ORIGINAL ARTICLE

Maternal compliance with nutritional recommendations in an allergy preventive programme

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Aims: To assess maternal compliance with nutritional recommendations in an allergy preventive programme, and identify factors influencing compliance behaviour.
Methods: Randomised double-blind intervention study on the effect of infant formulas with reduced allergenicity in healthy, term newborns at risk of atopy. Maternal compliance with dietary recommendations concerning milk and solid food feeding was categorised.
Results: A total of 2252 newborns were randomised to one of four study formulas. The drop out rate during the first year of life was 13.5% (n = 304). The rates of high, medium, and low compliance to milk feeding during weeks 1–16 were 83.4%, 4.0%, and 7.5%; the corresponding rates to solid food feeding during weeks 1–24 were 60.0%, 12.1%, and 22.9%. In 5.1% of subjects no nutritional information was available. Low compliance was more frequent among non-German parents, parents with a low level of education, young mothers, smoking mothers, and those who weaned their infant before the age of 2 months.
Conclusions: Evaluation of allergy preventive programmes should take into account non-compliance for assessing the preventive effectiveness on study outcome.

Research on compliance with dietary recommendations has predominantly dealt with patients' adherence to therapeutic regimens prescribed for specific diseases like diabetes or obesity. Little information exists with regard to compliance of parents following allergy preventive recommendations for the benefit of their infants at allergic risk. A major problem in such prevention trials is that subjects may not comply with the programme, may change treatment, or may withdraw from participation before treatment or follow up are complete. In most studies on allergy prevention, little if any information is given on definition of compliance, ascertainment of adherence to the preventive recommendations, assessment of compliance behaviour, and evaluation strategies with respect to non-compliance.

While efficacy is of primary interest when evaluating the biological effect of a treatment or prevention programme under optimal conditions, effectiveness concerns the success under real life conditions. Treatments can be efficacious without being effective, if they are not accepted by the at risk population. Effectiveness is one of the criteria that should be known when judging the success of allergy preventive strategies.[1]

The objective of this study was to investigate maternal compliance with an infant feeding intervention programme for prevention of atopic diseases in a cohort of high risk infants. The study is part of the German Infant Nutritional Intervention (GINI) programme, a prospective randomised controlled cohort study, conducted to assess the preventive effect of three different preparations of hydrolysed infant formulas in comparison with a conventional cows' milk formula. Maternal compliance with nutritional recommendations was evaluated and determinants associated with compliance behaviour were identified.

SUBJECTS AND METHODS

Subjects and design

Families with a history of atopic diseases, who attended one of 16 maternity hospitals in the two study regions of Munich (Bavaria) and Wesel (North-Rhine-Westfalia), were invited to participate in the study. Infants were included if the following criteria were fulfilled: (1) at least one atopic parent or sibling; (2) healthy, term newborn; (3) no feeding of non-study formula before randomisation; (4) sufficient parental knowledge of the German language; and (5) written informed consent. Between September 1995 and July 1998, a total of 2252 newborns were enrolled in the study. Infants were randomly assigned to one of four study formulas shortly after birth by a computer generated list of random letters. Parents and study observers were blinded with regard to the study formula of the infants. The infants' physicians were informed about the objectives and the design of the study.

Dietary recommendations

Parents received detailed recommendations on the infant's nutrition in a verbal and written form. Mothers were encouraged to breast feed as long as possible. If breast feeding was not possible, insufficient, or refused, feeding the randomised formula was advised for at least the first four months of life. Families received the study formulas free of charge in coded tins. It was recommended not to introduce solid foods during the first four months of life and thereafter to introduce only one new food per week. Potentially allergenic foods such as cows' milk and dairy products, eggs, fish, tomatoes, nuts, soya products, and citrus fruits were to be avoided during the whole first year. Families who decided not to follow the nutritional recommendations were encouraged not to feel guilty and to continue the follow up programme.

