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Cost-effectiveness of the 'Stay One Step Ahead' Home Safety programme for the prevention of injuries among children under 5 years

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ABSTRACT

Background Unintentional injuries are a common cause of morbidity and mortality in the under-5s, but undertaking home safety practices can reduce injury risk. Stay One Step Ahead (SOSA) is an evidence-based standardised home safety programme. This study evaluates the cost-effectiveness of SOSA versus usual care in Nottingham, UK.

Methods Cost-effectiveness analysis from a National Health Service and personal social services perspective. SOSA activity data, injury occurrence and associated short-term healthcare costs were collected within a controlled before-and-after study from 2017 to 2020. The primary outcome was the incremental cost-effectiveness ratio (ICER) per additional home adopting three key safety practices (working smoke alarm, safe poisons storage and fitted stair gate). Secondary outcomes were ICERs per injury avoided and quality-adjusted life-years (QALYs) gained.

Results SOSA costs £30 per child but reduces short-term healthcare expenditure by £42. SOSA increased the number of homes with three key safety practices by 0.02 per child, reduced injuries per child by 0.15 and gained 0.0036 QALYs per child. SOSA was dominant as it was cheaper and more effective than current practice. ICERs were –£590 per additional home deemed safe, –£77 per injury avoided and –£3225 per QALY gained. Focusing on healthcare expenditure alone, SOSA saved £1.39 for every pound spent.

Conclusions SOSA is a cost-saving intervention. Commissioners should consider implementing SOSA.

INTRODUCTION

Unintentional injuries are a common cause of morbidity and mortality in 0–5 years.¹ Most of these injuries occur in the home environment and are preventable.^{2,3} The most frequently occurring avoidable causes are falls, unintentional poisonings and scalds.¹ Injuries from these causes are associated with considerable costs, both to the affected families and to health services.⁴

Injury risks can be reduced by safety practices which may involve modifying homes or undertaking certain safety behaviours. Many of these safety practices can be improved through educational interventions.⁵ Examples of these that have the strongest evidence for effectiveness include having a fitted and working smoke alarm; storing household

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Unintentional injuries among children under 5 years old are a common cause of morbidity and mortality. Multicomponent interventions to reduce injuries have been shown to be effective but not cost-effective.

WHAT THIS STUDY ADDS

⇒ The multicomponent intervention was found to be more effective at making homes safer, reducing injuries and increasing health. The intervention cost was smaller than healthcare savings resulting from the intervention. The intervention was cost saving.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Funders should commission evidence-based multicomponent interventions for preschool children as they are cost saving.

poisons (cleaning products and medications) out of children's reach; and having a stair gate (also known as a safety gate) on stairs.^{5–11} Though some types of intervention are effective in improving home safety or reducing the risk of injury,⁵ their cost-effectiveness may vary.^{12–14} Providing robust economic evaluations, therefore, is crucial in informing child injury prevention strategies, policies and funding decisions.^{15,16} Current guidance in England and Wales recommends that health and social care services provide safety advice, home safety assessments or safety equipment to families whose children are at increased risk of injury,¹⁷ but there is a lack of consistent implementation.⁶

The Stay One Step Ahead ('SOSA') programme is a multicomponent intervention that was implemented in Nottingham City in electoral wards with high levels of health, social and educational needs.¹⁸ The purpose of SOSA was to increase home safety practices and reduce child injuries within these electoral wards. The aim of this study was to estimate the cost-effectiveness of the SOSA programme compared with usual care in increasing the number of homes with the three key safety practices (having at least one fitted and working smoke alarm, a safety gate on stairs and storing poisons out of reach) and reducing the number of child injuries. The effectiveness of the programme is reported elsewhere.¹⁹



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Table 1 Key components of the economic evaluation of the SOSA programme

