Controlled trial of a few foods diet in severe atopic dermatitis

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Abstract
Eighty five children (median age 2-3 years, range 0-3 to 13-3 years) with refractory atopic dermatitis affecting more than 12% of the body surface area, were randomly allocated to receive a few foods diet (eliminating all but five to eight foods) supplemented with either a whey hydrolysate (n=27) or a casein hydrolysate formula (n=32), or to remain on their usual diet and act as controls (n=26), for a six week period. Thirty five patients who received the diet and four controls had to be withdrawn because of non-compliance with the diet or intercurrent illness. The change in dermatitis severity was evaluated by a blinded observer who estimated the extent and severity of the dermatitis, using a skin severity score. After six weeks, there was a significant reduction in all three groups in the percentage of surface area involved (controls, median reduction (MR)=4.9% (95% confidence interval 1.5%, 11.9%); whey hydrolysate group, MR=17.8% (8.3%, 23.0%); casein hydrolysate group, MR=5% (1.6%, 21.2%); whey hydrolysate formula (controls, MR=15-9 (5-0, 22-5); whey hydrolysate group, MR=21.8 (12-8, 30-2); casein hydrolysate group, MR=13.5 (3-4, 38-0). Sixteen (73%) of the 22 controls and 15 (58%) of the 24 who received the diet showed a greater than 20% improvement in the skin severity score. This study failed to show benefit from a few foods diet.

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Keywords: atopic dermatitis, few foods diet.

Considering the widespread interest in elimination diets in children with atopic dermatitis, it is remarkable that there have been so few controlled studies. Two published studies have examined the effect of cows’ milk and egg exclusion1,2 with opposite results. In 1978, Atherton et al1 performed a double blind, placebo controlled crossover study of 20 children and found a significant reduction in disease activity and improvement in 13 patients during the period of diet, whereas only three improved during the placebo period. Although there were important differences such as the age range of the patients and duration of the diet which make direct comparison difficult, Neild et al2 in 1986 performed a similar study to that of Atherton et al, and found no significant change in disease activity while on the elimination diet. More recently, in 1993, Aylett et al, in a double blind crossover study of 25 infants placed on a cows’ milk and egg exclusion diet supplemented with either a whey hydrolysate or standard modified cows’ milk formula, failed to show a significant benefit of diet, but there was a trend towards improvement, particularly in infants under eight months (Aylett S, Atherton DJ, Shaw V, unpublished data).

A few foods diet is one which excludes all foods except five or six (such as lamb, potato, rice, including Rice Krispies, one of the brassicas, pear, and tap water), but there have been no controlled studies of this type of diet in atopic dermatitis. Uncontrolled studies performed in our unit14,15 and elsewhere6,9 have reported that various elimination diets may be associated with improvement in children with atopic dermatitis. Diets, however, are known to have a marked placebo effect7 and the lack of a control group in these studies makes it impossible to determine whether or not the improvement was due to the diet or to a placebo effect.

One problem with a few foods diet is poor adherence,8,9 because the diet is so restrictive. For example, in one study of a six foods diet,3 the families of nine of 63 children studied (14%) were unable to cope even for an initial six week trial of that diet, and Van Asperen et al in 1983 reported that 16 of 29 children aged between two and 12 years (55%) were withdrawn from their study because of failure to adhere to a diet which eliminated all but 20 foods.6

An additional problem of elimination diets is the risk of nutritional deficiency, particularly of calcium.10,11 The addition of a hydrolysate milk formula might make the dietary regimen more acceptable and might reduce the risk of calcium deficiency. Soya milks could be used, but soya protein intolerance has been found in 8% of children with preceding cows’ milk protein intolerance12 and soya is a commonly reported trigger in atopic dermatitis. Although intolerance to both casein and whey hydrolysates has been reported in cases of cows’ milk protein intolerance,13-16 such cases are rare and there is little risk that the addition of such a formula would reduce the chances of the diet being effective. Unfortunately, casein hydrolysate formulas have a poor flavour and are often refused by children over 12 months of age. Offering a casein hydrolysate formula to supplement a few foods diet in a 3 year old, for example, would be of little use if the child declined to take the formula, although small amounts might be used in cooking. It is claimed by their manufacturers, however, that certain whey hydrolysate formulas are more palatable.
Few foods diet in atopic dermatitis

We therefore conducted a single blind controlled trial to study the short term effect of few foods diets on atopic dermatitis, and incorporated into the study a comparison of supplementation of the diet with either Nutramigen (Mead Johnson), an established casein hydrolysate, or Nutrilon Pepti Plus (Nutricia Cow and Gate), a recently developed whey hydrolysate.