Data collection

Mothers kept a diary on a weekly basis during the first 24 weeks, which gave information on the infant's nutrition—that is, on the kind of milk the infant was fed (breast milk, study formula, or brand and amount of non-study formula), as well

Abbreviations: GINI, German Infant Nutritional Intervention

as time of introduction and kind of solid foods. Additional data were collected on family history of atopy, sociodemographic factors, living conditions, smoking habits, and health problems of the infant. The subjects were seen by a physician in the study centre at age 1, 4, 8, and 12 months.

Methods of assessing compliance

Generally, compliance (or adherence) is defined as the extent to which a person's behaviour (in terms of taking medication or following a diet) coincides with medical or health advice.[2] In this study, compliance was assessed by three aspects of parental adherence to the study protocol, with emphasis on the nutritional recommendations: (1) completeness of the infant's diaries as precondition for obtaining the necessary information; (2) compliance with the milk feeding recommendations; and (3) compliance with the solid food feeding recommendations.

Mothers' compliance was categorised into high, medium, and low preventive behaviour. Table 1 shows the specific items used for the assessment. Compliance was judged as high if the mother had filled in all infant diaries and had adhered to all nutritional recommendations. Before randomisation, two amino acid based formulas and one cows' milk free hydrolysate were allowed. For therapy of intolerance to study formula or breast milk, one amino acid based formula and two extensive hydrolysates were allowed.

The degree of compliance necessary to achieve the desired goal of allergy prevention is currently unknown. Two groups of non-compliance (medium and low) were therefore constructed. The cut off between these groups was set arbitrarily; factors such as age of the infant at time of introduction, and kind and amount of non-allowed formulas and foods influenced the categorisation. Compliance was judged as medium if a mother had deviated from the study protocol only slightly or if she had shown a reasonable allergy preventive behaviour. For example, a mother who changed the infant's milk from the randomised study formula to a non-study hypoallergenic formula, may be highly non-compliant concerning the study protocol. However, with regard to atopy prevention, this behaviour cannot be considered as poor compliance in a randomised blinded study with a risk of being allocated to a conventional cows' milk formula. Compliance was judged as low if serious offences against the dietary regimen were evident. Subjects whose diaries were missing completely and early drop outs make up a subgroup of low compliers.

Factors associated with compliance behaviour

Compliance was judged with respect to the following factors: (1) atopic affection of individual family members; (2) sociodemographic factors such as nationality, parental school education, maternal age, and number of siblings; and (3) health related behaviours such as smoking and early weaning. Breast feeding was part of the nutritional recommendations of the study, but advice concerning smoking was not given to the parents.

Statistical methods

Frequencies of high, medium, and low compliance were calculated. Associations betweeen degree of compliance and factors potentially influencing compliance behaviour were analysed by means of a χ^2 test. Statistical significance was set at the conventional 0.05 level. All computations were performed using the statistical analysis package SAS for Windows, version 6.12 (SAS Institute, Cary, North Carolina).

RESULTS

From the 2252 enrolled subjects, a total of 304 infants (13.5%) dropped out during the first year of life, a majority (n = 190) within the strict intervention period. Reasons for withdrawal were: (1) refusal of a blinded formula by the parents after randomisation (n = 17); (2) nutritional problems (maternal complaints: infant's refusal of the formula, spitting, vomiting, diarrhoea, constipation, non-satisfaction, sleep disturbances, poor weight gain), which led to discontinuation of the intervention by the mothers themselves or the infant's paediatrician (n = 96); (3) change of residence or loss to follow up (n = 31); (4) lack of time, failing to attend follow up appointments, too much stress and time spent on follow up visits, personal problems (n = 124); and (5) sudden infant death or severe disease of the study infant (n = 4). For 32 mothers, no information on reasons for dropping out was obtained.

