

The Behaviour of Three Year Olds in Relation to Allergy and Exposure to Artificial Additives

Volume Two of Two

Belinda J Bateman, BSoc.Sci, BM, MRCPCH

Submitted for consideration for Doctor of Medicine

School of Medicine

Faculty of Medicine, Health and Biological Sciences

Date of submission: July 2004

APPENDICES

- A - Mailshot Letter
- B - 1st and 2nd Reminder
- C - Screening Questionnaire
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- E - Medical Questionnaire
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- G - Food Information Booklet
- H - Behaviour Diary
- I - Snack Diary
- J - Health and Behaviour Questionnaire
- K - 3rd Reminder
- L - Psychology Scoring Sheets

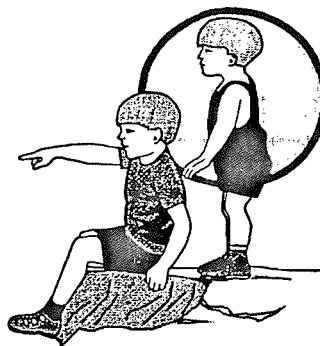
Appendix A

Mailshot Letter

This is the initial letter of introduction to the project that was sent to all the parents of 3 year olds resident on the Isle of Wight.

FAB study

The David Hide Asthma & Allergy Research Centre
St. Mary's Hospital
Newport
Isle of Wight
PO30 5TG



Research Team:

Dr Belinda Bateman
Mrs Carole Gant
Mrs Sharon Matthey
Mrs Brenda Fishwick

Tel: (01983) 5341
Fax: (01983) 8229

Dear parent/guardian of

We are a research team working at the David Hide Asthma and Allergy Centre, at St Mary's Hospital.

As you may know we are already involved in research studies which have become nationally and internationally renowned and many families on the Isle of Wight have kindly helped us with our research.

A new study, "FAB", involves seeing all the three year old children on the Island born between 1.9.94 and 31.8.96, over the next two years and asking about their development and behaviour. We would like to go through a simple 15 minute questionnaire with you when your child is about 3½ years old. Some children will then be asked to participate in the next stage of the study.

We would like to see you in a place which will be most convenient to you and would be grateful if you would tick the appropriate boxes on the enclosed form and return it to us in the stamped addressed envelope. *Please tick more than one box if you are able to be flexible, but if you like, indicate your first, second, third and fourth choice!*

All information you give to us will be treated with the utmost confidentiality.

Do not hesitate to contact us directly at the Asthma & Allergy Centre, by phone or letter if you have any questions. Ask for Brenda Fishwick our co-ordinator.

You may hear more about us in the County Press, spread the word among your friends, family and colleagues about this important study on the Island.

We look forward to meeting you soon.

Yours sincerely,

Dr Belinda Bateman (Research Paediatrician)

PLEASE TURN OVER AND COMPLETE THE OTHER SIDE OF THIS LETTER AND POST IT IN THE BUSINESS REPLY ENVELOPE PROVIDED, THANKYOU.

NUMBER

Office Use Only

1	2	3
---	---	---

NAME OF CHILD:

DATE OF BIRTH

NAME OF PERSON COMPLETING THIS FORM

RELATIONSHIP TO CHILD:

ADDRESS:

<input type="text"/>	
<input type="text"/>	
<input type="text"/>	
<input type="text"/>	Post Code: <input type="text"/>

Telephone
Numbers:

daytime	<input type="text"/>
evening	<input type="text"/>
other contact no.	<input type="text"/>

Please tick more than one box if you are able to be flexible, but if you like, Indicate your first, second, third and fourth choice!

☐ I would prefer to answer the questions over the phone ☐ be seen at home

☐ I would prefer to be seen at the Asthma and Allergy Centre

☐ I would like to be seen at the surgery or clinic before/after my child's three year check.
(Three year checks are sometimes done by a GP and sometimes a CMO (School Dr.))

My child's three year development check is on:

Date Time Place

☐ I would like to be seen before or during my child's playgroup session

My child's playgroup is at

The sessions s/he attends are

Day:	<input type="text"/>	Times:	<input type="text"/>
Day:	<input type="text"/>	Times:	<input type="text"/>
Day:	<input type="text"/>	Times:	<input type="text"/>

☐ I do not wish to take part in the study.

Thank you very much

URGENT! URGENT! URGENT! URGENT!
URGENT! URGENT! URGENT! URGENT!
URGENT! URGENT! URGENT! URGENT!
URGENT! URGENT! URGENT! URGENT!



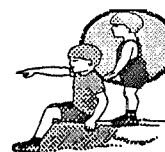
We have now received an amazing 60% response to our original letter asking for *your* help with our FAB study into 3 year olds' behaviour.

We know how busy you all are, and that this letter may now be lost, be at the bottom of the pile on the kitchen table or the dog may indeed have eaten it!

Don't worry, but please take a few moments to complete the other side of this form and pop it in the envelope provided.

FAB Study, David Hide Asthma and Allergy Research Centre, St Mary's Hospital, Newport, Isle of Wight PO30 5TG. TEL: 01983 534113

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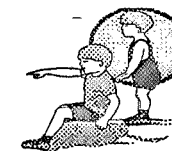
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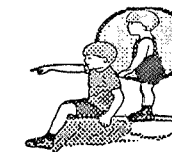
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Study No.

Name of Child: _____

- ☐ I am happy to answer the questions over the phone
- ☐ I would like to answer the questions in my own home
- ☐ I would like to be seen at the Asthma & Allergy Centre,
St Mary's Hospital, Newport

Telephone

daytime	
evening	

- ☐ I do not wish to take part in this study

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daytime	
evening	

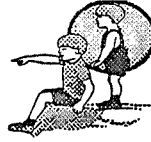
☐

Appendix B

1st and 2nd Reminder

These are the reminders sent if parents did not respond to the initial Mailshot letter.

HELP! - WE NEED ALL 3 YEAR OLDS



Sadly 50% of Island parents have not yet responded to our original letter.

Please please! Complete and return the brief form overleaf or give us a ring - NOW!

Dr Belinda Bateman - FAB Study
The David Hide Asthma & Allergy Research Centre
St. Mary's Hospital
Newport
Isle of Wight PO30 5TG Telephone 01983 534113

We need your help to make this study a success.

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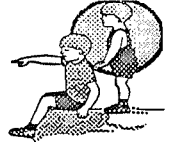
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nostc2.bre

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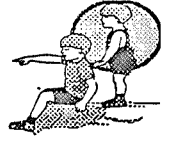
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- ☐ I would like to answer the questions in my own home
- ☐ I would like to be seen at the Asthma & Allergy Centre,
St Mary's Hospital, Newport

Telephone	daytime	<input type="text"/>
	evening	<input type="text"/>

- ☐ I do not wish to take part in this study

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Telephone	daytime	<input type="text"/>
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Telephone	daytime	<input type="text"/>
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St Mary's Hospital, Newport

Telephone	daytime	<input type="text"/>
	evening	<input type="text"/>

- ☐ I do not wish to take part in this study

Appendix C

Screening Questionnaire

This is the behaviour questionnaire, it consists of: 1) The activity component of the Emotionality, Activity and Sociability Temperament questionnaire (EAS)³; 2) Weiss-Werry-Peters Activity Scale (WWP)² and the child's general behaviour was assessed using a Behaviour Checklist (BCL)¹.

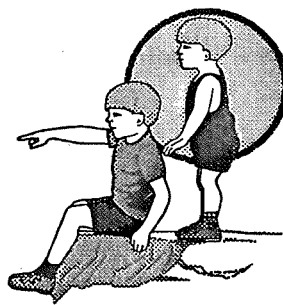
FAB study

*The David Hide Asthma & Allergy Research Centre
St. Mary's Hospital
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Research Team:

Dr Belinda Bateman
Mrs Carole Gant
Mrs Sharon Matthews
Mrs Jane Grundy
Mrs Brenda Fishwick

Tel: (01983) 53411
Fax: (01983) 82292



*Supported by The Ministry of Agriculture, Fisheries and Food and carried out in collaboration with University of Southampton
Members of steering group: Dr H Arshad; Dr J Dean; Dr P Rawlance; Prof J Sterkman and Prof J O Warner*

INFORMATION FOR PARENTS/GUARDIANS

We are a research group from the David Hide Asthma and Allergy Centre, St Marys Hospital, Newport, The Isle of Wight. Contact Brenda, Study Co-ordinator on 534113.

We are carrying out a study looking at the behaviour of toddlers.

You will be asked some simple questions about things to do with your child.

All the information which you give us will be treated with the utmost confidentiality.

