POWER2DM

"Predictive model-based decision support for diabetes patient empowerment"

Research and Innovation Project
PHC 28 – 2015: Self-management of health and disease and decision support systems based on predictive computer modelling used by the patient him or herself

Deliverable 5.4

D 5.4- Feasibility Studies Outcomes

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EXECUTIVE SUMMARY

The purpose of this deliverable is to summarize the procedures performed in the Feasibility Studies (FS) of both clinical centres and the main impressions of the patients regarding this step of the project. This deliverable is structured as follows:

1. Definition of the different models of FS used
2. Result of the Joint Demo Session
3. Results of the FS in Spain
4. Results of the FS in Netherlands
5. Main results and discussion
6. Implications for the Evaluation Campaign (EC)

POWER2DM Consortium Partners

Abbv	Participant Organization Name	Country
TNO	Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek	Netherlands
IDK	Institute of Diabetes “Gerhardt Katsch” Karlsburg	Germany
SRDC	SRDC Yazilim Arastirma ve Gelistirme ve Danismanlik Ticaret Limited Sirketi	Turkey
LUMC	Leiden University Medical Center	Netherlands
SAS	SAS Servicio Andaluz de Salud	Spain
SRFG	Salzburg Research Forschungs Gesellschaft	Austria
PD	PrimeData	Netherlands
iHealth	iHealthLabs Europe	France

Abbreviations and Acronyms

Table 1 List of Abbreviations and Acronyms

Abbreviation/ Acronym	DEFINITION
FS	Feasibility Study
EC	Evaluation Campaign
SDMA	Shared Decission Making Application
SMSS	Self Management Support System
HP	Healthcare provider
P1	Prototype 1 of P2DM System

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1 Definition of the different models of Feasibility studies used

Prototype 1 (P1) was not completely available at the time that FS was predicted (the different parts of the system had not been totally integrated yet). In order to get the greater opinion possible of patients about the current prototype, a two-model FS was performed in the 2 clinical centres:

1) A Joint Demo session organized by TNO and LUMC was celebrated, inviting the Dutch Patient Organization, to critically check the current state of the P1 at that moment.
2) A standard FS, in the two clinical centres (Spain and Netherlands), to check the usability of the P1, acceptance and issues reported both by patients and health care users.

2 Results of the Joint Demo Session:

A Joint Demos Session was performed at TNO Leiden. First the POWER2DM system was introduced to the audience in a presentation, in which the goal and the structure of the system was explained. Then there was a session showing a demo of a shared decision-making consultation making use of the SDMA. Afterward the patients were able to test the SDMA themselves in group using mock-up data.

The third session was about the Self-Management Support system (both the web application and the mobile application), where again there was a demo plus testing the applications by the participants. Feeback was given by the participants on a feedback form and also oral feedback was noted.

Patients were emphasized to report the improvement areas in the P1. This was the feedback received from the patients:

General

Fear that the system is only useful to patients who already understand their disease quite well. Advice to think of ways to make it more accessible for everyone.

Data should be as much open source as possible to link as much devices and other platforms as possible

Some people wanted a competition with follow users. This need to be optional also because of privacy reasons.

People would really like if the system at some point would notify when things were not going well in the self-management phase and an appointment with a health care provider might be needed. In that case, the health care provider gets a notification and can make an appointment or the patient gets the advice to make an appointment.

People really liked the KADIS simulation model. Wanted to have it in the self-management support system as well (so not only when looking at the SDMA with the health care professional). The P2DM team explained the (liability) problems with that.

Being able to export the data for their own calculations would be nice.

Being able to have a platform for users to share excel calculation file would be nice.

Would be nice if preparation question will be sent via the SMSS before every visit with the health care provider. Both the patient and the health care provider (which can see the answers on those questions beforehand) will be better prepared then.

Shared Decision Making Dashboard

Hard to oversee all the data during the 10-30 minutes with the health care provider. Might be an idea to have been shown a (light) version of the dashboard beforehand (with or without data).

Risk scores are useless when the outcome has already happened. There should be an option to blur that particular risk score out in that case.

The grey compasses are hard to see

The severity of the barrier should also determine the colour of that compass and/or influence the number.

