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)

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Short title: Stay One Step Ahead Implementation Study

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Synopsis

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 (SSBC))
Acronym	SOSA
Short title	Stay One Step Ahead Implementation Study
Chief Investigator	**Dr Elizabeth Orton**
Objectives	Primary objective: To determine 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). Secondary objectives: To evaluate the implementation of systematic evidence based home safety promotion in terms of: a. impact on medically attended child home injury rates b. impact on other home safety practices (other than those encompassed in the primary objective) c. the extent to which home safety promotion differs between SSBC wards and control wards d. impact of home safety promotion on parental knowledge of child development and injury risk e. parental self-efficacy to prevent injuries to their children f. acceptability of, and satisfaction with, home safety promotion amongst parents g. acceptability of, and satisfaction with, home safety promotion amongst providers h. barriers and facilitators to changing home safety behaviours amongst parents i. barriers and facilitators to implementing home safety promotion amongst providers j. cost-effectiveness of home safety promotion in the SSBC wards compared to control wards
Trial Configuration	This is a non-randomised, controlled before and after study (CBA), with nested interviews, observations of home safety promotion and an economic evaluation.

Setting	Four electoral wards that receive Nottingham CityCare's Big Lottery Funded SSBC programme and five control wards that are not receiving the SSBC programme.
Sample size estimate	Sample size calculations for the CBA are based on previous research which found 54% of families have a smoke alarm, and a safety gate in the home (if applicable e.g. if stairs present) and store poisons out of reach. This is therefore assumed to be the control arm prevalence of the primary outcome measure. A total of 237 families in the SSBC wards and 237 in control wards would provide 80% power to detect an absolute difference of 13% or 90% power to detect an absolute difference of 15% between SSBC and control wards. To allow for losses to follow-up, 400 families in SSBC and 400 families in control wards will be recruited (minimum follow-up rate 60%). Allocation is at ward level. From previous research, the ICC for electoral ward level smoke alarm ownership is <0.00001, hence the design effect is effectively 1, and the sample size adjusting for clustering is the same as that unadjusted for clustering.
Number of participants	The figures below are given as an example. If a higher than anticipated response rate is achieved, all participants will be included in the study and the final analysis. o Approximately 400-500 SSBC ward families and 400-500 control ward families will be recruited to the CBA. o Approximately 100 families will be recruited to the economic evaluation (50 from SSBC wards and 50 from control wards). o Approximately 20 parent participants will be recruited to nested interviews (10 from SSBC wards and 10 from control wards). o Approximately 20 parent participants will be recruited to nested observations of home safety promotion (10 from SSBC wards and 10 from control wards) o Approximately 23 service providers will be recruited to nested interviews (14 from SSBC and 9 from control wards). o Approximately 20 service providers will be recruited to nested observations of home safety promotion (10 from SSBC wards and 10 from control wards).
Eligibility criteria	**<u>Parent participants</u>** *Eligibility criteria for the CBA:* • Parents of children residing in the 4 SSBC wards identified by the SSBC programme; Arboretum, Aspley, Bulwell and St Ann's, and the 5 control wards identified by the study; Clifton North and South, Bestwood, Bridge and Sherwood. • Parents must be aged 18 years or over • Children must be 2 to 7 months old when study invites are sent • Children must be living in their usual place of residence (i.e. not in temporary accommodation such as a refuge or foster care) • Parents must return a completed baseline questionnaire

	Eligibility criteria for parent interviews • Parents taking part in the CBA • Able to provide written informed consent or verbal informed consent over the telephone to take part in the interview • 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) respectively. • If the 9-12 month is amended following the interviews above, parents for the telephone interview must have had an amended 9-12 month child health review and must reside in an SSBC ward. *Observations of 9-12 month and 2-2.5 year child health reviews:* • Parents taking part in the CBA. • Able to provide written informed consent to have their child's review observed • Parents whose child's review is undertaken in English *Economic evaluation* • Parents taking part in the CBA • Able to provide written informed consent to extract data from their child's medical records *Exclusion criteria for parents* • Parents not residing in SSBC or control wards • Parents aged under 18 years • Children not aged 2-7 months old when study invites sent • Parents not returning completed baseline home safety questionnaire • Parents not providing written informed consent or verbal informed consent over the telephone for interviews, written informed consent for observations of 9-12 month or 2-2.5 year child health reviews or for extraction of data from medical records • Parents whose child's review is not undertaken in English **<u>Service provider participants</u>** *Interviews* • 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. • 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* • 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 *Exclusion criteria for service providers* • 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.
Description of interventions	This is an observational research study. It is evaluating the implementation of systematic evidence-based home safety promotion provided as part of routine care in the SSBC programme in 4 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 (a key delivery mechanism within the SSBC programme) and early years providers, referral or signposting to partner organisations and use of evidence-based resources. The remainder of the electoral wards in Nottingham city which are not part of the SSBC programme will continue to provide the home safety promotion they currently provide. Five of these electoral wards have been chosen as control wards.
Duration of study	Overall study duration is four years. Start date 1/4/17. Participant recruitment commences 1/9/17 and the SSBC programme evidence-based home safety promotion commences 1/10/17. The study duration for parent participants in the CBA will be 30 months. The study duration for parent and service provider participants taking part in nested interviews or observations of home safety promotion will be the duration of the interview or of the observation. The study duration for parent participants taking part in the economic evaluation will be the duration of extracting data from the child's medical records.
Randomisation and blinding	Not applicable
Outcome measures	Primary endpoint • **Endpoint 1**: Home safety practices including equipment use (having at least one 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 endpoints (letters relate to the secondary objectives) • **Endpoint 2a**: Medically attended injuries: o Parent-reported medically attended home injury rates at 12 and 24 months post recruitment and by type of medical attendance: ▪ Primary care attendances ▪ Emergency department attendances ▪ Hospital admissions o Validation of parent reported medically attended injuries using medical record data o Aggregated data will be collected retrospectively on unintentional injuries to children aged under 5 years attending the Emergency Department at Nottingham University Hospital NHS Trust at electoral ward level for each of the following years September 2016 to August 2017, September 2017 to August 2018, September 2018 to August 2019 and September 2019 to August 2020. • **Endpoint 2b:** Other home safety practices and equipment use at 12 and 24 months post recruitment (i.e. in addition to those encompassed in the primary outcome measure) • **Endpoint 2c:** Extent to which home safety promotion differs between SSBC and control wards: o Observed home safety promotion at 9-12 month and 2-2.5 year child health reviews o Parent-reported receipt of home safety promotion at 12 and 24 months post recruitment • **Endpoint 2d:** Parental knowledge of child development and child injury risk at 12 and 24 months post recruitment • **Endpoint 2e:** Parental self-efficacy to prevent injuries to their children at 12 and 24 months post recruitment • **Endpoint 2f:** Acceptability of and satisfaction with home safety promotion amongst parents: o Acceptability of home safety promotion amongst parents o Acceptability of the amended 9-12 month review amongst SSBC parents. This will only occur if the 9-12 month review is amended due to parent feedback o Acceptability of post-accident contacts amongst parents reporting injuries o Parental satisfaction with home safety promotion at 12 and 24 months post recruitment

	• **Endpoint 2g:** Acceptability of and satisfaction with home safety promotion amongst providers: o Acceptability of home safety promotion and post-accident contacts amongst providers who conduct 9-12 month or 2-2.5 year child health reviews o Acceptability of home safety promotion amongst providers who don't conduct 9-12 month or 2-2.5 year child health reviews • **Endpoint 2h:** Barriers and facilitators to changing home safety behaviours amongst parents • **Endpoint 2i:** Barriers and facilitators to implementing home safety promotion o Barriers and facilitators to implementing home safety promotion amongst providers who conduct 9-12 month or 2-2.5 year child health reviews o Barriers and facilitators to implementing home safety promotion amongst providers who don't conduct 9-12 month or 2-2.5 year child health reviews • **Endpoint 2j:** Cost-effectiveness: o Incremental cost per additional family with the three key home safety practices (see primary endpoint) at 12 and 24 months post recruitment o Incremental cost per medically attended injury avoided at 12 and 24 months post recruitment
Statistical methods	• **Endpoint 1:** The proportion of families with at least one fitted and working smoke alarm, and a safety gate on stairs (where applicable) and storing poisons out of reach will be described and compared between SSBC and control wards at 12 and 24 months post recruitment using multilevel logistic regression. • **Endpoint 2a:** The rate of home injuries in the index child will be described and compared between SSBC and control wards at 12 and 24 months post recruitment using multilevel Poisson or negative binomial regression. The rate of injuries in the index child, by type of attendance (primary care attendances, emergency department attendances and hospital admissions for home injuries) will be described and compared between SSBC and control wards at 12 and 24 months post recruitment using multilevel Poisson or negative binomial regression. Parent reported medically attended injuries will be compared with injuries recorded in the medical records by calculating kappa coefficients and 95% confidence intervals and sensitivity, specificity and predictive values, assuming the medical record is the gold standard.

	The ward level emergency department attendance rate will be calculated for each year using ward level population data for the under-fives as the denominator. Changes in rates will be compared between SSBC and control wards over time using Poisson or negative binomial regression. • **Endpoint 2b:** The proportion of families with other home safety practices will be described and compared between SSBC and control wards at 12 and 24 months post recruitment using multilevel logistic regression. • **Endpoint 2c**: Home safety promotion will be described for SSBC and control wards in terms of: 1) The proportion of families with a record of home safety promotion in their medical record, including at 9-12 month and 2-2.5 year child health reviews, post-accident visits and at other contacts. Quantitative comparisons will not be made between SSBC and control wards as numbers will be small. 2) Observations of home safety promotion in terms of the content of the home safety promotion, whether home safety topics were discussed in relation to child development, what resources were used in the discussion, what referrals were made, which services parents were signposted to and adherence to the principles of behaviour change recommended for individual level interventions by NICE. Quantitative comparisons will not be made between SSBC and control wards as numbers will be small. 3) The proportion of parents reporting receiving home safety advice at 12 and 24 months. This will be compared between SSBC and control wards using multilevel logistic regression, with family at level 1 and ward at level 2. • **Endpoint 2d:** Parental knowledge of child development and injury risk scores will be described and compared between SSBC and control arms using multilevel linear regression, with family at level 1 and ward at level 2. • **Endpoint 2e:** Parental self-efficacy for home safety will be described and compared between SSBC and control wards using means (SD) or medians (IQR) for the self-efficacy scale and multilevel linear regression with family at level 1 and ward at level 2. • **Endpoints 2f to 2i:** The following secondary outcomes will be assessed qualitatively: o Acceptability of home safety promotion to parents, and barriers and facilitators to changing home safety behaviours

	o Acceptability of home safety promotion to providers, and barriers and facilitators to implementing home safety promotion o Acceptability of post-accident contact for parents and providers o Acceptability of amended 9-12 month review for parents in SSBC wards Interviews will be analysed using thematic analysis. • **Endpoint 2j:** An incremental cost-effectiveness analysis will be performed, using a time horizon of two years. Service provision and healthcare costs will be combined to estimate an expected mean total cost. There will be two measures of effectiveness; (a) incremental cost per additional family with the three key home safety practices (see primary endpoint) and (b) incremental cost per medically attended injury prevented amongst children. To control for uncertainty, a probabilistic sensitivity analysis will be performed using bootstrapping on costs and effectiveness, with output including cost-effectiveness scatterplots and cost-effectiveness acceptability curves. Analyses will take account of under or over-reporting of service use and injury related healthcare utilisation ascertained from the validation of self-reported data described above.

Abbreviations

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
ED	Emergency department
GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
IPB	Injury Prevention Briefing
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
ONS	Office for National Statistics
PIS	Participant Information Sheet
REC	Research Ethics Committee
R&D	Research and Development department
SSBC	Small Steps Big Changes

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Study background information and rationale

Unintentional injuries represent a significant cause of morbidity and mortality for children under 18. In 2004, almost 950,000 children died of an injury around the world[1]. Children from low socio-economic countries are more likely to suffer from an injury and die as a result of it than those in wealthier countries[2], and those that are under 5 years of age experience higher mortality rates than older children[3].

In England, approximately 40,000 children under the age of 5 are admitted to hospital each year with an unintentional injury[4]The vast majority of these are non-fatal, however they are still responsible for approximately 60 deaths per year[4-7]. Putting this into perspective, unintentional injuries are the third most common reason for death in children aged 1-4 following neoplasms (most common cause), and congenital related illnesses and diseases of the respiratory system (joint 2nd cause)[5].

The location where injuries are more likely to occur depends on the age of the child. In those that are younger than 5, the vast majority occur in the home[8, 9]. As the child gets older, these injuries start to occur outside the home.

A number of socio-economic factors play a role in determining unintentional injury rates in children. One major risk factor is deprivation and it is well recognised that children living in more disadvantaged circumstances are at higher risk of injury with a thirteen fold difference in mortality rates being found between children of parents in socio-economic class I (high managerial, administrative and professional occupations) and class 8 (never worked and long-term unemployed)[10]. Living in rented accommodation is associated with higher unintentional injury rates[11], and this may be explained in part by, for example, difficulties in installing and utilising safety equipment[12].

Parental factors associated with higher rates of unintentional injury include young maternal age at the time of delivery[11, 13] single-parent families[14-16], and parental mental health problems[8, 15, 16].

Injuries do not only have immediate physical effects on the child. Longer term consequences may occur, for example, with injuries like burns and scalds, which may lead to scarring and deformities and impact on the child's psychological and social wellbeing[1, 4]. A major injury resulting in a disability will have a large impact on family life and may lead to financial constraints, family tension and effects on mental health[17].

It is therefore important to reduce and prevent the occurrence of unintentional injuries, particularly in those aged under 5. Recently, the National Institute for Health and Care Excellence (NICE) published 3 public health guidelines on the prevention of unintentional injuries amongst those less than 15 years of age[18-20] with some specific recommendations being made for this vulnerable age group.

Two recent Cochrane Reviews have found that interventions delivered to parents, aiming to educate them about unintentional injuries in children and how to prevent them, are successful in improving safety practices in the home and may also help to reduce rates of injuries[21, 22]. The majority of the interventions in the two reviews were delivered in the home on a one-to-one basis as part of a wider programme.

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 and part of this money has been used to set up the Small Steps Big Changes Programme (SSBC)[23]. SSBC focusses on four electoral wards in Nottingham – Arboretum, Aspley, Bulwell

and St Ann's. These wards were chosen on the basis of deprivation and high levels of need amongst children in terms of a range of health, education and social indicators, high child populations and cultural and ethnic diversity.

Child home safety services in the SSBC programme will be delivered as usual care to all families within the SSBC wards. 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[24] to help and support parents make the necessary changes to enhance home safety. Service providers will be trained to deliver home safety promotion. Home safety promotion will include home safety education, tailored to the family's needs, provided by health visiting teams, family mentors (a key delivery mechanism within the SSBC programme) and early years providers and referral or signposting to partner organisations such as the fire and rescue service for home fire risk assessments or the Nottingham City Safer Homes team for housing safety issues for families living in private rented accommodation. Evidence-based resources such as the Injury Prevention Briefing[25] produced by researchers at the University of Nottingham and endorsed by NICE will be used to support home safety education. A home safety equipment and education scheme is currently provided across Nottingham City funded by Nottingham City CCG and if further funding is obtained, referral to this scheme will form part of the home safety promotion. The SSBC home safety promotion is being co-produced by service providers and parents, with evidence provided by the research team and the Child Accident Prevention Trust.

This protocol describes an observational research study evaluating the implementation of systematic, evidence-based home safety promotion in the SSBC wards by comparing outcomes in the four SSBC wards and five control wards, selected because of comparable injury rates, deprivation and populations aged 0-4 years, different care delivery groups and minimal overlap of health visiting teams with the SSBC wards. Outcomes include parental home safety practices, knowledge of child development and injury risk, behaviours and self-efficacy and medically-attended unintentional child injuries. 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. Ethical approval for the service evaluation will be sought from the University of Nottingham ethics committee.

The study will derive new knowledge about the impact, acceptability, implementation facilitators and barriers and cost-effectiveness of evidence based home safety promotion. Given the similarity of health visiting and children's centre service provision across the UK, study findings should be generalisable across the country. Findings will inform child home safety promotion across Nottingham city wards in the later years of the Small Steps Big Changes programme, and importantly, they will inform development and commissioning of child home safety promotion in other areas of the UK.

Study objectives and purpose

Purpose

The implementation of systematic evidence-based home safety promotion in SSBC wards will be evaluated using a controlled before and after research study design, comparing home safety practices, medically attended injuries, parental knowledge of child development and injury risk and parental self-efficacy between SSBC and control wards. The provision of home safety promotion will be compared between SSBC and control wards, along with satisfaction, acceptability and barriers and facilitators for home safety promotion amongst parents and service providers. An economic evaluation will assess the cost-effectiveness of the home safety promotion.

Primary objective

1. To determine 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).

Secondary objectives

2. To evaluate the implementation of systematic evidence based home safety promotion in terms of:

    a. impact on medically attended child home injury rates

    b. impact on other home safety practices (other than those encompassed in the primary objective)

    c. the extent to which home safety promotion differs between SSBC wards and control wards

    d. impact of home safety promotion on parental knowledge of child development and injury risk

    e. parental self-efficacy to prevent injuries to their children

    f. acceptability of, and satisfaction with, home safety promotion amongst parents

    g. acceptability of, and satisfaction with, home safety promotion amongst providers

    h. barriers and facilitators to changing home safety behaviours amongst parents

    i. barriers and facilitators to implementing home safety promotion amongst providers

    j. cost-effectiveness of home safety promotion in the SSBC wards compared to control wards

Study design

Study configuration

This is a non-randomised, controlled before and after research study, with nested interviews, observations of home safety promotion and an economic evaluation.

Primary endpoint

- **Endpoint 1**: Home safety practices including equipment use (having at least one 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.

The primary endpoint has been chosen as a combination of three key safety practices and equipment use as there is evidence that home safety education and provision of safety equipment can increase these behaviours or equipment use[21] and there is evidence that these behaviours or equipment use are associated with a reduced risk of injury[26-29]. Injury rates have been chosen as a secondary endpoint as the study is unlikely to be adequately powered to detect anything but a large reduction in injury rates.