One of us will go through the questions with you. It will take about 15 minutes.

We will want to see some of the children again, over the next six months to carry out a more detailed study.

If you are willing to take part in this second part of the study we will give you more detailed information then.

We would like you to complete both sections of the consent opposite.

**Brenda Fishwick
Clinical Trial Co-ordinator**

Study No. _____

SCREENING QUESTIONNAIRE

DATE:

--

Interviewer		BB	CG	JG	BF	Other:
Interviewee	Mother	Father	Other:			
Location	Phone	Home	AA Clinic	3Y Clinic	Playgroup	Other:

M ⁰	F ¹
----------------	----------------

CONSENT A

I the parent/guardian of agree to answer the 15 minute questionnaire about my child's behaviour as explained to me by

I understand that it will not in any way jeopardise the treatment I would receive for myself or my family.

Signature

Date .../.../...

.....

CONSENT B YES/NO

I the parent/guardian of would like to be contacted at a later date to receive information about the more detailed second part of the study. I will decide then if I want to participate further. I understand that signing this letter does not oblige me to continue with the study.

Signature

Date .../.../...

BEHAVIOUR CHECK LIST

To give us an overall picture of your child can we ask you to fill in the following checklist of children's behaviours. Please fill in each question even if you feel the questions are not relevant. Opposite each behaviour, please put a cross (X) in the columns which you think applies best to your child.

b1.	Usually has good appetite.	
	Sometimes has a poor appetite.	
	Nearly always has a poor appetite.	
b2.	Not faddy about eating.	
	Has a few fads won't eat certain things.	
	Very faddy won't eat many different foods	
b3.	Never wets at night.	
	Wets the bed up to once or twice a week.	
	Wets the bed three or more times a week.	
b4.	Never wets during the day.	
	Wets during the day up to once or twice a week.	
	Wets during the day three or more times a week.	
b5.	Completely bowel trained. Never dirties pants.	
	Occasionally soils, up to once or twice a week.	
	Soils pants three or more times a week.	
b6.	Easy to get to bed and to sleep.	
	Some difficulties in settling at bedtime.	
	Often takes over an hour to settle at bedtime.	
b7.	Hardly ever wakes up at night.	
	Sometimes wakes at night.	
	Frequently wakes at night and difficult to settle.	
b8.	Never sleeps with parent.	
	Occasionally sleeps with parent because upset or doesn't want to sleep alone.	
	Frequently sleeps with parents because upset or doesn't want to sleep alone.	
b9.	Not active enough.	
	Not markedly active.	
	Very active.	
	Too active, won't sit still for meals or at other time for more than 5 minutes.	



b10.	Concentrates on play indoors for 15 minutes or more.	
	Concentration 5 to 15 minutes or very variable.	
	Hardly ever concentrates for more than 5 minutes on play indoors.	
b11.	Not clinging, can easily be left with people he/she knows.	
	Gets upset if away from mother, but gets over it.	
	Very clinging; can't be left with others.	
b12.	Independent; doesn't ask for a lot of attention.	
	Sometimes asks for a lot of attention, follows mother around all day.	
	Demands too much attention, follows mother around all day.	
b13.	Easy to manage and control.	
	Sometimes difficult to manage or control.	
	Frequently very difficult to manage or control.	
b14.	Doesn't have temper tantrums.	
	Sometimes has tantrums (last a few minutes)	
	Has frequent or long temper tantrums.	
b15.	Usually happy except for brief periods, when tired for instance.	
	Sometimes miserable or irritable.	
	Frequently miserable or irritable.	
b16.	Not a worrier.	
	Sometimes worried for short periods.	
	Has many different worries, broods over things, e.g. illness, accidents, monsters, changes.	
b17.	Few or no fears.	
	Has some fears.	
	Very fearful, has lots of different fears.	
b18.	Gets on well with all brothers and sisters.	
	Some difficulties with brothers and sisters.	
	Gets on badly with brothers and sisters.	
b19.	Gets on well with other children.	
	Some difficulties playing with other children.	
	Finds it very difficult to play with other children.	

ACTIVITY QUESTIONNAIRE

We are now going to ask questions about how active your child is when she or he is doing different things:-

		0	1	2
		No or Hardly Ever	Yes Fairly Often	Yes Very Often
a1.	During meals is the child up and down at the table?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a2.	During meals, does the child interrupt without regard to what others are trying to say?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a3.	During meals, does the child wriggle?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a4.	During meals, does the child fiddle with things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a5.	During meals, does the child talk too much?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a6.	When watching television, does the child get up and down during the programme?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a7.	When watching television, does the child wriggle.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a8.	When watching television, does the child play with objects or his own body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a9.	When watching television, does the child talk too much?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		0 No or Hardly Ever	1 Yes Fairly Often	2 Yes Very Often
a10	When watching television, does the child play which interrupts others ability to watch the programme?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a11	When drawing, colouring or writing does the child get up and down?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a12	When drawing, colouring or writing does the child wriggle?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a13	When drawing, colouring or writing does the child play with objects or his own body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a14	When drawing, colouring or writing does the child talk too much?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a15	When drawing, colouring or writing does the child require adult supervision or attendance?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a16	Is your child unable to play quietly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a17	When at play, does the child keep going from one toy to another?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a18	When at play, does the child seek attention of an adult?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a19	When at play, does the child talk too much?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a20	When at play, does the child disrupt the play of other children?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		0 No or Hardly Ever	1 Yes Fairly Often	2 Yes Very Often
a21	Does the child have difficulty settling down for sleep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a22	Does the child get too little sleep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a23	Is the child restless during sleep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a24	Is the child restless during travel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a25	Is the child restless during shopping (including touching everything)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a26	Is the child restless during church, at the cinema or watching a school play etc?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a27	Is the child restless while visiting friends or relatives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please answer the items below by circling one of the numbers to indicate how well they describe your child. We know that no item will apply to a child in every situation but try to consider their usual or general behaviour. Please answer honestly.....there are no right or wrong answers.

EAS Activity items		Not at all (strongly disagree)			A lot (strongly agree)	
e1	Child is always on the go	1	2	3	4	5
e2	Child is off and running as soon as she/he wakes up in the morning	1	2	3	4	5
e3	Child cannot sit still long	1	2	3	4	5
e4	Child prefers quiet games such as block play or colouring to more active games	1	2	3	4	5
e5	Child fidgets at meals and similar occasions	1	2	3	4	5

We would now like to ask you some more questions about your child's behaviour.

Would you describe your child as being:			
		1	2
p1	Restless	Yes	No
p2	Hyperactive	Yes	No
p3	Impulsive	Yes	No
p4	Fidgety	Yes	No
p5	Aggressive	Yes	No
Do you think that for your child that these kind of behaviours are influenced by:			
p6	Being tired	Yes	No
p7	Drinking certain drinks	Yes	No
p8	Being told off	Yes	No
p9	Being with other children	Yes	No
p10	Eating certain foods	Yes	No
p11	Being upset	Yes	No
p12	Being at home	Yes	No
P13	Just born this way	Yes	No

To be able to check we have got a sample representative of the Island population we would just like to ask you a further question.

Ed.Q. | Mother finished full-time education - Age in years _____

Thank you very much for you co-operation. If you have agreed to participate in the second part of the study we will be contacting you shortly.

Appendix D

Skin Prick Test

This is the form used to record the skin prick tests for each child.

Phase II FAB SPT

NAME

STUDY
NUMBER

DATE

 / /

TESTER (initials)

ALLERGEN	WHEAL	MEAN DIAM.
Histamine		
N. Saline		
House dust mite		
Grass pollen		
Cat		
Milk		
Egg		
Peanut		

ATOPIC

☐

NOT ATOPIC

☐

Appendix E

Medical Questionnaire

This is the questionnaire used to gather socio-demographic and health information from the child and family, and record the general examination.

Date _____

Study No. _____

MEDICAL QUESTIONNAIRE

ID NAME OF CHILD:

--

Sex Male/Female

M ⁰	F ¹
----------------	----------------

Height

			.	
--	--	--	---	--

Weight

		.	
--	--	---	--

DOB Date of Birth

--	--	--

Rivwee NAME OF PERSON COMPLETING
QUESTIONNAIRE:

GP

Mum ¹	Grandma ³	Legal guardian ⁵
Dad ²	Grandad ⁴	Other ⁶
Mum & Dad ⁷		

BIRTH HISTORY

These are some questions about your child's first few weeks and months of life.

A1 Gestation (completed weeks)

--	--

A2 Did the child's mother smoke during pregnancy?

