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# **ORIGINAL ARTICLE**

# Cycle helmet ownership and use; a cluster randomised controlled trial in primary school children in deprived areas

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Aims: To assess the effectiveness of two different educational interventions plus free cycle helmets, in increasing cycle helmet ownership and use.

Methods: A cluster randomised controlled trial was carried out in 28 primary schools in deprived areas of Nottingham, involving 1213 year 5 schoolchildren (age 9 and 10). Children received either a helmet + educational pack (educational pack and order form for free cycle helmet) or a helmet + multifaceted intervention (educational pack, order form for free cycle helmet, school assembly, lesson devoted to cycle helmet education, and an invitation to a school based cycling event).

authors' affiliations Results: The helmet + educational pack was as effective as the helmet + multifaceted intervention in terms of Correspondence to: Dr D Kendrick, Division of helmet ownership (OR 1.51, 95% CI 0.50 to 4.58) and wearing (OR 0.98, 95% CI 0.57 to 1.68). Helmet ownership significantly increased from baseline with both interventions, and wearing significantly General Practice, increased from baseline with the helmet + educational pack. The interventions reduced the inequality in Nottingham NG7 2RD, helmet ownership between children residing in deprived and non-deprived areas that had been present

> prior to the study. Conclusions: An educational pack plus a form to order a free cycle helmet is an effective way of increasing bicycle helmet ownership and use and reduces inequalities in helmet ownership among children in deprived areas. Further work is needed to determine the length of the effect of such interventions.

**D** icycle helmets afford protection against head and brain injuries to wearers of all ages involved in all types of Binjuries to weaters of an ages inverse in a crash, whether or not another vehicle is involved." Although childhood cycle injuries appear to be reducing in incidence,<sup>2</sup> there were still more than 7500 children under 16 admitted to NHS hospitals between 1991 and 1995 with bicycle related head injuries.3

There is a steep social class gradient in mortality from pedal cycle injury, with children from social class V having a mortality rate four times higher than children from social class I.<sup>4</sup> Hospital admission rates for cycling injuries are 61% higher among children from deprived than affluent areas.<sup>5</sup> We have recently shown that fewer children in deprived areas own cycle helmets than in affluent areas, but that once a child owns a helmet, helmet wearing is not related to deprivation.<sup>6</sup> Previous work suggests the cost of a helmet can act as a barrier to its purchase,7 and cycle helmet subsidies have been shown to be effective in increasing helmet use among children in low income areas in the USA.8

At present there are relatively few randomised controlled trials of interventions to promote helmet use in children without enacting legislation.9-15 Four of the trials examined the effectiveness of physician counselling. Two of these found no effect on helmet ownership,9 10 one found counselling plus a helmet discount coupon increased helmet purchase,12 and the fourth found counselling increased self reported helmet wearing.15 A further trial assessed the effect of co-payments for helmets in addition to physician counselling and found co-payments increased self reported helmet wearing as effectively as providing free helmets.<sup>14</sup> A school based trial found that subsidised helmets increased observed helmet wearing rates and that education without subsidised helmets had no effect.11 Finally a trial of a school based bicycle skills training programme found no effect on self reported helmet use.13 More non-randomised studies exist,8 16-25 many of which used complex multifaceted interventions. At present it is not clear whether some elements of these interventions

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are more effective than others, and if so, which elements this applies to. Several studies have also assessed the effect of the interventions by social group, finding conflicting results.<sup>7 8 18 19 24</sup> There is therefore a need to determine which elements of a cycle helmet programme are effective, and whether such programmes are equally effective in children from different social groups. This information is important to ensure effective use of resources for injury prevention and the reduction of health inequalities.

The objectives of this study were therefore to evaluate the effectiveness of two different educational interventions in addition to free cycle helmets in increasing cycle helmet ownership and wearing among 9 and 10 year olds from deprived areas of Nottingham, and to examine whether the effect differed by social group.

# METHODS

All year 5 children registered at participating schools were eligible to take part in the study. All 120 primary schools in deprived areas in Nottingham (defined as a ward with a Townsend score >0) were invited to participate. Twenty nine schools participated in the study, and a further school acted as a pilot for the baseline data collection and interventions.

#### Interventions

The study compared two different educational interventions. Intervention 1 comprised an educational pack plus a form to order a free cycle helmet. Intervention 2 comprised an educational pack, a form to order a free helmet, an assembly, one lesson devoted to cycle helmet education, and an invitation to a cycling event. The educational pack included a road safety quiz, two educational booklets, a cycling fact sheet produced by Nottingham City Council Road Safety and Environmental Services Department, a helmet order form for the child to choose from five helmet designs, and a covering letter encouraging parent participation. Children were asked

to complete the quiz with their parents and return it to the school with the helmet order form. Helmets were delivered to the schools direct from the manufacturer with written instructions on how to fit the helmet. The assembly, undertaken by a local doctor included an explanation of the effect of a head injury on a child's life, a video of a local child with a head injury, and an egg drop with and without a helmet. The objectives of the cycle helmet lesson were to increase understanding of how an injury affects the brain and its functioning, the need for protection of the brain when engaging in risky activity, and the impact a head injury can have on the life of a child and their family. Teachers were provided with a lesson plan, the Bicycle Helmet Initiative Trust video Happy Birthday Paul with a list of questions and answers to lead discussion after the video, and a human skull. All children were invited to a cycling event at a local school where cycle control skills were demonstrated and children had the opportunity to try activities aimed at increasing their control over their bike. The interventions took place in June and July 2001.

The interventions were designed based on the findings from three focus groups held with local children aged 11–12 who had taken part in a cycle helmet project the previous year, and from a review of the literature, and was informed by advice from teachers, health promotion specialists, school nurses, road safety officers, the British Cycling Federation, paediatricians, accident and emergency department consultants, and general practitioners. It was piloted in one school not taking part in the project.

# Outcomes

The primary outcomes for the study were the proportion of children owning and wearing a cycle helmet. These were assessed by anonymous self completion questionnaire, based on questions used in previous cycle helmet research,<sup>26 27</sup> using two cross-sectional surveys; the baseline assessment took place in June 2001 and the follow up assessment in September 2001.

Observations of cycle helmet wearing were carried out to validate self reported helmet wearing. Only 2% of children in participating schools rode to school, hence we organised cycling events in four schools (two in each treatment group) two weeks following completion of the follow up questionnaire to observe helmet wearing. Children were invited to attend, and the invitation purposely did not make any specific mention of cycle helmets. A member of the research team observed the proportion of children riding bikes at the event who were wearing a helmet.

#### Sample size

The study had 80% power to detect a difference in the percentage of children owning a helmet from 81% to 90% between the two treatment groups, at the 5% significance level. The intra-class correlation coefficient (ICC) calculated from our sample was 0.09. It had 80% power to detect a difference in the percentage of children always wearing a helmet from 34% to 44.5%, at the 5% significance level. The ICC for helmet wearing calculated from our sample was 0.04.

### Randomisation

Participating schools were stratified by Townsend score into three strata (0.1–2.99, 3.0–6.99, and  $\geq$ 7). Schools were randomly allocated within each stratum to treatment group. One member of the research team generated the allocation schedule, and a second member of the research allocated the schools to treatment group team blind to the identity of each school.

## Blinding

It was not possible to blind the schools or the investigators to treatment group. The data were analysed blind to treatment group.

### Primary analyses

Comparability of treatment groups at baseline was assessed informally. Data were analysed using STATA version 7, SPSS version 11.0, and MLwiN version 1.1.<sup>28</sup> Analyses were undertaken on an intention to treat basis. The primary analysis of helmet ownership and always wearing a helmet was undertaken using *t* tests weighted by the number of children in each school. We have adjusted for baseline helmet ownership and for factors associated with helmet ownership or wearing,<sup>6</sup> where there were large baseline differences between treatment groups using random effects logistic regression (MLwiN) to adjust for clustering.<sup>29</sup>

#### Secondary analyses

To assess whether the helmet + educational pack or the helmet + multifaceted intervention was more effective for children living in deprived areas we added a term for the interaction between treatment group and deprived area to the random effects logistic regression. Prior to the trial we reported that fewer children in deprived areas owned a helmet.6 To assess whether the interventions reduced this inequality, we examined the change in the relation between school level helmet ownership and deprivation at baseline and at follow up using linear regression. We used the difference in the proportion of children in each school owning a helmet (follow up proportion - baseline proportion) as the dependent variable and the median Townsend score for the school as the explanatory variable. Assumptions for the regression analyses were checked by examining plots of residuals.

Changes from baseline in helmet ownership and wearing were assessed using paired *t* tests, weighted by the number of children in each school.

# RESULTS

Figure 1 shows the progress of the 29 randomised schools and their 1213 children through the trial. Table 1 shows the characteristics of treatment groups at baseline. More children in the helmet + multifaceted intervention group were male, lived in a deprived area, and had been encouraged by their family to wear a helmet. Fewer children in the helmet + multifaceted intervention group used their bike to ride to friends and owned a helmet before the interventions started.

