DESIGNING PERSONAL HEALTH TECHNOLOGIES

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Mads Frost: *Designing Personal Health Technologies,*
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Abstract

What is health? How do we improve it? Why should we improve it? These are questions people don't think much about until they become "unhealthy". An increasing number of personal health technologies are being designed, which help people collect and reflect on their health and wellness. These technologies are components that can support the prevention, diagnosis and treatment of health and wellness issues. The thesis is focusing on these personal health technologies, and the research is situated in the MONARCA project, where a system supporting the treatment of bipolar disorder have been designed, implemented and clinically tested. The contributions include both a novel system, the outcomes of the clinical trials reporting of the usability and usefulness of the system, as well as findings on how the technology improves the actual treatment, all based on the included six papers. This thesis further provides conceptual contributions in terms of perspectives with which to guide the design of new personal health technologies. It identifies four core design elements of personal health technologies, as well as three design targets for an improved management of health. The contributions should be of interest to researchers working with personal health technologies in HCI, Ubicomp and in clinical research, as well as to practitioners and designers tasked with designing and implementing new types of personal health technologies. More broadly, this dissertation also has implications for the construction of sensing and feedback technology in general, including domains such as pervasive health, health behavior change and personal informatics.

Preface

This thesis is submitted to obtain the PhD degree at the IT University of Copenhagen. The work described in the thesis was carried out between December 2010 and January 2014.

During my PhD, I had the pleasure of meeting a lot of inspiring researchers, clinicians, and patients whom I want to thank. First and foremost, I owe thanks to my supervisor, Jakob E. Bardram, for his confidence, insightful guidance and never failing support, making my PhD experience productive and stimulating. Thank you.

At the Affective Research Unit at the University Hospital of Copenhagen, Rigshospitalet, I would especially like to thank Lars Vedel Kessing, Maria Faurholt-Jepsen and Maj Vinberg, with whom I have collaborated closely throughout the process. Also a big thanks to all the clinicians and patients from the Affective Disorder Clinic who have participated in design and trials of our system, I hope it was worth the effort.

Through the end of 2012 and the beginning of 2013, I was affiliated with Ubiquitous Interaction Group within CREATE-NET in Trento, Italy. I want to especially thank Oscar Mayora who invited me, as well as Silvia Gabrielli and Venet Osmani for the privilege of close collaborative work on MONARCA , and ability to discuss and present my work there.

Finally, but not least, I want to thank the members of the Pervasive Interaction Technology Laboratory (PIT Lab) for being inspiring and interested colleagues - as John Buchan once said: *"To live for a time close to great minds is the best kind of education"*.

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Overview of the Thesis

This thesis consists of a collection of four published papers, two submitted papers, and an introductory part, which provides a background and overview of the present work. The thesis is divided into two parts: Part one provides an overview of the problem area addressed, presents the theoretical and empirical work, and finally sums up the contributions. Part two consists of the included papers.

In part one, the **Introduction** chapter introduces the background and motivation for the thesis. It further introduces personal health technologies, and the MONARCA research project, which forms the basis for the present thesis. Finally it presents the research approach taken throughout the work presented. The **Empirical Research** chapter introduces the empirical research on designing, building and evaluating personal health technologies used in the treatment of bipolar disorder. It introduces the clinical background of bipolar disorder and the treatment setting in which the system is used, the developed MONARCA system, the methods for design, and the results from the clinical trials. The **Design Elements of Personal Health Technologies** chapter presents the perspective of personal health technologies, and outlines the four core design elements of these types of systems. These design elements are; *Collection*, *Management*, *Feedback*, and *Sharing*. The **Design Targets for Personal Health Technologies** chapter introduces three design targets of *Awareness*, *Insight*, and *Change*, evolved from the empirical work. The **Conclusions** chapter concludes part one, outlining the main achievements of the thesis, and propose possible directions for future work.

In general, scientific work of others that is related to the thesis is discussed throughout part one and in the included papers where it is found relevant. Hence, the thesis does not contain a chapter entitled "Related Work", as I have found it more valuable to cite the work of others where it is relevant.

Part two consists of the six papers included in the thesis. They are included in their original form, and an overview of the papers including an abstract of each paper can be found below. Publication details can be found after this overview. References to these papers in the first part of the thesis are made by using braces, i.e. "{ .. }"

Paper 1: The MONARCA self-assessment system: a persuasive personal monitoring system for bipolar patients
The paper presents the first version of the MONARCA system. It describes the user-centered design process of the system, the user experience, and the technical implementation. This system is one of the first examples of the use of personal health technologies to support the treatment of mental illness, and discuss lessons learned and how others can use our experience in the design of such systems for the treatment of this important, yet challenging, patient group.

Paper 2: Designing mobile health technology for bipolar disorder: A field trial of the MONARCA system

The paper presents the first study of the MONARCA system, conducted through a 14 week clinical trial in which 12 patients used the system. It report findings focusing on their experiences. The results were positive; compared to using paper-based forms, the adherence to self-assessment improved; the system was considered very easy to use; and the perceived usefulness of the system was high. Based on this study, the paper discusses three HCI questions related to the design of personal health technologies; how to design for disease awareness and self-treatment, how to ensure adherence to personal health technologies, and the roles of different types of technology platforms.

Paper 3: Supporting situational awareness through a patient overview screen for bipolar disorder treatment

The short paper presents the design and evaluation of a detailed patient overview screen for the MONARCA system. It presents the user-centered design process, the design, and a a formative evaluation. The results showed the design was perceived as useful, the clinicians prefer system support to improve perception rather than comprehension, and that the approach supported both the doctors and nurses in their different approaches to treatment with a unified design.

Paper 4: Supporting disease insight through data analysis: refinements of the MONARCA self-assessment system

The paper presents the second version of the MONARCA system, which focuses on an automation of the system, from data collection through sensors to data analysis and feedback, all aiming at improving the patients' disease insight. It describes the user-centered design and the technical implementation of the system, as well as findings from an initial 6 month clinical trial. The results show the system is able to closely estimate the current and future mood state, and that the automated data features are strong indicators of the mood. It highlights activity, stress, sleep, and phone usage as the parameters with the highest correlation with mood, as well as patients and clinicians involved in the study reported a high degree of satisfaction with the usefulness and usability of the system.

Paper 5: Improvements and Challenges in using Personal Health Technologies in Treatment of Bipolar Disorder: Qualitative study
The first version of the MONARCA system was deployed in a randomized clinical trial where 35 outpatients and 2 nurses used the system over a period of 2 years. Open ended interviews were conducted with the 2 nurses at the end of the trial, where they discussed their daily use of the system and responded to longitudinal views of implications for treatment. From the study it is evident that the use of the system in the treatment of bipolar disorder improved the process. The nurses found the use improved patients' adherence to treatment, as well as an increased awareness and insight of the disease. The nurses furthermore found that the use of the system increased clinicians' awareness of their patients and their state, allowing for more focused treatment and faster interventions. However, it also posed challenges in terms of the nurses' experience of responsibility and liability for treatment and intervention.

Paper 6: Increasing Awareness, Insight and Adherence in Treatment of Bipolar Disorder through Personal Health Technology: Pilot Study
This paper examines the use of the second version of the MONARCA system in psychoeducative treatment of patients suffering from bipolar disorder. This is done in a single-arm feasibility trial where 18 outpatients suffering from bipolar disorder use the system for 19 weeks. The study proved that patients had a high adherence rate to the use of the system. I was found to help patients with an increased awareness and insight into the relationship between behavior and their disease, and helpful with prompt assistance. Prior clinical evidence have shown that these factors all improve on clinical outcomes in treatment of bipolar disorder. The system was further able to estimate the patients' future mood state up to 5 days ahead in time with a high accuracy, while the detection of mood swings were less successful.

References to Included Papers

Paper 1 (page 63)
Jakob E Bardram, Mads Frost, Károly Szántó and Gabriela Marcu. The MONARCA self-assessment system: a persuasive personal monitoring system for bipolar patients. In *Proceedings of the 2nd ACM SIGHIT International Health Informatics Symposium* (IHI'12). 2012, 21-30.

Paper 2 (page 77)
Jakob E Bardram, Mads Frost, Károly Szántó, Maria Faurholt-Jepsen, Maj Vinberg and Lars Vedel Kessing. Designing mobile health technology for bipolar disorder: a field trial of the MONARCA system. In *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems* (CHI'13). 2013, 2627-2636.

Paper 3 (page 93)
Mads Frost and Silvia Gabrielli. Supporting situational awareness through a patient overview screen for bipolar disorder treatment. In *Proceedings of the 7th International Conference on Pervasive Computing Technologies for Healthcare* (PervasiveHealth'13). ICST (Institute for Computer Sciences, Social-Informatics and Telecommunications Engineering), 2013, 298-301.

Paper 4 (page 99)
Mads Frost, Afsaneh Doryab, Maria Faurholt-Jepsen, Lars Vedel Kessing and Jakob E Bardram. Supporting disease insight through data analysis: refinements of the MONARCA self-assessment system. In *Proceedings of the 2013 ACM international joint conference on Pervasive and ubiquitous computing* (UbiComp '13). 2013, 133-142.

Paper 5 (page 114)
Mads Frost, Maria Faurholt-Jepsen, Lars Vedel Kessing and Jakob E Bardram. Improvements and Challenges in using Personal Health Technologies in Treatment of Bipolar Disorder: Qualitative study. *Paper submitted for review to the Journal of Internet Interventions (INVENT).*

Paper 6 (page 138)
Mads Frost, Maria Faurholt-Jepsen, Afsaneh Doryab, Lars Vedel Kessing and Jakob E Bardram. Increasing Awareness, Insight and Adherence in Treatment of Bipolar Disorder through Personal Health Technology: Pilot Study. *Paper submitted for review to the Journal of Medical Internet Research (JMIR).*

Part 1

Chapter 1

Introduction

The present thesis addresses the design and evaluation of personal health technology for bipolar disorder patients, situated within an EU funded research project called MONARCA – an abbreviation of *"MONitoring, treAtment and pRediCtion of bipolAr Disorder Episodes"*. This chapter presents the thesis, the background and motivation for the research, provides an overview of the MONARCA project, situates my contributions in the project, and presents the research approach taken in the research.

1.1 Background and Motivation

The World Health Organization (WHO) defined health in its broader sense in 1946 as *"a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity"* [163]. The western world is facing a health situation without precedent: We are getting older – we will soon have more older people than children and more people at extreme old age than ever before [162]. We are getting unhealthier – the majority of adults have more than one out of the four main health risks, which comprises of smoking, alcohol consumption, physical inactivity and overweight [45]. And we are challenged by a deeply fragmented, transaction-focused and highly complex health care system, where health care workers are under increasing pressure to provide better services to more people, using limited financial and human resources.

In the United States, the four main health risks of smoking, alcohol consumption, physical inactivity, and overweight, are the primary cause for the increase in chronic conditions such as diabetes, heart disease, and lung disease, which take a heavy toll on health. Chronic conditions also cost vast amounts of money, and the trends are going in the wrong direction. Chronic diseases - many of which are preventable with better lifestyle choices - account for \$1.5 trillion USD, or roughly 75 % of the annual cost of health care in the U.S., and chronic diseases cause 7 in 10 deaths each year [19, 20].

WHO further find mental disorders as one of the most pressing healthcare concerns worldwide [166]. About 450 million people suffer from mental and behavioral disorders, and approximately one in four persons will develop one or more disorders during their lifetime. Factoring in the limitations of the current effectiveness of the treatment approaches of mental disorders, prevention is seen as the only sustainable method for reducing the burden [63].

Thus, designing personal health systems that promote healthy living, help individuals care for him or herself, and in general provides the individual with greater self-awareness about his or her health condition, is perceived as serious part of the answer to these challenges. This is acknowledged by the EU commission, who in the current Horizon 2020 research funding calls have a specific challenge looking at empowering citizens to manage their own health and disease. This is pressumed to result in more cost-effective health care systems by improving utilisation of health care, enabling the management of chronic diseases outside institutions, improving health outcomes, and encourage healthy citizens to remain so [43]. This focus is also seen in a Danish context, where the Danish Regions' new set of focus points aims at strengthening the encounter between citizens and health care professionals with coherent, effective and uniform digital opportunities [129]. Likewise, the industry has opened its eyes to this challenge, as venture capital funding for health care IT in the US has skyrocketed - tripling over the last three years from $343 million to $955 million USD [165].

There is clearly a need for action, and the recent advancements in technology allows for this progress. The advent of portable computing devices and new sensing abilities presents many new opportunities for personal health care. Formerly, most medical sensing devices were used in a hospital setting, while many devices today are worn throughout an individual's daily life or are installed a home. The devises are able to collect health related data for many purposes, by patients with medical conditions, or individuals seeking to change to a healthier behavior. For the last 20 years, technology has reshaped our economy while bringing in a new era of consumerism, making things simpler, more affordable and more accessible. This has created tech savvy individuals who expects simplicity, accessibility, and an experience customized to their individual needs.

From a scientific perspective, the design of personal health technologies have had a high focus in the last decade, drawing on research disciplines such as computer science, human-computer interaction, information visualization, psychology, sociology, etc., which have used technology to empower people to gain a better understanding of their health, enabling them to make better choices. Personal health technologies have the potential to reduce long-term costs and improve quality of service, but it also faces many technical, design, and administrative challenges, which needs to be addressed in order for the technology to help relieve the world of the oncoming burden. Trying to understand the use and the design of technology may in the end help individual to not only become more healthy, but also to stay that way.

1.2 Personal Health Technologies

Personal health technologies is a hypernym used for technologies employed for the management of aspects of personal health. It is commonly used in reference to using mobile communication devices, such as mobile phones, tablet computers and PDAs, where these are combined with some form of data collection – be it automatically collected sensor data and/or a self-rated health status. The aim of these technologies is assisting the user in managing the targeted health issue. This is achieved through awareness of current health state, detection and prevention of health deterioration, as well as support and motivation of adaptation of healthier behaviors. This is enabled through access to information and knowledge at the right time at the right place. Recent advances in network connectivity, small inexpensive sensors, low-power processing, available platforms and infrastructures through e.g. Smartphones and Smartwatches, and progress in activity modeling and recognition, have all enabled these technologies to gather and process a wide range of information regarding the user's status. Hence, the term *Personal Health Technologies* should not be seen as revolutionary new, but more as an evolution of technologies for managing personal health. However, there is no established term for these types of technologies yet.

A number of personal health technologies have been suggested for the management of a wide range of conditions. Research has targeted *wellness* issues such as physical activity [31, 32, 38, 49, 88], eating habits [17, 84, 123], use of sunscreen [4], water intake [21], stress [59], and smoking [61, 115, 131, 134, 161]. Research have also targeted treatment of *illness* issues such as cardiac rehabilitation [94, 136, 159], obesity [119], cancer [71, 82], medication intake [35] and management of chronic illnesses like diabetes [75, 95, 96, 151], psoriasis [141], and asthma [3, 62, 62, 85].

Recent research has started to focus on mobile phone systems for mental illness like depression [18, 70, 112, 133], borderline personality disorder [132], schizophrenia [40, 53, 154], and more general-purpose mobile phone systems for mood charting to be used in Cognitive Behavioral Therapy (CBT) has been suggested [9, 100, 101, 109, 160]. For bipolar disorder, not much prior work have been done. Scharer et al. created life charts on a palmtop computer, which was the first attempt where an electronic diary for bipolar patients were examined in a feasibility study [140]. Obtaining mood data based on responses to weekly cell phone text messages or e-mail prompts has been suggested and studied [16]. Also more comprehensive electronic monitoring systems have been presented for patients with bipolar disorder including self-monitoring of medication, mood, sleep, life events, weight, menstrual data, etc. [118, 127, 164]. However, so far none of these systems have included combined self-monitoring and automatic data collection of the disorder, and none of them have build-in mechanisms for providing feedback directly to the patient.

1.3 The MONARCA Project

MONARCA[1] is an EU funded research project with 12 partners from 5 different countries. There are partner from both industry (Aipermon, Meditrainment, Systema), universities (BITZ, ETH Zürich, IT University of Copenhagen, SUPSI, University of Bielefeld, TU Kaiserslautern), a research institution (CREATE-NET), and two university hospitals (Psychiatric State Hospital of Tiroler Landeskrankenanstalten GmbH, University Hospital of Copenhagen). MONARCA is an abbreviation of monitoring, treatment and prediction of bipolar disorder episodes. The overall goal of the project is to develop and validate a solution for monitoring patients, used in the management, treatment, and self-treatment of bipolar disorder. The solution should comply with all relevant security, privacy and medical regulations, and should be useful for both patients and clinicians in use. The effects of the system is examined through a range of clinical trials and a randomized clinical trial.

Figure 1.1: The MONARCA solution's 4 components. From the left the Smartphone, the wrist worn activity monitor, the "sock integrated" physiological sensor, and the stationary EEG system.

The overall MONARCA solution consists of four components, as seen in Figure 1.1. The components comprise of a sensor enabled Smartphone, a wrist worn activity monitor, a novel "sock integrated" physiological sensor, and a stationary EEG system. The data collected through the different components provides the basis for a behavioral profile of each patient. Combining this information with patients' medical records and established psychiatric knowledge, quantitative assessment of patients' condition and prediction of depressive and manic episodes is implemented. A loop back to the patients provisioning warnings with appropriate action to take, as well as a coaching for self treatment is implemented. For the medical staff, interfaces for data interpretation and treatment management is further developed and tested.

The IT University of Copenhagen has been responsible for the sensor enabled Smartphone with an underlying infrastructure and web portal. As seen in Figure 1.2, this part of the project has contained three design phases, three clinical trials, and a randomized clinical trial. The design and trials have been done in close collaboration with clinical researchers at the University Hospital of Copenhagen and have involved several patients and clinicians.

[1] Project website at http://www.monarca-project.eu, where more details can be found.

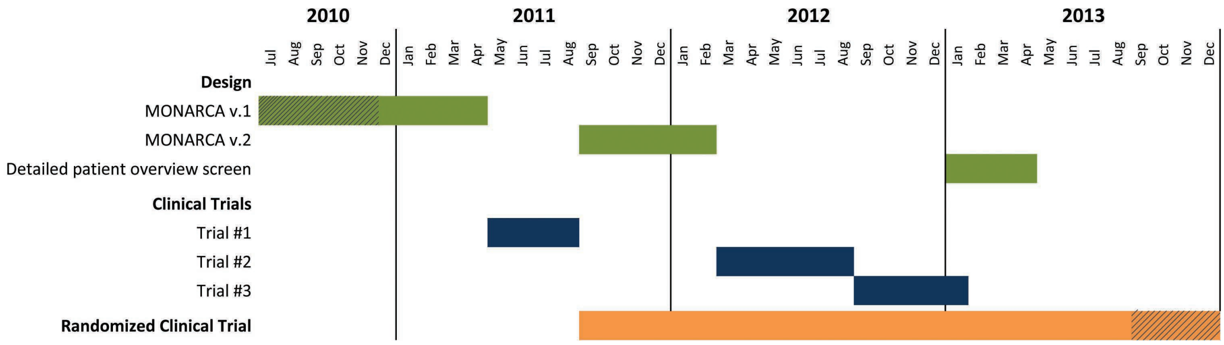

Figure 1.2: Overview of the activities in the MONARCA project.

The developed system consists of an Android application for patients, supporting both the daily reporting of self-assessments, as well as an automatic collection of sensor data. Feedback based on the collected data is provided directly to the patient with strategies and actions for self-help. There is further a loop between the patients and the clinic, enabled through a web portal for both patients and clinicians, allowing for access and configuration of the system. This provides the ability to perform early interventions from the clinicians if they find any issues in the collected data. The system has an advanced data analysis features, where it daily calculates what impacts the patients mood state as well as forecast the patients future mood state. The system is described in more detail on page 13, as well as in {1,3,4}. We have implemented and deployed the systems in a total of three clinical trials {2,4,6} and in one single blinded, randomized controlled clinical trial [44]. All trials were done as part of regular treatment of patients.

The team who have been working on the MONARCA project at the IT University of Copenhagen consists of Afsaneh Doryab (AD), Gabiela Marcu (GM), Jakob Bardram (JB), a couple of student programmers (P), and myself (MF). Table 1.1 provides an overview of who participated in the different tasks. MF joined JB and GM in the middle of the design phase of the first version of the MONARCA system in December 2010. To illustrate MF's entry point, the prior green area in the design of the first version is shaded in the illustration in Figure 1.2. The MONARCA system has been implemented by P and MF, where P implemented the Android application, while MF implemented the web portal as well as the server infrastructure and database. The design of the second version was performed by MF, while AD and MF together designed the data analysis component. AD implemented the algorithms, and MF together with P implemented the component in the system. The detailed patient overview screen (DPOS) was designed, build and evaluated by MF. All clinical trials have been carried out by MF, performing all evaluations and interviews. Finally, MF has been responsible for the technical support and maintenance of the MONARCA system in the randomized clinical trial. The last patient finished the trial in August 2013. However, the data from the trial is still being processed, which is illustrated by the shading in Figure 1.2 in the following months.

	Design	Implementation	Trials
MONARCA v.1	GM / JB / MF	F / P	MF
MONARCA v.2	MF	AD / MF / P	MF
DPOS	MF	MF	MF

Table 1.1: Overview of activities and participants in design, implementation, and evaluation of the MONARCA Smartphone system developed at the IT University of Copenhagen.

1.4 Research Approach

The thesis is based upon extensive empirical research on personal health technology used in treatment of bipolar disorder. It comprising of actual practical design, software construction, and deployments of the developed system used in treatment. These different aspects requires different methods. Methods for performing this type of research are numerous, and techniques are chosen from a broad selection of both qualitative and quantitative methods from different research fields [83]. Mackey [93] argues that different methods uncover different perspectives of the same phenomena, and thus improves the scientific basis. This approach, the different perspectives, is core to this thesis through the different focus of the included papers, all on the same application area and system. According to Cresswell and Plano [34], a multiphase design occurs when a problem or a topic is examined through an iteration of connected studies that are sequentially aligned, where each iteration builds upon what was learned previously, all to address a central objective.

In the empirical research performed, the focus have been on the users and their perspectives and experiences when designing and using the technology – both in relation to the system and to the treatment. Empirical research is a way of gaining knowledge by means of direct and indirect observation or experience through a systematic use of a set of methods, trying to increase the understanding of a phenomena [102]. The empirical setting for this thesis has a double origin. First, from an HCI perspective, where the phenomena of interest is the user, the user's actions, and aspect of the system with which the user interacts. Secondly, and in comparison, from a clinical perspective, where the prime interest is efficacy in treatment and not the user. Hence, the research performed in the empirical part of the research is a combination of design and preclinical research, focusing on system design and development, as well as the clinical trials which paves the way for the randomized clinical trial [64].

The research performed follows Mackay's triangulation process [92], as depicted in Figure 1.3. The triangulation process defines three HCI perspectives at work when approaching a problem: theory, observation, and design. However, in this thesis, observations have been replaces with *clinical trials*, as the developed system have been evaluated in an actual clinical treatment practice. This research follows a distinct path between the different perspectives which outlines the relationships between them.

As illustrated in Figure 1.3, the research started with the design and development of the first

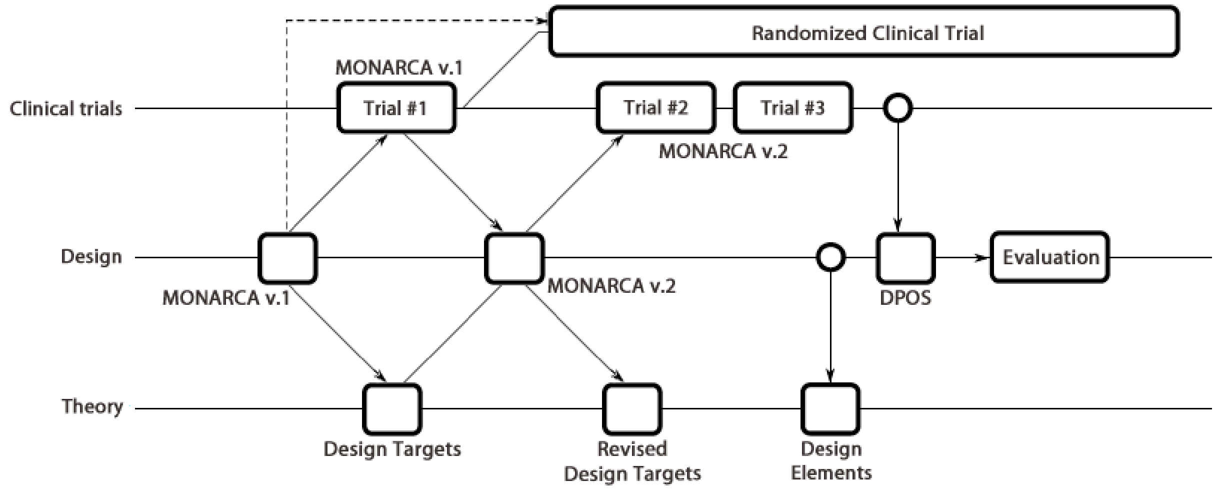

Figure 1.3: Triangulation process perspective for the thesis.

version of the MONARCA system. The design and the process are published in {1}. The system was then deployed in the first clinical trial, ensuring the feasibility of the design and the stability of the system. The outcome of the trial is documented in {2}. During the design of the first version, considerations on how these personal health systems helped the management of personal health were made, informing the grounds for the design targets, introduced in chapter 4. On the basis of the successful outcome of the first trial, the system was deployed in a randomized clinical trial[2]. Further based on the outcome and lessons learned from the first clinical trial, the design of a revised and improved version of the system was designed and developed. This second version of the system was again evaluated in a clinical trial, and the outcome along with the design is published in {4}. The design process of the second version also further helped crystallize the previous mentioned design targets. The second version of the system was then deployed in an additional clinical trial, where the focus was on the effects of using the system in treatment. The outcome is described in {6}. The outcome of the different clinical trials disclosed an important need for supporting the clinicians' overview of the individual patients in the system. Thus research was performed to improve this, and the detailed patient overview screen (DPOS) were designed and evaluated by the clinicians using the system. The design and the evaluation results are published in {3}. Throughout the clinical trials, focus has been on the patients' experience on the use of the system. However, the system has been used by the clinicians as well. Especially the nurses involved in the randomized clinical trial had used the system, and {5} describes their experiences with using the system from a treatment perspective. Finally, all the work done on designing the system informed the design elements, introduced in greater detail in chapter 3.

