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Minding blood sugar: how misperceptions of sugar consumption influence patients with type 2 diabetes

Submission date
03/06/2019

Recruitment status
No longer recruiting

Registration date
09/07/2019

Overall study status
Completed

Last Edited
07/09/2021

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
This study investigates whether expectations affect diabetic metabolism. To determine whether cognition affects glucose levels, the study examines study participants who have type 2 diabetes in which the body fails to generate sufficient insulin or use it properly. The researchers' previous work found that the subjective perception of time exerts a stronger influence on blood glucose level changes in people with type 2 diabetes than the objective passage of time. In this study, the researchers targeted the amount of sugar believed to be consumed by diabetics. Sugar consumption is perhaps the most widely accepted factor in explaining blood glucose fluctuations.

Who can participate?
Patients aged 18 and over who have insulin-independent type 2 diabetes mellitus

What does the study involve?
Participants are instructed to come to the laboratory twice at three-day intervals. At each session, participants sample one of the two beverages which are actually identical but had labels indicating different sugar levels. Blood glucose levels are measured at the start and after 20, 40 and 60 minutes.

What are the possible benefits and risks of participating?
Possible benefits to participants may include improved understanding of their experience. Participants may experience minimal discomfort associated with participation, but there were no adverse events associated with this trial.

Where is the study run from?
Harvard University (USA)

When is the study starting and how long is it expected to run for?
April 2017 to April 2018

Who is funding the study?
National Science Foundation (USA)

Who is the main contact?
Mr Chanmo Park
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Minding blood sugar: how misperceptions of sugar consumption influence patients with type 2 diabetes

Study objectives
Perceived rather than actual sugar consumption would influence blood glucose levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 20/04/2017, Harvard University-Area Committee on the Use of Human Subjects (Smith Campus Center, Suite 935, 1350 Massachusetts Ave., Cambridge, MA 02138, USA; IRB Registration- IRB00000109; Federal Wide Assurance - FWA00004837), ref: IRB16-1833

Study design
Randomised cross over trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Insulin-independent type 2 diabetes mellitus

Interventions
Participants were instructed to come to the laboratory twice, at three-day intervals. At each session, participants sampled one of the two beverages, which were actually identical but had labels indicating different sugar levels. The researchers counterbalanced order of presentation based on a block randomization procedure, creating two equally sized group samples. They controlled for consumption speed by instructing participants to completely consume the beverage in 3 minutes.

Intervention Type
Other

Primary outcome(s)
Blood glucose levels (mg/dL) measured at baseline, 20, 40 and 60 minutes

Key secondary outcome(s))
1. Perceived stress measured using Perceived Stress Scale (PSS, 10-item version) at baseline during the first session
2. Eating behaviors measured using Dutch Eating Behavior Questionnaire (DEBQ) at 60 minutes during the post-intervention of the first session
3. Affectivity measured using Positive Affect and Negative Affect Scale (PANAS) at baseline, 20, and 60 minutes
4. Hunger measured using Satiety Labeled Intensity Magnitude (SLIM) at baseline, 20, and 60 minutes

Completion date
19/04/2018

Eligibility

Key inclusion criteria
1. Individuals (≥ age 18) who have insulin-independent type 2 diabetes mellitus
2. Individuals who hold a minimum of 12 months duration from diagnosis
3. Individuals who do not have any serious illnesses other than type 2 diabetes and who do not

have diabetes-related complications
4. Individuals with a text-enabled phone for the duration of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
34

Key exclusion criteria
1. Individuals under the age 18
2. Individuals who do not have insulin-independent type 2 diabetes mellitus
2. Individuals who do not hold a duration of 12 months from diagnosis
3. Individuals who have any serious illnesses other than type 2 diabetes and who do not have diabetes-related complications
4. Individuals without access to a text-enabled phone for the duration of the study

Date of first enrolment
20/04/2017

Date of final enrolment
19/04/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Harvard University
33 Kirkland Street
Cambridge
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Sponsor information

Organisation
National Science Foundation

ROR
https://ror.org/021nxhr62

Funder(s)

Funder type
Government

Funder Name
National Science Foundation GRFP under Grant No. (NSF 16-588).

Alternative Name(s)
U.S. National Science Foundation, US National Science Foundation, NSF, US NSF, USA NSF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data that support the findings of this study have been deposited in Harvard Dataverse with the identifier (https://doi.org/10.7910/DVN/2WC8LC) and will be made publically available at a later date.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/09/2020	07/09/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes