

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

Submission date 03/06/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/09/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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
Mr Chanmo Park

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised cross over trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Psychology Study Pool at Harvard (<https://studypool.psychology.fas.harvard.edu>)

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 measure

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

Secondary outcome measures

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

Overall study start date

20/04/2017

Completion date

19/04/2018

Eligibility

Key inclusion criteria

1. Individuals (\geq 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

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

United States of America

02138

Sponsor information

Organisation

National Science Foundation

Sponsor details

2415 Eisenhower Avenue

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22314

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Sponsor type

Government

Website

<https://www.nsf.gov>

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, NSF, US NSF, USA NSF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Publication and dissemination plan

The researchers will present their findings to scientific conferences in the United States. They are also currently preparing to disseminate their findings via journal publication.

Intention to publish date

01/09/2019

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

Stored in repository

Study outputs

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