

Tiny Tastes in Gemini - a postal intervention to increase vegetable acceptance in pre-school twins

Submission date 05/10/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/11/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/11/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The study aims to test whether the Tiny Tastes intervention is associated with increased liking for, and consumption of, the target vegetable after 14 daily tastings in a home setting, and to evaluate the acceptability of the mailed version of Tiny Tastes as a stand-alone intervention in a home setting.

Who can participate?

Participants are families with pre-school twins who are taking part in the Gemini study.

What does the study involve?

All families in the Gemini study will be sent a questionnaire which will include information about the Tiny Tastes intervention. Parents will have the opportunity to opt-in to the study by ticking a box at the end of the questionnaire booklet. Families who have responded positively to the invitation by March 2011 will be randomly allocated to either the intervention or the control group. Parents in both groups will be sent an information sheet, test instructions and a study plan. They will be asked to select a vegetable that both of their twins dislike and then to carry out three taste tests with each twin (two pre-tests and one post-test). The tests will each be completed 15 days apart. Parents will be sent clear instructions on how to conduct the tests and will receive a study diary to help them remember the study schedule. The outcome measures of the tests will be the child's intake (number of pieces) of the target vegetable and the child's liking (maternal rating) of the test food. The intervention group will also receive a sealed envelope containing an information letter and a Tiny Tastes pack, with instructions to open this after they have completed pre-test test 2. The Tiny Tastes pack will explain how to complete 15 days of tiny tastes with each twin, including information on the importance of repeated exposure, techniques of exposure feeding with repeated tiny tastes, the need for patience and persistence, and parenting techniques and suggestions for praise. Parents will also be directed to a website where they can view a video demonstrating the Tiny Tastes procedures. Participants in the control group will receive no additional intervention materials in the first instance. They will complete the three tests 15 days apart with no change to normal feeding habits in the intervening period. Control group families will be sent the Tiny Tastes materials and

information following completion of the third test. The remaining families in the Gemini study will also be sent the Tiny Tastes materials to maintain consistency of treatment across the whole sample.

What are the possible benefits and risks of participating?
We do not expect any risks for participants completing this study.

Where is the study run from?
University College London (UK).

When is the study starting and how long is it expected to run for?
It started in March 2011 and will be completed by December 2012.

Who is funding the study?
Cancer Research UK.

Who is the main contact?
Professor Jane Wardle
j.wardle@ucl.ac.uk

Study website
<http://www.geministudy.co.uk>

Contact information

Type(s)
Scientific

Contact name
Prof Jane Wardle

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BRD/07/136 (version 1, 7th December 2010)

Study information

Scientific Title

Tiny Tastes in Gemini - a postal intervention to increase vegetable acceptance in a cohort of pre-school twins: a randomised study

Study objectives

Compared with those in the no treatment control group, 3-5 year old twins in the intervention group will show increased liking for and consumption of a previously disliked vegetable after 14 daily tastings combined with rewards.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS Research Ethics Committee, 01/01/2008, ref: 07/H0714/116. Amendments accepted 26/01/2011

Study design

Home-based parent-led randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Children's nutrition

Interventions

1. All children will participate in two pre-intervention and one post-intervention assessments conducted in their home by their caregiver (following detailed instructions provided by the research team)
2. Families will be randomly assigned to one of two conditions:
 - 2.1. Intervention condition: daily offer of target vegetable for 14 days with a sticker reward given for tasting
 - 2.3. Control: no tasting between assessment sessions
3. All caregivers will be sent a follow-up questionnaire following the completion of the assessments

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Children's liking of their target vegetable (assessed by caregivers on a 9-point scale)
2. Consumption of the target vegetable in pieces
3. Both measures taken twice pre-intervention and once post-intervention

Secondary outcome measures

1. Acceptability of Intervention measured by a follow-up questionnaire
2. Heritability of response to intervention

Overall study start date

01/03/2011

Completion date

31/12/2012

Eligibility**Key inclusion criteria**

Families of 3 year old twins, taking part in the Gemini Study

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Years

Upper age limit

3 Years

Sex

Both

Target number of participants

200

Key exclusion criteria

Significant learning difficulties or physical problems affecting feeding and eating

Date of first enrolment

01/03/2011

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University College London

London

United Kingdom

WC1E 6BT

Sponsor information

Organisation

University College London (UK)

Sponsor details

Department of Epidemiology and Public Health

Health Behaviour Research Centre

Gower Street

London

England

United Kingdom

WC1E6BT

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Sponsor type

University/education

Website

<http://www.ucl.ac.uk/>

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research [CRUK] (UK)

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?
Results article	results	01/06/2014		Yes	No