[2]The first version of the system was deployed in the randomized clinical trial due to project time constrains. Under normal circumstances it would have made sense to deploy the revised and improved second version.

Chapter 2

Empirical Research

This chapter describes the empirical research performed as a part of the thesis in more detail. It introduces the clinical background of bipolar disorder and the treatment setting the designed system is deployed in. It further introduces the methods used for design, the system itself, and finally summarizes the results from the clinical trials of the system.

2.1 Clinical Background

The goal of the MONARCA system is to support the treatment of bipolar disorder. To understand the design and the results of the deployments, it is important to know the background of both the disorder and the treatment setting the system have been designed for.

2.1.1 Bipolar Disorder

Bipolar disorder, previously known as manic-depressive disorder, is a common and complex mental disorder, which accounts as one of the most important causes of disability worldwide for patients at age 15-44 [122]. It is a long-term and chronic disease with need for treatment over many years [2], and it is associated with high morbidity and disability [111], as well as with a high risk of relapse and hospitalization [90]. In its broadest sense, bipolar disorder has a community lifetime prevalence of 4% [74].

Bipolar disorder is characterized by episodes of an elevated mood known as mania alternating with episodes of depression. Mania is defined by periods of least four days with elevated mood, usually accompanied by changes in activity and energy together with other symptoms such as reduced need for sleep, increased self-esteem or grandiosity, disinhibition, and increased talkativeness. Depression is defined by core symptoms of depressed mood for at least two weeks, usually accompanied with other symptoms such as changes in sleep pattern, appetite and concentration, low self-esteem, hopelessness, self-blame and suicidal thoughts. Psychotic symptoms such as delusions and hallucinations are seen in a substantial proportion of patients in either the manic or depressed phases of the disorder [5]. The highs and the lows can be seen as two poles of mood, hence the name *bipolar* disorder, and most patients spend more time in depressed phases than in manic phases. In between those periods, they usually feel normal.

The recurrence of episodes is frequent. 50 % happen within the first year, and 70 % within four years after a manic episode [33, 50, 60, 72, 116, 158]. There is a high attempted and completed suicide rate, as well as a risks to others through violent or reckless behavior [52, 110]. Furthermore symptoms impair patients' functional level, thus impacting social relationships, employment and quality of life [50, 68, 117].

A lot is known about bipolar disorder, yet the high rates of recurrence still occur, as little is known about how to best treat it [157]. A range of effective treatments such as pharmacotherapy [8, 25, 50, 76] and more resent approaches through psychotherapy [58, 67], such as cognitive-behavioral therapy [91, 145], family-focused therapy [103, 107, 108], interpersonal and social rhythm therapy [47, 48, 147] as well as psychoeducation [23, 28], have all been researched. Scott and Gutierrez [143] finds that there are several common themes across the different psychotherapies as they all target one or more of the following areas; the individuals awareness and understanding of bipolar disorder, their adherence with the treatment regime, the stability of their social rhythms and their ability to recognize and manage the early warning signs of relapses, or the internal and external stressors that may increase their vulnerability to future relapses. Further across the different psychotherapy approaches, it is found that it facilitates fewer [22, 30, 79] and shorter [26, 30] hospitalizations, fewer days in episodes [80], improved medication understanding and adherence [22, 79, 105], improved social [79] and global functioning [144], as well as increased stability of social routines [46].

In light of the latter, it is evident that bipolar disorder is a complex disorder of mood and behavior, which requires a multimodal treatment approach. This has been pointed out in resent studies where self-help and psychoeducation in addition to pharmacotherapy has proven as a good combination of treatments [25, 73], where psychoeducation and focus on self-help empower the patients and enable them to take more control over their care and life decisions.

2.1.2 Treatment Setting

The MONARCA system is designed to be used in an optimised pharmacotherapy [25] and psychological treatment of bipolar disorder, where the aim is to support the psychoeducative process the patients are going through [73]. Information provided to patients regarding their diagnosis, treatment and prognosis, as well as regarding how they can help themselves to manage their disease, is in broad terms what can be considered *psychoeducation* [152]. Similarly, psychoeducation as applied to bipolar disorder can be defined as any intervention that educates patients and/or their families about their illness with a view to improving their long-term outcome [152]. In the past 15 years there has been increasing interest in psychoeducational interventions delivered as adjuncts to conventional treatment. Several definitions of psychoeducation support exist in the literature, and several studies have investigated the effectiveness of psychoeducational treatments delivered in a variety of formats, such as individual psychoeducation [68, 69, 120], family-focused psychoeducation [104, 105, 106, 128], group psychoeducation [27, 28, 29, 30], caregiver group psychoeducation [130], and psychoeducation delivered as part of a comprehensive management programme [149, 150].

Psychoeducation seeks to empower patients with ways that allow them to be more active in their therapy process. There is no unifying theory behind psychoeducation in bipolar disorder, as it is a simple pragmatic program [155], while it is often approached trough self-ratings performed by patients. Psychoeducation uses elements from cognitive behavioral therapy (CBT) and interpersonal therapy (IPT), and aims at improving the treatment outcome of patients with bipolar disorder as well as enhancing the prevention of future episodes. This is done by delivering information-based behavioral training aimed at adjusting patient lifestyle and strategies of coping with bipolar disorder, including enhancement of disease awareness, treatment adherence, avoidance of potentially harmful behavior, and early detection of relapses [138]. Furthermore, the prediction and prevention of episodes through psychoeducation by recognizing patients' early warning signs – symptoms indicative of an oncoming episode – has proven to have a high long-term effect [121, 142].

2.2 Design Methods

The MONARCA system went through 2 main cycles of iteration, as well as a detailed patient overview screen has been designed and evaluated. The design was done in a user-centered approach set in a participatory design process [13, 14, 15, 55], employed across the different stages of design in all parts of the system.

On a generalized level, user-centered design is an approach to design that grounds the process in information about the users of the product, where the emphasis is on the importance of having a good understanding of the users throughout the system life cycle [114]. Principles that facilitate the development, communication and assessment of user centered design processes for creating usable interactive systems, covering analysis, design, evaluation, construction, and implementation, have further been reflected upon during the design and development of the system [57].

The design processes have evolved around the Patient- Clinician- Designer- (PCD) Framework, which applies a user-centered design process that is especially sensitive to the complexity of bipolar disorder, the difficulty of treatment, its stigma, and the goals for the patients [97].

In total 21 design workshops was performed; 13 in the design of the first version of the system, each with a duration of three hours, five in the design of the second version, each with a duration of two hours, and finally three in the design of the detailed patient overview screen, also with a duration of two hours each.

The initial workshops on designing the first version involved patients and clinicians, and included discussions about how patient were affected by their disease and how they coped with it in daily life. Furthermore, high-level goals for the system and more detailed system features and functionality were discussed, based on the development of mock-ups and paper prototypes of the system [153]. Thus, all design decisions were based on the outcome of these workshops, focused around the participants' knowledge, ideas and feedback, based on the paper prototypes and the participants' daily life. Images from the workshops can be seen in Figure 2.1.

Figure 2.1: Images from the design sessions of the first version of the MONARCA system.

In the design of the second version of the system, the patients and clinicians involved in the design process all had an extensive experience from using the first version, and thus possessed valuable input on how to improve and extend the system. The design was approached using rapid prototyping [36], where the patients had a functioning prototype installed on their phones. The outcomes of the workshops would be implemented in the prototype and updated on the patients' phones, allowing for use of the system with the proposed changes. This enabled the patients to provide hands-on feedback at the next design workshop.

The design of the detailed overview screen for the system involved nurses and doctors with experience from using the system in treatment of their patients. The design was approached again using the paper prototype approach [153]. Here materials such as large poster paper, writing materials, post-it notes, scissors, and tape was used, and the sketches that came out of this initial brainstorming formed the basis for the first mock-up, seen in Figure 2.2.

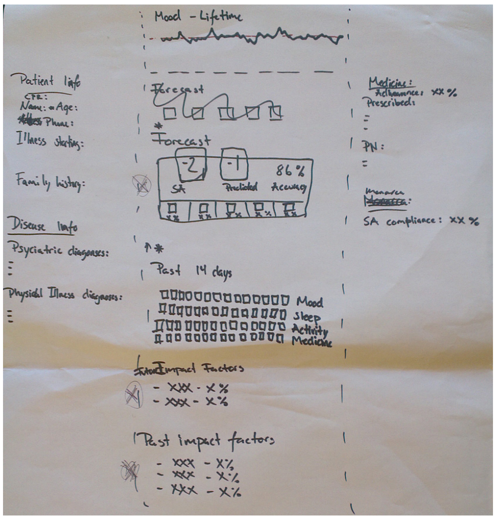

Figure 2.2: A mock-up of the detailed patient overview screen. The implemented version can be seen in Figure 2.6.

Finally, to evaluate the design of the detailed patient overview screen, a heuristic evaluation [113] was performed by usability experts, as well as the screen was evaluated by clinicians using the 'thinkaloud protocol' method [42].

2.3 The MONARCA Self-Assessment System

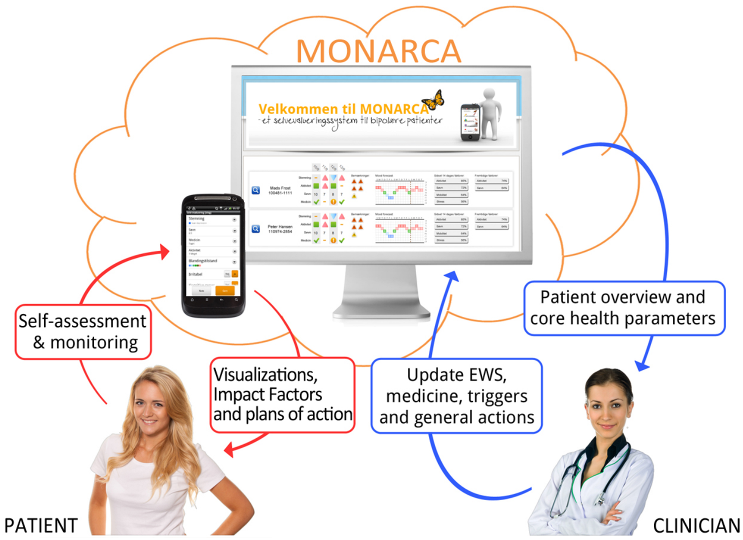

Figure 2.3: Patient - Clinician loop through the system.

The system is presented in the following section. It presents the final versions, which contains both the elements from the initial design {1}, the revisions and additions made in the second version {4}, and the additional designed detailed patient overview screen {3}. The MONARCA system is designed to support the treatment of bipolar disorder through a loop of monitoring and feedback between the patient and the clinician via the system, illustrated in Figure 2.3.

The system consists of two main parts; an Android Smartphone application used by the patients, and a web portal used by patients and the clinicians.

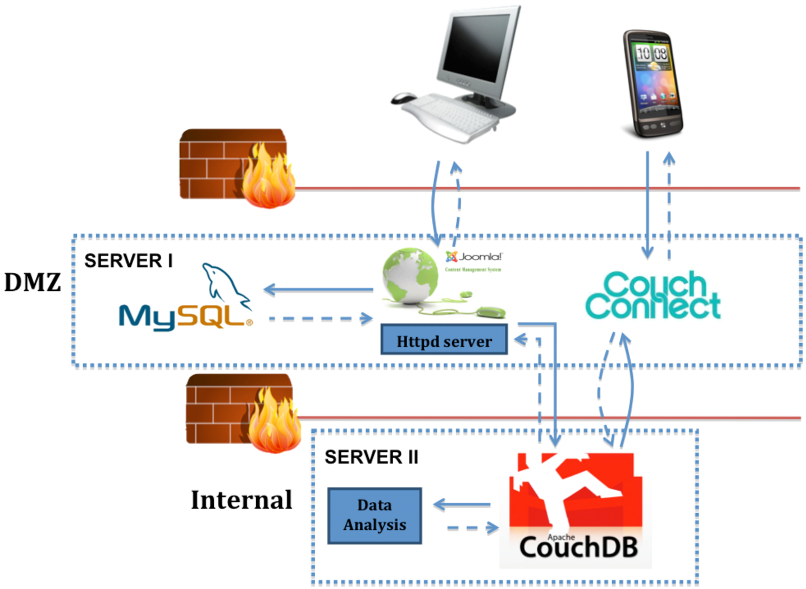

Figure 2.4: The MONARCA System overview.

The system design, including the hosting and deployment setup, is illustrated in Figure 2.4. It is a simple system setup consisting of two clients (the phone and a web browser), one server in a demilitarized zone (DMZ) and one server in a internal zone. Overall, the system setup consists of the following main components and communication pathways; (i) an Android based Smartphone, (ii) a standard web browser, (iii) CouchConnect, a data synchronization process, (iv) CouchDB, a database storing all patient-related data, (v) Data Analysis, computing data at night (vi) Joomla, a Content Management System (CMS) that runs the web portal, and (vii) MySQL, a database containing the configurations of the Joomla CMS.

The system contains four core elements supporting the treatment of bipolar disorder; (i) collection of data from daily self-assessment of parameters as well as automatic data sampling from sensors in the Smartphone, (ii) management of historical overview of the collected data as well as the actions to take and medication, along with an automatic data analysis calculating impact factors and forecast patients' mood (iii) feedback in terms of visualizations as well as coaching & self-treatment suggestions based on customizable triggers, detection of early warning signs, and impact factors, and (iv) support contact between the patient and the clinician through data sharing.

For example, patients and their clinicians can use the data to determine adherence to medications, investigate illness patterns and identify early warning signs for upcoming affective episodes, or test potentially beneficial behavior changes. It can help patients implement effective short-term responses to risk situations and preventative long-term habits, by increasing their disease awareness and insight. It supports an upstream treatment approach, allowing for prompt intervention through the information from daily self-assessments, and even further by the forecast of patients' mood. Table 2.1 provides an overview of the different features in the system along with a short description, relating to the elements mentioned above.

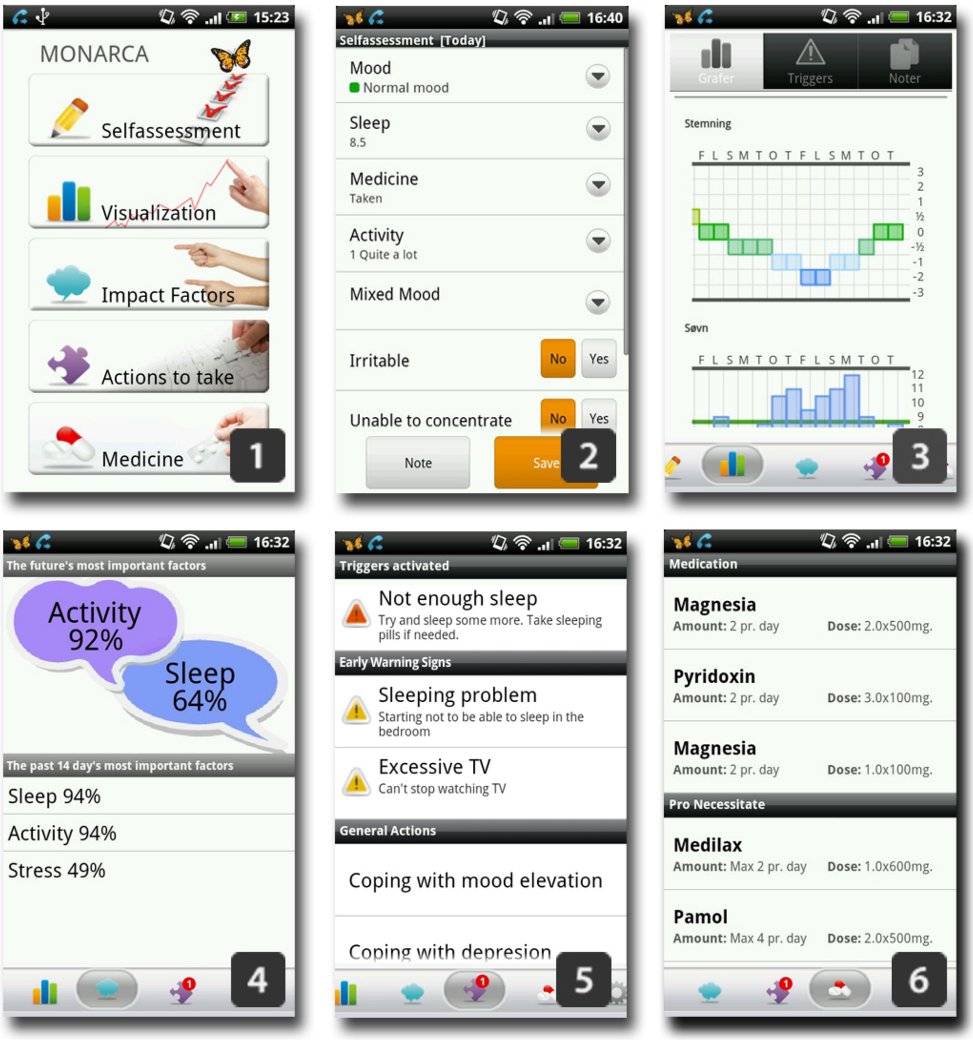

Figure 2.5: The MONARCA Android application user interface. (1) Menu; (2) Self-Assessment; (3) Visualizations; (4) Impact Factors; (5) Plans of Action; and (6) Medicine

Feature	**Description**
Actions To Take	Actions To Take is a generalization of the feedback the patients receive from both Triggers, Early Warning Signs, and General Actions.
Early Warning Signs	Early warning signs (EWS) are personal signs of an impending episode, which are configured specifically to the patient. If an EWS is activated, the patient receive personalized strategies and actions for self-help and clinicians are notified in the Dashboard.
Forecast	A forecast of patients' mood 5 days ahead in time is computed daily, based on the collected data. The outcome of the forecast is shown only to the clinician in the overview screen.
General Actions	General actions, also known as action plans, contains personalized information regarding how the patient can manage the disorder. It focuses on the manic and depressed state, and each cover three aspects; "How to help myself", "Things that help", and "Others can help me by..".
Graphs	The graphs consists of three items; graphs, triggers and notes, and is the central feedback mechanism to the patient since it is shown every time the patient have entered a Self-Assessment. The visualization provides an overview of the last 14 days.
Impact Factors	Impact Factors are computed daily through a correlation analysis based on the collected data, pointing out which collected data has the biggest impact on a patient's mood. Feedback is provided along with the impact factors, focusing on strategies and actions for self-help on each factor.
Live Wallpaper	The live wallpaper visualizes the patient's Impact Factors using animated speech bubbles in different colors and sizes, which moves calmly around in the background of the phone's home screen. If a bubble is pressed, it enters the Impact Factor screen in the MONARCA application.
Medication	Medication provides an overview of a patient's regular and p.n. medication, along with detailed information on each prescribed drug.
Retrospect	The retrospect feature allows patients to re-assess a previous mood score, adding a retrospect score to the system up to two weeks back in time. This is due to the perception of mood can be influence by the mood itself, and the lapse of time can improve the understanding.
Self-Assessment	Primary; Mood, Sleep, Activity, and Medicine.
	Secondary; Mixed mood, Cognitive problems, Irritability, Alcohol, Stress, Menstruation and a Note.
	Personal; Early warning signs and up to 3 custom user-defined items through predefined scales.
Sensor based data collection	Physical Activity; Sampled through the accelerometer every 5 minutes.
	Social Activity; Number of in- and outgoing text messages and phone calls, as well as length of calls.
	Mobility; Monitoring the number of times the phone changes the cell tower it is connected to.
	Phone Usage; How much the phone is used, e.g. how long the screen is turned on, etc.
Triggers	Triggers are monitoring the submitted self-assessment data based on a user defined set of rules, e.g. sleeping less than 6 hours 3 night in a row. If a trigger is activated, the patients receive personalized strategies and actions for self-help and clinicians are notified in the Dashboard.

Table 2.1: An overview of the features in the MONARCA system.

2.3.1 Android Smartphone Application

The overview of the interfaces of the application can be seen in Figure 2.5. On a daily basis, an alarm on the Smartphone reminds the patient to fill out the self-assessment (Figure 2.5(2)). As described in Table 2.1, the self-assessment is divided into 3 overall sets of parameters. First the *primary* parameters, which must to be entered on a daily basis. The core parameter is the patient's mood, which the patients rate on a 9-point scale spanning from highly depressed (-3) to highly manic ($+3$), including ($+0.5$) and (-0.5) point scores. Secondly, the *secondary* parameters, which are useful supplement to the mandatory parameters, but are not required for the patients to fill in. Finally the *personal* parameters, which are custom user-defined parameters the patients can create together with their clinician. This is due to the great individual variability in bipolar disorder. A self-assessment can be modified throughout a day, but is closed at midnight and cannot be changed hereafter. If a patient forgets to fill in the self-assessment all together, it is possible to go back two days in time and fill it in. When a self-assessment is saved, the application presents the patients with an overview of the data from the past 14 days (Figure 2.5(3)). Besides the self-assessment, the Smartphone continuously samples data automatically through different sensors in the phone. There are 4 different types of sensor data; Physical Activity, Social Activity, Mobility, and Phone Usage. They are described in detail in Table 2.1.

Furthermore, the application provides patients with personalized context-appropriate clinical responses on the data through triggers and impact factors, it keeps track of early warning signs, and helps patients manage their general actions (Figure 2.5(5)) as well as their prescribed medication (Figure 2.5(6)). In the design of the system, a lot of effort has gone into designing the application as concise and simple as possible. This means the use of the system only requires the patients to fill in a self-assessment once a day, which only takes approximately 10 seconds. The main reason for using a Smartphone application is that the phone is almost always with the patient [39]. This is useful not only for the automated data collection, but also for collecting the self-assessment data since a Smartphone is much easier available compared to paper based mood charts or a web browser {2}.

2.3.2 Web Portal

The system is available to patients and clinicians through a web portal. Patients can review their personal data and configure the system. When clinicians log in, they get an dashboard providing an overview of their patients and how they are doing. The dashboard is shown in Figure 2.6.

The dashboard displays the core parameters of mood, activity, sleep, and medicine adherence for the last four days, as well as notifications, the mood forecast for the next five days, and impact factors. From the dashboard, the clinicians can select individual patients and re-

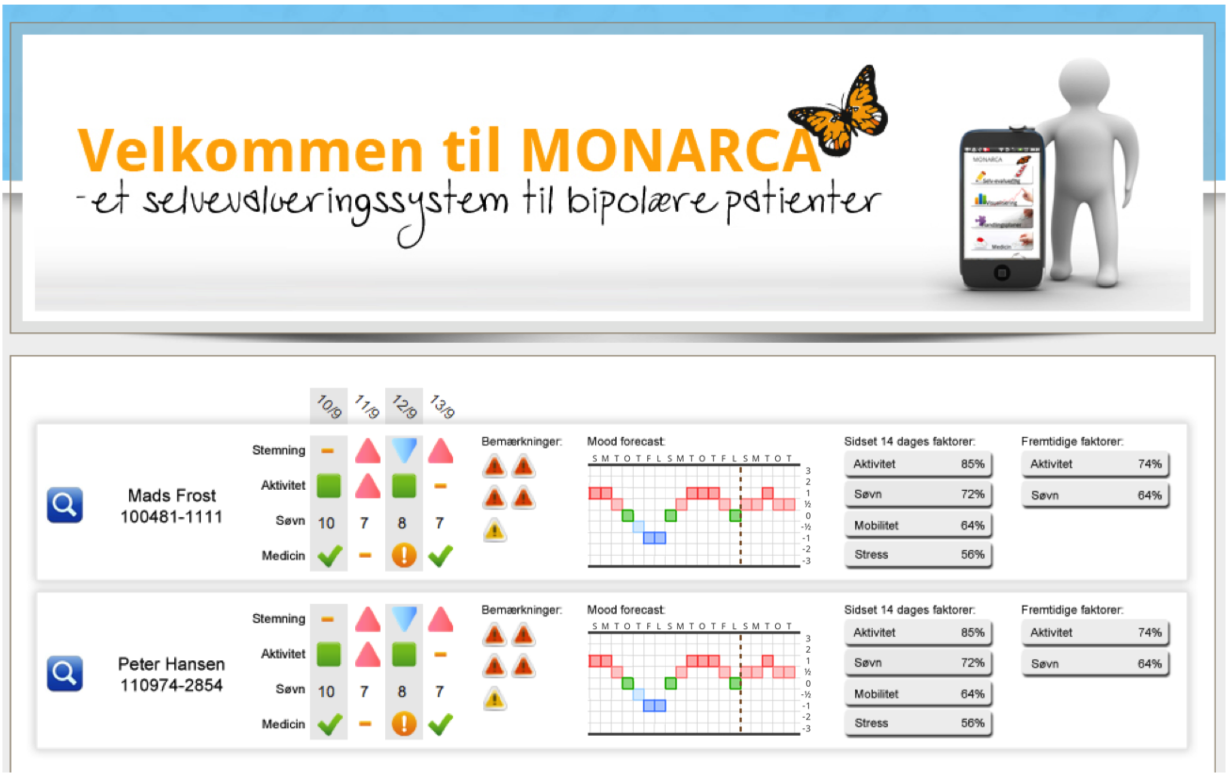

Figure 2.6: Web Portal - The Clinician Dashboard. Each line is a patient (name and ID number in the left column), showing mood, activity, sleep, and medicine data for the past 4 days. Then Triggers and Early Warning Signs activated, the mood forecast for the next 5 days, and to the far right is the impact factors.

view their data in more detail. This is done in the detailed patient overview screen, seen in Figure 2.7. It contains detailed information regarding the patient, including their personal information, diagnoses, last medical contact, detailed data monitored through the system, and the problem areas and issues in focus in the treatment.

Through the use of the web portal it is further possible for the clinicians to configure the settings by updating prescribed medication, personalized general actions as well as create triggers and early warning signs.

2.3.3 Data Analysis

The data collected through the use of the system collects from each patient allows for not only reporting what happened and why, but also to build models that may predict what will happen, and indicate what is presumed to cause it – at least to a certain degree. Informing patients of factors important for their health and how to handle these, as well as inform clinicians regarding their patients' future mood state, all allow both patients and clinicians to be proactive and prevent possible manic or depressive episodes. The following is a high-level

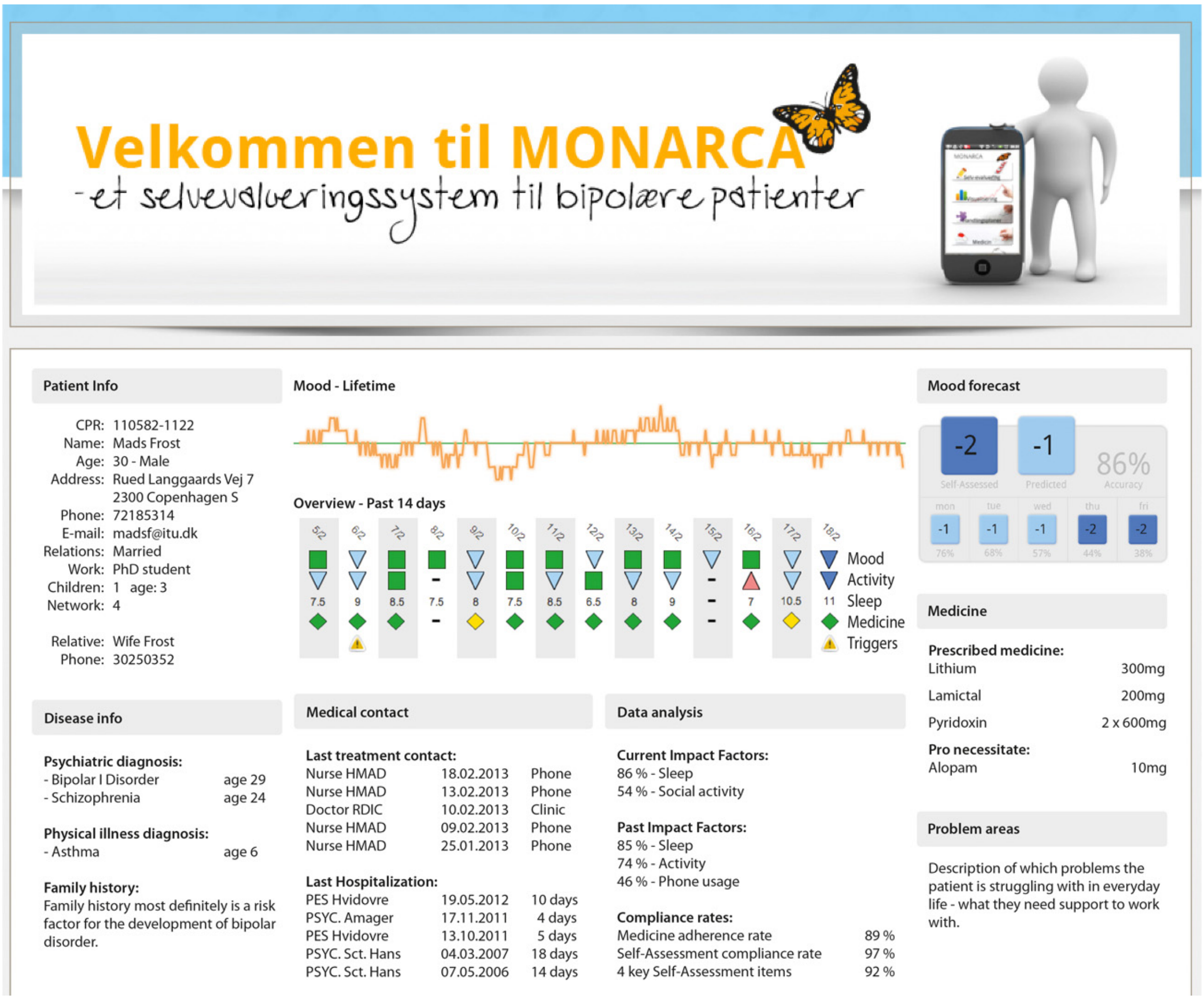

Figure 2.7: Detailed Patient Overview Screen (DPOS)

description of the data analysis, while further details can be found in {4}.

To estimate the tendency of the mental state, the system performs a time series forecast, where the patients' mood is predicted for the coming five days. The mood forecast is computed on a daily basis by looking at the pattern of the data from the past 14 days, evaluated based on a personalized model generated on the full data history of each patient. The outcome of the forecast is a floating-point number for each forecast day. This number is rounded to the nearest category in the 9-point mood scale before being displayed to the clinicians in the dashboard (Figure 2.6).

The factors important for the patients' health – the Impact Factors – highlights which of the parameters from both the self-assessment and the automatically collected data have the highest impact on a patient's mood. There are two types of impact factors; current and past. The impact factors are calculated daily through different evaluators, and the parameters that are common in at least two evaluators with an accuracy higher that 25% are selected as impact factors. These factors are displayed both to the patients through the impact factor screen in the Android application (Figure 2.5(4)), as well as in the Live Wallpaper on the phone. They are also displayed to the clinicians in the dashboard (Figure 2.6).

2.4 Clinical Trials

There has been a total of 3 clinical trials of the MONARCA system. The randomized clinical trial is not described in this section, but information regarding the trial setup is published in [44]. All trials were performed at The Clinic of Affective Disorder, Psychiatric Centre Copenhagen, Rigshospitalet, Denmark. They have been approved by the Regional Ethics Committee in The Capital Region of Denmark (H-2-2011-056) and The Danish Data Protection Agency (2013-41-1710). All electronic data from the Smartphones were stored at a secure server at It-, Medico- og Telephoneorganization (IMT), in the Capital Region, Copenhagen, Denmark (I-suite number RHP-2011-03). Written and oral information about the study was presented to all eligible patients before informed consent was obtained. All patients were free to withdraw their consent for participating in the trials at any time without this interfering with their treatment at the clinic.

For all clinical trials, the inclusion criteria were an age between 18-60 years and a bipolar disorder diagnosis according to ICD-10 using Schedules for Clinical Assessment of Neuropsychiatry (SCAN (15)). Exclusion criteria were unwillingness to use the MONARCA Smartphone as the primary cell phone, inability to learn the necessary technical skills for being able to use the Smartphone, lack of Danish language skills, and pregnancy.

The first trial ran from May to August 2011, a total of 14 weeks. 28 patients were approached out of which 14 were enrolled in the trial. 2 patients dropped out underway, thus a total of 12 patients finished the trial. This was the initial trial of the first version of the system. The main objective of this trial was to gauge the feasibility of the system as used by patients suffering from bipolar disorder. Further, if this study was positive, to move into a randomized clinical trial. The trial is published in {2}.

In the second trial, the system was deployed in a 6-month field trial from March to August 2012, a total of 26 weeks. 6 patients were approached. All enrolled in the trial, whereof none dropped out. This was the first trial of the 2^{nd} version of the system. The purpose of this trial was to verify the redesign of the system as useful in treatment, and to investigate if the new data analysis functionality was working as intended, and to evaluate the outcome of the forecast. The trial is published in {4}.

The final clinical trial was from September 2012 to January 2013, a total of 18 weeks. 21 patients were approached, whereof 18 accepted to join the trial. No patients dropped out of the trial. The trial examined to what degree the system supported the treatment, and the ability to detect future mood changes. The trial is reported in {6}.

To evaluate the use of the system in treatment of bipolar disorder, different methods have been applied. The usability of the system have been assessed by applying the IBM Computer System Usability Questionnaire (CSUQ) [87], measured using a 7-point Likert scale from ‘Strongly Agree’ (1) to ‘Strongly Disagree’ (7). A questionnaire with statement regarding the usefulness of the system during the trial period have been applied, also assessed on the 7-point Likert scale. A questionnaire containing the same questions, but now in future tense, have been used to investigate the *perceived* usefulness of the system in the future. This is done as there is a significant correlation between users’ perceived usefulness of a system, and its actual future usefulness [37]. The perceived usefulness is likewise assessed on the 7-point Likert scale. Furthermore, interviews with all participants have been performed at the end of the trials, which have been analyse using Kvale’s first two levels of conversation analysis; self-perception and critical common sense understanding [77]. Finally, the forecast is evaluated through comparing the historical sequence of mood forecasts with the actual mood values provided through the self-assessments.

2.5 Empirical & Clinical Results

The system have undergone extensive deployments, through multiple clinical trials and a randomized clinical trial. The following section summarizes these findings. However, at present time, the clinical effects from the randomized clinical trial are not finalized as the data analysis is still ongoing. Thus the results are not published yet and are not touched upon in this section. However, {5} does report from the clinicians’ experience from using the system during this trial.

As the system is designed to support the treatment, it makes sense to view the results from both perspectives – the system and the treatment. This is done through the different themes addressed in the evaluations. The results are divided into themes, to be able to describe the results across the different trials. The key themes in the following sections address adherence, usefulness, usability, and forecast. The themes does not elaborate on all findings from all the trials, but highlight the most important.

2.5.1 Adherence

When referring to adherence, it refers to the use of the system and how often the patients have filled in their self-assessments. It does not refer to medication adherence or behavior changes performed based on the use of the system.

Adherence to technology have an impact on its efficiency in treatment. In a 2003 report entitled "Adherence to Long Term Therapies, Evidence for Action" the WHO claimed that *"increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatment"* [137]. High adherence to self-reporting and engagement is also found to be crucial in efficient psychoeducative treatment [22, 30, 41]. This implies that ensuring adherence to the use of personal health technologies is core to their success.

Looking across the deployments of the system, patients' adherence to the use of the system have been very high. The rates were 87% in the first trial, 91% in the second trial, and 88% in last trial. These adherence rates are higher than the 65% found in the Mobile Mood Diary system [100], which, however, was tested in a much longer period and may suffer from long-term effects, while it is similar to the findings with the ChronoRecord where 80% of the patients had an adherence rate over 90% [7]. Compared to paper-based self-assessment, which is known to suffers from a range of problems, such as low adherence rates, unreliable retrospective completion, and time intensive data entry [9, 100, 156], the MONARCA system provides much more valid day-by-day data {2}. This was also found by the nurses in the randomized clinical trial, who found that the use of the system improved the patients' adherence to reporting their self-assessment compared to a paper based approach {5}.

2.5.2 Usefulness

Usefulness can be seen as a function of how the system fit according to the task at hand [37]. The usefulness of health systems is considered highly important, as it impacts the adoption and efficiency of the systems [89].

From the questionnaires it is found that the usefulness of the system for disease management during the first trial scored an average of 3.16 {2}. This means that patients agree (though not strongly) that the system helped them in managing their disorder. However, the perceived usefulness of managing their illness scored an average of 2.16, indicating that the system would – if used in the future – assist them in managing their disease.

From the interviews with the nurses {5}, it was found that the use of the system in the treatment improved the process. It was reported to increase awareness and insight of the disease. It furthermore found that the use of the system increased clinicians' awareness of their patients and their state, allowing for more focused treatment and faster interventions. These findings match the outcome of the trials, where the patients found that the use of the system created and supported awareness and insight during the trial, with a score of $\tilde{x} = 2.00$; $iqr = 3.00$ {6}. Improving disease awareness is vital for an effective treatment of bipolar disorder [24, 139], and having patients monitor their mood while promoting insight and good strategies for coping with their risk situations, is important for patients in their management of the disease [78, 121]. The patients further found that the system supported a prompt assistance through both the tie to the clinic and the automated responses from the system, with a score of $\tilde{x} = 3.00$; $iqr = 3.00$. Enabling patients to receive prompt treatment when experiencing early symptoms of relapse is associated with high clinical outcomes [121].

2.5.3 Usability

Usability refers to the ease of use and learnability of the system. The usability evaluates how well the interaction with technology is designed. Measuring usability is particularly difficult because usability is not a unidimensional characteristic, but emerges as multidimensional in the context of users performing tasks with a technology in a specific environment [146].

In the first trial of the system {2}, the usability scores showed that the overall usability of the system is good (OVERALL = 2.60) and the users found the system very useful (SYSUSE = 1.93). This reflects a low score in simplicity, comfortability and learnability, and efficiency. The information quality score is lower (INFOQUAL = 3.25) which can be ascribed to problems with the error messages of the system, which scored 5.33, and did not help users fix the problems they may have experienced. Finally, the system scores well in interface quality in general (INTERQUAL = 2.86). However, the trial also found that the system did not have all the functions and capabilities that patients expected. This was voiced by the patients in the interviews as a need for customizing the self-assessment to the individual patient, as there is a great individual variability in bipolar disorder. When interviewing patients from the second trial {4}, they reported that the redesign had improved the overall usability of the system, which supported the need for customization. This is also evident from the last trial, where usability was investigates but not reported in the article. Here the OVERALL usability score was 1.67.

2.5.4 Forecast

The growing sophistication of systems and data presents opportunities for forecasting patient's future health state [86]. The approach taken in the MONARCA system is the first attempt at trying to forecast the future mood state of mentally ill patients. Mood forecasting enables proactive illness management, but the data quantity and quality challenges the accuracy.

The ability to forecast patients' mood was evaluated in the second trial {4}, where mood estimation model built upon both sensor based and self-assessed data provided an average minimum mean absolute error of 0.40. This was compared to a model built with only sensor based data, which provided an average minimum mean absolute error of 0.45. This means that even though the combination of sensor based and self-assessed data gave slightly better results, the use of only sensor based data still provides a close estimation of the mood. The forecast was also analyzed in the last trial {6}, based on the model including both sensor based and self-assessed data. Here the mean absolute error was 0.30 for the precision on forecasting one day ahead in time, 0.35 for forecasting two days ahead, 0.37 for three day ahead, 0.35 for four days ahead, and finally 0.37 for five days ahead in time. However, when observing the data more closely, we found that the system is highly accurate when forecasting the patients neutral state (between $(+0.5)$ and (-0.5)), with an accuracy of 96%. But when it comes to forecasting mood states above $(+0.5)$ and under (-0.5), it performs poorly. It only had a accuracy of 8%, while the accuracy increases to 42% if we include the 1^{st} neighboring scores. The poor results in the determination of manic or depressed mood states can be caused by several issues; the algorithm not being optimized, the data grounds not being sufficiently informative, or the nature of the disease being too difficult to model – even on a personalized level.

2.5.5 Summary of Empirical & Clinical Results

In general, the trials included in this thesis show promising results for the use of the MONARCA system in the treatment of bipolar disorder. The three trials provide good usability and feasibility outcomes that report high rates of adherence to the use, good usefulness ratings, high usability scores, and a general satisfaction with the system from both patients and clinicians. Prior research suggests that the approach of repeated self-monitoring over time increases awareness and insight, and thereby improves the management and treatment of bipolar disorder. The development of the Smartphone application has facilitated the self-monitoring through the collection of relevant self-assessed and automatically collected sensor data, thereby providing a portable and convenient approach with which patients can gather relevant information regarding their daily lives. The use of the system showed considerable potential in revealing interplay between mood, cognition, and behavior, which increase patients' awareness and insight. This, supported by a timely personalized feedback to prompt patients with action to take along with the tie to the clinic, is found to enhance the treatment.

However, common technical problems such as accuracy of sensor data, battery consumption, connectivity, etc., all poses as challenges for the solution. And even though MONARCA shows promising results in predicting patients' neutral mood states, it needs to be further optimized to be able to accurately predict mood swings, which holds promise for enabling effective early interventions.

The studies also have a number of limitations that needs to be addressed. First, the number of included patients and clinicians in the trials were low, which restrict the power of the MONARCA system's perceived effect on improving treatment. Secondly, the duration of the trial is also a limitation in terms of assessing the long-term effect of the use. Finally, the trials are based on patients' and clinicians' experiences with the use of the system, and thus do not hold unequivocal clinical evidence that the MONARCA system had a clinical effect. However, this effect is being investigated in the randomized clinical trial.

Chapter 3

Design Elements of Personal Health Technologies

Research on personal health technologies have targeted a wide range of health conditions, focusing on systems for both wellness as well as use in treatment. This research comes from both health sciences and from disciplines in computer science, such as HCI and ubiquitous computing. However, it is important not only knowing about these systems, but moreover to understand the fundamental elements these systems are designed on. This is needed in order to analyze and compare existing personal health technologies. Hence, the design elements serve the purpose of providing a common vocabulary with which to discuss and analyze these technologies.

3.1 Review of Personal Health Technologies

To understand and define the design elements of personal health technologies, a list of systems was reviewed and synthesized. The systems use in the analysis were identified through a search of PubMed, IEEE eXplore, and ACM Digital Library, which are the main databases that index research literature on personal health technologies. PubMed was searched using the following terms: “technology”, “personal”, “health”, and “design”. The IEEE and ACM databases were searched for combinations of the term “system” and the terms listed above. Based on the abstracts retrieved through these queries, articles were identified that were consistent with the notion of personal health technologies. For each article in the resulting set, along with articles found through the citations in the search results and the empirical work on designing the MONARCA system, the approaches were then iteratively clustered, until four key design elements was apparent. This approach to disseminate personal health technologies is believed to both help the readers to understand the key elements of personal health technologies and to help analyze and compare existing instances in order to inform future designs through an understanding the general construct of these technologies. Although the elements covers the aspects identified in the search, the following description of the four elements does not touch on all personal health technologies found in the literature. As the goal of the design elements is to inform the analysis and understanding through a review of the technologies, only illustrative examples are presented from seven selected articles to underpin the identified design elements, together with the MONARCA system. The eight systems are chosen on the basis of attempting to depict the width of the term personal health technologies, by presenting systems that targets both wellness and treatment, different types of health issues, different age groups, and using different approaches and technologies. However, a larger selection of the systems are mentioned in the introduction of personal health technologies on page 4. In order to better understand the design elements, the selected seven systems are first briefly introduced.

MAHI is an abbreviation of *Mobile Access to Health Information*, which is a system that assists newly diagnosed patients with diabetes in acquiring and developing reflective thinking skills through social interaction with diabetes educators [96]. It consists of a mobile application including a conventional blood glucose meter and a website supporting subjective data collection as well as communication with the diabetes educators. The components can be seen in Figure 3.1. Patients with diabetes use MAHI to record their blood sugar levels and diabetes-related challenges, such as questions, problems, or activities of interest through the phone's image and audio capturing capabilities. They share these records with a diabetes educator through a website, where they engage in a discussion over the content.

Figure 3.1: The components of MAHI – The phone and glucose meter on the left, and the website displaying data on the right [96].

Fish'n'Steps promotes an increase in physical activity through a social computer game, where a player's daily foot step count measured by a pedometer adds to the growth and activity of an animated virtual character, a fish in a fish tank [88]. The personal fish tank and the kiosk where data is uploaded to the system can be seen in Figure 3.2. The fish tank also displays other players' fish, which creates an environment of both cooperation and competition, and foster communication between the players.

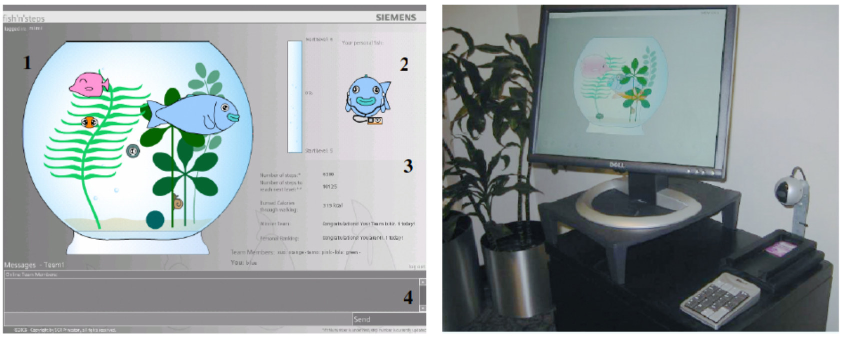

Figure 3.2: Fish'n'Steps – The personal interface on the left, and the public kiosk and pedometer platform on the right [88].

Mobilyze! is a system that supports disease management through context sensing and patient education, targeted depression [18]. The patient daily report the mental state through a self-assessments questionnaire, while the system automatically collects data from a patient's phone. Machine learning approaches are utilized to predicted patients' mood, emotions, cognitive/motivational states, activities, environmental context, and social context. A website is used to display graphs illustrating correlations between patients' self-reported states, as well as contain didactics and tools for teaching patients behavioral activation concepts.

BeWell is a system designed to help people manage their overall wellness [81]. It continuously monitors multiple dimensions of behavior through automatic sensor data collection and incorporates a graphical user feedback increasing awareness of how different aspects of lifestyle impact the user's personal wellbeing. This feedback is given directly to the user on the phone through a live wallpaper, while a web portal provides access to an automated diary of activities and wellbeing scores. Examples of the live wall paper and the web diary can be seen in Figure 3.3

Figure 3.3: BeWell – The personal web diary of activities and wellbeing scores on the left, and the live wallpaper on the right [81].

Time to eat aim at motivating children to practice healthy eating habits through a phone-based game, which lets them care for a virtual pet by sending it photos of the food they consume [123]. Based on nutrition scores of the reported food consumption, the children receive feedback through a personalized pet, visualized as either happy or sad. The application further help provide an overview of the consumed food, allowing the children reflect on their eating habits. An example of a child's pet and the overview of consumed food can be seen in Figure 3.4

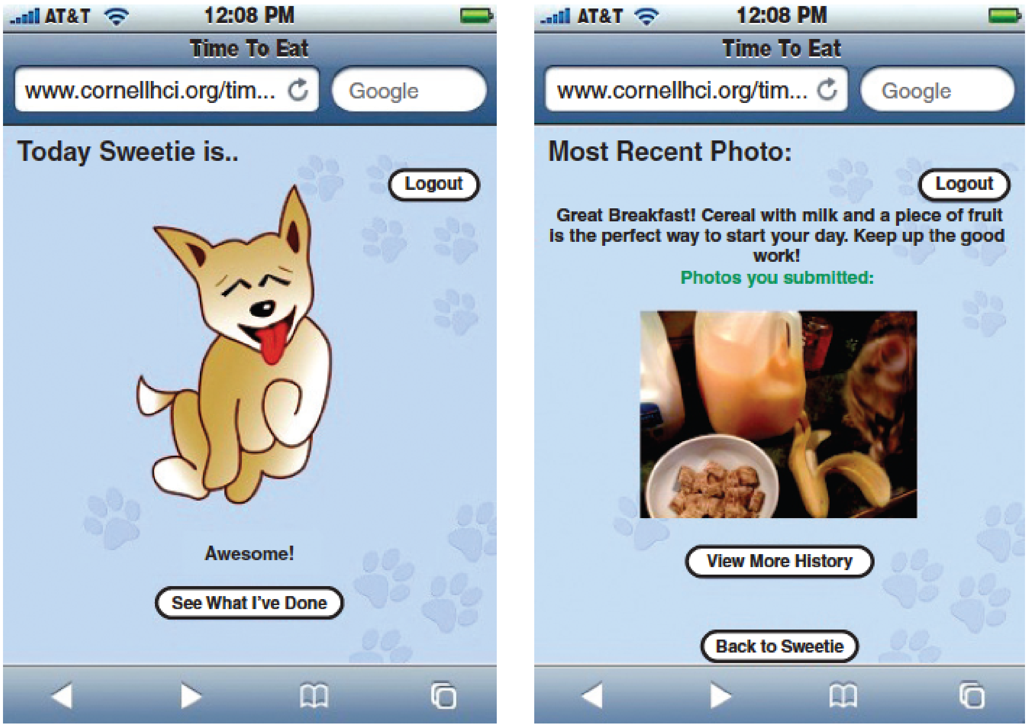

Figure 3.4: Time To Eat – The visualization of the child's pet status on the left, and the overview of the consumed food on the right [123].

Asthmon is a system that combines a mini peak-flow meter and an asthma action plan into a blowing game with a virtual pet [85]. The Asthmon system consists of two components; (i) A portable toy for asthmatic children, and (ii) a software that is for use by parents and caregivers. The toy can be seen in Figure 3.5 together with the interface. When a child use the peak-flow meter, the system provides immediate clinical feedback to the child on what to do in the given situation, as well as syncs the data to the parents or care-givers, allowing for remote monitoring.

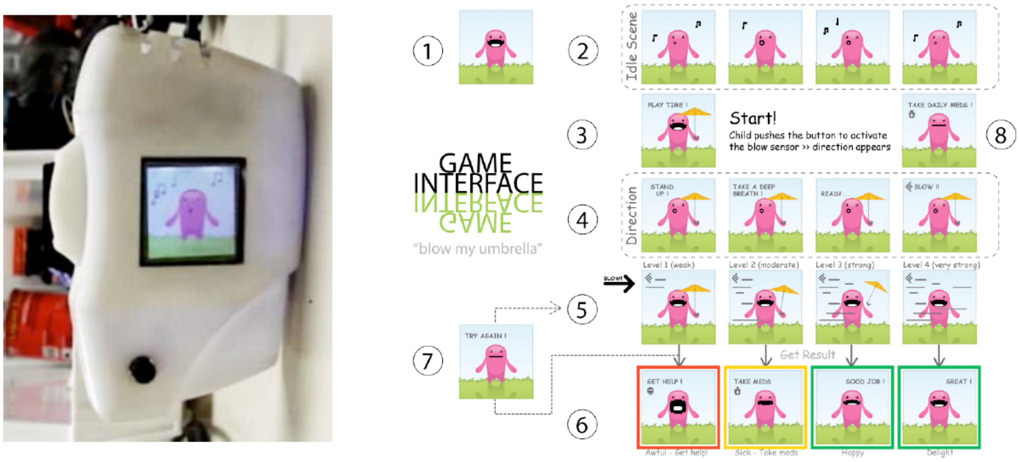

Figure 3.5: Asthmon – The peak-flow toy with interface on the left, and overview of the process of the game on the right [85].

Mobile Mood Diary is a system for engaging young patients in psychotherapeutic activities through a symptom tracking system [100]. It consists of a phone-based application for self-reporting, and a website used for visual feedback of the reported experiences to the user. These can be seen in Figure 3.6. The data collection and visualization targets reflection for the patient, as well as the data can be used in the treatment during consultations between the patient and the clinician.

