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

Submission date
04/04/2018

Recruitment status
No longer recruiting

Registration date
03/05/2018

Overall study status
Completed

Last Edited
22/03/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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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Study website
https://www.york.ac.uk/healthsciences/research/public-health/projects/cancer-prevention-behaviours/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)

Prevention

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
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 measure
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).

Secondary outcome measures
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.

Overall study start date
24/04/2017

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/m2) or obese (BMI = over 30 kg/m2)
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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
152

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/m2
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

Sponsor details
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Heslington, York YO10 5DD
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England
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Sponsor type
University/education

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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of study results in a high-impact peer reviewed journal

Intention to publish date
31/01/2020

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?
Protocol article	protocol	20/03/2019		Yes	No