Decision problem	Does the SOSA programme offer value for money for improving home safety, reducing childhood injuries and improving health?
Type of evaluation	Cost-effectiveness and cost-utility analyses alongside a non-randomised controlled before and after study
Population	Children aged between 2 and 7 months of age with parents aged 18 years or older, residing in within one of eight electoral wards of Nottingham City. Cohort 1 was recruited in September 2017, cohort 2 in March 2018 and cohort 3 in September 2018.
Setting and perspective	Eight electoral wards in Nottingham city, NHS and local authority perspective ²⁸
Time horizon	Two years for each cohort
Intervention	<p>The SOSA programme involved using evidence-based home safety promotion delivered to families within the four SOSA wards. Service providers (health visiting team members, family mentors (peer family support workers) and children's centres staff) were specifically trained to deliver the SOSA programme. The SOSA programme was tailored to a family's needs, and included referral/signposting to partner organisations for additional risk assessments (eg, home fire risk assessments provided by the fire service), and referral to charities for safety equipment (if available).</p> <p>The components delivered by each practitioner group were:</p> <p>Health visiting teams:</p> <ol style="list-style-type: none"> 1. Provided home safety advice through use of age-specific checklists at infant (9–12 months) and toddler (2–2.5 years) child health reviews. 2. Used the checklists to guide advice to families following attendance at the emergency department for an injury as required. 3. Discussed with or distributed monthly safety messages and safety week resources to parents in ad-hoc contacts or clinics. <p>Family mentors:</p> <ol style="list-style-type: none"> 1. Undertook home safety activities from the family mentor manual. 2. Discussed with or distributed monthly safety messages to parents at home visits. <p>Children's centres:</p> <ol style="list-style-type: none"> 1. Ran four safety weeks per year. 2. Discussed with or distributed monthly safety messages to parents.
Comparator	Usual care: Four wards received home safety promotion from health visiting teams and children's centres that was already provided as part of routine care and did not have access to the SOSA programme. Family mentors were not available in control wards.
Costs	National currency (£) at 2019/2020 prices
Outcomes	Primary outcome: Number of homes which adopted the three key safety practices (one fitted and working smoke alarm, a safety gate on stairs and storing poisons out of reach) Secondary outcomes: Number of injuries avoided, Quality-Adjusted Life Years (QALYs) gained
Discounting	3.5% per annum
Analytical strategy	<ol style="list-style-type: none"> 1. For each cohort, we estimated the total healthcare cost, number of homes with the three key safety practices, number of injuries and QALYs 2. Incremental healthcare costs, number of homes with the three key safety practices, number of injuries, and QALYs were estimated using regression modelling with variables specified a-priori using multi-level mixed regression analysis controlling for²⁹: <ul style="list-style-type: none"> ▶ Matched ward. ▶ Mother's age at birth of first child. ▶ Number of children (aged under 16 years) at home. ▶ Single-parent family. ▶ Index of Multiple Deprivation 2019 score. ▶ Whether the house had the three key safety practices at baseline (excluded from primary analysis as that analysis took account of change from baseline). <p>(3) The primary measure of cost-effectiveness was the incremental cost-effectiveness ratio (ICER) per additional house with the three key safety practices ($ICER_{3KSP}$) defined as</p> $ICER_{3KSP} = \frac{\text{Incremental Healthcare Cost} + \text{Intervention Cost}}{\text{Incremental homes with three key safety practices}}$ <p>Secondary measures of cost-effectiveness were</p> <p>ICER per injury avoided ($ICER_{IA}$):</p> $ICER_{IA} = \frac{\text{Incremental Healthcare Cost} + \text{Intervention Cost}}{\text{Incremental injuries avoided}}$ <p>And ICER per QALY gained ($ICER_{QALY}$):</p> $ICER_{QALY} = \frac{\text{Incremental Healthcare Cost} + \text{Intervention Cost}}{\text{Incremental QALYs}}$
One-way sensitivity analyses	Varying SOSA programme costs, incremental healthcare costs, incremental homes with three key safety practices, incremental injuries avoided, and incremental QALYs gained were varied between 0.5 and 2 times their initial value. Results were plotted using a Tornado Plot.
Probabilistic sensitivity analysis	Bootstrapping with replication, sampling 10 000 times, generating pairwise incremental costs and outcomes, allowing estimation of 95% CIs on ICERs, and generation of scatterplots of incremental cost versus incremental outcomes and cost-effectiveness acceptability curves. ³⁰

NHS, National Health Service; SOSA, Stay One Step Ahead.

MATERIALS AND METHODS

Objectives

The objectives of this study were to:

- ▶ Estimate the cost of the SOSA programme as delivered.
- ▶ Estimate the number of injuries in children aged under 5 years over the 24-month follow-up for SOSA and usual care wards, and their associated healthcare cost and health-related quality of life.
- ▶ Estimate the number of homes with the three key safety practices for both SOSA and usual care wards.
- ▶ Demonstrate the cost-effectiveness of the SOSA programme for increasing the number of homes with the three key safety practices, avoiding injuries among children and increasing quality-adjusted life-years (QALYs).

Study design

The economic evaluation was done alongside a non-randomised controlled before-and-after study.^{18 19} The key components of

the economic evaluation including population, intervention, comparator, perspectives outcomes and analytical strategy can be found in [table 1](#). The SOSA programme was delivered in four electoral wards in Nottingham City, UK. SOSA wards were chosen due to high levels of health, education and social needs, with four matched control wards, matched on the basis of rate of emergency department injury presentation by 0–5 years,²⁰ income deprivation affecting children, similar child population sizes of children aged 0–5 and minimising health visitor service caseload overlap.

Patient and public involvement

The SOSA intervention was coproduced with parents from Nottingham City. These 'Parent Champions' were parents of young children, residents of the intervention wards and part of the SSBC programme. They contributed to developing parent recruitment and retention strategies, designing data collection tools, study oversight and dissemination.

Microcosting of the SOSA programme

A detailed description and breakdown of the microcosting of the SOSA programme can be found in online supplemental information S1. In summary, costs were split into two categories: programme development and day-to-day running. Development costs represented the resources required to create and refine the materials and resources required for the SOSA programme through consultations with stakeholders (parents, health visiting teams, family mentors, children's centre staff, the Fire and Rescue service and an injury prevention expert from the Child Accident Prevention Trust) as part of a series of workshops.

For day-to-day running costs, activity was split into six categories: children's centre activity, family mentor activity, health visiting team activity, provision of interpreters, provider training and central administration. Information regarding activity related to children's centres, family mentors, health visiting teams and interpreters was estimated where possible on a per ward basis, to allow for any variation of SOSA delivery that might occur across wards. This was done by direct contact with each team (if possible) with requests for a summary of their SOSA programme-related activity and the length of time spent on each activity. Details of reported activity can be found in online supplemental file S11. Costs were estimated on a per each occurrence basis (eg, cost per safety week, costs per monthly safety message), at a ward level where possible. If a ward was missing information on activity, then an average cost across the other wards was used as an estimate. For each provider training session, the total cost was estimated by multiplying the length of time at the session by the number of attendees by their salary, as well as the number and level of instructors at the session. Costs of central administration were collected directly by the study team. These included staff time for printing resources for monthly safety messages, safety weeks and home safety checklists, the costs of printing materials and the postage required to send materials to relevant teams.

Total SOSA programme costs were estimated for each financial quarter over the full duration of the programme. For each cohort of children, we then estimated the cost per child of the SOSA programme by dividing the total SOSA programme cost per financial quarter by the number of children aged 0–5 years on health visitor caseloads within SOSA programme wards. Next, we summed the cost per quarter over the 2-year follow-up to estimate the total cost per child for each cohort. Finally, we took the average total cost per child across the three cohorts. A detailed description is given in online supplemental file S11.

Costing healthcare consultations

Data on injury occurrence and associated healthcare consultations were obtained from 3-monthly administered parent self-reported questionnaires. A recall period of 3 months was used to assess injury occurrence as previous research suggests parents recall over 80% of minor injuries to their children which resulted in attendance at an urgent care provider or emergency department or major injuries regardless of place of treatment.²¹ They included the number of injuries and healthcare provided for each injury (general practitioner consultation, emergency department visit, urgent care/walk-in centre consultation, hospital admission and outpatient follow-up). For each child, the number of health service consultations was totalled for year 1 and year 2 of follow-up. Prices for each type of National Health Service (NHS) consultation can be found in online supplemental file S12. All prices were inflated to 2019/2020 prices using the NHS Cost Inflation Index.²² The unit prices of an emergency department visit and an outpatient visit were taken as the average

weighted price across all emergency department visits and all outpatient visits reported in NHS Reference Costs, as per standard approaches.²³ For the cost of hospital admission, as data on length of stay were not recorded, we used a weighted average for the total cost of admission for an injury as reported in Cooper *et al.*⁴ Parental self-reported injury data were validated against injuries recorded in medical records for 22 participants whose parents gave consent for injury data to be extracted from their child's medical records.

Primary outcome measure

Data on the three key safety practices (having at least one fitted and working smoke alarm, a safety gate on stairs and storing poisons out of reach) were obtained by parent-completed questionnaires at recruitment, 12-month and 24-month follow-up. Further information can be found elsewhere.¹⁹

Estimating QALYs

Utilities for children were taken from published literature,²⁴ and further details as to how utility weights were applied to estimate QALYs can be found in online supplemental file S13.

Secondary analysis

Two secondary analyses were conducted:

1. Inclusion of development costs attributed in the first financial quarter.
2. Using per family as the denominator in estimating incremental costs and outcomes rather than per child as some families had more than one child aged under 5 years, based on health visitor caseloads.

RESULTS

Cost of SOSA programme

The total discounted total cost of the SOSA programme was £216 805. A breakdown of costs by activity can be found in table 2. The average cost per child of the SOSA programme across the three cohorts was £30.

Number of injuries and their associated cost

Data from 764 children across all wards were collected over 2 years. 110 had missing outcome data for both first-year and second-year follow-up while a further 58 children had missing data on prespecified independent variables, leaving 596 children with complete data in the analysis (278 children in SOSA wards and 318 in usual care wards). 154 children reported having one or more injuries, with a total of 235 injuries over the 2-year follow-up requiring 291 healthcare consultations. The total discounted healthcare cost was £45 497 for both usual care and SOSA wards (see table 3). Validation of self-reported injuries on 22 participants found that parents reported 29 medically attended injuries in the 2-year follow-up period while medical records reported 28 medically attended injuries.

Home safety practices

At recruitment, 103 homes in the usual care wards and 94 homes in SOSA wards had the three key safety practices, increasing to 141 and 129 homes in usual care and SOSA wards respectively at 24 months follow-up.

Base case analysis

SOSA wards were associated with a saving of £42 per child in healthcare costs while increasing the number of homes with the three key safety practices by 0.02 per child, reducing injuries by

Table 2 Total discounted (3.5% per annum) cost for SOSA programme by activity, excluding development costs

Financial year	Quarter	Total cost per activity (£)						Total cost
		Training	Central administration	Health visiting	Family mentors	Children's centres	Provision of interpreters	
2017–2018	3	13 597	425	962	9005	1026	397	25 412
2017–2018	4	0	647	2199	8965	4512	395	16 718
2018–2019	1	1296	765	3015	8926	5482	392	19 876
2018–2019	2	0	881	3840	8887	6435	392	20 434
2018–2019	3	653	874	3790	8810	6380	385	20 893
2018–2019	4	0	746	2944	8699	5342	382	18 112
2019–2020	1	324	739	2900	8624	5296	374	18 258
2019–2020	2	266	733	2917	8550	5251	386	18 103
2019–2020	3	0	727	2867	8477	5206	376	17 652
2019–2020	4	419	721	2834	8404	5161	370	17 909
2020–2021	1	0	621	2433	8332	0*	364	11 751
2020–2021	2	0	616	2444	8261	0*	366	11 688
Total cost		16 555	8496	33 145	103 941	50 091	4578	216 805
Percentage of total cost (%)		8	34	15	48	23	2	

*Children's centres were closed during the COVID-19 pandemic, so no cost was applied in these quarters while other aspects of the programme continued remotely. SOSA, Stay One Step Ahead.