Methods
This parallel group, randomised, single blind study was carried out between May 1992 and September 1993. Eighty five children, median age 2:3 years (range 0:3-13:3 years) were entered. The study was approved by the ethics committee of North Manchester Health District. Patients were randomly allocated, using random number tables and blocks of three, to remain on their normal diet (controls), a few foods diet supplemented with the whey hydrolysate formula, or a few foods diet supplemented with the casein hydrolysate formula, for six weeks. The parents and dietitian (AES) who advised on the diet were blind to the identity of the milk that the child had received but were not blind to whether the child was receiving the diet or not. A single observer (DCM) was blind both to whether the child was receiving a diet and to which milk the child was receiving during the six weeks of diet.

Thereafter, patients who were on the diet and who had experienced a greater than 20% improvement in skin severity score (see below) remained on the diet and new foods were added to the diet by open challenge at home at the rate of one new food every week to identify trigger foods that caused worsening of the atopic dermatitis.9 The new food was taken at least once daily for the first week after reintroduction and thereafter according to the parents' wish. Intolerance was defined as a reaction which was reported to occur on at least two separate occasions and which comprised either an acute erythematous rash within four hours of ingestion, an exacerbation of the dermatitis within five days of ingestion of the food, or wheeze, vomiting, or loose stools. Patients who showed less than a 20% improvement in skin severity score after the initial six weeks of diet were put back onto a normal diet, as the few foods diet was deemed to have been ineffective.

The inclusion criteria were that patients should be under the age of 15 years at the time of entry, fulfil the criteria of Hanifin and Rajka17 for the diagnosis of atopic dermatitis, and regularly attend the University of Manchester Department of Child Health at Booth Hall Children's Hospital; all should have atopic dermatitis which persisted despite conventional treatment and which was sufficiently widespread (involving more than 12% of body surface area) to justify the inconvenience of a trial of elimination diet. Patients were excluded (1) if they were breast fed, because of the difficulty of avoiding food antigens transferred in breast milk,18 (2) if they had unstable or infected atopic dermatitis, (3) if they were intolerant of casein or whey hydrolysate formulas, or (4) if they had received oral corticosteroids within the preceding four weeks. The criteria for withdrawal were (1) a major change in treatment (defined as the prescription of a topical corticosteroid of greater potency than used at entry, using the British National Formulary classification,19 antibiotics, or any other new treatment for atopic dermatitis), (2) evidence of intolerance to the study milk, such as urticaria or wheeze, (3) an unacceptable level of dietary indiscretion (defined as taking more than three excluded foods per week), as assessed by the research dietitian, and (4) bacterial or viral infection of the skin. Bacterial infection was defined as the appearance of pustules, a purulent discharge or crusting of the eczematous lesions and herpes simplex virus (HSV) infection defined as the appearance of a vesiculopustular rash of typical morphology.20