Secondary endpoints (letters relate to the secondary objectives)

- **Endpoint 2a**: Medically attended injuries:
    - Parent-reported medically attended home injury rates at 12 and 24 months post recruitment and by type of medical attendance:
        - Primary care attendances
        - Emergency department attendances
        - Hospital admissions
    - Validation of parent reported medically attended injuries using medical record data
    - Aggregated data will be collected retrospectively on unintentional injuries to children aged under 5 years attending the Emergency Department at Nottingham University Hospital NHS Trust at electoral ward level for each of the following years September 2016 to August 2017, September 2017 to August 2018, September 2018 to August 2019 and September 2019 to August 2020.

- **Endpoint 2b:** Other home safety practices and equipment use at 12 and 24 months post recruitment (i.e. in addition to those encompassed in the primary outcome measure)

- **Endpoint 2c:** Extent to which home safety promotion differs between SSBC and control wards:
    - Observed home safety promotion at 9-12 month and 2-2.5 year child health reviews
    - Parent-reported receipt of home safety promotion at 12 and 24 months post recruitment
    - Home safety promotion recorded in medical records

- **Endpoint 2d**. Parental knowledge of child development and child injury risk at 12 and 24 months post recruitment

- **Endpoint 2e.** Parental self-efficacy to prevent injuries to their children at 12 and 24 months post recruitment

- **Endpoint 2f**. Acceptability of and satisfaction with home safety promotion amongst parents:
    - Acceptability of home safety promotion amongst parents
    - Acceptability of the amended 9-12 month child health review amongst SSBC parents. This will only occur if the 9-12 month child health review is amended due to parent feedback
    - Acceptability of post-accident contacts amongst parents reporting injuries
    - Parental satisfaction with home safety promotion at 12 and 24 months post recruitment

- **Endpoint 2g.** Acceptability of and satisfaction with home safety promotion amongst providers:
    - Acceptability of home safety promotion and post-accident contacts amongst providers who conduct 9-12 month or 2-2.5 year child health reviews
    - Acceptability of home safety promotion amongst providers who don't conduct 9-12 month or 2-2.5 year child health reviews

- **Endpoint 2h**. Barriers and facilitators to changing home safety behaviours amongst parents

- **Endpoint 2i.** Barriers and facilitators to implementing home safety promotion
    - Barriers and facilitators to implementing home safety promotion amongst providers who conduct 9-12 month or 2-2.5 year child health reviews
    - Barriers and facilitators to implementing home safety promotion amongst providers who don't conduct 9-12 month or 2-2.5 year child health reviews

- **Endpoint 2j**. Cost-effectiveness:
  - Incremental cost per additional family with the three key home safety practices (see primary endpoint) at 12 and 24 months post recruitment
  - Incremental cost per medically attended injury prevented at 12 and 24 months post recruitment

Safety endpoints

Not applicable as the research study is evaluating the implementation of home safety promotion delivered as part of usual care.

Stopping rules and discontinuation

Not applicable as the research study is evaluating the implementation of home safety promotion delivered as part of usual care.

Randomization and blinding

This is a non-randomised controlled before-and-after research study. The SSBC wards were pre-determined by the SSBC programme, chosen to meet criteria for Big Lottery funding. These were that:

- the area for the programme should have a total population of between 30,000 and 70,000 people,
- there should be evidence of deprivation and
- high levels of need amongst children in terms of a range of health, education and social indicators.

The four SSBC wards were chosen because they gave the highest density in terms of child population and provided ethnic and cultural diversity, in addition to meeting the criteria above.

Five control wards were matched to SSBC wards based on injury rates, deprivation, population aged 0-4 years, care delivery groups and with the minimum overlap between health visiting team caseloads between SSBC and control wards. The process was as follows:

1. All Nottingham city wards were ranked based on emergency department (ED) attendance rate for injuries in 0-5 year olds (based on 2015 Joint Strategic Needs Assessment data for Nottingham city)
2. The 9 wards not in care delivery groups containing SSBC wards were considered for being control wards. This was aimed at minimising contamination between SSBC and control wards.
3. Where there was more than one possible control ward with an ED attendance rate within 20/1000 of the SSBC ward, the control ward with the Nottingham City rank for income deprivation affecting children closest to the SSBC ward was chosen
4. This resulted in four control wards (Clifton South, Bestwood, Bridge and Sherwood) matched to SSBC wards, but the combined population aged 0-4 years across SSBC wards was 5118 children and 4033 in control wards. A fifth control ward was therefore chosen. Of the remaining 5 possible control wards, the ward with the injury rate closest to the combined injury rate for the 4 SSBC wards and with the minimum overlap between health visiting caseloads between SSBC and control wards was chosen (Clifton North). This resulted in 5 control wards (Clifton South (matched to Aspley), Clifton North and Bridge (matched to Arboretum), Bestwood (matched to St Ann's) and Sherwood (matched to Bulwell). The combined injury rate in the SSBC wards was 237/1000/year (95%CI 225-250) and the

combined injury rate in the control wards was 229/1000/year (95%CI 217-241). The combined population of 0-4 year olds in SSBC wards was 5518 and in control wards was 4804.

It will not be possible to blind participants, researchers or service providers to group allocation. Quantitative analyses will be undertaken blinded to group allocation.

Study management

The Chief Investigator has overall responsibility for the study and shall oversee all study management. The data custodian will be the Chief Investigator.

The researcher will be responsible for contacting the participants when required.

A project steering group will be established to oversee the study. It will meet three times a year. There will be a local management group that will meet monthly to ensure progression of the study.

Duration of the study and participant involvement

The study will begin in April 2017. Recruitment of parent participants will commence in September 2017. The SSBC home safety promotion programme will commence in October 2017. The study will be publicised in SSBC and control wards via a range of mechanisms including primary care, early years' services and other community venues and activities, using posters, leaflets, social media or verbal communications.

Recruitment will take place in 3 cohorts to ensure a sufficient number of families are invited to the study. Recruitment of the first cohort of parents with children aged 2 to 7 months will commence in September 2017, recruitment of the second cohort will commence in March 2018 and recruitment of the third cohort will commence in September 2018. Study participation will end 30 months post recruitment.

Timing and methods of endpoint measurement are given in Table 1 (page 36).

Interviews

Parents from SSBC and control wards who have had a 9-12 month or 2-2.5 year child health review will be invited to participate in face to face or telephone interviews. Parents from each recruitment cohort will be sampled separately. Study participation will end following completion of the interview.

Service providers from SSBC and control wards who conduct 9-12 month or 2-2.5 year child health reviews will be invited to participate in face to face or telephone interviews. Study participation will end following completion of the interview. Service providers from SSBC and control wards who don't conduct 9-12 month or 2-2.5 year child health reviews will be invited to participate in face to face or telephone interviews. Study participation will end following completion of the interview. In SSBC wards, the 9-12 month child health reviews may be amended due to parent feedback. In this case, a separate sample of parents from SSBC wards will be invited to participate in telephone interviews. The interviews will focus on the acceptability of the amended 9-12 month child health reviews. Study participation will end following completion of the interview.

Observations of home safety promotion

A sample of parents and service providers in SSBC and control wards will be invited to participate in observations of the 9-12 month and/or 2-2.5 year child health reviews. Study participation will end following completion of the observation.

Economic evaluation

All parents who complete the 24 month home safety questionnaire (September 2019 to March 2020) and who have reported an injury to their child in the 24 months of the study, will be invited to participate in the economic evaluation. Participation will involve providing access to their children's medical records to determine the nature of the injury to be able to validate self-reported injuries and to cost any treatment required by the child. We will aim to recruit 50 parents from SSBC wards and 50 parents from control wards. Study participation will end following completion of data extraction from the child's medical records.

The completion date for the study will be the latest of: return of the last questionnaire from cohort 3 or completion of the last interview.

Selection and withdrawal of participants

Recruitment

Recruitment will firstly be described for parents and then for service providers.

Parents

All parents in SSBC and control wards with children aged 2-7 months at the time of study invitation (September 2017, March 2018 and September 2018) who fulfil eligibility criteria will be invited to take part in the study. This will include completing baseline, 12 and 24 month questionnaires and for those who agree, completing injury questionnaires 3-6 monthly for 2 years.

The study will be publicised using posters/leaflets, social media and verbal communications via primary care, early year's services and other community-based opportunities in SSBC and control wards and interested parents will be invited to contact the research team. Nottingham CityCare will identify all families with children aged 2-7 months at the date of study invitation (September 2017, March 2018 and September 2018), living in an SSBC or control wards from SystemOne computerised records. (SystemOne is the computerised clinical record system used by Nottingham CityCare). This will allow two months for children to be entered onto SystemOne post birth. Nottingham CityCare will exclude families where the mother is aged under 18 years and the child is not living at their usual place of residence using data from SystemOne. Nottingham CityCare will send parents, by post, an information pack which includes an invitation letter and information about the study (PIS), a baseline questionnaire, a gift voucher form containing contact details and a freepost envelope. Parents who have had multiple births will be sent one information pack as the parents are asked to complete the baseline questionnaire based on the baby that was born first. Up to 2 reminders will be sent to non-responders by Nottingham CityCare at 3-4 weekly intervals after the original mailing.

If the required sample size is not reached by postal recruitment, parents will also be given the information pack during face-face contacts by family mentors, early years staff and by researchers at child health clinics and early years venues. Clinic and early years staff will be asked to approach parents and ask them if they are willing to talk to a researcher about the study. Parents will be asked their postcode to ensure only parents in SSBC and control wards are invited to the study.

Parents will be considered to be recruited if they complete and return the baseline questionnaire.

Parents will be asked on the gift voucher form if they are interested in taking part in other parts of the study (interviews, observations of home safety promotion or the economic evaluation). Those expressing interest in writing will be invited separately to these as described below.

Interviews

There are two types of interviews parents can be invited to. These are (a) interviews about the acceptability of home safety promotion, the child health reviews and post-accident contacts and barriers/facilitators to changing home safety behaviour; (b) interviews about the 9-12 month child health review if the child health review is amended.

a) Recruitment for interviews regarding acceptability of home safety promotion, the child health reviews and post-accident contacts and barriers/facilitators to changing home safety behaviours:

- A total of 10 parents will be recruited from SSBC wards and 10 from control wards.
- Maximum variation sampling will be used to ensure variation in ward, child age and gender. Different parents will be approached for each set of interviews. Separate sampling frames will be drawn up for SSBC and control wards.
- Parents from all three cohorts will be approached, with each cohort being separately sampled. Parents who expressed interest in taking part in interviews at recruitment will be sent an invite letter, a PIS, a reply slip and a freepost envelope by post, or an invite letter, a PIS and a reply slip by email. Initially 50 parents will be invited from each cohort from SSBC and 50 from each cohort of control wards, but more may be invited depending on the response rate. Those agreeing to be contacted will be telephoned to discuss this study and answer any questions. An interview date will be arranged and participants will be asked to complete the consent form at the time of the interview for face to face interviews. For telephone interviews, parents will be sent the consent form and asked to complete and return by post or asked to provide verbal informed consent over the telephone prior to the interviews. Experience of a child health review is an inclusion criterion and will be established during the initial telephone call by the researcher.
- A £20 gift voucher will be given to those completing the interview.

b) Recruitment for interviews regarding the amended 9-12 month child health review:

- If the 9-12 month child health review is amended, a further additional sample of 10 parents from SSBC wards will be invited to participate in telephone interviews.
- Maximum variation sampling will be used to ensure variation in ward, child age and gender.
- Parents who expressed interest in taking part in interviews at recruitment will be sent an invite letter, a PIS, a reply slip and a freepost envelope. Initially 50 parents, chosen at random, will be invited from SSBC wards, but more may be invited depending on the response rate. Those agreeing to be contacted will be telephoned to discuss this study and answer any questions. An interview date will be arranged and parents will be sent the consent form and asked to complete and return by post or asked to provide verbal informed consent over the telephone prior to the interview.
- These interviews will focus on the amended 9-12 month child health review. Experience of receiving the child health review since the amendments were made is therefore an inclusion criterion and will be established during the initial telephone call by the researcher.
- A £20 gift voucher will be given to those completing the interview.

Observations

Recruitment for observation of 9-12 month and 2-2.5 year child health reviews:

- 10 service provider-parent pairs will be recruited from SSBC wards and 10 from control wards for observation of the 9-12 month or 2-2.5 year child health reviews.
- All parents who have expressed interest in the nested studies and who are on the caseload of service providers agreeing to participate in the observations, will be invited to participate. They will be sent a study invite, a PIS, a reply slip and a freepost envelope. A sampling frame of service provider-parent pairs will be drawn up and pairs sampled to provide variation across wards and service provider team members (health visitors, nursery nurses, other staff etc.). Separate sampling frames will be drawn up for SSBC and control wards. Parents will be asked to sign a consent form at the 9-12 month or 2-2.5 year child health review.
- A £20 gift voucher will be given to parents whose child health reviews are observed.

Economic evaluation

Recruitment for economic evaluation

All parents who return the 24 month questionnaire and have reported an injury to their child during the study duration will be invited to participate in the economic evaluation, with the aim of recruiting 50 parents from SSBC wards and 50 from control wards. Parents will be approached by letter with a PIS, a reply slip and a freepost envelope by post, or will be sent an invite letter, a PIS and a reply slip by email. A member of the study team will approach, by telephone, parents who express interest to determine whether permission can be sought to access the child's medical records. If the parent agrees, written permission will be sought by post or email using a consent form and freepost envelope (for postal invites) to return to the study team. For non-responders to the initial invite and consent form mail outs, one follow-up telephone call to parents will be performed at least two weeks after the initial mail out and consent form mail out to enquire if parents have received the documents, and if so, whether they are interested in participating in the study. Recruitment will stop once 50 parents from SSBC and 50 parents from control wards have been recruited. A £10 gift voucher will be given to parents who have consented to participate in the economic evaluation.

Service providers

Service providers will be invited to take part in interviews and have 9-12 month and 2-2.5 year child health reviews observed.

Interviews

Recruitment for interviews of providers who conduct 9-12 month or 2-2.5 year child health reviews regarding acceptability of home safety promotion, barriers/facilitators to implementing home safety promotion and post-accident contacts:

- 5 service providers who conduct 9-12 month or 2-2.5 year child health reviews will be recruited from SSBC wards and 5 will be recruited from control wards.
- Maximum variation sampling will be used to ensure variation in service provider (health visitors, nursery nurses, and other staff), type of post-accident contact (face to face or phone) if service providers provide post-accident contacts and ward. Separate sampling frames will be drawn up for SSBC and control wards.

- Service provider managers/coordinators will be asked to send an invite letter, a PIS, a reply slip and a freepost envelope to all eligible service providers by post, or an invite letter, a PIS and a reply slip byemail. Service providers expressing interest will be entered into the sampling frame and sampling will continue until 5 providers from SSBC wards and 5 from control wards have been recruited who provide variation as described above. Service providers will be telephoned to discuss this study and answer any questions. An interview date will be arranged and participants will be asked to complete the consent form at the time of the interview for face to face interviews. For telephone interviews, service providers will be sent the consent form and asked to complete and return by post or asked to provide verbal informed consent over the telephone prior to the interviews. The same service provider will not be interviewed at multiple time points.

- Experience of conducting the 9-12 month or 2-2.5 year child health reviews since the start of the SSBC programme is an inclusion criterion. This will be established during the initial telephone call by the researcher.

Recruitment for interviews of providers who don't conduct 9-12 month or 2-2.5 year child health reviews regarding acceptability of home safety promotion and barriers/facilitators to implementing home safety promotion:

- 9 service providers who don't conduct 9-12 month or 2-2.5 year child health reviews (e.g. family mentors, early years staff, other members of health visiting teams) will be recruited from SSBC wards and 4 will be recruited from control wards for face to face or telephone interviews.

- Maximum variation sampling will be used to ensure variation in service provider (family mentors, children's centre staff, and other staff) and ward. The sampling frame will comprise all eligible service providers. Separate sampling frames will be drawn up for SSBC and control wards.

- Service provider managers/coordinators will be asked to send an invite letter, a PIS, a reply slip and a freepost envelope to all eligible service providers by post, or an invite letter, a PIS and a reply slip by email. Service providers expressing interest will be entered into the sampling frame and sampling will continue until 9 providers from SSBC wards and 4 from control wards have been recruited who provide variation as described above. Service providers will be telephoned to discuss this study and answer any questions. An interview date will be arranged and participants will be asked to complete the consent form at the time of the interview for face to face interviews. For telephone interviews, service providers will be sent the consent form and asked to complete and return by post or asked to provide verbal informed consent over the telephone prior to the interviews.

Observations

Observation of 9-12 month and 2-2.5 year child health reviews

- 10 service provider-parent pairs will be recruited from SSBC wards and 10 from control wards for observation of the 9-12 month or 2-2.5 year child health reviews.
- Service provider managers will be asked to send an invite letter, a PIS, a reply slip and a freepost envelope to all eligible service providers. These invites will be sent prior to inviting parents to take part in the observations. Service providers expressing interest will be phoned by the research team to discuss the observations and answer any questions. They will be asked to sign and return a consent form to the study team. A sampling frame of service provider-parent pairs will be drawn up and pairs sampled to provide variation across wards and service provider team members (health visitors, nursery nurses, other staff etc.). Separate sampling frames will be drawn up for SSBC and control wards.

Inclusion / exclusion criteria for parents and children

Controlled before and after study

- Parents of children residing in the 4 SSBC wards identified by the SSBC programme; Arboretum, Aspley, Bulwell and St Ann's, and the 5 control wards identified by the study; Clifton South, Clifton North, Bestwood, Bridge and Sherwood.
- Parents must be aged 18 years or over
- Children must be 2 to 7 months old when study invites sent
- Children must be living in their usual place of residence (i.e. not in temporary accommodation such as a refuge or foster care)
- Parents must return a completed baseline questionnaire. Completion of questionnaires will be taken as implied consent

Interviews (face to face and/or telephone)

- Parents taking part in the CBA.
- Able to provide written informed consent or verbal informed consent over the telephone to take part in the interview
- Parents must have had either a 9-12 month review or a 2-2.5 year review.
- For the telephone interviews regarding the amended 9-12 month child health review, parents must reside in an SSBC ward and have had the 9-12 month child health review since the amendments were made.