# **Primary analyses**

Table 2 shows the primary outcomes. We found no significant difference between the treatment groups in either helmet ownership or wearing. The unadjusted odds ratio for cycle helmet ownership comparing the helmet + multifaceted intervention with the helmet + educational pack was 1.54 (95% CI 0.62 to 3.84) and 1.51 (95% CI 0.50 to 4.58) after adjusting for helmet ownership at baseline, residence in deprived area, frequency of riding bike, parental warning about danger of not wearing a helmet, and family encouragement to wear helmet. The unadjusted odds ratio for helmet wearing was 1.05 (95% CI 0.65 to 1.68) and 0.98 (95% CI 0.57 to 1.68) after adjusting for family encouragement to wear a helmet, best friend wearing a helmet, uses bike to ride to friends, and thinks comfort of helmet is important.

#### Secondary analyses

The helmet + multifaceted intervention did not appear to be more effective than the helmet + educational pack among children living in a deprived area (helmet ownership All primary schools with Townsend score >0 invited to participate n = 120 Figure 1 Progress of schools and children through the trial. Excluded schools n = 91Schools not responding to intervention n = 85 Did not meet eligibility criteria n = 2 (only enrolled children aged 5–7) School declined to participate n = 3School used as pilot for surveys and intervention n = 1Schools agreeing to participate and eligible n = 29 Schools randomised n = 29Helmet + educational pack n = 15 Helmet + multi-faceted intervention n = 14Children in brief intervention schools n = 704Children in intensive intervention schools n = 5221 school withdrew prior to baseline assessment (13 children) Children remaining in helmet + educational pack schools n = 691 Baseline assessment Children in school on day of survey n = 597Children in school on day of survey n = 464Completed baseline assessment 100% (n = 464) Completed baseline assessment 100% (n = 597) Intervention Schools received intervention n = 14Schools received intervention n = 14Children received helmet n = 351 Children received helmet n = 352 Children returned road safety quiz n = 324 Children returned road safety quiz n = 269Children attended cycling event n = 60Follow up assessment

Children in school on day of survey n = 605	Children in school on day of survey n = 459
Completed follow up assessment 76.7% (n – 464)	Completed follow up assessment 97.8% (n = 119)
$Completed follow up assessment 7 0.7 \ (if = 404)$	Completed follow up assessment $77.0\%$ (if = 447)

p = 0.90, helmet wearing p = 0.72). We therefore combined the data from both treatment groups to examine the relation between deprivation and helmet ownership at baseline and at follow up. Figure 2 shows that as the degree of deprivation increased the proportion of children owning a helmet decreased, and that this was more marked at baseline than at follow up (b = 0.027, 95% CI 0.004 to 0.050, p = 0.026). Table 3 shows a significant increase from baseline helmet ownership in both groups and in helmet wearing in the helmet + educational pack group.

#### Cycle helmet observations

We observed 60 children riding their bike at the cycling events in the helmet + educational pack group and 45 in the helmet + multifaceted intervention group, of which 48 (80%) and 20 (44.4%) respectively were wearing a helmet. These observed helmet wearing rates are higher than the self reported rates for always wearing a helmet at follow up for both groups (table 2).

# DISCUSSION

This study is the first randomised controlled trial aimed at increasing cycle helmet use in the UK. It has shown that a free helmet and an educational pack were as effective as a

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free helmet plus a multifaceted intervention in increasing helmet ownership and wearing in the short term. Both interventions reduced the inequality in helmet ownership between children residing in deprived and non-deprived areas that had been present prior to the study. This is important as we have previously shown that once a helmet is owned, wearing rates do not differ between children residing in deprived and non-deprived areas.<sup>6</sup>

# Limitations of the study

Our study did not include a group that did not receive any intervention because we know from previous research that providing or subsidising helmets increases owner-ship<sup>8 11 14 16 21 23 25</sup> and that education without subsidised helmets does not.<sup>11</sup> We think it is highly unlikely that helmet ownership would increase from 50% to 80% over the three month study period for reasons other than the interventions, as there were no other cycle helmet schemes targeted at children from these schools during this time period.

We used self reported helmet ownership and wearing as the primary outcome measures, but self reports may not accurately reflect actual wearing rates.<sup>30</sup> Observations of helmet wearing are usually used to validate self reported wearing, but as the intervention was restricted to a single

	Helmet + educational pack (n = 597)	Helmet + multifaceted intervention (n = 464)
Sex (male)	285 (47.7)	248 (53.5)
Resides in deprived area	230 (44.4) [94]	288 (55.6) [67]
Owns bike	556 (93.1)	399 (86.0)
Rides bike*		
4 or more days per week	300 (54.6) [7]	209 (53.6) [9]
3 days a week or less	249 (45.4)	181 (46.4)
Rides bike*		
To and from school	18 (3.2)	5 (1.3)
To visit friends	296 (53.2)	188 (47.2)
For fun	489 (88.0)	348 (87.2)
Only when has to	62 (11.2)	25 (6.3)
For sport	187 (33.6)	149 (37.3)
Owns helmet*	310 (55.8)	185 (46.4)
Encouraged by family members to	346 (64.2) [17]	266 (70.2) [20]
wear helmet*		
I lold about dangers of not wearing		
helmet by:	(00 (70 0)	220 /70 1)
Parent	490 (78.2)	339 (78.1)
School nurse	44 (7.0)	200 (11.8) 200 (40 7)
Dester	407 (04.7)	270(00.7)
Doctor	109 (17.4)	/4(1/.1)
Pond safety officer	380 (40 4)	290 (66.8)
Bost friend wears helmot	217 (38 0) [24]	150 (35 5) [14]
Had accident on bike requiring	104 (17 4)	96 (20 7)
medical attention	104 (17.4)	/0 (20.7)
Wears helmet when ridinat		
Always	86 (28 3) [6]	56 (30 6) [2]
Sometimes	154 (50.7)	80 (43.7)
Never	64 (21.1)	47 (25.7)

year group within each school, and only 2% of children rode to school, we were limited in how we could conduct observations. We piloted observations with a year 5 teacher from participating schools and a researcher driving in the catchment area of the school, with the teacher identifying year 5 children from the school. We observed 99 children during five observations, only nine of which belonged to year 5, making it unfeasible to observe sufficient children within



**Figure 2** Scatterplot of the proportion of children owning a helmet in each school against the median Townsend score for each school, at baseline and at follow up.

the time scale and budget of the trial. We therefore organised cycling events at schools in both treatment groups after the follow up questionnaire to observe helmet wearing. The observations found higher wearing rates than self reported rates of always wearing a helmet. These findings are similar to a large study that observed more than 900 children riding and performed classroom surveys of more than 8000 children; it found classroom self reported always wearing rates (15%) were lower than observed wearing rates (20%), self reported use of helmet on day of survey (26%), or parent report of child always wearing a helmet (37%).<sup>31</sup> This suggests classroom self reported rates of always wearing a helmet may be the most conservative estimates of helmet wearing rates.

The response rate to the follow up survey was lower in the helmet + educational pack group than the helmet + multifaceted intervention group, and this may have biased our

 Table 2
 Number of children owning and always wearing a helmet by school and treatment group post-intervention (percentage)

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Owns a helmet			Always wears a helmet				
School number	Helmet + multifaceted intervention	School number	Helmet + educational pack	School number	Helmet + multifaceted intervention	School number	Helmet + educationc pack
1	38/47 (81)	15	5/7 (71)	1	10/38 (26)	15	2/5 (40)
2	18/18 (100)	16	18/31 (58)	2	8/17 (47)	16	8/18 (44)
3	15/29 (52)	17	30/34 (88)	3	7/15 (47)	17	12/30 (40)
4	12/15 (80)	18	13/17 (76)	4	3/11 (28)	18	2/13 (15)
5	12/13 (92)	19	15/18 (83)	5	2/11 (18)	19	4/15 (27)
6	20/22 (91)	20	34/49 (69)	6	6/20 (30)	20	4/34 (12)
7	20/20 (100)	21	6/6 (100)	7	4/19 (21)	21	2/6 (33)
8	17/24 (71)	22	16/17 (94)	8	5/17 (29)	22	4/16 (25)
9	40/50 (80)	23	14/23 (61)	9	14/40 (35)	23	6/14 (43)
10	30/40 (75)	24	92/100 (92)	10	8/30 (27)	24	49/92 (53)
11	55/55 (100)	25	15/18 (83)	11	25/55 (45)	25	3/15 (20)
12	22/22 (100)	26	49/64 (77)	12	10/22 (45)	26	11/49 (22)
13	5/9 (56)	27	19/20 (95)	13	0/5 (0)	27	4/19 (21)
14	10/10 (100)	28	26/31 (84)	14	2/10 (20)	28	10/26 (38)
Mean perc	entage across schools (SE)*						
	84.0 (4.2)		80.9 (3.8)		33.1 (2.9)		33.8 (5.7)
Difference	between means (95% CI)						
			3.0 (-8.5 to 14.6), p=	0.59		-0.6 (-13	.8 to 12.5), p=0.92

Table 3	Changes in c	cycle he	lmet owners	ship and	wearing	from base	line by	treatment
group								

