

# Changing how people think and feel about healthy eating: Translating neuroscience into population health for cancer prevention

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|----------------------------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>04/04/2018   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>03/05/2018 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>22/03/2019       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Cancer can be prevented by reducing cancer risk behaviours, like overeating, and increasing healthy behaviours, like healthy eating. Most people do not meet the recommended guidelines for healthy diet. One contributing factor is that healthy behaviours are more effortful and less pleasurable than competing unhealthy behaviours.

Health behaviours such as eating are regulated by two separate brain systems: the regulation network which includes brain regions associated with cognitive (related to thought processes, memory etc) control and emotion regulation, and the reward network which includes brain regions associated with reward processing. Obese people have been shown to have an overactive reward system. One way to potentially increase healthy behaviours, such as eating nutritionally balanced foods, is to increase the reward value and positive associations of healthy food, therefore making those healthy food options more preferable than unhealthy ones. In addition, overweight and obese people have been shown to favour moderate but immediate gains over high value future gains (i.e. they have higher temporal discounting (TD), e.g. devaluing future weight loss in favour of the immediately rewarding taste of a donut). If individuals are able to lower their TD, it may be easier for them to favour the long-term gain (e.g., healthy body weight) over the immediately rewarding unhealthy food choice. Positive episodic future thinking (i.e., the ability to project oneself into the future) has been shown to lower TD.

The current study aims to examine the unique and combined effects of positive affect and positive episodic future thinking interventions on TD, healthy food demand and healthy food choice.

### Who can participate?

You can participate if you are:

Adults who are overweight or obese and are not limited by a medical condition in their food choices.

### What does the study involve?

The study involves attending 2 in-person laboratory sessions and completing brief daily food consumption surveys.

During the first laboratory session, you will answer questions that assess positive and negative mood and then complete a brief delay discounting task on the computer. After the task you will be randomly allocated to one of the following interventions:

1. Positive affect and Episodic future thinking: Participants will be guided through a body scan meditation and instructed to imagine themselves eating a healthy food and think about the positive effect the healthy food is having on the various regions of their body, including providing essential nutrients that enrich bodily function and increase positive mood. Participants will also be instructed to imagine a future version of themselves that has been enriched by healthy foods over time - and to imagine that healthy future self in the present moment.
2. Positive affect and No episodic future thinking: Participants will be guided through a body scan meditation and instructed to imagine themselves eating a healthy food and think about the positive effect the healthy food is having on the various regions of their body, including providing essential nutrients that enrich bodily function and increase positive mood.
3. Neutral affect and Episodic future thinking: Participants will be instructed to imagine a future version of themselves that has been enriched by healthy foods over time - and to imagine the healthy future self in the present moment.
4. Neutral affect and No episodic future thinking: Participants will be guided through a body scan meditation focused on observing the various regions of their body.

After the intervention, you will complete a post-manipulation TD task and a modified TD task that assess your demand for food items. You will also be asked to complete a second set of questionnaires assessing basic health status and other psychological measures. Finally, anthropometric (physical) measurements will be taken, including height, weight and waist circumference.

At the second laboratory session (1week later), you will again complete the TD task and the modified TD food task and complete a brief set of health and psychological questionnaires.

In addition to laboratory sessions, you will be emailed or texted (depending on your preference) a separate daily food consumption survey for each day for entering the number of fruit, vegetable, protein, fat, and carbohydrate servings consumed that day, as well as a question in which you can also describe/state the food items you consumed that day.

What are the possible benefits and risks of participating?

We cannot promise that your participation will benefit you in any way. However, if the interventions show promise then we will proceed to conduct a bigger effectiveness study. If the interventions are found effective, it may help improve the health and wellbeing of overweight and obese individuals.

You may experience emotional distress and embarrassment from completing some of the questionnaires and during height and weight measurements. The likelihood of this occurring is rare. To minimize these risks, anthropometric measurements will be done in private. You will not be obliged to disclose any information you are not comfortable with, and are free to withdraw from the study at any point without consequence.

Total participation time is approximately 3 hours. There will be 7 total contacts per participant, including the first in-person laboratory session (90 minutes), the second in-person laboratory session (60minutes) and the interim 5 daily food consumption surveys (5 minutes each).

Where is the study run from?

Participants will be recruited from the University of North Carolina at Charlotte (UNCC) campus and Charlotte community.

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

The study starts in April 2018 and is expected to run for 9 months. Your participation in the

study will last for up to 1 week. You will be asked to visit the study laboratory twice: at the beginning and 1 week later.

Who is funding the study?

Cancer Research UK

Who is the main contact?

Dr Sara Levens,

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Sara Levens

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## Additional identifiers

**Protocol serial number**

C63941/A25647

## **Study information**

**Scientific Title**

The effects of positive affect and episodic future thinking on temporal discounting, healthy food demand and healthy food choice among overweight and obese individuals: a laboratory-based 2x2 factorial randomized controlled study

**Study objectives**

We predict that positive affect and episodic future thinking will with have unique effects, and will interact to make healthy behaviour, specifically healthy eating, more pleasurable compared to either process alone. This increase in pleasure and positive associations with healthy food options will then translate to increased preference and demand for healthier food options.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The study protocol has received ethics approval from:

1. University of North Carolina at Charlotte (Study #: 17-0388; approval date 06 Oct 2017)
2. University of York Health Sciences Research Governance Committee (no reference number; approval date 13 Oct 2017), and
3. Rutgers University (Study ID:Pro20170000955; approval date 17 Sep 2017)

**Primary study design**

Interventional

**Study design**

Double-blind randomised controlled trial

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Overweight and Obesity

**Interventions**

Participants will be randomly assigned through computer generated random sequence to one of four experimental conditions that will each feature a modified semi-guided mental imagery scripts in accordance with 2 (Positive affect: Yes/No) by 2 (Episodic future thinking: Yes/No) design: 1) Positive affect and Episodic future thinking, 2) Positive affect and No episodic future thinking, 3) Neutral affect and Episodic future thinking, and 4) Neutral affect and No episodic future thinking.

1. Positive affect and Episodic future thinking condition: Participants will be guided through a body scan meditation and instructed to imagine themselves eating a healthy food and think about the positive effect the healthy food is having on the various regions of their body, including providing essential nutrients that enrich bodily function and increase positive mood. Participants will also be instructed to imagine a future version of themselves that has been

enriched by healthy foods over time - and to imagine that healthy future self in the present moment.

2. Positive affect and No episodic future thinking condition: Participants will be guided through a body scan meditation and instructed to imagine themselves eating a healthy food and think about the positive effect the healthy food is having on the various regions of their body, including providing essential nutrients that enrich bodily function and increase positive mood.

3. Neutral affect and Episodic future thinking condition: Participants will be instructed to imagine a future version of themselves that has been enriched by healthy foods over time - and to imagine the healthy future self in the present moment.

4. Neutral affect and No episodic future thinking condition: Participants will be guided through a body scan meditation focused on observing the various regions of their body.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

1. Temporal discounting (TD) rate: the rate at which individuals discount rewards as a function of time. Temporal discounting is measured at baseline (before the intervention), immediately after the intervention, and 1 week later at follow up. Temporal Discounting is assessed via a questionnaire that asks the participant's preference for one monetary option over another (e.g. \$500 in one year, or \$100 now).

## **Key secondary outcome(s)**

1. Food Demand. Food demand is measured at baseline (before the intervention), immediately after the intervention, and 1 week later at follow-up. Food demand is assessed via a questionnaire that asks the participant how many servings of a snack option (e.g. an apple or candy bar) the participant would purchase if the snack option cost a certain amount. The cost options are varied (e.g. \$1 or \$1.25) and used to estimate what a participant would be willing to pay for a snack option.

2. Food Choice. Food choice is assessed immediately after the intervention and at follow-up 1 week later. Participants are presented with various healthy and unhealthy snack options and are told that they can select as many snack options as they would like to either eat or take with them. Their choices are recorded.

## **Completion date**

31/01/2019

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 years or older
2. Able to read and write English fluently
3. Have a body mass composition that indicates that they are overweight (BMI = 25-29.99 kg/m<sup>2</sup>) or obese (BMI = over 30 kg/m<sup>2</sup>)
4. Not diagnosed with any medical conditions that affect dietary choices (e.g. celiac disease, history of gastric bypass surgery)

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Key exclusion criteria**

1. Under 18 years of age,
2. Unable to read and write English fluently
3. Have a body mass index under 24.99 kg/m<sup>2</sup>
4. Have a diagnosis of a medical condition that affects dietary choice such as type 1 diabetes, celiac disease or gluten intolerance, and history of gastric bypass surgery.

**Date of first enrolment**

12/04/2018

**Date of final enrolment**

31/01/2019

## Locations

**Countries of recruitment**

United States of America

**Study participating centre**

**University of North Carolina at Charlotte**

University of North Carolina at Charlotte

9201 University City Blvd.

Charlotte, NC 28223

USA

United States of America

28223

## Sponsor information

**Organisation**

University of York

**ROR**

<https://ror.org/04m01e293>

# Funder(s)

## Funder type

Not defined

## Funder Name

Cancer Research UK

## Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

## 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

Data sharing statement to be made available at a later date

## Study outputs

| Output type                      | Details       | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol      | 20/03/2019   |            | Yes            | No              |
| <a href="#">Study website</a>    | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |