ICT4Depression

User-friendly ICT Tools to Enhance Self-Management and Effective Treatment of Depression in the EU

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Dissemination Level		
PU	Public	
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Executive Summary

This document constitutes the Final Evaluation Report for the technical ICT4Depression system, as developed in the ICT4Depression project. **This is a revised version that includes an analysis of the usage during the Dutch trail.** The empirical evaluation of the system from a psychological perspective is described in Deliverable 5.3.

The document starts with a recap of the context of the work to be undertaken, which was defined in four main phases. Within that context the most significant program revisions are described, in which the changes in the objectives, scope or in the activities and the reasons behind those changes are explained. Some of these changes constitute challenges that bring the project beyond the initial objectives, which are reported too. The following section is a brief description of the overall system. Most of the information summarized here was previously detailed in prior deliverables.

The assessment methodology has a clear description and justification of the evaluation methods used, while it demonstrates that evaluation and procedures for collecting data were carefully and systematically planned, also provides documentation that project staff can use to repeat procedures if they want to collect comparable data in the future. This was divided in two subchapters: a) the type of information collected, and the meaning that it has to the psychologist and the treatment itself, b) and the other focus on the tools that allows collecting and processing those data.

The next two chapters focus on the results and statistics from the system usage during the trial and the analysis and conclusions available.

Included in this document there are also some technical annexes to help to deploy and understand the installed infrastructure.

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1 Introduction

In the ICT4Depression project a system was developed aimed to improve the outcome of the treatments for depression, featuring several innovative aspects to the clinical treatment of depression.

From the clinical perspective the system build up to a stepped care framework, which makes use of ecological momentary assessment and intervention techniques (EMA and EMI) including the assessment of physiological symptoms in an integrated manner which enables timely interactive feedback and treatment adaptation, if needed for patients and professionals alike. From the software engineering perspective it maps to a service oriented architecture (SOA) constituting a federation or resources which client applications use and bind together to provide a tailored outcome.

In ICT4Depression, the SOA resources are made available by means of secure web services providing access to the underlying domain model for several psychotherapies (the interventions), generate advance feedback towards the best treatment course as well as tools for relapse prevention. The system also leverages on the popularity of the smart phones, on the advances in the fields of mobile and pervasive computing and body area networks to provide and innovative client application for the Android platform. The mobile platform not only provides access to the implemented psychotherapy interventions, but also alternative ways of assessment based on body-worn sensors.

Besides different forms of psychotherapies, use of antidepressant medicines has also been shown to be effective in the treatment of depression. The effectiveness of prescribed antidepressant medication depends upon the adherence to dosing instructions. Correct dosing, is necessary for the prescribed medication to work most effectively. The ICT4Depression system addresses support to both treatment approaches offering a unique opportunity to provide support for the self-management of both psychotherapy and pharmacotherapy.

1.1 Glossary, Acronyms and Abbreviations

AJAX	Asynchronous JavaScript and XML.
BLE	Bluetooth Low Energy.
BMQ	Beliefs about Medicines Questionnaire.
BVP	Blood Volume Pulse
CMS	Content Management System.
CSS	Cascading Style Sheets.
DAL	Data Access Layer.
DBMM	Data Base Module Maker.
EMA	Ecological Momentary Assessment.
EMI	Ecological Momentary Intervention.
GSM	Global System for Mobile Communications.
GUI	Graphic User Interface
HTML	HyperText Markup Language
HTTPS	Hypertext Transfer Protocol Secure.
IIS	Internet Information Services.
JSON	JavaScript Object Notation.
MAC (address)	Media Access Control address.
PC	Personal Computer
SOAP	Simple Object Access Protocol.
SSL	Secure Sockets Layer.
TDE	Transparent Data Encryption.
TLS	Transport Layer Security.
USB	Universal Serial Bus.
WCF	Windows Communication Foundation.
WS	Web Service(s).
WSDL	Web Service Definition Language

2 Development and Implementation

2.1 Overview

The overall work plan of the project was planned in four phases.

2.1.1 Phase 1

The first phase, which was addressed in the WP1, was defined to adapt existing treatment modules for depression, in such a way that they can be used within an automated self-management system, using mobile phone and web-based communication. The existing treatments would be made suitable for the proposed setup. In addition, a treatment would be built to prevent relapse, i.e. to keep recovered patients healthy. It was also defined to include a module to help the patient to stop with the medication after successful treatment. These treatments need to be designed in such a way that they can be applied consecutively: i.e. when the first module is not effective, the patient will receive the second module.

2.1.2 Phase 2

In the second phase, relating to WP2 and WP3, a smart monitoring and support system for the modules developed in the first phase was designed. This phase consists of three activities, of which the first two will use a mutually synchronised iterative process to facilitate progress monitoring and early integration of results.

1. The first activity consists of the development of computational modules that allow a computer to reason about the progress of a patient that follows a specific therapeutic module.
2. The development of actual measurements regarding the behaviour and physical state of the patient was the second activity in this phase. Those include a) a cell phone to measure pre-determined activities of the patients; b) an automated medicine box to register medication intake; c) miniaturized wearable sensors for the physiological measurements.
3. The third activity was the development of the computational model (*virtual patient*) to allow the computer to reason about the overall progress of the patient, based on his history, state and treatment modules followed up.

2.1.3 Phase 3

In the third phase an integrated support system was developed to use the devices developed in the previous phase. The support systems include two main components:

1. The automated feedback and reminders through the mobile phone and the website – these deliver insight in the progress of patient therapy and allows the latter to increase the effect of their therapy. The psychological content of the feedback was determined in WP1, whereas the decision on when and how to provide feedback and

reminders was provided by the reasoning modules ("Reasoning Engine") of WP3. The user interface on the mobile phone was developed in WP2 and for the web counterpart in WP4.

2. An automated feedback system to the general practitioner about the progress of their patients.

The design of the integrated architecture and the actual integration and technical implementation has taken place in the WP4.

2.1.4 Phase 4

This phase helped to iterate thought the components in evolution from WP2, WP3 and WP4. It started with a pilot study in which the focus was on the technical aspects and the tuning of the system towards human users. The design of the supportive devices was then improved and technical issues optimized. The integrated architecture was proved to work feasible, to support not only the devices, but also the therapeutic modules and the feedback system, at the time, with only the Behavioral Activation working. The rest of the therapeutic modules and their fine integration and sequencing were performed.

The study with depressed primary care patients in Sweden and in the Netherlands is been taking through, and from which we can already derive the final evaluation, in from the technical perspective.

This phase 4 also includes the economic costs from the societal perspective to give first impression of the economic benefits of the developed system and the models for further dissemination of the developed techniques in routine care, which are concerns of the WP5, and the dissemination on WP6.

The core of the treatment system spans through five therapeutic modules:

- Psycho Education and Motivation;
- Behavioral Activation;
- Problem Solving Therapy;
- Cognitive Restructuring;
- Exercise Therapy.

They constitute the base of the self-help intervention, in which the mobile phone, in the role of a personal health assistant, helps to bring even closer to patient. The information enclosed in the exercises comprised in these therapies is full available and complemented by using the web client application.

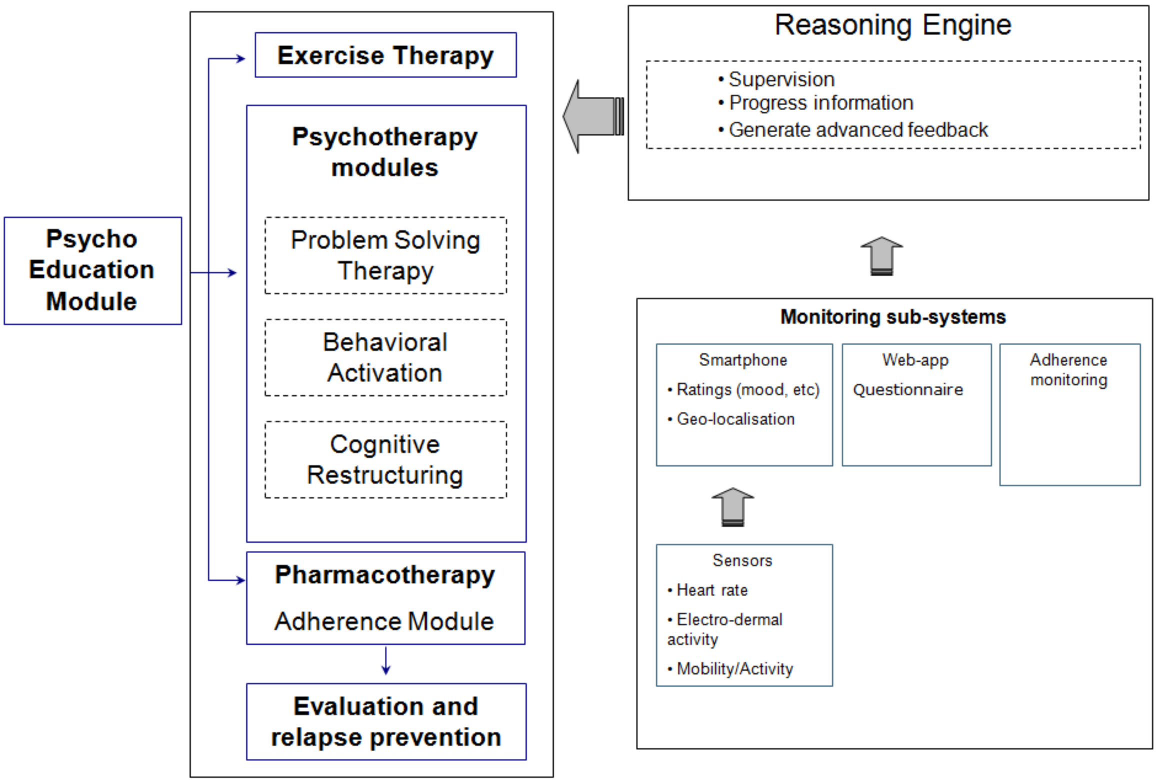


Figure 1: Overview of the ICT4Depression

Patient improvement is measured by means of web questionnaire in the end of each therapeutic module and complemented by body-worn sensor information conveyed to the system by means of the smart phone. The Exercise Therapy takes advantage of the sensor information from using mobility and activity information.

The systems use the mood ratings for daily base patient progress monitoring, when the Reasoning Engine deems appropriate. This subsystem is also in charge of providing the patient with personalized feedback to advise the best treatment course.

The necessary level of adherence for prescribed medication to work most effectively is monitoring in a dedicated subsystem to monitor adherence. This subsystem helps to:

- Monitor adherence data;
- Transfer adherence data to a dedicated server;
- Provide information on adherence to the patient and his/her healthcare provider.

In order to respond to requirements a collection of software modules and subsystems has been developed and deployed, binding together in the form of a service oriented architecture.

2.2 Significant Program Revisions

In this section will be described any changes to the program's objectives or activities that occurred prior to or during the evaluation, and provide a rationale for those changes.

2.2.1 Biomedical Sensors

Regarding the biomedical sensors, the main changes to what was envisioned on the proposal were: a) Slight revision of sensor options; and b) Part of the hardware specifications.

In terms of sensor options, the proposal initially considered the inclusion of a peripheral temperature sensor, which was later abandoned during the hardware design stage in favour of a Blood Volume Pulse (BVP) sensor. This decision was made due to the additional information that can be extracted from the BVP data; during the course of the project, the heart rate information was found in the state-of-the-art literature to be more informative than peripheral temperature. Furthermore, information related with the vasoconstriction effect can also be extracted from the BVP. Still, the hardware base for the devices is general purpose, enabling the introduction of a peripheral temperature sensor in the post-project for other applications where it might be of use.

Regarding the hardware specifications, the proposal was initially designed taking into consideration the announced and expected availability of Bluetooth Low Energy (BLE) wireless radios. During the course of the project it became clear that the access to this technology would be very limited, and a mitigation measure to adopt another radio option was thus taken, to prevent mobile phone compatibility issues, supply shortage or other problems that might compromise the success of the project. Several low-power alternatives were considered, including ZigBee/IEEE802.15.4, ANT, Nordic nRF, and other chips, however, the solution that would simultaneous provide adequate interoperability with the mobile phone and the Android operating system, and adequate power consumption requirements was found to be Bluetooth wireless, which was ultimately used for the hardware base of the devices. The consequence of this mandatory mitigation action was that the envisioned dimensions, autonomy, and protocol synchronization were compromised in relation to our expected progress beyond the state-of-the-art, which would otherwise been achieved had BLE became duly available.

2.2.2 Medicine Adherence

During the first year of this project, an important decision was taken regarding the way to transfer adherence data to the smart phone. It was decided that the MEMS monitor (pill box) would not be equipped with a Bluetooth interface for two reasons:

- Researches performed during the first year of the project have shown that the Bluetooth interface would lead to unacceptably high power consumption.

- AARDEX could also not rely on the availability of Bluetooth low energy to develop its solution.

Instead of using a Bluetooth communication between the MEMS® pill box and the smart phone, AARDEX decided to develop a base station which communicates with the back-end system through the mobile network. Adherence data would then be accessible through web services from different clients, including an Android client developed for the smart phone.

2.2.3 Mobile Application

Results from WP1 demonstrated that implementation of the various treatment modules on the mobile phone was both possible and likely beneficial to the user, Hence, the mobile application, which was originally intended to act as a sensor aggregator and present the user with questionnaires was significantly extended:

- Therapy modules were made fully accessible through the mobile phone.
- User homework exercises were made available on the mobile phone.
- A calendar was added.
- User information on progress (in terms of exercises performed for each module) was added.

The resulting application allows the user to follow their therapy almost fully through the mobile interface. A few of the exercises were deemed to be too complicated for integration in the mobile application and can only be accessed through the web interface. The extent to which the mobile application can be used as the sole interface between user and system is illustrated in section **Error! Reference source not found.**.

2.2.3.1 Mobile Sensor Aggregator

The mobile sensor aggregator has seen two major deviations:

1. The original approach for inclusion of the medication adherence system was as a sensor that communicated to the system through the sensor aggregator. During the course of the project it was decided that the medication adherence system would use cellular communications to communicate with a dedicated data store which in turn was coupled to the ICT4Depression system.
2. In the original project plan, the sensor aggregator was largely thought to be a transparent piece of functionality. During the course of the project, this perception changed for various reasons:
    - Sensors communicate with the mobile phone over a Bluetooth link and, as low power Bluetooth was not available, for energy limitations it was not possible to sustain this link for a full day whilst also allowing intensive interaction with the mobile phone.

- Users are unlikely to wear the chest strap and wrist strap for prolonged periods of time and hence it is necessary to give the user control over the sensor aggregator.

Hence the sensor aggregator became a visible part of the main application and allows the user to schedule measurement periods. The sensors are automatically turned on and off and warn the user in case no sensors are present during periods chosen by the user as sensing periods.

2.2.4 Therapeutic Modules

In phase 1 all therapeutic modules were adapted to make them suitable for use on the Internet and the mobile phone. In the proposal it was envisioned to include a module to help the patient to stop with the medication after successful treatment. In the Netherlands change of medication or stopping with medication are decisions that the patient makes in consultation with the GP. Therefore, the medication adherence module in this project only focuses on trying to keep the patient adherent to his medication. If the patient improves and wants to quit medication he does this in consultation with his GP.

2.3 Progress Beyond Initial Objectives

2.3.1 Biomedical Sensors

During the project, the electronic for both devices was greatly improved in order to increase the usability of the system and the comfort for the patient. For that, a more miniaturized biosignal acquisition unit was developed, together with a set of improved sensors, which built on the state-of-the-art technology from PLUX, and provide further advances, namely the elimination of the need of gel or conductive paste in certain data acquisition conditions. Also, initially we had only envisioned the integration of the sensors in clothing items; a concept that was further developed during the project, leading to exclusively engineering clothing-like items, specifically designed to overcome several problems found in long-term monitoring scenarios. Two garments were developed, namely a chest strap and a glove, that work as enclosures for the biosignal acquisition devices and sensors; this solution is more flexible since users can have very distinct tastes in clothing items (e.g. women and men), and work as a multipurpose solution that leaves the user free to use his regular garments, with the biomedical sensors working as a mere add-on.

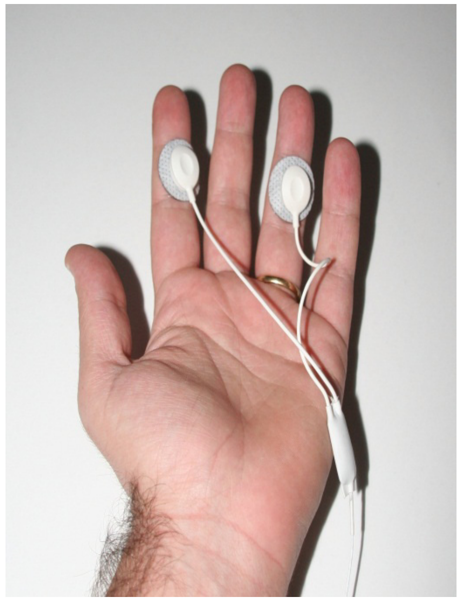


Figure 2: Normal approach to EDA

A unique chest strap was created, that is fully produced in non-allergic and machine washable materials, and that includes a shoulder loop to prevent the strap from sliding down the trunk as is frequent in the devices found in the state-of-the-art. Further details on the chest strap can be found in D4.6.

Figure 3: Normal approach to BVP

The glove is also unique, as it was designed to integrate, in a minimally-intrusive way, sensors which are normally placed at the fingers to perform their intended function. Figure 2 shows a traditional placement of Electrodermal Activity (EDA) electrodes, while Figure 3 shows the normal application of a Blood Volume Pulse (BVP) sensor on the finger; our innovative approach to the problem of sensor location, which can be seen in Figure 4, constitutes a major progress beyond the state-of-the-art.

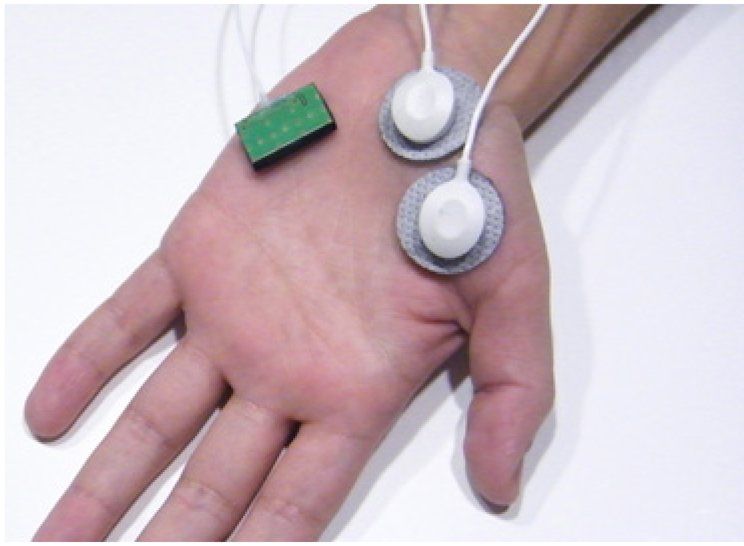


Figure 4: ICT4Depression approach to BVP (hypothenar eminence) and EDA (thenar eminence)

2.3.2 Medicine Adherence

Figure 5 shows the adherence monitoring sub-system used in this project. In addition to the MEMS® monitor that records time of openings of the container and provides direct feedback to the patient, the wireless reader allows a wireless transfer of adherence data to the back-end system. The adherence data are then available to different clients through web services.

The solution for monitoring adherence developed in this project goes beyond the state-of-the art by

- Allowing wireless transfer of adherence data without compromising battery life;
- Allowing a quick detection of adherence issues by the use of the adherence back-end;
- Providing advanced feedback at the point of need through the Smartphone;
- Focusing on the usability of the adherence system;
- Supporting the self-management of adherence to drug therapy;
- Increasing the availability and accessibility to adherence data to other actors.

From a more technical perspective, the architecture chosen and implemented here goes beyond the state-of-the art by:

- Providing not only adherence data but information on the patient's adherence;
- Allowing the integration of adherence information into external systems through a web services oriented architecture.

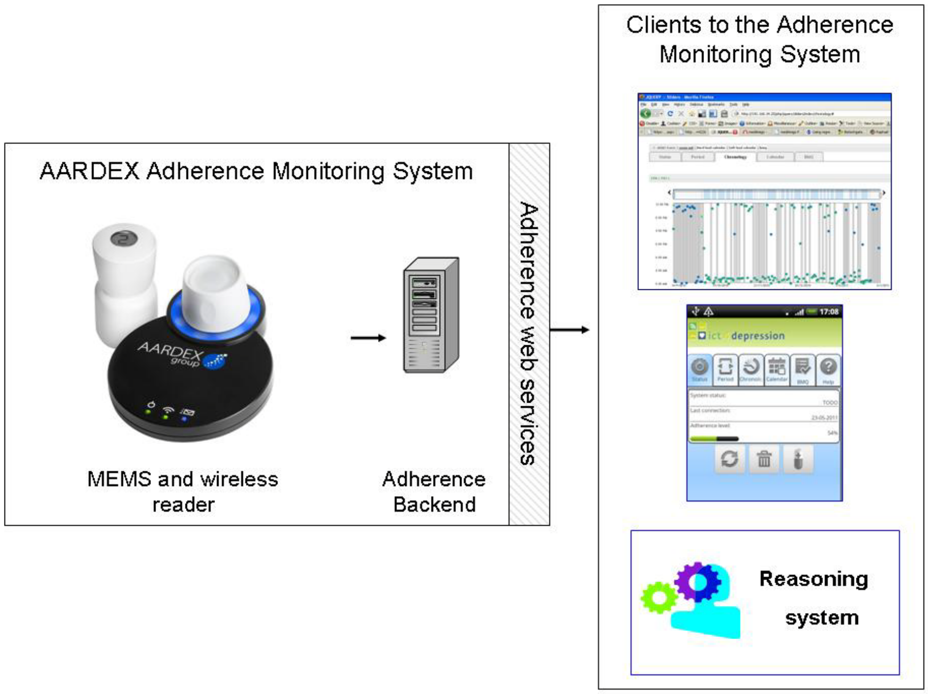


Figure 5: Adherence monitoring sub-system

2.3.3 Mobile Application

As discussed in section 2.2.3, the mobile application was significantly extended. This has resulted in a mobile app which can be used as the primary means of interaction with the system. This in turn allows the user to take part in their treatment whenever and wherever they are, which is an important factor, making treatments more effective and increasing adherence.

The mobile application uses HTML source to display content to the user and allows flexible interaction with the HTML source through a JavaScript interface. This approach allows for easy adaptation of the content such that further innovations in the presentation of therapies to the user can be easily accommodated and it is expected that the application can be leveraged in future projects.

2.3.4 Therapeutic Modules Requirements

The therapeutic modules were defined during the WP1 and their use cases detailed in the D2.1 and D4.1. However the progress done to the actual system of therapeutic modules is far complex and blended to obtain the actual system. The first major difference is that each module is not only questionnaire based form, from which the previous modules derive, but they include steps to perform, the notion of iteration that can be done, and aspects such as precedencies and pre-requisites within the same or in inter-therapeutic modules. The second major difference is that therapeutic modules were augmented so that the v*irtual patient* and new features could be developed. The presence of the Calendar and the end module questionnaires, which were thought to be external to the system and are now included, were also new requirements and challenges defined beyond the initial objectives.

These change in requirements has cause the natural augment in the complexity and size of the therapeutic modules, both for mobile and web applications, which in turn requires new functionalities, and for that new webmethods were developed, which in turn required more data record, retrieve and querying, thus forwarding down to the database model the growth in the number of tables, relations and constraints.

2.3.5 Exercise Builder

The therapeutic modules are generated by the “Data Base Module Maker” (DBMM), which is a friendly tool to easily generate the static (reading) pages of the modules. The therapists are capable of adapting the content of the modules and then upload those changes to the server. However, due to the complexity of the exercise pages, this back office tool is unable to create them. While uploading the adapted modules, the exercise pages were overridden by reading pages, which causes the necessary intervention of the system administrator to mount the exercises again. In order to solve this issue it was developed a tool that will easily upload the module generated by the DBMM, and with a simple click build the exercise pages instantly. This tool allows the therapist to perform any changes required without having to appeal the help of a system administrator and also simplify the method of upload the modules.

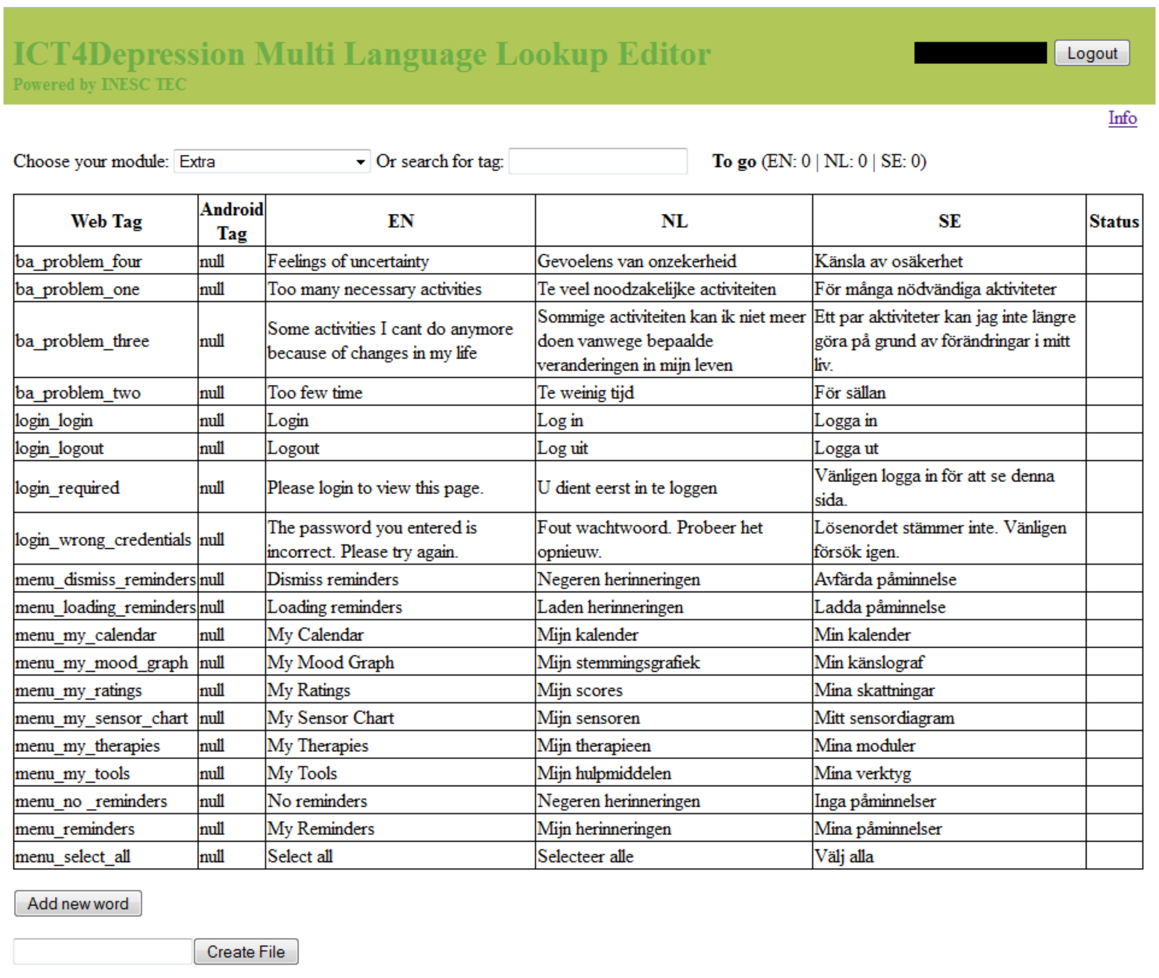
It is important to emphasize that DBMM is a great tool drawn to generate the therapeutic modules for both mobile and web version of the therapeutic module application. The natural evolution in the system requirements and the augment in the complexity degree of the therapeutic modules have limited this tool. The exercise pages then require technical intervention from the developer team. What DBMM produce in these cases were dummy exercise pages. The software developers build the functional exercise pages in accordance with the system requirements.

2.3.6 Multi-language Lookup Editor

The time-consuming task process which translates the texts included in the exercise pages required put in evidence a new tool to aid and speed the development. It was necessary, besides the translation, to manually copy the translated text to the dictionaries, all this for each language. In order to fill in that gap it was developed a tool “ICT4Depression Multi

Language Lookup Editor", that allow the translators to easily translate the exercise pages' text. It also helps to deploy the dictionaries into the system. Instead of manually copy the translated text into the dictionaries all one has to do is click a button to automatically generate the dictionaries for all the defined languages.

It is a very handy tool that was rapidly adopted by the mobile system. It gave some autonomy to the person responsible for the translation and save the lots of repetitive work to the developers and constitutes a progress beyond the initial objectives.



Web Tag	Android Tag	EN	NL	SE	Status
ba_problem_four	null	Feelings of uncertainty	Gevoelens van onzekerheid	Känsla av osäkerhet	
ba_problem_one	null	Too many necessary activities	Te veel noodzakelijke activiteiten	För många nödvändiga aktiviteter	
ba_problem_three	null	Some activities I cant do anymore because of changes in my life	Sommige activiteiten kan ik niet meer doen vanwege bepaalde veranderingen in mijn leven	Ett par aktiviteter kan jag inte längre göra på grund av förändringar i mitt liv.	
ba_problem_two	null	Too few time	Te weinig tijd	För sällan	
login_login	null	Login	Log in	Logga in	
login_logout	null	Logout	Log uit	Logga ut	
login_required	null	Please login to view this page.	U dient eerst in te loggen	Vänligen logga in för att se denna sida.	
login_wrong_credentials	null	The password you entered is incorrect. Please try again.	Fout wachtwoord. Probeer het opnieuw.	Lösenordet stämmer inte. Vänligen försök igen.	
menu_dismiss_reminders	null	Dismiss reminders	Negeren herinneringen	Avfärda påminnelse	
menu_loading_reminders	null	Loading reminders	Laden herinneringen	Ladda påminnelse	
menu_my_calendar	null	My Calendar	Mijn kalender	Min kalender	
menu_my_mood_graph	null	My Mood Graph	Mijn stemmingsgrafiek	Min känslograf	
menu_my_ratings	null	My Ratings	Mijn scores	Mina skattningar	
menu_my_sensor_chart	null	My Sensor Chart	Mijn sensoren	Mitt sensordiagram	
menu_my_therapies	null	My Therapies	Mijn therapieen	Mina moduler	
menu_my_tools	null	My Tools	Mijn hulpmiddelen	Mina verktyg	
menu_no _reminders	null	No reminders	Negeren herinneringen	Inga påminnelser	
menu_reminders	null	My Reminders	Mijn herinneringen	Mina påminnelser	
menu_select_all	null	Select all	Selecteer alle	Välj alla	

Figure 6: Multi language lookup editor

2.4 Description

The ICT4Depression system infrastructure overview is shown in Figure 7. The user can interact with the system through a Samsung Galaxy S smart phone or through a personal computer (PC) based interface. A dedicated graphical user interface presents the user with information on the treatment, allows the user to take part in the treatment by making exercises and by answering questionnaires and frequent ratings. Furthermore, it incorporates a calendar. Whereas the PC-based version of the system allows the user to interact with the system in a more elaborate way (e.g. textual input is easier with a full keyboard), the mobile version of the system allows the user to interact with the system whenever and wherever the user wishes and acts as a sensor data aggregator for the biomedical sensors. The biomedical sensors consists of a hand worn device for the measurement of heart rate and sympathetic nervous system responses and a chest strap that provides heart rate, respiration rate and an acceleration data that can be used to infer the trunk orientation of the user (further and more detailed information on the sensors and their use can be found in D4.6). The latter data is combined with motion data measured directly on the smart phone to obtain accurate information on patient physical activities. Both devices transmit the collected data wirelessly over Bluetooth connection, and were designed to be fully wearable, maximize the comfort and minimize the impact to the patient daily life when used for prolonged periods of time.

Treatment of depression is normally supported by medication and the adherence to the prescribed medication regimen is often low. For this reason, a smart pillbox is used to monitor medication intake. All sensor data is sent to a dedicated server where analysis of the data takes place in a reasoning system that incorporates models of the user and their progression. This system can assess whether the treatment is successful and provides the medical staff and user with advice for further treatment.

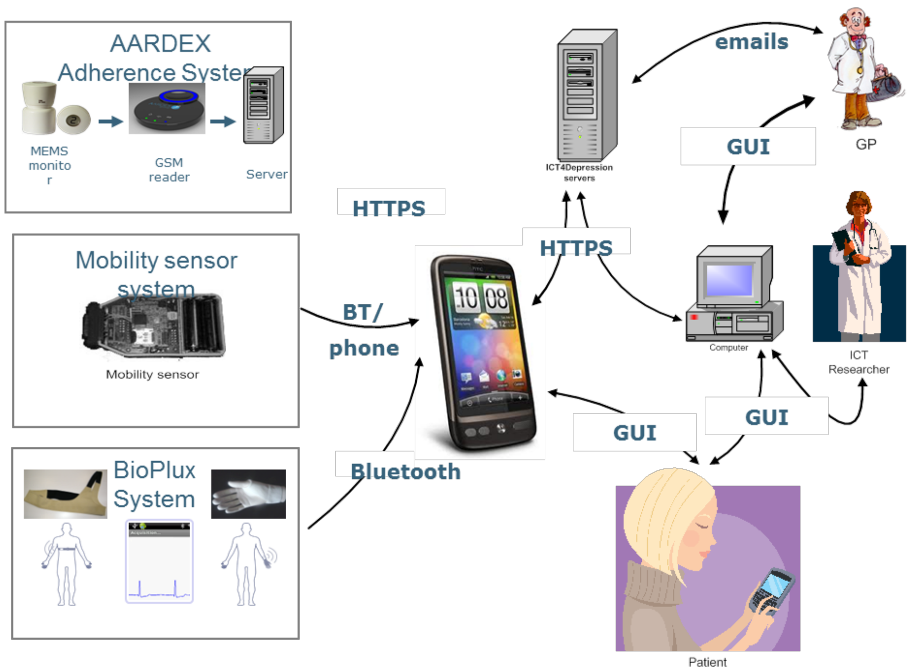


Figure 7: Infrastructure overview

2.4.1 Biomedical Sensor Devices

The BVP sensor adopts a reflective principle, with a novel sensor arrangement in a side-by-side, dual-emitter, single detector configuration, to allow signal acquisition at the base of the hypothenar eminence, near the point where it meets the wrist. The EDA sensor was designed to work both with dry and pre-gelled electrodes, and to be able to performed signal acquisition at the thenar eminence. Both of these are developments that extend the state-of-the-art, and are crucial for the measurement of BVP and EDA data in ambulatory scenarios without limiting the capability of the user to perform his regular activities. The block diagrams of BVP and EDA sensors as well as the placement at the hand are detailed in D4.6.

The two wearable biomedical sensor devices that were created to enable monitoring of multimodal psychophysiological data on the users were successfully implemented and are meaningful exploitable results of the project.

The chest strap is a discrete device designed for long-term use at the trunk, concealed under the regular clothing, and which can be used to measure both cardiorespiratory and posture/actigraphy data. Figure 8 shows the final textile enclosure and device, and we refer the reader to D4.6 for additional technical details.

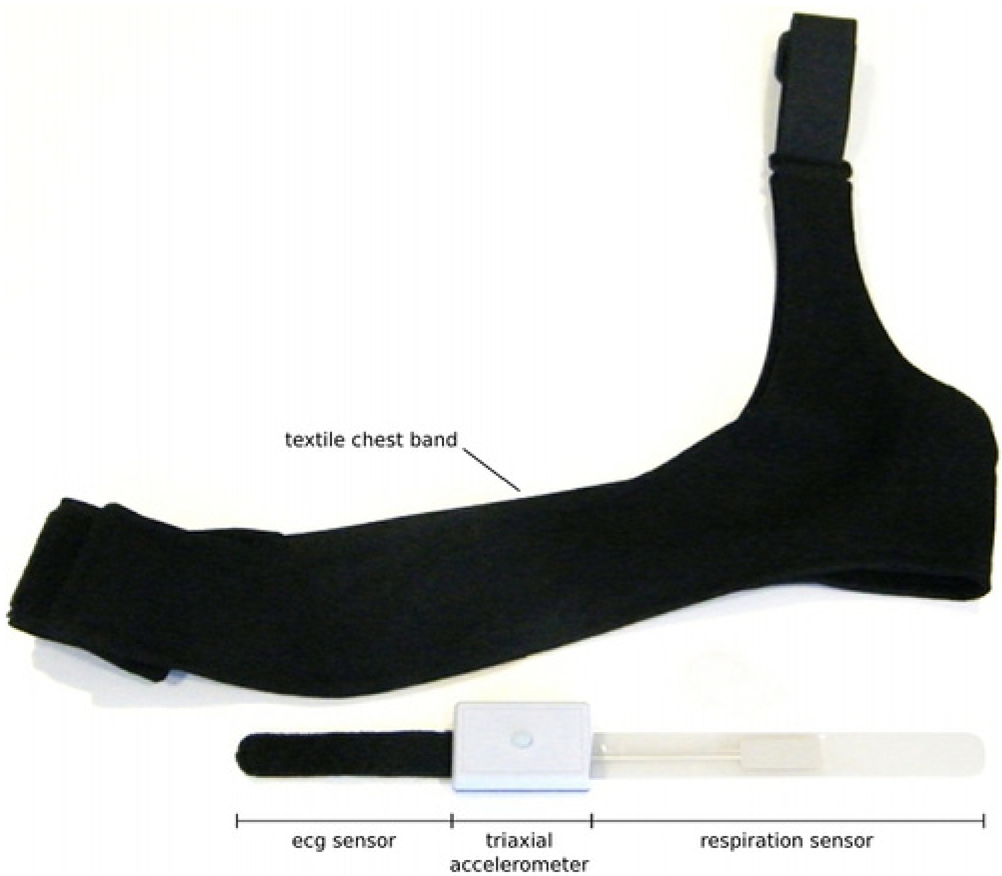


Figure 8: Chest strap enclosure and device

The glove is a device for temporary or long-term use at the hand; it was designed to be as discrete as possible, while preserving functionality. Due to its particular placement at the hand level (a more exposed location), the design originated novel contributions in terms of sensing technologies, so that the device would have a minimal interference in the users' regular routines. Figure 9 and Figure 10 show the glove enclosure and corresponding device and we refer the reader to D4.6 for additional technical details.

Figure 9: Glove enclosure

Despite having different sensors and functions, both devices were devised to share a common hardware framework, composed by the analogical-to-digital conversion and Bluetooth wireless transmission subsystems; this enabled the rational use of the project resources, and provides scale economy in the production of the systems in the long term.

Figure 10: Glove device

Each device has its own enclosure, specially created to provide comfort and ease of maintenance; a textile-based approach was followed, with materials especially selected for prolonged use. The enclosures for each device (chest strap and glove) are available in three different sizes (S, M and L), with both male and female designs in the case of the chest strap; because the enclosure is independent of the device, many more variations can be created, and customization is also possible (e.g. colours, patterns, etc.).

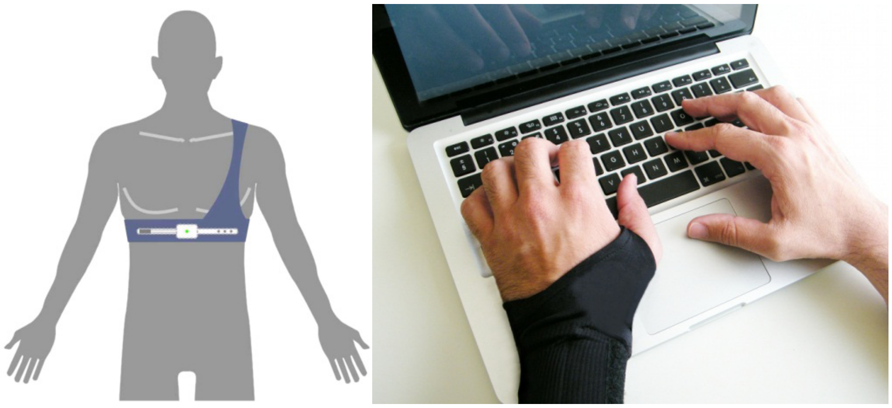


Figure 11: Chest strap and glove placement

Textiles are naturally tolerated for long periods of application to the body, unlike synthetic materials with which most devices found on the state-of-the-art are built (e.g. personal heart rate monitors); furthermore, textiles can be easily machine washed together with other clothing items, and can be easily replaced when damaged or worn out. Figure 11 illustrates the application of the chest strap to the body of a user; note the shoulder loop, specifically introduced in our design to prevent the device from sliding down the trunk of the user when worn for long periods of time (a frequent problem in off-the-shelf devices). Figure 11 also depicts a real-world use scenario of the glove, where the user is wearing the device while working with a laptop computer.

The mobile phone contains two built-in sensors: an activity and mobility monitor and the Proxiometer, a geo-location based monitor of high-level data relating to the user's whereabouts.

The mobility monitor is automatically turned on and off to monitor the user's activity and physical exertion levels. Data is reported to the server at 10 minute intervals and contains of:

- Percentage: lying, sitting, standing, walking, running and cycling in any period;
- Cumulative daily activity normalized to a number between 0 and 10.

The Proxiometer monitors the user's whereabouts. In particular is keeps track of the frequency and duration of visits to geo-locations the user has indicated as having a special meaning in terms of two categories: social interaction and physical activity. Rather than notifying the ICT4Depression system of the actual geo-location, for privacy reasons the Proxiometer only reports that the user has been in a social interaction / physical exercise location for a time. Setup of the Proxiometer is discussed in section 2.4.3.

2.4.2 Medicine Adherence

Figure 12 shows the main elements of the adherence monitoring system. The MEMS® monitor is a standalone device that can be used to automatically record the openings of a vial containing the drug. The MEMS® is screwed on a standard vial containing the monitored drug.

Figure 12: Main elements of the adherence monitoring system

Each time the patient opens and closes the MEMS monitor, it registers the date and time of opening. It also provides basic feedbacks to the patient through a small LCD screen. The LCD helps the patient to manage their prescribed regimen by providing a simple feedback:

- The number in the centre indicates the number of openings of the vial since the beginning of the day. It will be reinitialized during the night.
- The 12 segments in a circle around the central number indicate the number of hours that have passed since the last opening. Each segment represents one hour.

The wireless reader is used to download data from the MEMS® monitor and transfer these data. This reader is a fixed based that stays at home and is used by the patient to transfer the adherence data on a regular basis. With this type of system, the patient has two options. He may take the drug at home from the vial equipped with a MEMS monitor and put the MEMS immediately after on the wireless reader. He may also leave home with the vial equipped with a MEMS monitor and transfer the data later when he is back at home.

Additionally, adherence data are also accessible using a JavaScript viewer and an Android viewer. These viewers provide more feedbacks through different views. The first view, called Status, provides information about the status of the system but more importantly the observed level of adherence. Two complementary views provide details about adherence. The chronology plot displays adherence data over a given period of time. In this view, the x-axis represents the date whereas the y-axis represents the time. In this view each opening of the MEMS monitor is represented by a blue dot. Grey rectangles are used a highlight skipped doses. Chronology plots contains all the information about adherence but can be complemented by a calendar plot. If the chronology is well suited to detect timing issue, the calendar view is a useful complement to easily spot adherence issue related to weekend or holidays.

2.4.3 Mobile Sensor Aggregator

The mobile phone acts as a sensor aggregator for the wireless sensors and its own built-in sensors. Data is collected continuously during monitoring periods and stored locally. Every 10 minutes this data is communicated to the server after which the local data is removed.

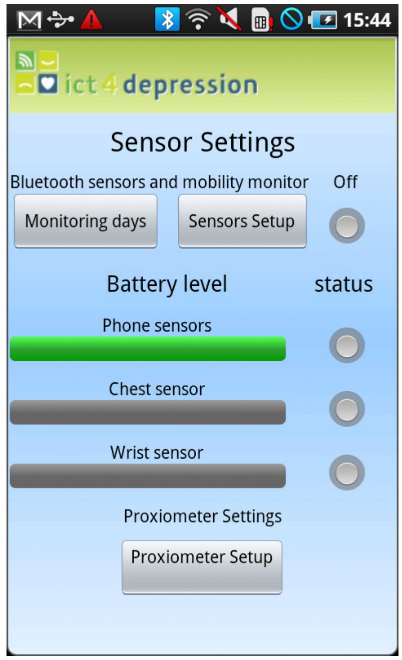


Figure 13: Sensor settings screen

The patient can set the days and times that they want to be monitored, with the button ‘Monitoring Days’. To monitor within the constraints imposed by the phone’s power source, the application will choose suitable monitoring periods based on the patient’s calendar entries, or randomly spread throughout the chosen monitoring period if no calendar entries were set.

The battery levels of the phone, the chest sensor and the wrist sensor are shown in the three bars under the test ‘Battery Level’ on. These give an indication of whether charging is required.

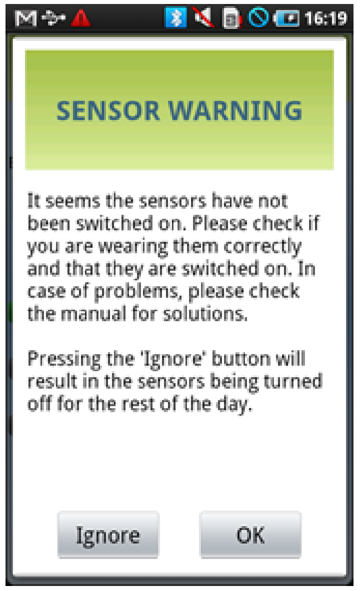


Figure 14: Sensor warning

When a value is received from one of the sensors, this will be indicated with the green status lights on the right hand side of the battery level bars. A green light means that a value has just been received and this can be used to see if the sensors are working correctly. If no sensor data is received by the mobile phone, something may be wrong with the sensors. For example, the user may have forgotten to turn on the sensors or charge the batteries. In this case a pop-up as shown in Figure 14 will appear. The patient can now address the problem and press ‘Ok’ to try again, or choose to ‘Ignore’ the problem, which means that the faulty sensor will be stopped for the rest of that monitoring period.

The bottom of the screen is devoted to the Proxiometer. The On/Off button allows manual control over the Proxiometer. As for the other sensors, the Proxiometer is controlled automatically by the system, so turning on/off the sensors is not normally necessary. The locations stored in and recognised by the Proxiometer can be managed under the ‘Proxiometer Setup’ button.

To start using the Proxiometer the user selects the button ‘Proxiometer’ on the sensors screen (Figure 13). When starting for the first time, the user will be presented with the screen in Figure 15, which prompts the user to select locations of social interaction and exercise activity by zooming in on the location and performing a long press. Figure 16 and Figure 17 show a map view and satellite view respectively. The latter allows for the location to be visually verified and accurately indicated by a long press.

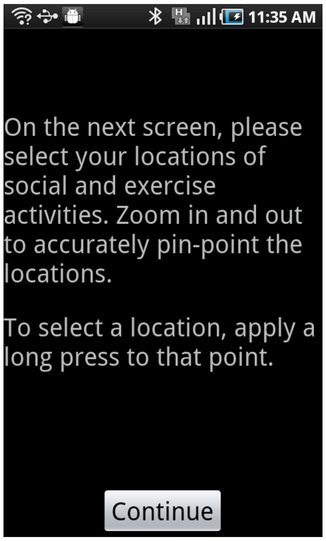


Figure 15: Initial proxiometer screen

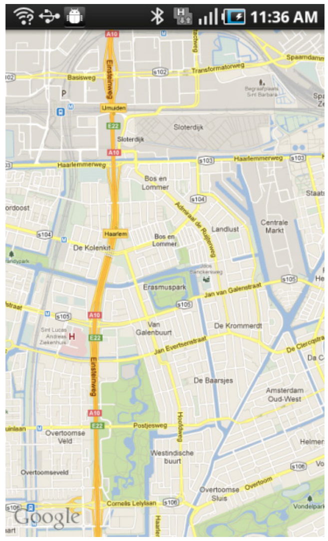


Figure 16: Map view to select location

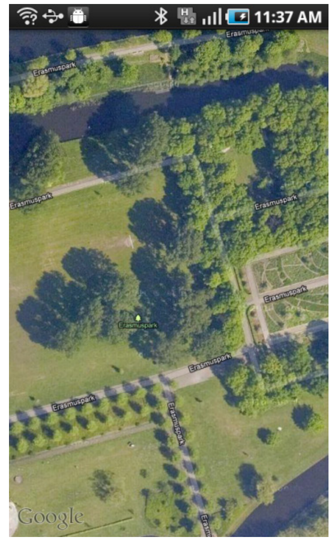


Figure 17: Satellite view to select location

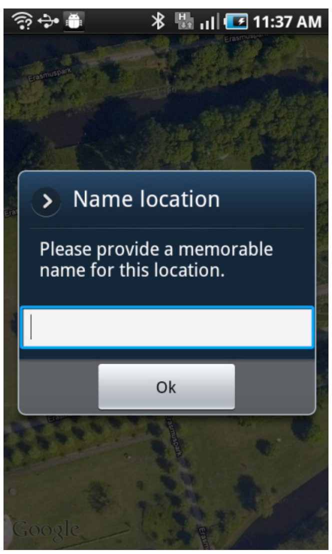


Figure 18: Providing user chosen name for location

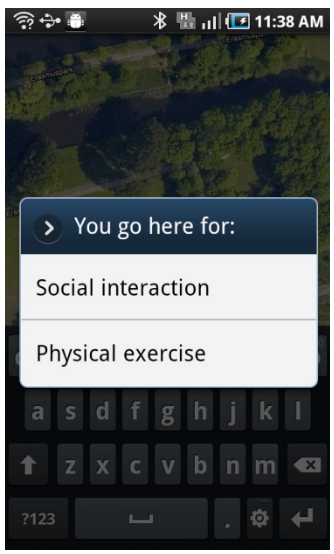


Figure 19: Selecting type of interaction

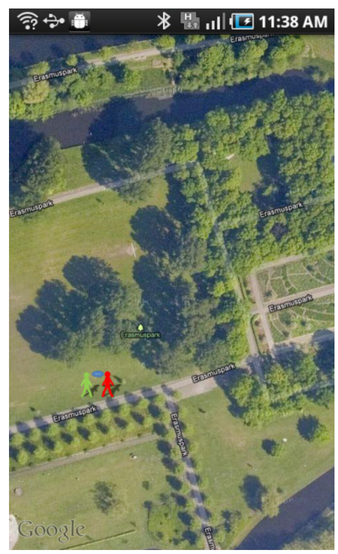


Figure 20: Location of social interaction indicated with symbol

Once the location has been chosen, a pop-up will suggest known locations close by that can help to further obtain the exact location. Upon selecting a location, the last pop-up will allow to choose between social interaction and exercise activity. Once a choice has been made, the location on the map will be marked with either of the following symbols:

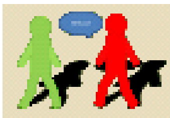


Figure 21: Symbol for Social Interaction location

Figure 22: Symbol for Exercise activity location

Note that the exact geo-location will not be reported back to the system. The only information collected is how often and how long the user was in locations which were indicated as having an exercise activities or social interaction context to the user.

2.4.4 System Server Repository

The ICT4Depressiont repository includes, within other the following information classes:

- The patient therapeutic module data;
- The patient sensors data;
- The reasoning engine aggregate data;
- The reminders, feedback, module completion and logs.
- General practitioners and ICT4Depression research lookup values;
- Multi-language values for therapeutic exercises;
- Mobile phone, sensors identification and assignment relation to patients.

The database management system in use was the Microsoft SQL 2008. The required data protection is based in the database TDE (Transport Data Encryption) feature.

2.4.5 Webservices

As was mentioned, the ICT4Depression is a SOA (Service Oriented Architecture) that relies on WS (Web Services) to send and receive data. The main advantage is the loose coupling between client applications and repository. This implies that any client created on any platform can connect to the ICT4Depression system according to established information access policies, as long as essential contracts are met.

For the information exchange the option in use was the Web Service development over the WCF (Windows Communication Foundation) targeting .NET framework. As other modern frameworks, allows the use of WS standard, which enabled the development of service oriented applications.

The current client applications are WS client applications, a web client PHP application and a mobile application running on Android. They implement the therapy modules and use XML/JSON over HTTPS to communicate to the server, which implements both synchronous and asynchronous web method invocation.

The complete list of webmethod and description can be found in the section **Error! Reference source not found.** (annexes).

2.4.6 Therapeutic Modules Application

The approach defined consists of a set of modules accessible via website and smart phone (Android) by means of secure web services. These therapies are integrated in an intelligent self-help system leveraging on the Reasoning Engine and have been designed in close collaboration with the psychologist partners, having in mind the end-user experience and feedback. All patients start with the Psycho Education module.

The Psycho Education module consists of general information about depression and the available treatments for this disorder. Information is also given about all the modules that can be followed after psycho education. To increase motivation, exercises are included in the module that focuses on goal setting. At the end of this module patients need to fill in a questionnaire of which the scores determine the advice about best suitable modules to continue with.

The Behavioral Activation module treat depression through techniques designed to reinforce pleasant and reduce unpleasant activities. The patient uses the Calendar/Agenda to schedule both activities and is advised to increase, if necessary to balance, the number of pleasant activities. It helps the patient during the day to work through the behavioural treatment by reminding of activities, prompting for mood ratings and giving personalized feedback.

The Problem Solving module helps the patient to take control of life again, by determining things that are important, coping with situations he cannot change and spending energy on things that matter. The patient learns to differentiate between different types of problems (1. unimportant problems, 2. important and solvable problems and 3. important but unsolvable problems). The main focus of the module lies on solving the solvable problems by means of a six step procedure.

The cognitive Restructuring module helps the patient to work on and control negative automatic thoughts, which are related to depression. This module challenges the patient to reason if these thoughts are just interpretations and not actual truths. It aims to make the patient more logical about his beliefs and to consider all the evidences and be aware of the so-called thinking errors.

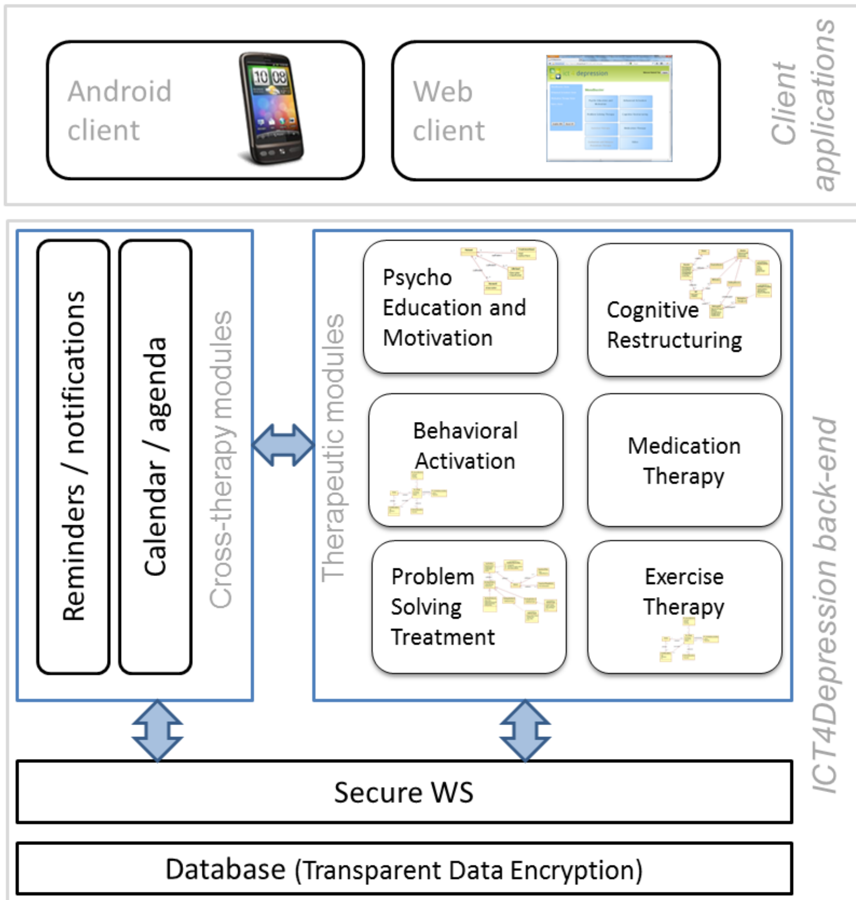


Figure 23: Therapeutic modules overview

The Exercise Therapy module helps patient to raise is exercise threshold, which is not only healthy, it is also a non-stigmatizing way of treatment depression. It his supported by the mobile phone mobility sensor in conjunction with Calendar/Agenda, to detect if the schedule exercises/games have been performed and encourage the patient to increase his levels of physical activity.

The Medication Therapy provides adequate and personalized support for the management of patient drug intakes.

During the relapse prevention module, the patient learns to recognize signs of a relapse of depression. The exercises within the module focus on making plans to cope with these signals and to cope with future life events, which can trigger a depressive period. Also, suggestions for a healthy life style are given.

The Figure 23 shows also cross-therapy components. They address the goal of assessing the progress in the patient's recovery. The Reasoning engine collects data from the Therapeutic

Modules and provides automated feedback. The patient has then a better insight in the progress of their therapy and allows them to increase the effect of the therapy. The Calendar/Agenda works as a backbone interconnecting several Therapeutic Modules, by allowing the user to schedule activities, plan their exercises and helping the Reasoning Engine to determine the adequate timing for feedback reminders, notifications or rewards.

Refer to the D4.6 version 2, for details on the use of the Therapeutic Modules.

2.4.6.1 Mobile

The mobile interface is developed using html and java scripts, which are stored on the phone such that the application can also be used if there is no connectivity. For conformity in the presentation of the treatment modules to the patient *and* for ease of treatment module development, a structure of available module screens was developed.
The first category of screens is the *navigation screen*, which is depicted in Figure 24. Its primary function is to facilitate navigation through and around the application. Through the use of these screens, patients can access further navigation controls, read module content or undertake module centric activities.

The *module content screens*, as depicted in Figure 25**Error! Reference source not found.**, allow the patient to read about the treatments available in the ICT4Depression application.
The third category of screen is the *patient input screen*, an example of which is shown in Figure 26. This page type requires interaction between the patient and the module to assist in the patient's treatment.

A logo is present on every screen which acts as a link that will allow the patient to immediately link back to their home page. Because the patient should be able to return to the source screen, a button with sitemap functionality is integrated into the application. On clicking this button, the patient is able to navigate back to a previous screen. An additional button for inclusion in the ICT4Depression application is the calendar quick link. This button enables the patient to view, edit and add module activities to their personalised calendar as necessary. Finally an activities quick link was included to enable patients to access their exercises and activities from anywhere within the application.

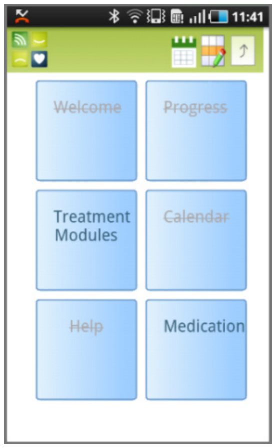


Figure 24: Navigation Screen

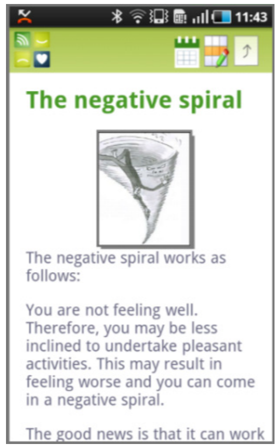


Figure 25: Module Content Screen

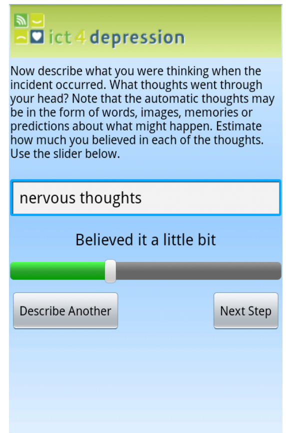


Figure 26: Patient input screen

Throughout the mobile application, a menu is available with the choices depicted in Figure 27. From left to right, these icons are described in the following paragraphs

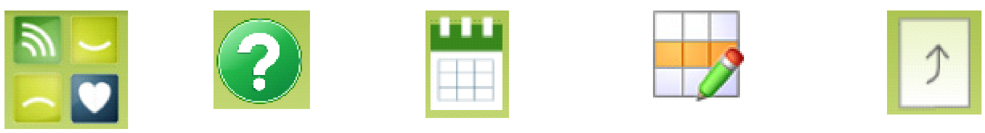


Figure 27: Mobile application menu icons

The “Moodbuster Logo” can be used to return to the home screen or exit the application. The “Help page” quick link leads to a short help file on use of the Moodbuster application. The “Calendar” quick link can be used to start the calendar, which is also available from the home screen. The same holds for the “Progress” quick link which leads to an overview of the exercises performed in each module. The last button on the menu bar, the “Up button” can be used to navigate through the module in a faster way. As previously described, each module contains button pages which link to other pages in the module. The resulting structure is a tree-like structure where the parent of each page is a button page. The up button allows the user to navigate back to the current pages parent button page. This allows the user to quickly find the next topic on the same level (by navigating up and going down to the next topic by choosing the next button on the parent button page) or indeed go up several levels.

Modules can, and normally should be followed in normal page order and this is made possible through swipes or flings.

2.4.6.2 Web

The Web client makes the requests to the webserver at INESCPorto, which is based on Apache HTTP Server with PHP5. The server was configured to support various features such as SSL.
The web version was developed using the following languages:

- Server-side: PHP5
- Client-side: HTML; CSS; JavaScript

The server-side the system must be able to communicate, securely using the SSL protocol, with the WCF Web Services, which defines the system logic behind the mobile and web clients. In order to establish communication, the webserver read and interpret the WSDL file containing the description of the services, creating a file (stub) that acts as a bridge between the Web Services and the PHP. The “wsld2php.php” tool was used to generate proxy classes that are used to access the Web Services via SOAP calls. With the generated file the server is able to record and retrieve all the information from the Web Services and provide them to and from the client.

On his side, the client communicates with the server using AJAX. The server provides well-structured data that is used by the client to build elements containing that information and present them to the user. To enhance the web version’s elements it was used a JavaScript Library called “jQuery” that simplifies the event handling, animations and AJAX interactions. Elements like the Datepicker, Sliders, Progress Bar and Accordion (commonly used in all the therapeutic modules) are elements available on the “jQuery UI”. Those elements were improved in order to fulfil the requirements of the Moodbuster. All the elements are described on the end-user’s manual (D4.6).

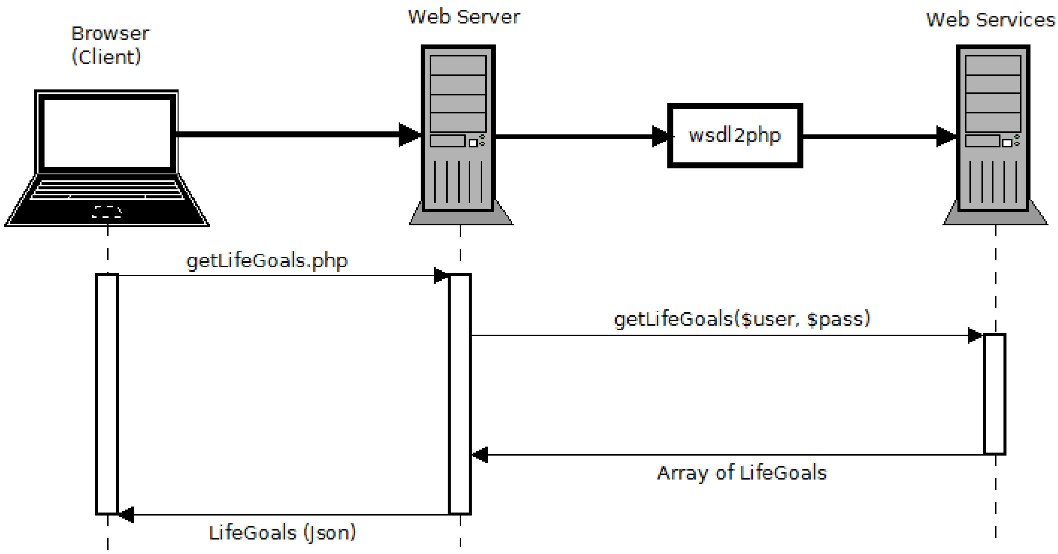


Figure 28: Communication example - getting list of life goals

In Figure 28, is an example of communication between the components that are part of the web system. In this specific example the user opens the page of Exercise 1 from the Psycho Education Module. The client browser requests the server for the list of Life Goals for that specific user, the server will make a SOAP call to web services with the same request that will answer with an array of Life Goals Objects through the "wsdl2php". Finally the webserver will encode the Life Goals using JSON and presenting that data to the client that will build an Accordion with the Life Goals.

The web version of the Moodbuster is constituted by three working areas. The header (top of the page) where are present the logo of the system (Moodbuster), this logo acts like a home button, bringing the user back to the home page every time the logo is pressed. The login area that allows the user to gain access to the system and the flags, located beneath the login area to allow the user to change the system output language.

The web version is available in three different languages English, Dutch and Swedish. When a patient logs in into the system, the web version will present the language that was defined on the Management Tools.

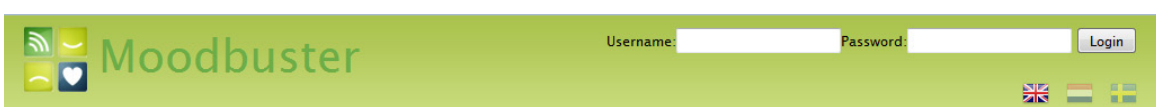


Figure 29: Header area

The left menu, Figure 30 that contains three distinct areas:

- "My Reminders" where the feedback messages from the Reasoning Engine will appear.
- "My Tools" with direct link to some components of the web version such as "My Calendar", "My Mood Graph", "My Sensor Chart" and "My Ratings".
- "My Therapies" where are present the quick links for the available modules.

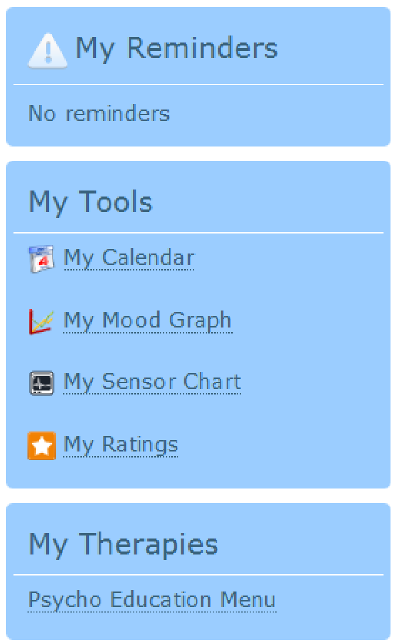


Figure 30: Left menu area

The main area is the located at the centre of the screen and is where the content of the therapeutic modules will appear.

Due to the impossibility of the JavaScript language communicates directly with an external server (Reasoning Engine), was built on the webserver a proxy, in this case using PHP, which allows the client to get information from the Reasoning Engine.
When the user gains access to the system, the client make a first request to the Reasoning Engine, via the PHP proxy, to get the recommendation scores for each module. After receiving the rates from the webserver will normalize the results from -1 to 5 stars where -1 means that the module is blocked. The star rating will be visible inside the button, right below the name of the module, as it can be seen in Figure 31.

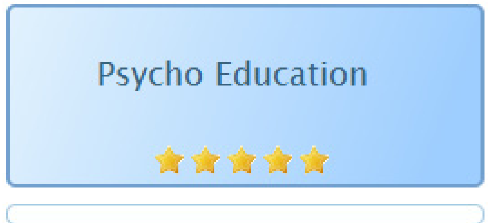


Figure 31: Module button with star rating

Case the system can't establish connection with the Reasoning Engine it will appear a red box with the message "Reasoning Engine Error", just above the "My Reminders" section. In that case, there is no recommendation available and all the modules will be unlocked.

Figure 32: Reasoning Engine connection error

My Reminders

The Reasoning Engine derives for the patient the required interactions, which are set into the database. The webserver fetch those feedback messages and present them in this section. The patient can dismiss those reminders selecting them and then pressing the "Dismiss" button. The system will mark the selected message(s) as acknowledge and will not present them again.

My Calendar

The Calendar page is one of the few pages where the left menu isn't available, the left menu was replaced by a section called "My Activities" where are presented all the pleasant, necessary, important and physical activities that were inserted on the therapeutic modules. The user will be able to drag and drop those activities directly to the calendar.
To build the calendar it was used an open source jQuery plugin called "FullCalendar"; this plugin provides a full-sized, drag and drop calendar that uses AJAX to fetch events on-the-fly for each month. As in other components, it was required to develop new features to respond to the requirements and others were added improve the user experience. The user can mark an activity as complete, just by clicking on the activity he/she wishes to mark and then select "Mark as Complete" from the context menu, after that a green marker will appear on that activity. For instance, the context menu and green marker weren't present on the "FullCalendar" package.

Figure 33: Calendar view

The major development effort was the Calendar integration with the overall application logic and the related therapeutic modules.

Reference to “FullCalendar”: http://arshaw.com/fullcalendar/

My Mood Graph & My Sensor Chart

The first prototypes didn’t include a consistent mechanism to depict a set of variables in observation of the patient state and actions. In response to this two charts were add to the web therapeutic module application. Both charts, under “My Tools” were built using Highcharts JS from Highsoft with a non-commercial license for non-profit organizations. When the user enter one of these sections, the server retrieves the information about the “Daily Average Mood” and the number of “Pleasant”, “Necessary” and “Physical” activities for that day in case of “My Mood Graph” selection. If the choice is to check “My Sensor Chart” the server retrieves information about the “Skin Conductance”, “Heart Rate” and “Breath Rate”. That information is then processed and injected into the Highchart that generates the charts for each section, as can be seen in Figure 34.

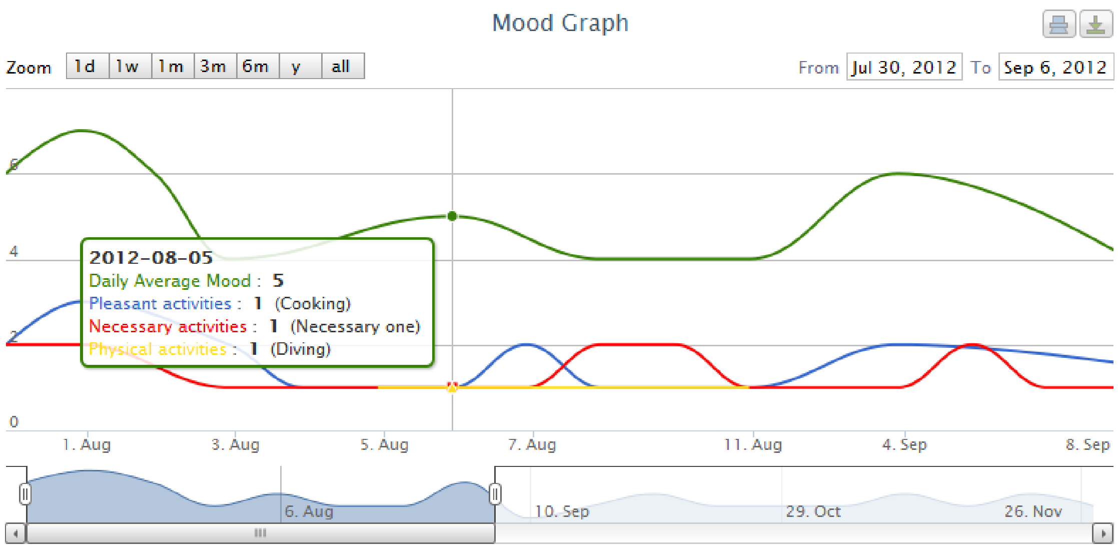


Figure 34: Mood graph view

Reference to “Highcharts”: http://www.highcharts.com/

My Ratings

In this page the user can rate his mood, anxiety, quality of life, sleep, motivation and physical health. An intuitive ten star rating system is presented. The user can easily rate by clicking the star that represents the number considered the most appropriate for each condition.

Figure 35: Rate your mood example

Therapeutic Modules

All the therapeutic modules have the similar operating functioning, with reading pages and exercise pages.

The reading pages include examples and observations that allow the user to understand the steps of the therapeutic modules. One can easily navigate the pages using the navigation arrows at the bottom of the page.

The exercise pages are slightly different. They require a set of actions from the user, which depend from the therapeutic module in use. In all the cases the exercises require patient actions: choices to characterize situations or feelings, descriptions of goals and challenges, problems to solve, strategies to define, physical exercises to schedule, etc., for example, his life goals. In that case there will be an element called the "Accordion" that stores and present the life goals inserted using the text box just beneath the "Accordion". To save the list, the user has to press the forward arrow on the navigation buttons. The information about the status of the saving will be presented in a status bar just above the navigation buttons.

More information about each of the therapeutic modules and elements that are part of the exercise pages are available at the user's manual (D4.6) – further details on D4.6 revision 2.

Questionnaires

At the end of each module is presented the end-module questionnaire to eval the patient improvement and the module effectiveness. To build the questionnaires it was used an open source application called "LimeSurvey", which is very complete application when used as standalone application, but has limitations when it comes to integration.

The "LimeSurvey" application uses a token system in order to identify the users on the non-anonymous surveys. Each survey has a table of tokens that will be used to manage the usage of the survey.

To overcome the incapability of linking the surveys to the users was created a stored procedure that will propagate the tokens for each survey, a list of tokens for all available users: with that the tokens linked to the users, acts as a foreign key, which brings the ability to get patient answers to each one of the questionnaires fulfilled.

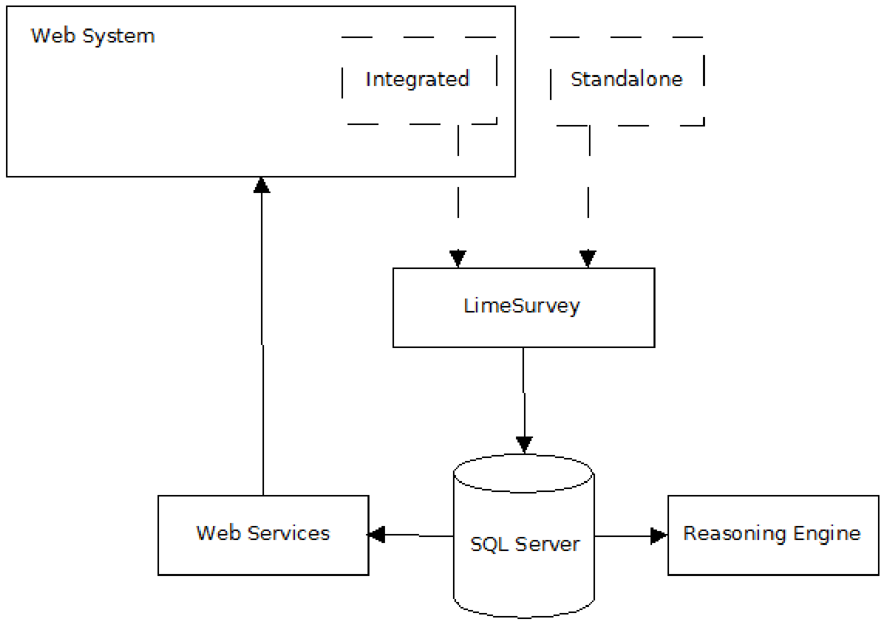


Figure 36: Lime survey integration perspective

The structure that stores the answers of the surveys can be a little abstruse and is another weak point when it comes to integration. The information collected by the questionnaire is relevant so that the Reasoning Engine be capable of evaluate the results and then provide the right feedback to the user. However many of the information store in the tables of the "LimeSurvey" application is there for internal purpose and not ready for raw consuming from the Reasoning Engine. To overcome this was defined another stored procedure that extracts to the Reasoning Engine all the information required to operate – update the virtual patient and to provide feedback and reminders.

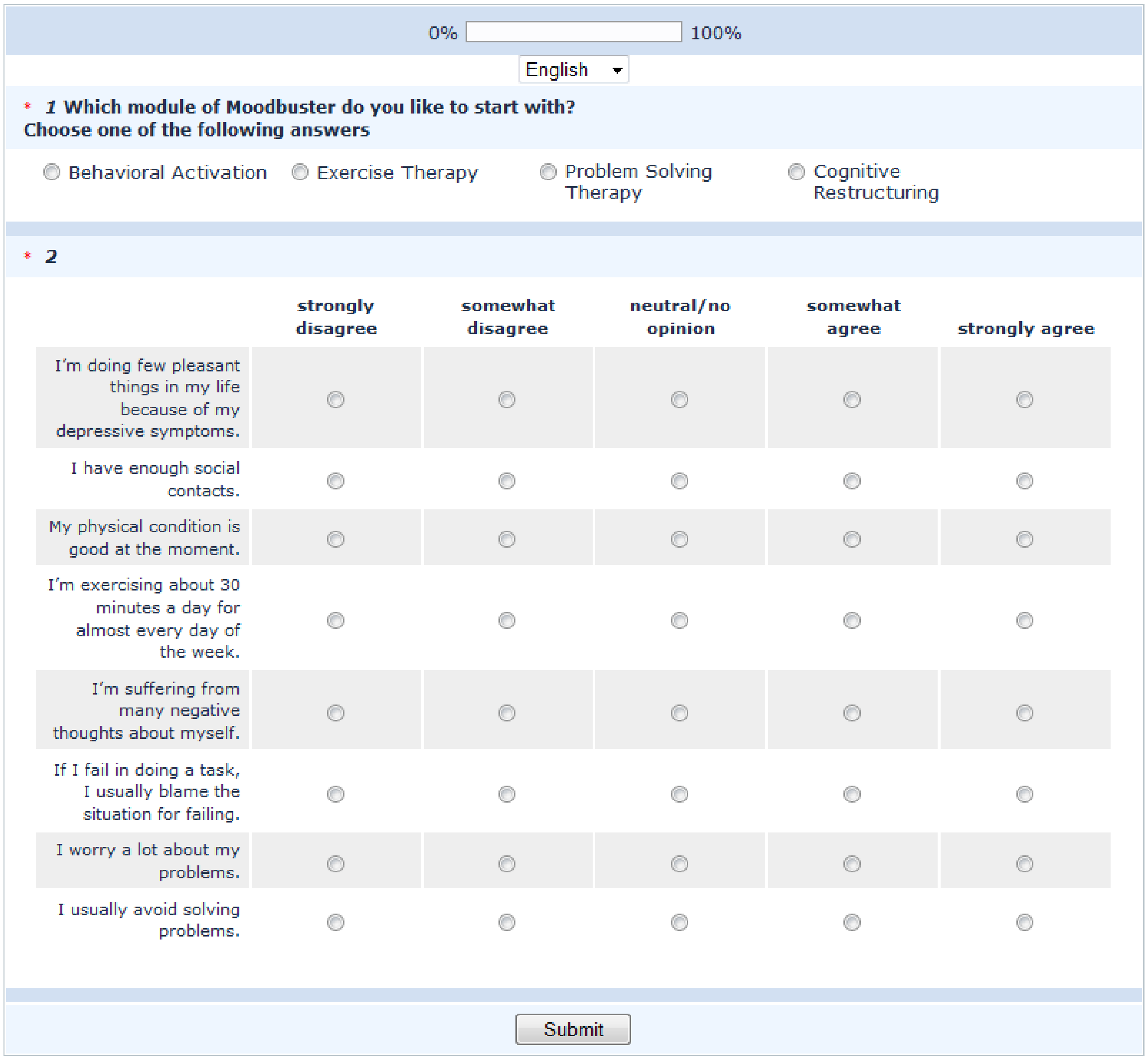


Figure 37: Lime survey end module page view questionnaire

With the "LimeSurvey" back office tools the therapists are able to change the questionnaires and also create new ones that can be use aside of the system. It can be accessed at: https://testix.inescporto.pt:448/limesurvey/admin/.

Reference to "LimeSurvey": http://www.limesurvey.org/

3 Assessment Methodology

3.1 Type of Information Collected

3.1.1 Biomedical Sensor Data

The biomedical sensors underwent extensive evaluation at three levels: a) wearability; b) laboratorial; and c) experimental. Table 1 summarizes the different parameters measured by each device.

Parameter	Chest Strap	Glove
Heart Rate	Yes[1]	Yes[2]
Respiration	Yes	
Electrodermal Activity		Yes
Physical Activity	Yes	

Table 1: Parameters measured by each device

As previously presented in D4.2, a wearability pilot was performed by LIU, together with PLUX, in which a set of 30 participants tested the sensors in their home environment to rank and evaluate the form factors with respect to 6 criteria that included material comfort, ease of application and removal, discreteness, among others. These tests provided invaluable feedback in the form of comments and suggestions that were incorporated in the final versions of the devices, leading to a set of devices and form factors that the users accept and feel comfortable to use in their daily lives. We refer the reader to D4.2 for additional details on the results of these tests and how they influenced the design process for the final devices.

PLUX also performed laboratorial tests to the sensors and acquisition devices, the results of which were described in D2.4. Among other things, these tests shown that the novel BVP sensor configuration has a good correlation with gold standard equipment in terms of heart rate measurement, and that the EDA sensor with dry electrodes at the thenar eminence also provides an adequate output. Furthermore, these tests enabled the characterization of the chest strap and glove devices in low, medium and high intensity activities, in order to determine the behaviour of the sensors in each situation. These tests enabled the team to adapt the experimental protocol to the operating characteristics of the sensors, and enabled

[1] Derived from Electrocardiographic (ECG) data
[2] Derived from Blood Volume Pulse (BVP) data

the identification of several topics for future work. We refer the reader to D2.4 for further details regarding these tests.

A pilot study was performed by VUA, which involved 27 healthy subjects that performed a 24h data acquisition protocol, divided in two parts, in which 1h was composed by a set of predefined tasks and supervised by the psychology team, and the remaining 23h (second part of the protocol) were a free-living scenario in which the users would take the devices home with them and would wear them until the next day. These tests assessed again the usability of the form factors, and assessed the technical behaviour of the sensors in real-world free-living conditions, with positive results. We refer the reader to D5.2 for further details regarding the pilot study and its results.

3.1.2 Medicine Adherence Sensor Data

In this section, we consider only the data recorded by the MEMS®. Each time the patient opens and closes the vial containing the drug, the MEMS® monitor registers the date and time of the opening. Importantly, these timestamp are meaningless in absence of contextual information such the drug regimen. For example, the patient may be instructed to take the drug once a day or twice a day. Some time constraints may also be prescribed. The combination of the timestamps with these contextual data will provide further information about patients' adherence.

3.1.3 Patient Questionnaires

At the end of each therapeutic module the patient fills in a short questionnaire (only available in Web client) to assess three aspects, namely the severity of the depressive symptoms (Q1), to assess satisfaction about the module he just completed (Q2) and to assess skills/symptoms that are being tackled by the different modules (Q3).

3.1.3.1 Q1 – Severity of symptoms

The severity of symptoms is measured by the Beck Depression Inventory (BDI-II). This is a 21-question multiple-choice self-report inventory, one of the most widely used instruments for measuring the severity of depression.

3.1.3.2 Q2 – Evaluation of module

To assess satisfaction about the module the patient is asked to rate how much they learned from the module, whether he would use the module in the future again and whether he would recommend this module to other people with the same problems.

3.1.3.3 Focus of module

The therapeutic modules all focus on a different problem area, which is all related to depression. The cognitive module teaches the patient to recognize and change negative automatic thoughts. During the problem-solving module the patient learns to solve problems in a structured way. In the exercise module the patient is stimulated to get more physically active and in the behavioural activation module the patient learns to do more pleasant things. These four problem areas (negative thoughts, low problem solving skills, reduced exercise and reduced level of pleasant activities) are being assessed in this questionnaire.

3.2 Data Collection Tools

3.2.1 Biomedical Sensors

A set of Application Programming Interfaces (API) was developed, to enable the mobile application to communicate and retrieve data in real-time from each device. Each device is identified by a unique MAC address, and the mobile application has the responsibility to initialize the used sensors, start and stop the monitoring, and collected the acquired parameters. The application creates an instance of the device class in the API, with the MAC address, and configures the sensors; event handler objects in the API enable the mobile application to receive the data from the sensors. The monitoring process begins when a method to start the acquisition is called and stops when a method to stop the acquisition is called. The number of events and periodicity depends on the sensor type and algorithm used to calculate the data. For development and testing purposes, the API provides an automated device discovery method that searches and list all the devices within radio reach of the mobile phone. A Software Development Kit (SDK) on the mobile phone integrates the algorithms used for sensor data calculation. Furthermore, PLUX developed a test application for Android OS, which enables the real-time data visualization and sensor demonstration (Figure 38 and Figure 39). We refer the reader to D2.1, where additional details about the data collection API are provided.

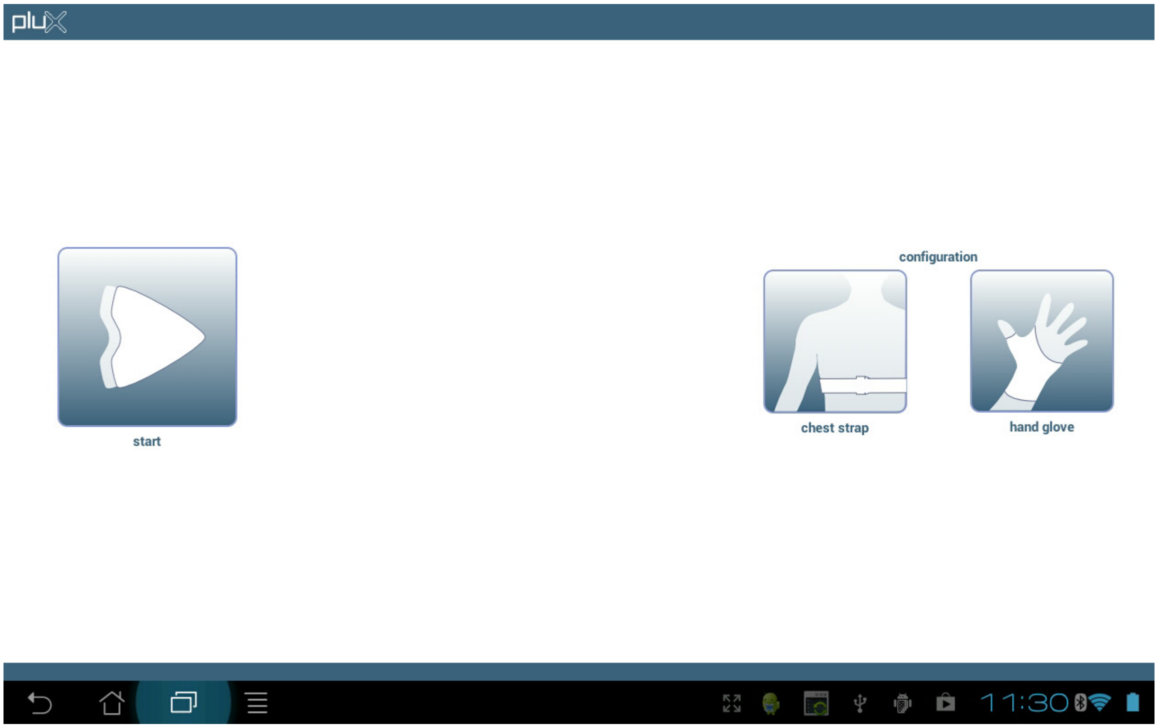


Figure 38: Main screen of the biomedical sensor monitoring application

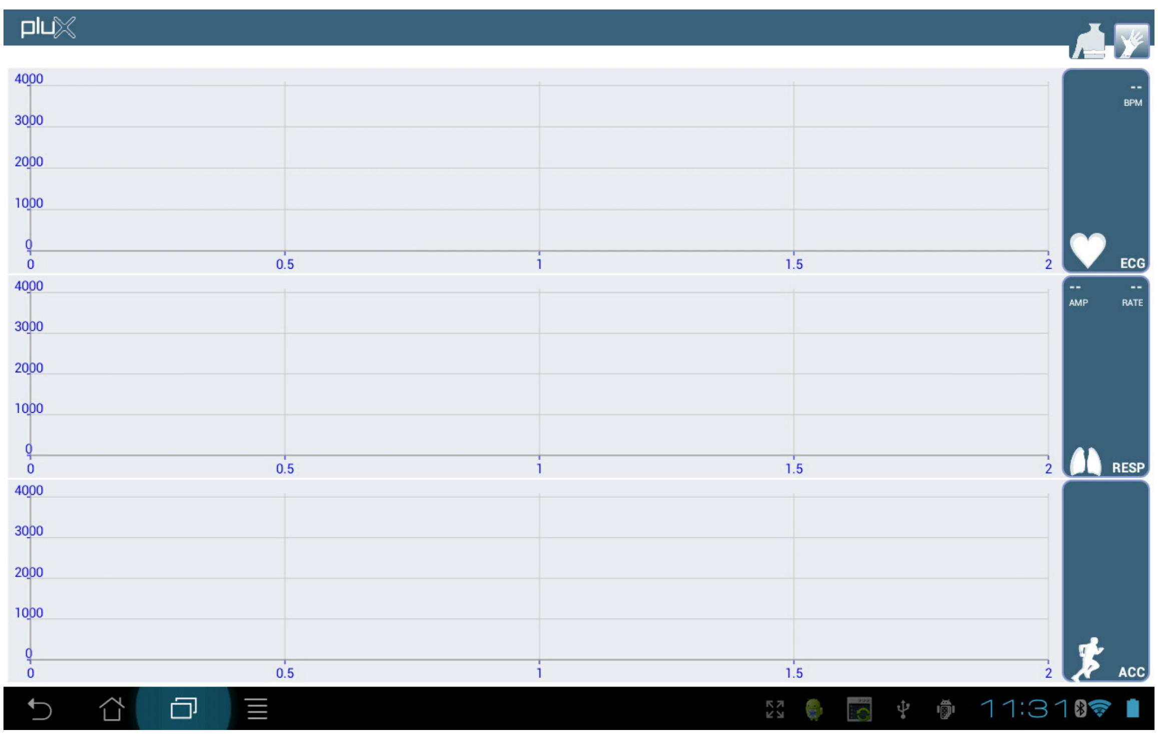


Figure 39: Chest strap monitoring console of the biomedical sensor monitoring application

3.2.2 Medicine Adherence

As mentioned above, the MEMS® records timestamps that can be interpreted as drug intake. After a comparison with the expected regimen, these timestamps can be translated into a level of adherence, the higher the better. The percentage of days with correct dosing has been used to provide the patient with a measure of his/her adherence to the drug therapy.

3.2.3 Mobile Application

The mobile application gathers data using the mechanisms described in section 2.4.3. This section will provide some more detail on the exact information collected. Sensor information is only stored on the phone to provided buffered communication with the server. Upon successful transmission, the data is removed from the mobile phone hence reducing the risk of abuse of sensitive data.

On-board sensors

The mobile application gathers information regarding the phone's acceleration and location. Acceleration information is obtained using's the phone's built-in 3 axis accelerometer at a rate of around 120Hz (sampling rate is dependent on processing resources available and is thus time-varying; linear interpolation is used to obtain a fixed sampling interval). The resulting data is first down-sampled at 20 Hz after which the data is used to determine the user activities.

To this end, the low pass filtered signal is high pass filtered at 1 Hz to obtain an approximation of the gravity vector, which is subsequently used to obtain an estimate of the time-dependent orientation of the phone. Once this orientation is known, the following user activities can be recognized:

- Lying;
- Sitting;
- Standing;
- Walking;
- Running cycling.

	Sitting | Lying	Standing	Walking	Running	Cycling
Sitting | Lying	0.9963	0.0000	0.0037	0.0000	0.0000
Standing	0.0000	0.9056	0.0047	0.0000	0.0000
Walking	0.0000	0.0000	0.8640	0.1360	0.0000
Running	0.0000	0.0000	0.1312	0.8533	0.0155
Cycling	0.0000	0.0000	0.0115	0.1668	0.8217

Table 2: Confusion matrix for matrix active and static activities

With accuracies as indicated in Table 2. It should be noted that Sitting and Lying activities were combined in these trials as these were performed without the PLUX chest strap. Splitting this combined category is relatively easily done by obtaining the trunk orientation from the chest strap accelerometers.

In addition to these activities, the user's physical activity levels accumulated over the day are reported to the server at frequent intervals. This data is normalized on a scale of 1 to 10 (with 1 indicating very low and 10 indicating very high user activity) for use by the Reasoning Engine.

Biomedical sensors

Data from the two Bluetooth sensors is gathered on the phone and buffered for energy efficient communication with the server. At default intervals of 10 minutes (this is user adjustable), the following information is forwarded to the server and the local buffers are flushed upon a successful transmission:

- For the wrist sensor:
  - Electrodermal activity: duration in seconds and amplitude in kilo-Siemens.
- For the chest sensor:
  - Heart rate in beats-per-minute;
  - Respiration frequency in breaths-per-minute.

Ecological momentary assessments

At times specified by the Reasoning Engine, the user is presented with any of three types of ratings: mood, sleep or anxiety. To prevent undue obtrusiveness, the ratings are presented for up to an hour after which they are cancelled if the user has not responded to the rating. This response consists of choosing a number between 0 and 10 to indicate the current mood, last night's sleep quality or current feelings of anxiety.

3.2.4 Web Application

The major collectors of data in the Web Application are the Exercise Pages. They collect data that the patient deliberately inserts into the elements that are part of the exercise pages, described on the user's manual (D4.6). It also tracks the user through the navigation between exercises with entry and exit logs. This information is useful both for therapists as for the system in order to adapt the information to the user.

What was to be a set of simple questionnaires to collect information about the patient, became a powerful system that uses more assertively the information collected in all stages improving the user experience. In Figure 40 is an example of the use of the attribute "Pleasant Activities" during the first three exercises of the module "Behavioral Activation". The system will use the information collected in Exercise 1 to present the rates in Exercise 2 and also present the pleasant activities that the user can drag to the Calendar so that he can schedule his pleasant activities.

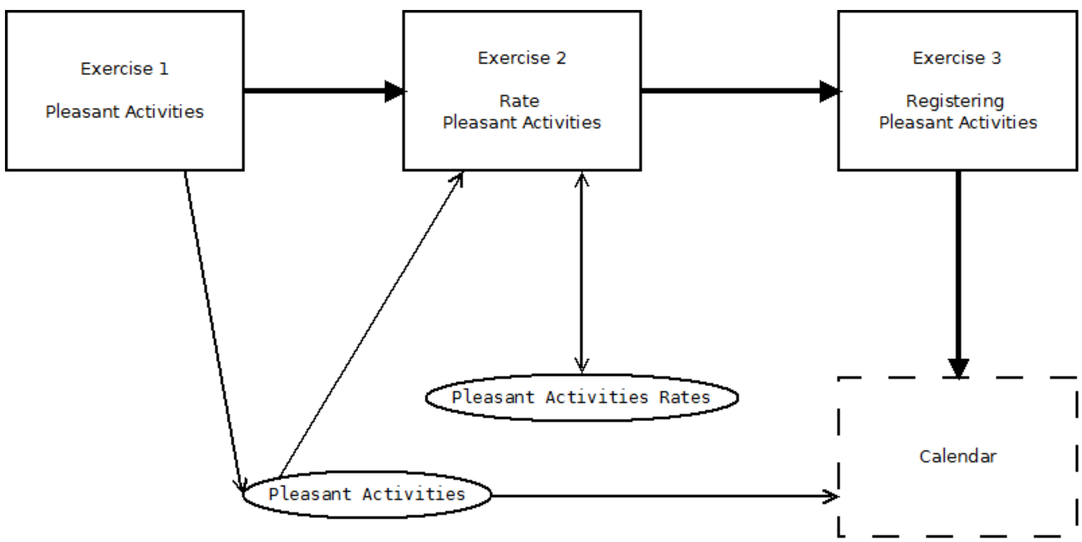


Figure 40: Behavioral Activation and Calendar integration

Another good example that this system is far more complex than a questionnaire is the "Cognitive Restructuring" module. Figure 41 shows the sequence of the exercise pages: in Exercise 4 the patient will start challenging his thoughts; at the end of the challenge, the patient can go back to the start of the exercise and challenge a new thought or even re-challenge the same thought. The reuse of attributes are also present in this module, a good example of this is the step 4 of exercise 1, where the patient writes the emotions felt during a situation, then in step 3 of exercise 4 those emotions are suggested to the patient like emotions for that specific thought.

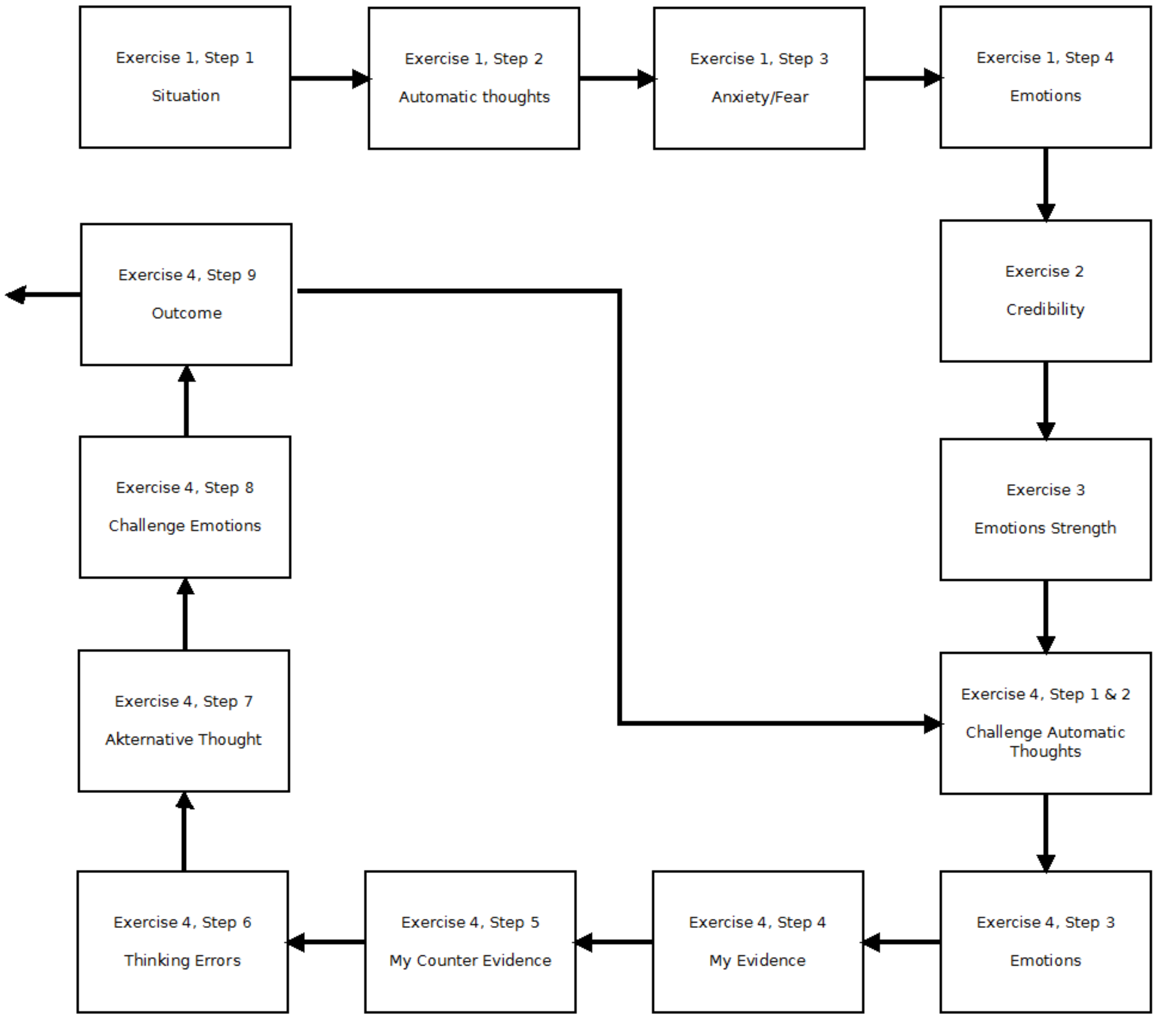


Figure 41: Cognitive Restructuring exercise pages sequence

The other therapeutic modules exercise page sequences will be depicted in the next figures. They constitute a summary of the implementation effort and reinforce richness of the therapeutic module final implementation.

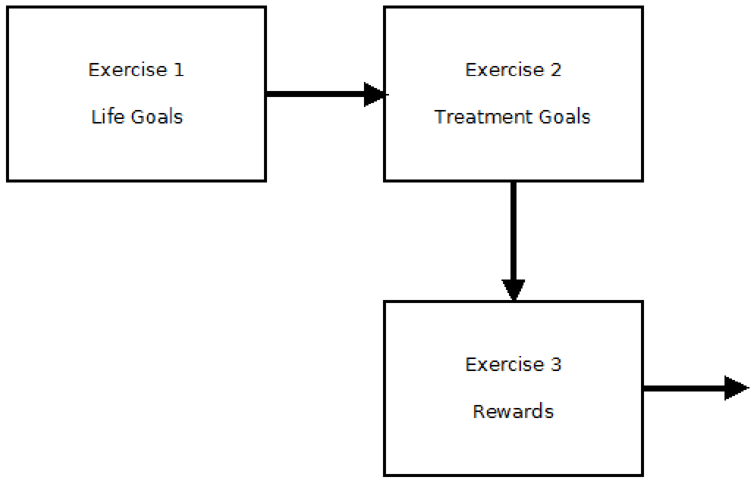


Figure 42: Psycho Education exercise pages sequence

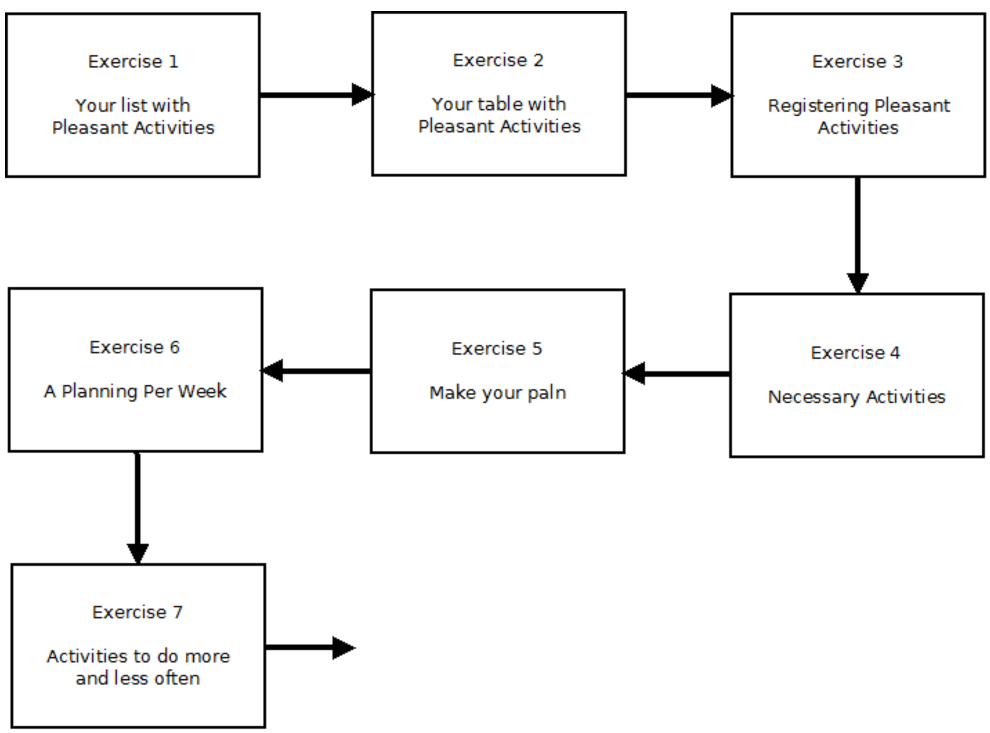


Figure 43: Behavioral Activation exercise pages sequence

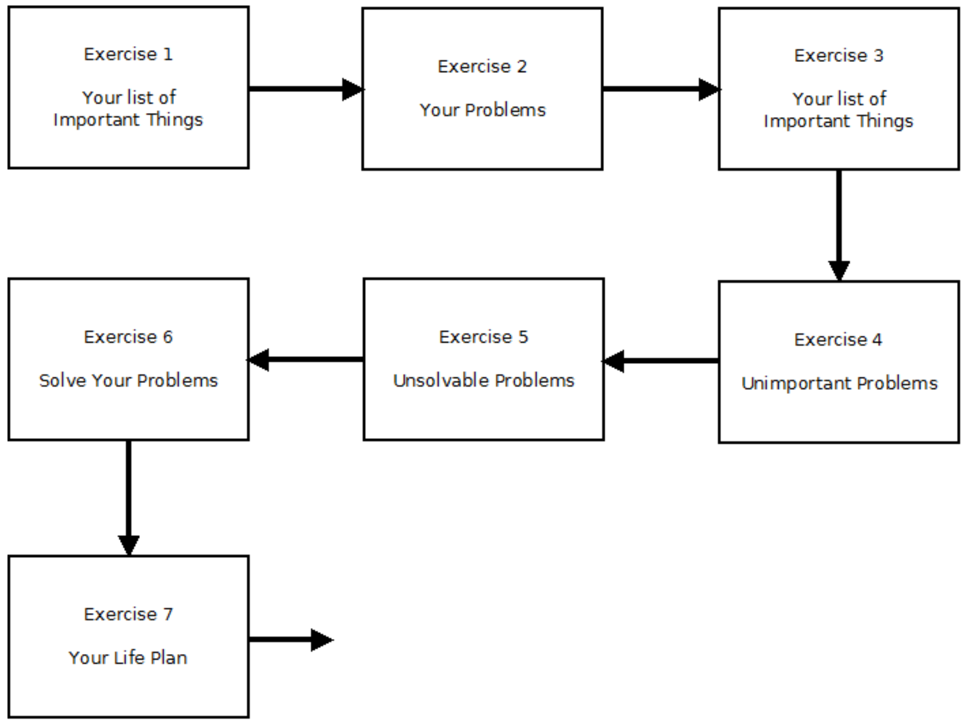


Figure 44: Problem Solving Therapy exercise pages sequence

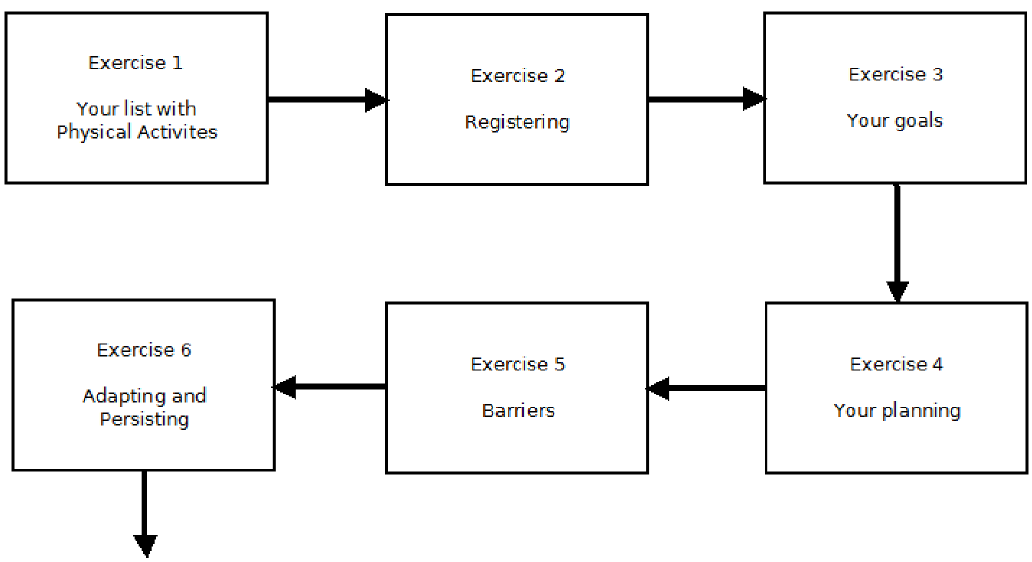


Figure 45: Exercise Therapy

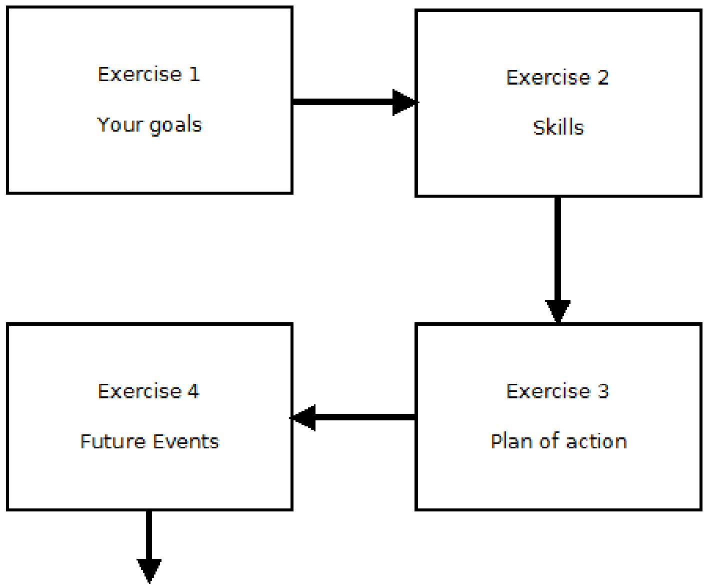


Figure 46: Relapse Prevention

3.2.5 Reasoning Engine

The Reasoning Engine is responsible for assessing the state of the patient, determining the most appropriate therapy, scheduling the ratings, and giving personalized feedback to the users. This assessment is based on information collected by other components of the system, e.g. the answers to the questionnaire, the involvement in the system as a whole, the performed activities (partly determined based on the sensor-data), and the adherence data. On itself, the Reasoning Engine does not collect information, but periodically determines the state of the patient.

4 Technical Assessment

4.1 Patient population characterization

4.1.1 Sweden trial

The patients were recruited from the student population, which differs slightly from the general population. The decision to do so was because researchers want to make sure that the patients in the study would be able to understand and use the mobile application.

There were twenty five (25) selected/interviewed patients for the trials. One of the patients (*patient10*) has abandoned before receiving the biosensor devices and access credentials. The population characteristics/demographics at baseline are summarized in the following tables – based on the twenty four (24) *active* patients.

Mean age	24.1 years
Males	13 (54.2%)
Women	11 (45,8%)

Mean PHQ-9 (Depression)	13.04 [Moderate level of depression]
Mean GAD-7 (Anxiety)	09.29 [Moderate level of anxiety]

Single	15/24 (62.5%)
In a relationship	09/24 (37.5%)

Mean economic situation	2.71	1. Very bad 2. Bad 3. Neither good nor bad 4. Good 5. Very good
Mean health situation	2.83	1. Very bad 2. Bad 3. Neither good nor bad 4. Good 5. Very Good

Previous pharmacological treatment	
Never	21/24 (87.5%)
Previous, and have quit	2/24 (8.3%)
Current	1/24 (4.2%)

Mean computer experience	4.71 [in a maximum of 5]
Mean smartphone experience	4.13 [in a maximum of 5]

4.1.2 Netherlands trial

Dutch patients were recruited from the general population. Because of this, this trial provided insight in possible differences between the students included in the Swedish trial and a more heterogenuous population. There were twenty five (25) selected/interviewed patients for the trials. Three patients dropped out at an early stage, leaving n = 22 active participants. Demographic characteristics are summarized below. Typical participants were middle-aged, female and highly educated. Pretest symptom levels were moderate, in accordance to the inclusion protocol.

Age	43 years (range: 20-65)
Males	36%
Women	64%
High education	68%

Mean BDI (Depression)	27 [Moderate level of depression]
Mean HADS (Anxiety Scale)	13 [Moderate level of anxiety]

4.2 Treatment data assessment

4.2.1 Sweden trial

The values collected and data processed for technical assessment are based on the collected data from the trials conducted by LIU in Sweden. In analysis are the data collected from the universe of 25 patients between 5 November and 4 December 2012.

In both mobile and web therapeutic application the actions of the patient on the exercise pages are tracked and stored in the system so it can be used by the Reasoning Engine to derive the *virtual patient* in order increase the efficiency of the treatments. It will be presented, in the next three tables, information about the daily usage of the system in both mobile and web platforms, the usage by patient and the usage per module.

Date	Web	Mobile	Total
05-11-2012	35	187	222
06-11-2012	38	142	180

07-11-2012	12	101	113
08-11-2012	33	47	80
09-11-2012	37	51	88
10-11-2012	2	20	22
11-11-2012	10	32	42
12-11-2012	36	49	85
13-11-2012	19	71	90
14-11-2012	7	10	17
15-11-2012	75	47	122
16-11-2012	5	4	9
17-11-2012	24	3	27
18-11-2012	3	1	4
19-11-2012	4	34	38
20-11-2012	21	5	26
21-11-2012	34	7	41
22-11-2012	54	29	83
23-11-2012	16	9	25
24-11-2012	0	0	0
25-11-2012	39	36	75
26-11-2012	50	14	64
27-11-2012	9	17	26
28-11-2012	23	10	33
29-11-2012	31	13	44
30-11-2012	15	6	21
01-12-2012	11	0	11
02-12-2012	60	1	61
03-12-2012	30	2	32
04-12-2012	0	0	0
Total	733	948	1681

Table 3: Daily usage

The count of usage per day, from which Table 3 and the usage graphic were constructed, sums the count of the following events, within the 25 patients:

- Starting a new module;
- Entry on exercise pages;
- Exit (conclusion) of exercise pages;

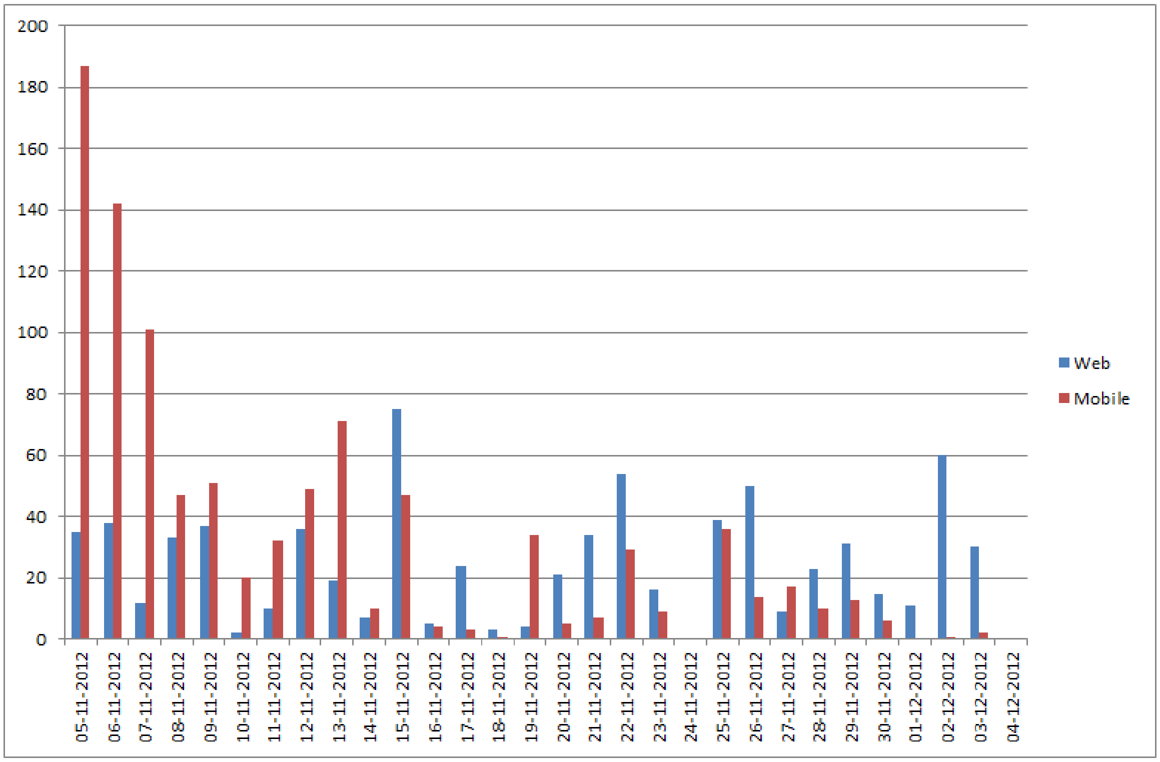


Figure 47: System daily usage

As was expected, the Mobile platform has more adherences, at least while the system is novelty to patients. After the first two weeks both clients have similar usage. The overall usage is depicted in the next graphic.

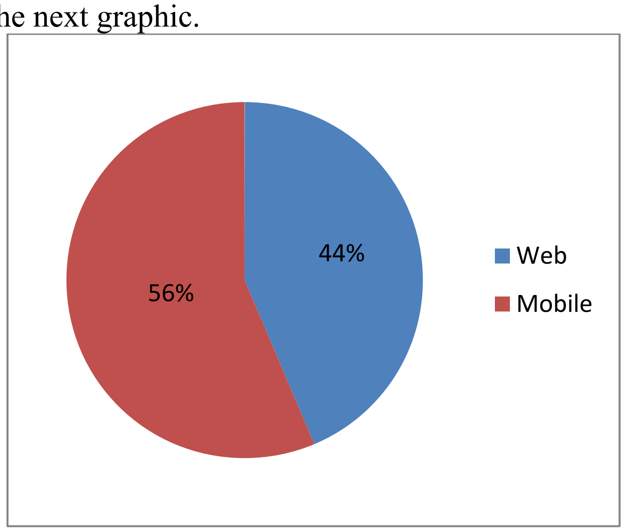


Figure 48: First month system usage by platform

The next table and correspondent graphic summarizes a different perspective, detailing the usage of both platforms per patient. There are patients that shows have never accessed the system and patients that use exclusively the mobile client platform.

	Web	Mobile	Total	Web (%)	Mobile (%)
Patient 1	9	24	33	27%	73%
Patient 2	0	5	5	0%	100%
Patient 3	35	52	87	40%	60%
Patient 4	65	58	123	53%	47%
Patient 5	1	39	40	2%	98%
Patient 6	24	62	86	28%	72%
Patient 7	14	29	43	33%	67%
Patient 8	79	33	112	71%	29%
Patient 9	19	14	33	58%	42%
Patient 10	0	0	0	0%	0%
Patient 11	21	16	37	57%	43%
Patient 12	10	28	38	26%	74%
Patient 13	67	44	111	60%	40%
Patient 14	51	48	99	52%	48%
Patient 15	0	15	15	0%	100%
Patient 16	20	21	41	49%	51%
Patient 17	30	27	57	53%	47%
Patient 18	60	60	120	50%	50%
Patient 19	52	60	112	46%	54%
Patient 20	8	70	78	10%	90%
Patient 21	23	76	99	23%	77%
Patient 22	48	36	84	57%	43%
Patient 23	3	44	47	6%	94%
Patient 24	91	11	102	89%	11%
Patient 25	3	76	79	4%	96%
Total	733	948	1681	44%	56%

Table 4: Therapeutic modules usage by platform per patient

The graphic helps to check that one patient hasn't make any use of the therapeutic modules and also (not included in the table/graphic) he/she hasn't wear any of the biomedical sensors.

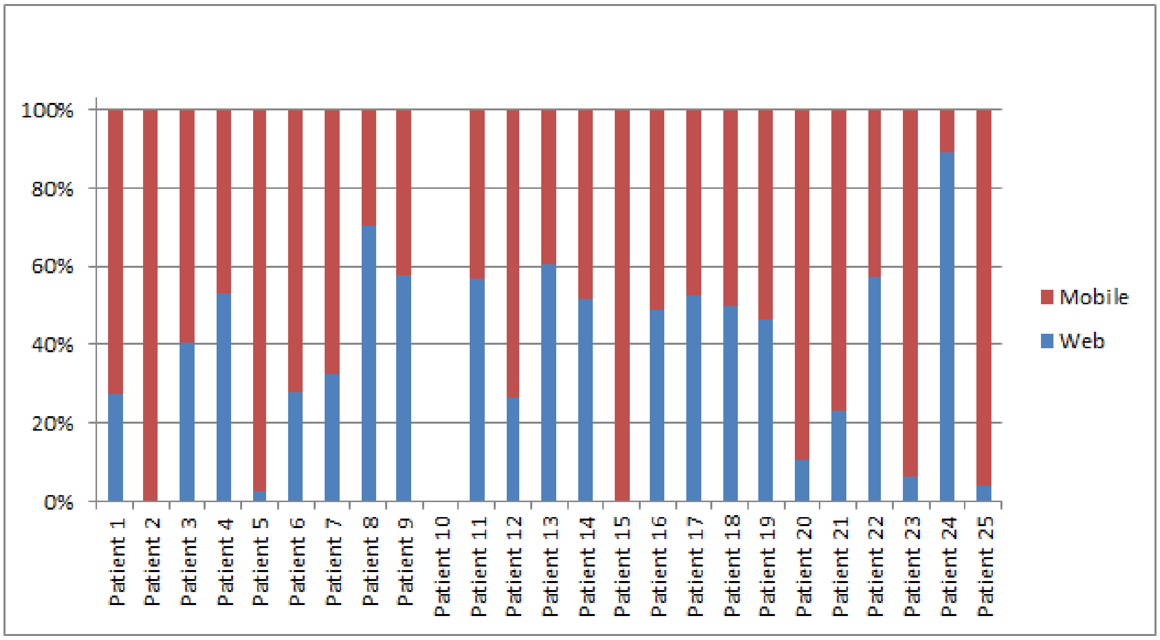


Figure 49: Therapeutic modules usage by platform per patient

The following table shows the system events associated to each module. The totals are in respect to each one of the modules. Since the system was designed to implement a three month therapy is natural not having Relapse Prevention accesses.

It is also convenient to report that a small issue was detected and was already corrected in the mobile application, which prevents the detection on the *start module* event, then causing the zeroed values on the mobile platform column.

	Web	Mobile	Total
Psycho Education			
Start Module	19	0	19
Entry Pages	53	378	431
Exit Pages	37	111	148
Total	109	489	598
Behavioral Activation			
Start Module	12	0	12
Entry Pages	182	146	328
Exit Pages	128	65	193
Total	322	211	533

Problem Solving Therapy				
	Start Module	12	0	12
	Entry Pages	95	122	217
	Exit Pages	66	46	112
	Total	173	168	341
Cognitive Restructuring				
	Start Module	4	0	4
	Entry Pages	27	50	77
	Exit Pages	14	6	20
	Total	45	56	101
Exercise Therapy				
	Start Module	7	0	7
	Entry Pages	44	17	61
	Exit Pages	33	7	40
	Total	84	24	108
Relapse Prevention				
	Start Module	0	0	0
	Entry Pages	0	0	0
	Exit Pages	0	0	0
	Total	0	0	0

Table 5: System usage by module

The difference between *entry pages* and *exit pages* values reflect that patient has started the exercise, which spans over one or more pages, and hasn't yet finished. The system stores the information that allow at any time, and event changing the client platform, to resume the point he/she was before.

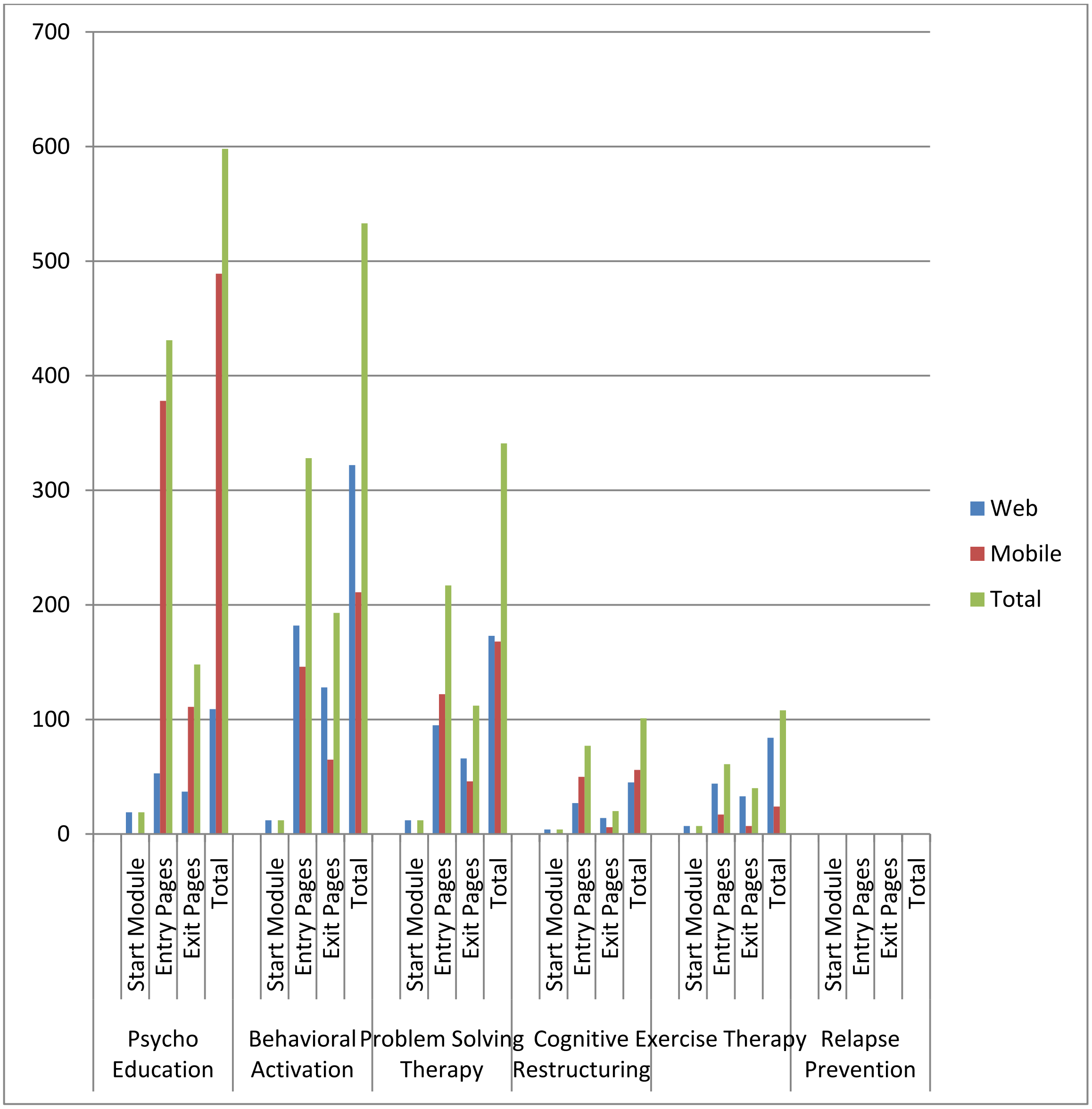


Figure 50: System usage by module

The Psycho Education module is the entry point of the treatment. Since the values considered here (Figure 50) reflect approximately the first month of the trials, is understandable that some modules have less activity, and no patients have entered yet the relapse prevention. Each patient after the Psycho Education, has his own treatment path evaluated and is advised to follow different subsequent therapeutic module, based on the inferred status derived from the Reasoning Engine.

4.2.1.1 End-Module Questionnaires

In similar way as was presented before for the therapeutic modules, this section will present statistic data about end-module questionnaires, including Psycho Education module. Table 6 resumes the daily usage (count) of the end-module questionnaire fulfilled.

Date	Entries
05-11-2012	5
06-11-2012	3
07-11-2012	1
08-11-2012	3
09-11-2012	2
10-11-2012	0
11-11-2012	1
12-11-2012	5
13-11-2012	1
14-11-2012	1
15-11-2012	1
16-11-2012	0
17-11-2012	1
18-11-2012	0
19-11-2012	0
20-11-2012	3
21-11-2012	3
22-11-2012	1
23-11-2012	0
24-11-2012	0
25-11-2012	4
26-11-2012	3
27-11-2012	1
28-11-2012	0
29-11-2012	1
30-11-2012	0
01-12-2012	0
02-12-2012	3
03-12-2012	0
04-12-2012	0
Total	43

Table 6: Questionnaires daily usage

The correspondent graphic view perspective is shown in Figure 51.

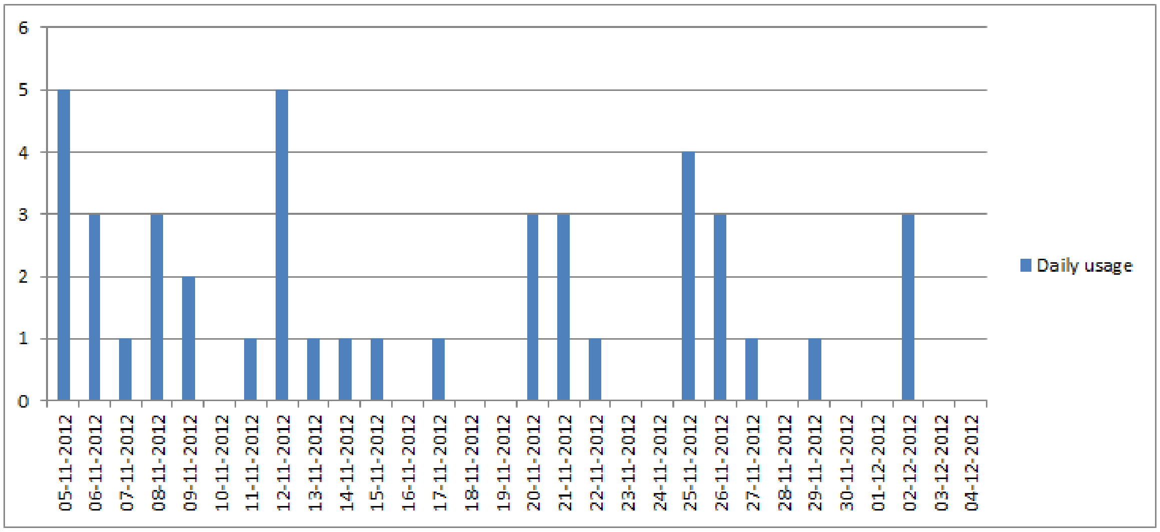


Figure 51: Questionnaire daily usage

There are three types of questionnaires available, although only Psycho Education has all types of questionnaires available at the end of the module. All the other therapeutic modules have only two types of questionnaires (Q1 & Q2). The next table presents the times each patient perform each type of questionnaire, in a quick analysis it can be checked that those numbers don't reflect any type of abnormality. The number of times that the Q1 and Q2 were performed is the same, and the Q3 was performed 28 times which means that, 65% of the questionnaires were performed at the end of the Psycho Education module.

There are some patients like number 2, 10 and 15 doesn't perform any questionnaire.

	Q1	Q2	Q3
Patient 1	1	1	1
Patient 2	0	0	0
Patient 3	3	3	1
Patient 4	2	2	1
Patient 5	1	1	1
Patient 6	2	2	1

Patient 7	2	2	2
Patient 8	2	2	1
Patient 9	1	1	1
Patient 10	0	0	0
Patient 11	1	1	1
Patient 12	2	2	1
Patient 13	4	4	1
Patient 14	2	2	1
Patient 15	0	0	0
Patient 16	4	4	4
Patient 17	1	1	1
Patient 18	2	2	2
Patient 19	2	2	1
Patient 20	1	1	1
Patient 21	2	2	1
Patient 22	3	3	2
Patient 23	1	1	1
Patient 24	3	3	1
Patient 25	1	1	1
Total	43	43	28

Table 7: Questionnaires usage by type

Table 8 presents the information about the usage of the questionnaires in each module.

	Psycho Education	**Behavioral Activation**	**Problem Solving Therapy**	**Cognitive Restructuring**	**Exercise Therapy**
Patient 1	1	0	0	0	0
Patient 2	0	0	0	0	0
Patient 3	1	1	0	0	1
Patient 4	1	1	0	0	0
Patient 5	1	0	0	0	0
Patient 6	1	0	0	1	0
Patient 7	2	0	0	0	0
Patient 8	1	0	1	0	0
Patient 9	1	0	0	0	0
Patient 10	0	0	0	0	0
Patient 11	1	0	0	0	0

Patient 12	1	1	0	0	0
Patient 13	1	1	1	0	1
Patient 14	1	0	1	0	0
Patient 15	0	0	0	0	0
Patient 16	4	0	0	0	0
Patient 17	1	0	0	0	0
Patient 18	2	0	0	0	0
Patient 19	1	1	0	0	0
Patient 20	1	0	0	0	0
Patient 21	1	0	0	1	0
Patient 22	2	1	0	0	0
Patient 23	1	0	0	0	0
Patient 24	1	1	0	0	1
Patient 25	1	0	0	0	0
Total	28	7	3	2	3

Table 8: Questionnaire usage by module

The graphic in Figure 52 synthesis the above tabled values.

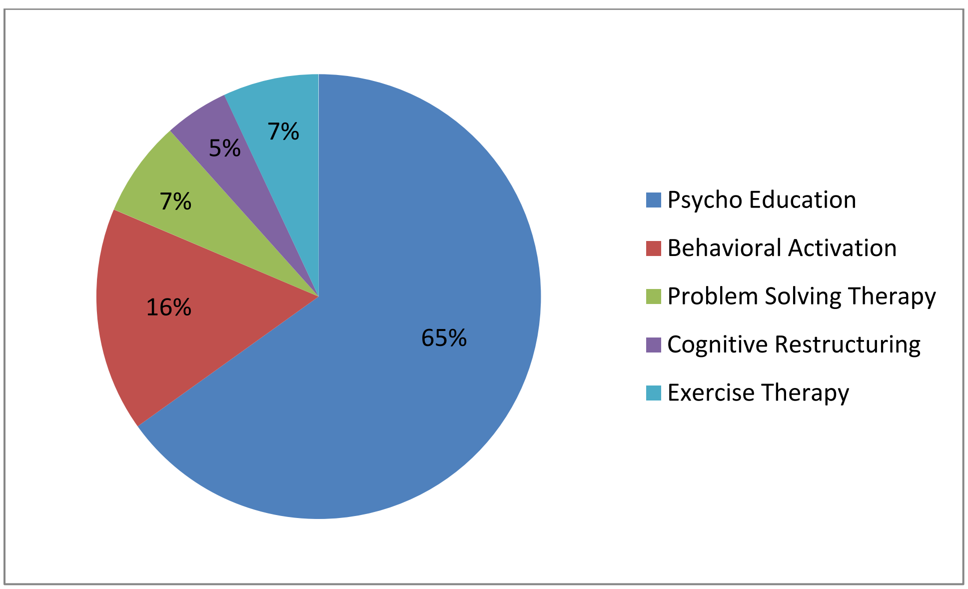


Figure 52: Questionnaires usage by module

A different perspective of the questionnaires is the view of the module completion, which is committed at end module questionnaire fulfil. Is simple to conclude that the ICT4D system allows the patients to have their own rhythm while perform the treatment.

