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Web-based interventions helping people with type 2 diabetes become regularly active: importance of online peer-support versus personalized delivery of content.

Submission date
25/03/2015

Recruitment status
No longer recruiting

Registration date
16/04/2015

Overall study status
Completed

Last Edited
15/02/2016

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
Diabetes is a condition that causes a person's blood sugar level to become too high. Insulin is the hormone made by beta-cells in the pancreas and controls the amount of glucose in the blood. In type 2 diabetes, the body does not produce enough insulin for it to work properly or the body cells do not react properly to insulin (insulin resistance). A person is more likely to develop diabetes if they are overweight, do not do a lot of exercise, eat an unhealthy diet or are an older person. Type 2 diabetes is a major challenge for Canadian public health authorities and regular physical activity is very important in the management of this disease. Given that less than half of people with type 2 diabetes in Canada are sufficiently active to meet the recommendations, programs that help them to become active on a regular basis are in demand. Many researchers have argued that web-based interventions (programs) can help people to practice more physical activities and they are a promising avenue in the public health domain. However, it remains unclear if this type of intervention works for people with type 2 diabetes. This study will test two internet-based interventions designed to help people with type 2 diabetes to do regular physical activities. One of these two interventions will provide personalized content related to physical activity for its users. On the other hand, the second intervention will provide non-personalized content related to physical activity to its users, but will be combined with a Facebook group moderated by a clinical nurse who will help users with their journey toward being more regularly active. In summary, the study aims to measure how well both of these interventions work and thus compare them to identify which one works best.

Who can participate?
French speaking Canadian men and women with type 2 diabetes.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 are given access to a fully-automated, computer-tailored, web-based program for eight weeks. Those in group 2 are given access to a Facebook-assisted web-based program for eight weeks. Those in group 3

are in the control group and are not given access to any intervention. All three groups are given questionnaires at the start of the study, 3 months after the study begins and then 9 months later. Once the last follow-up has been completed, those participants in the control group are given access to the intervention has been proven to work best by the study.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Diabetes Québec (Diabète Québec) (Canada)

When is the study starting and how long is it expected to run for?
September 2013 to June 2015

Who is funding the study?
1. Fonds de Recherche en Santé du Québec (FRQS) (Canada)
2. Diabetes Québec (Diabète Québec) (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
FRQS-22855 (Fonds de Recherche en Santé du Québec)

Study information

Scientific Title

Effectiveness of a fully-automated, computer-tailored, web-based intervention and a Facebook-assisted, generic, web-based intervention promoting regular physical activity among insufficiently active adults with type 2 diabetes

Acronym
DEF (Diabète en Forme)

Study objectives
1. Our first hypothesis is that the fully-automated, computer-tailored, Web-based intervention and the Facebook-assisted, generic, Web-based intervention will be more effective at increasing aerobic PA compared to a control group receiving no intervention.
2. Our second hypothesis is that the fully-automated, computer-tailored intervention will result in greater aerobic PA increase compared to the Facebook-assisted, generic intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Research with Humans (CEREH) from the Université du Québec à Trois-Rivières, 30/06/2011, ref: CER-11-169-06.08
2. Ethics Committee of Research with Humans (CEREH) from the Université du Québec à Trois-Rivières, 20/09/2013, ref: CER-13-194-08.03.04

Primary study design
Interventional

Study design
Double-blinded three-arm parallel and non-inferiority randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Intervention 1: Fully-automated, computer-tailored, web-based intervention
Intervention 2: Facebook-assisted, generic, web-based intervention
Control group: Participants do not participate in any intervention, not even a more general one, for the duration of the study
The duration of the interventions is 8 weeks. All three study groups are invited to complete baseline, 3-month and 9-month follow-up questionnaires during the same time period. Following the last follow-up questionnaire, participants from the control group will be offered the intervention that had the best effectiveness of the two interventions evaluated in this study.

Intervention Type
Behavioural

Primary outcome(s)

Physical activity levels will be evaluated from an adapted version of the Godin Leisure Time Exercise Questionnaire (GLTEQ). To explain, the measures will be self-reported via the intervention websites, where participants will indicate:
1. The frequency with which they practiced intensity-specific PA activities (i.e. low, moderate, vigorous) for a typical 7-day week (closed question)
2. The average duration, in minutes, of these activities for each intensity category.
3. Final PA levels will be obtained by calculating the converted total minutes per week of moderate intensity PA participants are practicing during a typical week, while only considering moderate (4 METS) to vigorous (7.5 METS) types of PA, and where the total minutes of vigorous PA/week will be considered as 1.875x minutes of moderate PA/week (7.5 METS/4 METS = 1.875). Using this method, a participant will be considered "regularly active" with a PA level that is equal to or greater than 150 minutes of moderate physical activity/week. This threshold corresponds to the recommendations of the Canadian Diabetes Association for aerobic physical activity.

Key secondary outcome(s)
Items related to intention, attitude, self-efficacy, social influence and type of motivation will be assessed. Data collected from these items will again be self-reported, as participants will provide their answers during baseline, 3-month follow-up, and 9-month follow-up assessments directly on the interventions' Websites.

Regarding the items related to intention, attitude, self-efficacy and social influence, these were validated during a previous study of Boudreau and Godin. The items were submitted to a test-retest procedure over a two-week period to a subgroup of 30 individuals with type 2 diabetes. The mean age of participants was 58.9 years (SD = 9.8), 33% were male and 33% had completed postsecondary education. Test-retest intraclass correlation coefficients and Cronbach's alpha coefficients were verified and are reported elsewhere.

As for the items assessing the type of motivation of participants, a modified, validated, francophone version of the BREQ-2 [85] (Behavioral Regulation in Exercise Questionnaire, version 2) was used to measure all possible types of motivation a participant can hold, including integrated motivation, which is normally absent in the standard BREQ-2. Construct & discriminant validity was assessed with confirmatory factor analysis by the investigators who developed the questionnaire used for the present study.

Completion date
31/10/2015

Eligibility

Key inclusion criteria
1. The target population for this research project are Canadian men and women with type 2 diabetes
2. Patients not meeting the Canadian Diabetes Association guidelines related to aerobic PA
3. Being able to understand French
4. Being able to navigate on the Internet
5. Being between 18 and 65 years of age
6. Not having medical indications limiting the practice of PA

Investigators will be able to judge if inclusion criteria are satisfied with a self-reported questionnaire administered to potential participants via the interventions' websites, during the study registration process.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Not being a member of the Diabète Québec newsletter.
2. Not being between 18 and 65 years of age.

Date of first enrolment
15/09/2014

Date of final enrolment
28/09/2014

Locations

Countries of recruitment
Canada

Study participating centre
Diabetes Québec (Diabète Québec)
8550 boul Pie-IX bureau 300
Montréal
Canada
H1Z4G2

Sponsor information

Organisation

Fonds de Recherche en Santé du Québec (FRQS)

Organisation
Université du Québec à Trois-Rivières

Organisation
Fonds de Recherche du Québec - Santé

ROR
https://ror.org/02eqrsj93

Funder(s)

Funder type
Government

Funder Name
Fonds de Recherche en Santé du Québec (FRQS)

Alternative Name(s)
Fonds de Recherche du Québec - Sante, Fonds de la recherche en sante du Quebec, Fonds de Recherche du Québec - Santé, Fonds de Recherche du Québec - Santé (FRQS), SciChefQC, FRQS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Funder Name
Diabetes Québec (Diabète Québec)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/02/2016		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes