

# Primary care

## Providing child safety equipment to prevent injuries: randomised controlled trial

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### Abstract

**Objective** To assess the effectiveness of safety advice and safety equipment in reducing unintentional injuries for families with children aged under 5 years and living in deprived areas.

**Design** Randomised controlled trial.

**Setting** 47 general practices in Nottingham.

**Participants** 3428 families with children under 5.

**Intervention** A standardised safety consultation and provision of free and fitted stair gates, fire guards, smoke alarms, cupboard locks, and window locks.

**Main outcome measures** Primary outcome measures were whether a child in the family had at least one injury that required medical attendance and rates of attendance in primary and secondary care and of hospital admission for injury over a two year period. Secondary outcome measures included possession of safety equipment and safety practices.

**Results** No significant difference was found in the proportion of families in which a child had a medically attended injury (odds ratio 1.14, 95% confidence interval 0.98 to 1.50) or in the rates of attendance in secondary care (incidence rate ratio 1.02, 0.90 to 1.13) or admission to hospital (1.02, 0.70 to 1.48). However, children in the intervention arm had a significantly higher attendance rate for injuries in primary care (1.37, 1.11 to 1.70,  $P=0.003$ ). At both one and two years' follow up, families in the intervention arm were significantly more likely to have a range of safety practices, but absolute differences in the percentages were relatively small.

**Conclusions** The intervention resulted in significant improvements in safety practices for up to two years but did not reduce injuries that necessitated medical attendance. Although equipment was provided and fitted free of charge, the observed changes in safety practices may not have been large enough to affect injury rates.

### Introduction

Unintentional injury is the leading cause of death in children in the United Kingdom.<sup>1</sup> Moreover, it is a major cause of ill health and disability. Most unintentional injuries to children under 5 take place in the home, and children at socioeconomic disadvantage are at greater risk of injury.<sup>2</sup>

Primary healthcare teams have an important contribution to make to the prevention of unintentional injuries in children,<sup>3-5</sup> including home safety counselling and participation in safety equipment schemes. However, there is little evidence in the United Kingdom that they can be effective in reducing unintentional injuries.

Systematic reviews have found that home safety counselling or education, with or without the provision of safety equipment, can increase the use of some items of safety equipment and improve safety behaviours in the short term, but the effect on unintentional injury is less clear.<sup>6-9</sup> Many of the trials included in these reviews were conducted in the United States, which limits generalisability to UK settings. In addition, the reviews have highlighted the lack of high quality randomised controlled trials, specifically trials with adequate allocation concealment, blinded outcome assessment, adequate power, and a sufficient follow up period.

The high cost of safety equipment and the difficulty of installing some devices have been identified as barriers to families' implementing advice on home safety.<sup>8</sup> No trials to date have examined the effect of providing as well as fitting equipment free of charge.

We report the main results of a randomised controlled trial assessing the effectiveness of an intervention in increasing safety practices and reducing unintentional injuries in families with children aged under 5 years, living in deprived areas.

### Methods

#### Participants

All health visitors working in practices from deprived areas in Nottingham Health Authority with Townsend scores above zero<sup>10</sup> (78 health visitors and 60 practices) received an invitation to take part in the study, and 62 health visitors from 47 practices participated.

Our study population comprised families with one or more children younger than 5 years from the caseloads of participating health visitors, recruited via a postal invitation.<sup>11</sup> We did not invite families in which one or more children were on the Child Protection Register or a child had experienced a fatal unintentional injury. All participants gave written consent.

#### Interventions

The intervention comprised a standardised consultation on safety that had previously been used in a randomised controlled trial in general practice<sup>12</sup> and was adapted to conform to educational principles found in a systematic review to increase the effectiveness of health educational interventions.<sup>13 14</sup>

Health visitors conducted the consultations at the client's home or in dedicated clinics at separate times from general surveillance of children's health. Each structured but individualised consultation was specific to the children's ages in each family and took about 20 minutes.<sup>15</sup>

The health visitors offered stair gates, fire guards, smoke alarms, cupboard locks, and window locks free of charge to low

income families in the intervention arm, and these were fitted free of charge. We defined low income families as those receiving means tested benefits. Families not on a low income were offered equipment at cost price and a delivery service to their home.

Families randomised to the control arm received usual care. They did not have access to the research documentation, free or low cost safety equipment, or the fitting scheme.

### Objective

To evaluate the effectiveness of health visitors' advice and the provision of free or low cost safety equipment in increasing safety practices and reducing unintentional injuries in families with children under 5 years, living in deprived areas.

### Outcome measures

Primary outcome measures were whether a child in the family had at least one medically attended injury and the rates of attendance in primary and secondary care and of hospital admission for injury during the two year follow up period. We obtained these data from the primary and secondary care records for all children aged under 5 at the start of the trial and for new births during the study period. Secondary outcome measures included severity of injury, measured by using the abbreviated injury scale<sup>16</sup> and a severity scale for more minor injuries,<sup>17</sup> assessed from primary and secondary care records. We assessed possession of safety equipment, safety practices, self reported injury, and satisfaction with the intervention, at 12 and 24 months' follow up by two postal questionnaires to separate random samples of 1000 families from each treatment arm. We validated responses to the 12 month questionnaire by home visits to 64 families from a random sample, which indicated that seven of the nine safety practices we measured had sensitivity and specificity greater than 74%.<sup>18</sup> We obtained baseline data on sociodemographic characteristics, possession of safety equipment, and safety practices from a postal questionnaire, sent with the postal invitation to participate in the trial, but 151 (4.4%) families did not complete a baseline questionnaire as they also participated in a study comparing sending a study invitation with sending an invitation plus questionnaire.<sup>11</sup> We assessed satisfaction among health visitors with the intervention by postal questionnaire at the end of the intervention period.

### Sample size

We estimated that a sample size of 3400 families, 1700 in each arm, would give 80% power to detect at the 5% significance level a relative reduction of 10% in medically attended injuries between treatment arms. This calculation assumed that 50% of control families would have at least one child having one or more medically attended injuries over the two year follow up period and allowed for up to 10% loss to follow up.

### Randomisation

Randomisation took place after the baseline questionnaires had been returned. We stratified participants by health visitor and randomised them in blocks of eight to treatment arms. One member of the research team generated the randomisation schedule by computer, and a researcher who was not part of the research team (blind to any family's identity) allocated participants. The health visitors then received a list of the intervention families to contact.

### Blinding

It was not possible to blind participants because of the type of intervention that we used. Health visitors were aware of which clients were in the intervention arm but were not provided with a list of controls, in order to minimise the chance of contamina-

tion. We kept outcome assessors blind to the treatment arm of the families.

### Statistical analysis

Our analysis was by intention to treat and based on a prespecified analysis plan. We used multilevel logistic regression to compare whether at least one child in the family had one or more medically attended injuries (only including families with outcome data available for the entire follow up period for all children) and whether family safety practices varied between treatment arms. We used two level random intercepts models, with health visitor at level 2 and family at level 1.

To compare injury rates we used multilevel Poisson regression, with the number of injuries for each child as the dependent variable and the length of follow up time for the child as the offset term. We used a three level random intercepts model, with health visitor at level 3, family at level 2, and child at level 1. We used a three level random intercepts logistic regression model to compare the odds of a child having an injury with a severity score of 2 or more between the treatment arms. To assess significance we used Wald tests.