Fear that clinicians are making even less eye contact with the patient

Print out of the different simulations/compasses for afterwards

SMSS web application

Would like to see more (raw) data here. So data from the diary, from the iHealth, from the FSL and from the fitbit, shown in graphs. It would be preferred that all the data would be presented in one graph. The time frame of this graph needs to be very flexible. So see data of one day up unto 3 months. Select for instance only the Sunday and Thursday etc.

It would be nice if the data can be shown aggerated (as mean per day for 1 month) or individually as days after each other or under each other. We should look how other system present this (like Medtronic in Carelink)

The device column was not understood.

Height was not registered when filled in.

Why no BMI or waist circumference

Difference which goals are set by the doctor and which by the patient is not clear.

SMSS mobile application

Colours are hard to see for the colour blind

Units of insulin should be filled in with number instead of needing to press up 50 times

People would like to discriminate blood and interstitial glucose when filling in glucose

People would also like to see graphs of at least the glucose here, preferable of all the data

Too long medication list, not in alphabetical order, some things are missing. Please make this list patient specific.

3 Results of the FS in Spain

A Standard Operative procedure for the FS was created by LUMC and SAS (Annex 1).
Five patients underwent the FS in Spain, ten in Netherlands. FS started on Sept-6th , 2018, and lasted until 14 days. During those days, Shared Decision Making Application (SDMA), Self Management Support System (SMSS) and mobile App were used by patients, as it were the different wearable devices.
At the end of the FS, both questionnaires for patients and healthcare providers were filled out. The questionnaire is attached as Annex 2 at the end of this document.

3.1 Outcomes from the patients:
A total of 5 patients used the system and filled the Questionnaire at the end of the FS. Here we report the main responses to the questions provided by patients:

A) Mobile App:
   a. 2/5 patients were not able to program/see their tasks in the mobile App.
   b. Push Notifications were not received by any patient.
   c. The medication was correctly included in the list of medications that the App had.
   d. 4/5 patients found convenient the utility by which when a medication is selected for the first time in the App, it moves to the upper part of the list, making easier to find it for next record.
   e. All measurements made by means of the App were properly stored.
   f. The record process was easy. One patient reported that only one time he was not able to save measurements easy. The rest of the times he did, as all the times of the rest of patients.
   g. The patients found easy and convenient the tracking of the progress in the main screen of the App.
   h. The graphics showing the glucose monitoring were understandable and nice to see. One patient asked for adjusting timeframe for future versions.

i. The patients found suitable the graphics in the glucose chart, and did not find any potential way of improvement for that.
j. The patients found easy and fast the process of input of measurements in the App
k. Main free field requests of patients deal with potential improvements for future versions of P2DM. All patients filled in the free field question, what speaks about the high acceptance of the mobile App.

b) iHealth glucometer (BG5):

a. One patient experienced problem pairing the glucometer to the mobile phone on a Samsung Galaxy S6. The rest of patients did not report problems to pair the glucometer to the mobile phone.
b. Patients experienced difficulties for the glucometer to send the results to the App. Most of the times they finally resolved this.
c. About the future improvements, patients remarked the difficulty to pair the app to the glucometer.

c) SMSS:

a. Patients found easy to add their own goals to the SMSS, as they found to add personal tasks in the calendar
b. Patients chose the graphs of glucose and weight as those with higher use, acceptance of SMSS
c. Patients ranked as easily understandable the graphics of the SMSS. They found interesting that the graphics in the SMSS are automatically available if they fill in the data in the mobile app.
d. The patients did not find any counselling to do regarding improvements in SMSS graphic performance
e. SMSS was punctuated as 7/10 on the user-friendly scale.
f. In the free field, patients asked for future higher synchronization between mobile app and SMSS, and being able to use SMSS-only features through the app.

d) Instructing:

a. The patients found correct the instructions given by the healthcare staff to control the P2DM system. However, one patient felt that he would have needed a little more of info regarding the emotional tools and the value compass in SMSS.

e) General Use:

a. Patients reported that they needed an average of 20 mins a day to fully test the P2DM system. The found it an acceptable time to spend.
b. One patient reported that mobility should be increased in the System. He suggested to increase the mobile App features to partially substitute SMSS.