0.15 per child and gaining 0.0036 QALYs per child. Incremental total cost was –£12, suggesting that the SOSA programme was dominant as it was more effective than usual care and saved money. The respective incremental cost-effectiveness ratios (ICERs) were –£590 per additional home deemed safe, –£77 per injury avoided and £3225 per QALY gained. The Stay One Step Ahead (ROI) was £1.39, suggesting that for every pound spent on the SOSA programme there was a return of £1.39 in healthcare savings.

Sensitivity analyses

ICERs were most sensitive to changes in the overall incremental SOSA programme cost and incremental healthcare savings while changes in the incremental number of homes with the three key safety practices safe and injuries avoided had little impact on the ICERs (see online supplemental file SI4).

The probabilistic sensitivity analysis suggested considerable uncertainty in the base case findings with wide 95% CIs (see table 4), with the possibility that the SOSA programme did not

reduce healthcare costs, increase homes with the three key safety practices, reduce injuries or increase QALYs. Mean ICERs were £350 (95% CI –£1621 to £1490) per additional home with the three key safety practices, –£206 (95% CI –£1161 to £983) per injury avoided and £6600 (95% CI –£42 876 to £64 771) per QALY gained. There was a 62% chance that SOSA was cost saving (ie, greater reductions in healthcare expenditure than the increase in programme cost per child), a 52% chance that the SOSA programme led to an improvement in homes with the three key safety practices, a 75% chance that there was a reduction in injuries, and a 95% chance that there was an increase in QALYs (see figure 1 and online supplemental file SI5). The ROI for the SOSA programme was £1.28 (95% CI –£0.33 to £3.08), suggesting on average there was a £1.28 return in healthcare savings for every £1 spent on the SOSA programme.

Secondary analyses

The total cost of developing the SOSA programme was £12 275, increasing the cost of the SOSA programme to £229 080 and the average cost per child to £33. This reduced incremental cost to –£9 per child. Therefore, the SOSA programme remained dominant. ICERs were now –£468 per additional home with the three key safety practices, –£61 per injury avoided and –£2559 per QALY gained. The ROI was reduced to £1.29, suggesting that for every pound spent on the SOSA intervention returned £1.29 in healthcare savings.

The SOSA programme cost was £39 per household. Data on households registered to health visitors per financial quarter indicated there were on average 1.31 children per household in SOSA wards, therefore, we multiplied the base case incremental healthcare savings, incremental injuries avoided, incremental homes with the three key safety practices and incremental QALYs by 1.31, giving £55, 0.20, 0.03 and 0.0047, respectively, per household. The incremental cost per household was –£16, hence the SOSA programme was still estimated to be dominant. ICERs were now –£613 per additional household with the three key safety practices, –£82 per injury avoided and –£3405 per QALY gained. The SOSA programme had an ROI of £1.41, which meant a return of £1.41 was made per household for every pound spent on the programme.

Table 3 Discounted costs (3.5% per annum) for healthcare by consultation type and ward

Time	Consultation type	Discounted costs (£)		
		Usual care wards	SOSA wards	Total
Year 1	GP	490	641	1130
	Urgent care/walk-in centre	239	334	573
	Emergency department	5739	4264	10 003
	Hospital admission	3964	991	4956
	Outpatient	1754	626	2380
	Total	12 186	6856	19 042
Year 2	GP	510	364	874
	Urgent care/walk-in centre	508	277	785
	Emergency department	8239	5387	13 625
	Hospital admission	5746	1915	7661
	Outpatient	1573	1936	3510
	Total	16 575	9880	26 455
Total across all 2 years of follow-up	28 761	16 736	45 497	

GP, general practitioner; SOSA, Stay One Step Ahead.

