Evaluation of the effectiveness, implementation and cost-effectiveness of the Stay One Step Ahead home safety promotion intervention for pre-school children: a study protocol

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EO, DK, MW, MH, MJ, CC, HC designed the main study methods, data analysis plan and data collection tools. MJ led the design of the economic study and its data collection tools with input from all other authors. CT and HC prepared documentation for the ethics committee. EO, DK and MW drafted the manuscript with revisions additionally from MH, MJ, CC, CT, TP and HC. EO is guarantor of the manuscript.

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Abstract

Background

Unintentional injuries in children under 5 commonly occur in the home and disproportionately affect those living in disadvantaged circumstances. Targeted home safety promotion should be offered to families most at risk but there is a paucity of standardised evidence-based resources available for use across family-support practitioners.

Objective

To assess the effectiveness, implementation and cost-effectiveness of a 2-year home safety programme (Stay One Step Ahead) developed by parents, practitioners and researchers, and delivered by a range of family support providers in inner-city localities, compared to usual care in matched control localities.

Methods

Parents of children aged 0-7 months will be recruited to a controlled before and after observational study. The primary outcome is home safety assessed by the proportion of families with a fitted and working smoke alarm, safety gate on stairs (where applicable) and poisons stored out of reach, assessed using parent-administered questionnaires at baseline, 12 and 24 months.

Secondary outcomes include: the impact on other parent-reported safety behaviours, medicallyattended injuries, self-efficacy for home safety and knowledge of child development and injury risk using questionnaires and emergency department attendance data; implementation (reach, acceptability, barriers, facilitators) of home safety promotion assessed through interviews and observations; and cost-effectiveness using medically-attended injury costs ascertained from healthcare records.

Conclusions

If shown to be effective and cost-effective this study will provide a practical resource to underpin national guidance. The study could inform public health prevention strategies to reduce home injury in children most at risk, whilst delivering cost savings to health and care services.

Introduction

Unintentional injuries represent a significant cause of childhood morbidity and mortality. [1, 2] Globally more than 270,000 children under the age of 5 years lose their lives every year to injuries[3]. Importantly, the burden of injury falls unequally whereby children in low-income countries and those from poorer neighbourhoods in high-income countries are the most vulnerable.[4-6]

In England, each year unintentional injuries in children aged under 5 result in an estimated 370,000 visits to emergency departments and approximately 40,000 emergency hospital admissions.[7] The vast majority of these injuries occur in the home[6] and are non-fatal; however they are still responsible for approximately 55 deaths per year.

Injuries have an immediate physical effect on the child and may also result in longer term consequences. For example, injuries like burns and scalds may lead to scarring and deformities and impact on the child's psychological and social wellbeing.[5, 7] A major injury resulting in a disability will also have a large impact on family life and may lead to financial constraints, family tension and effects on mental health.[8, 9]

A number of risk factors play a role in determining unintentional injury rates in children. 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 also associated with higher unintentional injury rates, [11] potentially explained in part by difficulties in accessing, installing and utilising safety equipment.[12, 13] Parental factors associated with higher rates of unintentional injury include young maternal age at the time of delivery,[11, 14] single-parent families,[15-17] and parental mental health problems.[16-18]

In England, the National Institute for Health and Care Excellence (NICE) has published public health guidelines on the prevention of unintentional injuries amongst those less than 15 years of age with specific recommendations being made for child home safety.[19] More recently NICE has endorsed an Injury Prevention Briefing (IPB) for practitioners, linked to the guidelines. [20] The target audiences for the IPB are managers and practitioners of organisations such as family support centres known as children's centres in the UK, public health nursing teams referred to health visiting teams in the UK, other family support agencies, and fire and rescue services.

Systematic review evidence from the Cochrane Collaboration have found that home safety interventions most commonly delivered to parents in the home, including education and in some

cases also including safety equipment provision are successful in improving safety practices in the home and may also help to reduce rates of injuries.[21]

Research aims and objectives

This protocol describes a controlled before and after observational research study evaluating the effectiveness and implementation of an evidence-based home safety intervention called Stay One Step Ahead (SOSA).