3.2 Outcomes from the Healthcare providers:

a) Patient Informing and recruitment:

The Healthcare Providers (HP) found easy/medium to explain the nature of the project, the different devices and software and the expected activities to be done by patients during the FS. 2/3 HP reported differences in the level of difficulty for these tasks when working with T2DM vs T1DM. They reported less technology knowledge by T2DM to explain these differences.

b) Installing devices and software:
HP found easy to install/activate the wearables/devices. HP found medium/hard the ability to install software by part of the patients. They reported that they felt that the cause for that was the mobile phones of the patients were outdated.

c) Consult:
HP found that the patients adhered to the FS, and that they were positive/motivated when coming to consult

d) Devices returning:
All patients returned the devices in good conditions.

4 Results of FS in Netherlands

The same Standard Operative procedure for the FS was used for the LUMC as was used by SAS(Annex 1).
Ten patients participated in Netherlands. It started on Sept-6th , 2018, and lasted 14 days. During those days, Shared Decision Making Application (SDMA), Self Management Support System (SMSS) and mobile App were used by patients, as were the different wearable devices.

At the end of the FS, a questionnaire was filled out by the patients in order to get structured feedback. The questionnaire is attached as Annex 2 at the end of this document.

3.1 Outcomes from the patients:
A total of 5 patients used the system and filled the Questionnaire at the end of the FS. Here we report the main responses to the questions provided by patients:

a) Mobile application:

   a. If would be nice to also be able to delete data in the diary instead of only being able to edit it.
   b. Insulins seemed to be missing on the enter medication list
   c. There were no Push notification received by all ten participants on their mobile phones.
   d. Synchronisation between the mobile application and the web application takes (too) long
   e. Sometimes one of parameters entered in the diary was not registered while the other parameters entered simultaneously were saved.

f. 1/10 found that using the app needed to many steps and was in a sense counterintuitive.
g. The save button was hard to find when filling in the diary (via the plus sign). Better to have a separate button.
h. Glucose graph continued out of the screen.
i. The clock when changing the time of the diary log is not very practical (Android only)
j. It would be convenient if more than one medication could be logged simultaneously
k. When looking on the overview of the logs of the diary, only the blood sugar could be seen. It would be handy if also the other parameters were shown here.
l. Some patients would prefer to be able to fill in the exact amount of carbohydrates for their meal instead of the categories now used.
m. It would be nice if tasks on the task list would change colour when that task is done.
n. The fixed distance between every time point on the glucose graph was no found to be convenient by a participant
o. People thought in general that registering data in the diary went pretty quickly
p. The app was given a 5.8/10 for user friendliness

b) iHealth glucometer (BG5):

a. One participant noted that using the Bluetooth device with all its steps was more laborious than manually filling in the blood glucose from the own glucose meter
b. People had difficulty using the device. This could be resolved by proper instruction in most cases.
c. The device was given a 7.6/10 for user friendliness

c) Self-management support system (web application):
a. For registering activities, two option were ‘walking’ and ‘walking in nature’. Somebody noted this distinction made little sense
b. For registering activities, vacuuming and ironing could be registered. Why not the general term ‘doing the household’.
c. Taken medication can nowhere be found in the SMSS
d. People would have liked if the functions of the SMSS were also available on the mobile application (like setting goals and tasks)
e. People like the graphs in the SMSS
f. The SMSS was given a 6.3/10 for user friendliness
d) Instruction
a. People found in general that the instruction was sufficient. One person noted that it would have been nice to have some information at home beforehand te come better prepared
e) General use

a. People reported at average 23 minutes of using the system per day. And all found this acceptable and worth it. One participant noted that she could only do it maximally for a few weeks at a time, not continuously.

5 Main results and discussion

The outcomes from Feasibility Studies show a good performance of the system, and a good acceptability by both patients and HP. The main objective of this phase was the evaluation of potential critical limitations in the System that were not found. Patient recruitment was easy, and all patients who entered the FS ended successfully, with no drop-out.

Regarding usability, patients ranked high the System, highlighting the easiness of use. The main problem found was the inability to receive push notifications. They found easy and nice the measurement process, the recording of data and the tracking of progress. Patients liked the graphics, especially in the SMSS. Regarding Glucometer, the patients found some difficulties when pairing the app/mobile phone with the glucometer. Other than that, the experience was positive. SMSS had a high acceptance by users. They liked the easiness of inserting goals, the graphics and they found it very intuitive. When asked about instructions given, time spent by HP was adequate, and they felt them supportive. Average of use of P2DM (20 mins) was perceived as adequate by patients.