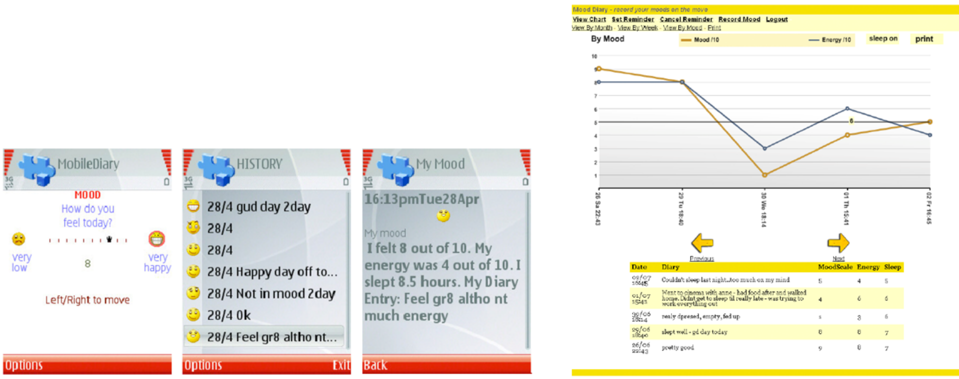

Figure 3.6: Mobile Mood Diary – The phone interface with an overview of ratings on the left, and overview of the graphs on the website on the right [100].

3.2 The Four Design Elements

The four identified design elements consists of *Collection, Management, Feedback,* and *Sharing*, and are explained in more detail in the following section through examples from the eight selected systems. An overview of the eight systems and how they are defined through the four design elements can be seen in Table 3.1.

System	Collection	Management	Feedback	Sharing
Wellness				
BeWell - General wellness	Automatic sensor data: - Sleep - Physical Activity - Social Interaction	Historic overview of data Data Analysis: - Wellbeing score	Graphs Live Wallaper	%
Fish'n'Steps - Physical Activity	Manual sensor data: - Pedometer	Goals Data Analysis: - Burned calories	Graphs Live Wallpaper	Team members
Time To Eat - Food Intake	Manual sensor data: - Pictures	Historic overview of data Data analysis: - Nutrition scores	Virtual pet	%
Treatment				
Asthmon - Asthma	Manual sensor data: - Peak-flow	Historic overview of data	Virtual pet Automatic responses: - Clinical actions to take based on sensor data	Parents
MAHI - Diabetes	Manual sensor data: - Blood glucose - Audio - Pictures Free text self-reports	Historic overview of data	Manual responses: - Feedback from the diabetes educators	Diabetes Educators
Mobile Mood Diary - Mental health (CBT)	Self-assessment questionnaire Free text self-reports	Historic overview of data	Graphs	Can be shared with clinicians during consultations
Mobilyze! - Depression	Automatic sensor data: - A total of 38 sensor inputs Self-assessment questionnaire	Historic overview of data Didactic health lessons Activity calendar General actions Data analysis: - Location - Activity - Mood - Emotions - Cognitive state	Graphs (future automated responces planned based on data analysis)	Clinicians
MONARCA - Bipolar Disorder	Automatic sensor data: - Physical Activity - Social Activity - Mobility - Phone Usage Self-assessment questionnaire Free text self-reports	Historic overview of data General actions Medication Data analysis: - Impact Factors - Forecast	Graphs Live Wallpaper Automated responses: - Triggers - Early Warning Signs - Impact Factors	Clinicians

Table 3.1: Systems Overview

3.2.1 Collection

One of the core elements of personal health technologies is to use the technology for tracking health-related behaviors, physiological states, symptoms, and other parameters relevant to health. The process of tracking is often referred to as self-monitoring, and it creates the basis for these technologies. In personal health technologies, self-monitoring has been implement in two overarching way: through self-reports and automatic data collection. The data collection varies in size, from only one source with one type of information to elaborate data collection approaches with multiple sources and types of data. For instance, Asthmon only track children's peak-flow scores, while MAHI combines the collection of data from a conventional blood glucose meter with flexible self-reports by capturing diabetes-related challenges, such as questions, problems, or activities of interest using the phone's image and audio capturing abilities. However, both systems' data is all manually logged. In terms of automatic data collection, BeWell is based solely on this approach. It measures sleep, physical activity and social interactions through sensors embedded in the user's Smartphone, without any user involvement. Finally, systems like Mobilyze! and MONARCA use a combination of both self-reports by having the patients fill out daily questionnaires, as well as automatically collects data from a variety of sensors, all providing better grounds to understand the patient's behavior and health patterns.

3.2.2 Management

The collected data as well as information related to the health issue of the user is maintained through the system. Keeping track of the personal health history is a vital precursor for activities that support and inform the users health-related decisions and planning. With health information available in an electronic platform, users will be able to manage their information and monitor important health issues, whenever and wherever. In this way, personal health technologies can make it easier for the users to manage their health more consistently and, thus, more effectively. Simple solutions solely provides an overview of the collected data, as seen in MAHI and Mobile Mood Diary, while more elaborate systems combine the data with health information, such as the activity calendar and didactic health lessons in Mobilyze! and the medication and general actions in MONARCA. However, the issue of consolidating the wealth of information related to the users' health could introduce an overwhelming volume of fragmented information, making it difficult for them to gain a proper overview and understanding of its relevance and implications. In this regard, the potential is to help analyze a user's health profile to identify health concerns and possible improvement based on an analysis of the collected data. This is done from simple analyses of burned calories and nutrition scores in Fish'n'Steps and Time To Eat, while Mobilyse! and MONARCA apply more sophisticated approaches of context and correlation analyses, as well as mood forecasting.

3.2.3 Feedback

One of the chief advantages of using personal health technologies for health management is the provision of feedback that can be delivered to the users, without any effort on their part. Feedback is needed to help understand and respond to a given health issue. This is accomplished through providing awareness, health information, and other kinds of content that can help users manage their health. Two types of feedback, visualizations and direct responses, leverage personal health technologies to keep the users informed of their state and facilitates care interactions. Visualizations consists of concrete visualizations like graphs, used both in BeWell, Fish'n'Steps, Mobile Mood Diary, Mobilyze! and MONARCA. Further, visualizations also employ abstractions, such as the virtual pets in Time To Eat and Asthmon, the fish in BeWell and Fish'n'Steps, and the bubbles in MONARCA. Direct responses supports the users with feedback on a given event or recording of data, and these are provided in 2 different ways; manually or automatic. Manually is facilitated by the sharing of data, where friends or caregivers provides feedback based on the collected data, such as the diabetes educators in MAHI. Other systems approach the direct responses in an automated and instantaneous way, where Asthemon informs children on what clinical actions to take upon the outcome of their peak-flow score, and MONARCA provides patients with strategies for action and self-help through trigger, early warning signs, and impact factors.

3.2.4 Sharing

Although personal health technologies are empowering users to better manage their health issues, the effective management of many health issues requires and improves from help and support of individuals related to the user, be it family, friends, or caregivers. Especially in treatment-based systems, the technologies are commonly used to monitor patients' health and inform the caregivers of the user's symptoms, activities, and physiological parameters. This allows for a better informed treatment, early interventions, and remote coaching, making it easier for caregivers to care for the patient by facilitating continuous communication as opposed to episodic. On an overall level, sharing has two main purposes; enticement or support. Fish'n'Steps share the data between user's team members, as an enticement for improved outcomes, while Asthmon's sharing support parents' care for their children by follow their peak-flow scores. The degree of sharing is further varying according to the purpose. For instance in the Mobile Mood Diary, the data can be shared with the clinician during consultations if allowed by the patient, while systems like MONARCA and Mobilyze! have sharing embedded as core components, as treatment is carried out through the use of the systems. On the other hand, if sharing is not in any way relevant, the technologies do not facilitate this aspect. For instance, in the BeWell system, the data is not shared with anyone, as it is only intended to inform the user of the wellness status.

3.3 Summary of Design Elements

Regardless of whether users of personal health technologies are faced with a disease or are trying to attain a more health lifestyle, they are supported through the use of these technologies as they address the challenges the users are faced with. This is done by involving and better informing the users in the management of their health, as a part of their daily lives. Personal health technologies facilitate real-time symptom and activity monitoring, while it allows for the analysis and tracking of progress over time. This provides the means for personalized feedback and in the process of informing and promoting health outcomes. Further connecting users, families, and health care providers, assists' motivational support and facilitate an easier care for the users through continuous communication. However, challenges still persist in how we address these issues of managing health through the design of the systems. These challenges are addressed in the following chapter in terms of proposing more refined design targets for personal health technologies, supporting the process of obtaining improved health.

Chapter 4

Design Targets for Personal Health Technologies

The overall target for personal health technologies is to foster behavior change. However, the empirical work with designing the MONARCA system disclosed that behavior change is not the only target relevant for these types of systems. The purpose of this chapter is to inform designers of the importance of considering nuanced targets in regards to the health issue they are designing for.

In the workshops on designing the first version of the MONARCA system, different approaches on how to interact with the patients through the system were discussed, in order to facilitate behavior changes. However, the work was influenced by a view that there were more to the management of bipolar disorder than just making changes to behavior and thus a refined approach was examined. This shifted the considerations from the regular behavior change approach onto further reflections on what it is these systems actually are able to support in the management of personal health. These thoughts were further informed by the psychoeducational approach used in the treatment of bipolar disorder, where a lot of effort is put into increasing patients' insight into their disease. It evolves around the patients' understanding of their experiences and how to handle these. Hence, the core target of psychoeducation is not behavior change, but an improved insight, which then foster the necessary behavior changes. In addition, behavior change theories point towards that individuals who have successfully changed behavior, rarely does this spontaneously. The process of change is perceived as continues moves between a series of stages, where the actual change is the final stage. This implies the end result of behavior change is not the only target important for behavior change, and that the stages in the process that leads to behavior change can be seen as targets in themselves. In this light, three design targets consisting of *Awareness*, *Insight* and *Change* are found as individual targets for personal health technologies.

To justify these design targets, and to understand what it is that makes individuals motivated to changes while others are stuck in existing patterns of behavior, there is a need for realizing the motives behind the behavior as well as understand the mechanisms that characterize change. In the following sections, two theories of behavior change are described, which both provide their view on important factors in relation to change. Theory on awareness & insight is further described, and the three design targets are presented in more detail along with examples of features in the MONARCA system, describing how they address each target.

4.1 Behavior Change

Behavior change refers to any transformation or modification of human behavior, and behavioral change theories' are attempts to explain why behaviors change. Many theories have different perspectives in behavior and change, and I have chosen to focus on two different theories; the Health Belief Model and The Transtheoretical Model of Behavior Change. These theories are chosen as they have previously been drawn upon in designs of personal health technologies [31, 56, 88]. Other theories include the Relapse Prevention Model [99], Theory of Reasoned Action [148], Social Cognitive Theory [6], and Theory of Planned Behavior [1], while many more exist. In the following parts of this section the two theories of behavior change is introduced in more detail.

4.1.1 Health Belief Model

The health belief model is a conceptual framework used to understand health behavior and possible reactions for non-compliance with recommended health actions [11, 135]. The model can be seen in Figure 4.1. The core belief in the model is, that our health behavior is controlled by different health beliefs; (i) the desire to either avoid illness or to get well, and (ii) the assumptions about what behavior can prevent or help cure illness. The theory thus departs in the notion that people react differently to threats to their health, and that people try to behave in the manner that they perceive will improve their health. The decision to try and change the present health behaviors is dependent on an assessment of pros and cons by the change. It is inherent in the model that people will try to change the behavior they experience as a threat to their health, unless they experience barriers so large, that it is perceived at not worth the effort. Furthermore, stimulus or a cue to action must be present in order to trigger the health-promoting behavior [66].

There are six major constructs in the health belief model are proposed to vary between individuals and predict engagement in health-related behaviors [51]:

Perceived Seriousness and Susceptibility – The construct of perceived seriousness refers to the subjective assessment of the severity of a health problem and its potential consequences,

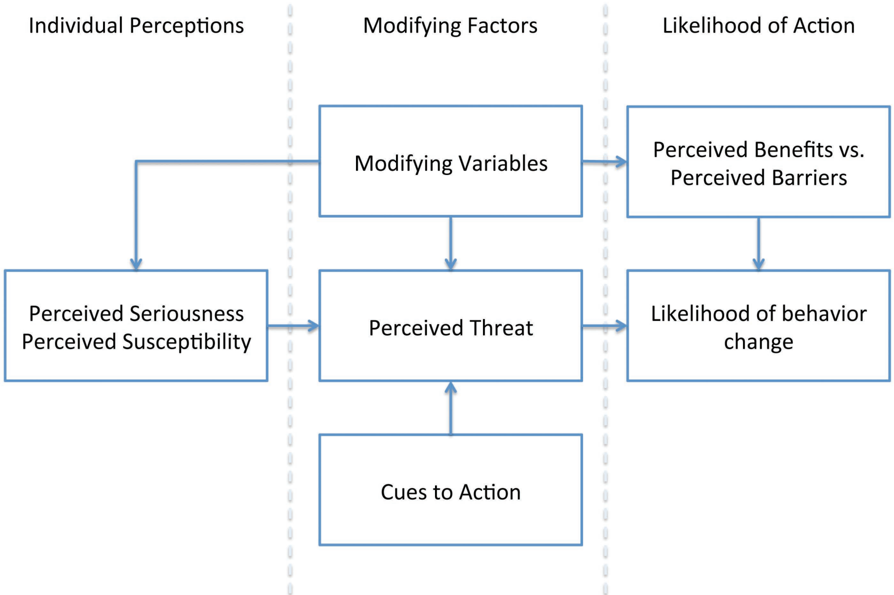

Figure 4.1: The Health Belief Model

while the construct of perceived susceptibility refers to the subjective assessment of risk of developing a health problem. The combination of perceived seriousness and perceived susceptibility is referred to as perceived threat, the model predicts that a higher perceived threat leads to a higher likelihood of engagement in health-promoting behaviors.

Perceived Benefits and Barriers – Health-related behaviors are influenced by the construct of perceived benefits of taking action, which refers to an individual's assessment of the value or efficacy of engaging in a health-promoting behavior to decrease risk of disease. On the other hand, health-related behaviors are also a function of the construct of perceived barriers to taking action, which refers to an individual's assessment of the obstacles to behavior change.

Modifying Variables – The construct of modifying variables are an individual's personal factors that affect whether the new behavior is adopted. These factors includes demographic, psychosocial, and structural variables, can affect perceptions – the perceived seriousness, susceptibility, benefits, and barriers, of health-related behaviors.

Cues to Action – The construct of cues to action is those factors that will start an individual on the way to change behavior. The cues – or trigger – are consider as necessary for prompting engagement in health-promoting behaviors, and can be realized both internally or externally.

In summary, the modifying variable and cues to action affect individual's perception of susceptibility, seriousness, benefits, and barriers, and, therefore, our behavior. Hence people's behavior regarding their health should be seen in the light of their perception of the health threat, and the benefits and barriers by changing behavior. In the next section the Transtheoretical Model of Behavior Change is introduced. It is transtheoretical due to its utilization of elements from different theoretical directions, especially within psychology.

4.1.2 The Transtheoretical Model of Behavior Change

The Transtheoretical Model of Behavior Change (TTM) [124, 126] is a unifying model to conceptualize the process of intentional behavioral change. The model is developed based on observations of individuals, who on their own have gone through a behavior change. Whereas other models of behavioral change focus exclusively on certain dimensions of change, TTM includes and integrate key constructs from other theories. Thus generating an overall approach to a comprehensive theory of change, which can be applied to a wide variety of behaviors, populations, and settings. The model consists of four core constructs; stages of change, processes of change, decisional balance, and self-efficacy [125], unfolded in the following description.

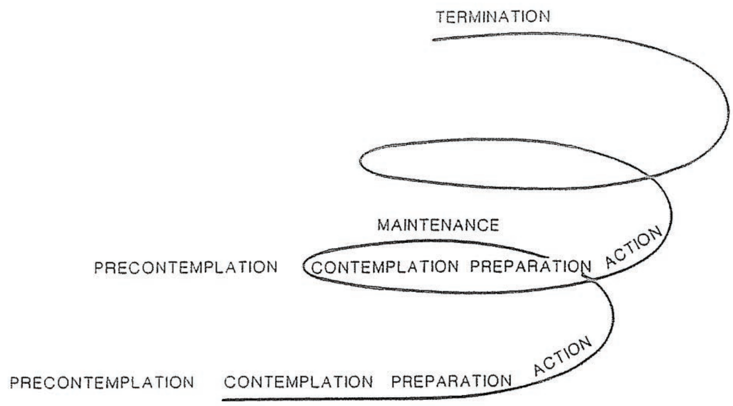

Figure 4.2: A Spiral Model of the Stages of Change [126].

As seen in Figure 4.2, stages of change is a as an iterative process that consists of five stages that depend on the differences in individuals' desire and ability to change their behavior. The stages are Precontemplation, Contemplation, Preparation, Action, and Maintenance. *Precontemplation* is where individuals are not intending to take action in the foreseeable future, and can be unaware that their behavior is problematic. *Contemplation* is where individuals are beginning to recognize that their behavior is problematic, and start to look at the pros and cons of their continued actions. *Preparation* is where individuals are intending to take action in the immediate future, and may begin taking small steps toward behavior change. *Action* is where individuals have made specific overt modifications in modifying their problem behavior or in acquiring new healthy behaviors, and finally *Maintenance* is where individuals have been able to sustain action for a while and are working to prevent relapse. In addition, relapse is conceptualized not as stage in itself, but rather the return from Action or Maintenance onto an earlier stage, when individuals fail to implement or maintain the desired change. Finally, when individuals have zero temptation and they are sure they will not return to their old unhealthy habit as a way of coping, the change is regarded as terminated.

In general, for individuals to progress through the stages, they need: (i) A growing awareness that the advantages – the "Pros" – of changing outweigh the disadvantages – the "Cons" –, which is defined as the decisional balance, and can be seen as a form of "balance sheet" of comparative potential gains and losses [65]. (ii) Confidence that individuals can make and maintain change in situations that tempt them to return to their old, unhealthy behavior, is defined as self-efficacy. (iii) Strategies that help individuals achieve and maintain change, which is defined as processes of change.

4.2 Awareness & Insight

It is important to highlight the distinction between awareness and insight. Firstly, because awareness and insight have previously been interchangeably used to describe the same phenomenon. Secondly, in clinical psychiatry, the notion of insight has become conceptualized as an independent phenomenon, one that not only could be observed in patients with mental illness, but also could be measured and related to other clinical and non-clinical health issues. In Western cultures, this definition of insight became possible in the context of a psychological background of encouraging self-observation and self-understanding, the changing ideas concerning the nature of mental illness itself, and due to an environment that fostered close clinical observation [98]. Thirdly, because it is important for future designers to be aware of, as these are different design targets.

Awareness refers to the simplest perception or direct appraisal of a particular state in an individual, while insight refers to a more complex and diverse judgment made by an individual, based on the perceived state [98]. In other words, 'awareness' is being aware of a state, and 'insight' is what we gain to be able to understand and act upon the state – the judgment we make upon it. Furthermore, the judgment depends on, and relate to, an initial awareness of a particular state. This means that in order to have insight of a state in the wider sense, the individual first need an awareness of the state and subsequently, on the basis of that awareness, can elaborate further judgments. Thus, the relationship between awareness and insight can be formulated as awareness provides the core elements to insight as a whole [98].

4.3 Awareness, Insight and Change as Design Targets

The design targets supports the need for refinement of the overall target of behavior change. There is a total of three design targets, illustrated in Figure 4.3. The targets consists of *Awareness*, *Insight*, and *Change*. The purpose of the design targets is to increase the attention to

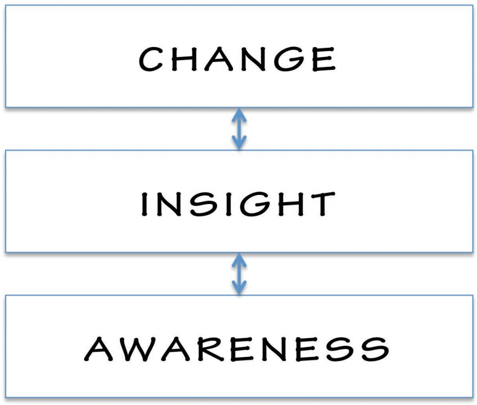

Figure 4.3: Design Targets for Personal Health Technologies

both awareness and insight, as they are important and relevant targets in themselves. The three targets are equal in importance as they all support the process of change, and they are ranked, as awareness supports insight and insight support change. TTM describes change as a process of constant movement between the five stages. Thus it is relevant to highlight elements of the process of change in such a way that design considerations can be made to support the different stages where is it perceived as most important. It should be noted that improving awareness and insight in regards to a future change may be the most appropriate approach to take in relation to an individual's wishes or readiness - and perhaps the most effective way of creating incentives a fruitful process that leads to change in the long term.

The design targets do not suggest particular approaches to achieve these targets, such as the previous presented elements of personal health technologies. Hence, the targets' purpose is to provide designers with an understanding of the process of managing health, and why it is important to design technology to support this. The following section will define each design target and present in detail how the features from the MONARCA system listed in Table 4.1 support the design target. The features mentioned are previously described in more detail in Table 2.1 on page 16.

Looking across the development process of the MONARCA system, the first version of the system had a higher focus on the target of awareness through the collection and visualization of data. The second version focused highly on the target of insight, performed through the data analysis and the conveying of data. This explains the weight of features supporting awareness and insight compared to change.

4.3.1 Awareness

Awareness refers to the narrow concept of insight, which defines awareness as the simplest perception or direct appraisal of a particular state in an individual. Supporting the creation of

	Live wallpaper	Medication	Self-assessment	Graphs	General actions	Retrospect	Sensor based data collection	Early warning signs	Impact factors	Triggers
Awareness	X	X	X	X						X
Insight				X	X	X	X	X	X	
Change								X	X	X

Table 4.1: Features in the MONARCA system and their design targets.

the initial awareness, the first thing that makes a health issue evident to a person, is considered to be key in relation to the person's desire or "readiness" for change. This is what creates an effective incentive for a process, leading to change in the long term. Awareness can be seen as the *'Cues to Action'*, which is defined in the health belief model as prompting engagement and start the individual on the way to change behavior. It can be perceived as a form of *'Contemplation'* from TTM, where the individual is beginning to recognize that his or hers behavior is problematic, yet the key here is not that the behavior is necessarily problematic, but the fact that individuals are recognizing their behavior in respect to their targeted health. In other words, awareness occurs when *'an experience'* becomes *'my experience'*.

Awareness is targeted through different features in the MONARCA system. The Live Wallpaper visualizes the patient's impact factors using animated speech bubbles in the background of the phone's home screen. In this way, the patient are presented with visualizations of the data each time the screen is turn on. Medication provides an overview of the patient's medication, along with details of each prescribed drug. The medication is further highlighted through the indication of medicine intake in the self-assessment, having to indicate what has been taken or changed. The self-assessment is the patient's daily assessment of a range of parameters found important in relation to the disease. As the self-assessment focus on key parameters, it makes the patient consider *how* s/he is actually doing and feeling. The graphs provides a visualization of the collected data of the system, which the patient is automatically presented with after having saved the daily self-assessment. Finally triggers also support awareness, as the trigger mechanism makes the patient aware of a current health issue through spawning an notification on the Smartphone.

4.3.2 Insight

Insight refers to the wide concept of insight, which defines insight as the complex and diverse judgments made by an individual concerning the perceived health state. These judgments are complex in type because they refer to an appraisal and possible acknowledgement of the current health state, and is depending on a range of subsidiary judgments relating to an individual's general knowledge, views, perceptions, past experiences, etc. Insight is furthermore formed on the basis of the created awareness, and involves a periodic assessment of the relevance, performance, efficiency and impact of the assessed information with respect to the individual's targeted health issue.

The background for the judgments can be seen as the *'Construct of modifying variables'* in the Health Belief Model, where an individual's personal factors including demographic, psychosocial, and structural variables, affect perceptions combined with the *'Perceived Seriousness and Susceptibility'*, and the *'Benefits and Barriers'*, of health-related behaviors. It constitutes the background of who we are as individuals, our knowledge, as well as our understanding of the health issue. In terms of TTM, Insight can be seen as the process between *'Contemplation'* and *'Preparation'* stages, as it is the considerations regarding how to act upon the given health issue.

Insight is targeted through a range of features in the MONARCA system. The graphs contain the data visualization of both the data from the self-assessment as well as the automatically collected sensor data obtained through the Smartphone. They presents these data in a way that provides an overview of the different parameters over the past 14 days, allowing the patient to follow the development over time, and observe the different parameters in relation to each other. This supports the patient in reflecting upon the presented data. General actions contain personalized information regarding how the patient can manage the disorder. It aims at teaching the patients the underlying reasons for their behavior, and provides information regarding common challenges and actions for self-help, useful for patients with bipolar disorder. The retrospect feature allows the patient to re-assess a previous mood score by adding an additional retrospect mood score, aiming at improving the classification of mood more accurately. Through the reflections, the patient builds upon the understanding of the disease. Sensor based data collection occurs automatically on the patient's phone when it is turned on. The patient is not aware of the collection, but is presented with the data in the graphs. Thus the data serves as an insight to the patient by quantifying behavior. Early warning signs are the personal signs of an impending episode. These combine the knowledge the patient and the disease, providing insight into the situations or events to be aware of. Finally, impact factors are calculated based on the collected data. They highlight important parameters the patient should attend to, as they are found to have an impact on their health. They provide knowledge the patient is not able to infer by simply looking at the graphs.

4.3.3 Change

Change is characterized by the new behavior tested in practice, incorporated into daily life. Change refers to any transformation or modification of human behavior, and it occur when the individual chooses the appropriate action to take upon their awareness and insight of the health state. The change vary according to the targeted health state, and can imply change to the individual's physical, emotional, and mental state according to the issue. Also the size of the change may vary accordingly.

Change is targeted through early warning signs, impact factors and triggers in the MONARCA system, which all provides feedback consisting of personalized context-appropriate actions to take in a given situation. This helps the patient to take action and adjust behavior accordingly.