Y ⁰	N ¹
----------------	----------------

A3 Type of delivery

NVD

EI SCS

Em SCS

Assisted delivery (forceps/ventouse)

1
2
3
4

A4/5

Birth Weight

.....

	lb		oz
--	----	--	----

A6

	.			kg
--	---	--	--	----

A7 Did your child go to SCBU at all?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q A9

A8 Time ventilated/oxygen dependent (days)

--	--

A9 Age breast fed until (months)

--	--

A10 Age at weaning (months)

--	--

Date _____

Study No. _____

PAST MEDICAL HISTORY

These are some questions about your child's past health and illnesses:

- B1 Has your child had any illnesses or operations involving hospitalisation?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to QB6

	ILLNESS/OPERATION	DATES
B2		
B3		
B4		
B5		

Has your child ever received help from any of the following people?

- B6 Hospital Paediatrician

Y ⁰	N ¹
----------------	----------------

- B7 Other consultant

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q B11

- B8 Who?

B9

B10

- B11 Alternative/Complementary therapist

Y ⁰	N ¹
----------------	----------------

- B12 Who?

1	Homeopath	2	Herbalist
3	Chiropracter	4	Acupuncturist
5	Other		

- B13 Physiotherapist/Occupational therapist

Y ⁰	N ¹
----------------	----------------

- B14 Speech therapist

Y ⁰	N ¹
----------------	----------------

- B15 Child psychiatrist/psychologist

Y ⁰	N ¹
----------------	----------------

- B16 Other

Y ⁰	N ¹
----------------	----------------

- B17 Who?

--

Sensory problems

- B18 Has the child ever had problems with his/her hearing?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q B21

- B20 Has your child currently got problems with his/her hearing?

Y ⁰	N ¹
----------------	----------------

- B21 Does your child have any problems with his/her vision?

Y ⁰	N ¹
----------------	----------------

Date _____

Study No. _____

DRUGS AND TREATMENT

C1 Does the child take any drugs/inhalers to help their chest?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q C13

C2 Ketotifen

Y ⁰	N ¹
----------------	----------------

C3 Oral bronchodilator

Y ⁰	N ¹
----------------	----------------

C4 Inhaled bronchodilators

Y ⁰	N ¹
----------------	----------------

C5 Inhaled sodium cromoglycate/ 'Intal'

Y ⁰	N ¹
----------------	----------------

C6 Inhaled steroids

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to question Q C11

C7	Type	1	budesonide
		2	fluticasone
		3	beclamethasone
		4	other _____
C8	Dose (per am/pm)	1	50mcg
		2	100mcg
		3	150mcg
		4	200mcg
		5	250mcg
		6	300mcg
		7	400mcg
		8	500mcg (0.5mg)
		9	800mcg
		10	1000mcg
		11	other _____
C9	Frequency	1	once/day
		2	two times/day
		3	three times/day
		4	four times/day
		5	infrequently
		6	with URTI
		7	other _____
C10	Delivery System	1	nebuliser
		2	spacer + MDI
		3	MDI
		4	breath activated device
		5	other _____

C11 Theophylline/aminophylline

Y ⁰	N ¹
----------------	----------------

C12 Has your child ever needed a course of oral steroids for his/her chest ?

Y ⁰	N ¹
----------------	----------------

Date _____

Study No. _____

- C13 Has your child been prescribed adrenaline as a pen or an inhaler to use in case of reactions to food or stings?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to QC16

- C14 Carries adrenaline injection

Y ⁰	N ¹
----------------	----------------

- C15 Carries adrenaline inhaler

Y ⁰	N ¹
----------------	----------------

- C16 Does the child take antihistamines?

No	1
PRN	2
Regularly	3

If 'NO' skip to QC18

- C17 Type of antihistamine

--

- C18 Does the child use any creams or ointments prescribed?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to QC23

- C19 Does the child use an emulsifying cream/ointment?

Y ⁰	N ¹
----------------	----------------

- C20 Type

--

- C21 Does the child use a steroid cream or ointment?

Y ⁰	N ¹
----------------	----------------

- C22 Type

--

- C23 Does the child use any nasal sprays?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q C26

- C24 Does the child use nasal/sodium cromoglycate? (rhinocrom)

Y ⁰	N ¹
----------------	----------------

- C25 Does the child use nasal steroids?

Y ⁰	N ¹
----------------	----------------

Other medication

- C26 Has your child been prescribed any other drugs, inhalers or creams?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q C33

Date _____

Study No. _____

	Drug	Dose	Freq.	Date Started
C27				
C28				
C29				
C30				
C31				
C32				

Immunisations

Has the child had the following immunisations?

C33 DPT and polio

Y ⁰	N ¹
----------------	----------------

C34 DPT and polio without pertussis

Y ⁰	N ¹
----------------	----------------

C35 HIB

Y ⁰	N ¹
----------------	----------------

C36 BCG

Y ⁰	N ¹
----------------	----------------

C37 MMR

Y ⁰	N ¹
----------------	----------------

C38 Other vaccinations

Y ⁰	N ¹
----------------	----------------

C39 What.....(string)

--

Atopic symptoms

Wheezing

D1 Has your child ever had wheezing or whistling in the chest at any time in the past?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q D6

D2 Has your child had wheezing or whistling in the chest in the last 12 months?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q D6

D3 How many attacks/episodes of wheezing has your child had in the last 12 months

0 ¹
1-3 ²
4-12 ³
>12 ⁴

D4 In the last 12 months how often on average has your child's sleep been disturbed due to wheezing?

Never
Less than one night/week
One or more nights/week

D5 In the last 12 months has wheezing ever been severe enough to limit your child's speech to only one or two words at a time between breaths?

Y ⁰	N ¹
----------------	----------------

D6 Has your child ever had asthma?

Y ⁰	N ¹
----------------	----------------

D7 In the last 12 months has your child's chest sounded wheezy during or after exercise?

Y ⁰	N ¹
----------------	----------------

D8 In the last 12 months has your child had a dry cough at night, apart from a cough associated with a cold or a chest infection?

Y ⁰	N ¹
----------------	----------------

D9 Is there anything that brings on or makes worse your child's cough or wheeze?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q E1

If 'YES'

- D10 pollens
 D11 animals
 D12 if yes what.....
 D13 foods
 D14 if yes what.....
 D15 dust
 D16 smoke
 D17 infection
 D18 exercise
 D19 emotion
 D20 other

Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹

Date _____

Study No. _____

Croup

- E1 Has your child ever had episodes of harsh noise and difficulty breathing (croup)?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q F1

- E2 Number of episodes in the last 12 months

0 ¹
1-3 ²
4-12 ³
>12 ⁴

- E3 Number of episodes ever

--	--

Nasal symptoms

- F1 Has your child ever had a problem with sneezing, or a runny, or a blocked nose when he/she did not have a cold or the flu?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to question Q F17

- F2 In the past 12 months has your child had a problem with sneezing, or a runny or blocked nose when he/she did not have a cold or the flu?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to question Q F17

- F3 In the past 12 months has this nose problem been accompanied by itchy-watery eyes?

Y ⁰	N ¹
----------------	----------------

- F4 In the past 12 months did this nose problem occur

1	Summer months only
2	Winter months only
3	All year round
4	other

- F16 In the past 12 months how much did this nose problem interfere with your child's daily activities?

Not at all
A little
A moderate amount
A lot

- F17 Has your child ever had hayfever?

Y ⁰	N ¹
----------------	----------------

- F18 Have you identified anything specific that triggers your child's nose and eye symptoms?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q G1

If 'YES'

- F19 pollens
 F20 animals
 F21 if yes what.....
 F22 foods
 F23 if yes what.....
 F24 dust
 F25 smoke
 F26 infection
 F27 exercise
 F28 emotion
 F29 other

	Y ^u	N ⁱ
	Y ^u	N ⁱ
	Y ^u	N ⁱ
	Y ^u	N ⁱ
	Y ^u	N ⁱ
	Y ^u	N ⁱ
	Y ^u	N ⁱ

Skin

- G1 Has your child ever had an itchy rash which was coming and going for at least 6 months?

Y ^u	N ⁱ
----------------	----------------

If 'NO' skip to Q G7

- G2 Has your child had this itchy rash at any time in the last 12 months?

Y ^u	N ⁱ
----------------	----------------

If 'NO' skip to question Q G7

- G3 Has this itchy rash at any time affected any of the following places: the folds of the elbows, behind the knees, in front of the ankles, under the buttocks or around the neck, ears, or eyes?

Y ^u	N ⁱ
----------------	----------------

- G4 At what age did this itchy rash first occur?

