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Behavioral changes in people living with diabetes using a mHealth application

Submission date
19/11/2018

Recruitment status
No longer recruiting

Registration date
30/11/2018

Overall study status
Completed

Last Edited
28/10/2022

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
Diabetes is becoming prevalent in the Middle Eastern region, specifically in Qatar. It is also estimated that there will be a 35% increase in diabetes rates in Qatar by 2040. So, the study aims to explore how a Mobile Health (mHealth) solution can support patients with diabetes type 2 to acquired a healthier lifestyle and manage their diabetes. In particular, we will explore how to create more convincing motivational messages for the diabetes mobile application by incorporating cultural aspects on the design of those messages. Incorporating social elements on the design of mobile applications for health is very important as many lifestyle aspects such as eating and exercising vary across cultures. In this project, participants are individuals who regularly visit Al-Alhi Hospital to see their doctor who manages their condition as they are living with diabetes type 2. Participants will be divided into two groups and two different versions of the messages will be given to them. One group will get weekly feedback messages without the cultural aspect being incorporated, while the other group will receive the feedback messages that have the cultural aspects incorporated. In terms of risks, they are very low as hospital data and regular meeting with the doctor at the hospital will never be impacted by the intervention. There are three organizations taking part in this trial. The lead institute that is running and funding this study is Hamad Bin Khalifa University in Qatar, in partnership with Droobi Company that developed the mobile application and Al-Ahli Hospital in Qatar.

Who can participate?
Adult patients with diabetes type II who attend the Al-Ahli Hospital in Doha Qatar.

What does the study involve?
Participants will be informed about the study and after checking eligibility criteria and signing informed consent they will be able to participate. They will receive a mobile application to access health education and behavioral change support, including access to diabetes educators. This mobile application will complement their regular care at the hospital that will not be affected. Some participants will be invited to fill some questionnaires for research proposes and invited to interviews to know more about the experience of using a mobile application for helping managing their diabetes.

What are the possible benefits and risks of participating?
The main benefit is that participants will have access to an English/Arabic mobile diabetes support program. As the mobile application does focus on lifestyle and it is fully integrated with the care team no health risks are foreseen. To avoid the risk of misusing the mobile application for emergencies, the participants will be instructed that access to an educator in a mobile application is not a substitute of the standard care, especially during emergencies.

Where is the study run from?
Al-Ahli Hospital in Doha Qatar is the clinical partner. The lead institute which is running and funding this study is Hamad Bin Khalifa University in Qatar, in partnership with Droobi Health.

When is the study starting and how long is it expected to run for?
The study will start 29th of November and recruited participants will be followed up for a period of 16-24 weeks.

Who is funding the study?
Hamad Bin Khalifa University - Qatar Foundation

Who is the main contact?
Dr Dena Al-Thani
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

QBRI-2018-021

Study information

Scientific Title
Testing tailored weekly feedback messages for behavioral changes in people living with diabetes using a mHealth application

Study objectives
The purpose of the study is to measure the impact of different types of the weekly feedback behavioral intervention messages designed for changing the behavior of people living with diabetes type II

Ethics approval required
Old ethics approval format

Ethics approval(s)
QBRI Institutional Review Board (IRB) in Qatar on the 26/07/2018. The protocol number is (2018-021).

Study design
Interventional randomised parallel controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
All participants participants will have access to a mobile application (Droobi Health) which includes a complete diabetes self-management and an educational programme designed to last for 16 weeks. The mobile application includes behavioral change elements (e.g. goal setting and tracking, health dashboards, educational materials, such as quizzes) and chat with health educators.
Participants will be randomised to two different versions of the app using a technique called A/B Testing, which is a real-time randomization mechanism that happens blindly to the user.

Participants will be randomly divided into two groups, a control group that receives weekly feedback behavioral intervention messages as is, while the experimental group receives the weekly feedback messages that have been re-formulated according to Cialdini's principles of persuasion.
The experiment is then evaluated based on the collected user metrics as well as statistical analysis collected data from the mobile application and available clinical data (e.g. data from the Electronic Health Records).
Follow-up will occur at 6 months.

Intervention Type
Behavioural

Primary outcome measure
1. Impact of the behavioural intervention messages:
1.1. Engagement at an aggregated level will be measured continuously from recruitment until drop-out of the end of the trial. Engagement will be assessed using the following data obtained from Google Analytics analysis of the Droobi database:
1.1.1. User level data (actions done by each user)
1.1.2. Session level data (frequency of individual visits to the application)
1.1.3. Page-view level data (frequency of each individual tab visited in the application)
1.1.4. Event level data (button clicks, message views)
1.1.5. User behaviour data, including how long the user stayed in the application, what is their first and last visited tab in the application and the most common "pathway" which the user goes through in the application
1.2. Engagement on an individual level will be assessed after 16 weeks follow-up using a thematic analysis approach to identify themes and patterns from the recorded interviews. This will be used to device coding themes in order identify issues across participants regarding their readiness for behavioral change.
2. The following clinical variables will be measured as an indicator of the effectiveness of the application:
2.1. HbA1c will be measured as part of routine care using clinical lab results
2.2. Weight gain will be measured as part of routine care by nurses.
2.3. Blood pressure will be measured as part of routine care by nurses.
2.4. Cholesterol will be measured as part of routine care using clinical lab results
2.5. Blood glucose levels will be measured as part of routine care using patient reported outcomes.

Secondary outcome measures
1. Effectiveness of weekly individual messages, assessed through an individual interview with participants at the end of the study (after 16 weeks)
2. Individual perceptions of the quality of the messages, assessed through an individual interview with participants at the end of the study (after 16 weeks)
3. Familiarity and attitude towards messages received, assessed using an interview at the baseline and at the end of the study (after 16 weeks), based on themes in the Theory of Planned Behavior questionnaire

Overall study start date
18/11/2018

Completion date
01/06/2020

Eligibility

Key inclusion criteria
The inclusion criteria for the study are individuals living with Diabetes type II, recruited from Al-Ahli Hospital in Qatar for the period of three months. The participants are at least 24 years old, are willing to start changing their lifestyle and adapting new habits and behavior, own a smartphone and know how to use it and have installed Droobi App recommended by the doctor from Google Play or the App Store.

1. Aged 24 years or older
2. Type 2 diabetes
3. Attending Al-Ahli Hospital in Qatar
4. Willing to change their lifestyle and adapt new habits and behaviour
5. Own and are able to use a smartphone
6. Installed the Droobi application, recommended by the doctor, from the Google Play or App Store

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
N/A

Date of first enrolment
27/11/2018

Date of final enrolment
30/03/2019

Locations

Countries of recruitment
Qatar

Study participating centre
Al-Ahli Hospital
Ahmed Bin Ali St.

Doha
Qatar
QA-00

Sponsor information

Organisation
Hamad Bin Khalifa University

Sponsor details
LAS Building
Education City
P.O. Box: 34110
Doha - Qatar
Doha
Qatar
DOHA

Sponsor type
University/education

Website
https://hbku.edu.qa/en

ROR
https://ror.org/03eyq4y97

Funder(s)

Funder type
University/education

Funder Name
Hamad Bin Khalifa University

Results and Publications

Publication and dissemination plan
We will disseminate our research through conventional academic outlets such as ACM, and IEEE sponsored conferences and health informatics journals. There is no intention to publish the work in any other venues.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. Data with be de-identified prior to the data analysis. After data analysis is completed the data will be fully and irreversible anonymised. In the case of the audio interviews, the content will be transcribed and any personal information such as names will be removed. Then audios will be permanently deleted. Anonymised data that can be shared according to legal and ethical guidelines (e.g. consent form) will be published as a data-appendix in an open access publication journal.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		05/11/2020	28/10/2022	No	No