Development and randomized controlled trial of a booklet of advice for parents

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SUMMARY. A booklet was developed in the author's practice that provided advice for parents on the home management of cough, fever, sore throat, diarrhoea and vomiting in children, and included specific recommendations about when to seek medical help. The effect of distributing this booklet on the frequency of parent-initiated consultations was evaluated in a randomized, controlled trial. The overall effect of the booklet was a statistically non-significant reduction in consultations for the symptoms that it addressed ('booklet symptoms'). However, this finding masked a statistically significant reduction in daytime home visits for booklet symptoms (especially for cough, fever and sore throat) and a significant increase in out of hours consultations (for fever, diarrhoea and vomiting). Had all the households in the practice been sent a copy of the booklet then it was estimated that over the following year some 28% fewer home visits and some 173% more out of hours consultations would have been undertaken for booklet symptoms than if none of the households had been sent a copy.

Introduction

MANY booklets have been written to provide advice for parents on the home management of illness in their children. However, such advice has rarely been evaluated in the community.

Cough, fever, sore throat, diarrhoea and vomiting are common symptoms in children. They are typically self-limiting, but are frequently presented to the family doctor.[1,2] A booklet was produced in the author's practice in Scotland to help parents to manage these symptoms and to decide when to seek professional advice. This report describes a randomized, controlled trial of the effect of distributing the booklet on the frequency of requests by parents for consultations.

Method

Development of the booklet

The booklet was written to address five common symptoms: cough, fever, sore throat, diarrhoea and vomiting, occurring in children aged two to 12 years inclusive. The lower age limit was chosen as it was felt that not all the advice would be appropriate for infants younger than two years. The upper limit represented the age at which reduced doses are conventionally replaced by adult doses of medicines. An introductory section, 'Nursing your sick child' offered general advice on home nursing. Each of the five sections that followed contained a short paragraph of background information about one of the five symptoms, followed by advice on home care specific to that symptom, and then explicit recommendations about when it would be appropriate to contact the family doctor.

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The first draft of the booklet was prepared by the author, following a review of a number of existing publications for parents. This draft was discussed with other members of the practice team. Following various amendments, the booklet was shown to and discussed with six mothers, none of whom was registered with the study practice and each of whom had at least two children aged over two years. A few more minor amendments were made in the light of these discussions and the final version was sent to the two local consultant paediatricians for their approval, which they gave without qualification. The final text had a Flesch reading ease score of 72, indicating that the booklet would be understood by approximately 80% of the adult population of Scotland.[3,4]

Randomized controlled trial of the booklet

A randomized, controlled trial of distributing the booklet to households in the author's practice in Scotland was performed over 12 months, preceded by a two month baseline period. From 1 December 1986 a contact record form was completed by the general practitioners for each contact with any child in the practice born between 1975 and 1984 inclusive. The only exceptions were children seen for routine immunizations or developmental assessment.

The contact record form provided a record of the child's name and date of birth, the date of consultation and place of contact, whether this was an initial or subsequent consultation during an illness episode and the reason for the consultation.[5] The doctor was invited to tick one only of: cough, fever, sore throat, diarrhoea and/or vomiting, painful ear, or other. Diarrhoea and vomiting were offered together as they commonly occur in the same illness. Painful ear was not specifically mentioned in the booklet, but was included on the record in order to see if distributing the booklet had any effect on the frequency of consultations for a symptom that the booklet did not address.

A list of all patients registered with the practice, classified by sex and by date of birth, was obtained from the local health board. On this were identified all those children born between 1975 and 1984 inclusive and each household was sent a questionnaire early in January 1987 with a covering letter and stamped envelope for reply. The questionnaire was designed to collect information about background variables of the households and to identify households no longer at that address. Space was provided for a list of all the medicines kept in the house for the children's use. The questionnaire then inquired about those sociodemographic features of the household which are known to be related to consultation rates.[6-12] Reminder letters, with second copies of the questionnaires, were sent to those households that did not return the first set. Households whose mailed items were returned 'not known at this address' and whose current address could not be identified were discarded. The remaining households were randomly allocated in equal numbers to booklet and control groups. Households in the booklet group were sent a copy of the booklet, posted to arrive on 1 February 1987. None was returned 'not known at this address'. A covering letter emphasized that the booklet was for the use of the addressees only. Households in the control group received no intervention.

After the two month baseline period, contact recording continued during the experimental 12 months from 1 February 1987

to 31 January 1988. Two weeks after the end of contact recording in the practice, a questionnaire designed to investigate recall of, attitudes towards, and use of the booklet was posted to the households in the booklet group. Up to two reminders were sent to households which did not respond.

The protocol for this study was approved by the Inverclyde ethical committee.

