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 5.5

D5.4.1 Completion of Quantification Campaign

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Task:	T 5.4
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PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

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V1.0	March 24th, 2017	First version	SAS	LUMC
V1.1	March 29th, 2017	LUMC data	SAS	LUMC
V1.2	March 31st,2017	Final review and IDK data	SAS	TNO

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EXECUTIVE SUMMARY

This deliverable describes the completion of the Quantification campaign in the three clinical settings:

- Cordoba Center (partner SAS, Spain)

- Leiden University Medical Center (partner LUMC, The Netherlands)

- Institut für Diabetes Karlsburgen the north and Diabetes-Klinik Bad Mergentheim, DKBM, in the south (partner IDK,Germany)

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

OPEN ISSUES

No:	Date	Issue	Resolved

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1 INTRODUCTION

1.1 Purpose and Scope

First partial result of Task 5.4: Completion of the Quantification campaign used to define the standard operation procedure (SOP) for the POWER2DM field trials. By 31th of March, the Quantification Campaign has been performed in the three clinical settings. This documents shows some demonstrators of this fact.

1.2 References to POWER2DM Documents

- POWER2DM Description of Work (Proposal)

1.3 Definitions, Abbreviations and Acronyms

Table 1 List of Abbreviations and Acronyms

Abbreviation/ Acronym	DEFINITION
SAS	Servicio Andaluz de Salud or Andalusian Health Service
IDK	Institute of Diabetes "Gerhardt Katsch" at Karlsburg
LUMC	Leiden University Medical Center
App	Mobile application
FSL	FreeStyle Libre

2 CHAPTER 2 QUANTIFICATION CAMPAIGN IN THE THREE CLINICAL SETTINGS

2.1 Cordoba Center (partner SAS, Spain)

Patient signing of the Informed Consent at the initial visit was done between January 12th and Feb 14th, 2017. Doctors attending these patients were Juan Francisco Alcalá Díaz, Francisco Fuentes-Jimenez, Antonio García-Ríos, Javier Delgado-Lista and Ana I Perez-Caballero. An image of the schedule chart is provided in figure 1. Names of patients have been blinded for confidential purposes.

POWER2DM

FECHA: MARTES 17 DE 01 DEL 2017(LISTAS PARA EL DOCTOR JAVIER DELGADO-LISTA)

HORA	NOMBRES Y APELLIDOS	CODE	NHC	OBSERVACIÓN
10:00 h	[redacted]	1009	437627	
10:00 h		1010	115126	
11:00 h		1011	IMIBIC04	
16:00 h		1012	IMIBIC05	
17:00 h		1013	179039	
17:00 h		1014	511886	
17:00 h		1015	198290	

Figure 1: The schedule chart in Cordoba Center, Spain

Patients were then seen by a project member, to help them with the installation of different electronic devices (see figure 2,3,4 and 5). This helped to obtain information for the development of the mobile application.

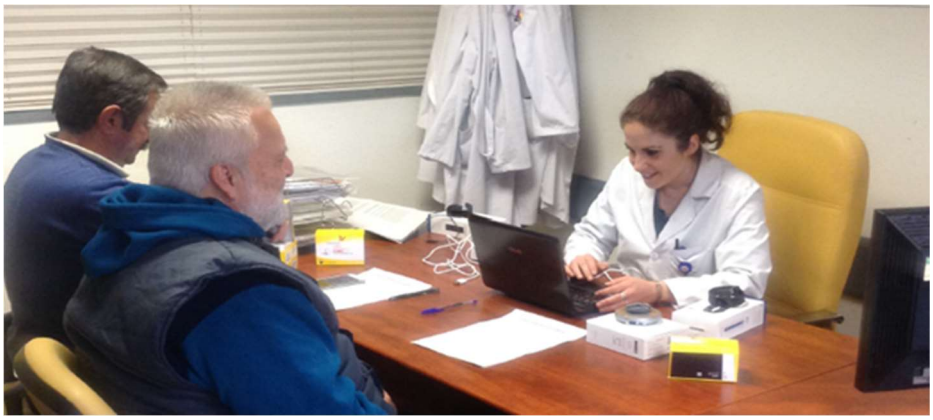


Figure 2: All patients gave written consent for their image to be recorded.