When asking HP about the experience, they had a good overall result of the implementation of the System. They experienced some difficulties when installing the software of some patients, especially due to low functionality/capacity of patients' mobile phones, being this more marked in T2DM.

6 Implications for the Evaluation Campaign

We have evaluated the outcomes of FS and we did not find any potential issues that may impede the implementation of P2DM. The useful information obtained in this step will for sure help us to improve the settings for the EC. Reviewing the push notifications system allowed us to find a problem and solve it before the initiation of EC.

7 Annex 1

SOP Feasibility

Preparation:

- Anonymizing of Data in Fitbit: Create 10 email addresses of the institution with passwords and print the combinations
- Create 10 FitBit accounts, using the e-mail adresses and passwords
- Activate these accounts by clicking on the activation links in the mailbox.
- Make sure all the devices (FitBit, iHealth glucometer, FSL's) are ready and charged, so they are ready to use.
- Prepare all the forms.
  - Travel expenses
  - Account + password
  - Loan agreement
  - Mail with all links to Power2dm system
  - Forms for feedback
  - Envelopes to send back FSL pro

Typical Agenda of the Feasibility:

09.00-09.15 Welcome with coffee/tea
09.15-09.30 Introduction POWER2DM system
09.30-10.30 Coupling of devices and data collection
10.30-12.00 Setting goals, making tasks and tracking of the tasks with the POWER2DM system
12.00-13.00 lunch
13.00-13.45 Extra time (for testing)
13.45-14.00 Closing after which the participants can keep on testing one week at home

General

In Holland, 10 participants and 5 instructors. We divide the group in 5 (2 participants and 1 instructor per group) to walk through the instructions and testing.
In Spain, 5 participants and 3 instructors dividing the patients in 2 (2 and 3 participants each one and 1 and 2 instructors per group respectively).

Development of the session

- **Introduction**
  - Goal of POWER2DM system
  - Different parts of the POWER2DM system
  - Goals of today
  - Agenda

Coupling of devices and gathering of data

- Create 10 POWER2DM accounts for the participants (using the created email addresses).
- Add all the care managers to the list of care managers in the system, so everyone is able to work with this patient in the SDMA
- Activation and coupling of Fitbit
    - Install the Fitbit app on the mobile phone of the patient and activate device by using the previous created credentials
    - Go to account manager: https://api.test.power2dm.eu/onauth/onauth-manager/user-invitation
    - Log in as patient
    - 'Couple' the Fitbit to the patient
    - Log out of the accountmanager
    - Login in patientcoach, select patient, go to accounts settings and fill in the Fitbit credentials at 3rd party app email and 3rd party app password, press “klik hier om uw Fitbit account te activeren”
- KADIS collection
    - Open SDMA: https://sdma.test.power2dm.eu/
    - Log in with care provider credentials
    - Select the patient in SDMA
    - Order KADIS fingerprint, set the right date to start collection (not during the first week, preferably at the beginning of the second week)
    - Go to medication tab in the KADIS fingerprint screen and add all the relevant medication to the SDMA in order to get the medication list synchronized in the POWER2DM mobile app
    - Log out of the SDMA

- Log in credentials
    - Provide login credentials (in duplicate to be sure) of the patient, together with the study number.

- Mobile application
    - Download the mobile application on https://ihealthnext.eu/power2dm/
    - Give application permission to use the microphone and things like that (in Android the phone asks this permission right after installation, in IOS you manually have to give the app permission)
    - Open the mobile app
    - Log in with POWER2DM patient credentials
    - Set glucose measurements to right units (NL: mmol/L, SP: mg/dl)
    - Explain to the patient how to use the application and how to save the entered data
- Filling out questionnaires in SMSS
    - Open SMSS: https://smss.test.power2dm.eu/
    - Log in with patient credentials (P2DM credentials as created in account manager)
    - Set glucose measurements to right units (NL: mmol/L, SP: mg/dl)
    - Open the different questionnaires and fill them out
    - Save and log out

- FSL pro's
  - Place one of the FSL pro's on the arm of the control patient
  - Explain how the FSL pro works and that regular blood measurements should be continued during this period (water resistant, send sensor back after 2 weeks)
- iHealth glucometer BG5
  - Provide patient with iHealth glucometer BG5 and 1 flacon of strips
  - Explain how online and offline measurements are made
  - Question: Ask whether the patient knows how to work with the mobile application (logging and editing), iHealth glucometer BG5(online and offline measurements), FitBit (and FSL . Also explain the KADIS fingerprint and the frequent measurements during the three days of collection for this system.
- Let participants practice with filling in the diary