A research dietitian (AES) instructed the parents on the few foods diet and on the weighing and recording of all food and drink taken during the periods of dietary assessment, using the weighed food technique31 over a six day period, including two weekend days. During a five week run-in period, the child stayed on a normal diet to allow baseline diary scores to be kept and a detailed dietary assessment to be carried out. A second detailed dietary assessment was undertaken during the second week of the diet, to ensure nutritional adequacy. Compliance with the diet was subjectively assessed by the dietitian, based on the weighed food assessments and by frequent telephone calls and interviews with the parents. The few foods diet comprised one meat (lamb, including lamb fat and offal), rice (including Rice Krispies which contain rice, sugar, vitamins, and minerals), potato, one of the brassicas (cabbage, sprouts, cauliflower, or broccoli), one fruit (usually pear), and the hydrolysate formula milk. The diets were tailored for each child individually and took into account the child's preferences. If there was a history of intolerance or aversion to one of the above foods, alternatives were used, such as carrot instead of a brassica or apple instead of pear, but avoiding commonly reported food triggers. Up to three additional foods were allowed if it was judged by the dietitian that compliance with the diet would otherwise be poor. For example, in one child, in addition to the five foods we allowed sunflower oil (to allow the inclusion of certain brands of plain crisp), cucumber, and pineapple. Children were permitted to drink tap water, the pure juice of whichever fruit had been selected, and the hydrolysate milk. Cordials and squashes were not allowed. No foods other than those chosen at the outset were allowed during the six weeks study period. The foods and the hydrolysate formula milk were sent directly to the parents by Nutricia Cow and Gate as a dry powder for reconstitution in packets marked 'protein hydrolysate'. Adverse events were recorded on a diary and parents were asked to contact the dietitian or clinician if they felt the child's skin condition had deteriorated or if they were experiencing...
any ill effect from the imposition of the diet. Control patients, who did not initially receive the few foods diet, were offered the diet, supplemented with either the casein hydrolysate openly or, if parents wished, with the casein hydrolysate or the whey hydrolysate blindly, as part of a second double blind study (unreported data). Controls also completed a detailed dietary assessment which was performed during the first week of the study. They were contacted by the research diettian at weekly intervals to ensure that parents had not withdrawn any foods from the child’s normal diet during the study period.

CLINICAL ASSESSMENT
Clinical assessment was carried out in all patients, including those not receiving diet, at visit 1 (entry), visit 2 (after one week run-in and two weeks of diet), and visit 3 (after six weeks of diet) by a single observer (DCM) who was blind to treatment category. Individual children were seen under consistent conditions to minimise changes due to room temperature, the time of day, or day of the week. Clinical assessment consisted of the estimation of the body surface area affected by dermatitis using charts that divide the body into 32 separate zones. The relative size of each of the 32 zones was derived from charts used for the assessment of burns in children and taken into account the changes in the contribution of individual zones according to age. For example, the head of a child under 1 year of age was taken to represent 18% of total body surface area, whereas in a child over 10 years it represents only 10% of the total body surface area. Charts were used for four age groups: 0–1 year, 1–5 years, 5–10 years, and over 10 years, according to the child’s age at entry. In addition, a skin severity score was derived as follows: for each of the 32 zones, the extent of area affected by dermatitis and the degree of erythema, on an arbitrary scale from 0 to 3 (0=none, 1=mild, 2=moderate, 3=severe, with half scores being available), was estimated and multiplied together. An overall skin severity score, with a possible range from 0 to 300, was achieved by summing all 32 zones.

SYMPTOM SCORES AND GLOBAL ASSESSMENT
Diary records were kept throughout the study period by parents who were asked to record each morning the amount of sleep disturbance caused by itching the child had experienced on the previous night on a four point scale (0=full night’s sleep, 1=occasional waking, 2=frequent waking, 3=very frequent waking). An average sleep disturbance score was calculated for two periods, during the one week run-in period before starting the diet and during the final seven nights before the second return visit, that is, the final week of the few foods diet. The parents also recorded each evening the amount of daytime scratching the child had experienced during the day on a four point scale (0=none, 1=occasional, 2=more frequent, 3=very frequent scratching). An average daytime itch score was calculated for two periods, as for the sleep disturbance score.

A global assessment was made by asking parents after six weeks of diet whether they felt the atopic dermatitis was better, worse, or the same as at entry. The effect of the diet was defined by the clinician as ‘better’ if the final skin severity score had reduced by more than 20% of the baseline score, ‘worse’ if the final skin severity score was 20% or greater than baseline, and ‘unchanged’ if the final score was within 20% either way of baseline. The figure of a 20% change in the severity of skin severity score was chosen arbitrarily but was considered the minimum change in score which would be sufficiently worthwhile for the child to continue to put up with the inconvenience of the diet.

Parents recorded on the diary card whether antihistamine was given at night, and the potency of topical corticosteroid preparations used was recorded by the observer at each visit.

STATISTICAL METHODS
The Kruskal-Wallis test was used to compare the age, duration of disease, body surface area affected, skin severity score, sleep disturbance score, and daytime itch score of all three groups at entry. The χ² test was used to compare the sex and topical corticosteroid potency at entry and parental and observer global assessment of the diet after the six weeks of diet. The Wilcoxon paired signed rank test was used to assess the difference in body surface area, skin severity score, sleep disturbance score, and daytime itch score of patients in all three groups between entry and two weeks and between entry and six weeks.