Chapter 5

Conclusions

The design of personal health technologies has had a high focus in the last decade. The use of these technologies as tools for health management is proposed to promote healthy living, help individuals care for themselves, improve treatment, and in general provide individuals with greater awareness and insight about their health condition. The work presented in this thesis has approached this challenge through the design of the MONARCA systems, a tool used in the management and treatment of bipolar disorder. Designed in a user-centered setting with an iterative development process, the technology has through several clinical trials proven its success with a high usefulness in management and treatment of the disorder. The process has further provided conceptual design consideration, important for the next researchers and practitioners embarking on the quest to design these types of systems. This concluding chapter summarizes the contributions of the presented work and discusses directions for future work.

5.1 Contributions

The contributions of this thesis is organized around three main areas; (i) Design and System Contributions, (ii) Clinical Contributions, and (iii) Conceptual Design Contributions.

5.1.1 Design and System Contributions

The design and development of the MONARCA system provided different contributions in terms of both the design and the development, and further illuminated by the trials of the system. The design of the overall MONARCA system, developed through 2 iterations and presented in $\{1,4\}$. The system was further supported by the design, development, and evaluation of the detailed patient overview screen supporting clinicians' situational awareness {3}. The evaluation of the MONARCA system, was performed from both from the patients' {2,4} and the clinicians' {4,5} perspective. In the trials, the patients reported a high usefulness of the system, with an even higher perceived usefulness, along with very good usability scores. Also judging by the interviews performed, the systems improved the patients' ability to better manage their disease {2}.

5.1.2 Clinical Contributions

The clinical trials of the MONARCA system provided several contributions from the findings, showing the effects of using the system for both the patients and clinicians to support the treatment of bipolar disorder. The support of the treatment by providing clinicians with improved and more accurate data grounds, which better informed the consultations between patients and clinicians, and allowed for early interventions {5}. The patients had a higher adherence to self-assessments, they became more aware of their disease and had improved insight into the management of the disorder {5,6}. Furthermore, the first forecast of bipolar disorder, and mental illness in general, was designed and tested {4,6}.

5.1.3 Conceptual Design Contributions

The empirical research further led to conceptual design contributions, helpful to designers and developers of personal health technologies in HCI and Ubicomp. Based on the empirical work of developing the MONARCA system, the design process informed and motivated further consideration on the construct and goals of these technologies. The process facilitated considerations of the overall understanding of these technologies, as well as a reconsideration of the target of personal health technologies. This facilitated the definition of four design elements and three design targets for personal health technologies. The four design elements of personal health technologies were synthesized from the design process of the MONARCA system and an analysis of related work. Concepts and frameworks help to outline and crystallize the focus, and the design elements serves both as a lens with which to analyze existing personal health technologies as well as a to guide development of new ones. The three proposed design targets for personal health technologies allow designers and practitioners to approach the design of these technologies with tangible targets that exposes assumptions underlying various behavior change theories. These targets are further seen as possible grounds for a reliable evaluation of the strengths and weaknesses of different approaches through an evaluation of the design targets.

5.2 Suggestions for Future Work

Throughout the work several issues have been raised, and further perspectives have emerged. The following are the ones I find most pressing to address in future work.

Trial lengths and use of control groups. In the field deployments, only short-term use is observed, without the use of control groups. Thus, the effects of long-term adaption and effect remains to be investigated. In this setting, it would also be interesting to examine which patient sub-groups are most likely to respond to the use of the system; for instance, do patients with certain traits and characteristics gain better awareness, insight or manage their illness better than others.

Validating the design targets. Even though there are different approaches both in the clinical domain [10, 12, 54] to evaluate awareness and insight, none of these capture the essence of the proposed design targets. Hence, the evaluation is difficult and a results difficult to validate. Thus, future work should be carried out on defining and validating an approach to measuring awareness and insight with patients, which is important for empirical research, enabling the comparison of approaches and systems' outcomes.

Data collection optimization. In the development of the system {1,4}, the parameters in the self-assessment were defined based on the clinicians' and patients' knowledge and experience of bipolar disorder. However, the exploration of using different parameters and data collection methods has not been considered, and this may prove to find additional correlations and insights into patients' illness and bipolar disorder in general. There is significant related work in the area of personal informatics and quantifies self, which could be drawn upon to explore this further. There is further potential findings in the data collected through all the trials, which is only briefly touched upon in the data analysis in {4}.

Relapse detection. From the forecast deployed in the system, we saw a reasonably high general accuracy of predicting patients future mood state, while the accuracy of forecasting elevated or lowered mood states was rather low. To further improve the effectiveness of mood forecasting, a better understanding of optimum predictive algorithms such as automated approaches that detect patterns and correlations – such as data mining and artificial intelligence – versus algorithms that incorporate investigator hypotheses and iterative feedback – such as structured and learning models – could be pursued. In this perspective, it is further important to consider if the optimal approach is to base forecasts on data from the psychoeducational approach taken in the MONARCA system, or it should be based on automated data collected by the system, as proposed in {4}. Furthermore, considerations should be made to combine these with different self-rated information focused especially on relapse detection, as highlighted in {5,6}.

Cross illness efficacy. Personal health technologies are proposed in the treatment of a wide range of different illnesses. Thus researching the effects of using the approach from MONARCA in treatment on different mental illnesses, such as schizophrenia, clinical depression, anxiety disorders, and psychotic illnesses, is worth investigating.

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Part 2

Paper 1
The MONARCA self-assessment system: a persuasive personal monitoring system for bipolar patients

Jakob E. Bardram, Mads Frost, Károly Szántó and Gabriela Marcu. The MONARCA self-assessment system: a persuasive personal monitoring system for bipolar patients. In *Proceedings of the 2nd ACM SIGHIT International Health Informatics Symposium* (IHI'12). 2012, 21-30.

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The MONARCA Self-Assessment System – A Persuasive Personal Monitoring System for Bipolar Patients

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ABSTRACT

An increasing number of persuasive personal healthcare monitoring systems are being researched, designed and tested. However, most of these systems have targeted somatic diseases and few have targeted mental illness. This paper describes the MONARCA system; a persuasive personal monitoring system for bipolar patients based on an Android mobile phone. The paper describes the user-centered design process behind the system, the user experience, and the technical implementation. This system is one of the first examples of the use of mobile monitoring to support the treatment of metal illness, and we discuss lessons learned and how others can use our experience in the design of such systems for the treatment of this important, yet challenging, patient group.

Keywords

Bipolar disorder, mental illness management, personal monitoring systems, Android, self-assessment

Categories and Subject Descriptors

J.3 [**Computer Applications**]: Life and Medical Sciences—*Health*; H.5.2 [**Information Interfaces and Presentation**]: User-centered design.

General Terms

Design, Human Factors.

1. INTRODUCTION

Persuasive personal monitoring systems have been suggested for the management of a wide range of health-related conditions. These types of systems help users by enabling them to monitor and visualize their behaviors, keeping them informed about their physical state, reminding them to perform specific tasks, providing feedback on the effectiveness of their behaviors, and recommending healthier behaviors or actions. In addition to numerous studies on general behavior change [12], research has also targeted health-related behavior change such as physical activity [7, 3], healthy eating habits [14], cardiac rehabilitation [8], and the management of chronic illnesses like diabetes [9, 20], chronic kidney disease [19], and asthma [6].

So far, most of this research has targeted somatic diseases and few have targeted mental illness. But such persuasive monitoring systems could also have the potential to help with the management of mental illnesses such as depression, bipolar disorder, and schizophrenia. Such systems would be able to monitor data on mood, behaviors, and activities, providing timely feedback to patients in order to help them adjust their behaviors. A few studies have focused on estimation and improvement of adherence to medication using electronic monitoring in patients with depression [16, 11, 2] or schizophrenia [4]. As for bipolar disorder is concerned, using weekly text messaging has been suggested and studied [1]. Also more comprehensive electronic monitoring systems have been presented for patients with bipolar disorder including self-monitoring of medication, mood, sleep, life events, weight, menstrual data, etc. [21, 15, 13]. But so far none of these systems have included combined self-monitoring and objective system recording of the disorder, and none of them have build-in mechanisms for providing feedback directly to the patient.

Designing for mental illness poses several challenges. Due to the complexity of mental illness, it is unclear what data should be monitored. Symptoms vary from patient to patient, and may be difficult to recognize. It is difficult for patients to reflect on their own mood and behavior, and their families and others around them may only recognize symptoms if they understand the illness and know what to look for. In addition to the complexity of an illness and its symptoms, the treatment process is equally complicated. There is no singular treatment regimen or set of medications that will work for all patients. Treatment of mental illness therefore requires an ongoing process of experimenting with different combinations of medications, and learning how to cope with and reduce symptoms through healthy behaviors (e.g., good sleeping habits, daily routines, avoidance of alcohol, etc.).

This paper presents the MONARCA system, which is designed for the treatment of patients suffering from bipolar disorder. The system is designed to be used by both patients, clinicians, and relatives. The system consists of two parts. The first part is an Android application, which is designed for patients and allows them to enter self-assessment data, collects sensor-based data from the phone, provides feedback on the data collected, and helps the patients manage their medicine. The second part is a website which provides access to the system for patients, clinicians and relatives. In addition to accessing the data for each patient, the website provides detailed historical overviews of data and allows for customization of the system according to the need of each individual patient. In the website, clinicians can furthermore get a quick overview of all

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their patients, which enables them to focus on the patients in need of immediate attention.

The MONARCA system has been designed in close collaboration with a group of bipolar patients and psychiatrists at a large university hospital in Denmark. This paper describes the user-centered design process, the system and user-interface design, and the technical implementation. The main contribution of this paper is the presentation and discussion of the design and technical implementation of a persuasive monitoring system for mental illness.

2. DESIGNING FOR BIPOLAR DISORDER

Bipolar disorder is a mental illness characterized by recurring episodes of both depression and mania. Treatment aims to reduce symptoms and prevent episodes through a combination of:

- Pharmacotherapy – Mood is stabilized, and symptoms are controlled, using a customized and difficult to determine combination of one or more of the following: antidepressants, antipsychotics, mood stabilizers, and other drugs such as sleeping pills.
- Psycho-education – Patients are taught about the complexities of bipolar disorder, causes of recurrence of episodes, and how to manage their illness.
- Psychotherapy – Patients are coached to deal with their symptoms and find practical ways to prevent episodes through actionable behavioral and life-style choices, such as routine, sleep, and social activity.

One particular approach to treatment is predicting and preventing episodes by training patients to recognize their Early Warning Signs (EWS) – symptoms indicative of an oncoming episode [18]. Training is resource-intensive and its success varies highly from patient to patient. Some patients are never able to identify patterns in their episodes that reveal EWS.

Mood charting, or creating daily records of mood states and behaviors, can help patients identify patterns and track their progress [17]. Mood charts are available as paper forms[1], websites[2], or mobile phone applications[3]. In Figure 1 is an example of a paper based mood chart, used at the university hospital in Denmark. We reviewed a variety of mood charting methods, and found significant limitations. Paper forms, which are handed out to patient by clinicians or distributed by medical organizations, are inconvenient to fill out and highly subjective. They are filled out inconsistently due to forgetfulness or symptoms. Subjectivity of measures, combined with a free form method of data collection, can result in data that is inconsistent due to changing scales or criteria based on subjective interpretation. Web-based or mobile phone solutions can make it easier for patients to report data, and also reduce data inconsistency by guiding data entry. However, existing websites and mobile phone applications tend to suffer from a lack of usability, a clinical perspective, and generalizability for a variety of patients.

The design of the MONARCA system was done in a user-centered design process involving both patients and clinicians affiliated with the psychiatric clinic of a large university hospital in Denmark [10]. Patients and clinicians participated in numerous collaborative design workshops – three-hour sessions which were held every other week for twelve months. Workshops involved discussions about how patient were affected by their illness and how they coped with in daily life, as well as designing overall goals for the new system

[1]E.g. HealthyPlace Bipolar Mood Chart at `healthyplace.com`
[2]E.g. Mood Chart at `mood-chart.com`
[3]E.g. Optimism at `optimismonline.com`

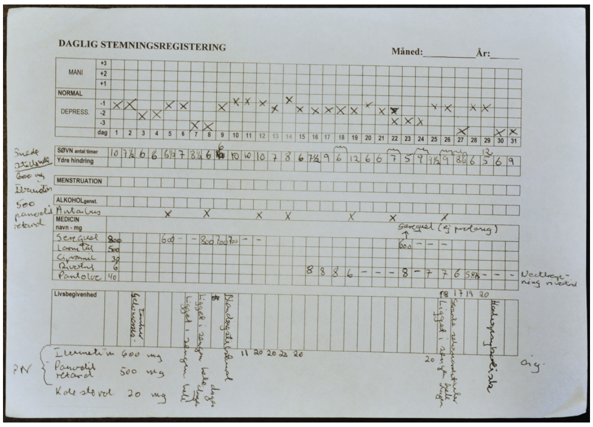

Figure 1: An example of a mood chart used at the hospital. The chart tracks mood, sleep, external obstacles, menstruation, alcohol, medication and life events.

Figure 2: A patient, designer, and psychiatrist working together on a design activity using prototyping materials.

and more detailed system features and functionality, based on presentations and hands-on use of paper-based mockups and early prototypes of the system [5]. Thus, all design decisions were based on these workshops, focussed on the patients' and clinicians' knowledge, ideas and feedback, based on prototypes and the participants' daily life.

Design activities at the workshops began with hands-on brainstorming and lo-fi prototyping (see Figure 2). We provided materials such as documents summarizing the goals of the system, images of existing tools and methods, large poster paper, writing materials, scissors, tape, etc. The sketches that came out of this initial brainstorming formed the basis for the first mockups. At each of the following workshops we (i) discussed targeted design goals and system features in depth, and (ii) received feedback on the next iteration of the mockups. Mock-ups presented during workshops progressed from sketches to wireframes to interactive prototypes.

One of the main goals of the user-centered design process was to design a system to help patients manage their own illness through monitoring and persuasive feedback. From a clinical viewpoint, the psychiatrists stated that the following three parameters are crucial in keeping a bipolar patient stable:

1. Adherence to prescribed medication: Taking all medications on a daily basis, exactly as prescribed.

2. Stable sleep patterns: Sleeping 8 hours every night and maintaining a consistent routine of going to bed and waking up.

3. Staying active both physically and socially: Getting out of the house every day, going to work, and engaging in social interaction.

At first glance, this list may seem simple, but the psychiatrists also stated that each of these items are very difficult to achieve for many patients, and achieving all three at the same time every day is inherently challenging in combination with a mental illness. Hence, the core challenge is to create technology that would help – or 'persuade' – patients to do these three things daily. Based on the 12 month design process, the group of psychiatrists and patients came down to the following core set of requirements for the MONARCA system:

Self-assessment – Subjective data should be self-reported on a one-page self-assessment form on the mobile phone, including mood, sleep, level of activity, and medication. Some items should be customizable to accommodate patient differences, while others are consistent to provide aggregate data for statistical analysis. An alarm should daily remind the patient to fill out the form.

Activity monitoring – Objective data should be collected to monitor level of engagement in daily activities (e.g., based on GPS and accelerometer), and the level of social activity (based e.g., on phone calls and text messages) should be collected. In order to protect patient privacy, this data can be abstracted for analysis.

Historical overview of data – When the patient has submitted data using the self-assessment form on the mobile phone, a two-week snapshot of their basic data should be shown for immediate feedback. On the website, both patients and clinicians should have access to a detailed historical overview of the data, giving them the means to explore the data in depth by going back and forth in time, and focusing on specific sets of variables at a time.

Coaching & self-treatment – Psychotherapy should be supported through everyday reinforcement in two ways. The system should support customizable triggers that can be set to have the system notify both patient and clinician when the data potentially indicates a warning sign or critical state. Moreover, patients should have access to adding their own EWS, empowering them to understand their own signs.

Data sharing – In order to strengthen the psychotherapy relationship, data and treatment decisions should be shared between the patient and his/her clinician. Similarly, sharing data with family members or other caregivers should be supported in order to support the treatment process. Finally, sharing data among patients will help with personal coping and management efforts by re-assuring patients that they are not alone, and helping them see how others manage their illness.

Figure 3: A bipolar patient using the Android phone app for filling in her self-assessment data by the end of the day.

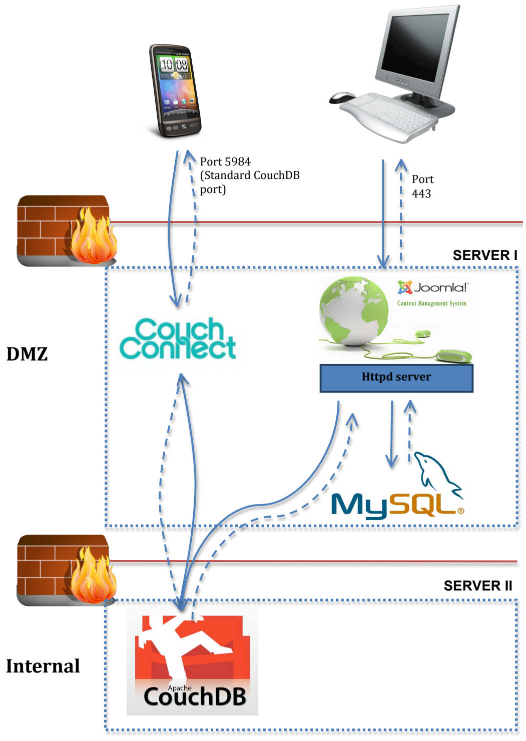

Figure 4: The MONARCA System overview.

3. THE MONARCA SYSTEM

The MONARCA system consists of two main parts; an Android mobile phone application and a website. As shown in Figure 3, the mobile phone application is used by patients. The website consisting of three main parts designed for three different groups of users: (i) patients can see and update their personal data; (ii) clinicians can get an overview of their patients and dig into detailed data for each patient; and (iii) relatives can – if granted access by the patient – look at (but not update) the patient's data.

The system design, including the hosting and deployment setup, is illustrated in Figure 4. It is a simple system setup consisting of two clients (the phone and the browser), one server in the demilitarized zone (DMZ) (SERVER I) and one server in the Internal zone (SERVER II). Overall, the system setup consists of the following main components and communication pathways: (i) an HTC Desire, Android based smartphone is used for data collection and data visualization; (ii) a standard web browser on a PC; (iii) CouchConnect, which is a data synchronization process using the CouchDB for synchronizing data between the smartphone and the CouchDB. (iv) CouchDB, which is a database storing all patient-related data (v) Joomla, a Content Management System (CMS) that runs the web application, and (vi) MySQL, a database holding the configuration and the web pages for the Joomla CMS.

In the following, we will detail how the patients and the clinicians are using the system, the interaction design of the system, and its technical implementation, including how sensing is done on the phone.

4. ANDROID PHONE APPLICATION

The main goals of the MONARCA phone application are; (i) to provide an input mechanisms for patients to fill in their self-assessment data; (ii) to collect objective sensor data from the phone; (iii) to provide a simple historic visualization of the data entered; (iv) to provide feedback and suggest actions to take in situations that presents risks; and (v) help patients to keep track of their prescribed medication.

The main reason for using a mobile phone application, is that the phone is with the patient always. This is useful not only for the objective sensing of the activity of the patient, but also for collecting the self-assessment data, since the phone is much easier available than a web browser. The user interface of the MONARCA Android phone application is shown in Figure 5, consisting of a main screen, linking to 5 different subscreens; (i) Self-assessment, (ii) Visualizations, (ii) Actions to take, (iv) Medicine and (v) Settings.

4.1 Self-Assessment and Sensed Data

Based on our close collaboration with the bipolar patients and psychiatrists, we have identified a set of self-assessment data points that the MONARCA system should collect. A constant concern was to make the self-assessment for the patient as simple and easy as possible, and avoid overloading with numerous of things to report. Therefore, we have constantly been striving to reduce the set of self-assessment items and have ended up with an absolute *minimum se*t of things to monitor for a bipolar patient. These self-assessment data can furthermore be divided into a set of *mandatory* self-assessment data, which is absolutely crucial to collect over time in the treatment of a bipolar patient, and a set of *optional* self-assessment data points, which are very useful to have as a supplement to the mandatory ones.

The mandatory self-assessment items are:

- *Mood* measured on a 7-point HAMD scale spanning from highly depressed (-3) to highly manic (+3).
- *Sleep* indicated in half-hour intervals.
- *Subjective Activity* on a 7-point scale spanning from totally inactive (-3) to highly active (+3).
- *Medicine Adherence* indicating whether prescribed medicine has been taken as prescribed, have been taken with modification, or not taken at all.

The optional self-assessment items include:

- *Universal Warning Signs*, which are signs that a psychiatric clinic can set up for all its patients. Such signs can e.g. include experience of so-called 'mixed mood', 'cognitive problems', or 'irritability'.
- *Early Warning Signs (EWS)*, which are *personal* signs that are tailored specifically for a patient to look out for. For example, if a patient starts sleeping in the living room rather than the bed room, this is a sign for him that a manic phase is starting.
- *Alcohol*, as measured in number of drinks.
- *Stress* measured on a 5-point scale from 0 to 5.
- *Menstruation*, only applied to females.
- *Note*, a free text entry done with an on-screen keyboard

All self-assessment data is entered on the phone's self-assessment screen as shown in Figure 5(i). In addition to these self-assessment data, the phone is collecting more objectively sensed data. This includes *physical activity* data as measured by the accelerometer in the phone and *social activity* as measured by the number of phone calls and text messages sent from the phone. More details on the objective measurement is given below.

4.2 Technical Implementation

A core technical requirement for the MONARCA phone application was that it should allow patients to enter and review their data at any time, even without network connectivity. Therefore, the application was designed to allow for data entry while offline with data synchronization when online. To achieve such data synchronization, the application is built around the Apache CouchDB[4], which is a document-oriented database that can be queried and indexed in a MapReduce fashion using JavaScript. CouchDB also offers incremental replication with bi-directional conflict detection and resolution, and it provides a RESTful JSON API than can be accessed from any environment that allows HTTP requests.

The client running on the phone consists of a single Android application which is structured as illustrated in Figure 6. Overall, the application consists of; (i) a CouchDB database for Android, running as a native process in the same process as the application; (ii) a few services, interfaces and classes which implement the application specific interaction with the database; (iii) a set of user interface Activities, which are responsible for the interaction with the user and data presentation, and (iv) a few background services responsible for gathering objective data from the sensors in the phone.

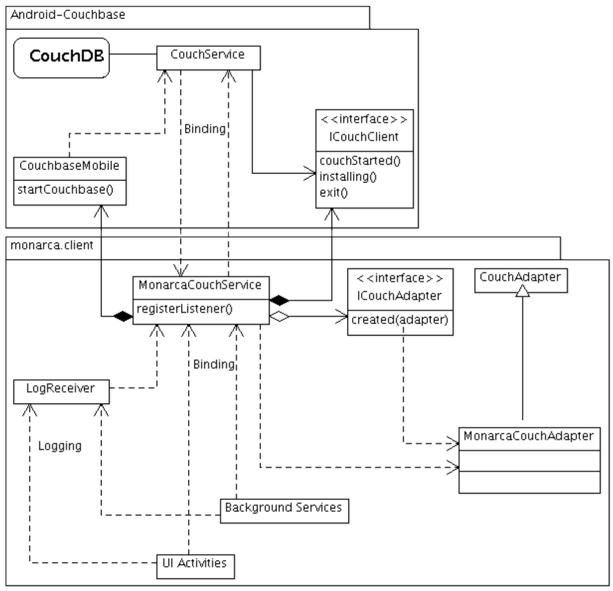

Figure 6: The MONARCA Android Architecture.

The `Android-Couchbase` component is an open source library running and managing the CouchDB database. Its main functional part is a native process, in which the actual database is running. The life-cycle of this process is managed through the `CouchService`, making use of the `CouchbaseMobile` class. Notifications on changes in the state of the database are provided through the methods of `ICouchClient`.

The MONARCA application logic is implemented in the `monarca.client` component. In order to create a robust and easy to use application, it is important to ensure that the database is always running before a component tries to operate with it. As a result, the MONARCA application has a set of components, which

[4] `http://couchdb.apache.org/`

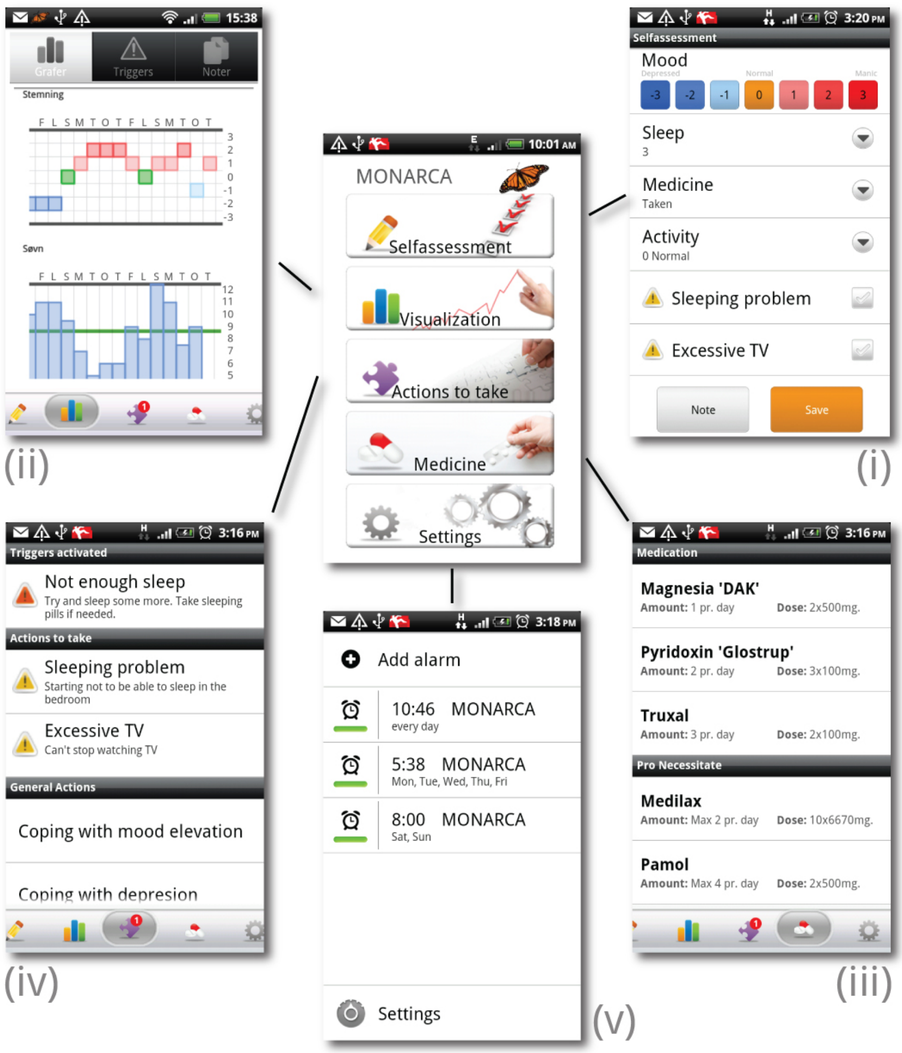

Figure 5: The MONARCA Android user interface.

are responsible for communicating and using the Android Couchbase:

- `MonarcaCouchService` is a background service that provides an easy way to manage the CouchDB. When created, it binds to the `CouchService`, receives an instance of the `ICouchService` interface, and attempts to start up the database. Depending on the state of the database, this might take up to a minute. Clients have to register an `ICouchAdapter` listener to receive a `Monarca CouchAdapter` instances once the database is up and running. Once the client is notified, the registered listener is removed.

- `ICouchAdapter` provides the `created()` callback method, which is called when the database is ready for communication. Hence, all database communication routines of a component should be placed inside this method.

- `MonarcaCouchAdapter` provides application specific operations with the database, making use of the RESTful interface provided by the CouchDB.

- `LogReceiver` is a subclass of `BroadcastReceiver`. It acts as a "sink" for logging messages inside the MONARCA application. When a component needs to log a specific message, all it has to do is to construct an Android `Intent` with one of the actions provided by the `LogReceiver` and the content which needs to be logged. Once created, the Intent is broadcasted, intercepted by the LogReceiver and appended to one of the many log documents in the CouchDB.

The User Interface of the MONARCA system (Figure 5) is implementations of the Android `Activity` interface. The self-assessment screen (Figure 5(i)) is a simple screen that takes input entered by the patient and uses the CouchDB setup described above to store this data. The Medicine screen is a simple screen that takes data from the CouchDB and lists it (Figure 5(iii)). The patient cannot modify the medication on this screen. The more complicated Visualization screen, the Trigger mechanisms, and the Alarm setup is further detailed below.

4.2.1 *The Visualization Screen*

The visualization screen, consisting of three tabs; graphs, triggers and notes, (Figure 5(ii)), is the central feedback mechanism to the patient since it is shown every time the patient has entered his or her self-assessment data. The graph visualization display is designed to be very simple and aesthetically pleasing, while giving an overview of most of the data entered into the application. The triggers and notes visualizasions are simple listings of the activated triggers and entered notes history. The visualization is restricted to the last 2 weeks (14 days), whereas longer periods of data can be reviewed on the web.

Due to the lack of mature plotting libraries for Android, the graph visualization screen is implemented using 'flot'[5], which is a pure Javascript plotting library for jQuery. The Graph Visualization screen consists of an `WebView`[6] component, which is a subclass of `View` with the ability to display web pages. The WebView loads a HTML file that defines the layout and contains a set of Javascript functions, which are responsible for drawing the graphs. The graph data is stored in a set of Java objects in the Android app, and WebView offers a way to bind these Java object to JavaScript so that the object's methods can be accessed from JavaScript.

4.2.2 *The Triggers Mechanism*

The *Automatic Trigger* feature in the MONARCA system is made up of a set of rules that apply to any self-assessment data being entered. For example, an automatic trigger can be set up to trigger if the patient reports that he has been sleeping less that 6 hours 3 days in a row. Automatic triggers play a crucial role in continuously feedback to the the patient as they consistently track patterns over time and can warn both the patient and the psychiatrist about things to be aware of.

When a trigger is activated, a notification is posted using Android's *Notification Manager* mechanism. The trigger is then displays as an item in the notification view on the Android phone (typically in the top pull-down curtain). When clicking the notification, the patient is taken to the *Actions-to-Take screen* (Figure 5(iii)), which lists all active triggers.

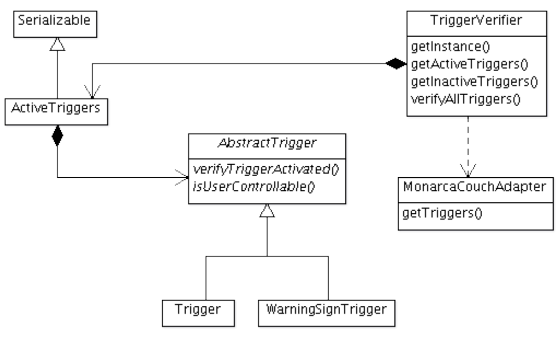

Figure 7: Triggers verification mechanism

As illustrated in Figure 7, `TriggersVerifier` is the central point of the trigger mechanism. It is a singleton providing methods to verify the triggers and to retrieve the active / inactive triggers in the system. As the self-assessment can be changed only by the patient, we verify the triggers after filling in the self-assessment form as well as right after the application is launched.

[5] `http://code.google.com/p/flot/`

[6] using the WebKit rendering engine to display web pages

After each verification, the list of active triggers is broadcasted as an intent and can be caught by any component implementing a `BroadcastReceiver`.

Whenever a trigger is triggered, this is logged into a special document in the database. In this way, triggers can be shown on the overview of patients that the clinicians have in the website (see Figure 13). Thus, clinicians are constantly aware of activated triggers and can look into the cause of this.

4.2.3 *The Alarm Mechanism*

Self-assessment is done by patient on a daily basis. The best approach is to fill in the data as soon as it is available; e.g. *sleep* could be entered in the morning, whereas *activity* and *stress* should be entered at the end of the day. The application itself provides no restrictions of when or how many times the self-assessment data can be entered. But in order to help patients remember to do the self-assessment, the MONARCA app has an alarm system, which resembles the regular Android alarm module. In this alarm mechanism, the patient can set up multiple alarms with a wide range of customizable options, such as time of day, days of week, repeating alarms, what ringtone to use, etc. When the alarm goes off, a dialog is shown, providing the user with three options: *OK*, will take the user to the self-assessment screen, *Snooze* will snooze the alarm for a configurable amount of time, and *Dismiss* which is provided as a sliding tab forcing the user to perform more than just a simple click. A snapshot of the dialog is depicted in Figure 8.

Figure 8: Alarm dialog

If users have filled in their self-assessment and do not want to be bothered by any other alarms that day, they can configure this behavior by checking the *Alarms and self-assessment* option in the general alarms settings. This option will disable the alerts for the present day, once the self-assessment is done.

4.3 Objective Data Sampling

As described above, the MONARCA system collect objective data on the behavior of the patient in terms of physical and social activity by sampling data from the phone's accelerometer and telephone plus messaging subsystems. From a technical point of view, this sampling is implemented as a background service, running also if the MONARCA application is stopped. To ensure this behavior, we start these services when the phone is started.

4.3.1 *Physical Data Sampling*

Accelerometer data is sampled every five minute, reading five consecutive samples from the accelerometer sensor. The samples consist of three real values, representing the values of the forces for each of the three axes in a three dimensional Cartesian coordinate system. The values for each axis are averaged out in absolute value and we store one vector with three real elements in the database every five minute.

Our goal for the data sampling was to create a simple mechanism for collecting data that roughly correlated with physical activity. Hence, we do not apply any activity recognition algorithm, but instead we do some trivial processing on the collected data and displays it in in the visualization on the phone and the web. This is done by computing a single number for each day, based on the accelerometer readings. The number represents the absolute average value of all readings for a specific day. We have observed, based on existing measurements, that this average is mostly between 0 and 40. It cannot be a negative number because we are working with absolute values, but sometimes it can exceed 40, in which case we the number is still interpreted as 40.

4.3.2 Social Data Sampling

Social activity is monitoring by sampling the number of *incoming* and *outgoing* phone calls, the *duration* of the calls, as well as the number of *incoming* and *outgoing* SMS messages. This data gives information on the patient's social activity and can indicate possible state changes. For example, if on one hand the patient does not use the phone at all s/he might be entering a depressive state; on the other hand, if the number of outgoing calls is high, the patient might be entering a manic state. On the visualization, social activity is shown on the same graph as the physical activity as the sum of all social data for a day.

5. WEBSITE

The website runs on a Windows 2008 R2 server, using a WampServer version 2.1 running Apache 2.2.17, MySQL 5.5.8 and PHP 5.3.1. The website is also accessing the central CouchDB, described in the *Technical implementation* section. On the WampServer we have installed a Joomla 1.6.0 content management system (CMS), which we use for generating all the web pages, managing user account, and other CMS related functionalities.

Joomla is an open source content management system, based on PHP using a MySQL database. It has a front-end holding all the end-user web pages and a back-end, where the administrator(s) can configure the whole site. We have installed Joomla version 1.6.0 along with 3 extensions. The first is Jumi 2.0.6, which allows us to embed custom PHP code into a standard Joomla web page, enabling the web page to get data from the CouchDB and display and edit it within the web page. For the PHP interaction with CouchDB, we use the "PHP on Couch" library. Joomla has a very simple infrastructure, in which the content to be displayed on a page is edited as a Joomla article. Articles can be edited via the standard Joomla editor and can be organized in a traditional menu structure.

Furthermore we have installed j4age 4.0.2.3 and JoomlaWatch 1.2.12, which monitor the site in regards to which users log in, what pages they visit, time spent at the different pages, and their system information in regards to IP and browser type. This data is very important in regards to the actual usage of the portal.

5.1 User Interaction Design

The main flowchart for the web pages in the MONARCA website are show in Figure 9, and the flowcharts for the patients', clinicians', and relatives' part of the website are shown in Figure 10, 11, and 12 respectively.

Within Joomla you are given a user group functionality, which allows you to add users to different user groups, and limit the menus and articles to only be shown to specific user groups. In this way we can have both patients (see figure 10), clinicians (see figure 11) and relatives (see figure 12) logging into the same system, and only displaying content relevant to them. An example of the clinician's "patient overview" can be seen in Figure 13, as well as an example

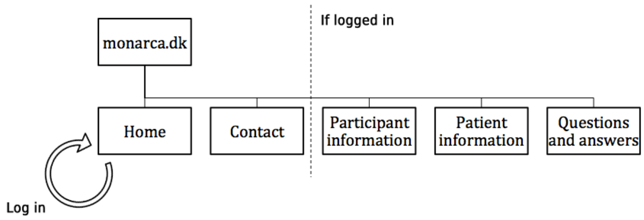

Figure 9: Website - Entrypoint flowchart

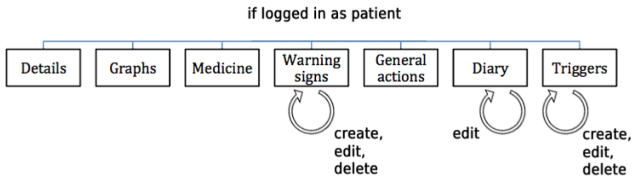

Figure 10: Website - Patient flowchart

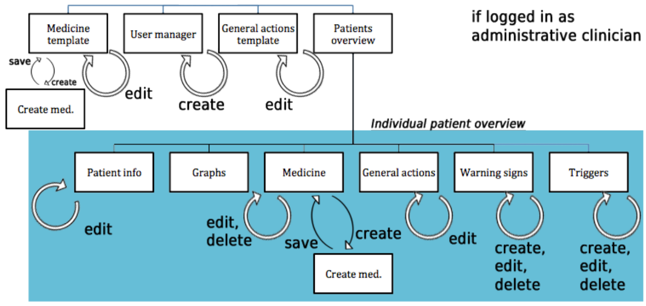

Figure 11: Website - Clinician flowchart

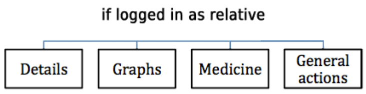

Figure 12: Website - Relative flowchart

of a patient's graphs in Figure 14, which is displayed in the same way for both clinicians, patients and relatives. The look-and-feel of the web pages is based on the '*shape5_intrigue*' template, modified to suit the needs of our system.

5.2 Data Synchronization

CouchDB offers a powerful synchronization mechanism, which allow us to keep the different CouchDB instances that run on every phone in continuous sync with the central CouchDB running on the DMZ server. Each phone only synchronize data that is relevant for this phone, i.e. data which is associated with the patient using this phone. The sync feature offered by CouchDB is called replication. Replication is triggered by sending a POST request to the `_replicate` URL with a JSON object in the body that includes a source and a target member. When syncing data, we issue a replication from the server to the phone to receive changes that might have been created by the website and a replication from the phone to the server, in order to transfer the collected subjective and objective data from the phone to the server.

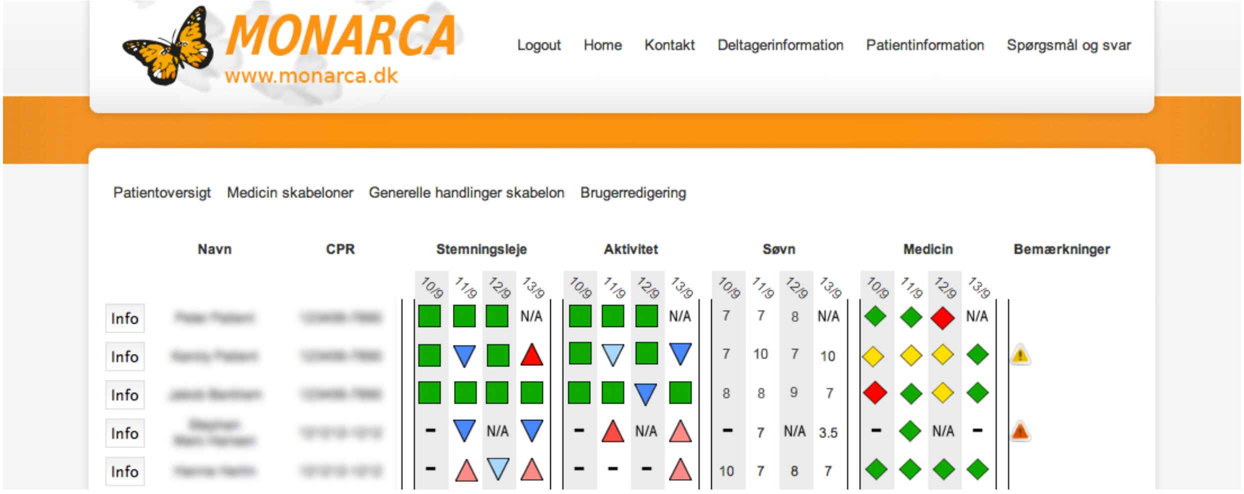

Figure 13: Website - Clinician overview. Each line is a patient (name and ID number in the left columns), showing mood, activity, sleep, and medicine data for the last 4 days. Triggers and Early Warning Signs are shown in the far right column.

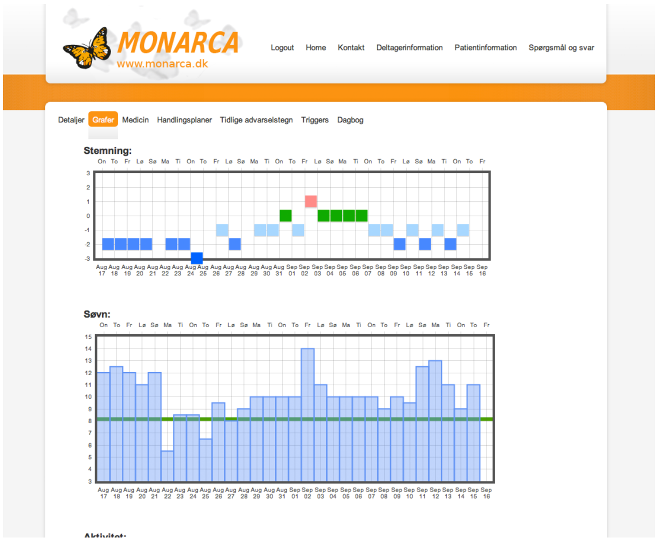

Figure 14: Website - Patient graphs

From version 1.1, CouchDB introduced native support for SSL communication. Therefore, we replicate encrypted data through a secure channel. To replicate only data relevant to each user, we make use of the filter mechanism of the CouchDB. Before replicating a document, CouchDB will apply any existing filters to in checking if the document can or cannot be replicated.

6. DISCUSSION AND LESSONS LEARNED

We are about to start a full scale pilot trial the MONARCA system. But as part of the design process, we have handed out phones and solicited user feedback from the patients who was part of the design group, and who was associated with the clinic. Based on this input, as obtained during the design process, combined with our observations during the technical implementation, this section discusses what lessons was learned in the design and implementation of the MONARCA system.

6.1 Using Smart Phones for Self-reporting

The overall question when designing the MONARCA system was clearly whether patients would be able to use the application for self-reporting data. So far they had been using paper-based forms, as seen in Figure 1, which are rather robust and easy to use for everyone. By giving the patients the MONARCA system, we were asking mentally ill patients to handle rather sophisticated smartphone technology, and it was by no mean obvious that they would be able to use the application.

However, all the participants reported that it was much easier to use the phone-based self-assessment approach rather than using the old paper-based ones. As one of them explains:

> *" First of all [the phone] reminds me to fill in my self-assessment. [And] all the data is gathered in one place, and not scattered on different pieces of paper. It provides an overview of the data, which you can't do yourself – unless you use a lot of time on it, which you don't – and because you have it with you everywhere you go.*

The participants found that entering self-assessment data was quick and smooth. They also found that the system is monitoring a useful set of data, and providing them with the option to enter personal warning signs gives them leeway to adjust for personal needs. However, in an early version of the system, the patients could only enter data for the current day. This was seen as very problematic because despite the alarm, you could often forget, or be unable to, fill in the self-report. Hence, the need to go back and fill in data for yesterday was deemed important.

But overall, based on input from the patients we have good reasons to believe that this kind of smartphone-based self-reporting and persuasive monitoring systems would also be feasible and beneficial for mentally ill patients. None of the patients who had been using the phone wanted to go back to the paper-based forms.

6.2 Phone versus Website

The use of a phone application and a website in the MONARCA system follows the common schema in most of these kinds of systems. The idea is often that people use the mobile phone as an input device, and use the website for looking at, and working with data and configuration parameters. However, during the design process and the short term use of the system, it became quite evident that few of the patients used the website. When they were initially handed the phone, the system was updated with their medicine, warning signs, triggers and general actions. This was done together with their clinician. When the patients then entered the website a few days later, there were not much for them to do there, mainly because they had only collected data for a few days. For example, the graphs were not really useful for such a short period.

Initially, not all the self-reported data or the objective data was visualized on the phone, but was only shown on the website. But all the patients found this highly annoying; they wanted to be able to get access to all data on the phone, and the visualization needed to incorporate all data. Hence, the visualization screen in Figure 5(ii) had to be updated and incorporate much more data. This was mainly because the users found it cumbersome to be forced to log into the website all the time. As one of the participants explained:

> *"I am tired of not having all the history on my phone because all the work takes place on it. I have actually only logged on the website once, and thought: 'What should I use this for?'. It is useful for setting up the system, but you could do this with your doctor or on the phone itself.*

This actually came as a bit of surprise to us, and in the future design of these kinds of systems, it is important to consider the exact role of a smartphone application and how it is linked into a server-based system, like a website. The conclusion from the MONARCA design process so far is, that users tend to want as much as possible ready-at-hand on the smartphone. But this clearly puts up some significant challenges in designing theses things to be simple to use due to limited resources on the smartphone.

6.3 Technical Lessons

From a more technical point of view, the technical design and implementation of the MONARCA system has learned us a couple of things. First, the use of the CouchDB setup has proved to be extremely strong. It is of utmost importance that data collection on the smartphone – especially objective sensor data – runs and works also in offline mode. Hence, asynchronous data synchronization is core to an application like MONARCA . Moreover, the document-based, no-schema nature of the CouchDB made it possible to extend the database and its content dynamically as needed. As such, once the Android version of CouchDB became stable (in version 1.1), this has helped us set up a rather robust distributed system capable of managing a rather sophisticated two-way synchronization setup with self-reporting and objective data floating in from phones, while updates to medicine and triggers float the other way.

Another technical aspects of the design of the MONARCA system is the use of power on the Android phones. Apparently, power management on the Android platform is hard, and one has to be very careful when sampling objective data. Even though we did manage to implement a solution which has a tolerable drain on the batteries, the constant need for charging the phone was a common complaint from the users. As such, when designing such data sampling apps on the Android phone, power-aware computing techniques are important to apply.

7. CONCLUSION

An increasing number of persuasive personal healthcare monitoring systems are being researched, designed and tested, but few of these have been targeted mental illness. In this paper we presented the MONARCA system, which is a persuasive personal monitoring system for bipolar patients based on an Android mobile phone and a website.

Based on user-centered design process lasting for 12 months, and involving a set of bipolar patients and psychiatrists in an affective disorder clinic at a large university hospital in Copenhagen, Denmark, we have solicited five core requirements for such a system supporting patient self-management; (i) self-assessment; (ii) activity monitoring; (iii) historical overview of data; (iv) coaching & self-treatment; and (v) data sharing.

We presented the MONARCA system, and described how it is designed to help patients manage their own illness through monitoring and a feedback mechanism using data visualization and triggers. The mobile phone part of the system has a set of unique features for allowing patient do simple self-assessment, for objective monitoring of physical and social activity, for keeping track of medicine adherence, for data visualization, and for setting up triggers and early warning signs. The system is build around the CouchDB, which provides the technical backbone for a very robust and stable system that works even under unstable network conditions. Moreover, the patients and clinicians can view all data on a shared website, which also allow for clinicians to have an overview of several patients at once.

The MONARCA system is one of the first examples of the use of mobile monitoring to help the treatment of metal illness and holds promises for the treatment of this important, yet challenging, patient group. Preliminary feedback from users showed that this system would be very beneficial in the daily life of a bipolar disorder patient, and would be a huge advantage over the current paper-based forms they use. The feedback also helped us identify areas for improving the design of the system, which will be incorporated before the pilot test is stated in near future.

8. ACKNOWLEDGEMENT

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Paper 2
Designing mobile health technology for bipolar disorder: A field trial of the MONARCA system

Jakob E Bardram, Mads Frost, Károly Szántó, Maria Faurholt-Jepsen, Maj Vinberg and Lars Vedel Kessing. Designing mobile health technology for bipolar disorder: a field trial of the MONARCA system. In *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems* (CHI '13). 2013, 2627-2636.

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Designing Mobile Health Technology for Bipolar Disorder: A Field Trial of the MONARCA System

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ABSTRACT
An increasing number of pervasive healthcare systems are being designed, that allow people to monitor and get feedback on their health and wellness. To address the challenges of self-management of mental illnesses, we have developed the MONARCA system – a personal monitoring system for bipolar patients. We conducted a 14 week field trial in which 12 patients used the system, and we report findings focusing on their experiences. The results were positive; compared to using paper-based forms, the adherence to self-assessment improved; the system was considered very easy to use; and the perceived usefulness of the system was high. Based on this study, the paper discusses three HCI questions related to the design of personal health technologies; how to design for disease awareness and self-treatment, how to ensure adherence to personal health technologies, and the roles of different types of technology platforms.

Author Keywords
Bipolar disorder; mental health; personal health systems; mobile application

ACM Classification Keywords
H.5.m. Information Interfaces and Presentation (e.g. HCI): Miscellaneous

General Terms
Design, Experimentation

INTRODUCTION
According to WHO, mental illness is one of the most pressing healthcare concerns worldwide [34]. Bipolar disorder in particular, has a community lifetime prevalence of 4% [16] and is associated with high morbidity and disability [25]. Personal health technologies hold promise for helping bipolar patients to monitor their mood patterns and symptoms, recognize so-called ‘early warning signs’, and to handle medication. Health technologies can – based on subjective and objective sensor input – provide timely feedback to the patient and thereby increase their awareness of the disease. Smartphones are a promising platform for such personal feedback systems due to their ubiquitous availability and connectivity. Consequently, a number of personal monitoring and feedback systems have been suggested for the management of a wide range of health-related conditions. In general, these types of systems help users by enabling them to monitor and visualize their behavior, keeping them informed about their physical state, reminding them to perform specific tasks, providing feedback on the effectiveness of their behavior, and recommending healthier behavior or actions.

However, introducing new technology for patients with psychiatric disorders, who often have a low coping ability, may be stressful for them and introduce a high cognitive load. Unfortunately, mentally ill patients tend to be socially challenged as well, having a larger tendency for unemployment and alcohol or substance abuse [14]. As such, designing for this group of users is challenging, and the introduction of new technology may not be well adopted and used. Hence, a core research question is to what degree systems for mentally ill patients can be designed, to what degree such technologies will be adopted and used, and how it will lead to new ways for the patients and clinicians to treat this group of patients, compared to the existing approaches.

In this study, we examined the use of a personal health monitoring and feedback system for patients suffering from bipolar disorder, called the MONARCA system [1]. The system lets patients enter self-assessment data, it collects sensor data, it provides feedback on the data collected, and helps them manage their medicine. The study is based on a 14 week field trial of the system. The main objective of this study was to establish the feasibility and usefulness of the system by looking into whether; (i) it is sufficiently stable for general use; (ii) the usability of the system, focusing especially on investigating if it is as easy to use as the currently used paper-based self-assessment forms; (iii) the general usefulness of the system in terms of helping bipolar disorder patients cope with their disease; and (iv) the system – if used on a daily basis by bipolar patients – will be useful to them in the future.

The results of this study are used in a discussion of the broader implications for design of personal health technologies by addressing three questions; (i) how to design for disease awareness and self-treatment; (ii) how to ensure adherence to using personal health technologies, and (iii) what are the roles of different types of technology platforms.

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BACKGROUND AND RELATED WORK

Bipolar disorder is a mental illness characterized by recurring episodes of both depression and mania. Treatment of bipolar disorder aims to reduce symptoms and prevent episodes through a combination of (i) pharmacotherapy where mood is stabilized, and symptoms are controlled, using a customized and difficult to determine combination of several drugs like antidepressants, antipsychotics, and mood stabilizers; (ii) psychoeducation where patients are taught about the complexities of bipolar disorder, causes of recurrence of episodes, and how to manage their illness, and (iii) psychotherapy where patients are coached to be aware of their symptoms and find practical ways to prevent episodes through actionable behavioral and lifestyle choices, such as routine, sleep, and social activity.