The study's primary objective is to determine whether implementing systematic evidence-based home safety promotion (the SOSA intervention) 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. This has been chosen as the primary outcome measure as there is evidence that home safety interventions can improve these safety practices and evidence that these safety practices are associated with reductions in injury risk.[21-25]

The secondary objectives are 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 home safety practices other than those included in the primary objective
- c) the extent to which home safety promotion differs between intervention 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
- cost-effectiveness of home safety promotion in the intervention wards compared to control wards

The Stay One Step Ahead Intervention

In 2014, a healthcare organisation (Nottingham CityCare) was awarded a 10 year grant to establish the Small Steps Big Changes (SSBC) programme, aimed at improving the lives and outcomes of young

children. The SSBC programme specifically targets four electoral wards in Nottingham City, chosen on the basis of 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. The SOSA home safety intervention was established as part of the wider SSBC programme.

The SOSA intervention was co-produced by parents, healthcare practitioners and researchers at the University of Nottingham. Development of the intervention is described elsewhere (*paper in preparation*). Practitioners delivering the intervention include health visiting teams, family mentors and children's centre staff. Family mentors are people with a lived experience of parenting, recruited and trained to deliver early intervention sessions about nutrition, language skills and the social and emotional development of babies. [26] Resources in the SOSA intervention include monthly safety messages (key messages on posters and flyers, quizzes and related activities, including those from the Injury Prevention Briefing endorsed by NICE[20]), home safety activities guided by family mentors and a home safety checklist for use by health visiting teams during child health reviews. Families are also invited to safety week activities four times per year that in turn focus on four of the most common causes of injury in young children, namely falls, poisonings, scalds and fires.[27] The home safety checklist incorporates behaviour change principles recommended by NICE to help and support parents make the necessary changes to enhance home safety.[28]

Methods

Study design and arms

This is a non-randomised, controlled before and after (CBA) observational study with nested qualitative and economic evaluations. It is set in nine electoral wards in Nottingham City, England. Intervention wards are the four SSBC wards: Arboretum, Aspley, Bulwell, and St Ann's. Control wards are five non-SSBC wards: Bestwood, Bridge, Clifton North, Clifton South and Sherwood. The control wards were matched to intervention wards based on emergency department injury attendance rates for children aged 0-5 (within 15/1000 of the intervention ward injury rate), followed by deprivation (based on Nottingham city wards ranked (1-20) by income deprivation affecting children), then followed by minimising overlap with health visitor caseloads in intervention wards. The intervention wards were larger than control wards, hence five control wards were needed to ensure similar number of children aged 0-5 years in intervention and control wards. The Bridge and Clifton North wards were adjacent to each other and both were matched to the same intervention ward as they had similar baseline injury rates. The total number of children aged 0-5 years in intervention for the same intervention and control wards were 5118 and 4804 respectively. Baseline injury rates for the combined intervention

and control wards were 237 (95%CI 225,250) and 229 (95%CI 217, 241) respectively. Characteristics of intervention and control wards are shown in table 1.

Intervention ward	2015 injury rate per 1000 children aged 0-5 years	Nottingham city wards ranked by income deprivation affecting children	Control ward	2015 injury rate per 1000 children aged 0-5 years	Nottingham city wards ranked by income deprivation affecting children	Percentage of control ward children receiving health visiting services from health visitors in intervention wards
Arboretum	226	3	Bridge	219	4	8%
			Clifton North	196	19	1%
Aspley	294	1	Clifton South	309	12	1%
Bulwell	157	6	Sherwood	163	16	2%
St Ann's	240	2	Bestwood	248	8	2%

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Recruitment

Parents

Parents or carers (including single parents/carer, hereafter referred to as 'parents') of children aged two to seven months between September 2017 and September 2018 and living in their usual place of residence (i.e. not in temporary accommodation such as a refuge or foster care) at time of recruitment will be invited to take part in the CBA study which is a questionnaire-based study. The age range two to seven months was selected as starting at age two months allows for the child's birth to be registered on the health systems and seven months allows the intervention to start before the first child health review at nine months of age. Those that participate in the CBA study will be invited to take part in nested qualitative interviews, observations and economic evaluation. The inclusion and exclusion criteria are listed in Figure 1.

All parents eligible for inclusion in the study will be assigned a unique study identifier and will be posted a study invitation pack containing an invite letter, information sheet, baseline home safety questionnaire, gift voucher claim form and a freepost reply envelope. To participate in the study and give implied consent, parents will need to complete and return the baseline home safety

questionnaire to the study team. Parents interested in taking part in other areas of the study (interviews, observations, additional injury questionnaires and economic evaluation) will need to tick the relevant box when they return their questionnaire.

Service providers

Family support practitioners eligible to take part in the study include health visiting team members, family mentors and children's centre staff who all have a role in delivering home safety advice to families in the included wards. The inclusion and exclusion criteria are listed in Figure 1. Eligible practitioners will be asked to take part in qualitative interviews and observations of home safety promotion during child health reviews.