- Filling out questionnaires in Patient Coach
  - Select 1 or 2 participants to test filling out the questionnaire in patient coach
  - Select the patient in Patient Coach and add the patient to the Kiosk (click on the K+ sign)
  - Go to the tab Kiosk, select a tablet (black or white in case of the NL)
  - Select the right questionnaire package and click 'coupling'
  - Open the Patient Coach application on the tablet. You should be directed to the questionnaires for this patient. Ask the patient to fill out the questionnaires and save the answers.

- SDMA
  - Open the Shared Decision-Making Dashboard and log in with your practitioner's credentials
  - Select the correct patient
  - Go with the patient through the system. Explain what is seen and what can be seen during next visits. Example of an order might be:
  - Blood glucose management page
  - Self management
  - Risk scores
  - Barriers (inquire if the patient recognizes one of the barriers, if so add barrier)
  - Goals
  - Discuss with the patient what the treatment goal(s) will be for the next period
  - Fill in the treatment goal(s) in the SDMA

- Explain SMSS web application
  - Treatment goals
  - Adopt Self-management goals
  - Calendar
  - Charts
  - Data-entry (also possible in the web page)
  - Weekly review

        - Optional (when indicated or interested): energy battery, value compass and relaxation tips
        - Let participants practice with setting goals
        - Further explain the SMSS mobile application
        - Glucose graph
        - Tasks
        - Push notifications (may not be ready yet)
        - Let participants practice with tracking goals, asking question

- Closing
    - Questions
    - Instructions 1 week testing at home (is not needed to fill in real data)
    - When patients are going to participate in the EC: instruction to stop using the system after 1 week (for validity of the upcoming study)
    - Instruct how feedback can be reported
    - Instruct patients to bring the devices back at first visit of the EC
    - Instructions how to send FSL pro sensor
    - Thank to the participants

8 Annex 2

Patients Feedback POWER2DM

Mobile app

Did you see the scheduled tasks in the app's task list?
Did you receive push notifications? If so, were they related to the three days of collecting data or achieving your goal?
Was your medication on the list? If not, which one was not?
Was the medication you use on the top of the medication list?
Were all measurements properly stored?
Was the progress of achieving your goal well tracked on the first page of the app? (Did the 0% change in 10%, for example, if the glucose was measured?)
Have you used the graph with blood glucose measurements in the app? If so, was this graph understandable and clearly visible?
Do you have any points for improvement regarding the visibility and comprehensibility of the glucose chart in the app?
How much time did it cost on average to fill in a measurement?
Are there points for improvement regarding the filling in of data?
How user-friendly was the mobile app? (Scale from 0-10, 0 = totally not user-friendly, 10 = perfect in terms of user-friendliness)
Other problems / points for improvement / suggestions regarding the mobile app?

iHealth glucose meter

Was it possible to measure the glucose with the iHealth glucose meter? If not, what went wrong?
Did the meter ever give an error? If so, which one (called ErA, ErB, ErC etc.)?
Were you always able to connect the meter to the mobile application?
How user-friendly was the glucose meter? (Scale from 0-10, 0 = totally not user-friendly, 10 = perfect in terms of user-friendliness)
Other problems / points for improvement / suggestion regarding the iHealth glucose meter?

Web application (Self-management support system)

Did you manage to add your own goals in the SMSS?
Did you manage to plan tasks in the calendar?
Could you find data from the Fitbit (the number of steps) somewhere in the web application?
Have you looked at the different graphs in the SMSS (blood glucose, movement, etc.)?
If so, were these graphs filled and understandable?
Do you have any points for improvement regarding the comprehensibility and visibility of the graphs in the SMSS?
How user-friendly was the web application?(Scale from 0-10, 0 = totally not user-friendly, 10 = perfect in terms of user-friendliness)

Problems / points for improvement / suggestion regarding the web application?

Instruction

Was the instruction beforehand sufficient to be able to use the system? If not, what should be explained better?

Other / general

How much time did the use of the POWER2DM system cost on average per day?
Did you find this time investment acceptable?
Are there any other comments and / or points for improvement about the POWER2DM system and the test session?