Results
Eighty five children with atopic dermatitis were studied. Thirty seven (43%) were female, 48 (57%) were male. Twenty six were controls, 27 received a diet with whey hydrolysate, and 32 received a diet with casein hydrolysate. The modal number of foods allowed in the few foods diet in addition to the supplemental milk was five (range five to eight foods). There was no significant difference between the three groups at entry in median age, median duration of illness, proportion of male and females, family history of atopy (defined as a first degree relative with a history of atopic dermatitis, asthma or allergic rhinoconjunctivitis), history of smoking in either parent, personal history of food intolerance, home ownership of pet animals, topical emollient, or topical corticosteroid usage (table 1). Eleven of the controls, four of the whey hydrolysate group, and nine of the casein hydrolysate group used antihistamines at night throughout the study.

Thirty nine of the patients (45.8%) were withdrawn from the study. Eighteen (67%) of the whey hydrolysate group, 17 (53%) of the casein hydrolysate group, and four (15%) of the control patients were withdrawn by the end of the study period. There were 15 withdrawals
Table 1  Comparison of groups by sex and clinical variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Controls</th>
<th>Whey hydrolysate</th>
<th>Casein hydrolysate</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median (range)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>2-7 (0-1-10-6)</td>
<td>2-6 (0-6-13-3)</td>
<td>2-1 (0-4-10-4)</td>
<td>H=2-57, df=2, p=0-23</td>
</tr>
<tr>
<td></td>
<td>n=26</td>
<td>n=27</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td>Duration (years)</td>
<td>2-2 (0-2-10-4)</td>
<td>1-6 (0-2-10-5)</td>
<td>2-9 (0-35-9-2)</td>
<td>H=1-43, df=2, p=0-49</td>
</tr>
<tr>
<td></td>
<td>n=26</td>
<td>n=27</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td>Number (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10 (38)</td>
<td>14 (52)</td>
<td>13 (40)</td>
<td>x²=1-14, df=2, p=0-56</td>
</tr>
<tr>
<td>Male</td>
<td>16 (62)</td>
<td>13 (48)</td>
<td>19 (60)</td>
<td></td>
</tr>
<tr>
<td>Family history of atopy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>20 (77)</td>
<td>22 (81-5)</td>
<td>26 (81)</td>
<td>x²=0-71, df=2, p=0-89</td>
</tr>
<tr>
<td>No</td>
<td>6 (23)</td>
<td>5 (18-5)</td>
<td>6 (19)</td>
<td></td>
</tr>
<tr>
<td>Exposure to smoke (either parent)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19 (73)</td>
<td>18 (66)</td>
<td>16 (50)</td>
<td>x²=3-57, df=2, p=0-16</td>
</tr>
<tr>
<td>No</td>
<td>7 (27)</td>
<td>9 (34)</td>
<td>16 (50)</td>
<td></td>
</tr>
<tr>
<td>History of food intolerance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7 (27)</td>
<td>7 (26)</td>
<td>6 (19)</td>
<td>x²=0-66, df=2, p=0-72</td>
</tr>
<tr>
<td>No</td>
<td>19 (73)</td>
<td>20 (74)</td>
<td>26 (81)</td>
<td></td>
</tr>
<tr>
<td>Exposure to furry animals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>15 (58)</td>
<td>9 (34)</td>
<td>11 (34)</td>
<td>x²=0-42, df=2, p=0-12</td>
</tr>
<tr>
<td>No</td>
<td>11 (42)</td>
<td>18 (66)</td>
<td>21 (66)</td>
<td></td>
</tr>
<tr>
<td>Enomil usage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>24 (92)</td>
<td>26 (96)</td>
<td>31 (97)</td>
<td>x²=0-76, df=2, p=0-69</td>
</tr>
<tr>
<td>No</td>
<td>29 (8)</td>
<td>1 (4)</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Usual topical steroid usage (British National Formulary category(a))</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weak</td>
<td>16 (62)</td>
<td>19 (70)</td>
<td>21 (66)</td>
<td></td>
</tr>
<tr>
<td>Weak and moderate</td>
<td>8 (30)</td>
<td>3 (11)</td>
<td>7 (22)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>2 (8)</td>
<td>3 (11)</td>
<td>3 (9)</td>
<td></td>
</tr>
<tr>
<td>Weak, moderate, and potent</td>
<td>0</td>
<td>2 (8)</td>
<td>1 (3)</td>
<td></td>
</tr>
</tbody>
</table>