Compliance to milk feeding recommendations was high in 83.4%, medium in 4.0%, and low in 7.5% (table 2). The corresponding rates for adherence to solid food recommendations were 60.0%, 12.1%, and 22.9%. In a subgroup of 115 low compliers (5.1%), information on the infants' nutrition was completely lacking. Compliance in both aspects was high in 58.1%, medium in 13.2%, and poor in 23.6% of the mothers.

Table 3 shows the cumulative incidence of non-compliance in four week intervals. At the end of the observation period, more than one third of the mothers (36.8%) had occasionally or permanently violated the instructions for the infants' nutrition.

Table 4 compares high (n = 1308) and low compliers (n = 531) (according to table 2) with respect to factors potentially associated with adherence behaviour. There was a small

Table 1 Categorisation of compliance behaviour

High compliance	Medium compliance	Low compliance
Milk feeding (weeks 1–16)		
Complete diaries	Missing 1–2 diary weeks	Missing >2 diary weeks
Exclusive breast feeding or feeding randomised formula as substitute or supplement during weeks 1–16	Feeding a non-randomised, self selected hypoallergenic formula during weeks 1–16	Feeding an adapted cows' milk or other protein based formula during weeks 1–4
Feeding the allowed amino acid based or cows' milk free hydrolysed formulas before randomisation	Feeding an adapted cows' milk or other protein based formula during weeks 5–14: ≤25 bottles altogether	Feeding an adapted cows' milk or other protein based formula during weeks 5–14: >25 bottles altogether
Feeding the allowed amino acid based or hydrolysed therapeutic formulas for suspected intolerance to study formula or breast milk	Feeding an adapted cows' milk or other protein based formula after week 14, independent of number of bottles	
Solid food feeding (weeks 1–24)		
Complete diaries	Missing 1–2 diary weeks	Missing >2 diary weeks
No solid foods during the first 16 weeks	1 solid food during the first 16 weeks	>1 solid food during the first 16 weeks
≤8 new solid foods during weeks 17–24	9–16 new solid foods during weeks 17–24	>16 new solid foods during weeks 17–24
No highly allergenic foods during weeks 1–24	1 highly allergenic food during weeks 1–24	>1 highly allergenic food during weeks 1–24

Table 2 Combination of compliance behaviour with respect to to milk (rows) and solid food feeding (columns)

	Solid food feeding				
Milk feeding	High compliance	Medium compliance	Low compliance	No nutritional information	Total
High compliance	1308 (58.1%)	245 (10.9%)	325 (14.4%)	0	1878 (83.4%)
Medium compliance	31 (1.4%)	22 (1.0%)	38 (1.7%)	0	91 (4.0%)
Low compliance	11 (0.5%)	5 (0.2%)	152 (6.8%)	0	168 (7.5%)
No diary information	0	0	0	115 (5.1%)	115 (5.1%)
Total	1350 (60.0%)	272 (12.1%)	515 (22.9%)	115 (5.1%)	2252 (100.0%)

Table 3 Cumulative incidence of non-compliance to milk and solid food feeding during weeks 1–24

	Weeks 1–4	Weeks 1–8	Weeks 1–12	Weeks 1–16	Weeks 1–20	Weeks 1–24	No nutritional information
Milk feeding	65 (2.9%)	154 (6.8%)	205 (9.1%)	259 (11.5%)			115 (5.1%)
Solid food feeding	18 (0.8%)	145 (6.4%)	231 (10.3%)	405 (18.0%)	584 (25.9%)	787 (34.9%)	115 (5.1%)
Milk and/or solid food feeding	70 (3.1%)	204 (9.1%)	303 (13.5%)	480 (21.3%)	636 (28.2%)	829 (36.8%)	115 (5.1%)

amount of missing data on some variables and therefore sample sizes in the groups may differ slightly. Non-German nationality of at least one parent, low educational level, and maternal age ⩽25 years showed significant associations with low maternal compliance behaviour. Mothers with high compliance had a significantly less frequent history of smoking and breast fed their infants longer than mothers with poor compliance. The subgroup of 115 low compliers, most of whom dropped out early, and who failed to deliver any nutritional or other information, was characterised by significantly higher rates of non-German parents, lower parental school education, and younger mothers (p values not shown).