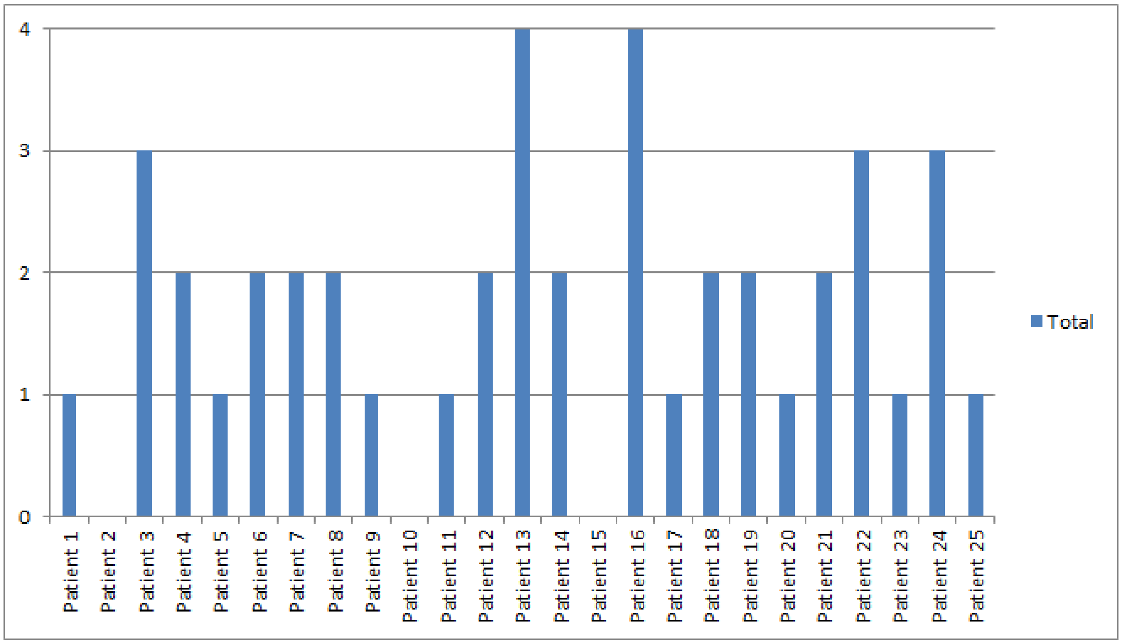


Figure 53: Number of end-module questionnaires answered per user

4.2.1.2 Ratings

The ratings are divided in six classes:

- Anxiety level;
- Self-efficacy;
- Generic mood;
- Motivation;
- Positive thoughts
- Sleeping quality.

When the deemed appropriate, the ICT4D system uses the mobile platform to remind the patient to answer to one or more rates. Then the Reasoning Engine will use these data to compose the *virtual patient* with the patient conditions.

	Web	Mobile	Total
05-11-2012	0	25	**25**
06-11-2012	0	45	**45**
07-11-2012	0	47	**47**

08-11-2012	5	49	**54**
09-11-2012	6	26	**32**
10-11-2012	10	1	**11**
11-11-2012	8	21	**29**
12-11-2012	4	43	**47**
13-11-2012	4	35	**39**
14-11-2012	6	18	**24**
15-11-2012	7	55	**62**
16-11-2012	0	54	**54**
17-11-2012	0	1	**1**
18-11-2012	0	0	**0**
19-11-2012	0	0	**0**
20-11-2012	7	0	**7**
21-11-2012	9	0	**9**
22-11-2012	18	0	**18**
23-11-2012	0	37	**37**
24-11-2012	0	0	**0**
25-11-2012	7	0	**7**
26-11-2012	7	41	**48**
27-11-2012	0	48	**48**
28-11-2012	6	0	**6**
29-11-2012	0	62	**62**
30-11-2012	0	53	**53**
01-12-2012	0	6	**6**
02-12-2012	0	37	**37**
03-12-2012	1	47	**48**
04-12-2012	0	5	**5**
Total	**105**	**756**	**861**

Table 9: Ratings by platform

The values in Table 9 reflect that even if the patient has also at hand the option to fulfil his ratings on the web platform, most of the ratings came from the mobile client. It was an option that the web solution would not include any reminder to fulfil the ratings. It is now interesting to observe the results, which are plenty perceptible from the Figure 54.

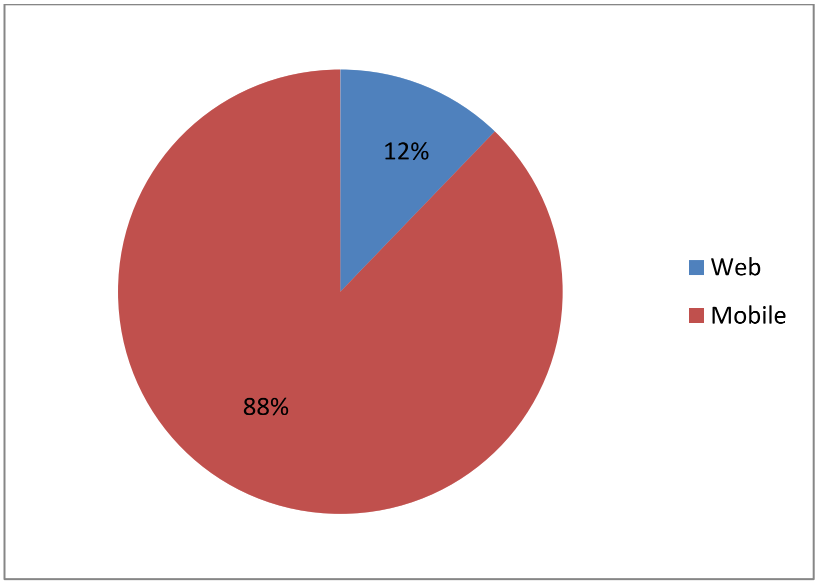


Figure 54: Ratings collected by platform

The Figure 55 shows a perspective of the temporal and used platform of rating collected values.

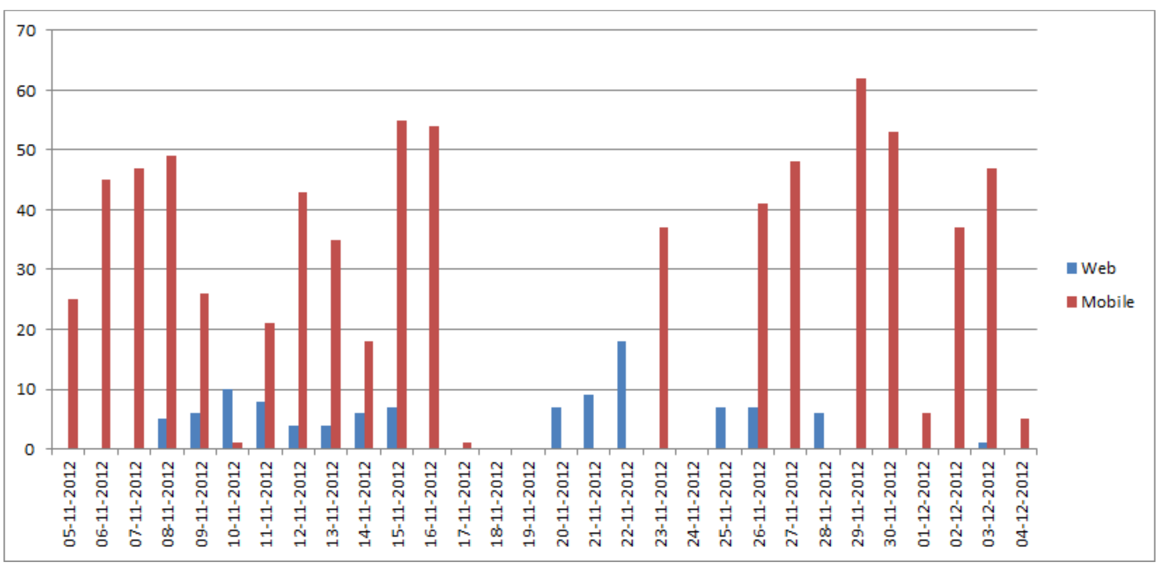


Figure 55: Ratings a day and usage by platform

Another detailed view can be found in Table 10, which shows the sum of ratings aggregated by patient.

	Web	Mobile	Total
Patient 1	0	27	27
Patient 2	0	19	19
Patient 3	0	51	51
Patient 4	7	16	23
Patient 5	0	41	41
Patient 6	0	31	31
Patient 7	0	9	9
Patient 8	18	19	37
Patient 9	6	18	24
Patient 10	0	0	0
Patient 11	0	39	39
Patient 12	0	25	25
Patient 13	4	74	78
Patient 14	0	19	19
Patient 15	0	55	55
Patient 16	0	27	27
Patient 17	0	47	47
Patient 18	0	13	13
Patient 19	63	32	95
Patient 20	0	23	23
Patient 21	0	51	51
Patient 22	0	29	29
Patient 23	0	45	45
Patient 24	7	34	41
Patient 25	0	12	12

Table 10: Ratings by patient in each platform

The Figure 56 shows the overall ratings for the considered period in analysis.

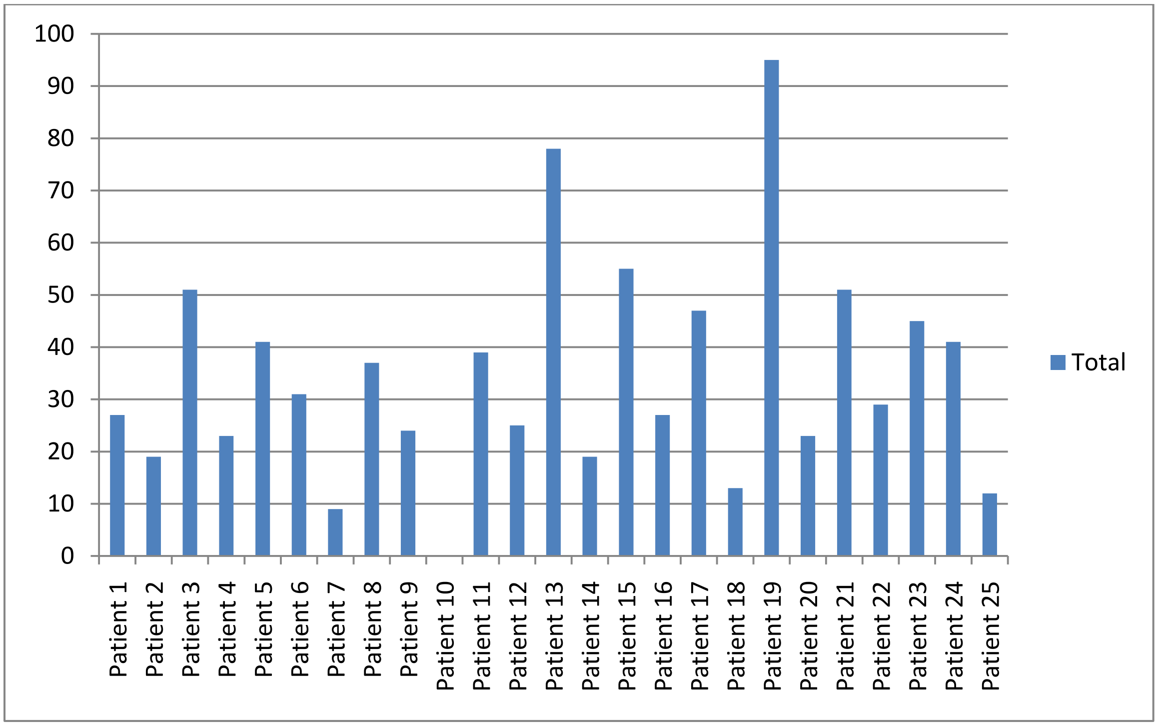


Figure 56: Ratings usage by user

4.2.1.3 Sensors

A similar approach for the sensors is presented in this section.

The Table 11 summarizes for each patient the number of reading periods – which can span more than one hour – of the sensor collected data during the first month of trials.

	Daily Activity	Activity	Breath Rate	Electrodermal Activity	Heart Rate	Total
Patient 1	7	51	4	20	2	**84**
Patient 2	6	49	2	19	0	**76**
Patient 3	7	50	18	20	15	**110**
Patient 4	3	26	7	22	2	**60**
Patient 5	5	18	8	6	5	**42**
Patient 6	11	70	27	59	8	**175**
Patient 7	3	12	4	2	3	**24**
Patient 8	8	71	9	59	1	**148**
Patient 9	3	12	0	0	0	**15**

Patient 10	0	0	0	0	0	**0**
Patient 11	9	48	14	31	4	**106**
Patient 12	5	80	6	26	4	**121**
Patient 13	13	97	10	74	2	**196**
Patient 14	6	50	5	18	0	**79**
Patient 15	6	39	7	11	2	**65**
Patient 16	8	48	7	21	4	**88**
Patient 17	6	73	4	52	0	**135**
Patient 18	7	73	11	45	1	**137**
Patient 19	5	55	17	34	0	**111**
Patient 20	8	63	20	22	7	**120**
Patient 21	5	34	22	24	18	**103**
Patient 22	6	27	14	22	2	**71**
Patient 23	9	58	3	25	0	**95**
Patient 24	5	47	6	33	3	**94**
Patient 25	3	24	3	12	0	**42**
Total	**154**	**1175**	**228**	**657**	**83**	**2297**

Table 11: Sensor usage by patient

On Figure 57 is depicted the overall periods of sensor collected data for each patient. Once again is easy to see that the same patient that didn't follow the therapeutic modules shows no adherence to wear the sensors, this including the mobile phone, which collects the Activity and Daily Activity metrics.

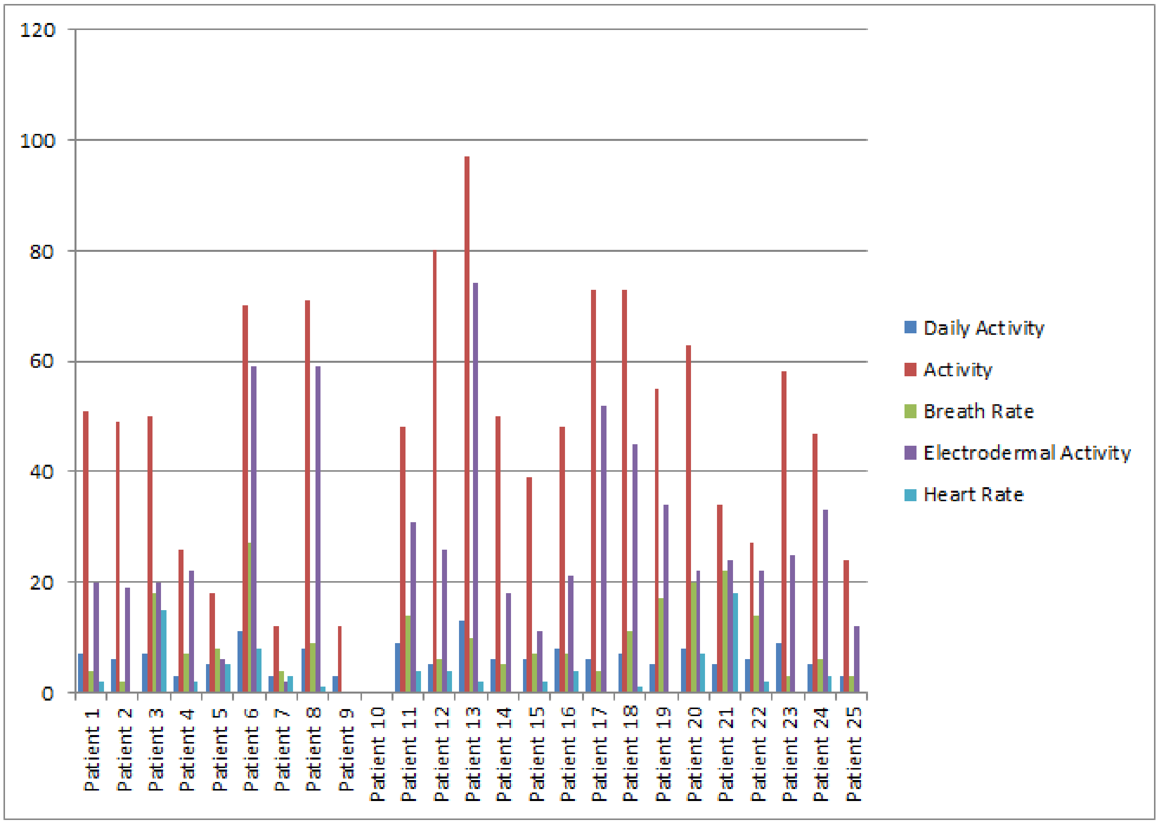


Figure 57: Sensor usage by sensor type per patient

A different perspective is the temporal distribution of sensor data collected within the period in analysis, Table 12.

	Daily Activity	Activity	Breath Rate	Electrodermal Activity	Heart Rate	Total
05-11-2012	2	15	5	13	2	**37**
06-11-2012	6	55	20	31	10	**122**
07-11-2012	4	40	15	38	8	**105**
08-11-2012	5	68	9	21	6	**109**
09-11-2012	6	33	5	19	2	**65**
10-11-2012	4	30	9	21	0	**64**
11-11-2012	8	74	9	54	2	**147**
12-11-2012	2	8	5	3	3	**21**
13-11-2012	6	53	6	31	0	**96**

14-11-2012	4	33	5	35	0	**77**
15-11-2012	9	59	20	41	10	**139**
16-11-2012	2	10	0	0	0	**12**
17-11-2012	7	68	18	56	4	**153**
18-11-2012	8	55	14	26	4	**107**
19-11-2012	6	25	1	9	0	**41**
20-11-2012	4	28	2	12	1	**47**
21-11-2012	3	23	2	13	0	**41**
22-11-2012	5	28	11	20	4	**68**
23-11-2012	8	34	17	6	11	**76**
24-11-2012	6	35	5	13	0	**59**
25-11-2012	7	51	6	14	3	**81**
26-11-2012	4	27	4	18	1	**54**
27-11-2012	4	19	5	15	3	**46**
28-11-2012	4	31	0	0	0	**35**
29-11-2012	6	60	10	27	3	**106**
30-11-2012	5	30	6	28	2	**71**
01-12-2012	6	75	10	27	3	**121**
02-12-2012	6	40	2	24	0	**72**
03-12-2012	4	34	7	31	1	**77**
04-12-2012	3	34	0	11	0	**48**
Total	**154**	**1175**	**228**	**657**	**83**	**2297**

Table 12: Sensor data collected by day

The same values help to construct the graphic in Figure 58. That perspective shows the variability across the days, including working and weekend days.

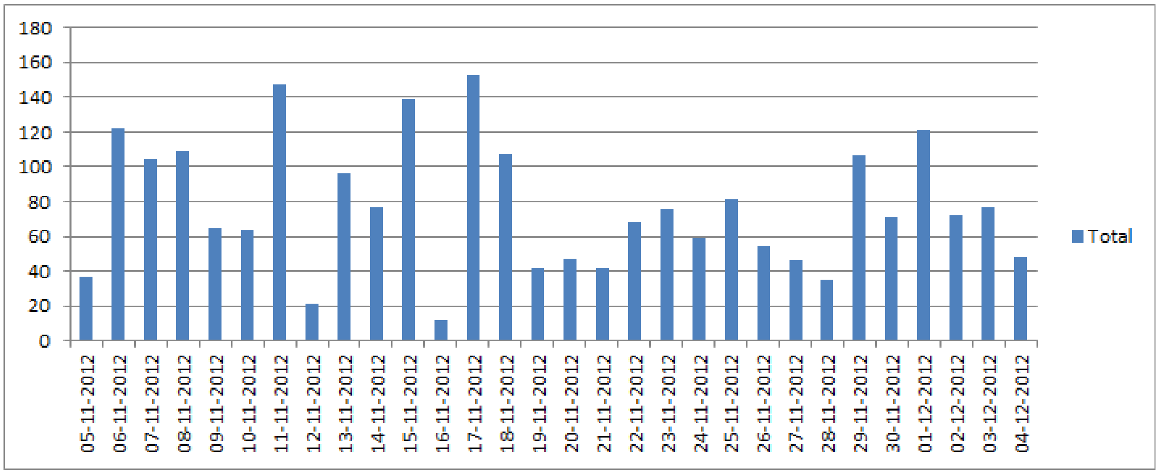


Figure 58: Sensor data collected by day

Finally Figure 59 shows the same temporal distribution considering the individual sensor classes.

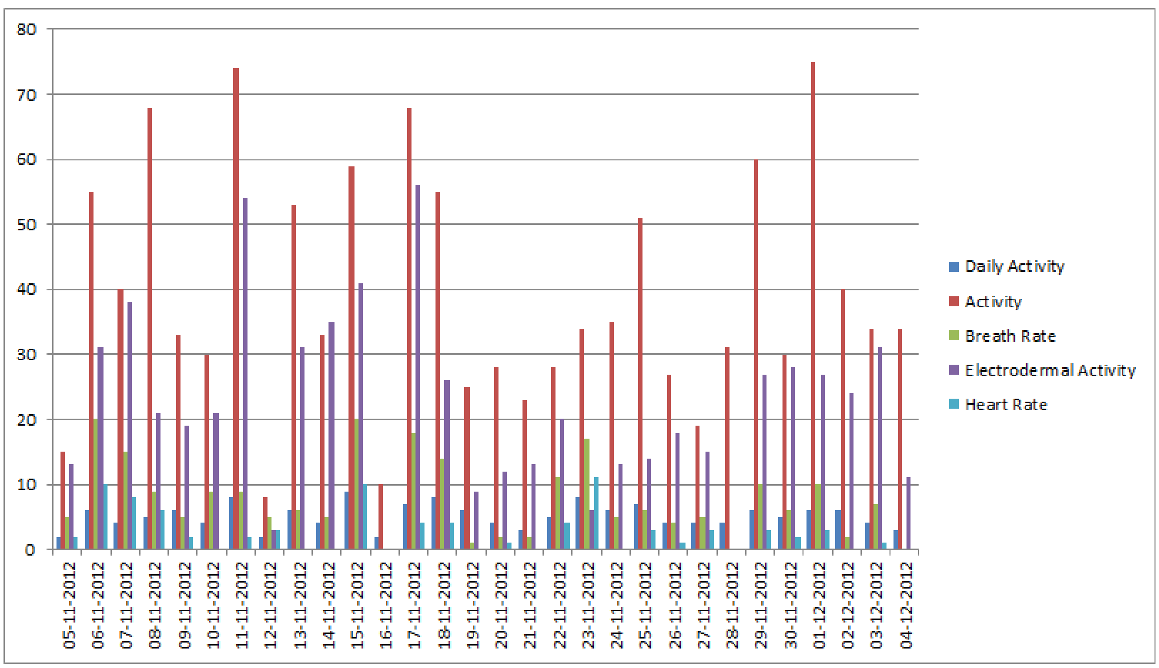


Figure 59: Sensor data collected by day per sensor class

4.2.1.4 Adherence data

The system was used by one participant. Table 13 contains the data gathered for this user whereas Figure 60 provides an overview of the data. The wireless reader was setup to

- Automatically establish a connexion with the back-end when starting up (Startup);
- Immediately transfer adherence data after the reading of data from the MEMS® (Data Transfer);
- Automatically establish a connection with the back-end 24 hours after its last connection (keep alive);

The adherence monitoring system was used during 35 days from November 5th until December 9th. The user opened the drug container usually in the morning expect on December 3rd and December 9th when the container was opened in the evening. The user did not open the vial on 7 days (4 consecutive days, followed by one skipped day, followed two consecutive days). This adherence pattern leads to an overall adherence of 80% days with correct dosing.

		Wireless Reader 20061			MEMS 287733
Date	**Day**	**Startup**	**Keep Alive**	**Data Transfer**	**Opening**
5/11/2012	MON	10:21:45 15:38:33		10:22:27/10:31:01/15:39:10/15:50:51	11:12 / 15:37
6/11/2012	TUE			9:37:59	9:37
7/11/2012	WED			1:02:16/09:06:45	9:06
8/11/2012	THU		9:00:42	10:45:25	10:44
9/11/2012	FRI		10:39:12	11:17:26	11:16
10/11/2012	SAT			9:55:04	9:54
11/11/2012	SUN		9:48:19	10:01:42	10:01
12/11/2012	MON			7:04:03	7:03
13/11/2012	TUE		6:57:53	9:43:57	9:43
14/11/2012	WED		9:38:05	9:50:37	9:50
15/11/2012	THU			7:29:40	7:29
16/11/2012	FRI		7:23:30	11:19:09	11:18
17/11/2012	SAT		11:12:27	12:28:42	12:28
18/11/2012	SUN			10:21:32	10:21
19/11/2012	MON			7:26:41	7:26
20/11/2012	TUE		7:20:36	9:48:35	9:48
21/11/2012	WED			9:25:06	9:24

22/11/2012	THU		9:19:13	11:45:13	10:51
23/11/2012	FRI			11:03:04	11:02
24/11/2012	SAT		10:56:51	12:41:52	12:41
25/11/2012	SUN			9:35:58	9:35
26/11/2012	MON		9:30:20	10:06:25	10:06
27/11/2012	TUE			9:36:25 / 22:29:46	9:36
28/11/2012	WED			8:02:20	8:01
29/11/2012	THU		7:56:05	No Transfer	No Intake
30/11/2012	FRI		7:50:18	No Transfer	No Intake
1/12/2012	SAT		7:44:32	No Transfer	No Intake
2/12/2012	SUN		7:38:50	No Transfer	No Intake
3/12/2012	MON		7:33:11	20:45:04	20:44
4/12/2012	TUE		20:39:28	No Transfer	No Intake
5/12/2012	WED			8:56:00	8:55
6/12/2012	THU		8:49:52	9:01:09	9:01
7/12/2012	FRI		8:55:11	No Transfer	No Intake
8/12/2012	SAT		8:49:33	No Transfer	No Intake
9/12/2012	SUN		8:43:53	21:49:50	21:49
10/12/2012	MON		21:44:20		

Table 13: Data recorded by the adherence monitoring system

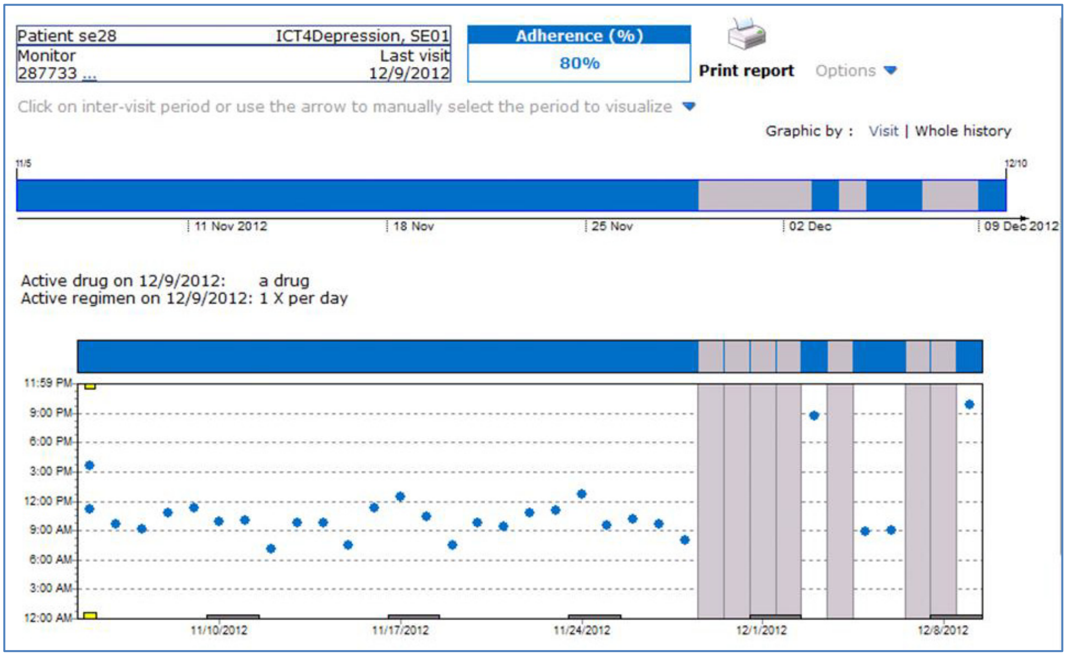


Figure 60: Visualization of the adherence data

4.2.2 Netherlands trials

In succession to the Swedish trial, VUA conducted a replication study was conducted in the Netherlands. This trial was conducted between in the first half of 2013 (January – May), and recruited 25 patients. Dutch patients activity was logged between 18-02-2013 to 31-05-2013. Details on daily usage of the ICT4Depression system are listed below.

Date	Web	Mobile	Total
18-02-2013	0	0	0
19-02-2013	8	0	8
20-02-2013	0	0	0
21-02-2013	1	0	1
22-02-2013	7	0	7
23-02-2013	0	0	0
24-02-2013	0	0	0
25-02-2013	4	0	4
26-02-2013	19	0	19
27-02-2013	14	0	14

28-02-2013	48	0	48
01-03-2013	8	0	8
02-03-2013	5	0	5
03-03-2013	0	3	3
04-03-2013	0	9	9
05-03-2013	1	0	1
06-03-2013	18	0	18
07-03-2013	11	4	15
08-03-2013	27	1	28
09-03-2013	0	0	0
10-03-2013	0	2	2
11-03-2013	45	2	47
12-03-2013	14	8	22
13-03-2013	0	5	5
14-03-2013	56	6	62
15-03-2013	30	5	35
16-03-2013	1	21	22
17-03-2013	1	0	1
18-03-2013	190	4	194
19-03-2013	38	5	43
20-03-2013	45	4	49
21-03-2013	36	12	48
22-03-2013	83	0	83
23-03-2013	59	3	62
24-03-2013	0	5	5
25-03-2013	0	0	0
26-03-2013	35	1	36
27-03-2013	0	0	0
28-03-2013	4	22	26
29-03-2013	0	15	15
30-03-2013	14	4	18
31-03-2013	133	23	156
01-04-2013	15	0	15
02-04-2013	29	27	56
03-04-2013	40	23	63
04-04-2013	9	16	25
05-04-2013	52	12	64
06-04-2013	54	18	72

07-04-2013	49	5	54
08-04-2013	43	2	45
09-04-2013	8	7	15
10-04-2013	35	0	35
11-04-2013	2	1	3
12-04-2013	0	5	5
13-04-2013	31	1	32
14-04-2013	67	24	91
15-04-2013	29	12	41
16-04-2013	14	5	19
17-04-2013	45	15	60
18-04-2013	41	5	46
19-04-2013	12	0	12
20-04-2013	15	11	26
21-04-2013	59	0	59
22-04-2013	0	3	3
23-04-2013	68	0	68
24-04-2013	0	0	0
25-04-2013	0	0	0
26-04-2013	41	17	58
27-04-2013	0	0	0
28-04-2013	0	0	0
29-04-2013	0	0	0
30-04-2013	0	1	1
01-05-2013	46	1	47
02-05-2013	1	0	1
03-05-2013	28	6	34
04-05-2013	0	0	0
05-05-2013	0	6	6
06-05-2013	15	0	15
07-05-2013	2	0	2
08-05-2013	11	7	18
09-05-2013	0	0	0
10-05-2013	0	0	0
11-05-2013	0	3	3
12-05-2013	0	0	0
13-05-2013	91	4	95
14-05-2013	0	0	0

15-05-2013	0	0	0
16-05-2013	0	0	0
17-05-2013	8	0	8
18-05-2013	0	0	0
19-05-2013	0	0	0
20-05-2013	26	0	26
21-05-2013	0	13	13
22-05-2013	0	0	0
23-05-2013	0	0	0
24-05-2013	0	0	0
25-05-2013	0	0	0
26-05-2013	0	0	0
27-05-2013	0	0	0
28-05-2013	0	0	0
29-05-2013	0	0	0
30-05-2013	0	0	0
31-05-2013	0	0	0
Total	1941	414	2355

Table 14: Daily usage

Figure 61: System daily usage depicts total daily usage (starting of new modules, exercise entry/exit pages) during the study period. Usage peaked in March, and was reasonably stable over time, although there were a few days in which no activity was recorded.

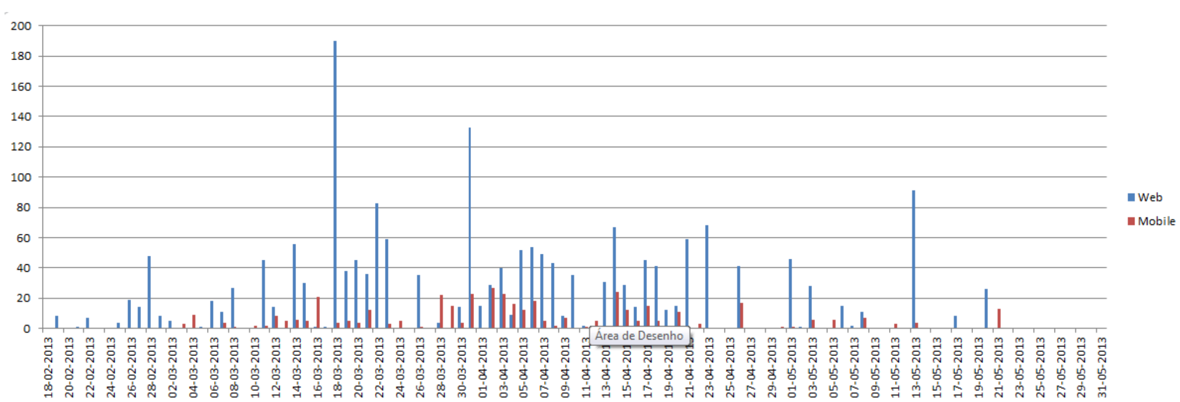


Figure 61: System daily usage

In contrast to the Swedish trial, treatment modules were used most on the Web (82%). This might be related to the fact that the Dutch trial recruited from the general community while the Swedish trial recruited studens. On average, Dutch participants were older (Mean: 47 yrs) in comparison to the Swedish sample (Mean: 24 years). Younger participants might be more experienced smartphone-users.