Statistical analysis

The frequency distributions of initial contacts per household during the two month baseline period, and again during the 12 months that followed distribution of the booklet, were compared between the booklet and control groups using the Wilcoxon rank sum test.[13] However, the booklet and control groups each contained different proportions of households with one child, two children and three children. It was necessary to adjust for this difference. The one child households in the booklet group were compared with those in the control group using the Wilcoxon test. The two child households and the three child households were also compared. The results of the three tests were then combined[14,15] to generate a single test statistic (Zc) which was used to test the null hypothesis that the booklet had no effect on the frequencies of initial contacts per household. The null hypothesis was rejected if Zc was equal to or greater than 1.96. This corresponded to accepting a maximum probability of 0.05 of falsely rejecting the null hypothesis.

Where the null hypothesis was rejected then the size of the effect of the booklet was obtained by estimating the change in the mean frequency of initial contacts per household that would have resulted from distribution of the booklet to all the households in the study, as a proportion of the estimated mean frequency had the booklet not been distributed to any household.

The distributions of those sociodemographic variables that were measured in the households of the booklet and control groups were compared using the Wilcoxon rank sum test or the chi-squared test as appropriate. Again, a maximum probability of 0.05 was accepted of a type one error.

Results

A total of 712 children born between 1975 and 1984 inclusive were identified from the practice list provided by the health board. The children lived in 465 households. The correct addresses of 41 households could not be identified after their questionnaires had been returned by the Post Office. The five households with more than three children born between 1975–84 were also excluded, so that 419 households with 634 children were finally included; 210 households with 318 children were allocated to the booklet group and 209 households with 316 children to the control group (Table 1).

The information collected on the sociodemographic questionnaire sent out at the beginning of the study was used to compare the households in the booklet and control groups. Copies of this questionnaire were returned by 357 (85%) of the households in the study. There was no significant difference in the numbers and types of medicines kept by the households in the two groups. The rest of the sociodemographic questionnaire was completed by mothers only, who represented 338 (95%) of the respondents. There were no significant differences between the mean ages of the mothers in the two groups (booklet group 31.1 years; control group 31.3 years); the mothers' mean age at finishing full time education (15.5 years; 15.7 years); the mean number of children (2.3; 2.4); marital status; occupational status of households; or mean number of adults per household (1.9; 1.9).

Completeness of contact recording

The practice reception staff were asked to record all health centre consultations and daytime home visits in the relevant practice appointment and visit books. The number of contacts with children born between 1975 and 1984 inclusive that were recorded in these books during the experimental year are given in Table 2 for comparison with the numbers of contact forms filled in by general practitioners. The latter were returned for approximately 89% of recorded daytime health centre consultations and 86% of daytime home visits.

All out of hours calls to the practice were dealt with by an extended rota service which operated from 16.00 to 08.00 hours on weekdays, plus Saturday afternoons and all day Sundays. All resulting contacts were recorded in the rota service's own clinical records. Contact record forms were completed from these. Out of hours contacts were not subdivided into those at the health centre and those undertaken at home.

It seems likely that many telephone consultations were not recorded and the nine forms that were returned were too few for analysis.

Effect of booklet on initial contact frequencies

Table 3 shows that for each household size the mean frequency of initial contacts per household for all symptoms in the two

Table 1. Number of households in the study by household size.

Household size (number of children born 1975–84 incl.)	Number of households	
	Not sent booklet (control group)	Sent booklet (booklet group)
1	118	125
2	75	62
3	16	23
Total	209	210

Table 2. Contacts recorded during the 12 months that followed distribution of the booklet.

Site and time of contact	Number of contacts	
	Recorded in practice books by staff	Recorded on forms by GPs
Health centre (daytime)	1163	1030
Home visit (daytime)	441	379
Telephone	—	9
Out of hours	—	189

Table 3. Mean and median number of initial contacts for all symptoms per household in booklet and control groups, stratified by household size.

Period	Household size (number of children born 1975–84 incl.)	Average number of initial contacts				
		Control group		Booklet group		
		Mean	Median	Mean	Median	Zc
Two month baseline	1	0.36	0	0.37	0	
	2	0.67	0	0.68	1	0.32,
	3	0.63	0	0.61	0	NS
Experimental year	1	1.64	1	1.54	1	
	2	3.36	3	2.56	2	−1.30,
	3	3.63	3	4.65	3	NS

NS = not significant.

month baseline period was similar in the two groups. During the 12 months that followed distribution of the booklet there were fewer contacts per household in the booklet group than in the control group for households with one or two children, but more for households with three children. However, the test statistic, Zc, did not reach significance.

