

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

**Submission date**  
18/07/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
02/08/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
07/12/2007

**Condition category**  
Mental and Behavioural Disorders

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Jim Stevenson

### Contact details

School of Psychology  
University of Southampton  
Highfield  
Southampton  
United Kingdom  
SO17 1BJ  
+44 (0)23 8059 2583  
jsteven@soton.ac.uk

## Additional identifiers

### Protocol serial number

pwh/ab/16/1/2491

## 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

**Study type(s)**

Prevention

**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(s)**

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

**Key secondary outcome(s))**

Sleep

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

3 years

**Upper age limit**

8 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**School of Psychology**  
Southampton  
United Kingdom  
SO17 1BJ

## **Sponsor information**

### **Organisation**

University of Southampton (UK)

### **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**

### **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