PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

EMPOWER - Support of Patient Empowerment by an intelligent self-management pathway for patients

Trial Acronym

EMPOWER

URL of the trial

http://www.empower-fp7.eu/

Brief Summary in Lay Language

Patient Empowerment involves patients to a greater extent in their own healthcare process and disease management becomes an integrated part of their daily life. The capability of self-management opens the possibility for patients not only to contribute to their own healthcare but also to be more in control of their disease. EMPOWER develops an patient-centered application which facilitates the self-management of diabetes patients based on personal health records and on context-aware, personalised services. EMPOWER focuses the research and development efforts on a patient-centric perspective that also involves healthcare professionals. EMPOWER provides knowledge-based Self-Management Pathways for diabetes patients and this includes services for the specification and execution of actions to change behaviour according to diabetes-specific health care needs and services for monitoring of vital, physical, mental parameters as well as physical and lifestyle activities based on health standards.

EMPOWER addresses long-term goals and short-term activities in order to facilitate the self-management of patients with diabetes and thus the treatment of chronic diseases. The pilot applications in Germany and Turkey demonstrate that the holistic and patient-centric approach of EMPOWER can improve disease management by personalised self-management services helping diabetes patients to cope better with their condition.

Brief Summary in Scientific Language

Patient Empowerment involves patients to a greater extent in their own healthcare process and disease management becomes an integrated part of their daily life. The capability of self-management opens the possibility for patients not only to contribute to their own healthcare but also to be more in control of their disease. EMPOWER develops a modular and standard-based Patient Empowerment Framework which facilitates the self-management of diabetes patients based on PHRs and on context-aware, personalised services. EMPOWER focuses the research and development efforts on a patient-centric perspective that also involves healthcare professionals. EMPOWER provides knowledge-based Self-Management Pathways for diabetes patients and this includes services for the

specification and execution of actions to change behaviour according to diabetes-specific health care needs and services for monitoring of vital, physical, mental parameters as well as physical and lifestyle activities based on health standards.

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Organizational Data

- DRKS-ID: **DRKS00007699**
- Date of Registration in DRKS: **2015/01/30**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **No approval required according to EC**
- (leading) Ethics Committee Nr.: **LDA.3-1085G44/13 , Bayerisches Landesamt für Datenschutzaufsicht**

Secondary IDs

Health condition or Problem studied

- ICD10: **E10 - Insulin-dependent diabetes mellitus**
- ICD10: **E11 - Non-insulin-dependent diabetes mellitus**

Interventions/Observational Groups

- Arm 1: **In the test-phase of EMPOWER, patients will be assigned to an intervention group and a control group. In accordance with the treating physician the intervention group will use the online EMPOWER platform on a regular basis over the time of three months.**

  The EMPOWER application encompasses four main objectives. The first one is to foster self-management with adaptive and secure patient pathways. The pathways are iterative and adaptable to the patients' skills (access, competence and motivation), requirements and needs, which will be assessed by the system according to different maturity levels. Maturity levels – novice, advanced, and expert – refer here to the stage reached by the patient in learning to self-manage his/her diabetes management tasks.
  A second objective is to support behavioral changes by integrating actions in patient's daily life through personalized action plans. These actions plans will

be based on recommendations from the treating physicians, personalized long-term goals, diabetes-relevant information material, and patients' preferences. In addition, actions can be related to reminders in order to bring them timely into the patient's mind. The third objective is to facilitate self-control by collecting patterns of daily living. Therefore, services for observations of daily living (ODLs) that allow patients to upload vital, physical (e.g. blood glucose levels) and mental parameters and physical and lifestyle activities are included in the system. The last objective is to include an open-source PHR system, which can be integrated into existing PHR or EHR systems.
During a routine consultation at the beginning of the intervention phase the collaborating physicians will specify treatment goals and recommendations regarding self-management goals together with the patient. This goal setting serves as the basis for the use of the EMPOWER system. Based on the patient`s consent the treating physician will be able to access the patient`s EMPOWER records and follow the patient´s self-management activities. Consequently, physicians will be able to detect possible causes for changes in the patient's condition, such as fluctuating blood glucose levels. In addition, the physician will be able to discuss the patient's goal pursuit process and to give advice on diabetes self-management.
The EMPOWER system is divided into two main blocks. The first block targeting the treating physician is called recommender engine. The second block is the self-management portal, dedicated to the patients. The physician can monitor the patient's health status through the recommender engine, which receives input from the patient's Observations of Daily Living (ODLs). As a result, the physician can give the patient recommendations. A patient can check his/her physician`s recommendations, set his/her personal goals and plan his/her weekly activities in the self-management portal.
The patient can create journal entries during the week in order to get an overview of his/her progress, and use the review at the end of the week to evaluate the journal entries and to plan the activities of the forthcoming week. The patient decides on his/her own whether or not to grant access to his/her data to the physician by using the consent editor.
As a constant support, the patient can also access a section called patient information material, which offers disease related information and can be of help in planning goals and activities.

