

# Chronic and Acute Effects of Artificial Colourings and Preservatives on Children's Behaviour

<b>Submission date</b> 18/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/12/2007	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# Study information

## Scientific Title

### Acronym

FABiC - Food And Behaviour in Children

### Study objectives

1. Do children show a behavioural response to the withdrawal and introduction of artificial food colourings and preservatives (AFCPs)?
2. What are the characteristics that differentiate responders to AFCPs and non-responders baseline attention deficit hyperactivity disorder (ADHD) symptom severity and/or their genotype?
3. Can any response that is found in the stage one trial be replicated in a blind acute challenge?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Prevention

### Participant information sheet

### Health condition(s) or problem(s) studied

Hyperactivity

### Interventions

A within subject double blind food challenge exposure to two additive mixes and one placebo mix - all children receiving all mixtures in a randomised order

### Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Artificial food colourings and preservatives (AFCPs)

**Primary outcome measure**

1. Direct observation of classroom behaviour
2. Parent and teacher ratings of hyperactive behaviour
3. Continuous performance test assessment of sustained attention

**Secondary outcome measures**

Sleep

**Overall study start date**

01/03/2005

**Completion date**

28/02/2007

**Eligibility****Key inclusion criteria**

Stage 1 - Chronic exposure - 120 three year old children and 120 eight year old children from the general population.

Stage 2 - Acute exposure - 45 eight year old children selected as being responders or non-responders in the Stage 1 challenge.

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

3 Years

**Upper age limit**

8 Years

**Sex**

Both

**Target number of participants**

153 3 year-olds and 144 8/9 year-olds

**Key exclusion criteria**

Those on special diets.

**Date of first enrolment**

01/03/2005

**Date of final enrolment**

28/02/2007

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**School of Psychology**

Southampton

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## **Sponsor information**

**Organisation**

University of Southampton (UK)

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**Sponsor type**

University/education

**ROR**

<https://ror.org/01ryk1543>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Food Standards Agency (UK) (Grant T07040)

**Alternative Name(s)**

The Food Standards Agency, FSA

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	03/11/2007		Yes	No