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SOSA: Stay one step ahead implementation study

Submission date	Recruitment status
04/11/2019	No longer recruiting
Registration date	**Overall study status**
16/01/2020	Completed
Last Edited	**Condition category**
02/02/2023	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In 2014, Nottingham CityCare partnership was awarded a 10 year grant from the Big Lottery Fund as part of the "A Better Start" programme to improve the lives and outcomes of young children via the Small Steps Big Changes (SSBC) Project. As part of the SSBC project, Nottingham CityCare are delivering evidence-based child home safety promotion in 4 wards in Nottingham. The Stay One Step Ahead research study is evaluating the implementation of this home safety promotion.

This research study aims to identify whether implementing systematic evidence-based home safety promotion improves key home safety practices (having at least one fitted and working smoke alarm, a safety gate on stairs (where applicable) and poisons stored out of reach). There are also a number of secondary outcomes including injury rates, acceptability to parents and service providers, implementation factors and economic outcomes. This is a non-randomised, controlled before and after research study (CBA), with nested interviews, observations of home safety promotion and an economic evaluation

Who can participate?
Parents of children residing in the 4 SSBC wards and the 5 control wards.

What does the study involve?
The research will compare four electoral wards that currently receive the Small Steps Big Change programme, and five control wards that are not receiving the programme.

In addition, families will be asked if they are interested in taking part in other parts of the study:
- Economic evaluation - consenting to access to medical records
- Face-to-face or telephone interviews
- Observations of 9 - 12 month and 2 year reviews

The study will recruit staff members for interviews and to take part in observations of the child reviews. There is also a service evaluation being conducted by the study team, running concurrently with this study. The service evaluation assesses service provider home safety activities and in-service training.

What are the possible benefits and risks of participating?
Benefits - Participants will not receive a direct benefit in taking part, however taking part may help other parents prevent accidents in the future.
Risks - The study will involve questionnaires, interviews with parents and observations of child health reviews. It is possible that parents may discuss experiences related to their child being injured or having an accident which may cause them to feel upset. Our research team has extensive experience of undertaking qualitative interviews about the circumstances surrounding child accidents and have not experienced parents getting upset during interviews in previous studies. We will ensure researchers are trained to interview parents in a sensitive way and to be alert to signs of parents being upset. The researcher would terminate an interview or observation early where the participant is upset and will ask whether he/she would like to end the interview/observation and provide signposting to the health visitor where necessary.

Where is the study run from?
University of Nottingham, UK

When is the study starting and how long is it expected to run for?
September 2017 to April 2021 (updated 07/04/2021, previously: March 2021)

Who is funding the study?
1. University of Nottingham, UK
2. Nottingham CityCare Partnership CIC

Who is the main contact?
Dr Elizabeth Orton
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Study website
https://www.nottingham.ac.uk/research/groups/injuryresearch/projects/index.aspx

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
17037

Study information

Scientific Title
Stay One Step Ahead: research study evaluating the implementation of systematic evidence-based child home safety promotion (part of the small steps big changes programme)

Acronym
SOSA

Study objectives
This research study aims to identify whether implementing systematic evidence-based home safety promotion improves key home safety practices (having at least one fitted and working smoke alarm, a safety gate on stairs (where applicable) and poisons stored out of reach). There are also a number of secondary outcomes including injury rates, acceptability to parents and service providers, implementation factors and economic outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 31/07/2017, East Midlands Leicester Central NHS Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8234; NRESCommittee.EastMidlands-LeicesterCentral@nhs.net), ref: 17/EM/0240
2. Approved 01/08/2017, HRA (Health Research Authority) (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH), ref: IRAS 218243

Study design
Non-randomized controlled before and after study with nested interviews observations of home safety promotion and economic evaluation

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Unintentional injuries

Interventions
Systematic evidence-based home safety promotion will be provided as part of routine care in the Small Steps Big Changes (SSBC) programme being provided in four electoral wards in Nottingham city. The home safety promotion will be evidence-based and delivered using a systematic standardised approach to ensure consistency within and across providers. It will be informed by the behaviour change principles recommended by NICE.

Service providers will be trained to deliver home safety promotion which will include home safety education, tailored to the family's needs, provided by health visiting teams, family mentors and early years providers, referral or signposting to partner organisations and use of evidence-based resources. Five electoral wards will act as control wards. Health care providers will provide their usual home safety promotion in these wards.

Intervention Type
Behavioural

Primary outcome measure
Primary outcome measure
Presence in the home of fitted and working smoke alarm, a safety gate on stairs (where applicable), and poisons stored out of reach at 12 and 24 months post recruitment

Secondary outcome measures
1. Medically attended child home injury rates - at 12 and 24 months post recruitment
2. Other home safety practices (other than those encompassed in the primary outcome measure) at 12 and 24 months post recruitment
3. Home safety promotion provided at 12 and 24 months post recruitment and during qualitative observations of 9-12 month and 2-2.5 year reviews between baseline and 24 months
4. Parental knowledge of child development and injury risk at 12 and 24 months post recruitment
5. Parental self-efficacy to prevent injuries to their children at 12 and 24 months post recruitment
6. Acceptability of, and satisfaction with, home safety promotion amongst parents qualitatively assessed during interviews between baseline-24 months
7. Acceptability of, and satisfaction with, home safety promotion amongst providers qualitatively assessed during interviews between baseline-24 months
8. Barriers and facilitators to changing home safety behaviours amongst parents qualitatively

assessed during interviews between baseline-24 months
9. Barriers and facilitators to implementing home safety promotion amongst providers qualitatively assessed during interviews between baseline-24 months
10. Cost-effectiveness of home safety promotion using primary outcome data (a) and cost data collected between 12 and 24 months

Overall study start date
01/04/2017

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Parent participants
1.1. Parents of children residing in the 4 SSBC wards and the 5 control wards
1.2. Parents must be aged 18 years or over
1.3. Children must be 2 to 7 months old when study invites are sent
1.4. Children must be living in their usual place of residence (i.e. not in temporary accommodation such as a refuge or foster care)
1.5. Parents must return a completed baseline questionnaire
1.6. Eligibility criteria for parent interviews
1.6.1. Parents taking part in the CBA
1.6.2. Able to provide written informed consent or verbal informed consent over the telephone to take part in the interview
1.6.3. Parents must have had either a 9-12 month review or a 2-2.5 year Healthy Child Programme review (hereafter referred to as child health review).
1.7. Observations of 9-12 month and 2-2.5 year child health reviews:
1.7.1. Parents taking part in the CBA
1.7.2. Able to provide written informed consent to have their child's review observed
1.7.3. Parents whose child's review is undertaken in English
1.8. Economic evaluation
1.8.1. Parents taking part in the CBA
1.8.2. Able to provide written informed consent to extract data from their child's medical records

2. Service provider participants:
Interviews:
2.1. Service providers (health visiting teams, family mentors and early years staff (e.g. children's centre managers and staff)) in SSBC and control wards who provide written informed consent or verbal informed consent over the telephone for interviews.
2.2. For the interviews with providers who conduct 9-12 month or 2-2.5 year child health reviews the provider must have experience of conducting 9-12 month or 2-2.5 year child health reviews since the start of the SSBC programme.
Observations:
2.3. Service providers (e.g. health visiting teams) in SSBC and control wards who provide written informed consent for observations of 9-12 month or 2-2.5 year child health reviews

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Approximately 400-500 SSBC ward families and 400-500 control ward families will be recruited to the CBA. Approximately 100 families will be recruited to the economic evaluation (50 from SSBC wards and 50 from control wards). Approximately 20 parent participants will be recruited to interviews (10 from SSBC wards and 10 from control wards). Approximately 20 parent participants will be recruited to observations of home safety promotion (10 from SSBC wards and 10 from control wards) Approximately 23 service providers will be recruited to interviews (14 from SSBC and 9 from control wards). Approximately 20 service providers will be recruited to observations of home safety promotion (10 from SSBC wards and 10 from control wards).

Total final enrolment
797

Key exclusion criteria
Parents:
1.1. Not residing in SSBC or control wards
1.2. Aged under 18 years
1.3. Children not aged 2-7 months old when study invites sent
1.4. Not returning completed baseline home safety questionnaire
1.5. Not providing written informed consent or verbal informed consent over the telephone for interviews, written informed consent for observations of child health reviews or for extraction of data from medical records
1.6 Parents whose child's review is not undertaken in English

Service providers:
2. Service providers not providing written informed consent or verbal informed consent over the telephone for interviews or written informed consent for observations of 9-12 month or 2-2.5 year child health reviews

Date of first enrolment
01/09/2017

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Division of Primary Care
Floor 13, Tower Building
University Park
Nottingham
United Kingdom
NG7 2RD

Study participating centre
Nottingham CityCare Partnership CIC
1 Standard Court
Park Row
Nottingham
United Kingdom
NG1 6GN

Sponsor information

Organisation
University of Nottingham

Sponsor details
Research and Graduate Services
King’s Meadow Campus
Lenton Lane
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NG7 2NR
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Sponsor type
Research organisation

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A summary of the study results will be disseminated to study participants (families and service providers) at the end of the study using a variety of methods such as post, email, study website and social media. The results will be disseminated to Nottingham CityCare via a final study report and presentation events, including events for service provider participants. Study findings will be presented at academic and practitioner conferences and in articles for publication in academic and practitioner journals. Participants will not be identified in any publications.

Intention to publish date
31/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as consent has not been obtained.

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	01/12/2020	20/10/2020	Yes	No
Protocol file	version v7.5	06/04/2020	05/01/2021	No	No
Results article		31/01/2023	02/02/2023	Yes	No
HRA research summary			28/06/2023	No	No