

Thinking about your best possible self: Using a psychological writing task to improve your diabetes self-management

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| | | <input type="checkbox"/> Protocol |
| Registration date 05/07/2017 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 26/11/2021 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Diabetes is a condition that causes a person's blood levels to be too high. Living with diabetes is not always easy and self-managing it can be stressful. However, empowerment and optimism can go a long way towards improving clinical outcomes and buffering against diabetes-related distress. The aim of this study is to assess whether a brief, self-administered psychological task known as the 'Best Possible Self' (BPS) exercise can improve diabetes self-management and blood sugar control by boosting mood and feelings of control. By getting people to write about themselves in the future, previous research has shown that the BPS can help people set goals, manage and restructure their priorities, and express and come to terms with their emotions. This has helped people with other health complaints improve their self-management strategies. Though the BPS has never been used to help people manage their diabetes specifically, similar tasks have had some considerable success. The aim of this study is to develop a new intervention for diabetes self-management as well as providing more understanding of how emotions influence coping with diabetes.

Who can participate?

Adults aged 18 and older who have either type 1 or type 2 diabetes.

What does the study involve?

Participants are randomly allocated to one of five groups. Those in the first two groups receive the treatment, which is the Best Possible Self programme. The participants in the first group receive the programme daily and those in the second group receive it twice weekly. The next two groups receive the placebo (a dummy) programme. Participants in the third group receive it daily and those in the fourth group receive it twice weekly. The fifth group participants are placed on a waiting list. All participants complete the programmes for four weeks where they are followed up with questionnaires about their behaviour, and mental wellbeing.

What are the possible benefits and risks of participating?

The study focuses on emotions and diabetes self-management. It is possible that you may receive small boosts to your psychological well-being during the course of the study. Your

participation will inform future research that could lead to the development of a rigorous, evidence-based diabetes intervention for improving diabetes self-management. However, if you are not comfortable with anything discussed, please do remember that you are able to withdraw without giving a reason. There are no other significant risks involved, though it is important to keep in mind that the BPS intervention is NOT a substitute for actual treatment and that regardless of the group you are assigned to, you should continue taking your medication and completing your self-management routine as normal. If you have any concerns about your health at all during the study period, you should contact your GP or healthcare professional immediately.

Where is the study run from?

Liverpool John Moores University (UK)

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

December 2016 to December 2018

Who is funding the study?

Liverpool John Moores University (UK)

Who is the main contact?

1. Mr. Benjamin Gibson

B.Gibson@2016.ljmu.ac.uk

2. Dr Kanayo Umeh

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Study website

https://ljmupsych.qualtrics.com/jfe/form/SV_cAaPkJYy41hAUwB

Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

17/NSP/026

Study information**Scientific Title**

Adopting the 'Best Possible Self' task to improve diabetes self-management: A randomised controlled trial

Study objectives

The 'Best Possible Self' task will bring about positive psychological changes, improved diabetes self-management behaviours, and blood sugar levels.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Liverpool John Moore's Research Ethics Committee, 12/12/2016, ref: 17/NSP/026

Study design

Double-blinded 3x2 randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

Participant information sheet

https://ljmupsych.qualtrics.com/jfe/form/SV_cAaPkJYy41hAUwB

Health condition(s) or problem(s) studied

Type 1 and Type 2 Diabetes

Interventions

Participants are randomly allocated to one of five groups based on intervention type and dosage level.

Those in the first two groups receive the 'treatment' condition: a tailored-for-diabetes version of the 'Best Possible Self' informed by feedback from diabetes patients as part of a previous study. These individuals are split based on whether they are in a 'daily' group or a 'twice weekly' group which indicates how frequently they have to do the task. This involves completing a series of questionnaires online that measures aspects of your self-management care and general well-being.

The next two groups receive the 'placebo' condition: a standard version of the 'Best Possible Self' task. They too are split into separate 'daily' or 'twice weekly' groups.

The fifth, and final, group are put on a waiting list; they act as the 'control' condition. All participants (with the exception of the placebo group) complete the task as frequently as they have been told to do for a period of four weeks. All participants (including the placebo group) are followed up at the end of this four week period.

Participants report recent blood sugar results as well as some basic personal information such as age, gender, ethnicity, and BMI.

Randomisation is handled by the Qualtrics software that hosts the trial. The software evenly presents information so that each group should have the same number of participants. Using the software to randomise group allocation allows the study to be double-blinded.

Intervention Type

Behavioural

Primary outcome measure

1. Positive psychological changes are measured using the PANAS questionnaire at baseline, immediately after allocation to assess exposure effects, and trial end (end of week 4)
2. Depression and anxiety levels are measured using the HADS questionnaire at baseline and trial end (end of week 4)
3. Self-Management behaviours are measured using the DSMQ questionnaire at baseline and trial end (end of week 4)

Secondary outcome measures

1. Blood sugar control is measured using changes in daily self-reported blood sugar results and changes in HbA1c results (if available) across the duration of the trial. Participants provide their last fasting and pre-prandial blood sugar results at baseline and then self-report subsequent results once a week in response to a reminder email. They provide their previous HbA1c at baseline and report any changes (if there were any during the trial period) at trial end (end of week 4).

Overall study start date

02/12/2016

Completion date

11/03/2019

Eligibility

Key inclusion criteria

1. Mentally healthy adults over the age of 18 with a formal diagnosis of type 1 or type 2 diabetes
2. Participants must already be daily self-monitoring their blood sugar levels
3. They must also regularly receive HbA1c levels from their health care professional (e.g. GP or nurse)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Minimum of 76 for a medium effect size

Key exclusion criteria

1. Under the age of 18
2. Have a form of diabetes not listed in the inclusion criteria such as gestational diabetes. This is simply because they are less common, preventing an easy split of the data.
3. Anyone with an affective disorder (e.g. anxiety, depression, eating disorders; all of which are common co-morbidities of diabetes) will also be excluded because of the nature of the study (i.e. a trial with a focus on emotions and emotion induction) as they might be at too much undue risk

Date of first enrolment

03/07/2017

Date of final enrolment

02/10/2017

Locations

Countries of recruitment

Australia

Canada

England

France

Germany

Italy

Netherlands

New Zealand

Spain

United Kingdom

United States of America

Study participating centre

Liverpool John Moores University

School of Natural Sciences & Psychology

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Sponsor information

Organisation

Liverpool John Moores University

Sponsor details

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L3 5UA

Sponsor type

University/education

ROR

<https://ror.org/04zfm737>

Funder(s)

Funder type

University/education

Funder Name

Liverpool John Moores University

Alternative Name(s)

LJMU

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal by the end of 2018/beginning of 2019.

Intention to publish date

31/01/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the primary researcher, Mr Ben Gibson at B.Gibson@2016.ljmu.ac.uk or alternatively call: +44 7968874746

IPD sharing plan summary

Available on request