Interactions between the sociodemographic factors of parental nationality, education, and maternal age were evaluated. The combination of low maternal age (⩽25 years) and lowest degree of school education changed compliance behaviour for the worse. The same effect was observed when combining maternal age and smoking behaviour.

DISCUSSION

It is assumed that the success of allergy prevention programmes depends on the extent to which at risk subjects follow the recommended preventive advice. In this study, the nutritional regimen was a composite of advice concerning early milk and solid food feeding. The degree of dietary adherence was much higher with regard to milk nutrition (83.4%) than to solid food nutrition (60.0%). Several reasons may be responsible for this difference. Firstly, the duration of the strict milk intervention period covered only the first 16 weeks of life, whereas solid food feeding recommendations related to the whole first year. It is supposed that compliance decreases with the duration of a dietary long term intervention programme. In an allergy prevention study by Halken *et al*, the recommendation of solid food avoidance until the age of 6 months was adhered by only 40% of parents.[4]

Secondly, the contact between mothers and the research staff was closer during the strict intervention period of the first four months than thereafter, thus enhancing the opportunity to give repeatedly careful nutritional advice, in order to control maternal feeding behaviour better, and to intervene when nutritional problems occurred. The investigators of the Isle of Wight study emphasise that good contact with the families is necessary if a complex allergen avoidance programme is to be followed.[3]

Thirdly, solid food feeding advice was more complex than milk feeding advice, thus limiting the acceptance and practicability. Long term and complex intervention programmes may be more liable to uncontrollable influences from outside, which may undermine the initial cooperative willingness. With increasing age of the infant, mothers may use other sources of information on infant nutrition. Advice from relatives, friends, paediatricians, and other health care providers may have conflicted with the advice of the study.

The combined rate of high compliance with milk and solid food recommendations (58.1%) was almost as high as the solid food compliance rate alone (60.0%). This means that mothers who had adhered to solid food advice had also followed the milk feeding advice. However, among the group of high compliers, the percentage of mothers who breast fed for more than two months was higher than among the low compliers, thus reducing the risk of failure to follow dietary recommendations. The present study confirms the findings of other studies that breast feeding mothers in general delay the introduction of solid foods compared with bottle feeding mothers.[4 5]

The study attempted to identify characteristics that may help to explain variations in compliance behaviour and to identify families in need of additional preventive counselling. In the group of low compliers, the percentage of non-German parents was higher than in the group of high compliers. It is assumed that this result is, on the one hand, caused by language difficulties leading to misunderstanding of dietary advice, and on the other hand by different cultural habits of infant nutrition. The level of parental school education was a strong factor associated with dietary adherence, which showed increasing non-compliance with lower educational level. Furthermore, failure to adhere was related to maternal age, with mothers below the age of 26 years being least likely to follow the nutritional advice. In the subgroup of low compliers for whom all nutritional data were missing and who withdrew from the study early, percentages of foreign parents, parents with low school education, and young mothers were highest compared with the other groups. These low compliers seem to form a special problem group with regard to adherence to health recommendations. Although immediate consultation via telephone or visit to the study centre was offered to all participating families in case of nutritional problems, these parents did not make use of this support.

