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Efficacy of online nutritional epigenetics tutorial on parent diet

Submission date	Recruitment status	[ ] Prospectively registered
09/05/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/05/2017	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/02/2024	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Behavioural problems in children are very common. There is evidence that the development of behavioural disorders such as ADHD (a condition which makes children hyperactive and impulsive, with short attention span, meaning they are easily distracted) and autism (a disorder which causes problems with the way that a person communicates and relates to others) are related to increased heavy metal exposure. This can happen from eating processed food products with ingredients containing allowed levels of inorganic mercury, lead and arsenic. This study is looking at a web-based nutrition tutorial which aims to help educate parents about what is in food. The aim of this study is to find out whether properly educating parents on the topic of toxic substances in the food supply and the negative effects of exposure to these toxic substances on child health can help them to make healthy dietary changes in the family home that may reduce problem behaviors in their child.

Who can participate?
A parent or guardian of children with learning difficulties, aged between 34 months and eight years.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in the web-based tutorial programme on light over a period of six weeks. This will help educate them about toxic substances in food and their effects on their child's health. Those in the second group continue as normal for the duration of the study. At the start of the study and after six weeks, participants in both groups complete surveys about their children's dietary habits.

What are the possible benefits and risks of participating?
Participants may benefit from improving the health of their child by following a healthier diet. There are no notable risks involved with participating.

Where is the study run from?
Food Ingredient and Health Research Institute (USA)

When is the study starting and how long is it expected to run for?
October 2015 to October 2016

Who is funding the study?
Food Ingredient and Health Research Institute (USA)

Who is the main contact?
Dr Renee Dufault

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
03

Study information

Scientific Title
Efficacy of online nutritional epigenetics tutorial on parent diet using a semi-randomized control group pretest-posttest study design

Study objectives
Hypothesis:
If parents are properly educated on the topic of toxic substances in the food supply and the adverse effects of exposure to these toxic substances on child health, then they can make dietary changes.

Study aim:
The aim of this study is to provide web based nutrition education for parents of learning-disabled children to enable them to make healthy dietary changes in the family home that may reduce problem behaviors in their child.

Ethics approval required
Old ethics approval format

Ethics approval(s)
A.T. Still University Institutional Review Board, 01/06/2015

Study design
Semi-randomised control group pretest-posttest design as described by Leedy and Ormond (2010) was used as the experimental study design to evaluate a web-based tutorial for use by parents of teach disabled children with problem behaviors to facilitate healthy dietary changes within a 6-week period.

Primary study design
Interventional

Secondary study design

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Learning disabilities associated with poor diet

Interventions
A web-based tutorial will be constructed online. Twenty parents are recruited to participate in the six week tutorial via Facebook. Interested parents fill out a screening questionnaire to determine their eligibility. Ten eligible parents are randomly assigned to participate in the six-week tutorial and ten eligible parents are assigned to the control group. Over the recruitment period, as the parents are enrolled in the study, one is assigned to the test group and the next one to enroll is assigned to the control group.

Intervention group: Participants receive six weeks of instruction that focuses on the nutritional factors known to impact gene behaviour to impact health and child behaviour.

Control group: Participants do not receive any instruction at all. They simply take the diet survey questionnaire pre and post intervention.

Pre and post intervention, all participants complete the online diet survey questionnaire comprised of 30 dietary habit questions and 10 participant characteristic questions.

Intervention Type
Behavioural

Primary outcome measure
Intake of highly processed food and whole foods is measured using survey questionnaire (by coding and determining diet scores for "intake of highly processed food" and "intake of whole and/or organic food") at baseline and after the six week tutorial.

Secondary outcome measures
No secondary outcome measures.

Overall study start date
03/10/2015

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. A parent or guardian of an un-medicated learning-disabled child between the ages of 34 months and 8 years with behavior problems
2. Parents have a home computer with daily access to the internet
3. Parents eat the western diet (aka SAD) at the beginning of the intervention along with their family members (e.g. no special diets)
4. Parents have a minimum educational level equivalent to a high school diploma or GED by self-report

Participant type(s)
Carer

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Parents with learning-disabled children on medication for the treatment of autism or ADHD
2. Parents with learning-disabled children on special diets (e.g. gluten or casein free, Feingold, etc.)
3. Parents with learning-disabled children under the age of 34 months or over the age of 8 years
4. Parents without access to the Internet

Date of first enrolment
01/07/2015

Date of final enrolment
15/08/2015

Locations

Countries of recruitment
United States of America

Study participating centre
Food Ingredient and Health Research Institute
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Sponsor information

Organisation
Food Ingredient and Health Research Institute

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Sponsor type
Research organisation

ROR
https://ror.org/004cvgs24

Funder(s)

Funder type
Research organisation

Funder Name
Food Ingredient and Health Research Institute

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/10/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at Survey Monkey.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/01/2024	12/02/2024	Yes	No