ISRCTN17923814 https://doi.org/10.1186/ISRCTN17923814

The effect of health promotion through text messages on the physical activity of diabetic patients in Jordan

Submission date
18/02/2021

Recruitment status
No longer recruiting

Registration date
19/02/2021

Overall study status
Completed

Last Edited
08/03/2021

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high. It can cause symptoms like excessive thirst, needing to pee a lot and tiredness. It can also increase your risk of getting serious problems with your eyes, heart and nerves. Diabetes' treatment is more focused on managing blood sugar (medication, diet, and exercise) and methods to avoid chronic complications by educating diabetic patients on a self-care strategy that can help them to achieve cost-effectiveness treatment and improve their outcomes.
This study aims to assess the impact of distant education delivered through SMS and based on Health Promotion Model (HPM) on improving the health status of diabetic patients.

Who can participate?
Adults over 18 years, with type 2 diabetes, who own a mobile phone and are able to walk for 30 minutes.

What does the study involve?
There will be two groups in this study; the SMS group who will receive the intervention (SMS), and a control group. The patients in the SMS group will receive educational messages for two weeks (two or three messages daily) in the field of physical activity based on HPM's constructs. Data from both groups will be collected at three stages: at the beginning of the study "baseline data", four weeks after the first visit, and two months later.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Jordan University of Science and Technology

When is the study starting and how long is it expected to run for?
January 2019 to March 2021

Who is funding the study?
Jordan University of Science and Technology

Who is the main contact?
Dr Nihaya Al-sheyab, nasheyab@just.edu.jo

Contact information

Type(s)
Scientific

Contact name
Dr Nihaya Al-sheyab

ORCID ID
http://orcid.org/0000-0002-6106-1099

Contact details
PO Box 3030
Irbid
Jordan
22110
+962 790463136
nasheyab@just.edu.jo

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of health promotion through short message service on the physical activity of type 2 diabetic patients in Jordan

Study objectives
Distant SMS-based educational intervention can affect the physical activity of type 2 diabetes patients on the basis of the Health Promotion Model

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 08/03/2020, Institutional review board, Jordan University of Science and Technology (Irbid PO Box 3030, 22110, Jordan; +962 7200610; irb@kauh.jo), ref: none provided

Study design
Quasi experimental interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
See additional files (in Arabic) ISRCTN17923814_PIS_14June2020 (added 01/03/2021)

Health condition(s) or problem(s) studied
Diabetes mellitus type 2

Interventions
Participants who are voluntarily willing and able to participate will be asked to sign a written consent form followed by the baseline questionnaire. The baseline-data questionnaire will comprise a demographic section, the HPM constructs and a 7-day physical activity recall questionnaire. The questionnaire will be filled by the researcher using a face-to-face interview with the presence of healthcare professionals in the clinic.

Interventional Group: The participants in the SMS group (intervention group) will receive educational messages based on the HPM constructs. We will send two or three messages per day for two weeks from Saturday to Thursday (12 days in total). These messages will include:
• Tips about the appropriate amount of physical activity required to control blood sugar
• Physical and mental benefits of physical activity for patients with diabetes
• Sports rules and some tips about hiking to change the physical activity step by step and to gradually increase this activity over the study period
• Specific rules before doing the physical activity
• Appropriate physical activity based on blood sugar, symptoms of low blood sugar and taking the appropriate measures to eliminate it

Control group participants will receive treatment as usual.

Data collection and follow-up: After two weeks of daily educational messages, the participants in the SMS group will receive two messages weekly on Monday and Wednesday morning (repeating the initial messages based on the HPM constructs). When the message is read by the individual in the SMS group, a confirmation message will be sent to the researcher from the

participant.
The data collection will be done in two stages: in the first stage, after four weeks of baseline data completion, the participants in both groups will complete the questionnaire based on the HPM constructs. In addition, after data collection in the second stage (at the end of the study), both groups will complete a questionnaire related to these constructs and a 7-day physical activity recall questionnaire.

Follow-up: The first follow up will be after four weeks of the baseline data completion. To collect the follow-up data, we will use face to face and telephone interviews to fill out the required questionnaire, while the second follow-up will be after two months (at the end of the study). Also, a confirmation message will be sent to the researcher from the participant when the message is read by the individual in the SMS group.

Intervention Type
Behavioural

Primary outcome measure
A questionnaire will be used at baseline, 4 weeks, 2 months:
1. Participant characteristics: age, gender, education, household income, body mass index (BMI), type of medication, prior related behaviors and experiences
2. Perceived health status will be determined by a 12-item short form health survey examining physical and mental health
3. Perceived benefits of the intervention: agreement or disagreement with the benefits of physical activity will examine by 28 questions, using a 4-point Likert scale
4. Perceived barriers to physical activity: a 4-point Likert scale will use to assess participants' perceptions of barriers to physical activity
5. Perceived social support: the participants' perceptions of support from family and friends in the field of physical activity will be measured by 15 and 5 questions, respectively (a total of 20 questions), with a 5-point Likert scale
6. Self-efficacy: we will adopt the questionnaire developed by Noroozi et al. to examine the confidence of the participants in undertaking regular physical activity under different conditions, this questionnaire has 18 questions, which are scored on a percentage scale (0 to 100%).
7. Physical activity based on a 7-day physical activity recall. The questionnaire will be completed using a face-to-face interview. The patients will be asked to determine the duration (in minutes), intensity (based on changes in heart rate as compared with walking and running), and type of each activity (daily activities or leisure activities), this questionnaire is a useful tool to assess the amount of physical activity

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
02/01/2019

Completion date
01/03/2021

Eligibility

Key inclusion criteria

1. Ability to write and read
2. Having a mobile phone
3. The ability to walk or to do exercise for 30 min
4. Willingness to participate in the study for two months
5. Having diabetes for one or more years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
98

Key exclusion criteria
1. Other comorbidities
2. Diabetic foot ulcer
3. Walk with a cane
4. Cardiovascular disease

Date of first enrolment
14/08/2020

Date of final enrolment
16/09/2020

Locations

Countries of recruitment
Jordan

Study participating centre
Jordan University of Science and Technology
PO Box 3030
Irbid
Jordan
22110

Sponsor information

Organisation
Jordan University of Science and Technology

Sponsor details
Deanship of research
PO Box 3030
Irbid
Jordan
22110
+962 7201000
info@just.edu.jo

Sponsor type
University/education

Website
https://www.just.edu.jo

ROR
https://ror.org/03y8mtb59

Funder(s)

Funder type
University/education

Funder Name
deanship of research, Jordan University of Science and Technology

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Jordan

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/04/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from (Dr. Nihaya A Al-sheyab; email: nasheyab@just.edu.jo. The type of data will be de-coded data on SPSS software, version 22. The data will become available on request for five years from now (until January 2026). Any researcher or healthcare professional would like to use the dataset AND agree to keep the participants' information private and confidential can have access to dataset. Consent form from participants will be obtained in regards to potential secondary analysis of the dataset.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		14/06/2020	01/03/2021	No	Yes