Finally, compliance was strongly associated with other health related behaviour. Mothers with poor compliance smoked more frequently compared with highly complying mothers. Smoking decreased in all compliance groups during

Table 4 Comparison of high and low compliers in relation to parental characteristics

	High compliance		Low compliance		No nutritional information		Total	
	n	%	n	%	n	%	n	p value*
Atopic affection of family members								
Mother	373	61.7	184	30.4	48	7.9	605	
Father	269	71.2	90	23.8	19	5.0	378	
One sibling	61	68.5	23	25.8	5	5.6	89	
Mother and one sibling	98	66.7	42	28.6	7	4.8	147	
Father and one sibling	66	68.8	24	25.0	6	6.3	96	
Both parents (and sibling)	417	70.6	147	24.9	27	4.6	591	0.084
Sociodemographic factors								
Nationality of parents								
Both parents German	1159	68.6	445	26.4	85	5.0	1689	
At least one parent foreign	145	57.8	81	32.3	25	10.0	251	0.012
Education of parents								
Elementary school	49	31.2	84	53.5	24	15.3	157	
Secondary school	306	58.9	176	33.9	38	7.3	520	
German high school graduation (Abitur)	951	75.3	266	21.1	46	3.6	1263	
Other/no degree	1	25.0	1	25.0	2	50.0	4	0.001
Age of mother								
⩽25 years	65	34.2	100	52.6	25	13.2	190	
26–30 years	446	63.1	217	30.7	44	6.2	707	
31–35 years	612	76.9	156	19.6	28	3.5	796	
>35 years	185	72.0	58	22.6	14	5.5	257	0.001
Number of siblings								
0	718	68.5	272	26.0	58	5.5	1048	
1	418	67.4	164	26.5	38	6.1	620	
>1	139	61.5	73	32.3	14	6.2	226	0.122
Health related behaviour								
Smoking before pregnancy								
No	990	72.5	302	22.1	73	5.4	1365	
Yes	305	53.7	225	39.6	38	6.7	568	0.001
Smoking during pregnancy								
No	1150	79.3	301	20.7	No data available		1451	
Yes	148	56.5	114	43.5			262	0.001
Smoking after pregnancy								
No	1155	80.2	285	19.8	No data available		1440	
Yes	142	52.2	130	47.8			272	0.001
Weaning ⩽2 months								
No	1134	76.3	353	23.7	No data available		1487	
Yes	174	49.4	178	50.6			352	0.001

*Only high and low compliers compared.

pregnancy, but poor compliers showed a slight tendency to resume smoking within the first four months after the child's birth. This was not found in high compliers. Furthermore, poor compliers weaned their infants earlier than good compliers. However, in this study compliance and breast feeding were not independent variables, as breast feeding belonged to the nutritional recommendations.

Similar results were found in an infant feeding programme by Shepherd *et al*, who showed that non-responders were more likely to be smokers, to come from a lower social class, and to bottle feed.[6] In a Finnish study on compliance with a dietary programme in infants at risk of atopy, poor parental compliance was associated with low maternal age, smoking, and low social class.[7] Although most sociodemographic factors cannot be changed, compliance rates might be improved by dietary education of subjects at risk of poor compliance. Following health care advice appears to be mediated through educational level,[5 8] and a mother's nutritional knowledge is related to infant feeding practices.[9]

There are several methodological limitations to the study. Firstly, the only available method for assessing dietary adherence was the mother's report on the infant's nutrition in the diaries. For assessing the accuracy and reliability of maternal records, no external criterion existed. Observation of maternal behaviour was not possible and categorising mothers' compliance on the basis of the infant's health outcome could lead to misleading conclusions in a prevention study. Thus it is assumed that the self reports overestimated compliance. Secondly, compliance rates in the majority of investigations must be considered to be underestimates of the problems as a result of sample selection procedures.[2] For example, it seems reasonable to assume that voluntary study subjects in a prevention programme are highly motivated to cooperate, thus making them more likely to comply with the preventive recommendations than subjects who are not willing to participate. One has to be cautious to conclude that compliance in the general target population at risk of allergy is as high as in this study group of highly motivated parents.