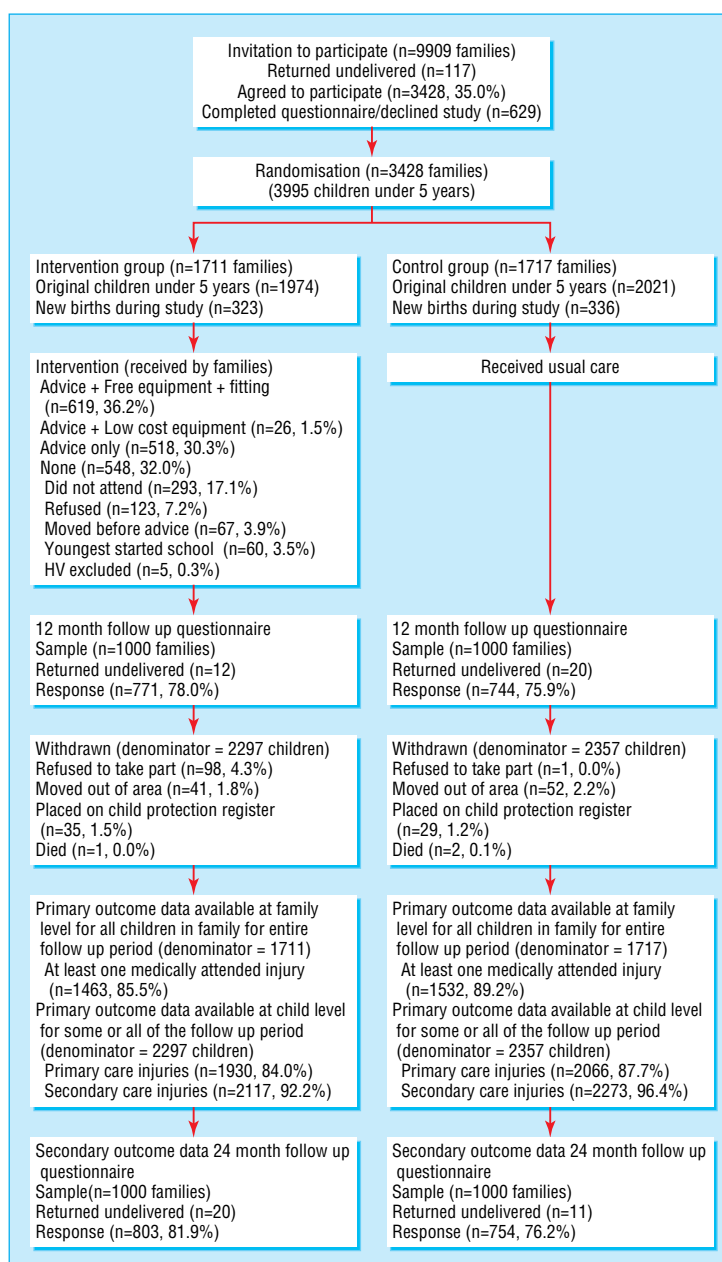
We examined the effect of compliance by comparing outcomes of participants in the intervention arm who did receive the safety consultation with those in the control arm. We studied interactions between the intervention and family income (receipt of means tested benefits) and child age (aged <3 years). We checked models by examining residual plots and assessing for overdispersion. We used MLwiN, version 1 (Institute of Education, University of London, 2000), for our analyses.

## Results

We recruited 3428 families (3995 children) between January and May 2000, with 1711 families in the intervention arm and 1717 families in the control arm. The follow up period started on 1 June 2000 and ended on 31 May 2002. The figure shows the flow of participants through the trial. The treatment arms were well balanced at baseline (table 1).

A total of 1163 (68%) families in the intervention arm received the safety consultation, and 619 families (36%) had free equipment fitted, and 26 (1.5%) bought equipment at low cost. Table 2 shows results for injury outcomes. The attendance rate for injury in primary care was higher (by 37%) for children in the intervention than in the control arm ( $P=0.003$ ). The treatment arms did not differ significantly for the other injury outcomes. We found no evidence that the effect of the intervention varied by family income or child age for any of the primary outcome measures ( $P>0.1$  for all interaction terms). A compliance analysis found similar results to the primary analysis, with a higher injury attendance rate in primary care in children in the intervention arm who received the safety consultation than in children in the control arm (incidence rate ratio 1.50, 95% confidence interval 1.21 to 1.88) but no difference in rates of attendance in secondary care or admission to hospital.