	Mean % in schools at baseline (SE)	Mean % in schools at follow up (SE)	Difference between means (95% CI)	p value
Helmet + educational pack				
Owns a helmet	56.2 (5.6)	80.9 (3.8)	24.7 (15.9 to 33.5)	< 0.001
Always wears helmet	26.8 (5.0)	33.8 (5.8)	6.9 (0.1 to 13.8)	0.048
Sometimes wears helmet	52.0 (4.4)	53.9 (3.5)	1.9 (-6.0 to 9.9)	0.61
Never wears helmet	21.2 (3.7)	12.3 (3.1)	-8.9 (-16.3 to -1.4)	0.024
Helmet + multifaceted intervention				
Owns a helmet	46.4 (3.6)	84.0 (4.3)	37.5 (22.8 to 52.2)	< 0.001
Always wears helmet	30.4 (3.6)	33.1 (3.0)	2.7 (-7.3 to 12.7)	0.57
Sometimes wears helmet	43.8 (3.9)	54.2 (2.8)	10.4 (-0.4 to 21.2)	0.057
Never wears helmet	25.7 (6.4)	12.6 (2.1)	-13.1 (-26.7 to 0.7)	0.061
Denominators for: Helmet ownership at baseline: helmet - Helmet ownership at follow up: helmet	+ educational po + educational p	ack = 556, helme back = 435, helme	t + multifaceted intervention et + multifaceted interventio	= 399 n = 374

Helmet wearing at follow up: helmet + educational pack = 352, helmet + multifaceted intervention = 310

results. If non-responders in the helmet + educational pack group were less likely to own or wear helmets than responders, this would tend to underestimate the effect of the helmet + multifaceted intervention. The worst case scenario is that helmet wearing rates among the non-responders in the helmet + educational pack group did not increase from those at baseline. Using the ownership and wearing rates for each school at baseline, we estimated the numbers of nonresponders in each school owning and wearing a helmet at follow up. Under this scenario, the helmet + educational pack group helmet ownership rate at follow up would reduce to 75% and the percentage always wearing a helmet to 33%. The differences between these figures and the helmet + multifaceted intervention group ownership and wearing rates would not alter the conclusions we have drawn from this study.

Finally we have only been able to show short term effects of the interventions used in this study. Future research should consider the use of a longer follow up period to determine the length of time for which the interventions remain effective and to assess whether helmet wearing continues into the teenage years, as wearing rates are usually lower in this age group.<sup>26 32-37</sup>

# How this study compares to previous studies

Several studies have assessed the impact of educational programmes plus subsidised helmets in low income communities.<sup>14 16 19 38</sup> Two showed increased helmet use among low income children,<sup>16 38</sup> one found requesting parents to pay a small amount towards helmets was as effective as providing free helmets in increasing helmet use,<sup>14</sup> and the fourth found subsidised helmets did not increase helmet use among children from low income families.<sup>19</sup> Our findings add weight to the three studies reporting the positive effect of helmet subsidies in low income communities, and confirm these findings in a UK context.

Studies that have undertaken subgroup analyses assessing the impact of educational interventions plus cycle helmet provision by social group have produced mixed results. One study found the intervention was associated with higher helmet wearing rates among children from low income communities,<sup>8</sup> while others found the intervention to be less effective in low income communities.<sup>7 I8 24</sup> We did not find a significant difference in the effectiveness of the interventions by residence in a deprived area, which is encouraging; however, the study was not designed to be adequately powered to detect such a difference, so care must be taken in interpreting these results.

## Implications for practice and research

Most reported helmet promotion programmes have employed multifaceted interventions and it is often not clear how each component contributes to the overall effectiveness of the programme. This study has shown that the many time consuming (and potentially expensive) components of a multifaceted intervention conferred little if any advantage in terms of helmet ownership or wearing over a simpler intervention, at least in the short term. In addition the interventions reduced the inequality in helmet ownership associated with living in a deprived area. Bicycle helmets are effective in reducing head and brain injuries and have been shown to be cost effective.<sup>39</sup> Primary Care Trusts and other agencies wishing to reduce both childhood injuries and inequalities should consider providing free helmets with an educational pack. More research is necessary to determine the length of the observed effect, particularly with respect to helmet wearing into the teenage years. Concerns have been expressed that increasing cycle helmet use may be associated with an increase in risk taking by helmeted  $\ensuremath{\text{cyclists}}^{40\text{--}42}$  and a reduction in cycling and its associated health benefits.<sup>1 41</sup> Agencies working to improve child health will need to implement other interventions in addition to cycle helmet promotion to achieve maximum injury reduction. Similarly maximising childhood exercise will require the promotion of exercise in its broadest sense, not just cycling.

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