The study is planned as a pre-post-design by administering questionnaires before and after the intervention. Participants will be randomly assigned to either the intervention or control group.
After being recruited participants will be asked to give their informed consent. They will then be administered an online questionnaire containing various measures on self-management and socio-demographics to assess their baseline values before using the EMPOWER system. In order to create familiarity with the tool all participants will take part in an introductory training. There, patients will be taught how to download, use, and integrate the application into their daily life.
Participants are supposed to use the system regularly for a period of three months. They will be contacted via telephone on a weekly basis to gather feedback on usability, discuss potential problems concerning the tool and reduce the loss to follow-up. After the three months patients are again asked to fill in an online questionnaire containing the same measures as the pre-questionnaire plus questions on usability and usefulness of the tool.
There won`t be any extraordinary consultations, besides those already planned, with the treating physician.

In addition, qualitative interviews will be conducted to collect extra

information on usability and usefulness.
Outcome measures include amongst others the Problem Areas in Diabetes questionnaire (PAID), the Summary of Diabetes Self-Care Activities and scales evaluating doctor-patient interaction. Physiological parameters, such as physical activity or blood glucose levels will be collected via the platform. Further, log files and number of logins will serve as independent variables.

- Arm 2: **The control groups will not be exposed to intervention and will only fill out the pre- and post-test.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **No treatment**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The pre-questionnaire will only contain questions on self-management related constructs and socio-demographics, the post-questionnaire will also measure the perceived usability and usefulness of the application. Both questionnaires will be administered online and take about 20 to 30 minutes. Pre-post-comparisons will be facilitated by the random and thus anonymous assignment of a unique code for each participant that has to be entered when starting the survey.

Patient Information
Basic recordings about the patients comprise information such as socio-demographic descriptions, number of physician consultations during the intervention phase, or his/her experience with using similar technologies. Besides, the usage of EMPOWER will be recorded for each participant, including a patient's number of logins to the system, the duration of use per visit, or the number of goals entered into the system. The records will show how often and intense the system was actually used by participants, and allow conclusions about the most useful features of the tool. Subjectively reported information from the patients will then be compared to objectively collected data.

Usability
Usability will be measured using the System Usability Scale. The scale was developed to assess the usability of interactive systems and is commonly used for this purpose. It consists of ten items that ask for a subjective assessment of the system, e.g. how easy it was to use it or how well integrated the various features of the system are. Both, reliability and validity of the scale have been proven. Questions to assess the perceived usefulness of the EMPOWER system are based on the Technology Acceptance Model. The model considers why technological

**systems are accepted or rejected by its users and how certain characteristics of the system determine this process. To measure the perceived usefulness of the EMPOWER system ten items from Davis' short screening scale on technology acceptance are used and were slightly adapted to the purposes of EMPOWER.
To assess whether the participating physicians perceive the EMPOWER system as useful in fostering patients' self-management semi-structured interviews will be conducted. This will be done during the intervention phase via short telephone interviews to gather current feedback on the tool and more detailed through face-to-face interviews after the intervention.**

Secondary Outcome

Empowerment
Patients' empowerment will be measured using Spreitzer's Empowerment Scale (1995) and The Problem Areas in Diabetes (PAID) Welche et al., 1997). Spreitzer's Empowerment Scale consists of twelve statements related to the patient's perceived importance, control, management, and autonomy concerning his/her diabetes. The PAID asks the patient whether he/she perceives twenty aspects, such as being limited concerning nutrition or not having treatment goals, as current problems.