Figure 1 Inclusion and exclusion criteria

Parents				
Inclusion criteria				
Controlled before and after study (CBA)				
 Parents of children residing in any of the intervention or control wards 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				
Parents taking part in the CBA study.				

- Able to provide written informed consent or verbal informed consent over the telephone to take part in the interview
- Their child must have had either a 9-12 month or a 2-2.5 year child health review undertaken by health visiting team member.

Observations of home safety promotion

- Parents taking part in the CBA
- Able to provide written informed consent to have their child's health review by health visiting team member observed by a researcher
- 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

- Parents not residing in intervention 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
- Parents deemed not appropriate to contact by SSBC (e.g. child has died, child taken into foster care)

Service providers

Inclusion criteria

Interviews

- Service providers in intervention 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 of home safety promotion

• Service providers (health visiting team staff) in intervention and control wards who provide written informed consent for observations of 9-12 month or 2-2.5 year child health reviews

Exclusion criteria

• 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.

Data collection

CBA home safety questionnaires

Home safety questionnaires will ask parents about their home safety practices, medically attended injuries their child had in the preceding 3 months and any treatment they had received, knowledge of child development and injury risk, self-efficacy to undertake home safety practices, and 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).

There will be three home safety questionnaires in total. Once parents have completed a baseline questionnaire, they will be asked to complete two follow up questionnaires at 12 and 24 months. Parents will receive a £10 high street voucher as a thank you for completing and returning each of the three questionnaires.

Injury questionnaires

Injury questionnaires will ask parents about any medically attended injuries their children had experienced and the treatment they had received in the preceding 3 months. There will be six injury questionnaires in total. Once parents have completed the baseline home safety questionnaire, they will be asked if they would like to complete the additional six injury questionnaires at the following time points post baseline; 3 months, 6 months, 9 months, 15 months, 18 months and 21 months. The same injury questions will be asked on the 12 and 24 month CBA questionnaires, so injury data is collected over a 2 year period. Parents will receive a maximum of £10 in high street vouchers for returning the additional injury questionnaires (allocated as £5 after 3, 6 and 9 months and £5 after 15, 18 and 21 months).

Both the home safety and injury questionnaires will be administered by post, online or by phone, with up to 3 reminders by post, text or telephone. Parents have the option of opting out of receiving follow up questionnaires at any point and an interpreting service will be available for parents who wish to complete the questionnaires in a language other than English.

Emergency Department injury data

Aggregated ward-level data on emergency department attendances by children living in control and intervention wards will be collected between September 2016 and August 2021 from the clinical patient system at Nottingham University Hospitals NHS Trust.

Interviews

Parents

A sample of parents expressing interest in taking part in qualitative interviews in both control and intervention wards will be sent an interview invitation pack containing an invite letter, an information sheet, a reply slip and a freepost reply envelope. This will continue until the required number of interviews have been completed and there is maximum spread of participants across the four study wards. An interview date will be arranged and informed consent obtained. Parents will receive a £20 high street voucher for being interviewed as a thank you for taking part.

Interviews will explore acceptability of, and satisfaction with, home safety promotion received, barriers and facilitators to home safety action, experiences of child home injuries, experiences of the 9-12 month and 2-2.5 year child health reviews, impact of home safety promotion on home safety, sources of home safety advice they have received, what their ideal advice/support would be and suggestions for improving current home safety promotion. For parents who have experienced a post-injury contact from a health visiting team member, interviews will include questions on the incident that led to the contact, subsequent health care received, parental perceptions of the attitudes of healthcare providers at the time of the incident and subsequently, impact of post-injury 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-injury contacts.

Family support practitioners

Interviews will be undertaken with a sample of family support practitioners from the different service providers operating in the intervention and control wards who do (e.g. health visiting team

members) and who do not (e.g. family mentors and children's centre staff) conduct child health reviews. Interviewees will be selected so that there is maximum spread of participants across the four study wards. Service provider managers will be asked to send an interview invitation pack to those eligible, comprising an invite letter, an information sheet, a reply slip and a freepost reply envelope. Practitioners expressing interest in taking part will be telephoned by a member of the research team to discuss the interview in more detail and to answer any questions. An interview date will be arranged and informed consent obtained.

Interviews will cover attitudes to home safety promotion, methods adopted when talking about home safety, parents' perceptions of home safety including after additional post-injury support if applicable, operational issues of working with partner agencies and barriers and facilitators to home safety promotion. Providers in intervention wards will also be asked about their experience of training to deliver the SOSA intervention.