Apart from the general advice given in the first chapter, the guidance in the booklet was concerned specifically with five symptoms. Table 4 refers to contacts for booklet symptoms only. Considering contacts at all sites, the differences between the booklet and control groups did not reach significance. Contacts for booklet symptoms were also analysed separately by site. Although there was no significant difference between booklet and control groups for daytime health centre contacts, there were differences for daytime home visits and for contacts out of hours. For daytime home visits, the mean frequency of initial contacts was substantially lower in the booklet group than in the control group for households with one or two children. It is not clear why this trend was reversed for households with three children. Despite this, had the booklet been mailed to all the households in the study then the estimated effect on the frequency of initial daytime home visits for booklet symptoms was −0.28, that is a 28% reduction. For out of hours contacts for booklet symptoms, the mean frequencies of initial contacts were higher in the booklet group than in the control group for all sizes of household. An estimated increase of 1.73, or 173%, in initial out of hours contacts would have occurred if the booklet had been distributed to all the households in the study.

When the frequencies of initial contacts per household were considered for each presenting symptom in turn, irrespective of the site of contact, a significant difference between the two experimental groups was detected only for sore throat (Zc = −2.06, $P<0.05$). Had the booklet been distributed to all the households in the study then a change of −0.51, that is a 51% reduction, was estimated in the frequency of initial contacts for this symptom.

It can be seen in Table 5 that the reduction in initial daytime home visits in the booklet group was a result of fewer consultations for cough, fever and sore throat. The significantly higher frequency of out of hours contacts in the booklet group was due to an excess of consultations for fever and for diarrhoea or vomiting. Whereas only 18% of initial contacts for fever were out of hours in the control group, 40% were out of hours in the booklet group. This difference in proportions was unlikely to have arisen by chance ($\chi^2 = 5.37$, df=1, $P<0.05$). For none of the other presenting symptoms did any difference in the proportions of out of hours initial contacts reach significance between the two groups.

Table 4. Mean and median frequencies during the experimental year of initial contacts recorded for booklet symptoms per household in booklet and control groups, stratified by household size.

Site	Household size (number of children born 1975–84 incl.)	Average number of initial contacts: Control group Mean	Control group Median	Booklet group Mean	Booklet group Median	Zc
All sites	1	0.91	0	0.74	0	
	2	1.75	1	1.00	1	−1.92,
	3	1.63	1	2.30	2	NS
Health centre (daytime)	1	0.47	0	0.40	0	
	2	1.10	0	0.45	0	−1.94,
	3	0.94	0	0.96	0	NS
At home (daytime)	1	0.40	0	0.24	0	
	2	0.55	0	0.32	0	−2.13,
	3	0.63	0	1.04	0	$P<0.05$
Out of hours	1	0.03	0	0.10	0	
	2	0.11	0	0.23	0	2.30,
	3	0.06	0	0.30	0	$P<0.05$

NS = not significant.

Survey of households in booklet group

The attitude questionnaire was posted to 203 of the 210 households in the booklet group. Seven families were omitted because they had left the practice area or had moved to some other, unknown address, or because a child in the family was seriously ill. Of the households mailed, eight were found to have moved without leaving a forwarding address. Hence, 195 questionnaires were successfully posted, of which 156 (80%) were returned. One hundred and thirty seven (88%) of the respondents remembered receiving a copy of the booklet, and 117 (75%) claimed still to possess their copy. One hundred and two respondents (74% of those who remembered receiving it) remembered consulting the booklet at least once. Parents with one child aged two to 12 years reported having used the booklet 2.6 times on average, parents with two children 3.0 times, and parents with three children 3.3 times.

Sixty eight (67%) parents who claimed to have consulted the booklet at least once thought that the advice given in the booklet had changed something that they would do for their child when ill, and 93 (91%) that the booklet had been useful to them. One hundred and twenty six (92%) of all those respondents who remembered it felt that the booklet would be useful to others (Table 6).

Table 5. Total frequencies of initial contacts recorded in the control and booklet groups during the experimental year, classified by presenting symptom and by site of contact.

	Number of initial contacts													
	Cough		Fever		Sore throat		Diarrhoea and vomiting		Painful ear		Other		All symptoms	
	Control	Booklet	Control	Booklet	Control	Booklet	Control	Booklet	Control	Booklet	Control	Booklet	Control	Booklet
All sites	116	90	56	47	65	32	27	38	40	42	200	210	504	459
Health centre (daytime)	84	66	14	8	39	12	11	16	27	26	144	156	319	284
Home (daytime)	32	23	32	20	24	16	15	13	5	6	39	39	147	117
Out of hours	0	1	10	19	2	4	1	9	8	10	17	15	38	58

Table 6. Postal survey of households 54 weeks after they had been sent a copy of the booklet: responses to questions on perceived usefulness of the booklet.

	Frequency of response				
	Yes definitely	Yes probably	Not sure	No probably not	No definitely not
Has the advice in the booklet changed anything that you would do for your child when he or she is ill?	21	47	17	15	1
Overall, has the booklet been useful to you?	41	52	7	2	0
Do you think that other families in the practice would find the booklet useful?	71	55	8	0	0

Discussion

During the 12 months after the booklet had been distributed, the frequency distributions of initial contacts differed significantly and substantially between the booklet and control groups. These differences were not apparent during the baseline period, and were only detected for symptoms addressed in the booklet. The households in the booklet and control groups did not differ significantly in the distributions of any of the sociodemographic variables that were measured. The results of the attitude questionnaire at 54 weeks suggested that the booklet was well received by the parents in the booklet group, most of whom remembered and made use of it. Given the randomized, controlled design of this trial, it is concluded that distributing the booklet was responsible for the differences in the distributions of consultations between the two groups.

It is possible that the effects of the booklet were greater than those detected. Contamination of the control group may have occurred. Although the author was not aware of any instances, parents in the control group may have been offered advice derived from the booklet by their friends or relatives in the booklet group. Any contamination that did occur would have reduced the power of the study to detect an effect of the booklet. The failure to record every contact must also have slightly reduced the power of the study.

It is unfortunate that telephone contacts were probably underrecorded by the doctors. The policy in the practice was to see all children on demand, in the surgery or at home at the discretion of their parents, with little attempt to modify the parents' request before the child had been seen and examined. Nevertheless, some parents did just telephone for advice, and it is possible that the booklet influenced this. Similarly, although this was not central to the aim of the study, it would have been interesting to have obtained details of attendances by the children at the local accident and emergency department. However, this was not possible.

Six previous studies have been found by the author which can be compared with the findings of the present study. In all cases the effects of written advice on the frequencies with which patients consult were measured in a randomized controlled trial.[16-21] A significant effect was detected in two of these.[18,21] In both cases the written advice was handed to the patient or to a family member during the course of an interview, the advice referred to a single clinical problem, and a reduction in consultations for that problem was the result.

In the present study, postal distribution of advice was found to be effective. Furthermore, the booklet did not merely provide non-specific encouragement or discouragement for parents to consult the practice for the symptoms described. The effect of the advice on consultation frequency depended on the child's symptoms. It is interesting to speculate on the reasons for this. Initial contacts for sore throat were significantly reduced in the booklet group. There were also fewer initial contacts for cough, although this did not reach significance. For both symptoms the advice given in the booklet was that antibiotics would not help the symptom get better any quicker. In a survey of 235 patients consulting their general practitioner with upper respiratory tract symptoms, 62% of those who responded expected medication of some kind, and 40% expected an antibiotic.[22] Possibly a number of parents in the booklet group either accepted the advice given in the booklet, or at least read it as implying that there was little point in asking for antibiotics for a cough or sore throat because the doctors in the practice would be unwilling to prescribe them.

Initial contacts for fever were significantly more likely to occur out of hours in the booklet group than in the control group. Again it is interesting to speculate on the reasons for this. Fever seems to be a particularly worrying symptom for parents.[23] Possibly parents were initially prepared to accept the advice in the booklet, or were otherwise dissuaded from consulting, but as the hours passed and as evening drew on their anxieties worsened to the point when some of them finally changed their minds. An excess of initial out of hours contacts for diarrhoea and/or vomiting was also observed in the booklet group but this difference between the groups was not statistically significant. However, a mechanism similar to that proposed for fever might have operated.

A surprising observation was that the effect of the booklet in households with three children did not appear to follow the pattern set by households with only one or two children. Among the three child households, for example, the mean initial contact frequency was higher in the booklet group than in the control group by day as well as out of hours. There were only 39 three child households in total, so that the observed contrast with the other households may have arisen purely by chance. However, the observation does raise the possibility that more experienced parents responded differently to the advice offered in the booklet.

Although the booklet was shown in this study to be an effective intervention in the consulting behaviour of parents, not all its effects were beneficial. There may be no advantage to either patients or doctors in a reduction in daytime demand which is partially offset by an increase in the demand for out of hours care. Furthermore, if parents are indeed put off contacting the practice for a feverish child until their anxieties get the better of them in the evening, then this is a most unattractive result for child, parents and doctor.

On the other hand, some potentially valuable effects were detected. The booklet reduced the number of consultations for sore throat, and possibly for cough. There was no reason to regard these effects as disadvantageous to either children or parents, while time saved in any aspect of the clinical services offered by a practice can potentially be used to provide benefits in another aspect.[24]

The distribution of written advice by post is a relatively cheap and simple process. The use that patients make of the primary care services is not entirely congruous with their apparent needs[25,26] so that the development of further written educational material seems worthwhile. However, any material that is developed must clearly be evaluated in a trial within the setting in which it is to be used before its widespread distribution.

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