ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: June 5, 2019

ClinicalTrials.gov ID: NCT03737877

Study Identification

Unique Protocol ID:	SMEC_2017-18_132
Brief Title:	The Feasibility of a Dietary Intervention in Children With ADHD
Official Title:	The Feasibility of a Microbiome Dietary Intervention in Children With ADHD
Secondary IDs:	

Study Status

Record Verification:	June 2019
Overall Status:	Active, not recruiting
Study Start:	May 14, 2019 [Actual]
Primary Completion:	July 2019 [Anticipated]
Study Completion:	July 2019 [Anticipated]

Sponsor/Collaborators

Sponsor:	St Mary's University College
Responsible Party:	Sponsor
Collaborators:	Goldsmiths, University of London

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: SMEC_2017-18_132 Board Name: St Mary's University Ethics Committee Board Affiliation: St Mary's University Phone: 020 8240 8228 Email: kim.wright@stmarys.ac.uk Address: Room D20 St Mary's University Waldegrave Road Twickenham TW1 4SX

UK

Data Monitoring:

Study Description

Brief Summary: The aim is to conduct a feasibility pilot study of a dietary intervention designed to optimise gut bacteria in children diagnosed with ADHD.

Detailed Description: Children with Attention Deficit Hyperactivity Disorder (ADHD) can suffer debilitating symptoms, including problematic behaviour and sleep. Research suggests dietary manipulations may be a helpful treatment option for children with ADHD, although the most effective are highly restrictive, with little known about why they might work. Optimising gut bacteria in individuals with ADHD may help alleviate some of the symptoms of this condition via the gut-brain-axis and would provide a plausible mechanism by which dietary interventions operate. We propose to conduct a feasibility pilot study of a dietary intervention designed to optimise gut bacteria in children diagnosed with ADHD.

Conditions

Conditions: ADHD
Diet Modification

Keywords: ADHD
Diet Modification

Study Design

Study Type: Interventional

Primary Purpose: Other

Study Phase: N/A

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: None (Open Label)

Allocation: N/A

Enrollment: 9 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Diet modification	Diet modification The parents will have four group sessions with a nutritional therapist, where in depth advice and information about the diet will be provided. Ongoing support will also be provided throughout the study by use of a closed Facebook or WhatsApp group (whichever the parents choose as most appropriate). The diet is based on five main principles: • Eat at least seven portions of different varieties of fruit and vegetables each day. • Have a 12 hour overnight break from food (water only during this time). • Drink a Kefir drink each day - provided free of charge. • Eat

Arms	Assigned Interventions
	a microbiome friendly, protein rich, breakfast from our menu. • Reduce sugar and artificial sweeteners.

Outcome Measures

Primary Outcome Measure:

1. Completion of study
   What proportion of participants completed the study?

   [Time Frame: final week]

Secondary Outcome Measure:

2. Adherence to diet
   Percentage adherence to diet over the 4-week period based on parental report (range 0-100 % - high score reflecting greater degree of adherence).

   [Time Frame: week 6 of diet]

3. Side-effects
   Parent-reported side effects during course of study. (Qualitative) (More/more side-effects reflect poorer outcome).

   [Time Frame: duration of the 6 week diet]

4. The Conners Clinical Index (Conners CI) - Parent-report
   Parental report of clinical symptoms (percentile score - higher score reflects more/more severe symptoms)

   a. Disruptive Behavior Indicator
   b. Learning and Language Disorder Indicator
   c. Mood Disorder Indicator
   d. Anxiety Disorder Indicator
   e. ADHD Indicator

   [Time Frame: Baseline and week 6 of diet]

5. The Conners Clinical Index (Conners CI) - Teacher-report
   Teacher report of clinical symptoms (percentile score - higher score reflects more/more severe symptoms)

   a. Disruptive Behavior Indicator
   b. Learning and Language Disorder Indicator
   c. Mood Disorder Indicator
   d. Anxiety Disorder Indicator
   e. ADHD Indicator

   [Time Frame: Baseline and week 6 of diet]

6. The Conners Clinical Index (Conners CI) - Self-report
   Child self-report of clinical symptoms (percentile score - higher score reflects more/more severe symptoms)

   a. Disruptive Behavior Indicator
   b. Learning and Language Disorder Indicator
   c. Mood Disorder Indicator
   d. Anxiety Disorder Indicator
   e. ADHD Indicator

   [Time Frame: Baseline and week 6 of diet]

7. Delayed Match to Sample test (Cambridge Neuropsychological Test Automated Battery - CANTAB) Latency (response time) Accuracy (correct patterns selected).
   Computerised test of visual working memory

   • DMS Percent Correct (overall, for all delays, simultaneous, 0 sec delay, 4 sec delay, 12 sec delay). Range 0-100% - higher score reflects greater accuracy.