Table 3 shows that at one year, families in the intervention arm were significantly more likely to be safe in terms of stairs ( $P=0.0004$ ), smoke alarms ( $P=0.0002$ ), windows ( $P=0.03$ ), and storage of cleaning products ( $P=0.006$ ) and sharp objects ( $P=0.005$ ) in the kitchen than families in the control arm. At two years, families in the intervention arm were significantly more likely to be safe in terms of smoke alarms ( $P=0.002$ ), storage of medicines ( $P=0.05$ ), and cleaning products ( $P=0.008$ ) in the kitchen than families in the control arm. Absolute differences in the percentages of families with safety practices were, however, small—none exceeded 10%.



Flow of participants through the trial

Among families responding to the 12 month questionnaire, 89% (286/322) of those receiving equipment agreed or strongly agreed that they were satisfied with the safety equipment, and 70% (411/589) of families who received the consultation agreed or strongly agreed that they were satisfied with the health visitor's advice. Ninety five per cent (53/56) of responding health visitors agreed or strongly agreed that the safety consultation should be used in routine practice.

## Discussion

A safety consultation with a health visitor and provision of free or low cost safety equipment, fitted in the homes of families with children under 5, resulted in significantly more families in the intervention arm having a range of safety practices for up to two years. However, children in the intervention arm did not have a lower rate of injuries that required medical attendance.

## Limitations of the study

Only 35% of eligible families invited to participate in the trial did so. Although this is not a particularly low recruitment rate for a trial set in a deprived area,<sup>19</sup> it may limit the generalisability of our findings. Participants may have been families most motivated to make their homes safer, so the intervention may not have reached those most at risk of injury, and the observed changes in safety practices may overestimate the effect of the intervention in other deprived populations.

As it was not possible to keep health visitors completely blind to the identity of families in the control arm, they may have given extra safety advice or obtained safety equipment from other sources for these families. However, for several reasons this is unlikely to explain our findings. Firstly, we measured the provision of safety advice in routine child health clinics before and after the trial started and did not find an increase in the pro-

**Table 1** Characteristics and safety practices of study families at baseline. Values are numbers (%) unless otherwise indicated

Characteristics	Intervention arm (n=1635)	Control arm (n=1642)
<b>Sociodemographic and family factors</b>		
Age of youngest child in years:		
0	437 (27.1)	416 (25.9)
1	387 (24.2)	394 (24.5)
2	317 (19.8)	338 (21.0)
3	267 (16.7)	258 (16.0)
4	192 (12.0)	202 (12.6)
No of children aged under 16:		
1	628 (38.5)	659 (40.3)
2	603 (36.9)	558 (34.1)
3	277 (17.0)	286 (17.5)
4 or more	124 (7.6)	134 (8.2)
Receipt of means tested benefits		
No car	486 (30.5)	499 (31.3)
Lives in rented accommodation	741 (45.8)	747 (45.9)
Overcrowding*	179 (11.1)	191 (11.8)
Single parent family	441 (27.4)	459 (28.4)
Teenage mother	365 (24.1)	354 (23.2)
Ethnic group non-white	226 (14.1)	243 (15.2)
Resides in deprived area†	1153 (70.9)	1153 (70.7)
Unemployment:		
One parent unemployed	580 (36.2)	581 (36.0)
Both parents unemployed‡	530 (33.1)	552 (34.2)
Child in family already had medically attended injury	209 (12.9)	214 (13.2)
<b>Safety practices</b>		
Fitted and always used fire guard	725 (45.9)	745 (46.7)
Fitted and used stair gate	720 (44.5)	738 (45.4)
Fitted and working smoke alarm	1203 (76.9)	1180 (75.5)
Fitted window locks	1027 (63.0)	1012 (61.8)
<b>Safe storage§</b>		
Medicines in kitchen	1402 (87.5)	1418 (88.3)
Cleaning products in kitchen	820 (50.6)	842 (51.8)
Sharp objects in kitchen	591 (36.6)	628 (38.7)
Cleaning products in bathroom	970 (66.2)	1026 (69.2)
Sharp objects in bathroom	1216 (87.5)	1238 (87.7)

Baseline questionnaires were completed by 3277 families (95.6%) as some families were not sent a baseline questionnaire as part of another study.<sup>10</sup>

\*Defined as more than one person per room excluding kitchens and bathrooms less than 2 metres wide.

†Defined as an enumeration district with a Townsend score >0.

‡Includes single parent family where single parent is unemployed.

§Defined as stored at adult eye level or above or in locked cupboards.

vision of such advice during these contacts.<sup>20</sup> Secondly, the fitting of equipment should have reduced the potential for its transfer between families in the two treatment arms. Thirdly, increases in possession and use of safety equipment in the control arm over the two year follow up period were small.

Our inability to blind families participating in the study may have led to differential over-reporting of safety practices, but our use of validated questions on safety practices should have minimised this. In addition, the primary outcome measures were not self reported but ascertained by blinded assessors.

Finally, 548 (32%) intervention arm families did not receive the safety consultation, and only 645 (38%) received safety equipment. This will have limited the potential for the intervention to show an effect. However, the compliance analysis found similar results to the main analysis, implying that families who had the consultation had similar injury rates to those who did not.

### Strengths of the study

We evaluated the effect of providing safety advice and free or low cost equipment in a clinical setting. Our study was adequately powered to detect a 10% reduction in medically attended injuries; allocation concealment was adequate; and we used an intention to treat analysis.

To our knowledge this trial had a longer follow up period than previous studies and achieved follow up on a high proportion of families. We used home observation to validate the questions used to measure self reported safety practices and found the questions to have high sensitivity and specificity.<sup>18</sup> Importantly, both the families who had the intervention and the health visitors who delivered reported high degrees of satisfaction with the safety consultation.

### Comparison with other studies

Our findings are consistent with previous systematic reviews in terms of possession and use of safety equipment, safety practices, and injury outcomes.<sup>6-9</sup> Only three previous studies that provided free or discounted safety equipment in a clinical setting have used occurrence of injury as an outcome measure.<sup>21-23</sup> One trial found a reduction in self reported injuries,<sup>21</sup> but none found a reduction in medically attended injuries, ascertained from medical records.<sup>21-23</sup>

### Interpretation of the findings

The increased possession and use of safety equipment among families in the intervention arm did not translate into a lower injury rate. A higher than expected number of families living in a deprived area possessed safety equipment at baseline.<sup>24</sup> Consequently, the absolute differences between treatment arms in the percentages of families with safety practices were relatively small, and a greater difference in safety practices may be required to affect the occurrence of injury. It is also possible that safety practices are not associated with reduced injury rates, but this is less plausible as several observational studies have shown a lower risk of injury among people with a range of safety practices.<sup>25-29</sup>

Several explanations are possible for the higher attendance rate in primary care among intervention arm children. Firstly, participation in the intervention arm of the trial may have raised parents' awareness about injury and changed their consulting behaviour for more minor injuries. Secondly, risk compensation<sup>30</sup> may have occurred. Further work is required to explore these hypotheses further.

### Implications for injury prevention practice and future research

Our findings in relation to safety practices and degrees of satisfaction are encouraging for safety equipment schemes such as those organised by SureStart ([www.surestart.gov.uk](http://www.surestart.gov.uk)) and primary healthcare teams. However, our findings also highlight the importance of rigorously evaluating the widespread provision of equipment not only in terms of safety practices but also in terms of injury outcomes and uptake of schemes by those most at risk. Although randomised controlled trials are the gold standard, they may not be able to show reductions in injuries as the prevalence of equipment use is high and the incidence of injuries that could be prevented by specific items of equipment is low. Consequently, very large trials are required, especially if contamination is considered sufficiently likely to warrant cluster allocation. One alternative is to conduct well designed case-control studies or cohort studies to examine the protective effect of specific items of equipment on the injuries they could prevent. These should be followed by randomised controlled trials investigating strategies to increase use of equipment, informed by an understanding