Under 1 year
1-2 years
2-4 years

- G5 Has this rash cleared completely at any time during the last 12 months?

Y ^u	N ⁱ
----------------	----------------

- G6 In the last twelve months, how often on average has your child been kept awake at night by this itchy rash?

Never
Less than 1 night per week
1 or more nights per week

- G7 Has your child ever had eczema?

Y ^u	N ⁱ
----------------	----------------

- G8 Any provoking factors?

Y ^u	N ⁱ
----------------	----------------

Date _____

Study No. _____

If 'NO' skip to Q H1

- If 'YES'
- G9 pollens
- G10 animals
- G11 If yes what.....
- G12 foods
- G13 If yes what.....
- G14 dust
- G15 smoke
- G16 infection
- G17 exercise
- G18 emotion
- G19 other

Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹

Gastrointestinal symptoms

- H1 Has your child ever had diarrhoea or vomiting which you think was related to an intolerance or allergy to a food or drink? (eg to formula milk as a baby)

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q I1

- H2 Has your child had these episodes in the last 12 months?

Y ⁰	N ¹
----------------	----------------

- H3 At what age did these episodes first occur?

Under 1 year
1-2 years
3-4 years

- H4 Any known provoking factors

Y ⁰	N ¹
----------------	----------------

If 'NO' please skip to Q I1

- If yes
- H5 milk/milk products
- H6 eggs
- H7 fish
- H8 nuts
- H11 other.....

Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹

Anaphylactic/anaphylactoid reactions

Has your child ever had the following?

- I1 Urticaria (An itchy rash which looks like nettle rash)
- I2 Lip swelling
- I3 Lip and face swelling
- I4 Swelling of back of mouth and throat
- I5 Collapse

Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹

If all 'NOs' please skip to Q J1

Date _____

Study No. _____

I7 Age when first episode:

Under 1 year	1
1- 2 years	2
3-4 years	3

I8 Number of episodes ever:

One	1
Two	2
Three	3
Four	4
Five or more	5

I9 Any provoking factors?

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q J1

I10 Peanuts

Y ⁰	N ¹
----------------	----------------

I11 Tree nut

Y ⁰	N ¹
----------------	----------------

I12 Type.....

I13 Milk

Y ⁰	N ¹
----------------	----------------

I14 Egg

Y ⁰	N ¹
----------------	----------------

I15 Other food substance

Y ⁰	N ¹
----------------	----------------

I16 What?.....

I17 Bee sting

Y ⁰	N ¹
----------------	----------------

I18 Wasp sting

Y ⁰	N ¹
----------------	----------------

I19 Other

Family Composition

(Home - main place of child's residence)

Carers

J1 Mother lives at home

Y ⁰	N ¹
----------------	----------------

J2 age (yrs)

--	--

J3 Father lives at home

Y ⁰	N ¹
----------------	----------------

J4 age (yrs)

--	--

If 'NO' Please record other adult(s) living at child's mainplace of residence

	Relationship (to mother)..... (code string)
J5 Adult 1	
J6 Adult 2	
J7 Adult 3	

J8 Total family income (estimate)

less than £12,000

£12,000 - £17,999

£18,000 - £29,999

£30,000 - £41,999

greater than £42,000

1
2
3
4
5

Date _____

Study No. _____

J9 Mother's F/T employed
 J10 employment..... P/T employed
 J11 Maternity leave
 J12 F/T student
 J13 P/T student
 J14 Other.....

Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹

K1 Do you or your partner own a vehicle?

Y ⁰	N ¹
----------------	----------------

K2 What type of house do you live in?

House - detached or semi
 Bungalow
 Flat
 Caravan/mobile home
 Other

1
2
3
4
5

K3 Tenure of housing -

Privately owned
 Private landlord
 Council rented
 Housing assocn rented

1
2
3
4

K4 Animals at home -

Inside and outside
 Inside only
 Outside only
 No

1
2
3
4

K5 Smoking -

inside home
 in porch/garden/shed
 at other place of care

Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹

Child's Siblings

L1 What number child of Mother is this?

--

	Child's Name	FS/HS/ADF/SS	AGE	SEX	AT HOM	
1.					Y ⁰	N ¹
2.					Y ⁰	N ¹
3.					Y ⁰	N ¹
4.					Y ⁰	N ¹
5.					Y ⁰	N ¹
6.					Y ⁰	N ¹
7.					Y ⁰	N ¹
8.					Y ⁰	N ¹
9.					Y ⁰	N ¹

Date _____

Study No. _____

Other Carers

M1 Attends Nursery/Playgroup
M2 Number of half days per week

Y ⁰	N ¹

M3 Other regular carer

Y ⁰	N ¹
----------------	----------------

If 'NO' skip to Q N¹

M4 Child's home
M5 Carer's home
M6 Who? Nanny
M7 Childminder
M8 Grandparents
M9 Other relative

Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹

M10 Number of half days per week

--	--

On Examination

N5 Head Circ. (cm)
N6 Centile

N7 Eyes redness
N8 swollen eyelids

Y ⁰	N ¹
Y ⁰	N ¹

N11 Skin dryness
N12 erythema
N13 papules/vesicles
N14 excoriation
N15 lichenification

Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹
Y ⁰	N ¹

N16 Eczema

Y ⁰	N ¹
----------------	----------------

N17 Respiratory system normal

Y ⁰	N ¹
----------------	----------------

N18 Chest deformity

Y ⁰	N ¹
----------------	----------------

N19 Wheeze

Y ⁰	N ¹
----------------	----------------

N20 Cardiovascular system normal

Y ⁰	N ¹
----------------	----------------

N21 Abdominal system normal

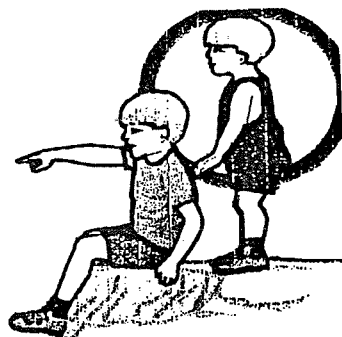
Y ⁰	N ¹
----------------	----------------

Appendix F

One Week Food Diary

This is a record of the Child's intake on normal diet prior to randomised controlled trial. This has not been analysed as part of this thesis.

F A B S T U D Y
O
ONE WEEK'S FOOD DIARY



DAY and DATE THURSDAY 23 April 1998

<u>Time/ Place</u>	EXAMPLE <u>Detailed description of food and drink taken</u>	<u>Weight/ Measure</u>
8am Home	Rice Krispies Sugar Semi skimmed milk White medium sliced bread - Safeways own label sunflower spread - thickly spread Peanut butter thinly spread and a little Marmite Semi skimmed milk	2 tbsps 1 tspn ½ cup 1 slice 1 tspn 1 full cup
10.30 Play- Group	Rich Tea Finger Biscuits 1 cup Robinsons "Special R" Apple & B'currant	2 200 ml
12.30 home	Cheese sandwich using 2 slices of wholemeal bread (medium sliced) spread thinly with margarine and thinly sliced Cheddar cheese Walkers ready salted crisps - 1 packet Banana	Ate all except crusts 25 gm medium
3.30	One small tube Smarties. Gave 6 smarties away!	Ate rest!
4 pm home	Yazoo Banana milk shake Ritz cheesy biscuits (dry)	200 ml 4
5.00 home	¼ large can Heinz baked beans with sausages in mixed with 2 egg sized boiled potatoes and 2 oz. broccoli and 1 small carrot	Ate half
	Bird's Angel Delight Strawberry - made up with full cream milk. 2 oz pure orange juice mixed with 2 oz. water	¼ of pkt Drank all
7.00 bedtime home	2 custard creams Cup of KiaOra orange squash Galaxy chocolate - 50gm bar	2 biscuits 5 oz. All of it!

DAY and DATE.....

<u>Time/ Place</u>	<u>Detailed description of food and drink taken</u>	<u>Weight/ Measure</u>

Name of child

Date of birth

Height

Weight

Is your child on any form of special diet?

YES

☐

NO

☐

If "Yes" please give details.

Is your child likely to drink 300 ml. ($\frac{1}{2}$ pint) of a mixed fruit juice drink, our special "FAB" drink, (predominantly blackcurrant), every day for a week? In addition they may of course have other drinks!