However, patients' decreased recognition and insight into the illness and poor adherence to medication [15] are major challenges which increase the risk of recurrence in bipolar disorder. Therefore, continuous mood tracking and graphing [30], recognizing and controlling so-called Early Warning Signs (EWS), activity logging, and medication compliance training are core ingredients in cognitive behavioral training (CBT) for the experienced, but not yet stable bipolar disorder patient [2].

Paper-based mood charting forms are frequently applied, but possess significant limitations; they are inconvenient to fill out, are highly subjective, and they are filled out inconsistently due to forgetfulness or symptoms. Research has shown that paper-based charting suffers from a range of problems [4, 23, 32]: low adherence rates, unreliable retrospective completion of diaries, and time intensive data entry.

Various electronic monitoring systems have been presented for patients with bipolar disorder including self-monitoring of medication, mood, sleep, life events, weight, and menstrual data. PC-based [33, 4] Web-based, SMS-based [5], and mobile phone [23, 27] solutions exist, which have been shown to make data reporting easier for patients, thereby reducing data inconsistency and increasing adherence rates. So far none of these monitoring systems have included combined self-monitoring and objective system recording of the disorder, and none of them have built-in mechanisms for providing historical data visualization or personal feedback directly to the patient on the phone.

Personal Health Technologies

Recently, several research projects have investigated the use of personal technology to encourage healthy behavior. Personal health technologies can be grouped into three broad categories.

The first set of systems can be labeled 'wellness' applications, which seek to 'persuade' users to make healthy behavior change such as increased physical activity [20, 7], healthy eating habits [26], or better sleep [3]. For example, Fish'n Steps [20] and UbiFit Garden [7] seek to encourage physical activity; the Time to Eat! iPhone application is a persuasive game encouraging healthy eating habits [26]. Lately, systems like the BeWell application have proposed a more comprehensive Smartphone-based approach that can track activities that impact physical, social, and mental wellbeing – namely, sleep, physical activity, and social interactions – and provides intelligent feedback to promote better health [17].

The second category comprises systems targeted management of chronic somatic diseases like diabetes [21], chronic kidney disease [31], and asthma [18].

The third category contains systems which address issues of mental health and illness such as stress [12] and depression [29, 6], and more general-purpose mobile phone systems for mood charting [23, 24]. Two systems of particular relevance to our study are the Mobile Mood Diary [23] and Mobilyze! [6]. The Mobile Mood Diary uses a mobile phone to allow patients to report mood, energy, and sleep levels, which can then be accessed on a website. The study showed increased patient adherence to mood charting using the phone as compared to using paper-based forms. Mobilyze! is a mobile phone application using machine learning models to predict patients moods, emotions, cognitive/motivational states, activities, environmental contexts, and social contexts, based on phone sensor data like GPS, ambient light, recent calls, etc. The website contains graphs illustrating patients self-reported states, as well as didactic tools, that teach patients behavioral activation concepts. The feedback mechanism uses telephone calls and emails from a clinician in order to promote adherence. A small feasibility study showed, among other things, that accuracy rates of up to 91% were achieved when predicting categorical contextual states (e.g., location), but that for states rated on scales, especially mood, predictive capability was poor. The study showed, however, that patients were satisfied with the phone application and it improved on their self-reported depressive symptoms.

The MONARCA system belongs to this third category. In some ways, it is similar to the Mobile Mood Diary and Mobilyze! systems, but the MONARCA system is targeted to bipolar disorder, rather than uni-polar depression. The MONARCA system also seeks to provide direct and timely feedback to the patient by visualizing self-assessment data and objectively sensed data directly on the phone. Moreover, rather than having clinicians phone or email patients, the MONARCA system has a built-in trigger and notification feature. The system is thus designed to scale better, organizationally, since the feedback mechanisms are not tied solely to a human actor (i.e. clinician).

THE MONARCA SYSTEM

The MONARCA system was designed in a user-centered participatory design process [13] involving a group of three psychiatrists and seven patients suffering form bipolar disorder. Specifically, we used the Patient-Clinician-Designer (PCD) Framework [22], which outlines how key principles of user-centered design – including user focus, active user involvement, evolutionary systems development, prototyping, and usability champions – can be applied in the context of designing for mental illness. Through the PCD process, patients and clinicians were instrumental in making decisions about system features through collaborative design workshops and iterative prototyping. Three-hour workshops were held every other week for six months. The designers led each workshop by facilitating discussion about particular design goals and issues, system features and functionality, and feedback on mockups and prototypes of the system.

The final design of the MONARCA system[1] contains 5 features that are targeted specifically to help bipolar patient manage their illness: (i) self-assessment of self-reported data like mood, sleep, and alcohol; (ii) activity monitoring in terms of sampling sensor data from the phone; (iii) historical overview of self-assessment and sensed data; (iv) coaching & self-treatment based on customizable triggers and detection of early warning signs (EWS); and (v) data sharing between the patient and the clinician.

The overall approach is that self-assessment and review of various parameters can support bipolar illness management. For example, patients and their clinicians can use the data to determine adherence to medications, investigate illness patterns and identify early warning signs for upcoming affective episodes, or test potentially beneficial behavior changes. Through monitoring and feedback, the MONARCA system may be able to help patients implement effective short-term responses to warning signs and preventative long-term habits.

Similar to other personal health technologies, the design of the MONARCA system employs a mobile phone application as the main component. Using a mobile phone was an obvious design choice since they were already used extensively by all patients.

Android Phone Application

Figure 1 shows the 5 main screens of the MONARCA Android application; (i) inputting self-assessment data, (ii) historic data visualizations, (iii) prescribed medicine; (iv) activated 'triggers' and suggestions for 'actions to take'; and (v) a screen for various settings, such as an alarm reminding the patients to enter their self-assessment data. In addition to collecting 'subjective' self-reported data, the application also collects 'objective' sensor data.

Subjective and Objective Data Sampling

A significant part of the design process was spent on designing the self-assessment form. First of all, it was important that relevant data for bipolar disorder patients were collected. As discussed in [22], there is a tradeoff between the clinicians' need to collect clinically relevant and 'objective' data, and the patients' need for collecting more personalized data. Second, significant effort has been put into designing the self-assessment form on the phone application, so that it is as simple and short as possible. A core requirement from the patients involved in the design process, was that the list of self-reported items should be kept to a minimum and that self-assessment should be done quickly.

Based on thorough design discussions, the final version of the MONARCA self-assessment form contains a minimum set of things to monitor, which can be divided into a set of

[1]The design of the MONARCA system and its technical implementation has been presented in [1], where many more technical details can be found. This section provides an overview of the system design and its core features.

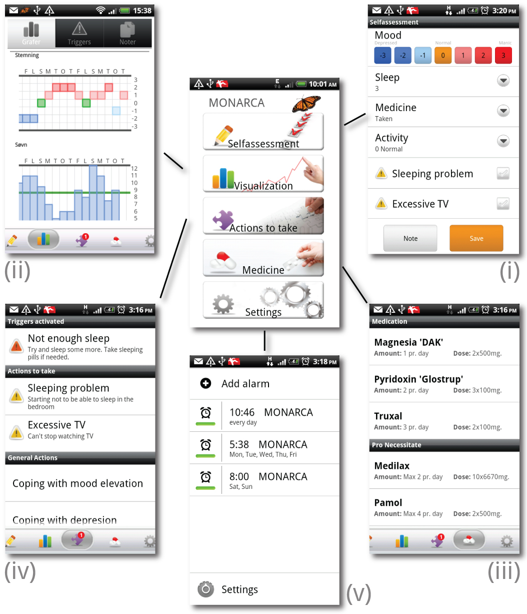

Figure 1. The MONARCA Android application user interface.

mandatory self-assessment items, which is absolutely crucial for clinicians to collect over time in the treatment of a bipolar patient, and a set of *optional* self-assessment items, which supplement the mandatory ones.

The mandatory self-assessment items are:

- *Mood* measured on a 7-point HAMD scale spanning from highly depressed (-3) to highly manic (+3). As a mood-disorder illness, self-reported mood is the main data parameter to follow for bipolar disorder patients.
- *Sleep* indicated in half-hour intervals. Significant clinical evidence shows a direct link between the mood of a bipolar patient and the amount of sleep (sleep increases during depressed periods, and decreases during manic periods).
- *Subjective Activity* on a 7-point scale spanning from totally inactive (-3) to highly active (+3). Bipolar disorder patients report themselves to be more active during manic periods and less active during depressed periods, and self-reported activity level is, like sleep, a very good indicator of the state of the illness.
- *Medicine Adherence* by specifying whether prescribed medicine has been taken as prescribed, have been taken with modification, or not taken at all. Since medical treatment of bipolar disorder is very effective and can significantly help stabilize the patient's mood, keeping track of medicine adherence is core to medical treatment.

The optional self-assessment items include:

- *Universal Warning Signs*, which are signs that a psychiatric clinic can set up for all its patients. Such signs can e.g. include experience of so-called 'mixed mood', 'cognitive problems', or 'irritability'.
- *Early Warning Signs (EWS)*, are *personal* signs that are tailored specifically to each patient, and inform them of things to look out for. For example, if a patient begins to sleep in

the living room, rather than the bed room, this is a sign for him that a manic phase is under way.

- *Alcohol*, as measured in number of drinks. For some bipolar patients, alcohol and drug abuse can be associated with their illness.
- *Stress* measured on a 6-point scale from 0 to 5. Self-perceived stress can be a significant trigger of a depressive period, and for some patients monitoring their stress level is important.
- *Note*, a free text entry done with an on-screen keyboard. This can be used to associate a note to the data entered or for entering more generic comments for this day.

On a daily basis, an alarm on the phone reminds the patient to report self-assessment data for that day. Only data for the current day can be entered and the system does not allow patients to revise earlier entries.

In addition to self-assessment data, the phone samples behavioral data via sensors in the phone. This includes *physical activity* data as measured by the accelerometer, and *social activity* as measured by the number of in- and outgoing phone calls and text messages. This sensor sampling is aggregated into two simple figures reflecting the level of physical and social activity on a given day, and is visualized as simple graphs on the data visualization screen.

Feedback Mechanisms – Visualization and Triggers

The visualization screen (Figure 1(ii)) is designed to be the main feedback mechanism to the patient. This screen is shown when the patient has entered his or her self-assessment data. The graph visualization display is designed to be very simple, while giving an overview of the self-assessment and sensed data. The phone only shows data for the past 14 days, whereas longer periods of data can be seen on the website.

The second feedback mechanism is the automatic trigger feature. A ‘trigger’ consists of a set of rules that apply to any self-assessment data being entered. For example, a trigger can be set up to trigger if the patient reports that he has been sleeping less that 6 hours, 3 days in a row. So-called ‘actions-to-take’ can be associated with a trigger. Actions-to-take are simple behavioral suggestions to a patient in different situations. For example, in case the patient sleeps to little, he or she can try using sleeping pills, or make sure to sleep in a cold and dark room. Triggers and actions-to-take are personalized to each patient.

When a trigger is activated, a notification is posted using Android’s notification mechanism. The trigger is then displayed as an item in the notification view on the Android phone (typically in the top pull-down curtain). When clicking the notification, the patient is taken to the *Actions-to-Take screen* (Figure 1(iv)), which lists all active triggers and their associated actions-to-take.

Automatic triggers are designed to play a core role in continuous and automatic feedback to the the patient, since they consistently track patterns over time and can warn both the patient and the psychiatrist about things to be aware of.

Website

The MONARCA system can also be accessed via a website, which is designed to be used by patients and clinicians. Patients can see and update their personal data as shown in Figure 2, manage personal triggers and early warning signs, and configure the system. Clinicians are shown a dashboard that provides an overview of their patients and how they are doing on the core parameters of mood, activity, sleep, and medicine adherence for the last 4 days. From this dashboard, they can access detailed data on each patient and customize the system according to the needs of each individual patient, including medication.

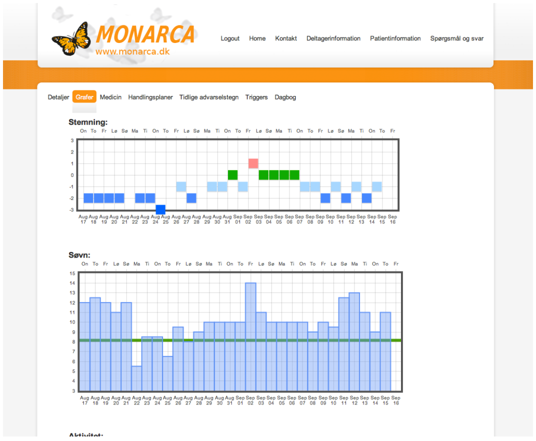

Figure 2. Website - Patient Data Visualization, showing the mood and sleep graphs.

FIELD TRIAL OF MONARCA

Clinical trials of inventions for mental health are very resource consuming, and often a staged evaluation strategy investigating both clinical and HCI issues can be more beneficial and informative [8, 23]. Hence, the MONARCA system was deployed in a single-arm feasibility trial that tested feasibility rather than efficacy. The study ran from May to August 2011, a total of 14 weeks. The study design was approved by the Danish National Committee on Health Research Ethics and the security and data handling was approved by the Danish Data Protection Agency, ensuring that everything was done according to standards. Informed consent was obtained from all patients.

The main objective of this study was to gauge the feasibility of the system as used by patients suffering from bipolar disorder. This was done by focusing on the following four questions:

$Q1$ – Is the system sufficiently stable for general use?

$Q2$ – How usable is the system and is it better than existing approaches for self-assessment and data collection?

$Q3$ – What is the usefulness of the system in terms of helping bipolar disorder patients in coping with their disease?

$Q4$ – Will this system – if used on a daily basis by bipolar patients – be useful to them in the future?

An important part of the study was to investigate the usefulness of the system during the trial ($Q3$) and the perceived usefulness in the future ($Q4$), and as such the study aimed at establishing the benefit for bipolar patients in managing their disease. As such, the goal of this study was to establish the feasibility of the system, and if this study was positive, to move into a clinical trial afterwards. Thus, the focus was on the patients using the system, and not the clinicians or the system used in treatment.

Trial Setup and Participant Recruitment

The study had three inclusion criteria: the patients should be; (i) between 18 and 65 years, (ii) able to use a mobile phone and a website; (iii) stable patients. No exclusion criteria were set up. Potential patients were referred to the study by doctors in the Affective Disorder Clinic at a university hospital. The doctor associated with the MONARCA study initially phoned each patient, introduced the project, and asked if they would be interested in participating. If so, they would meet with the doctor and a technician at the clinic, during which they were further informed of the project. If the patient was still interested in participating, an informed consent form was signed by the patient and the doctor. The patient then got a thorough introduction to the MONARCA system, received a printed user guide, and was issued a standard HTC Desire Smartphone. They were additionally helped to insert their SIM card, set up 3G internet, and transfer relevant content such as contacts. No compensation was paid to the patients, but they were reimbursed for their 3G internet subscription.

The patients received contact information (phone + email) for the MONARCA doctor and technician, whom the patients could contact if they had any questions or problems with the system. The MONARCA doctor would oversee the data on a daily basis and could contact the patients by phone if needed. The patients were still treated by their own doctor – who also had access to the patient's data via the website – but given that this was a feasibility study, the system was not fully integrated into the usual treatment at the hospital, as it would not be ethically sound to do this with an untested system. The MONARCA doctor would not engage in any treatment of the patients, but would notify the patient's doctor if necessary.

Methods

In order to answer the four questions above, we applied several methods. First, adherence to self-assessment was measured in two ways. Adherence to the paper-based forms was gauged by collecting and analyzing the paper-based mood assessment forms, used by the participants in 62 days from March to May 2011 (i.e., just prior to the launch of the MONARCA system). Adherence to the MONARCA system was measured by the number of daily self-assessments extracted from the system database. Second, we measured the usability of the MONARCA system by applying the IBM Computer System Usability Questionnaire (CSUQ) [19] online. Third, we issued an online questionnaire asking questions about the usefulness of the system during the trial period. Fourth, an online questionnaire containing the same questions, but now in future tense, was issued to investigate the *perceived* usefulness of the system in the future. There is a significant correlation between users' perceived usefulness of a system, and its actual future usefulness [9], and this analysis can hence be used to gauge the potential of the MONARCA system in a future clinical deployment. Fifth, we did semi-structured follow-up interviews with all participants at the end of the trial.

RESULTS

Participant Characteristics

28 patients were contacted initially, whereof 17 were interested and came to the clinic for further interviews. 14 patients were enrolled in the trial, of which 2 dropped out; one in week 2 because she wanted to go back to her iPhone, and one in week 7 due to a lack of time. Thus, a total of 12 bipolar patients participated in the field trial. The left column of Table 1 shows the list of participants and their demographic backgrounds. We were able to recruit a very diverse set of patients of different gender (5 male, 7 female); age (20–51 years); IT skills; and mobile phone experience. All participants were selected among stable patients having initial HAMD mood scores in the range of -1 to $+1$.

Participation

Figure 3 shows the use of the system during the trial period, including the number of phones reporting self-assessment ('Subjective') data as well as sensor ('Objective') data on a daily basis. The graph illustrates that phones were deployed during May, and usage peaked in mid June to mid August, and that almost all 12 phones reported data on a daily basis. During August, we experienced an error in the Android Market that locked the application. This was not discovered until the trial was over, and based on post-trial interviews, this error seems to explain the decline in use during August.

Adherence Results

Table 1 shows the rate of self-assessment when using both the paper-based forms as well as the MONARCA system. From this table we can observe several things.

First, on average, the length of the paper-based and phone-based trials are comparable (62 and 69 days), with some variation in the system trial. If the phone is working (i.e., charged), the application will sample objective data. On average, sampling was done 63 out of 69 days and the application was hence running 92% of the trial period.

Second, we can compare the adherence to self-assessment using the paper-based forms and the MONARCA system. In the paper-based forms, we count the number of days that any information is noted on the paper – irrespective of the level of detail. When using paper-based forms, the raw adherence percentage is 58%, which is similar to what was found in the Mobile Mood Diary study [23]. But, if not counting the four participants who did not fill in their self-assessment at all (P48;P63;P67;P70), the average adherence is 87%. The general adherence percentage when using the MONARCA system is 80% for all of the involved 12 participants. If we only take into consideration the days where the system was actually working (63 instead of 69), the adherence rate is 87%. Hence, the adherence rate for the paper-based and phone-based systems are comparable if only counting the days where data can be recorded and only involving participants who also reported data on their paper-based forms. However, the interviews revealed that paper-based forms were subject to significant retrofitting and we will discuss this further in the Discussion section below.

Participant	*Gender*	*Age*	*IT skills (1–5)*	*Mobile phone*	*Years of phone use*	*Mood score*	*Occupation*	*# self-assessment days*	*% adherence*	*# primary scores*	*# days participated*	*# self-assessment days*	*# days reporting data*	*% general adherence*	*% adherence (run. system)*	*# of 4 primary scores*	*# visits to website*
P48	m	29	4	iPhone	15	-1	Student	0	n/a	n/a	65	50	57	76	87	4.00	0
P49	f	50	4	Nokia	20	0	Unemployed	59	95	2.88	40	26	38	65	68	3.80	1
P55	m	29	2	Nokia	13	0	Shipping	59	95	2.97	99	60	60	60	100	3.87	0
P57	f	35	4	SonyE.	15	0	Accountant	62	100	3.00	90	76	86	84	88	4.00	0
P58	f	34	2	Samsung	10	0	Teacher	43	69	2.04	98	96	97	97	98	3.31	6
P59	f	38	4	Nokia	13	-1	Unemployed	43	69	2.77	98	74	92	75	80	3.77	0
P61	f	34	4	iPhone	14	0	Self-employed	59	95	2.34	68	64	68	94	94	3.56	1
P63	f	20	5	HTC	9	0	Student	0	n/a	n/a	22	8	14	36	57	3.38	0
P64	f	51	2	Nokia	14	1	Pensioner	59	95	2.22	77	77	77	100	100	3.87	15
P66	m	45	4	SonyE.	12	0	Student	50	80	3.00	70	61	69	87	88	3.80	51
P67	m	37	5	iPhone	15	1	Ph.D. student	0	n/a	n/a	53	46	52	86	88	3.78	11
P70	m	37	4	iPhone	15	-1	Musician	0	n/a	n/a	49	47	49	95	95	4.00	2
Avr.		36			14			36	87	2.65	69	57	63	80	87	3.76	7

Table 1. Participation in the MONARCA trial study. From left: participation ID; demographic data; and data from the normal paper-based self-assessment forms, and usage data for the 14 weeks trial study of the MONARCA system.

CSUQ item	*Description*	*avg.*	*sd.*
OVERALL	Overall satisfaction	2.60	1.01
SYSUSE	System usefulness	1.93	0.42
INFOQUAL	Information quality	3.32	1.10
INTERQUAL	Interface quality	2.71	0.93

Table 2. The CSUQ usability results on a Likert scale from 1–7: 1=Highly agree; 7=Highly disagree.

Third, looking specifically at the four mandatory self-assessment parameters of mood, sleep, activity, and medicine we see that all patients have high compliance scores (3.76 out of 4.00 is 94%), which is very positive since acquiring this data is a core goal of the system. On the paper-based self-assessment form, only 3 out of these four parameters can be reported (activity is missing), and we see a slightly lower degree of compliance (2.65 out of 3.00 is 88%).

Finally, looking at the use of the website, it is quite evident that this is not used by most of the participants. P66, P64 and P67 show moderate use. The extensive use by P66 is due to this patient being interested in the data visualization, where he accessed the website constantly, just to look at the graphs.

System Usability

Table 2 shows the usability scores as measured by the IBM Computer System Usability Questionnaire (CSUQ) on a 7-point Likert scale from ‘Strongly Agree’ (1) to ‘Strongly Disagree’ (7). From these scores we can conclude that the overall usability of the system is good (OVERALL = 2.60) and the users found the system very useful (SYSUSE = 1.93). This reflects a low score in simplicity, comfortability and learnability, and efficiency. The information quality score is lower (INFOQUAL = 3.25) which can be ascribed to problems with the error messages of the system, which scored 5.33, and did not help users fix the problems they may have experienced. Finally, the system scores well in interface quality in general (INTERQUAL = 2.86), but the study showed that it did not have all the functions and capabilities that patients expected. This was also mentioned in the interviews, and we will return to this in the discussion below.

	System Usefulness		*Perceived Usefulness*	
	avg.	*sd.*	*avg.*	*sd.*
Disease Mgmt.	3.16	1.55	2.16	1.02
Self-assessment	2.21	1.06	1.73	0.72
Visualization	2.22	1.39	1.66	0.78
Alarms	2.34	1.44	2.13	1.88
Triggers	3.59	1.31	2.71	1.02
Early Warning Signs	3.44	1.18	2.36	0.78
Actions to take	3.25	1.52	2.34	0.88
Medication	4.30	1.50	3.17	1.51
Website	3.00	1.70	2.63	1.76

Table 3. Questionnaire results on ‘System Usefulness’ as used in the trial period and ‘Perceived Usefulness’ in the future. Users reported on a 1–7 point Liket scale on the question of “The MONARCA system is useful for ...”: 1=Highly agree; 7=Highly disagree.

Usefulness and Perceived Usefulness

In the usefulness questionnaire we asked 38 questions divided into 10 categories, using the 7-point Likert scale. The categories and average scores are shown in Table 3. The usefulness of the system for disease management during the trial scored 3.16. This means that patients agree (though not strongly) that MONARCA helped them in managing their

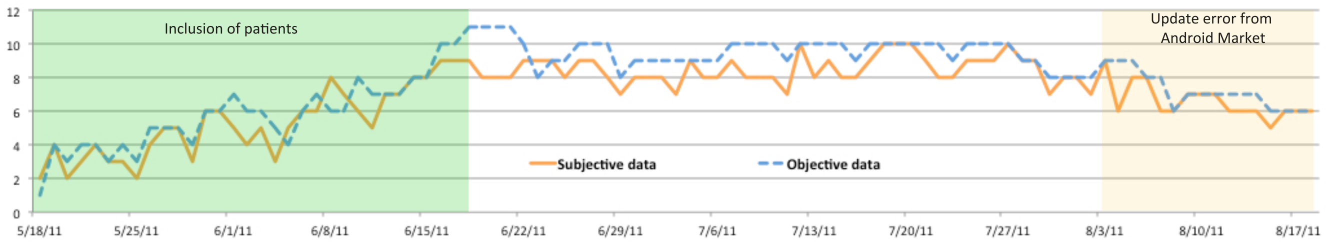

Figure 3. The usage of the MONARCA system during the trial period, showing the number of phones reporting subjective self-assessment data and objective sensor data on a daily basis.

bipolar disorder. This category addressed wether the patients became better at managing their disease (2.92), wether they were made more aware of their disease (2.50), the specific usefulness of the application for disease management (3.33), the usefulness of the website (4.33), and if the application made them change their lifestyle (4.00). Hence, a clear indication was that the system as such, did not have an effect on changing lifestyle, but more on disease management and awareness. When asking the same questions, but on perceived future usefulness, the patients generally agreed that the system would help them cultivate better disease management and awareness. Even the question on whether the system would make patients change their lifestyle scored relatively well (2.67). Hence, patients think that this system – if used in the future – would also assist in changing their lifestyle. The questionnaire also inquired about more specific aspects of the MONARCA system. Table 3 shows that the features of 'self-assessment', 'visualization', and 'alarms' were found to be the most useful features now and in the future. Hence, the patients found it very useful to be reminded to enter self-assessment data and see a temporal visualization of it. Moreover, the use of visualizations is perceived as the most useful feature of the system in future use. Features like 'triggers', 'early warning signs' and 'actions to take' are found to be useful, though less useful compared to the self-assessment functionality. Managing medication in the MONARCA system was found not to be useful. The usefulness of the website seems to be rather low and as shown in Table 1, it was not accessed by many patients.