Conclusions

Research on the efficacy of allergy preventive programmes in children at atopic risk should go hand in hand with research on parental compliance behaviour with allergen avoidance recommendations. Efficacious preventive programmes can only be recommended on a large scale to an at risk population, when there is sufficient evidence that advice will be largely accepted and followed by the parents. The necessary duration of an allergen avoidance programme has to be determined to keep the burden as small as possible to those who are concerned.

Factors that determine the decisions of parents to adhere to health recommendations for their infant have to be investigated further, with the aim of enabling physicians to distinguish those parents who will adhere well from those

who will adhere poorly. Parents suspected to be poorly compliant may be in need of special and repeated education at an early stage of the programme. These parents have to be encouraged to do something that is good for their child's immediate and future health.

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POSTCARD FROM DOWN UNDER

Poverty and Bugatti

We're in a taxi on our way to the airport in Mumbai, India. Which is much the same as saying that we are stuck in a very large traffic jam. It is about 10 o'clock at night. There is a knock on the window. Neither of us turn to look; we have been in India for some weeks now and we know what it is. Outside the window will be a small boy of 7 or 8 years and he'll have matches or a newspaper or cigarettes for sale. He'll be wearing a dirty, faded T-shirt, come full circle from the sweatshop; he'll have ragged trousers caked in dirt, and he'll be barefoot.

We know that if we don't look at him he'll knock a few more times and then wander off into the five lanes of congestion and smog. We know that if we do look at him he'll start his sales pitch. This 7 year old has lines that would make a man five times his age blush. He'll recognise the possibility—probability—that we are, at some level, soft and susceptible. "Please, please, please" he'll moan. Maybe crocodile tears. Sometimes when crying he'll look away to his friends (his family?) and smile. Then he'll catch us watching him do it, and smile, slyly and cynically at us. Forgive me; sometimes I might smile back.

Change the scene. We're in London, or Brisbane, or Glasgow. Same time at night, same traffic jam, same 7 or 8 year old boy. This is where I get hazy. You see,

I'd like to say that I'd leap out of the taxi, sweep the child up into my arms and carry him to safety, give him my coat, take him to a police station, call a social worker. No police or social worker? Well, I'd like to think that I'd do something. Anything. Anything, that is, except look straight ahead and hope, *wish*, that he'd go away.

It's different of course. Mumbai isn't Brisbane, and, besides, we liberals have the ultimate get out clause: "You can't do everything". Peter Singer, in his book "Writings on an Ethical Life" quotes another ethicist, Peter Unger, describing an interesting thought experiment. There is this man who, instead of having a retirement plan, has a valuable Bugatti motor car, in which he has invested everything. It is his financial security for the future; without it his retirement will be a long, hard struggle. He can't insure it, but loves to drive it and so takes it out one day. Perhaps foolishly, he parks at the end of a railway sidings, and heads off for a walk. However, as he is passing a set of railway points he notices two things. Firstly, there is a child on the track, a little way away. Secondly, there is a runaway train, with no one on board, heading towards this child. Standing at the points, there is no time to run to the child, or to run and move his car. He is faced with a stark alternative: divert the train into the sidings and destroy his beloved Bugatti—and with it his financial security—or stand and watch the child be killed.

I don't think that there is a choice in this situation. I think the Bugatti has to go. But then you get to the next part. Similar scenario; still the Bugatti or the child, but the owner is sitting at a computer the other side of the world, with control over the way that the points direct the train. The immediacy of today's technology means he can have a nearly instant impact; financial security versus the child's life. Again, the choice seems pretty easy.

Shift the scenario a little more; instead of the Bugatti and the points, there is a telephone and a credit card. Again, financial security versus the child's life. What would you do now? I sat in that taxi in Mumbai and stared straight ahead; focusing on the Bugatti. I muttered soothing liberal justifications to myself: "There are just too many", "You can't do everything", "You work pretty hard and give money to charity as it is". I sat in the taxi and watched the train bearing down, closer and closer to the points.

Funny really; I'd thought I was better than that.

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