Table 4 Results of probabilistic sensitivity analyses

	Mean	95% CI	Min	Max
Incremental SOSA programme cost (£)	30	28	32	27
Incremental healthcare cost (£)	-39	-92	10	-160
Incremental total cost (£)	-8	-62	40	-131
Incremental homes with the three key safety practices	0.0066	-0.4233	0.4258	-0.8404
ICER per additional home with the three key safety practices (£)	350	-1621	1490	-719 194
Incremental injury avoided	0.1403	-0.2673	0.5637	-0.7543
ICER per injury avoided (£)	-206	-1161	983	-1 032 089
Incremental QALYs	0.0034	-0.0007	0.0078	-0.0057
ICER per QALY gained (£)	6600	-42 876	64 771	-5 458 803
Return on investment (£)	1.28	-0.33	3.08	-2.08

ICER, incremental cost-effectiveness ratio; QALYs, quality-adjusted life-years; SOSA, Stay One Step Ahead.

DISCUSSION

The SOSA programme was found to increase the number of homes with the three key safety practices and gain QALYs while decreasing the number of injuries among children as well as reducing healthcare expenditure. Meanwhile, the SOSA programme cost was smaller than the healthcare savings, suggesting that the SOSA programme was a dominant intervention in that it saved money and was more effective. However, sensitivity analyses demonstrated considerable uncertainty regarding the result, with a 52% chance that the SOSA programme led to an improvement in homes with the three key safety practices, a 75% chance that there was a reduction in injuries and a 95% chance of increasing QALYs.

Strengths and limitations

We have investigated the cost-effectiveness of the SOSA programme in a real-world setting, using a combination of routinely collected data as well as data collected directly from families. The microcosting approach used provided an accurate picture of the costs of providing the SOSA programme.

Although we have captured most healthcare expenditure, we originally intended to capture more detailed healthcare data from

the medical records of a sample ($n=100$) of study participants but only recruited 22 parents, so our analysis is based on self-reported data. This meant that we did not capture prescription data for any injuries that occurred in the 2-year follow-up, and our analyses may, therefore, slightly underestimate healthcare expenditure. However, Cooper *et al* found that prescriptions costs were only a small amount of the total cost of an injury,⁴ with £0.16 being for prescriptions out of a total of £194.11 for a child who has a fall. Therefore, although we are missing this data, it is unlikely that this would change the main findings of our study.

Recall bias may have occurred in parents' self-reported injury data as this data was collected at 3-monthly intervals, a time period previously shown to have injury recall rates of between 58% for clinic visits and 86% for emergency department visits or hospital admissions.²¹ But the small amount of data we extracted from medical records found parents were accurately reporting their child's medically attended injuries, though numbers are too small to assess accuracy of reporting between the two arms.

Our analysis was only able to take account of short-term healthcare costs. This will underestimate the true cost of injuries to health services, education, social care, parents, children, and