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

To assess the delivery of home safety promotion, observations of 9-12 month and 2-2.5 year child health reviews will be conducted with parent-service provider pairs. First, service provider managers will be asked to send an invitation pack containing an invite letter, an information sheet, a reply slip and a freepost reply envelope to all eligible service providers in the intervention and control wards. Service providers expressing interest will be telephoned 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. Once they have returned their consent form, the research team will export a list of parents that are participating in the CBA study, have expressed interest in taking part in further research and reside in the ward covered by that service provider. To ensure the service provider can identify the children on their caseloads, the list will be anonymised and will contain the participants' unique identifier, the child's date of birth and gender, and their home address. The file will be encrypted and sent to the service provider for them to identify parents that are on their caseloads and are due for either a 9-12 month or 2-2.5 year child health review. These parents will then be invited to take part in the observations by the research team and will be sent a study invitation pack containing an invite letter, information sheet, reply slip and a freepost reply envelope. Those

expressing interest in the observations will be contacted to discuss the study in more detail and to answer any questions that they may have. Parents will be asked to complete a consent form at the time of the child health review and will receive a £20 high street shopping voucher as a thank you for taking part and we will seek to ensure that there is maximum spread of participants across the four study wards.

Economic evaluation

Parents are eligible to take part in the economic evaluation if they are participating in the CBA study, have returned their 24 month home safety questionnaire or reported an injury to their child during the study duration and have expressed interest in taking part in further research. This component of the study includes the validation of self-reported medically attended injuries and the collection of data on service provision and resource use. Eligible parents will be sent an invitation pack containing an invite letter, information sheet, a reply slip and a freepost reply envelope. Those expressing interest in the taking part will be contacted to discuss the study in more detail and to answer any questions that they may have. Parents will be asked to complete and return a consent form and will receive a £10 high street shopping voucher as a thank you for taking part. Recruitment will stop once 50 parents from intervention and 50 parents from control wards have been recruited.

Medical records data

Primary Care (GP) practices of parents wishing to participate in the economic evaluation will be recruited to take part in the data extraction from medical records. Extracted data will be used to validate parental self-reported medically attended injuries and to collect data on resource use e.g. treatment of injuries.

DATA ANALYSIS

Primary outcome

The proportion of families with a safe home as defined by having 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 intervention and control wards at 12 and 24 months post recruitment using multilevel logistic regression, with family at level 1 and ward at level 2. For safe smoke alarms, we define as at least one smoke alarm fitted and reported as working. For safe stairs, we define as safe if there is a safety gate at the top <u>or</u> bottom of the stairs, or where there are no stairs. For safe storage of poisonings, we define this either storing poisonous products at any height so long as there are cupboard locks on, or above eye level only with or without cupboard locks on.

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

If models do not converge we will simplify the model by omitting the fixed effect term for matchedpair wards. A sensitivity analysis will be conducted excluding families who move from intervention 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

a) Medically attended child home injury rates

Parent reported home injuries

Using parent self-reports from questionnaires, the rate of injuries in the index child will be described and compared between intervention 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 matching by adding a fixed effect term indicating the matched-pair of wards, the baseline injury rate (rate in the three months prior to being recruited to this study), and other family level variables imbalanced at baseline.

Injury rates will be analysed by type of attendance including primary care attendances, emergency department attendances and hospital admissions for home injuries. The rate of injuries in the index child will be described and compared between intervention 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 matching by adding a fixed effect term indicating the matched-pair of wards, the baseline injury rate (rate in the three months prior to being recruited to this study), and other family level variables imbalanced at baseline.

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 quarter (3 months) using ward level population data for the under-fives as the denominator. Changes in rates will be compared between intervention and control wards over time using Poisson or negative binomial regression by adding a time by intervention/control ward interaction term to the model.

b) Other home safety practices

The proportion of families with home safety practices other than the primary outcome practices will be described and compared between intervention 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 matching by adding a fixed effect term indicating the matched-pair of wards, baseline value of the outcome variable and other family level variables imbalanced at baseline.

c) Home safety promotion

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

- 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, during post-injury visits and at other contacts. Quantitative comparisons will not be made between intervention 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[29]. Quantitative comparisons will not be made between intervention 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 intervention and control wards using multilevel logistic regression, with family at level 1 and ward at level 2. Analyses will adjust for matching by adding a fixed effect term indicating the matched-pair of wards, baseline value of the outcome variable and other family level variables imbalanced at baseline.