Observations of 9-12 month and 2-2.5 year child health reviews

- Parents taking part in the CBA
- Able to provide written informed consent to have their child's review observed
- Parents whose child's review is undertaken in English

Economic evaluation

- Parents taking part in the CBA
- Able to provide written informed consent to extract data from their child's medical records

Exclusion criteria for parents and children

- Parents not residing in SSBC or control wards
- Parents aged under 18 years
- Children not aged 2-7 months old when study invites sent
- Children not living in their usual place of residence (e.g. in temporary accommodation such as a refuge or foster care)
- Parents not returning completed baseline home safety questionnaire. Parents not providing written informed consent or verbal informed consent over the telephone for interviews, written informed consent for observations of 9-12 month or 2-2.5 year child health reviews or for extraction of data from medical records

- Parents whose child's review is not undertaken in English

Inclusion /exclusion criteria for service providers

Interviews (face to face and/or telephone)

- 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
- 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

- 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

Exclusion criteria for service providers

- Service provider's 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.

Removal of Participants and Participant Withdrawal

Participants can withdraw from the study either at their own request or be withdrawn at the discretion of the Chief Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis. Nottingham CityCare will identify children not living at their usual place of residence prior to mail out of any study questionnaires or invites and these will be excluded.

Withdrawn participants will not be replaced.

Informed consent

Parents

Parents will be provided with a participant pack comprising a participant information sheet (PIS), a baseline questionnaire, a gift voucher form containing contact details and a freepost envelope. The PIS will describe the study and include a telephone number for potential participants to contact the study team to answer any questions or concerns regarding the study and participation. Parents participating in the controlled before and after questionnaire study will not be asked to sign a written consent form; the return of the questionnaires by parents will be taken as implied consent to take part in this study.

Parents will also be asked if they would be interested in taking part in interviews, observations or the economic evaluation and those expressing interest will be contacted at later time points and invited to participate in interviews, observations of 9-12 month and 2-2.5 year child health reviews or the economic evaluation. Parents will provide written informed consent or verbal informed consent over the telephone to participate in the interviews and written informed consent to participate in the observations and economic evaluation.

All parents from SSBC and control wards, whose service provider has agreed to have their 9-12 month or 2-2.5 year child health reviews observed, whose child's review is due to take place within

the specified time frame for the study (see Table 1 below for data collection time points) and who expressed interest in taking part in the observations will be contacted and asked to provide informed consent to observe one of these child health reviews, until the required number of child health reviews have been completed. Parents will be approached by letter, and will be sent a PIS, a reply slip and a freepost envelope. Prior to invites being sent Nottingham CityCare will check SystemOne records for vital status of the child and residence not at their usual place of residence and invites will not be sent to these families. Nottingham CityCare will also check for any changes of address. If a parent and child have moved to a new address, the researcher will telephone or email the parent, using the contact details the parent has provided the study team with, and ask for the new address details before the invites are sent. Those expressing interest will be phoned to discuss this aspect of the study and to ask whether their child's reviews are undertaken in English and those agreeing will be asked to complete a consent form at the time of the child health review.

All parents from SSBC and control wards expressing interest in taking part in the economic evaluation will be approached to take part in the validation of self-reported medically attended injuries and to collect data on service provision and resource use for the economic evaluation. They will be approached once they have returned their 24 month questionnaire and will be asked to provide informed consent. Parents will be approached by letter, and will be sent a PIS, a reply slip and a freepost envelope by post, or will be sent an invite letter, a PIS and a reply slip by email. Those expressing interest will be phoned to discuss this aspect of this study and those agreeing will be sent a consent form to complete and return to the study team.

Parents expressing interest in taking part in interviews will be sent a PIS, a reply slip and a freepost envelope by post, or will be sent an invite letter, a PIS and a reply slip by email. This will continue until the required number of interviews have been completed. Prior to invites being sent Nottingham CityCare will check SystemOne records for vital status of the child and residence not at their usual place of residence and invites will not be sent to these families. Nottingham CityCare will also check for any changes of address. If a parent and child have moved to a new address, the researcher will telephone or email the parent, using the contact details the parent has provided the study team with, and ask for the new address details before the invites are sent. Those expressing interest will be phoned by a member of the research team to explain the interview in more detail and answer any questions. An interview date will be arranged. Parents will be asked to provide written informed consent and sign a consent form at the interview for face to face interviews. For telephone interviews, parents will be sent the consent form and asked to complete and return it by post or asked to provide verbal informed consent prior to the interviews.

A copy of each consent form will be retained by the parent and the investigator and one copy will be sent to Nottingham CityCare for filing in the child's medical records.

If the final protocol were to be amended in such a way that it may affect the participant, a continuing consent form will be obtained using an amended consent form which will be signed and dated by the participant. Again, a copy will be retained by the parent, the investigator and filed in the child's medical records.

Service providers

Service providers invited to participate in face to face or telephone interviews will be sent a PIS, a reply slip and a freepost envelope by post, or will be sent an invite letter, a PIS and a reply slip by email. Those expressing interest will be phoned by a member of the research team to explain the interview in more detail and answer any questions. An interview date will be arranged and participants will be asked to complete the consent form at the time of the interview for face to face interviews. For telephone interviews, service providers will be sent the consent form and asked to complete and return by post or asked to provide verbal informed consent over the telephone prior to

the interviews. Service providers invited to have 9-12 month and 2-2.5 year child health reviews observed will be sent a PIS, a reply slip and a freepost envelope. Those expressing interest will be phoned by a member of the research team to explain the observation in more detail and answer any questions. They will be asked to complete and return a consent form prior to the observation.

A copy of the consent form will be retained by the service provider and the investigator. If the final protocol were to be amended in such a way that it may affect the service provider, a continuing consent form will be obtained using an amended consent form which will be signed and dated by the service provider. Again, a copy will be retained by the service provider and the investigator.

Data Collection

The data collection tools used in the study are described below. The number of participants on whom each type of data will be collected is described in the recruitment section above:

Parent-completed home safety questionnaires.

These will ask about home safety practices, medically attended injuries in the preceding 3 months and treatment received, knowledge of child development and injury risk, self-efficacy, receipt of, and satisfaction with home safety promotion, including referral to other services (e.g. fire and rescue service, safer housing team, home safety equipment referral). This will be administered by post, online or by phone depending on parent preference, with up to 3 reminders by the same methods plus text and telephone reminders. Nottingham CityCare will check vital status of the child, residence not at their usual residence and change of address prior to any questionnaire administration. If a parent and child have moved to a new address, the researcher will telephone or email the parent, using the contact details the parent has provided the study team with, and ask for the new address details before the questionnaire is sent.

Parent-completed injury questionnaires

These will ask about medically attended injuries in the preceding 3 months and treatment received. These will be administered by post, online or by phone depending on parent preference, with up to 3 reminders by the same methods plus text reminders and telephone reminders. Nottingham CityCare will check vital status of the child, residence not at their usual residence and change of address prior to any questionnaire administration. If a parent and child have moved to a new address, the researcher will telephone or email the parent, using the contact details the parent has provided the study team with, and ask for the new address details before the questionnaire is sent.

Interviews with parents and service providers

To explore acceptability of, and satisfaction with home safety promotion (including the 9-12 month and 2-2.5 year child health reviews and post-accident contacts, but also other aspects of the home safety promotion programme) and barriers and facilitators to home safety promotion. Nottingham CityCare will check vital status of the child, residence not at their usual residence and change of address prior to any invitations being sent. If a parent and child have moved to a new address, the researcher will telephone or email the parent, using the contact details the parent has provided the study team with, and ask for the new address details before sending the invitation.

The interview schedules for the qualitative interviews are described below.

Parents

Exploring acceptability of and satisfaction with home safety promotion and barriers and facilitators for home safety promotion:

a. For parents in SSBC wards, interviews will include questions on attitudes and behaviour regarding unintentional injuries and home safety, what helps and hinders them in making their home safe, experiences of child home injuries, experiences of the SSBC home safety

programme (including 9-12 month and 2-2.5 year child health reviews), impact of the programme on home safety, other sources of home safety advice they have received, what their ideal advice/support would be and suggestions for improving the SSBC home safety programme.

b. For parents in control wards, interviews will include questions on attitudes and behaviour regarding unintentional injuries and home safety, what helps and hinders them in making their home safe, experiences of child home injuries, experience of the 9-12 month and 2-2.5 year child health reviews, impact of home safety promotion on home safety, other sources of home safety advice they have received, what their ideal advice/support would be and suggestions for improving current home safety promotion.

c. For parents in SSBC and control wards who have experienced a post-accident contact, interviews will include questions on the accident that lead to the post-accident contact, subsequent healthcare received, parental perceptions of the attitudes of healthcare providers at the time of the accident and subsequently, expectations concerning the post-accident contact, experience of the post-accident contact, what worked well and what worked less well, impact of post-accident contact on home safety, on future intentions regarding seeking medical care for injuries and on relationship with health care providers and suggestions for improving post-accident contacts.

Exploring experiences of the amended 9-12 month child health review:

a. In SSBC wards, the 9-12 month child health review may be amended due to parent feedback. In this case, data on how parents experience the amended 9-12 month child health review will be collected using interview schedules which explore parental experiences of the 9-12 month child health review, impact on home safety, other sources of home safety advice they have received, what their ideal advice/support would be and suggestions for further improving the 9-12 month child health review.