Yes

☐

Yes possibly

☐

Unlikely/definitely not

☐

If "unlikely/definitely not", please tick as many of the following as you think your child is likely to take:

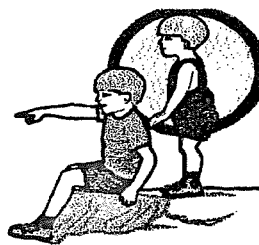
- Other drinks different juices ☐ *flavours:-.....*
 - fizzy drinks ☐ milk shakes ☐
- Lolly ices strawberry ☐ orange ☐
 - blackcurrant ☐ banana/lemon ☐
- Mousses - chocolate, ☐ strawberry, ☐
 - banana ☐ blackcurrant ☐
- Chocolate cake, with icing ☐ without icing ☐
- Tomato soup ☐
- Savoury Vegemince curry ☐ bolognaise ☐ Cottage pie ☐

Appendix G

Food Information Booklet

This is the booklet used by the dietician to explain the additive free diet to the families.

FAB STUDY
FOOD AND DRINK



**DAVID HIDE
ASTHMA AND ALLERGY RESEARCH
CENTRE**

**ST MARY'S HOSPITAL
NEWPORT
ISLE OF WIGHT
PO30 5TG**

**FOR FURTHER INFORMATION
PLEASE CONTACT:-**

ALLERGY RESEARCH DIETITIAN CAROLE GANT

**TELEPHONE 01983 534193 (DIRECT LINE TO DIETITIAN)
01983 534113 (BRENDA - FAB CO-ORDINATOR)
01983 3822928 (ANSWER PHONE AND FAX)**

DIETARY INFORMATION

For the 4 weeks of the trial we would ask you to try to ensure your 3 year old child does not eat or drink any food containing artificial colours or benzoate preservatives.

All other additives (with or without "E" numbers) are allowed.

This booklet will enable you to achieve this.

It includes:

1. A list of natural colours (in both number order and alphabetical order) that are suitable to include.
2. A list of artificial colours to avoid.
3. A list of preservatives to avoid.
4. Examples of drinks, and sweets etc. suitable to choose.
6. Examples of foods to avoid.

NATURAL COLOURS ACCEPTABLE TO CHOOSE
(In E number order)

E100	Curcumin
E101	Ribflavin (or riboflavin - 5' - phosphate)
E120	Cochineal, (or Carminic acid, or Carmines)
E140	Chlorophyll's (and chlorophyllins)
E141	Copper complexes of chlorophyll's & chlorophyllins
E150	Caramel (including sulphite and/or ammonia caramel)
E153	Vegetable carbon (or carbon black)
E160(a)	Carotene (alpha, beta or gamma) (also 160(e) and 164(f) related to carotene's). Apo-carotenal
E160(b)	Annatto
E160(c)	Paprika extract (or Capsanthin)
E160(d)	Lycopene
E161(b)	Lutein
E161(g)	Canthaxanthin
E162	Beetroot Red (or betanin)
E163	Anthocyanins
E170	Calcium Carbonate - (white)
E171	Titanium dioxide - (white)
E172	Iron oxides and hydroxides
E173	Aluminium (only used on sugar coatings on pills or cake decorating).
E174	Silver (only used on cake decoration)
E175	Gold (only used on cake decoration)

NATURAL COLOURS ACCEPTABLE TO CHOOSE
(In Alphabetical Order)

Annatto	E 160 (b)
Anthocyanin	E 163
Apo-carotenal	E 160 (a)
Beetroot Red	E 162
Beta Carotene	E 160 (a)
Betanin	E 162
Canthaxanthin	E 161 (g)
Capsanthian	E 160 (c)
Capsorubin	E 160 (c)
Caramel	E 150
Carmine	E 120
Carminic acid	E 120
Carotene	E 160 (a)
Chlorophyll	E 140
Cochineal	E 120
Copper Chlorophyllins	E 141
Curcumin	E 100
Lutein	E 161 (b)
Lycopene	E 160 (d)
Paprika Extract	E 160 (c)
Riboflavin	E 101
Turneric Extract	
Vegetable Carbon	E 153

FOODS ALLOWED FREELY

These are not allowed to contain any artificial colours although may contain natural colours:

All unprocessed foodstuffs
Bottled/packet water (unflavoured)
Milk - all types including cream and butter milk
Cocoa products and chocolate components in chocolate products and chocolate milk shakes or desserts.
Oils and fats including butter and margarine
Eggs
Cheese (except for the edible rind)
Flours and starches and grains
Bread and similar products including malt bread
Pasta and gnocchi
Sugar
Tomato Paste (puree)
Canned/bottled tomatoes
Tomato based sauces
Fruit juice and vegetable juice
Fruits (except processed cherries and other red fruits)
Vegetables (except for peas or olives)
Extra fruit jam, extra fruit jelly jams, honey, malt
Tea, coffee, fruit/herbal "teas"
Salt and spices
Foods for infants and young children.

ARTIFICIAL COLOURS TO AVOID

E102	Tartrazine
E104	Quinoline Yellow
E110	Sunset Yellow
E122	Carmoisine or Azorubine
E123	Amaranth (only found in alcohol or fish roe)
E124	Ponceau 4R or Cochineal Red A
E127	Erythrosine (only found in cherries)
E128	Red 2G (only found in some sausages and burgers)
E129	Allura Red
E131	Patent Blue
E132	Indigo Carmine (blue)
E133	Brilliant Blue FCF
E142	Green S
E151	Black PN or Brilliant Black PN
E154	Brown FK (only found in kippers)
E155	Brown HT
E180	Litholrubine BK or Pigment Rubine (only found in edible cheese rind)

FOOD WHICH MAY CONTAIN COLOURS - SO CHECK CAREFULLY

Flavoured Drinks
Confectionery
Jams and marmalades
Candied fruits and Vegetables (including glace cherries)
Preserves of red fruits e.g. canned rhubarb or raspberries or cherries in)
Olives (preserved)
Canned Peas
Decorations and coatings (e.g. coloured icing sugar)
Fine bakery wares - biscuits, cakes, wafers
Edible ices
Flavoured milk products (excluding chocolate flavour) e.g. drinks and
desserts such as pasteurised yoghurts or packet desserts.
Sauces and seasonings (e.g. curry powder, tandoori), pickles, relishes,
chutney, picallili, mint sauce.
Mustard
Edible cheese rind
Luncheon meat, sausages, burger meat (containing minimum of 4%
cereal content)
Vegetable proteins used to "look like" meat/fish
Smoked fish
Precooked shell fish
Salmon substitute
Fish paste
Fish roe
Savoury snacks (e.g. crisps, nuts)
Soups
Liquid nutritional supplements.

PRESERVATIVES TO AVOID

E 210 Benzoic Acid

This is found in home made wine! Also in McDonalds dill pickle slices which is put in all McDonalds burgers unless you especially ask for it not to be!

E 211 Sodium Benzoate

This is the most common benzoate preservative and is usually found in soft drinks such as fruit squashes and carbonated drinks

It is also in McDonalds barbeque and sweet & sour sauces. Occasionally may be found in snack foods (corn or potato crisps, coated nuts), salad creams or reduced sugar jams.

E 212 - E 219

These are less commonly used but are all variations of the same. "Benzoate" always forms part of the name.

These preservatives are most commonly in liquid medicines, such as Calpol or Tixylix.

Alternative medicines

Junior Meltus Expectorant (cough medicine from Tesco's pharmacy).

Augmentin fine suspension antibiotic

Junior Disprol soluble (contains same quantity of paracetamol as 1 tsp Calpol)

EXAMPLES OF DRINKS TO CHOOSE

EXAMPLES OF SQUASHES TO CHOOSE

Robinsons	<u>Special R:</u>	(All varieties)
	<u>No added Sugar Fruit & Barley Drink</u>	
		(All varieties)
	Whole Orange Drink	
Kia-ora	Lemon Barley Water	
	Orange Barley Water	
	No Added Sugar Drinks	
	Mixed Fruit Drink	
Safeway	Pear & Blackcurrant	
	High Juice	Orange
	Whole	Orange
	Orange, lemon & pineapple drink	
Somerfield	No added sugar orange drink	
	Sugar Free	Lemon
	High Juice	Blackcurrant
	Basics	Low Calorie whole orange
Tesco	Hi Juice	Orange, apple, lemon
	Whole orange, Whole orange sugar free	
Sunquick	Concentrated Orange (sold in Tesco)	
Iceland	Orange	
	No added sugar orange	
Marks & Spencer	Florida Orange	

Examples of concentrated drinks to choose continued.

Bottle Green Drinks Company:

Limeflower Cordial with Lime
Elderflower Cordial
Lemongrass & Ginger Cordial

Meridian Foods (sold in Health Food Shops)

5 different flavours of fruit concentrate
drinks

Baby Juices

Eg. Cow & Gate, Heinz, Boots

Spring water drinks

Oasis All varieties

EXAMPLES OF CARBONATED DRINKS TO CHOOSE

7 Up

Schweppes **Diet** lemonade
Tonic and slimline tonic
Ginger Ale (American, and dry ginger)

Ribena Spark Blackcurrant

Rio (Sparkling spring water with fruit juices in)

St Clements Sundaze

Appletise and Orangtise

Kiri

Supermarkets own brands of sparkling apple and grape juices

Schloer All varieties

OJ Sparkling fruit juice

Aquilibra Summerfruits

Thorncroft Sparkling Elderflower

Snapple

Gusto Lemonade (sold in Health Food Shops)

FRUIT JUICE DRINKS TO CHOOSE

All varieties of, long life **pure fruit juices** and freshly squeezed fruit juices (which will be re Fridgerated) are suitable to choose.

All varieties of "**ready to drink**" **fruit drinks** (still) are suitable. They are free of all colours but some may contain natural flavourings and quite likely citric acid but this is naturally in fruit anyway. They are not preserved.

Examples: Cartons of Ribena **drink** blackcurrant, raspberry or strawberry.

N.B. The red coloured Sunny Delight is not suitable

EXAMPLES OF MILK SHAKE DRINKS TO CHOOSE

Frijj	Fresh thick milk shake strawberry
Safeway	Fresh (refridgerated) milk flavoured drink - strawberry
Stripes	Low fat milk drink:- strawberry, banana, and chocolate flavours
Unigate	Crazy milk drink -strawberry and chocolate
Yazoo	Sterilized milk drink. banana and chocolate flavours
Yoplait Yop Shake	Strawberry flavour
Nesquik	Milk shake - strawberry, banana and chocolate flavours

EXAMPLES OF SWEETS TO CHOOSE

Most Chocolate,

White and ordinary chocolate, including chocolate bars and covered biscuits.

Eg. Mini eggs, maltesers, munchies, chocolate buttons

Fudge

Most vanilla Fudge

Toffees

Most toffees and caramels eg. toffos, cream-line/ mint/ banana split/ and treacle toffees and caramels.

Mints

Most white mints

eg original polos, mintoes, coolmints and mint creams. Not the extra strong mint or spearmint or soft mint flavours (as these are blue).

Barratt

Various gums

Eg. Assorted Tools, BlackJack chew bar, Coins, Fish 'n' Chips, Gum Cola Bottles, Pets, White Mice

Kia-ora

Real fruit pastilles (with Vitamins)

Chewits

All varieties.

Fruit-tella

Fruity flavoured chewy sweets

Trebor Turkish Delight (yellow and pink pieces)

Plain Liquorice sticks

Examples of sweets to choose continued

Various sweets from Woolworths :

Teletubbies jellies

Chupa Chups Lollipops (10 variety mix)

Fritt (strawberry chews plus Vitamin C)

Fruit Chews in a net (15 mixed flavours by Clec)

Softi Fruit (strawberry) Chews (20 in a net)

Softi Fruit Cubes (mixed flavours, 12 in a net)

Barrats Candy Sticks (4 pack with cartoon picture card)

Marks and Spencer

Percy Pigs

Fizzy Lemon Fish

Safeways

Bottles (fizzy cola) gums

Milkshakes (fruit flavour milk gums)

Supercook **Orange and lemon slices**

Jelly Diamonds

CAKE DECORATIONS

Supercook

Hundreds and thousands

Sugar Strands

Orange & lemon jelly slices

Jelly Diamonds

EXAMPLES OF ICE LOLLIES TO CHOOSE

Fab	Nestle
Feast	Wall's
Mister Long	Wall's
Opal Fruits	Mars
Safeway	10 assorted fruit lollies
Safeway	10 assorted fruit splits
Safeway	8 orange & lemon splits
Somerfield	10 orange flavour ice lollies
Sparkle (lemon)	Wall's
Sun Lolly	strawberry (10 ice lollies for home freezing)
Taz	Wall's
Twister	Wall's

SUITABLE MISCELLANEOUS ITEMS

Princes	Denice the Menace" Hotdogs (sold in Tesco)
----------------	--

EXAMPLES OF DESSERTS TO AVOID

Rowntrees Table Jelly - double orange
 Sugar Free Jelly Crystals - strawberry,
 raspberry, orange, lemon & lime.
 Ready To Eat Jelly

Dairybel Yogurts Strawberry and Raspberry Flavours

EXAMPLES OF MEAT PRODUCTS TO AVOID

St. Michael and other brands of **Chinese style chicken wings**.
Check other spicy coated meats!

McDonald's All burgers unless ask for them to be served
without dill pickle slices (which contains sodium benzoate)

Tesco's Hot dog sausages

MISCELLANEOUS ITEMS TO AVOID

Syrup Toppings Tops (Tate & Lyle) - strawberry
 Smuckers - strawberry

Puddis (whole milk UHT Dessert by Sudmilk) - strawberry

Colmans Fresh Garden Mint

McDonald's Barbeque and sweet & Sour sauces

SWEETS AND CHOCOLATES

All varieties of sweets and filled chocolates are likely to contain artificial colours and so avoid them unless you have been able to check the ingredients list carefully.

EXAMPLES OF CHOCOLATES TO AVOID

Cadbury's	Astro's, and Cream eggs, Contrast, Inspirations, Milk Tray and Roses
Mars	Galaxy Minstrels, and M & M's
Nestle	Smarties Aero (orange, peppermint), Black Magic

EXAMPLES OF BISCUITS TO AVOID

Burton's	Jammie Wagon Wheels, Jammie Dodgers
Rivington Foods Ltd.	Pink Panther Biscuits (Lemon Sherbet Fizz) Chocolate wafers
Jacobs	Mallows (raspberry and original) Trio strawberry milk shake bars
Crawfords	Iced Shorties, Jam rings, Pink wafers

SOME CAKES THAT MAY HAVE COLOURS IN

Jam Tarts, Congress Tarts, Bakewell Tart, Angel layer cake

Nuthalls Sultana Cake and Genoa Cake

Cherry Cakes. Any cakes and biscuits that contain cherries (contain E127)

Local Bakers:

Market Bakery carrot cake and carrot slice topping

Eric's (Newport) doughnuts and buns

Large Scale Catering:

Cake mixes, especially those used in large scale catering e.g. hospitals!

Batter mix used in large scale catering on fish etc.

EXAMPLES OF CRISPS AND SNACKS TO AVOID

K.P. Skips	Prawn cocktail flavour
Safeway Amigos	Tangy cheese flavour corn chips
Walkers Doritos	Tangy cheese flavour corn chips
Tesco's	Prawn cocktail snacks

EXAMPLES OF JAMS TO AVOID

Tesco's	"Value" jams
Safeway's	"Basics" jams
Jams used in the catering trade (e.g.hospitals and restaurants and bakeries (e.g. jam doughnuts!))	
Wiltshire red jam	

EXAMPLES OF ICE LOLLIES AND ICE CREAM BARS TO AVOID

Walls	Tricky Licky The Lost World (Jurassic Park) Kick Off (Strawberry) Spiderman, Fruit Flavour with Bubblegum Centre.
Freeze Pops	Munch bunch Flintstones
Rowntrees	Fruit Pastille Ice Lolly
Nerds	Ice Lolly

EXAMPLES OF MILK SHAKES AND YOGHURT DRINKS TO AVOID

Safeway	<u>Sterilised</u> skimmed milk drinks (strawberry and banana flavours)
Crusha	Milk Shake Mix (Syrup) Strawberry and Raspberry flavours only
Shake Rattle & Roll	- flavoured milk drinks Banana and Strawberry flavours
Unigate	Crazy milk drink - banana flavour
Yazoo	Strawberry flavour
Yop Shake	(by Yoplait) Strawberry flavour
Yoyo - Drink fit	Yoghurt drink plus 5 Vitamins by "Immergut (Germany) in blackcurrant and cherry flavours
Mc Donalds	Strawberry and banana milk shakes

TINNED FRUIT AND VEGETABLES TO AVOID

Peas	Most canned processed and mushy peas
Cherries	Anything with tinned cherries in including fruit cocktail.
Other red fruits	Other red tinned fruits should be checked carefully as many contain artificial red colour. E.g: <i>Safeways</i> Strawberries and Raspberries <i>John West</i> Red Plums Rhubarb (<i>check all makes</i>)

Appendix H

Behaviour Diary

This diary was used by the families to record the behaviour of their child each day throughout the 4 weeks of the randomised controlled trial.

FAB BEHAVIOUR DIARY

for use during 4 weeks of
artificial colouring and
benzoate free diet

Week 1

Name:

Study No:






This week's behaviour

We would like your views of how your child has behaved each day of this week.

