Sheffield

United Kingdom

S1 4DA

Sponsor information

Organisation

University of Sheffield (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.sheffield.ac.uk/>

ROR

<https://ror.org/05krs5044>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) - National Prevention Research Initiative (NPRI) Phase 4
Grant number R-129897

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/04/2016		Yes	No
Results article	qualitative study results	08/01/2018		Yes	No
Results article	results	05/02/2018		Yes	No
Results article	cost-effectiveness results	01/02/2020	11/05/2020	Yes	No
HRA research summary			28/06/2023	No	No