Service providers

Exploring experiences of providers who conduct 9-12 month or 2-2.5 year child health reviews regarding acceptability of home safety promotion, barriers/facilitators to implementing home safety promotion and post-accident contacts:

a. For service providers in SSBC wards, interviews will include questions on attitudes to home safety promotion, experience of the study training, methods of promoting home safety before and after SSBC, experience of implementing the programme (including the 9-12 month and 2-2.5 year child health reviews), extent to which they are using the home safety promotion resources and reasons why, whether they are using the resources as illustrated in their training and reasons why, how they feel parents are receiving the programme, sustainability, how partner agencies have worked together, what helps and hinders them in promoting home safety, what their ideal home safety promotion programme would be, suggestions for improvement, how they decided what type of post-accident contact to make, their experience of the post-accident contact, how they feel the parent perceived it, what worked well and what worked less well, likely impact of post-accident contact on home safety, on parents' future intentions regarding seeking medical care for injuries and on relationship with parents, suggestions for improving post-accident contacts, how the SSBC programme has changed the way in which they conduct post-accident contacts and reasons why if they haven't conducted a post-accident contact.

b. For service providers in control wards, interviews will include questions on attitudes to home safety promotion, methods of promoting home safety, experience of the 9-12 month and 2-2.5 year child health reviews, what the standard home safety promotion involves, extent to which they implement this and reasons why, whether they implement it in a standardised way

and reasons why, how they feel parents are receiving the standard home safety promotion, sustainability, how partner agencies have worked together, what helps and hinders them in promoting home safety, what their ideal home safety promotion programme would be, suggestions for improvement, how they decided what type of post-accident contact to make, their experience of the post-accident contact, how they feel the parent perceived it, what worked well and what worked less well, likely impact of post-accident contact on home safety, on parents' future intentions regarding seeking medical care for injuries and on relationship with parents, suggestions for improving post-accident contacts and reasons why if they haven't conducted a post-accident contact.

Exploring experiences of providers who don't conduct 9-12 month or 2-2.5 year child health reviews regarding acceptability of home safety promotion and barriers/facilitators to implementing home safety promotion:

a. For service providers in SSBC wards, interviews will include questions on attitudes to home safety promotion, experience of the study training, methods of promoting home safety before and after SSBC, experience of implementing the programme, how they feel parents are receiving the programme, sustainability, how partner agencies have worked together, what helps and hinders them in promoting home safety, what their ideal home safety promotion programme would be and suggestions for improvement.

b. For service providers in control wards, interviews will include questions on attitudes to home safety promotion, methods of promoting home safety, how they feel parents are receiving the standard home safety promotion, sustainability, how partner agencies have worked together, what helps and hinders them in promoting home safety, what their ideal home safety promotion programme would be and suggestions for improvement.

All interviews will last between 30 and 60 minutes and will be digitally recorded. Recordings will be transcribed verbatim. Recordings and transcripts will have an interviewee code as the identifier. For each different type of interview, the first three interviews will be pilot interviews and data from these interviews will be included in the analysis unless they result in substantial amendments to the interview guide.

Observations of 9-12 month and 2-2.5 year child health reviews

To assess content of the home safety promotion, discussion of home safety in relation to child development, resources used, referrals made, services signposted to and adherence to principles of behaviour change. Nottingham CityCare will check vital status of the child, residence not at their usual residence and change of address prior to any invitations being sent. If a parent and child have moved to a new address, the researcher will telephone or email the parent, using the contact details the parent has provided the study team with, and ask for the new address details before sending the invitation.

Extraction of data from primary and secondary care medical records

To validate parental self-reported medically attended injuries and to collect data on resource use (services provided (e.g. 9-12 month child health review, 2-2.5 year child health review, any recorded discussion of home safety, post-accident contacts, referral to other services) and treatment of medically attended injuries).

Aggregated ward level data on emergency department attendances at Nottingham University Hospitals NHS Trust

For unintentional injuries in children aged under five years in SSBC and control wards.

The timing of data collection for each endpoint and the tools used are shown in table 1 below.

Table 1: Timing and methods of endpoint measurement and data collection tools

Endpoint	**Data collection tool**	**0**	**3**	**6**	**6-9**	**9**	**12**	**13**	**15**	**18**	**21**	**24**	**26**	**36**
Endpoint 1:At least one fitted and working smoke alarm, a safety gate on stairs and poisons stored out of reach	Parent home safety questionnaire	x					x					x		
Endpoint 2a. Parent-reported medically attended home injury rates	Parent home safety questionnaire	x					x					x		
	Parent injury questionnaire		x	x		x			x	x	x			
	Validation of self-reported injuries from medical records												x	
Endpoint 2a. Injuries attended to in the Emergency Department or admitted to hospital at electoral ward level	Electoral ward level data from Nottingham University Hospitals NHS Trust													x
Endpoint 2b. Other home safety practices	Parent home safety questionnaire	x					x					x		
Endpoint 2c. Extent to which home safety promotion differs between SSBC and control wards:	Observations of 9-12 month and 2-2.5 year child health review	x	x	x	x	x	x	x	x	x	x	x	x	x
	Parent home safety questionnaire	x					x					x		
	Validation of parent reported home safety services from medical records												x	
Endpoint 2d. parental knowledge of child development and child injury risk	Parent home safety questionnaire	x					x					x		
Endpoint 2e. Parental self-efficacy to prevent injuries to their children	Parent home safety questionnaire	x					x					x		
	Parent interviews	x	x	x	x	x	x	x	x	x	x	x	x	x

Endpoint	**Data collection tool**	**0**	**3**	**6**	**6-9**	**9**	**12**	**13**	**15**	**18**	**21**	**24**	**26**	**36**
Endpoint 2f. Acceptability of and satisfaction with home safety promotion amongst parents														
	Parent interviews (amended 9-12 month child health review)							x	x	x	x	x	x	x
	Parent home safety questionnaire	x					x					x		
Endpoint 2g. Acceptability of and satisfaction with home safety promotion amongst providers:	Provider interviews (those that conduct 9-12 month or 2-2.5 year child health reviews)	x	x	x	x	x	x	x	x	x	x	x	x	x
	Provider interviews (those that don't conduct 9-12 month or 2-2.5 year child health reviews)	x	x	x	x	x	x	x	x	x	x	x	x	x
Endpoint 2h. Barriers and facilitators to changing home safety behaviours amongst parents	Parent interviews	x	x	x	x	x	x	x	x	x	x	x	x	x
Endpoint 2i. Barriers and facilitators to implementing home safety promotion amongst providers	Provider interviews (those that conduct 9-12 month or 2-2.5 year child health reviews)	x	x	x	x	x	x	x	x	x	x	x	x	x
	Provider interviews (those that don't conduct 9-12 month or 2-2.5 year child health reviews)	x	x	x	x	x	x	x	x	x	x	x	x	x
Endpoint 2j: Cost-effectiveness:	Parent –reported services received and resource use for injuries measured from parent home safety questionnaire	x					x					x		
	Parent-reported resource use for injuries measured from parent injury questionnaire		x	x		x			x	x	x			

Endpoint	**Data collection tool**	**0**	**3**	**6**	**6-9**	**9**	**12**	**13**	**15**	**18**	**21**	**24**	**26**	**36**
	Resource use for injuries and services provided measured from medical records												x	
	Services provided measured from provider activity questionnaire				x							x		
	Observations of 9-12 month and 2-2.5 year child health reviews	x	x	x	x	x	x	x	x	x	x	x	x	x

To thank them for their time, parents will be given a gift voucher for use in local shops on return of each completed home safety questionnaire: £5 for the baseline questionnaire, £10 for the 12 month questionnaire and £10 for the 24 month questionnaire. Parents completing all 6 injury questionnaires will be sent a £5 voucher after completing the first three injury questionnaires and a further £5 voucher after completing the final three injury questionnaires.

Study regimen

The study regimen is described in

Figure 1 below. Month 0 is September 2017. Study participants will include parents and service providers. Service providers include health visiting team members, family mentors and early year's staff. Service providers in SSBC wards will receive in-service training on evidence-based child home safety promotion prior to month 0 and will commence service delivery at month 1. Control wards will continue to provide their usual care. The home safety promotion will include home safety advice tailored to the child's age and stage of development at routine child health reviews, post-accident contacts, family mentor contacts and other contacts, signposting or referral to other services as appropriate (e.g. fire and rescue service for home fire risk assessments, Nottingham Safer Homes team for families in rented accommodation who have housing safety issues, to safety equipment schemes etc.), home safety advice and home safety sessions provided by early years staff in children's centres and child safety week events.

Parents will complete baseline, 12 and 24 month home safety questionnaires, plus injury questionnaires at 3, 6, 9, 15, 18 and 21 months. A sample of parents will be invited to face to face or telephone interviews regarding home safety promotion. A sample of parents from SSBC wards will be invited to telephone interviews regarding the amended 9-12 month child health review. A sample of parents will be invited to face to face or telephone interviews specifically regarding their child's post-accident contact. A sample of parents will have their child's 9-12 month and 2-2.5 year child health reviews observed by members of the research team. A sample of parents will have data extracted from their child's medical records to assess service provision, resource use and medically attended injury occurrence.

Home safety promotion by SSBC and control service providers will be assessed by observations of 9-12 month and 2-2.5 year child health reviews. A sample of service providers who conduct 9-12 month or 2-2.5 year child health reviews will be invited to face to face or telephone interviews regarding home safety promotion and post-accident contacts. A sample of service providers who don't conduct 9-12 month or 2-2.5 year child health reviews will be invited to face to face or telephone interviews regarding home safety promotion.

