Mock Clinical Trial activity

Clinical trials, compared to observational studies, are considered by many to be the gold standard method for evaluation of healthcare interventions. They contribute significantly to relevant research evidence developed by the National Institute for Health Research (NIHR) to support the NHS in England and other care providers (source www.nihr.ac.uk/documents/clinical-trials-guide/20595).

This exercise aims to demonstrate to you the process of taking part in clinical trials. We used two different types of Jaffa Cakes as Investigational Medicinal Products to assess "efficacy" through a taste preference. If these aren't available to you, you can use any items you can find in your house to compare such as, cola vs diet cola, full fat vs skimmed milk or even tap water from the kitchen cold tap vs the bathroom cold tap.

Read the below instructions and carry out the experiment with the people you are living with (the instructions may need to be changed slightly if you are trialling a different product). You will be the Principal Investigator in this study and have full overall responsibility for its delivery. You will also find a Patient Information Sheet which you must get all of your participants to read and you must obtain their informed consent to be included in your mock trial.

If you want to do some further research you can find out more about clinical trials on the National Institute for Health Research website.

Information and instructions for the Principal Investigator

Study type	Phase 3
Primary Objective	To evaluate the efficacy (taste) of a standard treatment (McVities' Jaffa Cake) versus the efficacy (taste) of a new treatment (supermarket own brand Jaffa Cake).
Secondary Objective	To explain the process of involvement in clinical trials to patients and the general public.
Study design	This is a one day double blind crossover study to evaluate the efficacy of a standard Jaffa cake treatment (McVities) versus the efficacy of a new Jaffa cake treatment (Supermarket own brand). Participants will be given a dose of each treatment and will be asked to rate the efficacy (taste quality) of each treatment. Efficacy (taste) data will be recorded using a visual analogue scale (VAS) where 10 tastes best and 1 tastes worst.
Sample size	Dependent of those living in the same household as the Principal Investigator
Inclusion criteria	1. Participant lives in the same household as the Principal Investigator 2. Participant is able to swallow; 3. Participant likes Jaffa Cakes; 4. Participant is willing to eat two Jaffa Cake; 5. Participant consents to participation in the study.
Exclusion criteria	1. Participant has a known allergy to any ingredients contained within the proposed treatments; 2. Participant does not like Jaffa Cakes; 3. Participant is a diabetic; 4. Participant is not able to swallow.
Criteria for withdrawal	1. Participant does not comply with, or is unable to complete, the procedure outlined in the protocol; 2. In the Principal Investigator's (PI) professional opinion it is no longer appropriate for the participant to continue on the study.
Investigational Medicinal Product (IMP)	Standard treatment: McVities' Jaffa Cakes (IMP A) New treatment: Supermarket own brand Jaffa Cakes (IMP B) Water : H2O
Dosage	1 x unit of IMP A , 1x cup of water, 1x IMP B
Form of administration	Oral
Preparation	IMP is delivered to study site prepared and ready for administration
Storage	The IMP should be stored at room temperature in an air tight container.

Procedure	1. Explain study and purpose to participant and gauge interest and assign a participant no and enter this on the Case Report Form (CRF) (no names to be used to protect confidentiality). 2. Each participant must have his /her own CRF. Check that each approached participant meets the inclusion criteria and does not meet the exclusion criteria. Confirm this in section 1 of their Case Report Form (CRF). 3. If person meets all the inclusion criteria obtain informed consent. 4. Each participant should be handed a plate IMP A and IMPB along with a cup of water. 5. Participant should consume IMP A and note down the efficacy using the VAS scale on the CRF. Participant should drink the supplied cup of water. Participant should consume IMP B and note down the efficacy using the VAS scale on the CRF. 6. At the end of the trial collate all results and calculate the efficacy of IMP A versus efficacy of IMP B. Treatment with a higher efficacy (taste) score will be deemed as most efficacious in satisfying a Jaffa Cake craving.

CASE REPORT FORM

The Jaffa Cake Study (Study number 123456)

Participant information sheet

15 June 2020

Thank you for taking part in our study

We would like to show you how a double blind crossover study works.

This is a one day double blind crossover study to evaluate the efficacy of a standard Jaffa cake treatment (McVities') versus the efficacy of a new Jaffa cake treatment (supermarket own brand).

Usually in clinical trials you would be given a minimum of 24 hours to decide whether or not you would like to take part.

What does taking part involve?

As a participant, you will be given a dose of each treatment and will be asked to rate the efficacy (taste quality) of each treatment. Efficacy (taste) data will be recorded using a visual analogue scale (VAS) where 10 tastes best and 1 tastes worst.

What if I don't want to take part?

You are welcome to withdraw from the study at any point.

For more information on current trials taking place within Guy's and St Thomas' NHS Foundation Trust please visit www.guysandstthomas.nhs.uk/research/patients/get-involved.aspx

To learn more about the Biomedical Research Centre please visit our website

www.guysandstthomasbrc.nihr.ac.uk/

To find out more how you can get involved in supporting research as a patient advisor at our Biomedical Research Centre contact claire.oneill@gstt.nhs.uk.

Section 1 -The Jaffa Cake Study Inclusion and exclusion criteria and consent.

Participant study ID [_____] Principal Investigator [_____]

Inclusion, exclusion and informed consent

Inclusion criteria:

1. Participant is a patient or visitor to Guy's or St Thomas' hospital Y/N
2. Participant is able to swallow Y / N
3. Participant likes Jaffa Cakes Y/N
4. Participant is willing to eat two Jaffa Cakes Y/N

Exclusion criteria:

1. Participant has a known allergy to any ingredients contained within the proposed treatments. Y/N
2. Participant does not like Jaffa Cakes Y/N
3. Participant is a diabetic Y/N
4. Participant is not able to swallow Y/N

Suitability for trial inclusion: Y/N

Informed Consent: Y/N Participant signature [_____]

Section 2 – Demographics:

Age: [___] Gender: Female / Male/Other

Section 3-The Jaffa Cake Study Clinical Report Form (CRF)

Participant study ID [_____] Principal Investigator [_____]

Investigational Medicinal Product A

Please rate from 1 (worst taste possible) to 10 (best taste possible)

1	2	3	4	5	6	7	8	9	10

Investigational Medicinal Product B

Please rate from 1 (worst taste possible) to 10 (best taste possible)

1	2	3	4	5	6	7	8	9	10

Date_____ Principal Investigator [_____]