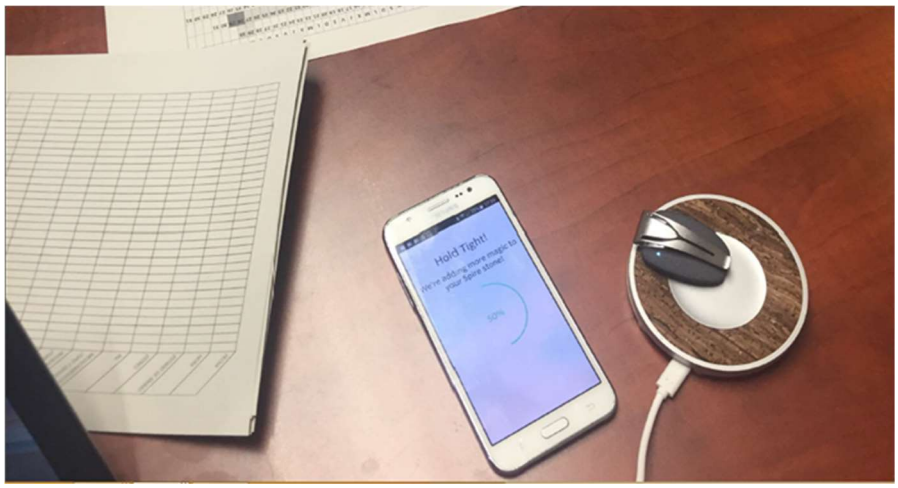


Figure 3: Fitbit

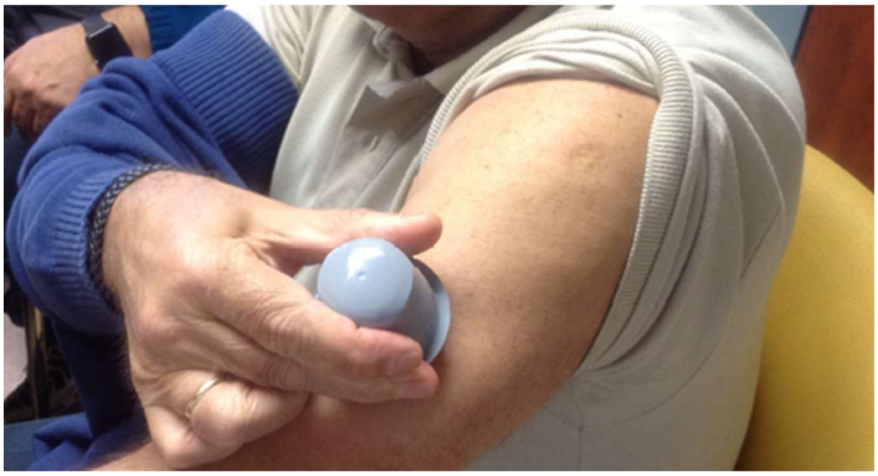


Figure 4: FreeStyle Sensor Free

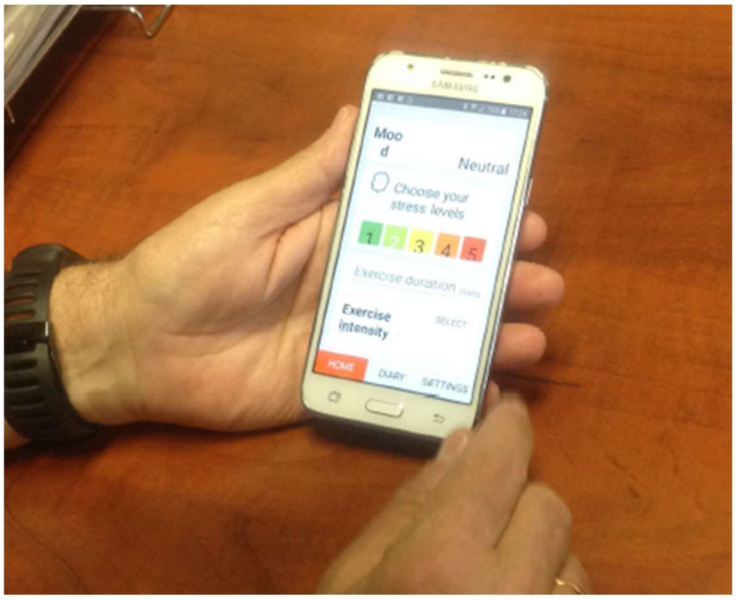


Figure 5: POWER2DM App

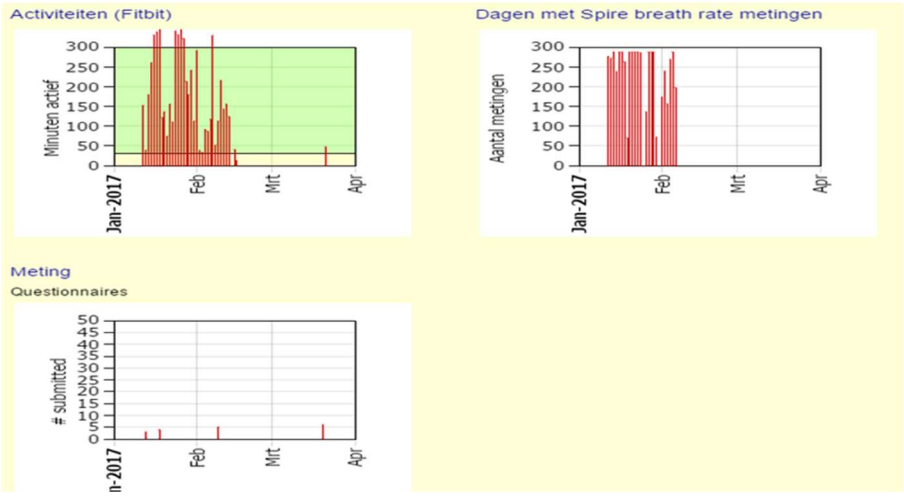
On the second day, we tested that all the electronic devices were properly installed on the patients' mobiles, the blood drawn was performed, and the questionnaire data collected through the Case Report Forms (CRF).

In the first three days of the study, in addition to carrying the sensor of the FreeStyle, they were tested for blood glucose by finger pricks, 8 times a day.

During the following days, patients received an e-mail survey to assess how they feel about diabetes.

Patients recorded data in the POWER2DM application (stress level, carbohydrate consumption, blood glucose level, physical activity level). Paper sheets were available and gave to patients for occasional loss of function of the App.