Aggregated ward level data on emergency department attendances at Nottingham University hospitals NHS Trust amongst children aged under 5 five years for unintentional injuries will be collected for SSBC and control wards for the following years: September 2016 to August 2017, September 2017 to August 2018, September 2018 to August 2019 and September 2019 to August 2020.

Figure 1: Study regimen

	SSBC wards	Months*	Control wards	
EVIDENCE BASED HOME SAFETY PROMOTION	Recruit parents Parent home safety questionnaire	0	Recruit parents Parent home safety questionnaire	USUAL CARE
	Parent injury questionnaire	3	Parent injury questionnaire	
	Observations of 9-12 month child health reviews	0-36	Observations of 9-12 month child health reviews	
	Parent injury questionnaire	6	Parent injury questionnaire	
	Parent interviews re. home safety promotion Service provider interviews re. home safety promotion (those who provide child health reviews)	0-36	Parent interviews re. usual care home safety promotion Service provider interviews re. usual care home safety promotion (those who provide child health reviews)	
	Parent injury questionnaire	9	Parent injury questionnaire	
	Parent home safety questionnaire	12	Parent home safety questionnaire	
	Parent interviews re. amended 9-12 month child health review	13-30		
	Parent injury questionnaire	15	Parent injury questionnaire	
	Parent injury questionnaire	18	Parent injury questionnaire	
	Parent interviews re. home safety promotion Service provider interviews re. home safety promotion (those who provide child health reviews and those who do not)	0-36	Parent interviews re. usual care home safety promotion Service provider interviews re. usual care home safety promotion (those who provide child health reviews and those who do not)	
	Observations of 2-2.5 year child health reviews	0-36	Observations of 2-2.5 year child health reviews	
	Parent injury questionnaire	21	Parent injury questionnaire	
	Parent home safety questionnaire	24	Parent home safety questionnaire	
	Medical record data extraction	26	Medical record data extraction	
	Collection of emergency department attendance data	36	Collection of emergency department attendance data	

*Months refers to months post recruitment of first cohort of patients. Month 0 is September 2017.

Compliance

Compliance will not be measured in this research study as it is evaluating the implementation of home safety promotion delivered as part of usual care.

Criteria for terminating study

Early termination of the research study is not anticipated as it is evaluating the implementation of home safety promotion delivered as part of usual care.

Statistics

Methods

Analysis of quantitative data will commence following the collection of the last questionnaires from participants and will be performed by researchers who will be blinded to group allocation.

Characteristics of families in the SSBC and control wards will be compared at baseline using descriptive statistics.

Primary outcome

Endpoint 1:

The proportion of families with at least one fitted and working smoke alarm, and a safety gate on stairs (where applicable) and storing poisons out of reach will be described and compared between SSBC and control wards at 12 and 24 months post recruitment using multilevel logistic regression, with family at level 1 and ward at level 2. Analyses will adjust for:

a. matching by adding a fixed effect term indicating the matched-pair of wards
b. having at least one fitted and working smoke alarm, and a safety gate on stairs (where applicable) and storing poisons out of reach at baseline
c. other family level variables imbalanced at baseline

If models do not converge we will simplify the model by omitting the fixed effect term for matched-pair wards. A sensitivity analysis will be conducted excluding families who move from SSBC to control wards and vice-versa during the 24 month follow-up period. These latter two points also apply to all secondary outcomes analysed using multilevel regression modelling, but are not reiterated below to prevent repetition.

Secondary outcomes

Endpoint 2a:

<u>Medically attended child home injury rates (all injuries attending primary or secondary care)</u>

The rate of injuries in the index child will be described and compared between SSBC and control wards at 12 and 24 months post recruitment using multilevel Poisson or negative binomial regression, with children at level 1 and ward at level 2. Analyses will adjust for:

a) matching by adding a fixed effect term indicating the matched-pair of wards
b) the baseline injury rate (rate in the three months prior to being recruited to this study)

c) other family level variables imbalanced at baseline

Medically attended home injuries, by type of attendance

a) Primary care attendances for home injuries

b) Emergency department attendances for home injuries

c) Hospital admissions for home injuries

The rate of injuries in the index child will be described and compared between SSBC and control wards at 12 and 24 months post recruitment using multilevel Poisson or negative binomial regression, with children at level 1 and ward at level 2. Analyses will adjust for:

a) matching by adding a fixed effect term indicating the matched-pair of wards

b) the baseline injury rate (rate in the three months prior to being recruited to this study)

c) other family level variables imbalanced at baseline

Validation of parent reported medically attended injuries

Parent reported medically attended injuries will be compared with injuries recorded in the medical records by calculating kappa coefficients and 95% confidence intervals and sensitivity, specificity and predictive values, assuming the medical record is the gold standard

Emergency department attendances at ward level

The injury rate will be calculated for each year using ward level population data for the under-fives as the denominator. Changes in rates will be compared between SSBC and control wards over time using Poisson or negative binomial regression by adding a time by SSBC/control ward interaction term to the model.

Endpoint 2b:

Other home safety practices

The proportion of families with other home safety practices will be described and compared between SSBC and control wards at 12 and 24 months post recruitment using multilevel logistic regression, with family at level 1 and ward at level 2. Analyses will adjust for:

a) matching by adding a fixed effect term indicating the matched-pair of wards

b) baseline value of the outcome variable

c) other family level variables imbalanced at baseline

Endpoint 2c:

Home safety promotion

This will be described for SSBC and control wards in terms of:

1) The proportion of families with a record of home safety promotion in their medical record, including at 9-12 month and 2-2.5 year child health reviews, post-accident visits and at other contacts. Quantitative comparisons will not be made between SSBC and control wards as numbers will be small.

2) Observations of home safety promotion in terms of the content of the home safety promotion, whether home safety topics were discussed in relation to child development, what resources

were used in the discussion, what referrals were made, which services parents were signposted to and adherence to the principles of behaviour change recommended for individual level interventions by NICE[24]. Quantitative comparisons will not be made between SSBC and control wards as numbers will be small.

3) The proportion of parents reporting receiving home safety advice at 12 and 24 months. This will be compared between SSBC and control wards using multilevel logistic regression, with family at level 1 and ward at level 2. Analyses will adjust for:

   a) matching by adding a fixed effect term indicating the matched-pair of wards

   b) baseline value of the outcome variable

   c) other family level variables imbalanced at baseline

Endpoint 2d:

The parental knowledge of child development and injury risk score will be described and compared between SSBC and control arms using multilevel linear regression, with family at level 1 and ward at level 2.

Endpoint 2e:

Parental self-efficacy for home safety will be described and compared between SSBC and control wards using means (SD) or medians (IQR) for the self-efficacy scale and multilevel linear regression with family at level 1 and ward at level 2.

Endpoints 2f to 2i:

The following secondary outcomes will be assessed qualitatively:

- Acceptability of home safety promotion to parents, and barriers and facilitators to changing home safety behaviours
- Acceptability of home safety promotion to providers, and barriers and facilitators to implementing home safety promotion
- Acceptability of post-accident contact for parents and providers
- Acceptability of amended 9-12 month child health review for parents in SSBC wards

Analysis of qualitative interviews will occur on an ongoing basis throughout the study. Interviews will be digitally recorded, transcribed verbatim and analysed using thematic analysis, following the guidelines prescribed by Braun and Clarke[30]. Coding will be independently validated by a second researcher. The same researcher will conduct and analyse the interviews, meaning that they will not be blinded to group allocation. For each type of interview (e.g., regarding the post-accident contact, or regarding the amended 9-12 month child health review), the first three interviews will be pilot interviews and data from these will be included in the analysis unless they result in substantial amendments to the interview guide.

Endpoint 2j:

We will use a NHS and Personal Social Services perspective. Only direct (e.g. healthcare, NHS staff) and indirect (e.g. travel expenses) to the NHS will be included. Costs will be calculated to the 2016-2017 price year once the National Schedules for NHS Reference Costs and Unit Costs of Health and Social Care (PSSRU) have been released. Costs will be split into two areas; intervention costs and healthcare costs. Where possible, costs relating to both the intervention and healthcare will be ascribed to individual families.

Intervention costs are costs associated with the delivery of the experimental and comparator interventions. Where possible, a 'bottom up' micro-costing approach will be adopted. NHS Reference Costs and PSSRU costs will be specified for (but not exhaustively):

- Individual appointments with each family
- Average reimbursed travel time
- Salary of staff delivering the intervention
- Any additional time spent in training to deliver the home safety intervention
- Any fitting of home safety equipment if provided by the NHS

Costs will be collected through contact between the health economist and the individual teams delivering these services for both SSBC wards and control wards. Where possible, individual components of costs will be summed based on activity reported for each individual family, however, if this is not possible, we will assume an average provision of service and apply this cost. Costs will be summed to give the total intervention cost for the SSBC and control interventions separately. From this, an expected mean cost and associated 95% confidence interval for SSBC and control will then be estimated.

Healthcare costs are costs associated with any healthcare required by a child during the study period associated with a preventable injury. This will include any General Practitioner visits, prescriptions, outpatient visits, inpatient stays, and Accident and Emergency attendances. Costs will be ascribed using a 'Top down' approach, using NHS Reference Costs and PSSRU costs. Primary data regarding a child's injury will be collected the child's medical records as taken from a sample of 100 parents (50 from SSBC wards and 50 from control wards) who have granted their permission. This will allow accurate estimation of treatment required for the injury. Amongst families where permission has not been granted or sought, if there is specific information regarding the injury reported in the parent's questionnaire, this will be used as the next best form of information to determine which treatments should be costed. If the parent questionnaire does not specify the injury, an average cost based on the sample data from medical records will be applied as a proxy. Data on each family will be collated to estimate expected mean cost and 95% confidence intervals.