Think of how your child normally behaves, in an average, 'nothing special' day.

Then.... each evening, think of how your child has been today.... and estimate whether you think they are worse, better or the same as on a normal day.

Here is an example.....

Behaviour that causes concern	much worse	worse	same	better	much better
Interaction with brothers or sisters					

The behaviours which you chose on the first day have been highlighted. **We would like you to make sure that you put a tick for all of these behaviours.**





























































If, on later days, other behaviours become a problem for you, you can add ticks for these too. **If you do this, you must carry on putting a tick for this behaviour for all of the following days.**

Add any comments, in the space provided.

Thank you for your help.

DAY ONE

DATE:

Behaviours that cause concern	much worse	worse	same	better	much better
Up and down from activity e.g. during meals					
Interrupting or talking too much					
Wriggling e.g. during meals					
Fiddling with objects or own body					
Needing lots of adult supervision or attendance					
Disturbing others e.g. during meals					
Difficulty settling down for sleep					
Restless e.g. during shopping					
Always on the go					
Concentration e.g. moving from one toy to another					
Temper tantrums					
Any other problem behaviour (describe below)					
<p>Comments:</p>					























































DAY TWO

DATE:

Behaviours that cause concern	much worse	worse	same	better	much better
Up and down from activity e.g. during meals					
Interrupting or talking too much					
Wriggling e.g. during meals					
Fiddling with objects or own body					
Needing lots of adult supervision or attendance					
Disturbing others e.g. during meals					
Difficulty settling down for sleep					
Restless e.g. during shopping					
Always on the go					
Concentration e.g. moving from one toy to another					
Temper tantrums					
Any other problem behaviour (describe below)					
<p><i>Comments:</i></p>					





























































DAY THREE

DATE:

Behaviours that cause concern	much worse	worse	same	better	much better
Up and down from activity e.g. during meals					
Interrupting or talking too much					
Wriggling e.g. during meals					
Fiddling with objects or own body					
Needing lots of adult supervision or attendance					
Disturbs others e.g. during meals					
Difficulty settling down for sleep					
Restless e.g. during shopping					
Always on the go					
Concentration e.g. moving from one toy to another					
Temper tantrums					
Any other problem behaviour (describe below)					
<p><i>Comments:</i></p>					





























































DAY FOUR

DATE:

Behaviours that cause concern	much worse	worse	same	better	much better
Up and down from activity e.g. during meals					
Interrupting or talking too much					
Wriggling e.g. during meals					
Fiddling with objects or own body					
Needing lots of adult supervision or attendance					
Disturbing others e.g. during meals					
Difficulty settling down for sleep					
Restless e.g. during shopping					
Always on the go					
Concentration e.g. moving from one toy to another					
Temper tantrums					
Any other problem behaviour (describe below)					
Comments:					





























































DAY FIVE

DATE:

Behaviours that cause concern	much worse	worse	same	better	much better
Up and down from activity e.g. during meals					
Interrupting or talking too much					
Wriggling e.g. during meals					
Fiddling with objects or own body					
Needing lots of adult supervision or attendance					
Disturbing others e.g. during meals					
Difficulty settling down for sleep					
Restless e.g. during shopping					
Always on the go					
Concentration e.g. moving from one toy to another					
Temper tantrums					
Any other problem behaviour (describe below)					
Comments:					

DAY SIX

DATE:

Behaviours that cause concern	much worse	worse	same	better	much better
Up and down from activity e.g. during meals					
Interrupting or talking too much					
Wriggling e.g. during meals					
Fiddling with objects or own body					
Needing lots of adult supervision or attendance					
Disturbs others e.g. during meals					
Difficulty settling down for sleep					
Restless e.g. during shopping					
Always on the go					
Concentration e.g. moving from one toy to another					
Temper tantrums					
Any other problem behaviour (describe below)					
<p><i>Comments:</i></p>					

DAY SEVEN

DATE:

Behaviours that cause concern	much worse	worse	same	better	much better
Up and down from activity e.g. during meals					
Interrupting or talking too much					
Wriggling e.g. during meals					
Fiddling with objects or own body					
Needing lots of adult supervision or attendance					
Disturbing others e.g. during meals					
Difficulty settling down for sleep					
Restless e.g. during shopping					
Always on the go					
Concentration e.g. moving from one toy to another					
Temper tantrums					
Any other problem behaviour (describe below)					

Comments:

Appendix I

Snack Diary

This is the diary used by the parents to record any 'mistakes' while the child was on the additive-free diet. They were asked to record **all snacks and drinks**, as these were likely to be the main source of additives.

Name

Study No.

FAB SNACK

DIARY

**for use during the month
of artificial colouring and
benzoate free diet
and FAB drinks**

Drinks ☐

Week number 4

Snacks ☐

Group

Day

Date

Time	<p>Please list details (brand and quantity eaten) of all snacks and processed foods e.g. drinks, biscuits, cakes, crisps, sweets, canned fruit and vegetables, packet or ready made desserts, ice creams and ice lollies.</p> <p>Also please record the approximate time and amount taken of the Special Fab Challenge drink (or food)</p> <p>Record any medicines taken. Thank you.</p>

FAB Drink completed

Yes

☐

No

☐

Appendix J

Health and Behaviour Questionnaire

This is the questionnaire used at each of the 5 visits for the parent to record a summary of the behaviour and allergic symptoms of the child for the preceding week.

This week's health and behaviour problems**1) Itches, scratches, coughs and wheezes**

We know that a tiny percentage of children may be affected in some physical way by diet. We would like you to complete the questionnaire below while you are waiting .

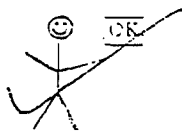
Think of how your child's health normally is, in an average, 'nothing-special' week.

Then..... think of how your child has been these last seven days...and estimate whether you think their health has been worse, better or the same.

If your child does not have the problem, and has never had the problem, simply tick the flag-flying, 'no problem' man.

Here is an example.....

eg. How has your child's appetite been this week?



No problems



**much
worse**



worse



same



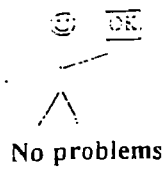
better



**much
better**

Please turn over now for the real thing!

Q1. This week, describe how your child's skin and any rashes (including eczema) have been?



much worse



worse



same

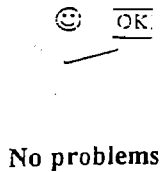


better



much better

Q2. Has your child's sleep been disturbed by his/her skin this week?



much worse



worse



same

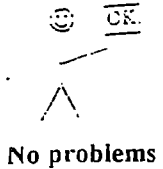


better



much better

Q3. Have you had to use more or less creams on their skin this week?



much more



more



same

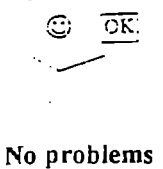


less



much less

Q4. Has your child needed more or less antihistamine medicine this week?



much more



more



same



less



much less

Q5. Has your child had itchier eyes and/or runny, snuffy nose this week?



much worse



worse



same

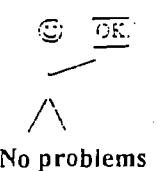


better



much better

Q6. Has your child coughed or wheezed more or less this week?



much more



more



same

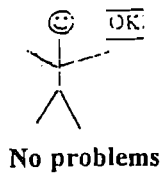


less



much less

Q7. Has your child's sleep been disturbed by **coughing** or **wheezing** this week?



much worse



worse



same

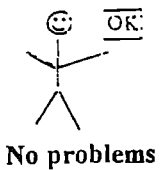


better



much better

Q8. Has your child needed more/less or the same of their 'reliever' (usually blue) inhaler/puffer this week?



much more



more



same



less



much less

2) Behaviour

Now we would like you to answer some questions about your child's behaviour over the last seven days, the last week.

They are similar to the questions we asked you in the original behaviour questionnaire, way back when your child was 3¼ years.

They are also similar to those on the 'daily behaviour diary', which you may already be completing each day this month.

So, think of how your child normally behaves, in an average, 'nothing-special' week.

Then.... think of how your child has behaved over the last seven days...and estimate whether you think they have been worse, better or the same.

Again, if your child does not have problems with this specific behaviour, tick the flag flying 'no problem' man.