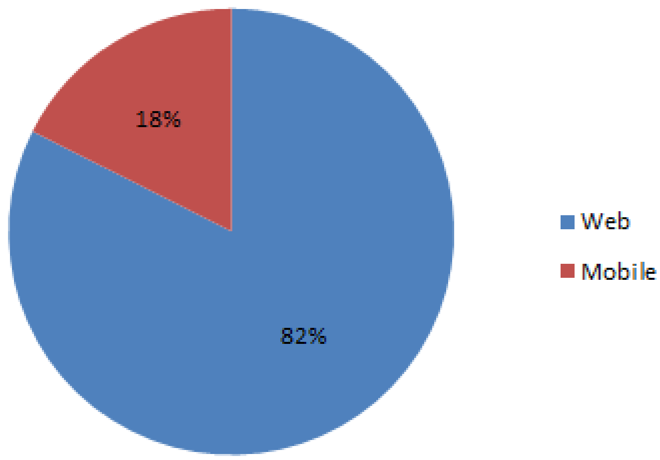


Figure 62: System usage

Closer inspection of usage patterns of individual patients reveals that about one third of the Dutch patients (8/25) used the mobile phone more for treatment module access. Four patients never accessed the treatment modules. They dropped out of the study.

	Web	Mobile	Total	Web	Mobile
Patient 26	0	0	0	0%	0%
Patient 27	14	24	38	37%	63%
Patient 28	71	5	76	93%	7%
Patient 29	118	0	118	100%	0%
Patient 30	343	24	367	93%	7%
Patient 31	33	50	83	40%	60%
Patient 32	22	28	50	44%	56%
Patient 33	71	11	82	87%	13%
Patient 34	0	0	0	0%	0%
Patient 35	104	32	136	76%	24%
Patient 36	438	40	478	92%	8%

Patient 37	33	3	36	92%	8%
Patient 38	26	32	58	45%	55%
Patient 39	24	55	79	30%	70%
Patient 40	0	0	0	0%	0%
Patient 41	430	0	430	100%	0%
Patient 42	44	2	46	96%	4%
Patient 43	3	34	37	8%	92%
Patient 44	0	33	33	0%	100%
Patient 45	23	1	24	96%	4%
Patient 46	0	2	2	0%	100%
Patient 47	68	15	83	82%	18%
Patient 48	0	0	0	0%	0%
Patient 49	76	23	99	77%	23%
Total	1941	414	2355	82%	18%

Table 15: Therapeutic modules usage by platform per patient

The graphic below shows that while Dutch patients preferred web-access, several individual patients did use the mobile interface as their primary access platform.

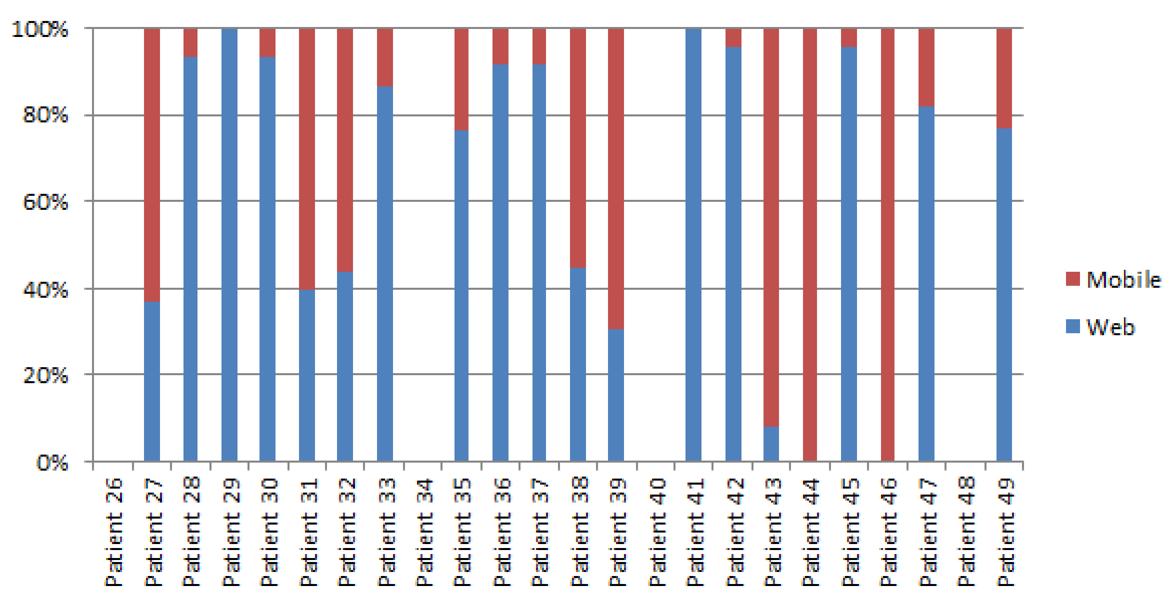


Figure 63: Therapeutic modules usage by platform per patient

Table 16 depicts usage patterns across the therapeutic modules. As in the Swedish trial, the prevention relapse module was accessed less frequently in comparison with the other therapeutic modules.

		Web	Mobile	Total
Psycho Education				
	Start Module	15	18	33
	End Module	22	0	22
	Entry Pages	93	102	195
	Exit Pages	77	79	156
	Total	207	199	406
Behavioral Activation				
	Start Module	34	3	37
	End Module	8	0	8
	Entry Pages	410	25	435
	Exit Pages	266	22	288
	Total	718	50	768
Problem Solving Therapy				
	Start Module	23	10	33
	End Module	10	0	10
	Entry Pages	230	27	257
	Exit Pages	161	28	189
	Total	424	65	489
Cognitive Restructuring				
	Start Module	30	5	35
	End Module	7	0	7
	Entry Pages	139	42	181
	Exit Pages	107	8	115
	Total	283	55	338
Exercise Therapy				
	Start Module	23	5	28
	End Module	4	0	4
	Entry Pages	139	20	159
	Exit Pages	112	20	132
	Total	278	45	323
Relapse Prevention				

	Start Module	2	0	2
	End Module	0	0	0
	Entry Pages	15	0	15
	Exit Pages	14	0	14
	Total	31	0	31

Table 16: System usage by module

Usage patterns were similar for each module, although the Behavioral Activation Module was accessed most frequently. The Dutch trial ran for a somewhat longer period in comparison to the Swedish trial, which might explain why the psychoeducation module was used less frequently by Dutch participants.

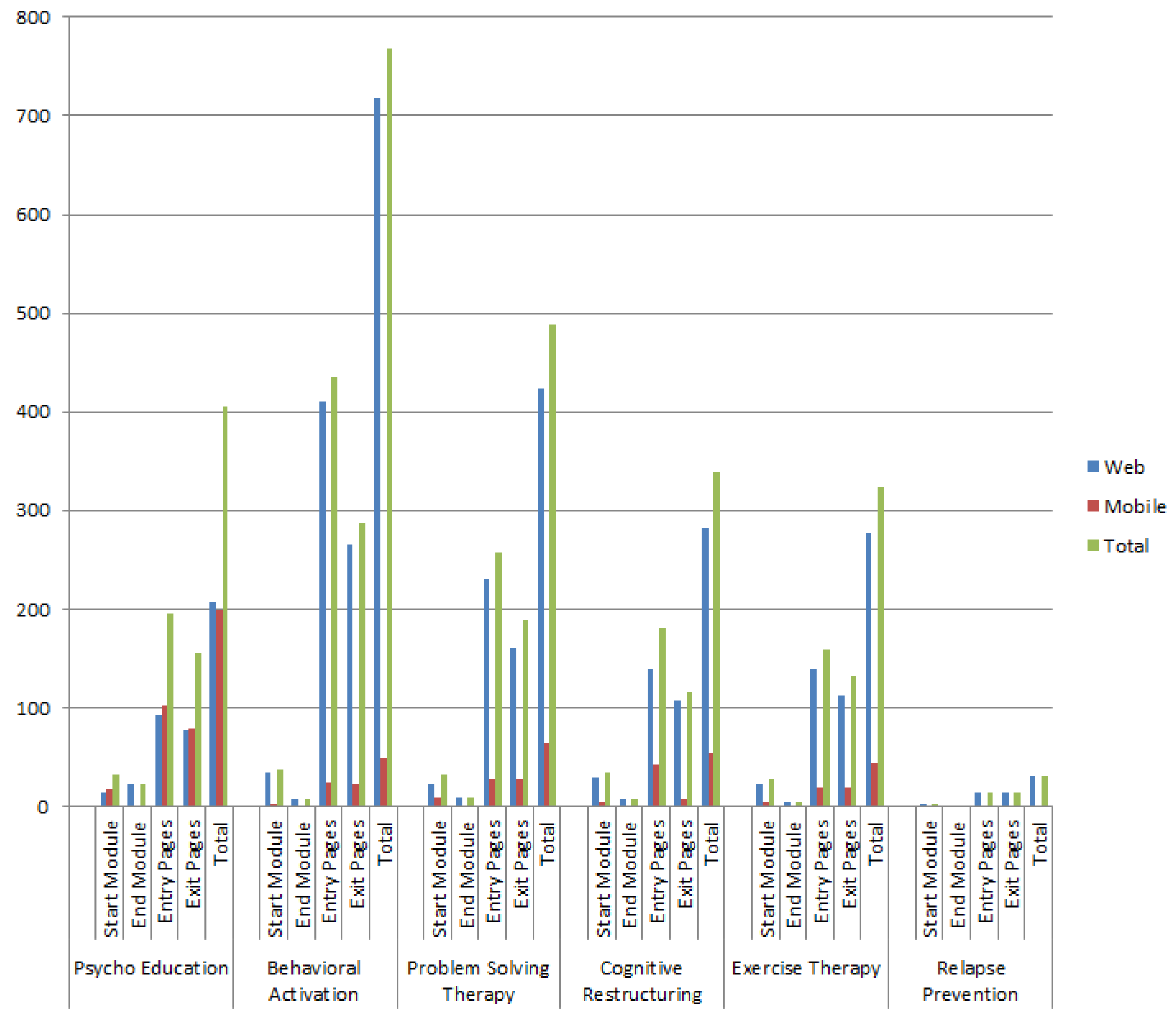


Figure 64: System usage by module

4.2.2.1 End-Module Questionnaires

During the study period, 52 end-of-module questionnaires were collected. Data collected from these assessments were used by the reasoning engine to determine the success of the treatment trajectory of the participants. Table 17 shows the dates at which the questionnaires were completed.

Date	Daily Usage

18-02-2013	0
19-02-2013	0
20-02-2013	0
21-02-2013	0
22-02-2013	0
23-02-2013	0
24-02-2013	0
25-02-2013	0
26-02-2013	2
27-02-2013	1
28-02-2013	2
01-03-2013	0
02-03-2013	0
03-03-2013	0
04-03-2013	0
05-03-2013	0
06-03-2013	1
07-03-2013	0
08-03-2013	1
09-03-2013	0
10-03-2013	0
11-03-2013	0
12-03-2013	2
13-03-2013	0
14-03-2013	2
15-03-2013	0
16-03-2013	1
17-03-2013	1
18-03-2013	1
19-03-2013	2
20-03-2013	0
21-03-2013	0
22-03-2013	1
23-03-2013	1
24-03-2013	0
25-03-2013	0
26-03-2013	0
27-03-2013	0

28-03-2013	0
29-03-2013	1
30-03-2013	1
31-03-2013	1
01-04-2013	0
02-04-2013	1
03-04-2013	1
04-04-2013	1
05-04-2013	1
06-04-2013	1
07-04-2013	0
08-04-2013	1
09-04-2013	1
10-04-2013	2
11-04-2013	0
12-04-2013	0
13-04-2013	2
14-04-2013	2
15-04-2013	1
16-04-2013	1
17-04-2013	1
18-04-2013	1
19-04-2013	0
20-04-2013	0
21-04-2013	3
22-04-2013	0
23-04-2013	0
24-04-2013	0
25-04-2013	0
26-04-2013	2
27-04-2013	0
28-04-2013	0
29-04-2013	0
30-04-2013	0
01-05-2013	1
02-05-2013	0
03-05-2013	0
04-05-2013	0

05-05-2013	0
06-05-2013	1
07-05-2013	0
08-05-2013	0
09-05-2013	0
10-05-2013	0
11-05-2013	0
12-05-2013	0
13-05-2013	5
14-05-2013	0
15-05-2013	0
16-05-2013	0
17-05-2013	0
18-05-2013	0
19-05-2013	0
20-05-2013	1
21-05-2013	0
22-05-2013	0
23-05-2013	0
24-05-2013	0
25-05-2013	0
26-05-2013	0
27-05-2013	0
28-05-2013	0
29-05-2013	0
30-05-2013	0
31-05-2013	0
Total	51

Table 17: Questionnaires daily usage

In comparison to the Swedish trial, end-of-treatment questionnaires were completed less, although more data was collected in absolute terms. This might be attributed to the lack of support in the Dutch trials. Perhaps Swedish participants might have been alerted to the importance of the questionnaires in the weekly telephone calls.

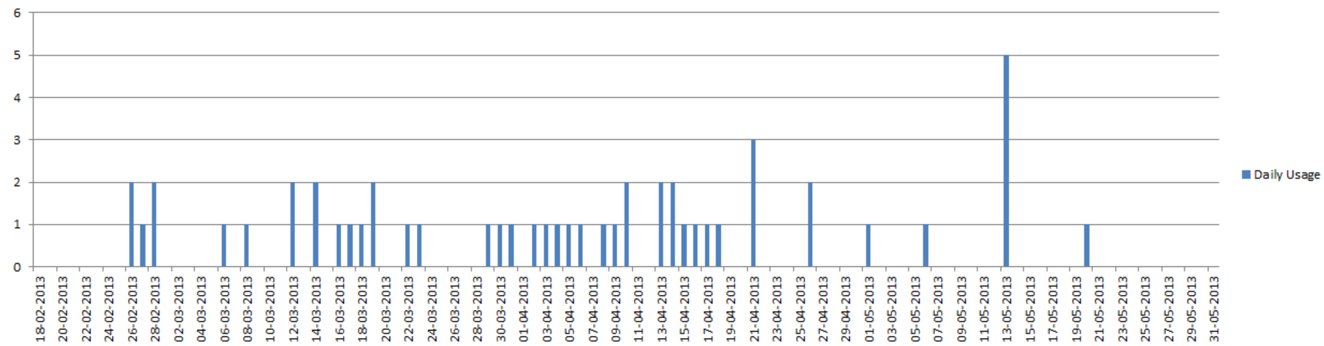


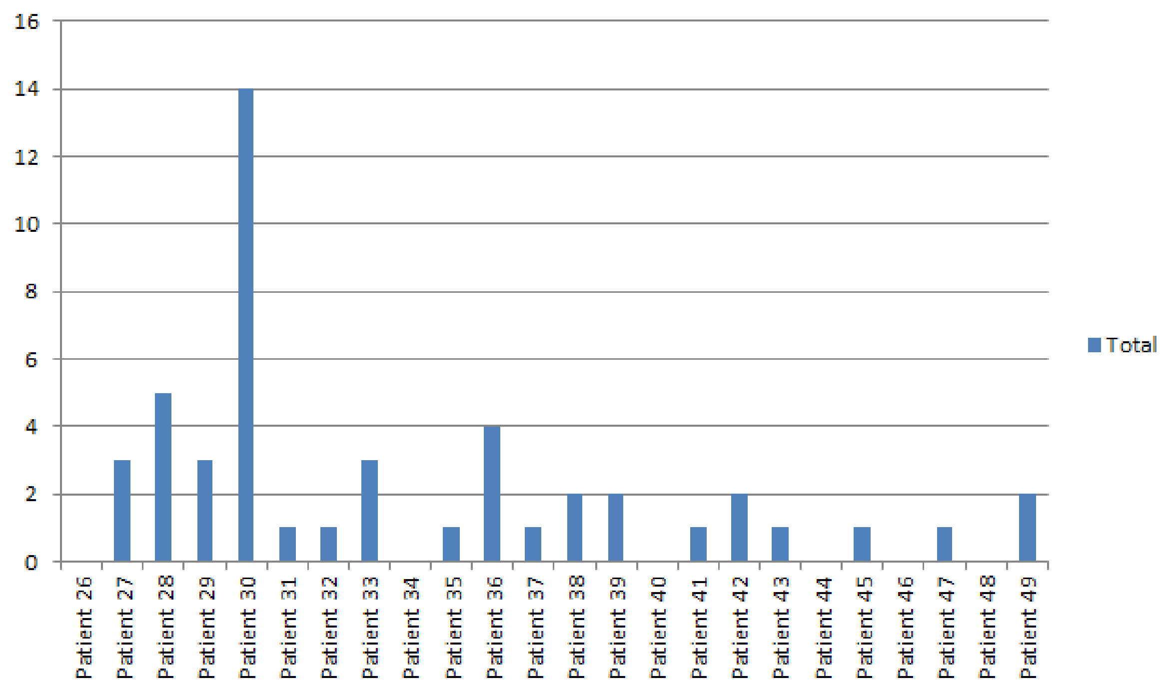
Figure 65: Questionnaire daily usage

Detailed breakdown of the end-of-module questionnaires, by patient and by questionnaire (Q1, Q2, Q3) reveals that the grand total is somewhat inflated by one patient (Patient 30). This patient completed a total of 30 questionnaires, which is substantially more in comparison to the other participants. This is most striking in the graphical depiction (below Table 18).

	Q1	Q2	Q3
Patient 26	0	0	0
Patient 27	3	3	3
Patient 28	5	5	3
Patient 29	4	3	1
Patient 30	14	14	2
Patient 31	2	1	2
Patient 32	1	1	0
Patient 33	3	3	1
Patient 34	0	0	0
Patient 35	1	1	1
Patient 36	4	4	1
Patient 37	1	1	1
Patient 38	2	2	1
Patient 39	2	2	1
Patient 40	0	0	0
Patient 41	1	1	1
Patient 42	2	2	1
Patient 43	1	1	1
Patient 44	1	1	1
Patient 45	1	1	1

Patient 46	0	0	0
Patient 47	1	1	1
Patient 48	0	0	0
Patient 49	2	2	1
Total	51	49	24

Table 18: Questionnaires usage by type



Most questionnaires (n = 22) were completed after the psycho-education module, Questionnaire completion was approximately the same in the other modules, with exception of the Exercise module, which had the lowest questionniare completion rate.

	Psycho Education	Behavioral Activation	Problem Solving Therapy	Cognitive Restructuring	Exercise Therapy
Patient 26	0	0	0	0	0
Patient 27	3	0	0	0	0
Patient 28	3	0	1	1	0
Patient 29	1	0	0	0	2
Patient 30	2	4	3	4	1
Patient 31	1	0	0	0	0

Patient 32	0	1	0	0	0
Patient 33	1	1	0	0	1
Patient 34	0	0	0	0	0
Patient 35	1	0	0	0	0
Patient 36	1	1	1	1	0
Patient 37	1	0	0	0	0
Patient 38	1	0	0	1	0
Patient 39	1	0	0	1	0
Patient 40	0	0	0	0	0
Patient 41	1	0	0	0	0
Patient 42	1	0	1	0	0
Patient 43	1	0	0	0	0
Patient 44	0	0	0	0	0
Patient 45	1	0	0	0	0
Patient 46	0	0	0	0	0
Patient 47	1	0	0	0	0
Patient 48	0	0	0	0	0
Patient 49	1	0	1	0	0
Total	22	7	7	8	4

Table 19: Questionnaire usage by module

Figure 66: Questionnaires usage by module depicts end-of-module questionnaire completion. In general, the pattern reflects the fact that the psycho education module had to be completed by all participants, and that the other modules were optional.

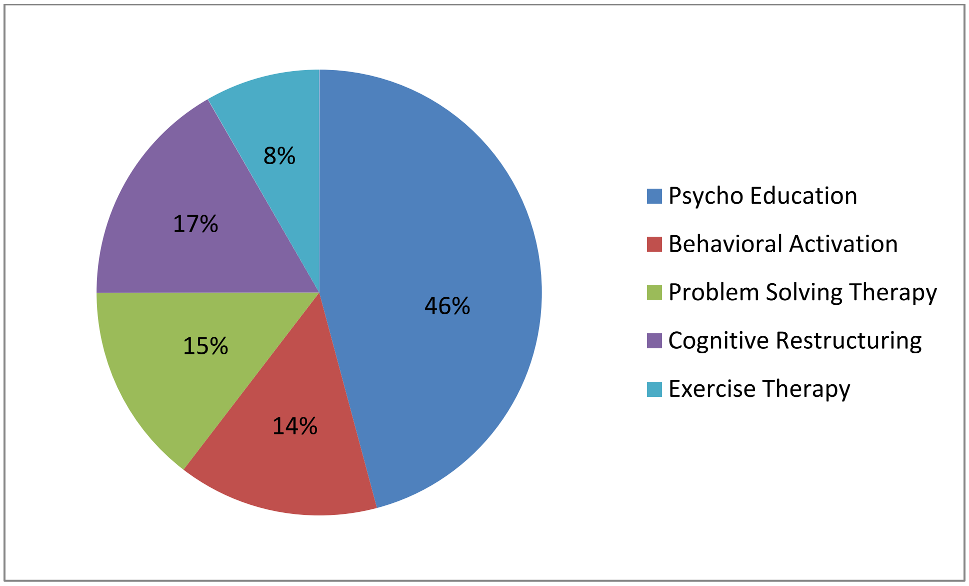


Figure 66: Questionnaires usage by module

Figure 67: Number of end-module questionnaires answered per user

4.2.2.2 Ratings

EMA ratings were succesfully collected. Dutch participants provided a total of N = 2568 EMA ratings, of which most were collected on the mobile phone (N = 2187; 85%).

	Web	Mobile	Total
18-02-2013	0	0	0
19-02-2013	0	0	0
20-02-2013	0	0	0
21-02-2013	0	0	0
22-02-2013	0	0	0
23-02-2013	0	0	0
24-02-2013	0	0	0
25-02-2013	0	0	0
26-02-2013	0	0	0
27-02-2013	0	0	0

28-02-2013	0	9	9
01-03-2013	0	0	0
02-03-2013	0	0	0
03-03-2013	0	0	0
04-03-2013	0	12	12
05-03-2013	0	17	17
06-03-2013	6	7	13
07-03-2013	6	14	20
08-03-2013	12	12	24
09-03-2013	6	3	9
10-03-2013	12	7	19
11-03-2013	4	13	17
12-03-2013	5	19	24
13-03-2013	0	26	26
14-03-2013	5	23	28
15-03-2013	6	30	36
16-03-2013	0	26	26
17-03-2013	11	27	38
18-03-2013	10	29	39
19-03-2013	4	34	38
20-03-2013	6	31	37
21-03-2013	10	37	47
22-03-2013	6	24	30
23-03-2013	5	22	27
24-03-2013	0	23	23
25-03-2013	0	35	35
26-03-2013	6	30	36
27-03-2013	0	36	36
28-03-2013	12	32	44
29-03-2013	0	2	2
30-03-2013	7	20	27
31-03-2013	6	23	29
01-04-2013	0	28	28
02-04-2013	5	39	44
03-04-2013	0	43	43
04-04-2013	10	40	50
05-04-2013	6	40	46
06-04-2013	11	41	52

07-04-2013	18	45	63
08-04-2013	10	55	65
09-04-2013	8	51	59
10-04-2013	5	43	48
11-04-2013	4	53	57
12-04-2013	4	45	49
13-04-2013	6	59	65
14-04-2013	12	40	52
15-04-2013	10	70	80
16-04-2013	15	46	61
17-04-2013	11	47	58
18-04-2013	10	34	44
19-04-2013	0	39	39
20-04-2013	14	36	50
21-04-2013	16	31	47
22-04-2013	0	40	40
23-04-2013	0	28	28
24-04-2013	0	22	22
25-04-2013	0	19	19
26-04-2013	6	23	29
27-04-2013	6	21	27
28-04-2013	0	23	23
29-04-2013	0	21	21
30-04-2013	7	24	31
01-05-2013	0	17	17
02-05-2013	0	23	23
03-05-2013	0	20	20
04-05-2013	0	15	15
05-05-2013	0	19	19
06-05-2013	0	16	16
07-05-2013	9	14	23
08-05-2013	6	15	21
09-05-2013	0	12	12
10-05-2013	0	15	15
11-05-2013	0	16	16
12-05-2013	0	8	8
13-05-2013	7	16	23
14-05-2013	0	12	12

15-05-2013	7	18	25
16-05-2013	6	14	20
17-05-2013	0	11	11
18-05-2013	0	13	13
19-05-2013	0	11	11
20-05-2013	0	14	14
21-05-2013	0	17	17
22-05-2013	0	16	16
23-05-2013	7	12	19
24-05-2013	0	11	11
25-05-2013	0	11	11
26-05-2013	0	13	13
27-05-2013	0	12	12
28-05-2013	0	9	9
29-05-2013	0	8	8
30-05-2013	0	10	10
31-05-2013	0	0	0
Total	381	2187	2568

Table 20: Ratings by platform

Figure 68 again shows that participants preferred the mobile phone to provide single-item ratings. Although this is as expected (since the app provides explicit notifications of rating requests), it is nonetheless striking since most participants used the web interface to complete the treatment modules.

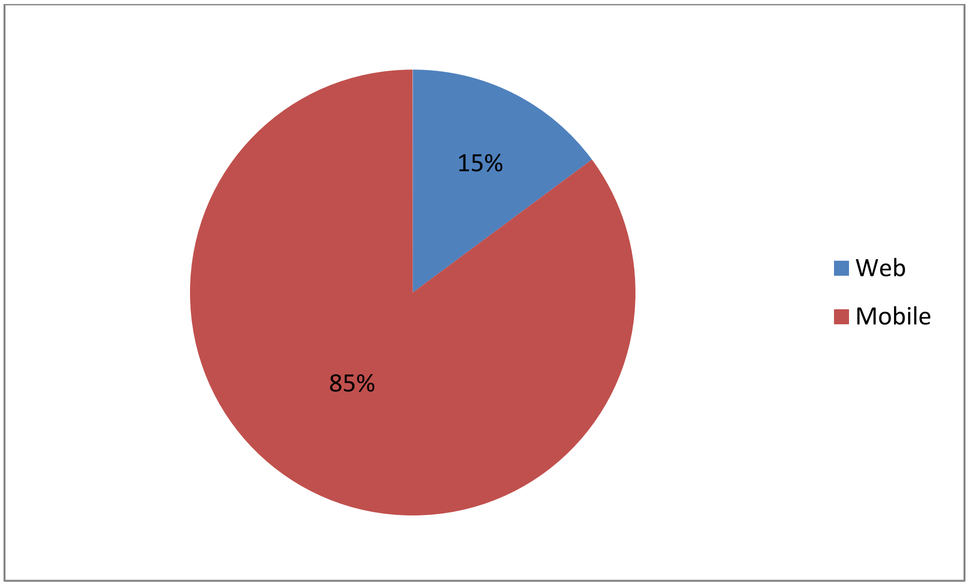


Figure 68: Ratings collected by platform

Rating frequencies over time show that ratings peaked around April 15 (at which time most participants had been granted access to the system). Overall, ratings were provided evenly across the study period, which is an indication of the stability of the system.

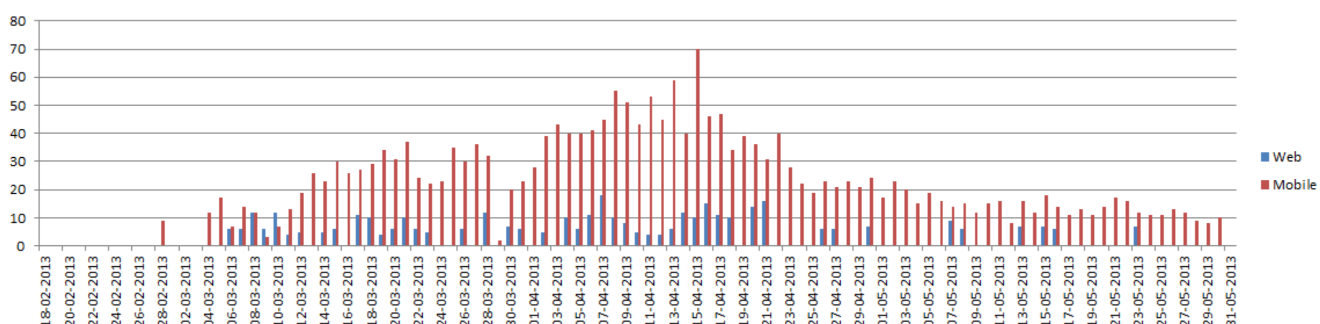


Figure 69: Ratings a day and usage by platform

Table 21 lists total n of ratings per participant. Responses varied considerably. Four participants did not provide any rating, while five patients provided over 200 ratings. On average, participants provided 107 ratings over the study period (SD: 99.7; range: 0-339).

	Web	Mobile	Total
Patient 26	0	0	0
Patient 27	32	171	203

Patient 28	5	149	154
Patient 29	0	0	0
Patient 30	28	244	272
Patient 31	16	72	88
Patient 32	6	45	51
Patient 33	0	120	120
Patient 34	0	17	17
Patient 35	30	72	102
Patient 36	0	339	339
Patient 37	0	128	128
Patient 38	5	74	79
Patient 39	0	53	53
Patient 40	0	0	0
Patient 41	121	162	283
Patient 42	10	115	125
Patient 43	60	191	251
Patient 44	0	97	97
Patient 45	0	9	9
Patient 46	0	0	0
Patient 47	0	116	116
Patient 48	0	2	2
Patient 49	68	1	69

Table 21: Ratings by patient in each platform

Figure 70 illustrates that the vast majority of participants provided at least 50 ratings during the study period. Given the intrusive nature of these ratings, this could be considered a success.

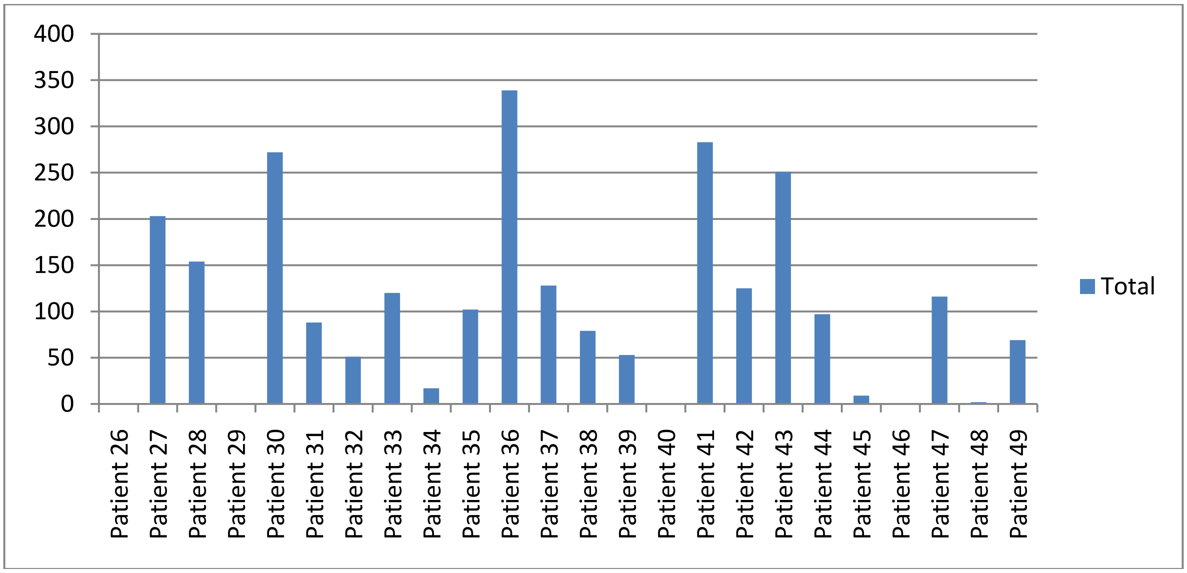


Figure 70: Ratings usage by user

4.2.2.3 Sensors

Table 22: Sensor usage by patient summarizes the number of reading periods of the sensor-collected data during the study period. With exception of the four participants that dropped out, all participants provided sensor-collected data. Most data was collected with regard to Activity (n = 910; 41% of data), while the least data was collected with regard to Daily Activity (n = 156; 5%). Both measures were collected on the mobile phone. The difference is that Activity was measured unobtrusively, while Daily Activity required explicit user input efforts.

	Daily Activity	Activity	Breath Rate	Electrodermal Activity	Heart Rate	Total
Patient 26	0	0	0	0	0	0
Patient 27	12	127	0	19	0	158
Patient 28	8	39	16	14	9	86
Patient 29	0	0	0	0	0	0
Patient 30	10	57	9	26	5	107
Patient 31	6	12	4	3	0	25
Patient 32	7	43	21	24	1	96
Patient 33	12	161	14	66	7	260
Patient 34	1	1	1	0	0	3

Patient 35	7	8	1	1	0	17
Patient 36	29	169	163	143	25	529
Patient 37	5	28	15	20	7	75
Patient 38	7	50	45	29	18	149
Patient 39	3	3	2	0	0	8
Patient 40	2	3	0	0	0	5
Patient 41	7	69	63	74	63	276
Patient 42	10	61	38	46	24	179
Patient 43	13	84	56	19	48	220
Patient 44	6	7	1	0	0	14
Patient 45	2	8	8	6	2	26
Patient 46	0	0	0	0	0	0
Patient 47	7	37	24	16	22	106
Patient 48	2	3	1	2	0	8
Patient 49	0	0	0	0	0	0
Total	156	970	482	508	231	2347

Table 22: Sensor usage by patient

Figure 71 reveals that a significant amount of sensor data was collected for 12 participants. Data collected among the other participants was less substantial.

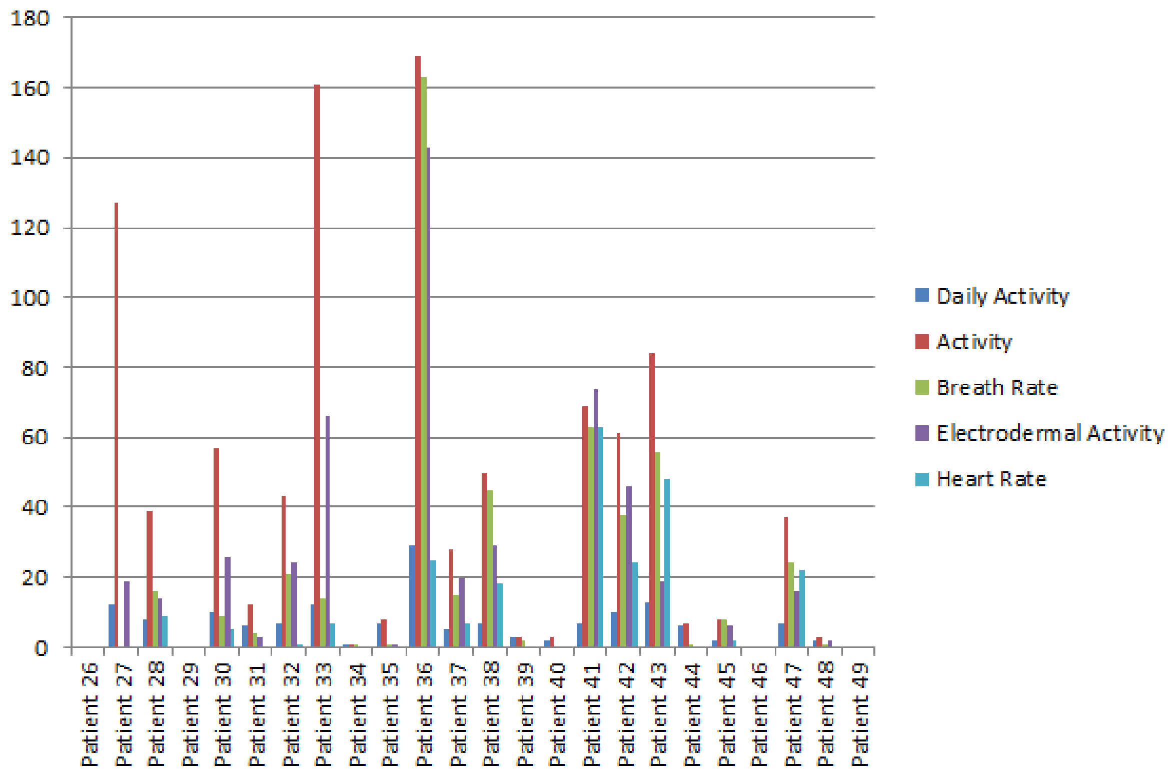


Figure 71: Sensor usage by sensor type per patient

Throughout the study period, sensor data were collected and processed, which provides an indication of system stability. Sensor data collection gradually rose and fell, in accordance with the recruitment process of the study. As the number of participants grew, the amount of sensor data increased. As more participants had finished the trial period, the amount of sensor data decreased (see also Figure 72).

	Daily Activity	Activity	Breath Rate	Electrodermal Activity	Heart Rate	Total
18-02-2013	0	0	0	0	0	**0**
19-02-2013	0	0	0	0	0	**0**
20-02-2013	1	10	2	0	0	**13**
21-02-2013	0	0	0	0	0	**0**
22-02-2013	0	0	0	0	0	**0**
23-02-2013	0	0	0	0	0	**0**
24-02-2013	0	0	0	0	0	**0**
25-02-2013	0	0	0	0	0	**0**
26-02-2013	0	0	0	0	0	**0**
27-02-2013	1	10	10	10	6	**37**

28-02-2013	1	5	2	7	0	**15**
01-03-2013	1	1	0	0	0	**2**
02-03-2013	1	1	0	0	0	**2**
03-03-2013	0	1	0	0	0	**1**
04-03-2013	1	7	8	6	2	**24**
05-03-2013	2	9	5	12	3	**31**
06-03-2013	0	0	0	0	0	**0**
07-03-2013	2	24	13	26	12	**77**
08-03-2013	2	3	0	0	0	**5**
09-03-2013	0	0	0	0	0	**0**
10-03-2013	0	0	0	0	0	**0**
11-03-2013	1	11	13	13	8	**46**
12-03-2013	3	27	22	22	15	**89**
13-03-2013	2	3	0	0	0	**5**
14-03-2013	1	12	6	11	1	**31**
15-03-2013	4	40	11	19	9	**83**
16-03-2013	2	10	8	7	1	**28**
17-03-2013	5	55	21	22	15	**118**
18-03-2013	1	1	0	0	0	**2**
19-03-2013	1	16	13	13	12	**55**
20-03-2013	1	1	0	0	0	**2**
21-03-2013	3	45	23	41	29	**141**
22-03-2013	2	30	12	26	0	**70**
23-03-2013	3	13	6	11	0	**33**
24-03-2013	0	0	0	0	0	**0**
25-03-2013	2	37	8	19	4	**70**
26-03-2013	2	11	12	11	0	**36**
27-03-2013	1	1	0	0	0	**2**
28-03-2013	4	29	15	14	1	**63**
29-03-2013	0	1	0	0	0	**1**
30-03-2013	1	1	0	0	0	**2**
31-03-2013	1	1	0	0	0	**2**
01-04-2013	4	22	8	7	1	**42**
02-04-2013	5	15	6	4	0	**30**
03-04-2013	5	32	14	5	11	**67**
04-04-2013	2	13	4	1	2	**22**
05-04-2013	1	11	0	0	0	**12**
06-04-2013	3	10	11	8	2	**34**

07-04-2013	3	36	25	33	11	**108**
08-04-2013	5	16	0	0	0	**21**
09-04-2013	3	21	26	2	13	**65**
10-04-2013	2	45	18	24	5	**94**
11-04-2013	4	46	12	12	0	**74**
12-04-2013	2	12	1	0	0	**15**
13-04-2013	2	15	12	2	11	**42**
14-04-2013	0	0	3	15	2	**20**
15-04-2013	8	40	5	11	3	**67**
16-04-2013	4	22	23	18	11	**78**
17-04-2013	3	7	3	3	0	**16**
18-04-2013	5	11	7	6	3	**32**
19-04-2013	1	13	14	8	13	**49**
20-04-2013	2	2	0	0	0	**4**
21-04-2013	2	20	10	8	9	**49**
22-04-2013	3	23	0	0	0	**26**
23-04-2013	1	11	12	10	0	**34**
24-04-2013	0	0	0	0	0	**0**
25-04-2013	2	3	0	0	0	**5**
26-04-2013	2	2	0	0	0	**4**
27-04-2013	3	17	17	16	0	**53**
28-04-2013	0	0	0	0	0	**0**
29-04-2013	1	11	0	0	0	**12**
30-04-2013	2	2	0	0	0	**4**
01-05-2013	1	1	0	0	0	**2**
02-05-2013	2	18	17	15	8	**60**
03-05-2013	2	3	5	2	0	**12**
04-05-2013	0	0	0	0	0	**0**
05-05-2013	1	11	9	0	8	**29**
06-05-2013	2	14	0	0	0	**16**
07-05-2013	1	5	0	0	0	**6**
08-05-2013	1	9	10	8	0	**28**
09-05-2013	1	1	0	0	0	**2**
10-05-2013	0	0	0	0	0	**0**
11-05-2013	0	0	0	0	0	**0**
12-05-2013	1	1	0	0	0	**2**
13-05-2013	0	0	0	0	0	**0**
14-05-2013	2	2	0	0	0	**4**

15-05-2013	0	0	0	0	0	**0**
16-05-2013	1	1	0	0	0	**2**
17-05-2013	1	1	0	0	0	**2**
18-05-2013	1	2	0	0	0	**3**
19-05-2013	2	2	0	0	0	**4**
20-05-2013	0	0	0	0	0	**0**
21-05-2013	0	0	0	0	0	**0**
22-05-2013	0	0	0	0	0	**0**
23-05-2013	2	2	0	0	0	**4**
24-05-2013	0	0	0	0	0	**0**
25-05-2013	0	0	0	0	0	**0**
26-05-2013	2	2	0	0	0	**4**
27-05-2013	0	0	0	0	0	**0**
28-05-2013	0	0	0	0	0	**0**
29-05-2013	1	1	0	0	0	**2**
30-05-2013	0	0	0	0	0	**0**
31-05-2013	0	0	0	0	0	**0**
Total	**156**	**970**	**482**	**508**	**231**	**2347**

Table 23: Sensor data collected by day

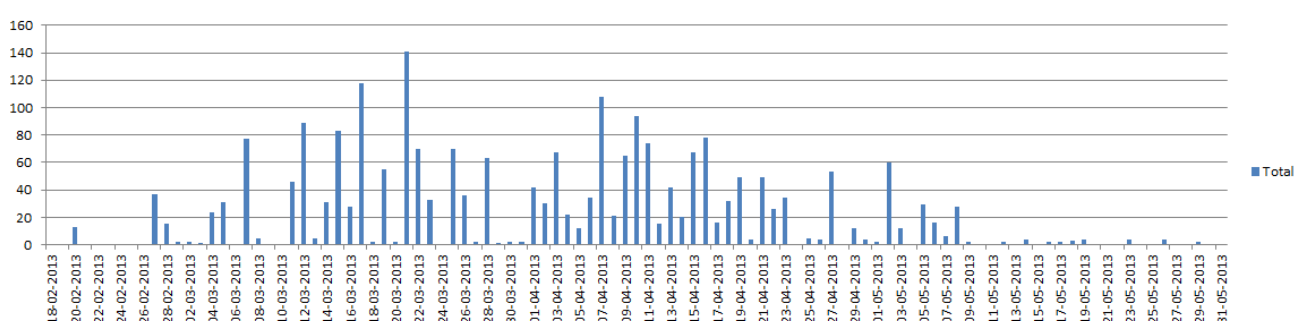


Figure 72: Sensor data collected by day

Figure 72 shows that data was collected by all sensor classes throughout the study period. Activity data was collected most frequently at all dates.

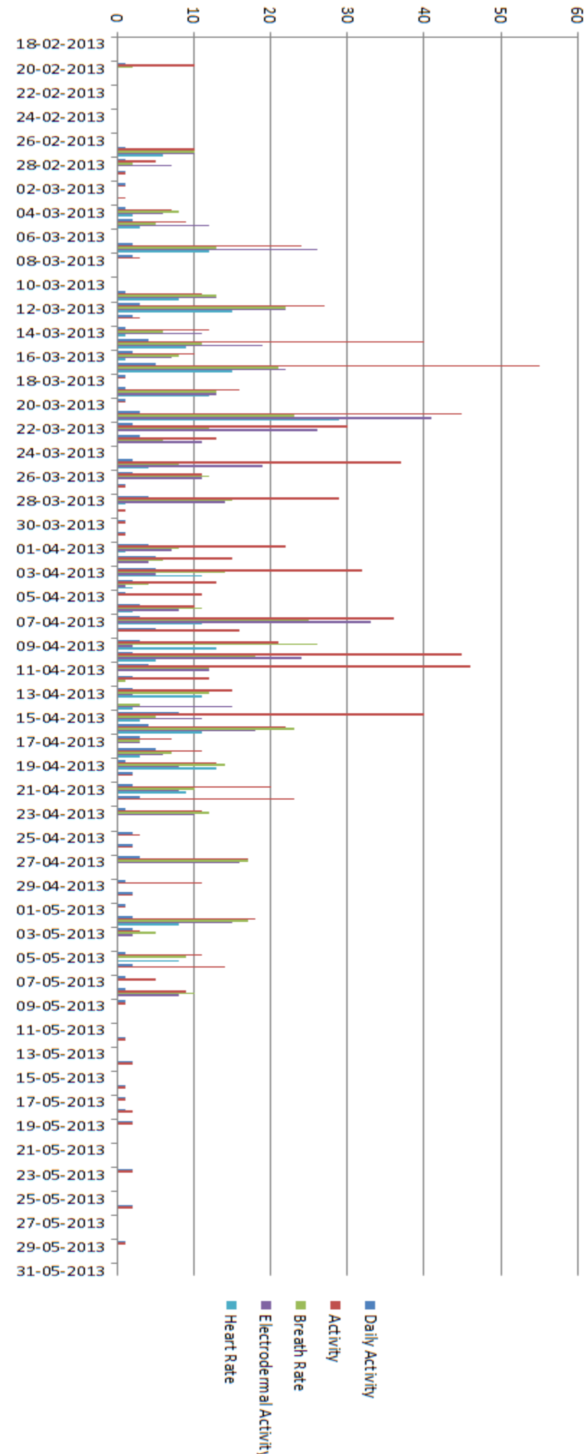


Figure 73: Sensor data collected by day per sensor class

4.2.2.4 Adherence Data

Patients were provided with a adherence monitoring system including one wireless reader and one MEMS. The MEMS is used to record the openings of the vial containing the drug whereas the wireless reader is used to transfer the adherence data to a central server.

In this setting, the wireless reader was setup to

- automatically establish a connexion with the back-end when starting up (Startup)
- immediately transfer adherence data after the reading of data from the MEMS® (Data Transfer)
- automatically establish a connection with the back-end 24 hours after its last connection (keep alive) in absence of data transfer.

The sections here below presents the data collected for the patients involved in the trials in Sweden and in the Netherlands who decided to use the adherence monitoring system.

The system was used by four participants. Below, detailed descriptions of usage patterns are provided for each of these participants.

Patient se28

Table 24 contains the data gathered for user *se28* whereas Figure 74 provides an overview of the adherence data. From Table 24, we see that the system was used as expected: the wireless reader was started on November 5th and remained active during the entire follow-up. We also observe that the absence of opening of the MEMS correlates with the absence of data transfer.

The adherence monitoring system was used during 36 days from November 5th until December 9th. The user opened the drug container usually in the morning expect on December 3rd and December 9th when the container was opened in the evening. The user did not open the vial on 7 days (4 consecutive days, followed by one skipped day, followed two consecutive days). This adherence pattern leads to an overall adherence of 80% days with correct dosing.

Figure 74. Patient *se28* : Visualization of the adherence data

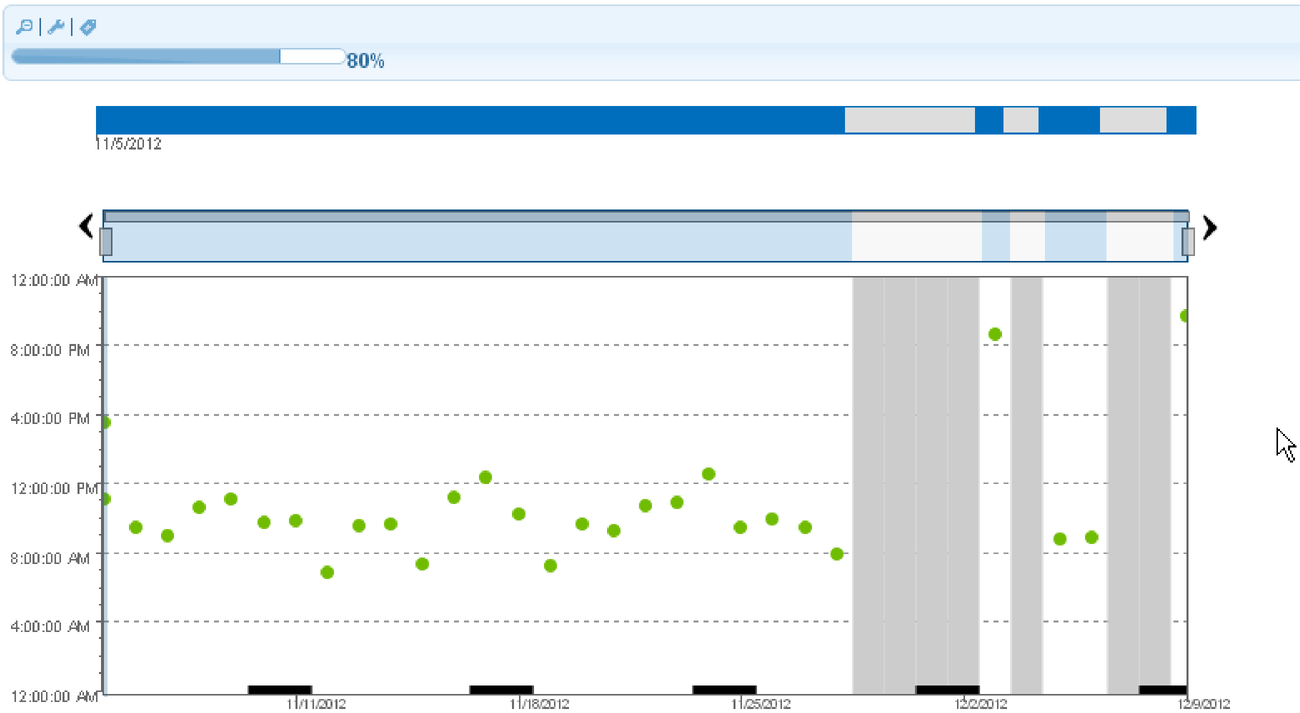


Table 24. Patient *se28* : Data recorded by the adherence monitoring system

			Wireless reader activity			MEMS activity
id	Date	Week Day	Startup	Keep Alive	Data Transfer	Intake
se28	5-Nov-2012	Mon	10:21:45/15:38:33		10:22:40/10:31:13/15:39:23/15:51:03	11:12/15:37
se28	6-Nov-2012	Tue			09:38:11	09:37
se28	7-Nov-2012	Wed			01:02:28/09:06:58	09:06
se28	8-Nov-2012	Thu		09:00:42	10:45:38	10:44
se28	9-Nov-2012	Fri		10:39:12	11:17:39	11:16
se28	10-Nov-2012	Sat			09:55:17	09:54
se28	11-Nov-2012	Sun		09:48:19	10:01:55	10:01
se28	12-Nov-2012	Mon			07:04:16	07:03
se28	13-Nov-2012	Tue		06:57:53	09:44:10	09:43
se28	14-Nov-2012	Wed		09:38:05	09:50:49	09:50
se28	15-Nov-2012	Thu			07:29:53	07:29
se28	16-Nov-2012	Fri		07:23:30	11:19:22	11:18
se28	17-Nov-2012	Sat		11:12:27	12:28:55	12:28
se28	18-Nov-2012	Sun			10:21:45	10:21
se28	19-Nov-2012	Mon			07:26:54	07:26
se28	20-Nov-2012	Tue		07:20:36	09:48:49	09:48
se28	21-Nov-2012	Wed			09:25:19	09:24
se28	22-Nov-2012	Thu		09:19:13	11:45:27	10:51
se28	23-Nov-2012	Fri			11:03:18	11:02
se28	24-Nov-2012	Sat		10:56:51	12:42:06	12:41
se28	25-Nov-2012	Sun			09:36:12	09:35
se28	26-Nov-2012	Mon		09:30:20	10:06:39	10:06
se28	27-Nov-2012	Tue			09:36:39/22:30:00	09:36
se28	28-Nov-2012	Wed			08:02:34	08:01
se28	29-Nov-2012	Thu		07:56:05	No Transfer	No Opening
se28	30-Nov-2012	Fri		07:50:18	No Transfer	No Opening
se28	1-Dec-2012	Sat		07:44:32	No Transfer	No Opening
se28	2-Dec-2012	Sun		07:38:50	No Transfer	No Opening
se28	3-Dec-2012	Mon		07:33:11	20:45:18	20:44
se28	4-Dec-2012	Tue		20:39:28	No Transfer	No Opening
se28	5-Dec-2012	Wed			08:56:14	08:55
se28	6-Dec-2012	Thu		08:49:52	09:01:23	09:01
se28	7-Dec-2012	Fri		08:55:11	No Transfer	No Opening
se28	8-Dec-2012	Sat		08:49:33	No Transfer	No Opening
se28	9-Dec-2012	Sun		08:43:53	21:50:04	21:49
se28	10-Dec-2012	Mon		21:44:20	No Transfer	No Opening

Patient nl08

Table 25 contains the data gathered for user *nl08* whereas Figure 75 provides an overview of the adherence data. From Table 25, we see that wireless reader was started on March 14th, March 21st and March 25th. It was not restarted between March 25th until May 2nd and was active as indicated by regular contacts with the back-end (keep alive). The use of the MEMS and the data transfers were regular during the first week and then became erratic.

The adherence monitoring system was used during 50 days from March 14th until May 2nd. The user opened the drug container usually in the evening. He/She was quite adherent during the first week of follow-up then only opened the vial a few occasion. This adherence pattern leads to an overall adherence of 31% days with correct dosing.

Figure 75. Patient *nl08* : Visualization of the adherence data

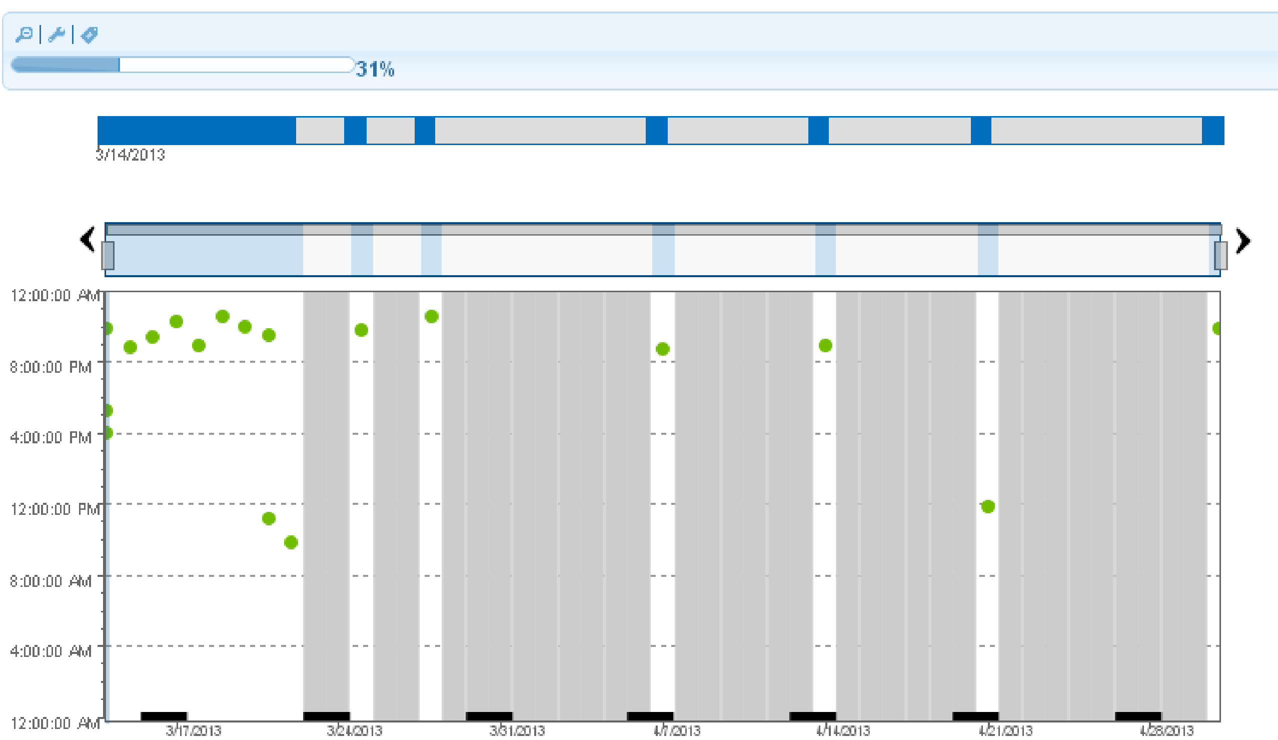


Table 25. Patient *nl08* : Data recorded by the adherence monitoring system

		Wireless reader activity			MEMS activity
Date	Day	Startup	Keep Alive	Data Transfer	Intake

14-Mar-2013	Thu	17:19:16		17:20:12/21:54:54	16:06/17:22/21:58
15-Mar-2013	Fri			20:55:29	20:58
16-Mar-2013	Sat		20:47:34	21:24:21	21:28
17-Mar-2013	Sun		21:16:46	22:20:24	22:24
18-Mar-2013	Mon			20:56:58	21:00
19-Mar-2013	Tue		20:48:45	22:38:36	22:42
20-Mar-2013	Wed			21:59:32	22:03
21-Mar-2013	Thu	15:10:51		15:11:45/21:30:53	11:20/21:34
22-Mar-2013	Fri			No Transfer	09:59
23-Mar-2013	Sat			No Transfer	No Opening
24-Mar-2013	Sun			No Transfer	No Opening
25-Mar-2013	Mon	21:49:32		21:50:28	21:52
26-Mar-2013	Tue		21:43:17	No Transfer	No Opening
27-Mar-2013	Wed		21:36:05	No Transfer	No Opening
28-Mar-2013	Thu		21:28:56	22:32:58	22:37
29-Mar-2013	Fri		22:25:36	No Transfer	No Opening
30-Mar-2013	Sat		22:18:30	22:24:34	No Opening
31-Mar-2013	Sun			22:43:33	No Opening
1-Apr-2013	Mon		22:36:29	No Transfer	No Opening
2-Apr-2013	Tue			21:01:15	No Opening
3-Apr-2013	Wed		20:53:40	No Transfer	No Opening
4-Apr-2013	Thu		20:46:31	No Transfer	No Opening
5-Apr-2013	Fri		20:39:25	No Transfer	No Opening
6-Apr-2013	Sat		20:32:22	22:28:47	No Opening
7-Apr-2013	Sun			20:45:28	20:49
8-Apr-2013	Mon		20:38:03	No Transfer	No Opening
9-Apr-2013	Tue		20:30:51	No Transfer	No Opening
10-Apr-2013	Wed		20:23:40	21:57:29	No Opening
11-Apr-2013	Thu		21:49:55	No Transfer	No Opening
12-Apr-2013	Fri		21:42:33	No Transfer	No Opening
13-Apr-2013	Sat		21:35:10	23:04:02	No Opening
14-Apr-2013	Sun			20:57:05	21:01
15-Apr-2013	Mon		20:49:16	No Transfer	No Opening
16-Apr-2013	Tue		20:41:45	22:36:39	No Opening
17-Apr-2013	Wed			21:48:45	No Opening
18-Apr-2013	Thu		21:40:15	No Transfer	No Opening
19-Apr-2013	Fri		21:32:53	No Transfer	No Opening
20-Apr-2013	Sat		21:25:39	No Transfer	No Opening
21-Apr-2013	Sun			11:53:54	11:58
22-Apr-2013	Mon		11:46:05	No Transfer	No Opening
23-Apr-2013	Tue		11:38:45	No Transfer	No Opening
24-Apr-2013	Wed		11:31:20	No Transfer	No Opening
25-Apr-2013	Thu		11:23:48	No Transfer	No Opening
26-Apr-2013	Fri		11:16:10	No Transfer	No Opening

27-Apr-2013	Sat		11:08:52	No Transfer	No Opening
28-Apr-2013	Sun		11:01:38	18:59:07	No Opening
29-Apr-2013	Mon		18:50:56	No Transfer	No Opening
30-Apr-2013	Tue		18:43:42	No Transfer	No Opening
1-May-2013	Wed		18:36:27	21:52:34	21:57
2-May-2013	Thu		21:45:12	No Transfer	No Opening

Patient nl13

Table 26 contains the data gathered for user *nl13* whereas Figure 76 provides an overview of the adherence data. From Table 26, we see that wireless reader was started on many occasions. During the first part of the follow-up it was started just before each data transfer. It was then started on April 26th and remained active until the end of the monitoring as indicated by regular contacts with the back-end (keep alive).

The adherence monitoring system was used during 33 days from April 4th until May 6th. The user opened the drug container usually around midnight. This adherence pattern leads to an overall adherence of 59% days with correct dosing but the fact that the intakes takes place around midnight tends to underestimate the adherence level. In this case, defining the change of the day later during the night or analysing interdose intervals would probably be more appropriate.

Figure 76. Patient *nl13* : Visualization of the adherence data

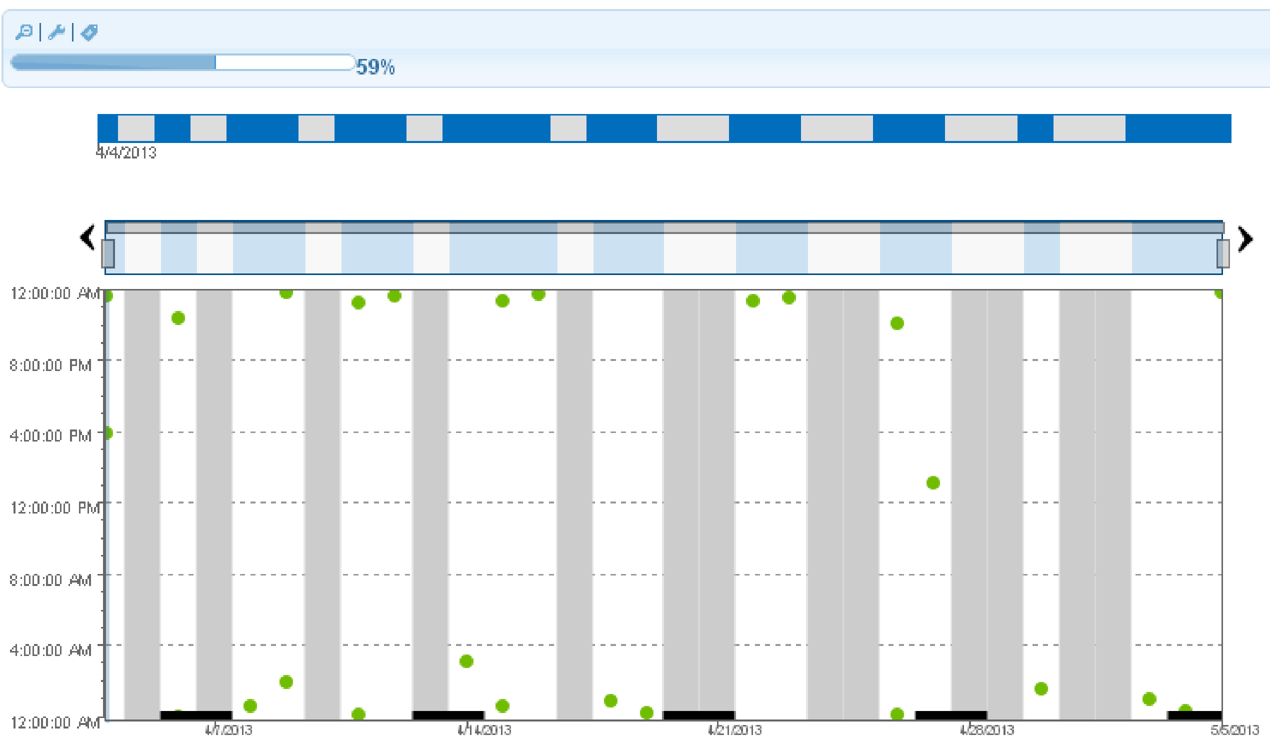


Table 26. Patient *nl13* : Data recorded by the adherence monitoring system

		Wireless reader activity			MEMS activity
Date	**Day**	**Startup**	**Keep Alive**	**Data Transfer**	**Intake**
4-Apr-2013	Thu	16:03:47/23:44:07		16:04:43	16:04/23:44
5-Apr-2013	Fri			No Transfer	No Opening
6-Apr-2013	Sat	00:11:48/22:25:34		No Transfer	00:12/22:26
7-Apr-2013	Sun			No Transfer	No Opening
8-Apr-2013	Mon	00:46:58		No Transfer	00:47
9-Apr-2013	Tue	02:05:19/23:51:43		02:06:12/23:52:36	02:06/23:52
10-Apr-2013	Wed			No Transfer	No Opening
11-Apr-2013	Thu	00:16:57/23:22:59		00:17:51/23:23:52	00:15/23:21
12-Apr-2013	Fri	23:41:44		23:42:38	23:40
13-Apr-2013	Sat			No Transfer	No Opening
14-Apr-2013	Sun	03:14:30		03:15:24	03:13
15-Apr-2013	Mon	00:45:15/23:26:26		00:46:09/23:27:18	00:44/23:25
16-Apr-2013	Tue	16:22:21		16:23:15/23:45:02	23:46
17-Apr-2013	Wed		23:35:06	No Transfer	No Opening
18-Apr-2013	Thu			01:03:55	01:05
19-Apr-2013	Fri	00:22:18		00:23:12	00:21
20-Apr-2013	Sat			No Transfer	No Opening
21-Apr-2013	Sun			No Transfer	No Opening
22-Apr-2013	Mon	23:26:29		23:27:22	23:25
23-Apr-2013	Tue	23:37:02		23:37:59	23:36
24-Apr-2013	Wed			No Transfer	No Opening
25-Apr-2013	Thu			No Transfer	No Opening
26-Apr-2013	Fri	00:15:45/22:09:39		00:16:40/22:10:36	00:15/22:09
27-Apr-2013	Sat			13:18:30	13:17
28-Apr-2013	Sun		13:09:02	No Transfer	No Opening
29-Apr-2013	Mon		12:59:59	No Transfer	No Opening
30-Apr-2013	Tue			01:42:39	01:44
1-May-2013	Wed		01:33:26	No Transfer	No Opening
2-May-2013	Thu		01:24:38	No Transfer	No Opening
3-May-2013	Fri			01:09:04	01:11
4-May-2013	Sat			00:27:46	00:29
5-May-2013	Sun		00:17:46	23:51:38	23:53
6-May-2013	Mon		23:41:29	No Transfer	No Opening

Patient nl110

Table 27 contains the data gathered for user *nl110* whereas Table 27 provides an overview of the adherence data. From Table 27, we see that wireless reader was started every days just before the data transfer which is not the expected way of using the reader

The adherence monitoring system was used during 79 days from March 15th until June 1st. The user opened the drug container every day around 8:00AM except on April 6th. This adherence pattern leads to an overall adherence of 99% days with correct dosing.

Figure 77. Patient *nl110* : Visualization of the adherence data

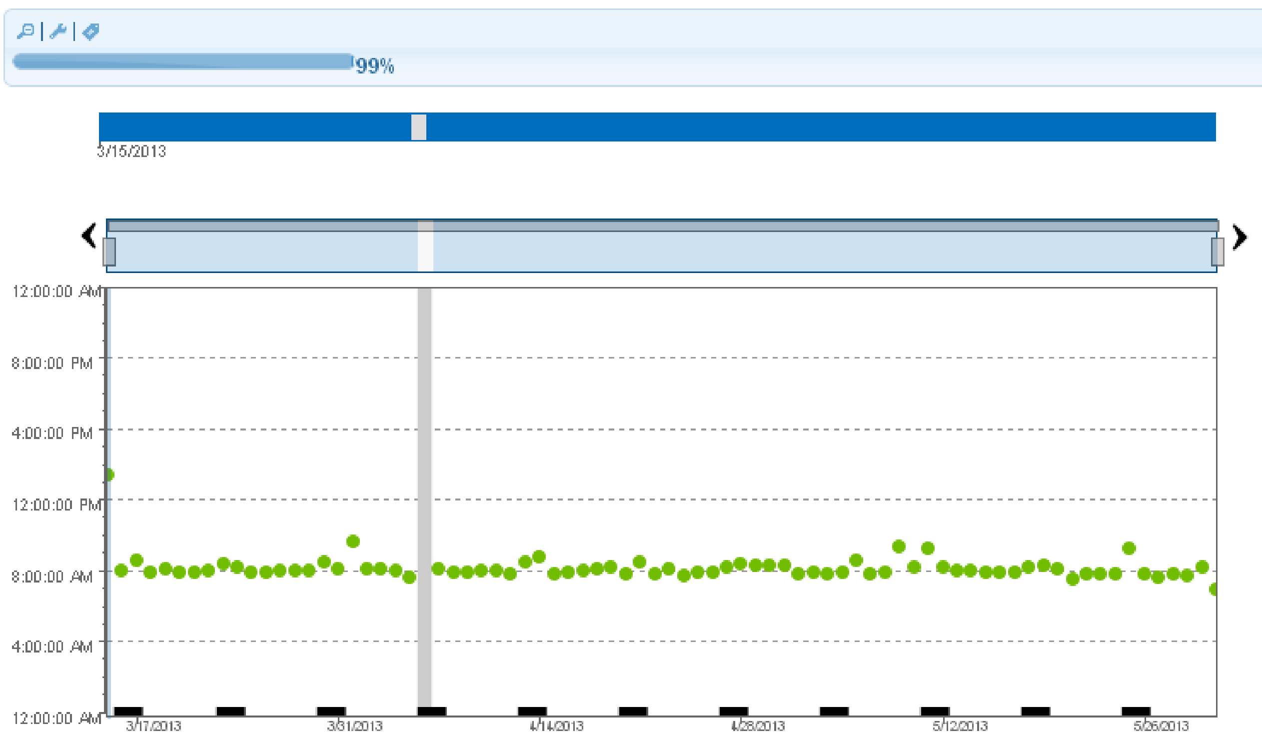


Table 27. Patient *nl110* : Data recorded by the adherence monitoring system

		Wireless reader activity			MEMS activity
Date	**Day**	**Startup**	**Keep Alive**	**Data Transfer**	**Intake**
15-Mar-2013	Fri	13:36:35		13:37:29/13:38:17	13:34
16-Mar-2013	Sat	23:46:18		No Transfer	08:10
17-Mar-2013	Sun	09:27:53		09:28:46	08:46
18-Mar-2013	Mon	22:39:17		22:40:13	08:03

19-Mar-2013	Tue	08:18:43		08:19:37	08:16
20-Mar-2013	Wed	08:08:10		08:09:05	08:05
21-Mar-2013	Thu	08:05:52		08:06:45	08:04
22-Mar-2013	Fri	08:15:41		08:18:36	08:12
23-Mar-2013	Sat	12:05:59		12:06:53	08:32
24-Mar-2013	Sun	08:24:57		08:25:51	08:23
25-Mar-2013	Mon	08:04:18		08:05:14	08:02
26-Mar-2013	Tue	08:03:19		08:04:13	08:01
27-Mar-2013	Wed	08:09:46		08:10:47	08:08
28-Mar-2013	Thu	08:13:26		08:14:22	08:11
29-Mar-2013	Fri	08:12:49		08:13:43	08:10
30-Mar-2013	Sat	08:39:23		08:40:17	08:37
31-Mar-2013	Sun	13:21:06		13:22:02	08:18
1-Apr-2013	Mon	09:47:43		09:48:37	09:45
2-Apr-2013	Tue	08:18:08		08:19:05	08:16
3-Apr-2013	Wed	08:19:01		08:19:55	08:15
4-Apr-2013	Thu	11:07:23		11:08:30	08:11
5-Apr-2013	Fri	07:51:19		07:52:15	07:49
6-Apr-2013	Sat	08:25:25		08:26:22	No Opening
7-Apr-2013	Sun	08:17:33		08:18:27	08:15
8-Apr-2013	Mon	08:07:47		08:08:42	08:05
9-Apr-2013	Tue	08:03:36		08:04:33	08:02
10-Apr-2013	Wed	08:14:19		08:15:15	08:12
11-Apr-2013	Thu	08:14:29		08:15:24	08:11
12-Apr-2013	Fri	08:03:27		08:04:23	07:59
13-Apr-2013	Sat	08:42:30		08:43:27	08:38
14-Apr-2013	Sun	09:21:39		09:22:38	08:56
15-Apr-2013	Mon	08:00:52		08:01:50	07:57
16-Apr-2013	Tue	08:08:45		08:09:43	08:05
17-Apr-2013	Wed	08:10:59		08:11:57	08:07
18-Apr-2013	Thu	08:18:29		08:19:26	08:14
19-Apr-2013	Fri	08:25:17		08:26:16	08:22
20-Apr-2013	Sat	08:03:31		08:04:29	08:00
21-Apr-2013	Sun	08:42:20		08:43:24	08:39
22-Apr-2013	Mon	08:02:13		08:03:11	07:58
23-Apr-2013	Tue	08:16:40		08:17:39	08:13
24-Apr-2013	Wed	07:55:57		07:56:54	07:53
25-Apr-2013	Thu	08:04:29		08:05:27	08:01
26-Apr-2013	Fri	08:07:29		08:08:28	08:03
27-Apr-2013	Sat	08:26:23		08:27:22	08:22
28-Apr-2013	Sun	08:36:13		08:37:12	08:31
29-Apr-2013	Mon	08:32:00		08:32:58	08:28
30-Apr-2013	Tue	08:27:38		08:28:37	08:25
1-May-2013	Wed	08:32:48		08:33:46	08:28

2-May-2013	Thu	08:03:27		08:04:27	08:00
3-May-2013	Fri	08:04:24		08:05:23	08:02
4-May-2013	Sat	07:59:17		08:00:15	07:56
5-May-2013	Sun	08:38:17		08:39:14	08:04
6-May-2013	Mon	08:47:26		08:48:24	08:43
7-May-2013	Tue	08:04:06		08:05:04	08:00
8-May-2013	Wed	08:04:41		08:05:40	08:01
9-May-2013	Thu	09:36:43		09:37:42	09:33
10-May-2013	Fri	08:28:09		08:29:09	08:24
11-May-2013	Sat	09:31:08		09:32:09	09:27
12-May-2013	Sun	08:26:53		08:27:50	08:23
13-May-2013	Mon	08:11:11		08:12:11	08:07
14-May-2013	Tue	08:11:10		08:12:10	08:08
15-May-2013	Wed	08:09:04		08:10:05	08:05
16-May-2013	Thu	08:06:02		08:07:03	08:02
17-May-2013	Fri	08:08:26		08:09:26	08:05
18-May-2013	Sat	08:24:58		08:26:02	08:22
19-May-2013	Sun	08:29:45		08:30:45	08:27
20-May-2013	Mon	08:16:54		08:17:55	08:14
21-May-2013	Tue	07:44:39		07:45:41	07:41
22-May-2013	Wed	08:02:51		08:03:55	07:59
23-May-2013	Thu	08:03:54		08:04:57	08:00
24-May-2013	Fri	08:03:25		08:04:26	08:00
25-May-2013	Sat	09:26:02		09:27:03	09:22
26-May-2013	Sun	08:39:08		08:40:11	08:00
27-May-2013	Mon			No Transfer	07:48
28-May-2013	Tue	07:59:34		08:00:36	07:56
29-May-2013	Wed	07:58:04		07:59:07	07:54
30-May-2013	Thu	08:26:10		08:27:15	08:22
31-May-2013	Fri	07:18:22		07:19:24	07:09
1-Jun-2013	Sat			No Transfer	No Opening

4.3 Biomedical sensors data

The biomedical sensors were developed considering the free-living environment, the patient as the center of the care, and having the therapy process in mind. Throughout the course of the project, PLUX has successfully addressed issues such as patient comfort and non-intrusiveness, while maintaining the quality of the signals, data integrity, low power consumption and miniaturization. Two novel devices, a chest strap and glove, for long-term biomedical data acquisition were created to measure heart rate, physical activity, respiration, and electrodermal activity. Both devices are fully functional and market-ready for specialty application (we refer the reader to D6.5 for additional details on this aspect). The work performed during the project allowed these devices differentiate quite substantially from the commercially available systems; some of the technical features include the access to raw signals, data acquisition at high sampling rates (up to 1000Hz), a high level of integration, and wearability associated with miniaturized devices.

The chest strap device integrates a shoulder loop, which is not found in off-the-shelf devices (e.g. POLAR; Vital Jacket), and prevents the device from sliding down the trunk when used for long term monitoring. Furthermore, existing devices possess a more limited number of monitored parameters, do not provide access to raw data, and/or are designed for short-term use in sports or leisure activities. The glove is a unique piece by itself, but the developments in terms of dry electrodes for electrodermal activity monitoring, and the novel dual-emitter reflective blood volume pulse sensor for heart rate monitor, completely distinguishes it from currently available technologies, which require multiple accessories to provide the same measurements and are more intrusive for the subject (NONIN Medical; Tough Technologies).

At software level, the developments on the interface of the devices with the Android operating system, has clearly extended the current state-of-the-art in mobile personal monitoring technologies. Furthermore, new algorithms for real-time, digital signal processing of heart rate and electrodermal activity signals were also developed in order to feed the ICT4Depression system with measurements regarding heart rate variability and electrodermal activity events.

5 Analysis of Results

5.1 System Architecture Analysis

The adopted Service Oriented Architecture (SOA) in ICT4Depression project has proven to be appropriate to apply the scenarios defined in the deliverables D2.1 and D4.1.

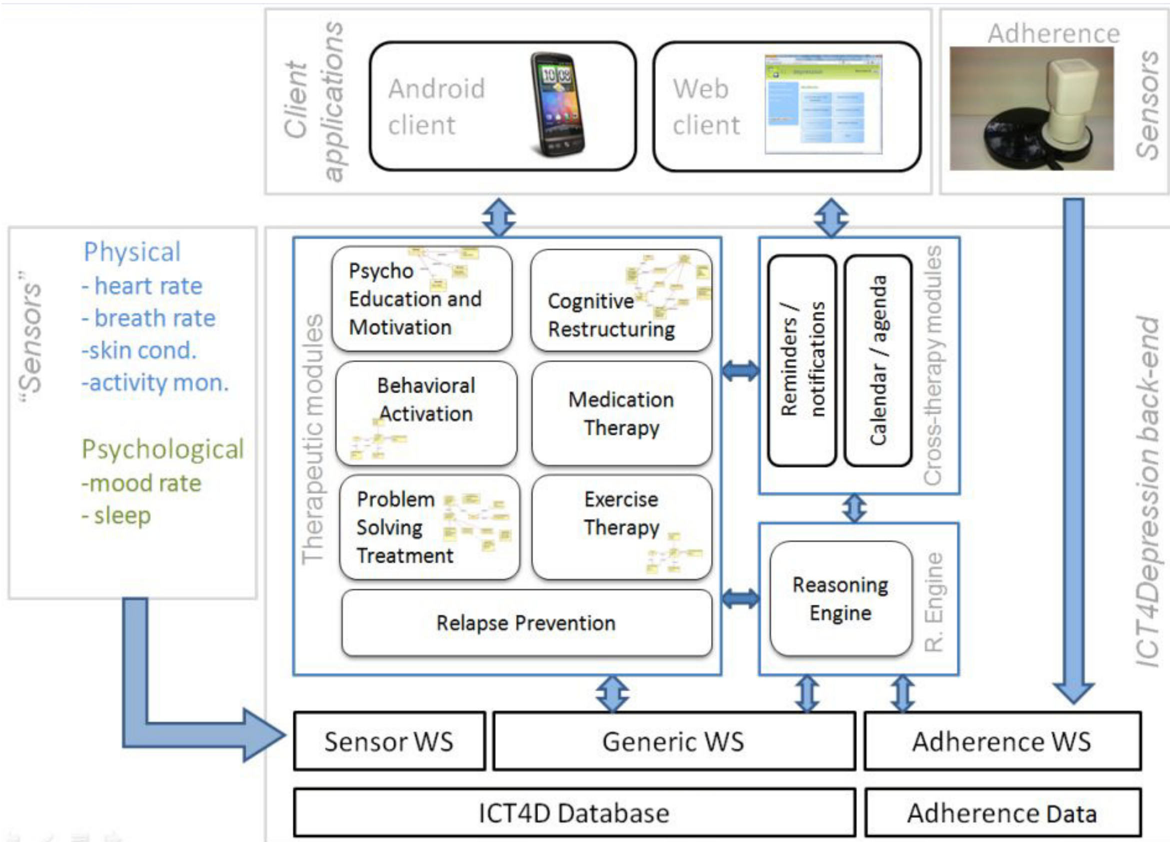


Figure 78: Overview - SOA, sensors and modules

The option for SOA was instantiated through web services. Those were thought based in the presence of certain conditionings – heterogeneous and distributed platforms, subsystems in geographic remote places, using different communication networks – but also from natural uncertain in requirements. Through SOA we could encapsulate business logic and tame the complexity of the underlying rules.

Another advantage of taking this approach was the decoupling of the services from the consuming clients. Both web and mobile clients were designed in the cutting edge of the platform technologies, which causes challenges to the developers. SOA provide a secure shield from those implementing concerns, leading to clear functionality design. Also was easy to develop test units and mock-up applications while clients were under construction.

5.2 Biomedical Sensors

Regarding the biomedical sensors, and in light of what was described in the previous sections, we consider the project outputs to be quite substantial and to successfully meet what was expected with respect to the initial objectives. Still, the ICT4Depression was an exploratory project, aimed to test the hypothesis that indirect measurements assessed during the daily life of the patient can contain relevant information related with the level of depression. Currently there is not a large amount of evidence relating the physiological measurements with depression, and as such the selection of the biomedical indicators was a challenging process, as certain assumptions needed to be made based on the state-of-the-art involving tests performed in laboratory settings, and which may not transpose directly to the real-world environment. Furthermore, since the ICT4Depression is targeted at users in a home scenario, an important interest in the project concerns the usability and wearability of the system to increase the patient comfort. Taking into account these issues, the technological partners worked in close relationship with the psychology partners to devise the form factor specifications, and assess end-user acceptability. This synergetic work led us to the chest strap and glove form factors with the specification which were already presented; the glove overcomes the need for gelled electrodes (in the case of EDA), and a finger clip (in the case of BVP), both cabled, and which are quite restrictive for everyday use, while the chest strap overcomes the limitations of standard devices, that only provide a very restricted set of parameters that are (generally only heart rate), and exhibit limited comfort for long-term use. Still, these new developments and current status are on the boundary between wearability and signal robustness, and although the newly developed sensors show promising results, when used in activities that require a very high physical activity level the measurements can be influenced by motion artifacts. Nonetheless, this compromise was the key to success in the use of sensors for biomedical data monitoring in patients in free-living scenarios.

5.3 Mobile Platform

5.3.1 Mobile GUI

The results in section 4 show that the mobile application was used extensively and in some cases exclusively. This would indicate that at least for some users, the mobile application is a suitable way of interfacing with the system. However, it should also be noted that the proportion of exercise entries to exercise exits as reported in Table 5 suggests that, upon starting an exercise, in some cases users chose to finalise the exercise in the pc version of Moodbuster. Although given the discrepancies between exercise entries and exits these numbers should be treated with care, this seems to suggest that the availability of the exercises on the mobile phone is valued, but that finalizing these exercises with the small (on screen) keyboard is not always suitable. This is not surprising seeing as the exercises require the user to input significant amounts of text and points at a further innovation aimed at altering exercises such that they rely significantly less on textual input. Nevertheless, the intensive use of the application demonstrates the successful implementation of treatment modules suitable for ICT support (O1.1).

5.3.2 Mobile Sensor Aggregator

The mobile sensor aggregator gathers sensor data from various sources. Biomedical sensor data and activity data are gathered from stand-alone devices and accelerometers on the mobile phone. Further feedback is obtained directly from the user through ratings.

5.3.2.1 Biomedical Sensor and Activity Gathering

The results on sensor data gathering presented in section 4.2.1.3 show that sensor data gathering was performed for most users, but that some users experienced chronic issues, particularly with the chest sensor. Table 11 shows that no biomedical sensor data was gathered for 1 user (*patient 9*) whereas for this user activity reports were received. This indicates that the user set the monitoring periods correctly, but either did not use the sensors or that something was wrong with the sensors and/or communication to the mobile phone consistently. For the quitting patient (*patient 10*) no biomedical sensor data was gathered no activity reports too. For various users it can be seen that breath rate data is gathered but no heart rate data. As both signals originate from the chest strap sensor, this indicates that the issue lies with the sensor itself or its use. The latter is the most likely reason as can be seen from the results for most users, which consistently show that more data on breath rate was gathered than on heart rate. This is also in agreement with development tests performed (as detailed in Deliverable D2.4 Deployment Report) which demonstrated that use of the ECG requires the user to remain relatively static.

Furthermore interesting is the temporal distribution of sensor data. There is no clear increasing or decreasing trend in the number of received readings over time, which suggests that adherence to use of the sensors is relatively constant. This is an important finding as it shows that users are willing to wear the sensors throughout their therapy.

The temporal overview of received data also shows that on two dates, 16 November and 28 November no biomedical sensor data was received whereas activity data was received. The existence of data on the server indicates that a server issue is very unlikely and it is also unlikely that all biomedical sensors were faulty or out of battery on the same day. Although we did ask patients about the reason, we were not able to identify the cause behind this lack of data.

Throughout the trial period, activities of daily living were consistently extracted from accelerometer data and reported to the server. As the trial, from a physical activity point, was an unsupervised trial, the accuracy of the activity recognition cannot be assessed, but this has been done previously as reported in deliverable D2.4 Deployment Report. Findings in this report were that the phone can be used as a reliable arbitrator of a set of physical activities (sitting, standing, running, walking and cycling).

5.3.2.2 Ratings

The overview of ratings responded to by the user shows that most of these ratings are done through the mobile sensor aggregator. As can be seen in both Table 9 and Figure 55, there are no mobile ratings during the period of November 17th till November 22nd, and some days afterwards. This has been traced back to a problem with the Reasoning Engine, which had stopped functioning due of a file-server crash and a wrongly restored back. Unfortunately, the patients did not receive rating request on their mobile phone during this period. It is interesting to see that some of the patients went to the website themselves to perform the ratings in an alternative way.

It is also a result under analysis that users did not bring their mobile phones to lectures as it was not possible to silence the reminders given by the application. This issue was resolved and users received an update on the 24th of November. Although on some of the remaining days no rating requests were received by the mobile phone, the last 6 days of the trial seem to indicate that the issue was largely resolved.

5.4 Web Client Platform

The results show a consistent use of the web application in complement to the use of the mobile application. However when the therapy steps are more elaborated the web client application still more comfort to use, which can be deduced by the analysis of graphic on Figure 50, for the Behavioral Activation and Problem Solving Therapy, which have a higher complexity in comparison to other modules.

6 Future Work

PLUX intends to continue the work on both devices to overcome some of the shortcomings that were previously identified; one of the aspects that will be improved is the robustness to motion artefacts through the development of signal processing algorithms based on adaptive filtering or independent component analysis techniques, that integrate motion/physical activity information into the filtering process in the digital domain, in order to cancel the effect of motion artefacts in sensors such as the BVP or the ECG with dry electrodes. In another front, PLUX will work to further improve the discreteness of the glove form factor, by placing both the EDA and BVP sensors at the wrist level, converting the glove to a wrist band; although several experiments on this respect were performed during the course of the ICT4Depression project, this option was not followed due to the high risk that it exhibited during the system engineering stage.

Annexes

7 Web Services and Webmethods

The Web Services are roughly divided in three major groups:

- Sensors and ratings;
- Therapeutic modules;
- Calendar and logging.

7.1 Sensors and Ratings

The Sensor Data include the following webmethods:

Name	Description
alive	It queries the underlying web service and the data access layer about their health/status.
doPing	The sensor manager (mobile phone) sends a short ping to the WS to inform is status which includes the power battery level and a bit octet about the readiness of the monitor sensors.
sendHeartRateBytes	The sensor manager sends an hour sample with the heart beats per minute.
sendBreathRateBytes	The sensor manager sends an hour sample with the breath rate per minute.
sendAnxietyRate	The sensor manager or the web application sends the current Anxiety rate [1..10], which include also a parameter if patient wants to add some comment to explain the current anxiety values.
sendEfficacyRate	The sensor manager or the web application sends the current Efficacy rate [1..10]
sendMoodRate	The mobile phone or the web application sends to the server the current Mood Rate value [1-10]
sendMotivationRate	The mobile phone or the web application sends to the server the current Motivation Rate value [1-10]
sendPositiveThoughtsRate	The mobile phone or the web application sends to the server the current Positive Thoughts Rate value [1-10]

sendSleepRate	The mobile phone or the web application sends to the server the current Sleep Rate value [1-10]
sendUserActivity	The mobile phone sends the user's activity pattern to the server.
sendSensorLocationGPS	The mobile phone sends the user's GPS location to the server. Location is specified as latitude/longitude and altitude.
sendSensorLocationGPSasString	The mobile phone sends the user's GPS location to the server. Location is specified as latitude/longitude and altitude.
sendSkinConductance	The sensor manager sends a list of measurements related with the Skin Conductance.
sendUserDailyActivitity	Daily resume value of the overall patient physical activity.
sendUserSocialActivitity	Daily resume value of the overall patient social activity.
sendProxiometerValue	Allow to save information about an Exercise or Social event deduced by the proxiometer.
getHeartRateBetweenDates	Obtain the Patient heart rate between two dates, or the most recent if no dates were provided.
getBreathRateBetweenDates	Obtain the Patient breath rate between two dates, or the most recent if no dates were provided.
getMoodRateBetweenDates	Obtain the Patient mood rate between two dates, or the most recent if no dates are provided.
getAllRates	Obtain a list of all rates of the Patient
getActivityBetweenDates	Retrieve activity values for the patient between two dates, or the most recent if no dates were provided.
getGPSLocationBetweenDates	Obtain the Patient GPS coordinates between two dates, or the most recent if no dates were provided.
getSkinConductanceBetweenDates	Obtain the Patient Skin Event history within a temporal interval.
getUserDailyActivitity	Obtain the Patient daily resume of physical activities within a temporal interval.
getUserSocialActivitity	Obtain the Patient daily resume of social activities within a temporal interval.
getProxiometer	Returns the set of values between the start and end dates.

Table 28: Sensor data webmethods summary

7.2 Therapeutic Modules

The Therapeutic Modules Data include the following webmethods:

Name	Description
addYourExerciseBarriers	Add a list of Barriers.
addYourExercises	Add a list of Exercises.
addYourList	Add a list of Activities that the patient considers Pleasant.
assessList	Add an assessment list of the pleasant activities.
deleteChallengeEmotions	Delete Emotions of a Challenge.
deleteFutureEvent	Delete a Future Event.
deleteImportantThingActivities	Delete list of Activities related to Important Things.
deleteImportantThings	Delete list of Important Things
deleteNATEmotions	Delete a list of Emotions related to an Automatic Thought.
deleteNATs	Delete a list of Automatic Thoughts.
deleteSituation	Delete a situation.
deleteSituationEmotions	Delete a list of Emotions related to a Situation.
deleteThinkingErrors	Delete a list of Thinking Errors.
deleteTreatmentSkills	Delete a list of Treatment Skills.
deleteWorkingProblems	Delete list of Working Problems.
deleteYourProblem	Delete list of Problems.
getAchievementLookup	Obtain a lookup list of Achievements.
getActionsLookup	Obtain a lookup list of Actions.
getActivities	Obtain a list of Activities.
getActivityAssessLookup	Obtain a lookup list of Pleasant Activities.
getAssessPastSituation	Obtain the last assessment of Pleasant Activities, to use as a

	suggestion when there is no current assessment.
getAssessSituation	Obtain the current assessment of the Pleasant Activities.
getBarrierTypeLookupValues	Obtain a lookup list of Exercise's Barriers.
getChallengeEmotions	Obtain a list of Emotion for a specific Challenge.
getEmotionLookupValues	Obtain a lookup list of Emotions.
getExerciseTypeLookupValues	Obtain a lookup list of Exercises – Physical Activities.
getFullThinkingErrorsLookupValues	Obtain a lookup list of Thinking Errors with respective full description of each one.
getFutureEventsActions	Obtain a list of Actions related with Future Events.
getGoalValues	Obtain the goal defined by the patient for the number of Pleasant and Necessary Activities to be performed.
getImportantThingActivities	Obtain a list of Activities related with an Important Thing.
getImportantThings	Obtain a list of Important Things.
getLifeGoals	Obtain a list of Life Goals and respective scores.
getNATEmotions	Obtain a list of Emotions related with an Automatic Thought.
getNATInfo	Obtain information of a specific Automatic Thought.
getScoreNecessary	Obtain the actual count of Necessary Activities on the calendar.
getScorePleasant	Obtain the actual count of Pleasant Activities on the calendar.
getSignsLookup	Obtain a lookup list of Signs.
getSituationEmotions	Obtain a list of Emotions related to a Situation.
getSituationNATs	Obtain a list of Automatic Thoughts related to a Situation.
getSituations	Obtain a list of Situations.
getSkillsLookup	Obtain a lookup list of Skills
getSolutionTypeALookup	Obtain a lookup list of Solution for Unimportant Problems (Type A).
getSolutionTypeCLookup	Obtain a lookup list of Solution for Unsolvable Problems (Type C).

getThinkingErrorsLookupValues	Obtain a lookup list of Thinking Errors.
getTreamentSigns	Obtain a list of Signs related to a Treatment.
getTreatmentAchievements	Obtain a list of Achievements related to a Treatment.
getTreatmentActions	Obtain a list of Actions related to a Treatment.
getTreatmentSkills	Obtain a list of Skills related to a Treatment.
getWorkingProblems	Obtain a list of Working Problems.
getYourExerciseBarriers	Obtain a list of Exercise's Barriers.
getYourExerciseGoals	Obtain a list of Goals related to an Exercise.
getYourExercises	Obtain a list of Exercises.
getYourProblems	Obtain a list of Problems.
getYourProblemsClass	Obtain a list of Problems by Class.
goalsAchieved	Obtain a list of Goals Achieved.
necessaryActivities	Obtain a list of Activities that the patient considers necessary and unpleasant.
planGoals	Save the number of pleasant and necessary activities to perform and also the rewards for the accomplishment.
rewardValues	Obtain the list of rewards.
saveChallengeEmotions	Save the list of Emotions related to a Challenge.
saveFutureEvents	Save the list of Future Events.
saveImportantThingActivities	Save the list of Activities related to an Important Thing.
saveImportantThings	Save the list of Important Things.
saveNAT	Saves an Automatic Thought.
saveNATChallenge	Save information about a Challenged Automatic Thought.
saveNATEmotions	Save list of Emotions related to a specific Automatic Thought.
saveNewSituation	Save a new Situation details.

savePatientLifeGoals	Save the list of Life Goals for a specific Patient.
savePatientRewards	Save the list of Rewards for a specific Patient.
savePatientTreatmentGoals	Save the list of Treatment Goals for a specific Patient.
savePlanActions	Save list of Actions.
savePlanSigns	Save list of Signs.
saveSituationAnxiety	Save the score of Anxiety for a specific Situation.
saveSituationEmotions	Save the list of Emotions related to a specific Situation.
saveThinkingErrors	Save the list of Thinking Errors.
saveTreatmentSkills	Save the list of Treatment Skills.
saveWorkingAProblem	Save the list for Working Unimportant Problems (Type A).
saveWorkingBProblem	Save the list for Working Unsolvable Problems (Type B).
saveWorkingCProblem	Save the list for Working Solvable Problems (Type C).
saveYourProblems	Save the list Problems of a specific Patient.
setExerciseGoals	Save the goal for the actual week and four weeks later and respective rewards for each exercise.
solveYourProblem	Mark a specific Problem as solved.
treatmentGoalValues	Obtain a list of Treatment Goals.
updateFutureEvents	Update the list of Future Events.
updateImportantThings	Update the list of Important Things.
updateNAT	Update information about previously saved Automatic Thought.
updateNATChallenge	Update information about previously saved challenge of the Automatic Thought.
updateSituation	Update information about a previously saved situation.
updateSituationEmotion	Update information about a previously saved emotion.
updateWorkingAProblem	Update information about a previously saved Working Unimportant Problem (Type A).

updateWorkingBProblem	Update information about a previously saved Working Unsolvable Problem (Type B).
updateWorkingCProblem	Update information about a previously saved Working Solvable Problem (Type C).
updateYourProblem	Update information about a previously saved Problem.

Table 29: Therapeutic data webmethods summary

7.3 Calendar and Questionnaires

To operate over the calendar and end-module questionnaires the following webmethods were developed:

Name	Description
addPeriodicEvent	Save information about a Periodic Event.
addSingleEvent	Save information about a Single Event.
deleteEvent	Delete an Event.
deleteEventAsCompleted	Mark an Event as undone, if was by error tagged as completed.
getEventByCod	Obtain information about an Event by Code.
getMonthEvents	Obtain the list of Events for a specific month.
getMonthEventsForGraph	Obtain the list of Events for a specific month (special case).
getTodayEvents	Obtain list of Events for a specific day.
LIME_propagateTokens	After patient definition propagate ids to the lime questionnaire tables.
markEventAsCompleted	Mark a specific Event as complete.
updateEventAsCompleted	Update a specific Event maintaining the Complete tag.

Table 30: Calendar and Questionnaires wemethods summary

7.4 System and Logging

Name	Description
absoluteFirstAndLastLog	Obtain the values of the first and last log on the system.
addLogEntry	Save a log with the last patient operation detected by the system.
alive	Query about availability of the web service and underlying data layer.
feedbackMessages	Obtain the list of Reminders for a specific patient.
feedbackRead	Set the list of Reminders as Read
feedbackReminder	
getModuleCompletion	Obtain the total number and the last exercise that the patient performed for each module.
getPatient	Retrieve basic data about patient: sensors, mobile and default language.
getPatientByMac	

Table 31: Other miscellaneous webmethods

8 Installations and deployments

8.1 Web server installation

An easiest way to install the web server (for the web client platform) is to install the open source package XAMPP, a cross-platform package and is available for Windows, Linux, Mac OS and Solaris. It can be downloaded at: http://www.apachefriends.org/
This package contains most of the elements that the web client needs to work, an Apache server, a MySQL database, an interpreter for PHP language and also OpenSSL that allows the functioning over HTTPS. The Apache Server and the MySQL database must be installed as Service.

In the case of the ICT4Depression project both Webservices and Web Client are installed in the same server. It is crucial to perform some configurations in order to run both systems. By default the Apache server is configured to work with port 80 for HTTP connections and 448 for HTTPS, both these ports are occupied by the Internet Information Services. It was defined the port 8080 for HTTP and 443 for the HTTPS, those changes are performed in:

Location	**Old configuration**	**New configuration**
/xampp/apache/conf/ httpd.conf		
	Listen [::]:80	Listen [::]:8080
	ServerName localhost:80	ServerName localhost:8080
/xampp/apache/conf/ extra/httpd-ssl.conf		
	Listen 443	Listen 448
	<VirtualHost _default_:443> #General setup for the virtual host DocumentRoot "C:/xampp/htdocs" ServerName localhost:443	<VirtualHost _default_:448> #General setup for the virtual host DocumentRoot "C:/xampp/htdocs" ServerName localhost:448
/xampp/php/php.ini		
		extension=php_openssl.dll;

The web server must be able to work with a MySQL database, included in the XAMPP package, that database will useful for back office tasks like the Multi Language Lookup Editor and the Exercise builder. And also with a Microsoft SQL Server where the tables of the system are being held, this configuration is crucial for the setup of the questionnaires. In order to establish the connection between the PHP and the Microsoft it is necessary to install MS SQL drivers for PHP, available at Microsoft website:
http://www.microsoft.com/en-us/download/details.aspx?displaylang=en&id=20098
After installation the following steps:

- Add 'php_pdo_sqlsrv_53_ts_vc9.dll' and 'php_sqlsrv_53_ts_vc9.dll' to '/xampp/php/ext' folder;

- Add those extensions to '/xampp/php/php.ini';
- Apache server must be restarted in order to apply the changes.

For the deployment all files must be uploaded to the 'root' folder, typically the located at '/xampp/htdocs/'. After this first deployment, the modules can be uploaded via Exercise Builder. All other files must be deployed directly in the root folder.