An incremental cost-effectiveness analysis will be performed[31] , using a time horizon of two years. Service provision and healthcare costs will be combined to estimate an expected mean total cost. There will be two measures of effectiveness; (a) the number of families with the three key safety practices (see primary endpoint) and (b) the number of injuries prevented amongst children. The primary outcome measures will be the incremental cost per additional family the three key safety practices and incremental cost per injury prevented amongst children. To control for uncertainty, a probabilistic sensitivity analysis will be performed using bootstrapping on costs and effectiveness[32], with output including cost-effectiveness scatterplots and cost-effectiveness acceptability curves. Analyses will take account of under or over-reporting of service use and injury related healthcare utilisation ascertained from the validation of self-reported data described above

Sample size and justification

Sample size calculations were based on a control group prevalence of the primary outcome measure of 54% (having at least one smoke alarm, and a safety gate in the home (if applicable e.g. if stairs present) and storing poisons out of reach). This estimate is from a previous study by the investigators[33]. Assuming 80% power, a 2-sided 5% significance level and an absolute difference of 13% points in the prevalence of the primary outcome, 237 families are required in the SSBC wards and 237 in control wards. This number (n=237) would provide 90% power (2-sided 5% significance

level) to detect an absolute difference of 15% points in the prevalence of the primary outcome measure between SSBC and control wards.

Mid-year population estimates from 2013 indicate there were 1047 children aged under 1 year in SSBC wards and 909 in control wards. To allow for losses to follow up 400 families will be recruited from SSBC and 400 from control wards (minimum follow up rate of 60%)[34]. Allocation is at electoral ward level. The ICC for electoral ward level smoke alarm ownership is <0.00001[35]. Hence the design effect is effectively 1, and the sample size adjusting for clustering is the same as that unadjusted for clustering.

We anticipate achieving data saturation for qualitative interviews with the number of interviews described above[36].

Assessment of efficacy

Not applicable as the research study is evaluating the implementation of home safety promotion delivered as part of usual care.

Assessment of safety

No adverse events are anticipated in this research study as it is evaluating the implementation of home safety promotion delivered as part of usual care.

Procedures for missing, unused and spurious data

The main analysis will be a complete case analysis. Missing data may be imputed using multiple imputation techniques depending on the amount of missing data and the pattern of missing data.

Definition of populations analysed

The full analysis set will be all parents with data on the primary endpoint available.

Adverse events

Adverse events are not expected to occur as a result of participating in the research study and no adverse event data will be collected as the research study is evaluating the implementation of home safety promotion delivered as part of usual care.

Ethical and regulatory aspects

Ethics committee and regulatory approvals

The study will not be initiated before the protocol, informed consent forms and participant information sheets have received approval / favourable opinion from the Health Research Authority. Should a protocol amendment be made that requires HRA approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the HRA. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the HRA are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

Informed consent and participant information

The process for obtaining participant informed consent will be in accordance with the HRA guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. Signed informed consent forms or digitally recorded verbal informed consent over the telephone will be required for parents and service providers taking part in study interviews. Signed consent forms will be required for parents and service providers agreeing to have 9-12 month and 2-2.5 year child health reviews observed and for parents providing access to medical records for collection of data on service provision and resource use. For written informed consent, the investigator/researcher and the participant shall both sign and date the informed consent form before the person can participate in the interviews, observations or before medical records can be accessed. As previously mentioned, completion, and subsequent return, of questionnaires by the participants will be taken as informed consent and separate written informed consent will not be sought for this part of the study.

Parents and service providers will receive a copy of the signed and dated consent forms and the original will be retained in the Study Master File. A second copy of parent consent forms will be sent to Nottingham CityCare to be filed in the child's medical notes.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to parents that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future access to services provided by Nottingham CityCare (for family participants), or loss of benefits to which the participant is otherwise entitled. There are no study-specific interventions as the research study is evaluating the implementation of home safety promotion delivered as part of usual care.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

Records

Case Report Forms

Each parent will be assigned a unique identification code (UIC) for use on study forms and documents (including interview transcripts), and the electronic database. The code will consist of:

- Two letters at the start to identify the ward of residence
- C1, C2 or C3 to identify the cohort they were recruited in
- A 4 digit number which is their ID number starting at 0001

Each service provider will be assigned a unique identification code (UIC) for use on study forms and documents (including interview transcripts), and the electronic database. The code will consist of:

- Two letters at the start to identify the ward they work in
- 1 letter for the service they provide
- A four digit number which is their ID number starting at 0001.

Study forms, documents, audio recordings and data will be treated as confidential documents and held securely in accordance with regulations. The research team will make a separate confidential record of the parent's name, date of birth, address and UIC and of service provider names, the service they provide, work address and UIC to permit identification of all participants enrolled in the study, in accordance with regulatory requirements and for follow-up as required.

Study forms and documents shall be restricted to those personnel approved by the Chief Investigator and recorded on the study records.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialed and dated.

The Chief Investigator shall sign a declaration ensuring accuracy of data recorded in the study forms and interview transcripts.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, questionnaires, consent forms, interview audio recordings, transcripts, 9-12 month and 2-2.5 year child health review checklist and data extracted from medical records. A CRF may also completely serve as its own source data. Only study staff as listed on the Delegation Log shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The CRF and all source documents, including progress notes shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities (e.g. DH).

Data protection

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The CRF will only collect the minimum required information for the purposes of the study. CRFs, consent forms, questionnaires, audio recordings, interview transcripts, child health review checklists and contact details will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and relevant regulatory authorities (see above). Computer held data including the study database and interview transcripts will be held securely and password protected. All data will be stored on a secure dedicated web server at the University of Nottingham. Access will be restricted by user identifiers and passwords.

Information about the study in the medical records of the child of participating parents will be treated confidentially in the same way as all other confidential medical information.

Electronic data saved on the University hard drives will be backed up every 24 hours.

The online questionnaires which will be developed for parents will use a web-based survey tool, for example SurveyMonkey, Bristol Online Survey, or similar. A copy of the data protection and security information from the tool's website will be obtained and stored in the study master file. These tools display their data security, back-up and encryption information on their websites.

Quality assurance and audit

Insurance and indemnity

Insurance and indemnity for study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical study's insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

Study conduct

Study conduct may be subject to systems audit of the Study Master File for inclusion of essential documents; permissions to conduct the study; Study Delegation Log; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, correct randomisation, timeliness of visits); adverse event recording and reporting; accountability of study materials and equipment calibration logs.

The Study Coordinator/Academic Supervisor, or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made to the Study Steering Committee.

Study data

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator/Academic Supervisor, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the study database will be checked. Where corrections are required these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by REC as required.

The data collected as part of the service evaluation will be analysed and reported with the results of the study data.

Record retention and archiving

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The Study Master File and study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all study databases and associated meta-data encryption codes.

Discontinuation of the study by the sponsor

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the Study Steering Committee and Data Monitoring Committee as appropriate in making this decision.

Statement of confidentiality

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

Publication and dissemination policy

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.

User and public involvement

SSBC has an active patient and public involvement programme and a number of “parent champions”. In collaboration with Nottingham CityCare, two meetings have been held with 18 parents of young children living in SSBC wards to advise the research team on the importance of research on child home safety and the research questions within this proposal, and to obtain advice about key elements of the research design. In addition, four further meetings have been held with SSBC community partnership members (parents, parent champions and service providers) to advise on recruitment strategies and study documentation. We have recruited four parent champions to sit on our project steering group who will provide advice on study recruitment, study documentation, interpretation of findings and dissemination of study findings to parent participants and the wider community of parents.

Study finances

Funding source

This study is funded by the Big Lottery. The funding is held by Nottingham CityCare Partnership as part of the Small Steps Big Change project.

Participant stipends and payments

Participants will not be paid to participate in the study. To thank them for their time, parents returning completed questionnaires will be given a gift voucher for each completed home safety questionnaire (£5 for the baseline questionnaire, £10 for the 12 month questionnaire and £10 for the 24 month questionnaire), a £5 voucher for completing the first three injury questionnaires and a £5 voucher for completing the final three injury questionnaires. Parents agreeing to have their child's 9-12 month and 24 month child health reviews observed and those participating in interviews will be given a £20 gift voucher to thank them for their time.

Signature pages

Signatories to Protocol:

Chief Investigator: (name)__Professor Denise Kendrick_____

Signature:_____

Date: __19/09/2019_____

Co- investigator: (name) __Dr Elizabeth Orton_____

Signature:__ _____

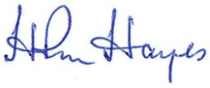
Date: _19/09/2019_____

Co- investigator: (name) __Dr Michael Watson_____

Signature:___  _____

Date: __30/05/17_____

Co- investigator: (name) __Dr Mike Hayes_____

Signature:___  _____

Date: __30/05/17 _____

Co- investigator: (name) ___Dr Matthew Jones_____

Signature:___  _____

Date: __01/06/17_____

Study Statistician: (name)__Professor Carol Coupland_____

Signature:___  _____

Date: _31/05/17_____

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