Self-Management Activities
**The impact of patient empowerment on self-management activities through the use of the EMPOWER system will be assessed by measuring the patients' pre- and post-intervention health status, diabetes self-care, health literacy, doctor-patient communication, and empowerment. To assess an overall effect of the application on the health status as perceived by the patient, a self-reported, one item measure will be used. Patients will be asked to rate their health independently from their diabetes to avoid negatively biased answers due to the chronic condition. Diabetes self-care will also be measured subjectively, using the SDSCA (Summary of Diabetes Self-Care
Activities Measure). The scale focuses on the patients' self-care across various dimensions such as diet, exercise, blood sugar testing, foot care, and smoking. The questions refer to the last seven days of a participant's routine diabetes self-care and therefore represent a comprehensive insight into the patient's self-management that will be completed by the objective data stemming from the user tracking.**

Health Literacy
As an adequate level of heath literacy is paramount for being an effective self-manager possible changes in health literacy due to the use of the EMPOWER system are assessed. Therefore, the Newest Vital Sign (NVS), an objective test of functional health literacy in form of a nutrition label will be employed. Further, a subjective measure consisting of three items related to the perceived ability to understand written medical information, namely the Chew Items, will be used. In order to gain insight in the patients' knowledge specifically about diabetes a range of knowledge items will be asked. Doctor-patient communication will be measured with scales from Kaplan and Heisler. While the first one assesses a physician's decision making style concerning the patient's involvement in treatment decisions, the latter one focuses on the provider communication. It thus considers the patient's satisfaction with his/her doctor's communication concerning disease and treatment.

Countries of recruitment

- DE **Germany**
- TR **Turkey**

Locations of Recruitment

- Doctor's Practice **Ingolstadt**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/08/01**
- Target Sample Size: **140**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Eligible participants are between 18 and 65 years of age and suffer from diabetes type 1 or 2. Moreover, they need to have access to internet, own a computer or smart phone and be able to use the EMPOWER application.

Exclusion criteria

Patients who:
- do not suffer from diabetes
- are younger than 18 years
- who have no internet access.

Addresses

- **Primary Sponsor**

  Gesundheitsorganisation GOIN
  Mr. Dr Siegfried Jedamzik
  Oberer Grasweg 45
  85055 Ingolstadt
  Germany

Primary Sponsor

Gesundheitsorganisation GOIN
Mr. Dr Siegfried Jedamzik
Oberer Grasweg 45
85055 Ingolstadt
Germany

Telephone: **0049 841 956161**
Fax: **[---]***
E-mail: **siegfreid.jedamzik at go-in-ingolstadt.de**
URL: **[---]***

■ **Contact for Scientific Queries**

Institute of Communication & Health, Università della Svizzera italiana
Mr. Professor Peter Schulz
Via G. Buffi 6
6900 Lugano
Switzerland

Telephone: **0041 58 666 4724**
Fax: **0041 58 666 4647**
E-mail: **peter.schulz at usi.ch**
URL: **http://www.ich.com.usi.ch/en/index**

■ **Contact for Public Queries**

Gesundheitsorganisation GOIN
Mr. Dr Siegfried Jedamzik
Oberer Grasweg 45
85055 Ingolstadt
Germany

Telephone: **0049 841 956161**
Fax: **[---]***
E-mail: **siegfried.jedamzik at go-in-ingolstadt.de**
URL: **[---]***

Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

EU 7th Framework Programme Theme ICTEC funding: Euro 3.024.340Instrument: STREPProject Identifier: FP7-ICT-2011-288209 European Commission
Covent Garden 2 - Place Rogier 16
1210 Brussels Saint-Josse
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Covent Garden 2 - Place Rogier 16
1210 Brussels Saint-Josse
Belgium

Telephone: **+352 2929 42210**
Fax: **[---]***
E-mail: **cordis at publications.europa.eu**
URL: **http://cordis.europa.eu**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*