**Table 2** Injury outcomes for injuries at the level of the family or child, at 24 months' follow up, by treatment arm

Injury outcomes	Intervention arm				Control arm				Effect size (95% CI)	
	No (%)	Denominator	Rate/1000 person years	Person years	No (%)	Denominator	Rate/1000 person years	Person years	Odds ratio (95% CI)	Incidence rate ratio (95% CI)
<b>At family level:</b>										
Child in family had medically attended injury	593 (40.5)	1463	—	—	574 (37.5)	1532	—	—	1.14 (0.98 to 1.50)	—
Phoned NHS Direct after an injury*	77 (10.0)	769	—	—	67 (9.3)	719	—	—	1.08 (0.76 to 1.52)	—
Attended walk-in centre after an injury*	29 (3.8)	767	—	—	28 (3.9)	712	—	—	0.94 (0.53 to 1.60)	—
<b>At child level:</b>										
Primary care attendance	220	—	61.2	3595.1	172	—	44.2	3887.7	—	1.37 (1.11 to 1.70)
Secondary care attendance	685	—	175.9	3895.0	743	—	174.1	4267.8	—	1.02 (0.90 to 1.13)
Hospital admission	54	—	13.9	3895.0	58	—	13.6	4267.8	—	1.02 (0.70 to 1.48)
Abbreviated injury scale ≥2	57 (12.1)	472	—	—	49 (10.8)	456	—	—	1.14 (0.76 to 1.71)	—
Minor injury severity score ≥2	215 (45)	478	—	—	206 (45.3)	455	—	—	0.98 (0.75 to 1.27)	—

\*Self reported on 24 month follow up questionnaire (denominators do not equal those in figure 1 as some respondents did not answer these questions).

of the reasons why, even when equipment is freely provided and fitted, a sizable proportion of families may not take up the offer.

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**Table 3** Prevalence of safety practices at 12 and 24 months' follow up, by treatment arm. Values are numbers (percentages) of families unless otherwise indicated

Safety practices	12 months' follow up			24 months' follow up		
	Intervention arm (n=771)*	Control arm (n=744)*	Odds ratio (95% CI)	Intervention arm (n=803)*	Control arm (n=754)*	Odds ratio (95% CI)
Fitted and always used fire guard	414 (54.3)	374 (50.9)	1.14 (0.93 to 1.40)	328 (42.1)	299 (40.0)	1.09 (0.88 to 1.33)
Fitted and used stair gate	408 (55.0)	328 (45.7)	1.46 (1.19 to 1.80)	239 (30.1)	240 (31.9)	0.92 (0.74 to 1.14)
Fitted and working smoke alarm	692 (90.6)	619 (84.0)	1.83 (1.33 to 2.52)	728 (91.5)	648 (86.5)	1.67 (1.21 to 2.32)
Fitted window locks	550 (71.7)	493 (66.5)	1.28 (1.02 to 1.59)	577 (72.4)	525 (70.0)	1.12 (0.90 to 1.40)
<b>Safe storage†</b>						
Medicines in kitchen	712 (93.4)	683 (92.6)	1.15 (0.76 to 1.73)	765 (95.5)	701 (93.2)	1.55 (1.00 to 2.40)
Cleaning products in kitchen	496 (65.5)	428 (58.6)	1.34 (1.09 to 1.66)	442 (55.3)	365 (48.5)	1.31 (1.07 to 1.60)
Sharp objects in kitchen	346 (45.4)	279 (38.2)	1.34 (1.09 to 1.65)	296 (36.9)	262 (34.8)	1.10 (0.91 to 1.32)
Cleaning products in bathroom	493 (70.4)	463 (68.5)	1.09 (0.87 to 1.38)	497 (63.1)	459 (61.7)	1.06 (0.86 to 1.31)
Sharp objects in bathroom	545 (81.2)	505 (78.3)	1.20 (0.92 to 1.57)	568 (73.2)	548 (75.1)	0.91 (0.72 to 1.14)

\*Denominators for percentages are those with valid responses.

†Defined as stored at adult eye level or above or in locked cupboards.

### What is already known on this topic

Unintentional injury is the main cause of death in childhood and a major cause of ill health and disability

There is a paucity of evidence on the effectiveness of primary care professionals in providing safety advice and equipment

### What this study adds

Advice that includes the offer of free home safety equipment, fitted free of charge, can improve safety practices of families living in deprived areas, for up to two years

Larger differences in safety practices may be required to affect injury rates

Even when equipment was provided and fitted free of charge, one third of families did not take advantage of this offer

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