from the whey hydrolysate group before the
first review appointment and of these, 10
(37%) were because of failure to adhere to the
diet, one did not return for any further assess-
mants, and four (15%) were the result of major
changes in therapy. Of these four, two patients
required oral corticosteroids because of exacer-
bation of their asthma, one developed eczema
herpeticum, and one required antibiotics for
bacterial skin infection. A further three
patients were excluded from analysis at the
second review (six weeks of diet), two because
they parents abandoned the diet and one be-
because of bacterial infection requiring anti-
biotics. Among the patients who received the
diet with casein hydrolysate, 12 were with-
drawn by the first review. Eight (25%) were
withdrawn because of failure to adhere to diet
and four (13%) did not return for follow up
after three weeks. A further five were with-
drawn by six weeks. Two of these required
antibiotics for bacterial skin infection, one
developed eczema herpeticum, one developed a
presumed viral gastroenteritis, and one aban-
donned the diet. No patients were withdrawn
because of intolerance of either of the
hydrolysate formulas. Three control patients
were withdrawn at the first review appoint-
ment; one had deteriorated after one week and
required major changes in therapy (addition of
trimethoprim tetrarate and antibiotics), one
because the mother felt that later dietary treat-
ment would be impossible to manage and
therefore did not return for further follow up,
and one because of an exacerbation in asthma
requiring oral corticosteroids. A fourth patient
returned for the first follow up appointment
but defaulted further appointments. Hence, 22
controls could be evaluated after two and six
weeks, whereas in the whey hydrolysate group
12 patients were evaluated after two weeks and
nine were evaluated after six weeks, and in the
casein hydrolysate group 20 could be evaluated
after two weeks and 15 after six weeks.

The median clinical and diary scores at each
visit and change in scores are given in table 2.
There was no significant difference between
the three groups at entry in the body surface
area affected (Kruskal-Wallis, H=3-47, degrees of
freedom (df)=2, p=0-18), the skin severity score
(H=2-31, df=2, p=0-32), daytime itch score
(H=1-48, df=2, p=0-48), or sleep disturbance score
(H=1-49, df=2, p=0-47). There was a statistically significant
reduction in the body surface area affected by
dermatitis and skin severity score in all three
groups over the six weeks. The reduction was
greater in the whey hydrolysate group than the
other two groups. There was a significant
reduction in the daytime itch score in the
casein hydrolysate group but no significant
change in either the control or the whey
hydrolysate group. The sleep disturbance score
was unchanged in any of the groups. The
global change in disease activity is given in
table 3.

Following the period of diet, foods were
openly reintroduced at the rate of one new
food per week in those children who were felt
to have improved on the diet. Six of the seven
patients who improved in the whey hydrolysate
group and four out of eight patients who
improved in the diet in the casein hydrolysate
group reacted to one or more foods after open
challenge. All reactions were cutaneous, either
an itchy erythematous rash within four hours
of ingestion or a deterioration in the atopic
dermatitis. No serious reactions to any foods
occurred. There was no evidence of
intolerance to either trial formula.