Turn over for the behaviour questions

Q1. Up and down from activity eg. during meals and when playing



No problems



much
worse



worse



same



better



much
better

Q2. Interrupting or talking too much



No problems



much
worse



worse



same



better



much
better

Q3. Wiggling eg. during meals, when watching television or when playing



No problems



much
worse



worse



same



better



much
better

Q4. Fiddling with objects or own body



No problems



much
worse



worse



same



better



much
better

Q5. Needing lots of adult supervision and attendance



No problems



much
worse



worse



same



better



much
better

Q6. Disturbing others eg. during meals, when playing and watching TV



No problems



much
worse



worse



same



better



much
better

Q7. Difficulty settling down for sleep



much worse



worse



same



better



much better

Q8. Restless eg. during shopping, watching television or when playing



much worse



worse



same

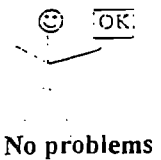


better



much better

Q9. Always on the go



much worse



worse



same



better



much better

Q10. Concentration eg moving from one toy to another



much worse



worse



same

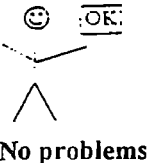


better



much better

Q11. Temper tantrums



much worse



worse



same

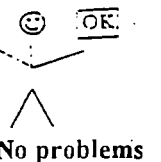


better



much better

Q12. Any other problem behaviour _____ (describe)



much worse



worse



same



better



much better

Comments - did anything unusual happen that might have affected your child's behaviour? Please put any comments overleaf

Thank you for your continuing help.....😊 😐 😞

Appendix K

3rd Reminder

This is the reminder used in the second year of the study if parents did **not** respond to the 1st and 2nd Reminders.

FAB STUDY

Parent/Guardian of:

Yes, its the FAB team again!

In the last three months the return rate to our recent letters has dropped and we really do need your help. As this would only take 10 minutes of your time for us to complete a behaviour questionnaire over the phone we would dearly love to hear from you.

If you feel you could do this please fill in your telephone number so we can get back to you - at a time convenient to you.

If your child was born in August 1996

WE NEED YOUR HELP!



Dr Belinda Bateman, Research Paediatrician, FAB Study
The David Hide Asthma and Allergy Research Centre, St Mary's Hospital, Newport, Isle of Wight
Tel: 01983 534113

Appendix L

Psychology Scoring Sheets

These scoring sheets facilitated the clinic tests used to assess the child's behaviour throughout the randomised controlled trial.

Name		Date		Time	
------	--	------	--	------	--

Actometer number	1	2	3	Assessor	Emma	Karen	Sophie	Other:
------------------	---	---	---	----------	------	-------	--------	--------

Wrist	L	R	None	Carer	Mother	Father	Other:
-------	---	---	------	-------	--------	--------	--------

Actometer	hrs	mins	secs	Tick if returned
reading				

Actual				
time on			.	

Daily behaviour diary	
Snack diary	
Health and behaviour questionnaire	

In to assessor - up to 5 mins of warm up with parent and assessor

Task one **Free play - 5 mins**

1 = train 2 = jigsaw 3 = teddy
4 = popoids 5 = doll 6 = bike
7 = truck 8 = ball 9 = no play
10 = other

Toys and other objects child contacted in each 15 second block										
15 s. blocks	Toys									
	1	2	3	4	5	6	7	8	9	10
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										

ACTIVITY LEVEL						
Locomotor activity	0	1	2	3		
	Underactive	occasionally moves - appropriate sitting still	moves about the room - normal tempo	moves about the room - increased tempo		
Minor motor activity	0	1	2	3		
	not fdgttg /sqmg	occasionally fdgttg./sqmg <3tms	often fdgttg /sqmg > 3 tms	constantly fdgttg/ sqmg		
Change of activity	0	1	2	3		
	none	seldom <3tms	frequently >3 tms	constantly		
ATTENTION						
Attending behaviour	0	1	2	3	8	
	engaged through session	¾ of time engaged	½ of time engaged	<¼ of time engaged	no engagement	
Toy change	0	1	2	3	4	8
	none	occasional toy change - adaptive play with >1 toy present	frequent toy changes - adaptive play with >1 toy present	frequent toy changes - only 1 adaptive play	many toy changes - no identifiable lasting adaptive play	no engagement with toys
Length of engagement - with one toy	0	1	2	3	8	
	focus on 1 toy for > 2 mins	focus on 1 toy for 1 - 2 mins	focus on 1 toy for few seconds	mainly engaged in other activities	no engagement	
Intensity of engagement	0	1	2	3	4	8
	gaze at toy throughout activity	occasionally referencing through activity	frequently referencing through activity	looking around / talking about irrelevant to play things	gaze seldom at toy	no engagement
Level of engagement	0	1	2	3	8	
	symbolic/ construction play	examines/ manipulates toys - no meaningful activity	repetitive play	offers the toys to the observers, holds passively	no engagement	
OTHER BEHAVIOURS						
Play-social orientation	0	1	2	3		
	play alone, completely engaged with toys	some social orientations with observers	many social orientations with observers, little independent play	completely engaged in social interaction		
Distress	0	1	2	3		
	no/little distress	shy/clingy or some whining and fussing	transient crying - some distress through session	marked distress persisting throughout		
Oppositional behaviours	0	1	2			
	none	some	marked			

Task two - Puppet game**Teaching phase**

	<u>Puppet</u>	<u>Part of body</u>	<u>Score</u>			
			0	1	2	3
1	Squeak	Tummy				
2	Squeak	Head				
3	Bubble	Tummy				
4	Bubble	Arm				

Test phase

	<u>Puppet</u>	<u>Part of body</u>	<u>Score</u>			
			0	1	2	3
1	Squeak	Tummy				
2	Bubble	Arm				
3	Squeak	Head				
4	Squeak	Head				
5	Bubble	Arm				
6	Bubble	Tummy				

etc. until 2 consecutive correct responses

Time taken to obtain 2 consecutive correct responses: mins.

OR:

Time taken trying to obtain 2 consecutive correct responses: mins.

AND:

Reason(s) not completed:

Trials

<u>Trial</u>	<u>Puppet</u>	<u>Part of body</u>	<u>Score</u>				<u>Squeak</u> good pig	0= incorrect (no move)
			0	1	2	3		1=move (wrong part)
1	S	A						2=partial move
2	B	A						3= correct move
3	B	H						
4	B	T						
5	B	T						
6	S	A						
7	B	T						
8	B	A						
9	S	T						
10	S	T						
11	S	A						
12	B	A						

<u>Bubble</u> bad cow	0= incorrect (move to named part)
	1=move (wrong part)
	2=partial move
	3= correct (no move)

Task three**Delay of gratification task****Teaching and test phases**

	Time delay (secs.)	
	Teaching	Test
	5	5
Correct response		
Good delay response		
Impulsive response		
Prompted correct response		
Prompted incorrect response		

Time taken to complete teaching and test:

 mins.

OR: Time taken trying to complete teaching and test:

 mins.

AND: Reason(s) not completed:

Trial phase

	Time delay (secs.)				
	45	35	25	5	15
Correct response					
Good delay response					
Impulsive response					
Prompted correct response					
Prompted incorrect response					
Total time taken if impulsive					
Total length of out-of-seat behaviour					
Total length of off-task behaviour					

Out-of-seat behaviour = total time when not sitting on chair

Off-task behaviour = paying attention to anything other than picture, cups or tester;
other activities eg. fiddling, talking about things other than the task

Task four Luria hand game**Teaching phase - imitation**

1 = correct

2 = incorrect, changed to correct

3 = correct, changed to incorrect

4 = incorrect

Fist	Finger	Fist	Finger

Test phase - imitation

<u>Trial</u>	<u>Fist/finger</u>	<u>Score</u>
1	Fist	
2	Fg	
3	Fg	
4	Fist	
5	Fist	
6	Fg	
etc. until 2 consecutive correct responses		

Teaching phase - opposite

Fist	Finger	Fist	Finger

Test phase - opposite

<u>Trial</u>	<u>Fist/finger</u>	<u>Score</u>
1	Fist	
2	Fist	
3	Fg	
4	Fist	
5	Fg	
6	Fg	
etc. until 2 consecutive correct responses		

Time taken to obtain 2 consecutive correct responses: mins.

OR:

Time taken trying to obtain 2 consecutive correct responses: mins.

AND: Reason(s) not completed:

Trial phase

Fg	F	Fg	F	Fg	Fg	Fg	Fg	F	F	F	Fg	F	Fg	F

Task five**Slowing down motor activity**

	Time (in half secs.)		
	Baseline	(1) Slow	(2) Fast
a) Telegraph poles			
	Baseline	(1) Slow	(2) Slow
b) Circle			
	Baseline	(1) Slow	(2) Slow
c) Walk a line slowly			

Actometer	hrs	mins	secs
reading	<input type="text"/>	<input type="text"/>	<input type="text"/>

Actual					
time off	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>