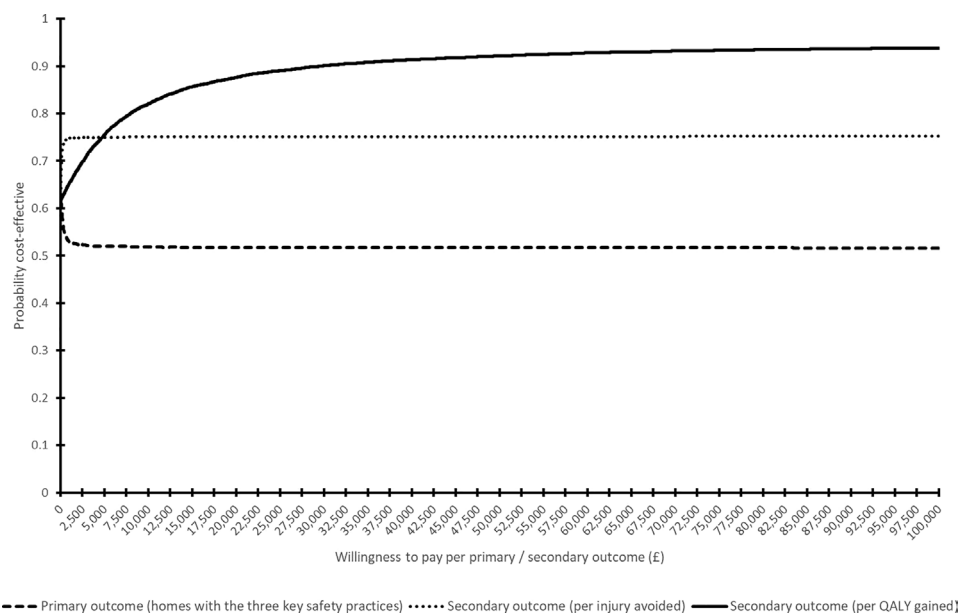


Figure 1 Cost-effectiveness acceptability curves for the SOSA programme per additional home with the three key safety practices and per injury avoided. QALY, quality-adjusted life-year; SOSA, Stay One Step Ahead.

wider society and hence our estimate of the cost-effectiveness of the SOSA programme is likely to be an underestimate.

The COVID-19 pandemic also impacted our study, with many of the SOSA programme activities becoming remote as face-to-face activities were suspended during periods of social restrictions, decreasing the provision of materials. This impacted the SOSA programme cost (see table 2 where the last two financial quarters are below the previous quarter's cost) and potentially the effectiveness of the SOSA programme.

The considerable uncertainty within the evaluation results may be of concern. However, the probabilistic sensitivity analysis demonstrates a 62% chance that the SOSA programme saved money even though the evaluation excludes longer-term health and social costs for more severe injuries, educational costs and productivity losses. This means that SOSA is more likely to be cost-effective than our evaluation finds.

In context with the literature

Findings of the economic evaluation of SOSA are consistent with studies indicating cost-effectiveness of interventions that improve home safety through home visiting,²⁵ and educational interventions promoting safe poison storage²⁶ and fire escape planning.¹⁴ Family mentors were a new type of role, and therefore, an economic evaluation of their inclusion in a child home safety intervention has not previously been performed. There is evidence, however, that interventions provided by trained laypersons to reduce child maltreatment (and therefore injuries) are cost-effective.²⁷ Previous research shows that promotion of safe poison storage is more cost-effective when provided in disadvantaged as opposed to more affluent areas, and the disadvantaged areas in which SOSA was delivered may partly explain its cost-effectiveness.²⁶

Implications for policy and research

Policy-makers and health and social care commissioners should note that SOSA is cost saving, returning £1.39 for every one pound spent on the SOSA programme, even when only short-term healthcare costs are included in the evaluation. Using costs associated with longer-term health, social care, education and productivity losses is only likely to make SOSA more cost saving. Commissioners should, therefore, consider commissioning the SOSA programme for families in disadvantaged areas. Further research, perhaps as part of larger studies and incorporating longer-term costs of injuries, would be helpful to produce more precise estimates of cost-effectiveness.

CONCLUSIONS

The SOSA programme was associated with an increase in the number of homes with the three key safety practices and a reduction in associated injuries. Despite the SOSA programme including only short-term healthcare costs, it returned £1.39 for every £1 spent on SOSA, with a 62% chance of SOSA producing cost savings. SOSA is a cost-saving intervention, and as such commissioners should consider implementing the SOSA programme. Further larger studies, particularly including the longer-term costs of injuries would provide more precise estimates of cost-effectiveness.

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DK planned and conducted the data analysis. CT prepared documentation for the ethics committee. CT, TP and RC collected the data. MJ, MJT, EO and DK drafted the manuscript with revisions additionally from CC, MH, MCW, RC, CT and TP. EO is the guarantor for the study.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the East Midlands Leicester Central Research Ethics Committee (reference: 17/EM/0240). Participants gave informed consent to participate in the study before taking part.

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