- DMS Mean & Median Correct Latency (overall, for all delays, simultaneous, 0 sec delay, 4 sec delay, 12 sec delay). Range 0-∞ ms – higher score reflects worse performance.
- DMS Correct Latency Standard Deviation. Range 0-∞ ms – higher score reflects worse performance.
- DMS Mean Choices to Correct response. Range 0-4 - higher score reflects worse performance.
- DMS Probability of Error Given Error. Range 0-1 - higher score reflects worse performance.

[Time Frame: Baseline and week 6 of diet]

8. The Consensus Sleep Diary
   Record of sleep - used qualitatively to detect and remove artefacts from the data.

   [Time Frame: Baseline and week 6 of diet]

9. Children's Sleep Habits Questionnaire
   Parental report of child's sleep A Total Sleep Disturbances score is calculated as the sum of all CSHQ scored questions, and can range from 33 to 99. A higher score indicates more problematic sleep.

   [Time Frame: Baseline and week 6 of diet]

10. Sleep self-report questionnaire
    Week long retrospective sleep survey (Scores range from 13-39 with a higher score indicating more/more severe sleep difficulties).

    [Time Frame: Baseline and week 6 of diet]

11. Actigraphy recordings
    Objective measure of sleep quality and daytime activity

    - Mean activity during sleep. Range 0-∞. A higher score = less sound sleep (worse).
    - Minutes spent awake during the down period. Range 0-∞. A higher score = less sound sleep (worse).
    - Sleep latency (time taken to fall asleep). Range 0-∞. A higher score = more time taken to fall asleep (worse).
    - Sleep efficiency (% down period spent asleep, after removing sleep latency). A higher score = better.
    - Wake after sleep onset (minutes spent awake during the down period after removing sleep latency). Range 0-∞. A higher score = less sound sleep (worse).
    - Sleep fragmentation (number of awakenings/ total minutes of sleep x 100) - Higher score = more fragmented sleep (worse).
    - Mean daytime activity (0-∞) not necessarily worse or better.

    [Time Frame: Baseline and week 6 of diet]

12. The Gastrointestinal Symptom Rating
    Questionnaire to evaluate common gastrointestinal symptoms Total scores range from 15-105 (with higher scores reflecting more/more severe gastrointestinal symptoms).

    Subscales:

    1. Abdominal pain (abdominal pain, hunger pains and nausea). Range 3-21 – a high score reflects worse symptoms.
    2. Reflux syndrome (heartburn and acid regurgitation). Range 3-21 – a high score reflects worse symptoms.
    3. Diarrhoea syndrome (diarrhoea, loose stools and urgent need for defecation). Range 3-21 – a high score reflects worse symptoms.
    4. Indigestion syndrome (borborygmus, abdominal distension, eructation and increased flatus). Range 3-21 – a high score reflects worse symptoms. Range 3-21 – a high score reflects worse symptoms.
    5. Constipation syndrome (constipation, hard stools and feeling of incomplete evacuation). Range 3-21 – a high score reflects worse symptoms.

    [Time Frame: Baseline and week 6 of diet]

13. Stool sample analysis for commensal bacteria and microbial diversity using 16S rRNA sequencing
    Analysis of bacterial strains and diversity within stool sample

    [Time Frame: Baseline and week 6 of diet]

14. Treatment Acceptability Scale
    Questionnaire to assess the acceptability of the diet to parents of the children taking part in the study Score range 6-42 (High score reflects more positive attitude to treatment)

[Time Frame: Baseline and week 6 of diet]

Eligibility

Minimum Age: 8 Years

Maximum Age: 13 Years

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Parent-reported diagnosis of ADHD.
2. Children aged between 8 years - 13 years 11 months at onset of study.
3. Children not taking ADHD medication (such as methylphenidate) at the time of the study.
4. Parental permission to attend three group sessions and for themselves and their child to complete the requisite assessments.
5. Both males and females are eligible to take part.
6. Children with a co-occurring diagnosis will be accepted onto the trial.
7. Children with food allergies/sensitivities/coeliac disease will be accepted onto the trial.

Exclusion Criteria:

1. Children undergoing a current course of behavioural therapy.
2. Children currently on ADHD medication (such as methylphenidate).
3. Children who have taken antibiotics in the past 3 months

Contacts/Locations

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IPDSharing

Plan to Share IPD: Undecided
At the request of individual researchers.

References

Citations:

Links:

Available IPD/Information:	