d) Parental knowledge of child development and injury risk score

These will be described by summing the total number of correct answers into a single score and describing the mean (SD) or median (IQR) score and compared between intervention and control arms using multilevel linear regression, with family at level 1 and ward at level 2.

e) Parental self-efficacy for home safety

This will be described and compared between intervention 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.

f) Other secondary outcomes

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-injury contact for parents and providers
- Acceptability of amended 9-12 month child health review for parents in intervention 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-injury 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.

j) Cost effectiveness

We will use a NHS and Personal Social Services perspective. Only direct (e.g. healthcare, NHS staff) and indirect (e.g. travel expenses) costs to the NHS will be included. Costs will be calculated to the 2018-2919 price year using the National Schedules for NHS Reference Costs and Unit Costs of Health and Social Care (PSSRU). 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 intervention and control/usual care 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

Costs will be collected through contact between the health economist and the individual teams delivering these services for intervention 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 intervention and control wards separately. From this, an expected mean cost and associated 95% confidence interval for intervention and control wards 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 Emergency Department 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 from the child's medical records for a sample of 100 parents (50 from intervention 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 outcome) and (b) the number of injuries prevented amongst children. The primary outcome measures will be the incremental cost per additional family with 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

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.

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

Sample size calculation

CBA study

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 data 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 intervention 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 intervention wards and 909 in control wards. To allow for losses to follow up 400 families will be recruited from intervention 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.

Interviews

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

1) Parents

For the home safety promotion interviews, 20 parents will be recruited in total; 10 from intervention wards and 10 from control wards. Maximum variation sampling will be used to ensure variation in ward, child age and gender and separate sampling frames will be drawn up for intervention and control wards.

2) Service providers

Separate sampling frames will be drawn up for the two types of interviews.

For service providers that <u>do</u> conduct child health reviews, maximum variation sampling will be used to ensure variation in type of child health review (9-12 month or 2-2.5 year), service provider, type of post-injury contact (face to face or phone if service providers provide post-injury contacts) and ward. Separate sampling frames will be drawn up for intervention and control wards. Service providers expressing interest will be entered into the relevant sampling frame and sampling will continue until 5 providers from intervention wards and 5 providers from control wards have been recruited who provide variation as described above. For service providers that <u>do not</u> conduct child health reviews, maximum variation sampling will be used to ensure variation in service provider, and ward. Separate sampling frames will be drawn up for intervention and control wards. Service providers expressing interest will be entered into the sampling frame and sampling will continue until 9 providers from intervention wards and 4 from control wards have been recruited who provide variation as described above.

Observations

Up to 10 service provider-parent pairs will be recruited from intervention wards and up to 10 from control wards for observation of the 9-12 month or 2-2.5 year child health reviews. 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 intervention and control wards.

Economic evaluation

We aim to recruit 100 families to the economic evaluation, 50 from intervention wards and 50 from control wards.

Patient and public involvement and engagement

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 intervention 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.

Timescale

Participant recruitment started in September 2017 and will be completed in December 2020.

Discussion

Delivery of home safety support and advice can be variable as standardised evidence-based resources and practice are not readily available in England. Whilst there is good evidence that parents can make their homes safer following support from health visiting teams,[37-39] the role of other family support practitioners such as family mentors and children's centre staff is less well understood. This study will examine the implementation, effectiveness and cost-effectiveness of a

standardised home safety programme (Stay One Step Ahead) delivered over a 2 year period in four socio-economically disadvantaged localities in Nottingham, England, and compare outcomes with matched localities that did not implement the programme.

Strengths of our study include co-production of an evidence-based standardised home safety intervention for delivery by a range of service providers and the use of a mixed-methods approach to quantitatively and qualitatively evaluate implementation, effectiveness and cost-effectiveness. As the SOSA intervention is embedded within an existing service it was not possible to randomly allocate wards to be intervention or control wards. We therefore matched control wards on baseline injury rates and these are similar to those in intervention wards. However, as a result of the selection of wards for the SSBC programme, control wards are inevitably less disadvantaged than intervention wards. The organisation of health visiting services is also complex, and although we chose control areas with the smallest overlap of caseloads with intervention areas, control areas still have a small percentage of families receiving health visiting services from intervention ward health visitors. It is therefore possible that a small percentage of control families may receive the health visiting part of the intervention.

This study has the potential to support injury prevention strategies to reduce home injuries to children in socio-economically disadvantaged areas. Results of the study would be used to provide further evidence and resources to underpin national guidelines.

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