Discussion
This controlled study failed to show benefit
from a few foods diet. The study, however,
does have a number of methodological draw-
backs: there was a high withdrawal rate, indi-
cating the difficulty of adherence to such strict
diets, but this was similar to that reported by
other groups\(5\); the foods included in the basic
Table 2  Clinical and diary scores at entry, after two weeks, and after six weeks in controls, whey hydrolysate (WH), and casein hydrolysate (CH) groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Entry median score (range)</th>
<th>2 Weeks median score (range)</th>
<th>Median change in score (95% CI)</th>
<th>p Value</th>
<th>6 Weeks median score (range)</th>
<th>Median change in score (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body surface area</td>
<td>34-8 (20-79-5)</td>
<td>31-2 (10-5-76-5)</td>
<td>-7.6 (-11-6, -0.9)</td>
<td>0.07</td>
<td>30-1 (10-2-57-5)</td>
<td>-4.9 (-12, -1-5)</td>
<td>0.02*</td>
</tr>
<tr>
<td>n=22</td>
<td>n=22</td>
<td>n=22</td>
<td></td>
<td></td>
<td>n=22</td>
<td></td>
<td></td>
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<tr>
<td>WH (n=19-5-89-5)</td>
<td>26-4 (9-0-84-5)</td>
<td>-5.4 (-13, 0)</td>
<td>0.06</td>
<td></td>
<td>23-2 (3-5-70-5)</td>
<td>-17.8 (-23, 8-3)</td>
<td>0.009*</td>
</tr>
<tr>
<td>n=12</td>
<td>n=12</td>
<td></td>
<td></td>
<td></td>
<td>n=9</td>
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<td></td>
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<tr>
<td>CH (12-5-80)</td>
<td>36-2 (9-88-5)</td>
<td>-3.5 (-10-6, 1-4)</td>
<td>0.12</td>
<td></td>
<td>35 (14-2-93-5)</td>
<td>-5 (-21-2, -1-6)</td>
<td>0.047*</td>
</tr>
<tr>
<td>n=20</td>
<td>n=20</td>
<td></td>
<td></td>
<td></td>
<td>n=15</td>
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<tr>
<td>Kruskal-Wallis</td>
<td>p=0.18</td>
<td>p=0.06</td>
<td>p=0.83</td>
<td></td>
<td>p=0.082</td>
<td>p=0.49</td>
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<tr>
<td>Skin severity score</td>
<td>54-5 (37-134)</td>
<td>40-2 (14-5-134)</td>
<td>-13.5 (-21, -3.6)</td>
<td>0.014*</td>
<td>40 (15-2-111)</td>
<td>-15.9 (-22-5, -5)</td>
<td>0.018*</td>
</tr>
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<td>n=22</td>
<td>n=22</td>
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<td>n=22</td>
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<tr>
<td>WH (26-5-141)</td>
<td>42-2 (9-129)</td>
<td>-11.6 (-24, 1-3)</td>
<td>0.08</td>
<td></td>
<td>40-5 (3-5-109)</td>
<td>-21.8 (-30-2, -12-8)</td>
<td>0.009*</td>
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<td></td>
<td>n=9</td>
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<tr>
<td>CH (19-5-182)</td>
<td>58-9 (13-5-203)</td>
<td>-5.4 (-23, 5-7)</td>
<td>0.22</td>
<td></td>
<td>57-7 (14-3-186)</td>
<td>-13.5 (-38, -13-4)</td>
<td>0.018*</td>
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<td>n=20</td>
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<td>n=15</td>
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<td>Kruskal-Wallis</td>
<td>p=0.52</td>
<td>p=0.08</td>
<td>p=0.83</td>
<td></td>
<td>p=0.22</td>
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<tr>
<td>Daytime itch score*</td>
<td>1-4 (0-0-3)</td>
<td>1-4 (0-3)</td>
<td>0 (-0-3, 0-2)</td>
<td>0.55</td>
<td>1-3 (0-7-3)</td>
<td>0 (-0-4, 0-14)</td>
<td>0.39</td>
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<tr>
<td>WH (1-2-7)</td>
<td>1-1 (0-42-2-6)</td>
<td>-0.1 (-0-7, -0-1)</td>
<td>0.03*</td>
<td></td>
<td>1-0 (0-1-1-4)</td>
<td>-0.1 (-1-7, 0-0)</td>
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<tr>
<td>CH (2-4-3)</td>
<td>1-3 (0-6-2-7)</td>
<td>-0.1 (-0-6, 0-1)</td>
<td>0.16</td>
<td></td>
<td>1-0 (0-2-3)</td>
<td>-0.6 (-1, -0-21)</td>
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<tr>
<td>Kruskal-Wallis</td>
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<td>p=0.55</td>
<td>p=0.38</td>
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<td>Sleep disturbance score*</td>
<td>1-1 (0-1-2-9)</td>
<td>1-5 (0-2-7)</td>
<td>-0.04 (-0-1, 0-4)</td>
<td>0.47</td>
<td>1-1 (0-2-6)</td>
<td>-0.1 (-0-2, 0-2)</td>
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<tr>
<td>WH (0-2-5)</td>
<td>0-7 (0-2-2)</td>
<td>-0.1 (-0-5, 0-1)</td>
<td>0.31</td>
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<td>0-6 (0-1-1-6)</td>
<td>-0.4 (-1-4, 0-3)</td>
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<tr>
<td>CH (0-2-4)</td>
<td>1 (0-2-6)</td>
<td>0 (-0-1, 0-4)</td>
<td>0.43</td>
<td></td>
<td>0-42 (0-2-4)</td>
<td>-0.2 (-0-7-0-1)</td>
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<td>n=14</td>
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<tr>
<td>Kruskal-Wallis</td>
<td>p=0.48</td>
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<td>p=0.06</td>
<td>p=0.08</td>
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</table>