Figure 6: different devices



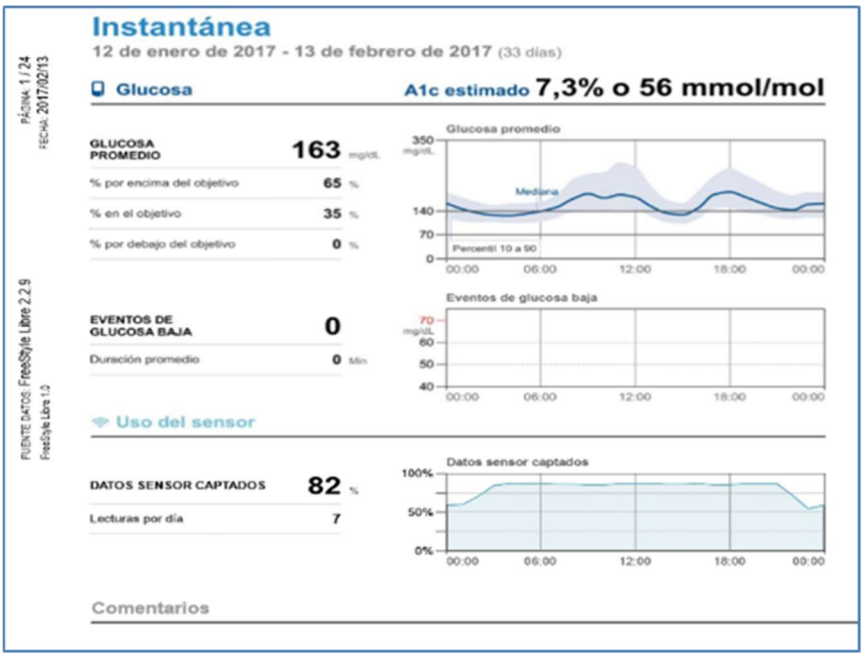


Figure 7: Patients recorded data

Once the patient data were collected, they were recorded in (HOME / PATIENTCOACH) so that we could remotely check that all records were made correctly. When any problem was detected, we contacted patients to solve it. Also, a double check was remotely performed at LUMC (Ian P. Smith), with fluid communication between centers.

The last patient to complete the first 3 days of the POWER2DM Quantification campaign was on 17 February 2017. All data was collected at the end of the QC.

During the rest of the first intensive period, and as explained in the protocol, the patients performed continuous glucose monitoring, daily tracking of diet, physical activity, diabetes medication usage, sleep, mood, and stress. Incidences on these procedures were resolved by tight contact between Spain and Holland centers. During the second period (week 11-12), as planned, the study participants performed again continuous glucose monitoring and daily tracking of diet, physical activity, diabetes medication usage, sleep, mood, and stress. Additionally, and as expected, psychosocial questionnaires were filled up in a webpage. When any participant had a problem to access this, they reported so and the could alternatively use paper forms which were after uploaded into the system.

2.2 Leiden University Medical Center (partner LUMC, The Netherlands)

Patients were identified from the Diabetes Out-Patient clinic at the Leiden University Medical Center (LUMC) by their treating internists. These patients were contacted regarding interest in participating in the quantification study by telephone and sent information letters describing what would be required of them. Within one week of sending the information letters the patients were contacted and asked if they would like to come to the LUMC to receive more information on the study. Patients who opted to come for more information had the study procedures further explained to them and, if they chose to

participate, signed an informed consent letter and the started the quantification campaign immediately thereafter. All patients at the LUMC stared the quantification campaign by signing an informed consent letter between January 18th 2017 and March 27th 2017.

The start of the quantification campaign involved a multi-hour appointment. During this appointment., a research team consisting of Dr. Bas Uitbeijerse (BU), research nurse Wilma Heemstra (WH), and researcher Ian Smith (IS) completed a medical anamnesis and physical examination of the patient, took blood and urine samples, and set- up and trained the patient on the procedures and usage of the Fitbit Charge, Spire, FSL and POWER2DM app designed by iHealth for the quantification campaign. All patients completed a baseline questionnaire packet while the devices and apps were set-up and connected.

The initial information briefing, signing of informed consent letters, medical anamnesis and physical examination were conducted in all cases by BU. Physical samples were collected by BU and WH. IS was responsible for set up of all devices except for the initial application and explanation of the FreeStyle Libre (FSL) which was done by BU or WH.

After completing the baseline appointment, patients started the monitoring phase of the quantification campaign. The monitoring phase consisted of the patient wearing the Fitbit Charge continuously except when under water (e.g. when bathing/showering or swimming), wearing the Spire when awake, scanning the FSL once every 8 hours (or more frequently as desired by the patient), and tracking their medication/insulin usage, carbohydrate intake, times of physical exertion, stress, and mood. Additionally, patients created an 8 point blood glucose curve during the first three days of the quantification campaign. Patient compliance with study requirements was monitored by IS using the PatientCoach platform built by Jaap Sont in the LUMC.