*Incomplete or illegible diaries were kept by some patients and so the number of patients used for analysis differs for the number used for assessment of clinical scores. CI=confidence interval. *Statistically significant (that is, p<0.05).

A few foods diet were chosen on empirical grounds on the basis of previous experience of the types of food commonly reported to provoke symptoms in atopic dermatitis; and the diet was not exactly the same for all children, because of the difficulty in devising a diet which would be acceptable to all, though the number of foods and range of alternatives was limited to a maximum of eight.

No objective measure of disease activity exists in atopic dermatitis, and the methods used for assessment were an attempt to reflect changes in the features of the disease which we felt were the most important, namely the extent of the disease, the degree of erythema, the disruption to sleep, and the amount of scratching. A single observer was required because of the subjective nature of the assessment, and until a validated reproducible scoring system for atopic dermatitis is devised all clinical studies will continue to share this disadvantage. In view of the open nature of the diet, parental assessment of the diet was subject to bias but, by keeping the observer blind and using a semiobjective scoring system any observer bias was applied equally to all three groups. The scoring system used has, however, been validated by comparing the results obtained by two observers (DCM and Dr L Patel, lecturer in child health at Manchester University, who is also undertaking clinical studies in children with atopic dermatitis), who made simultaneous observations and found a high degree of correlation between assessment of body surface area (r=0.88, p<0.0001) and skin severity score (r=0.9, p<0.0001) (data submitted by DCM to Dundee University as part of an MD thesis).

The improvement seen in all three groups, assessed by both the observer and parents, is consistent with the results of a previous study, which showed that 33 of 54 children who maintained a few foods diet for six weeks experienced improvement in their atopic dermatitis. However, when followed up for one year, there was a marked and equal improvement in those who responded to the diet, those who failed to respond, and those who were unable to adhere to the diet. This implies that the natural history of the condition, with its strong tendency to improve over time, was unchanged by the imposition of a few foods diet. In this study there was a discrepancy in the control group between the parental global assessment of the change in the skin condition and the observer’s assessment. This is not surprising, given that parents knew that the children were not on the diet whereas the observer was not aware.

It may be that we were unable to show diet to be an effective treatment for atopic dermatitis because of bias in the selection of patients for this study. It is possible that those patients whose dermatitis was made worse by food had
Few foods diet in atopic dermatitis

already been identified by parents and appropriate avoidance measures taken, and that those recruited to the study represent those in whom foods are unlikely to be an important trigger. It is also possible that foods represent only one of several triggers, such as house dust mite antigens, animal dander, or pollens, which may be important in the pathogenesis of the condition, and therefore that avoidance of a single type of trigger is ineffective in an unselected population. Although the history may give a clear indication that a particular trigger is important in an individual, the lack of a test which has the power to predict the success of any given avoidance regimen is a serious handicap. Another possible reason for the lack of success of the diet was that one or more of the foods chosen for inclusion in the study diet could have been triggers. This seems unlikely, given that the trend seen in the study was of improvement in all groups rather than deterioration in the two treatment groups.

There are as yet no convincing controlled trial data to show that few foods diets are beneficial in atopic dermatitis. These data, and those of a previous study performed in Manchester, have made us less enthusiastic about the dietary treatment of atopic dermatitis. However, the occasional dramatically good response to diet, and pressure from parents to try diets, means that a place will remain for this type of diet, performed as a supervised therapeutic trial.

We thank Sally Hollis of the Computation and Statistics Unit, Hope Hospital, Salford, John Stanton, Chief Dietitian, and Aileen Atherton, Chief Dietitian, for their help and advice. DCM and AES were supported by a grant from Nutricia Cow and Gate.