Patients were contacted weekly by WH, IS, or BU to inquire as to issues that the patients were having. After two weeks the patients were required to apply a new sensor. At the end of four weeks, a link to a follow-up questionnaire was sent to the patients automatically through the PatientCoach system and patients were contacted to inquire to their experience up to this point.

Ten weeks after the initial appointment, patients were or will be contacted by IS, WH, or BU to see whether the patient was or is prepared to participate in the final two week phase of the study. If the patient was or is prepared to do this, a final FSL sensor (with blood glucose strips where necessary) was or will be sent to the patients along with a new copy of the paper diary. Upon completion of the final two week phase, patients will return to the LUMC to return the Fitbit Charge and Spire devices, complete a debriefing, and give final hair and blood samples. All patients will have achieved the minimum required data for the quantification campaign as of March 30th 2017 with the final patients expected to complete the full quantification campaign on June 19th 2017.

The most frequent issue reported was with the POWER2DM app designed for the quantification campaign. Connectivity issues, log-in problems, and difficulties completing the logging process were frequently cited as aggravating factors for patients. To ensure optimal data collection, all patients were provided with paper data collection sheets while these technical issues were resolved. Additionally, connectivity issues with the Spire device were frequently identified amongst the patient population, two patients lost their Spire device (replacements provided as quickly as possible), and three patients had the FSL sensor lose its seating (one due to bleeding under the sensor) and required replacements, and two patient were unsuccessful in applying a new sensor and required assistance from others to accomplish the placing of a new sensor. No other complications resulting from participation in the study

have been reported by patients (including no issues related to skin irritations in connection with the devices or other adverse events).

Data gathered by the Fitbit and Spire were aggregated through the PatientCoach platform. Questionnaires and FSL data files were completed and submitted through SurveyGizmo. Any paper based data submitted by patients has been or will be input by IS and a student assistant. Data set compiling and cleaning is currently being conducted in the LUMC by IS and Jaap Sont for submission to other project partners for use.

In addition to LUMC specific tasks, IS assisted the other clinical centers in setting up and troubleshooting technical issues related to the devices and apps, assisted in monitoring the progress of patients and completion status of tasks, and reported to the clinical team as to the progress of the patients in the study through written reports and telephone conversations.

2.3 Institut für Diabetes Karlsburgen the north and Diabetes-Klinik Bad Mergentheim, DKBM, in the south (partner IDK,Germany)

Patients for IDK were identified through two diabetes clinics in Germany (Institut für Diabetes Karlsburg in the north and Diabetes-Klinik Bad Mergentheim, DKBM, in the south) as well as through personal networks. Patients were provided with information on the study and if they agreed to participate, signed and informed consent letter, had the study procedures explained to them, and were given the devices required for data collection. Patients completed the baseline questionnaire either online or on paper which was then uploaded by a researcher. Researchers at each institute (Eveline Ahrendt, Kordula Rudolph, and Anselm Puchert at IDK and Melanie Schipfer at DKBM) completed the baseline CRFs by extracting information from the patients' medical dossiers or by contacting the treating physicians. Lab values for baseline assessment were extracted from the most recent regular clinical assessment done as a part of the patients' diabetes care.

In total, 18 patients started the quantification campaign between the 28th of February and the 1stof March. Patients were contacted regularly throughout the month to ensure that the patients were collecting data according to the protocol and to help resolve any issues that the patients may have encountered. Issues surrounding initial set-up of devices and connecting to central data aggregators were a common problem but were quickly resolved through close collaboration with partners. Further, defective devices were an issue in three cases but were quickly resolved with new devices in two cases (the third occurred to close to the end of Phase I for a replacement to be delivered, but this will be in place prior to the start of Phase II). All patients have completed Phase I of the study by the 31st of March and are all scheduled to complete Phase II of the study by the 27th of May.