DISCUSSION

Personal health technologies hold promises for both clinical and qualitative improvements of the healthcare model of the Western world. Even though this study did not provide unequivocal clinical evidence that the MONARCA system had any effect (positive or negative) on the patients' disease, the field trial has shown that the system is definitely feasible to use for the management of bipolar disorder. To be successful, a core requirement for such systems is that they are easy to use and are perceived as useful by patients. As such, the design of personal health technologies is a highly important topic for human-computer interaction.

Based on the insights from this trial test of the MONARCA system, combined with existing human-computer interaction studies of the design and use of personal health technologies, we have identified three core questions, which have to be addressed in the design of personal health technologies:

1. How to design for disease awareness and self-treatment?
2. How to ensure adherence to using personal health technologies?
3. What are the roles of different types of technology platforms?

This section discusses these core human-computer interaction design questions for personal health technologies in greater detail.

Designing for Disease Awareness and Self-treatment

As described in the Background section, continuous mood tracking, recognizing and controlling early warning signs, activity logging, and medication compliance training are core ingredients in cognitive behavioral training (CBT) for bipolar disorder patients [30, 2].

The field trial indicates that this kind of disease awareness and self-treatment was supported by the MONARCA system. The usability and usefulness scores show that the patients found the system very usable and useful in disease management, which was also reflected in the interviews:

> *"I am surprised how much I like it! [...] [MONARCA] is filled with substance and I have really benefited from it in relation to my illness. I have never used the [paper-based] mood charts that much, and I have never had much awareness about my [data] history [...] so I have been extremely happy with it, and I really think it is great."* [P70]

This quote also hints at the main reason behind the usefulness of the system, as P70 argues that the awareness of the historic data is highly useful. P70 continues;

> *"What I saw [in the trial] is that it helped me keep on track. I try to keep track of the triggers [early warning signs], and my history – and in that way it has helped me enormously. Previously, I went into periods where I encountered random mood swings, up and down, and I did not have any history [data] to relate to, so it kind of surprised me. But now I can actually follow how I'm doing – also back in time – and what caused it. It has really been great, and I think I have been able to keep track of myself."* [P70]

This insight is also reflected in the study data. Table 3 shows that patients found the ability to enter self-assessment data and later to review them in the visualization to be the most useful features of the system.

In the design of the MONARCA system, several visualization techniques and metaphors were discussed. Similar to other personal health systems that use fishes and flowers as metaphors, we were looking for an appropriate metaphor for bipolar disorder. Many attempts were tried, including using metaphors like a scale, an equalizer, a river, a volcano, a dart board, and a radar, but we always had the case that some patients prefered one visualization, and others hated it – as put by P67 one day; "*I do not want my disease reduced to a game!*" In order to avoid problems, we designed the MONARCA system using a neutral graph visualization metaphor, but it seems that there is a need for allowing patients to use different visualizations. In general, it seems that support for tailorability and personalization of what self-assessment data to collect and how to visualize it, is important in the design of these types of systems.

Features like 'triggers', 'early warning signs' and 'actions to take' are also found to be useful for maintaining an awareness of the development of the disease, and to react if something change. The perceived usefulness of these features in the future is even higher.

The medicine overview was, however, not found to be particularly useful. In the interviews, patients explained that the overview was fine, but it did not increase their awareness of their medication. The patients wanted to be able to adjust their medication themselves; something they are allowed to do by the psychiatrist in order to fine-tune their medicine intake according to changes in mood and other symptoms. Also, the level of detail in the self-reporting on medicine intake was too coarse-grained; they could basically just specify if they took the prescribed amount of a drug, not if they took more or less.

In summary, the MONARCA system seems to be successful in providing the self-assessment and awareness of core disease parameters – except medication – which clinical studies have shown to have a positive effect on CBT treatment of bipolar patients.

Ensuring Adherence to Technology Use

As mentioned before, we saw that entering self-assessment data and using the system on a daily basis is core in building clinically beneficial disease awareness and self-treatment skills. This obviously then requires that the patient enters this data on a regular basis, and thus the whole complexity of 'adherence' becomes important in the design of personal health technologies.

The adherence rate of 87% in the MONARCA system is higher than the 65% adherence found in the Mobile Mood Diary system [23], which, however, was tested in a much longer period and may suffer from long-term effects that we did not encounter. We found that the adherence rate for the system was comparable to the paper-based forms. But several patients reported in the interviews that they actually retrofitted their paper-based self-assessment. As P49 said: *"The paper is more inaccurate – I sometimes put in data for several days at once, because I forget it"*. And P58 stated that: *"I used to fill out the paper for the whole week just before meeting with my doctor"*. This verifies the findings in the evaluation of the Mobile Mood Diary system, as well as other research, which has shown that paper-based charting suffers from a range of problems [4]: low adherence rates, unreliable retrospective completion of diaries, and time intensive data entry [32]. Note also, that in MONARCA, the patients can only fill in self-assessment scores on the current day; there is no way to report data back in time. As such, the MONARCA system provides much more valid day-by-day self-assessment data.

In the field trial, all patients reported that it is much easier to use the phone based self-assessment approach rather than using paper charts. As P49 explained:

> *"It is much easier to use the phone than the paper. I have the phone with me at all times, and I don't have to worry about the paper getting lost. It is very convenient that you can enter data when you experience things instead of having to recall it all when you fill in the paper"*. [P49]

An important factor in ensuring adherence to using the technology seems to be related to the 'alarm' feature. Initially, we feared that the alarm would be too obtrusive for the patients, but the evaluation showed that the patients found it very useful in reminding them to fill in the the self-assessment once a day. As P49 continues:

> *"I have to have this alarm on, otherwise I forget to fill in my self-assessment — I often forgot it using the paper. I could use a normal alarm, but I think it is nicer to have it as a part of the system"*. [P49]

In sum, ensuring adherence to the use of personal health technologies is core to their success. Based on our findings, adherence can be ensured by designing for simple and limited data input and using a reminder mechanism, like the alarm feature in the MONARCA system.

Technology Platforms for Personal Health Systems

This study showed that using a Smartphone that is always with the patient, ensures better adherence compared to paper-based charts. In this section we will discuss the applicability of different technology platforms for personal health systems, focusing specifically on the web and Smartphone platforms.

Several personal health systems rely on using web sites for treatment of mental disorders [28, 11] and have reported good results. However, the MONARCA study showed that only a few patients accessed the website. Information on medicine, warning signs, triggers, and general actions-to-take are configured for each patient together with the doctor at the clinic, but once this has been set up, the patients reported that there was little need to go trough the trouble of logging into the website; the settings seldomly needed to be changed and most of the data collected is available on the phone. As explained by P61:

> *"I logged on to the website the same evening I got the phone, but I didn't do anything there since my warning signs and triggers were already there. I have actually not visited it since, as I haven't had the need to alter anything, and I don't feel like I have enough data yet to actually go back and explore it."* [P61]

The usability scores (Table 2) show that the website scored lower than the rest of the system. The patients stated that it is partly because they did not have any real use for it, but also because they feel the design could be better. P57 states that *"compared to the phone, the website feels more disease-like, and not that personal."*

Turning to the Smartphone as a technology platform, the trial clearly indicates that this platform is well-suited to personal health systems. As argued by P49, "it is much easier to use the phone than the paper – I have the phone with me at all times". Studies show that Smartphones are within close distance to a user 90% of the time [10], and the fact that a Smartphone is a personal device which is always with the patient, makes it a good platform for these kind of systems.

This general finding is in line with other recent studies of personal health systems. For example, the Mobile Mood Diary study showed that a mobile phone was very useful for self-reporting of data and systems like the UbiFit Garden, Fishn Steps, BeWell, and Mobilize! have shown that Smartphones are useful for sensor data collection and visualization.

In contrast to the Mobile Mood Diary, however, the trial of the MONARCA system showed that text entry on the phone was not used. This again highlights that the design of personal health systems should take great care to limit the amount of self-reported data needed. However, during the interviews it became apparent that patients were not always satisfied with the current set of items; a fact that is also reflected in the mediocre score in the CSUQ information quality (INFOQUAL) score in Table 2. Given that bipolar disorder is an individual and diverse disease, it is important to be able to set up and track individual items other than the early warning signs. As argued by P67: *"I need to keep track of energy level and coffee"*, and P70: *"I feel there should be an anxiety item in the self-assessment, as it is important to me. I think all patients have different items that are important to them personally."*

CONCLUSION

This paper has reported one a 14 week field deployment and study of the MONARCA system, used by 12 patients. The MONARCA system helps patients suffering from bipolar disorder to do daily self-assessment and to get timely feedback on how they are doing using through visualization and feedback mechanisms. In the trial, we studied different aspects, including how the system was used and adopted as compared to the existing paper-based self-assessment forms, the usability of the system, and the usefulness of the system for the patients in managing their illness. The results were positive; compared to using paper-based forms, the adherence to self-assessment improved; the system was considered very easy to use; and the perceived usefulness of the system was high. As such, we can conclude that it is possible to design and deploy pervasive monitoring systems for mental illness such as bipolar disorder.

Based on the trial of the MONARCA system, we have discussed three core questions to address in the design of personal health technologies: (i) how to design for disease awareness and self-treatment; (ii) how to ensure adherence to using personal health technologies; and (iii) what is the role of different types of technology platforms. The presented trial of the MONARCA system showed that the system promoted disease awareness through self-assessment and temporal data visualization, adherence via the reminder system and the use of a Smartphone technology platform which is always with the patient. As a personal device, however, personal health systems should allow for personalization both in terms of what data to collect (self-reported and sensor-based) as well as how to visualize this data.

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Paper 3
Supporting situational awareness through a patient overview screen for bipolar disorder treatment

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I hereby declare that I am aware that the work in the paper

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who made a

☒ major

☐ proportional

☐ minor

contribution to the work both in the research and writing phase.

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Supporting situational awareness through a patient overview screen for Bipolar Disorder treatment

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***Abstract* - Situational awareness, and how systems can be designed to support it, has been a focus in many dynamic, safety critical contexts, with great success. The work presented here extends the study of situation awareness into the domain of patient overview screens in personal monitoring systems. In this paper we report on the design and formative evaluation of a detailed patient overview screen for supporting the treatment of bipolar disorder through MONARCA, a personal monitoring system. We define the key items for supporting situational awareness for clinicians, as well as discuss key findings such as doctors vs. nurses needs and the lack of need for situational awareness support.**

Keywords - healthcare, mental illness, situational awareness, bipolar disorder, personal monitoring system, overview screen, user centered design, usability evaluation.

INTRODUCTION

Bipolar disorder is associated with a high risk of relapse and hospitalization [1]. Major reasons for the decreased effect of interventions in clinical practice are delayed intervention for depressive and manic episodes [2, 3]. Recently, electronic solutions for self-monitoring of affective symptoms using cell phones have been suggested as an easy and cheap way to identify early signs of affective episodes [4, 5].

As the adoption of information technology has increased, so too has the demand that these systems adapt to the clinical environment, and make accessing and managing information easier [6]. With the introduction of personal monitoring systems for conditions like diabetes [7, 8], chronic kidney disease [9], and asthma [10], the amount of data to be interpreted by clinicians has increased.

In particular, clinicians should be supported in achieving a good level of *Situational Awareness* (SA) about their patient's condition at the point of care, when decisions need to be taken. SA refers to the capacity of "knowing what is going on around you to decide what to do" [11] and is a field of study concerned with understanding how perception, comprehension and projection processes can be supported in order to enable effective decision-making in complex, dynamic domains [12]. These are domains where the information flow is quite high and poor decisions may lead to serious consequences (e.g., air traffic control, emergency response and healthcare management). Situational awareness is a state achieved when information that is qualitatively and quantitatively relevant for the decision-maker is made available through appropriate systems and information exchange patterns [13].

Also, previous work in the field of Computerized Decision Support Systems has shown that health information technology components can positively impact chronic illness care [14]. Aspects of health IT systems found to be correlated with enhanced health outcome included, among the others, linkage between the technology system and an electronic medical record, computerized prompts during treatment decision-making, availability of progress reports and feedback, specialized decision support [15]. These studies have also pointed out the importance of providing clinician feedback at the time of the patient visit, in order to support the quality of their decision-making and their assessment of symptoms and side effects at the point of care [15]. Although health IT systems like EMRs can facilitate within-office care coordination, by providing access to data during patient encounters, it has also been shown that: (i) EMRs are less able to support coordination between clinicians and settings, in part due to their design and a lack of standardization of key data elements required for information exchange, and (ii) managing information overflow from EMRs is a challenge for clinicians [16]. Moreover, how medical information is presented (its context) is an important factor affecting data retrieval and interpretation by clinicians. Computer systems should be capable of producing well-structured information screens, based on relevant objective and subjective clinical data, so as to improve retrieval and assimilation of existing information on patients, improve comprehension and provide a more holistic view of the patient [17]. Usability is thus critical to successful health IT implementation and adoption and its subsequent ability to improve health care quality.

During the first field trial of the MONARCA Self-Assessment System, we found the need for a more effective design of overview interfaces, supporting the healthcare personnel involved in the treatment of bipolar patients. In particular, the need for supporting the SA at the point of care of doctors and nurses, by presenting them with the most relevant monitored data, provided through the use of the MONARCA system, and additional clinical data regarding the patients, which could inform clinicians' decision-making more effectively at the current point in treatment. Previously in the system, clinicians went from high-level overview of all patients directly into detailed data regarding the individual patient, leaving the clinician to rummage through vast amounts of data in order to get an overview of the patient. Therefore there was a need for an intermediate layer of

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information, consisting of an overview of the individual patient and the relevant information.

In this paper, we first describe how we approached the challenge of designing the detailed patient overview screen, the formative evaluations conducted with usability experts as well as clinical staff. We conclude with a discussion of the outcome and lessons learned from these evaluations.

DESIGN PROCESS

Designing for bipolar disorder poses several challenges. Due to its complexity, it is unclear what data are most important. Symptoms vary from patient to patient, and may be difficult to recognize. Thus, the design of the patient overview screen was done in a series of user-centered design workshops, involving three doctors and a nurse affiliated with the psychiatric clinic of a large university hospital in Denmark.

The initial idea was to design an intelligent user interface, which could be tailored to the needs of individual patients, following practical guidelines for treatment [18]. However, when this idea was presented to the clinicians in the workshop, they didn't see the need for an adaptive system - they much preferred a unified system, which always displayed the same key information they were interested in when treating the patient.

Long discussions were undertaken on perspectives of the treatment, different categories and items needed for providing the best possible overview of the patient, drawing from their respective best practices: both medically and practically. In this stage, it became evident that doctors and nurses have different needs and requirements based on their work with the patients, which is discussed in further detail in the discussion section of the paper. However, we did manage to find a solution, which meets both parties' needs. It contains the data needed for both parties to preform their work, but at the same time also makes it easier when collaborating on treating the patient, with a common reference point.

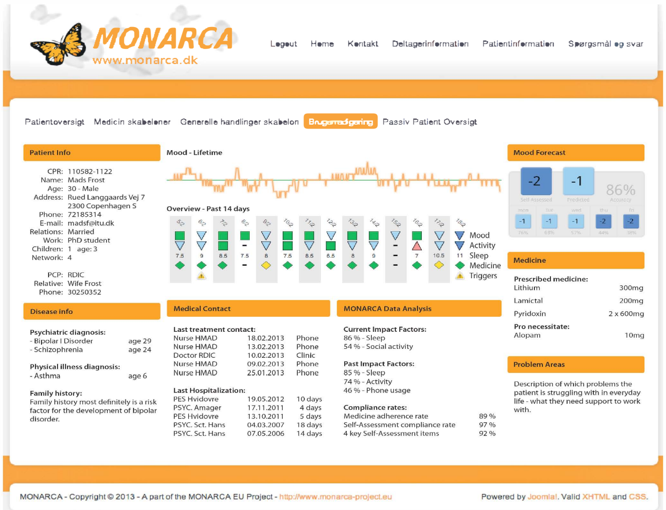

Figure 1: Patient overview screen mock-up, as used in the evaluation.

We provided the participants with materials such as large poster paper, writing materials, scissors, tape, *etc*. The sketches that came out of this initial brainstorming formed the basis for the first mockup. The mockup was then computerized, and discussed again, to provide the final evaluation version, as seen in Fig. 1.

PATIENT OVERVIEW SCREEN

The overview screen, as seen in Fig. 1, consists of 9 main categories. On the left side from the top;

- ***Patient info*** – containing Social security number, Name, Age, Address, Phone, E-mail, Relationship status, Work, Number and age of children, Network score on a 1-5 scale; the higher the number, the better help and support they have from family and friends, PCP – Primary Care Providers – the clinicians in charge of the patient's care, Name of Relative, and a contact number for the relative.
- **Disease info** – containing the patient's psychiatric and physical diagnoses, according to ICD-10 standards, the age at which they were diagnosed, as well as a *Family history* of relevant illnesses.

The center section from the top;

- **Lifetime mood scores** – depicted as a sparkline to provide an historical overview of mood swings.
- **14 day detailed overview** – provides the detailed scores of mood, sleep, activity and medication from the past 14 days, reported by the patient in the monitoring system, as well as highlight activated triggers.
- **Medical contact** - consist of two sub categories; *Last treatment contact*, showing when and how the last clinician had contact to the patient, and *Last hospitalization*, providing an overview of where, when and for how long the patient was hospitalized.
- **Data analysis** – shows the *Current* and *Past Impact Factors*, which are the factors that the system calculates as having the biggest influence on the patient's mood state. It also conveys the patient's *Adherence rates*, which describe how regularly the patient fills out self-assessments, and takes prescribed medicine.

The right side from the top;

- **Mood forecast** – provides the predicted current day mood score and accuracy, as well as a 5-day forecast of the patient's future mood state, based on the collected data from the monitoring system.
- **Medicine** – indicates which medication the patient has been prescribed – both regular and pro necessitate.
- **Problem areas** – an overview of the problems and focus areas the patient is struggling with in everyday life.

All the content is visible at all times. The information items may have a mouse-over effect, if they can provide you with more detail on the specific item, e.g. hovering over a diagnosis, will provide you with more information on the identity and location of the doctor that made the diagnosis; hovering over one of the items in last treatment contact will provide the journal entry from that day; hovering over an Impact Factor will provide you with the strategies for self-treatment given to the patient.

Formative Evaluation

For the formative evaluation, we preformed two different types of assessment of the proposed design, based on a paper prototype, as seen in Fig. 1. The prototype contains fictive data, but is modeled according to real patient data.

First, two usability and clinical information systems experts~~,~~ from the IT University of Copenhagen, performed a heuristic evaluation, which is a usability inspection method for software that helps to identify usability problems early in the user interface design. The evaluators examined the interface and judged its compliance with recognized usability principles - the 'heuristics'. [19].

Secondly, data were collected in the Affective Disorder Clinic at Rigshospitalet in Copenhagen, utilizing the 'Think-aloud protocol', which has been used successfully in user interface research [20]. This method is used frequently in single user performance evaluations, where the user is asked to voice their thoughts, feelings, and opinions during the evaluation.

A total of 7 clinicians - 3 nurses and 4 doctors - participated in the evaluation. All participants were familiar with the MONARCA system. The evaluation followed a detailed script, where the researcher first introduced the project, explained the think aloud procedures, and performed a brief training exercise to familiarize the participants with the concept. Hereafter, the clinician was given the following scenario:

"*The time is 13.50, and the last of six previous patients have just left your office. The next patient, whom you have not seen for one and a half months, is scheduled at 14.00. You enter the MONARCA system and select the before mentioned patient in the general overview screen. You are now presented with this new detailed patient overview screen*".

The participants then worked through the overview screen, and the researcher elicited more comments based on events that arose during the think aloud protocol. In the end, the participant was asked to rank the different categories according to importance to their work.

All the evaluation sessions were voice recorded, then analyzed using Kvale's first two levels of conversation analysis; self-perception and critical common sense understanding [21].

Results

From the heuristic evaluation, 4 main comments were provided by the experts; (i) the lifetime mood sparkline does not provide time indicators, (ii) there is inconsistency in headlines of *Lifetime mood* and *14 days overview*, which is not similar to the rest of the categories, (iii) there is too much detailed data in the *Patient info* category, where details on address, email, and relatives, were supposed to be too detailed for an overview, and finally (iv) the *Patient info* category could be improved by adding a picture of the patient, as it may support the clinician's recollection. Experts also noted that there was a lot of information in a small amount of space, which can seem overwhelming at first, but they deemed it useful given the goal of providing an overview.

The main outcome of the Think-aloud sessions was that ~~all~~ the clinicians' felt that the design presented "*a lot of data..*", but all had within the first minute made sense of the different information categories. The general feedback the clinicians provided can be summarized as follows: (i) *Time indicators* – All mentioned the lifetime mood sparkline needed time indicators, as they were not able to make sense of it without. (ii) *Orange color* - All mentioned that they did not like the orange color used. They said that they would prefer a blue or green nuance instead. (iii) *Picture of patients* – three of the clinicians mentioned that they would like to have a picture of the patient in the patient info section to help them recall the patients. (iv) *Latest journal entry* – All the nurses said that it would help their work if the latest entry in the journal were displayed in full text, and not only through a mouse-over function.

During the evaluation, the clinicians mentioned how having this type of overview would provide a much clearer overview, would be time saving, and they foresaw that fewer misunderstandings would occur in subsequent meetings with patients, as sometimes happens when clinicians are not informed of important patient events, e.g. hospitalizations.

When the clinicians were asked to rank the different categories, they were very reluctant to do so, as they found all of them important for the overview. However, the nurses ranked the *14 day detailed overview*, the *medicine*, the *patient info,* and *problem areas* as the most important details for their work. The clinicians ranked *disease info*, *14 day detailed overview*, *medicine,* and *medical contact* as most relevant.

Discussion

In the initial design phase, the clinicians were not really interested in getting aid from the system to change or focus the overview screen, based on a systemic interpretation of the patient – supporting comprehension. The clinicians made their own judgments based on the different sources of information, but recognized a great improvement in having all the relevant elements displayed at once – to improve perception. All the clinicians were very enthusiastic about the overview screen during the evaluations, except for one doctor who was not particularly fond of it, as it contained too much information. She knew her patients well and could recall a lot of details about each individual patient, even though there could be long periods between visits. Thus she was only interested in getting the relevant elements from the monitoring system, and not be presented with information she already knew. However, more long-term deployment of our overview solution in clinical settings might reveal cases and situations (e.g., assignment of larger numbers of patients to a doctor) when perception support tools become necessary and can make a difference in the quality of treatment provided.

In their daily work, the nurses are more focused on the subjective side of the treatment, dealing with psycho-educational aspects of a patient's treatment. They would use the screen as a reference point during the conversations with a patient, as it contains all the important items regarding their treatment. Doctors, however, are more interested in objective information, such as a patient's diagnosis, or the medication they have been prescribed, and put less emphasis on the particular issues the patients are struggling with in their everyday life. This is also evident from the ranking of categories, where the doctors focused on the diagnoses and prior contact, whereas the nurses looked at problem areas and patient info. Nevertheless, even though they have different focus areas, we found that the given solution would provide support for both, as all the categories included in the overview were found useful for all parts of the treatment.

CONCLUSION

We have introduced the design and evaluation process of a detailed patient overview screen for supporting the treatment of bipolar disorder patients through the use of a personal monitoring system. Moving through the development phases, we learned that (i) clinicians require a full overview of all patient-critical information on one screen, not hidden within dropdowns or menus, (ii) they are able to use the same overview for different approaches in the treatment, and finally (iii) they do not prefer content to differentiate between patients, diagnoses, or special characteristics. They require system support to improve perception, rather than comprehension processes. All the clinicians were very enthusiastic about the overview screen, and wanted it put to use right away.

The main limitation of this study consists in the fact that the results presented are based on a formative evaluation of our overview screen solution, involving a small group of clinicians and usability experts. However, the collection of these results was important, as they constitute the input to future design and implementation work. Specifically, a clinicians' component of the MONARCA system that will be deployed and further tested in different clinical settings over the next months. From this more complete testing of the whole system we expect to derive further insights on the contribution of the clinicians' overview screen to an improvement of current practice in the treatment of bipolar disorder.

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The final high quality image of the detailed patient overview screen can be downloaded from https://www.dropbox.com/s/cb3ebzkr85tjocz/detailed_patient_overview_screen.jpg?m

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Paper 4
Supporting disease insight through data analysis: refinements of the MONARCA self-assessment system

Mads Frost, Afsaneh Doryab, Maria Faurholt-Jepsen, Lars Vedel Kessing and Jakob E Bardram. Supporting disease insight through data analysis: refinements of the MONARCA self-assessment system. In *Proceedings of the 2013 ACM international joint conference on Pervasive and ubiquitous computing* (UbiComp '13). 2013, 133-142.

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Supporting Disease Insight through Data Analysis: Refinements of the MONARCA Self-Assessment System

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ABSTRACT
There is a growing interest in personal health technologies that sample behavioral data from a patient and visualize this data back to the patient for increased health awareness. However, a core challenge for patients is often to understand the connection between specific behaviors and health, i.e. to go beyond health awareness to disease insight. This paper presents MONARCA 2.0, which records subjective and objective data from patients suffering from bipolar disorder, processes this, and informs both the patient and clinicians on the importance of the different data items according to the patient's mood. The goal is to provide patients with a increased *insight* into the parameters influencing the nature of their disease. The paper describes the user-centered design and the technical implementation of the system, as well as findings from an initial field deployment.

Author Keywords
Pervasive Healthcare, Personal Health Monitoring, Mental Illness Management, Bipolar Disorder, Smartphone, Data analysis

ACM Classification Keywords
J.3 Life and Medical Sciences: Health; H.5.2 Information Interfaces and Presentation: User-centered design.

General Terms
Design; Human Factors; Algorithms

INTRODUCTION
The management of mental health and well-being through phone-based monitoring systems, tracking daily life and routines, is a promising, rapidly growing area in pervasive healthcare. Smartphones are capable of capturing multiple dimensions of human behavior, encompassing physical, mental and social aspects of well-being [12, 5]. Many Smartphone applications take advantage of persuasive visualizations and features that can help with adjustment of behaviors to improve adherence and consistency. For example, *UbiFitGarden* [6], and *Bewell* [12] collect behavioral data, such as physical activity from phone sensors and provide visual feedback such as an ambient display to promote healthy behavior.

In the clinical domain, systems are moving from reactive response to acute conditions to a proactive approach, characterized by early detection of conditions, prevention, and long-term management. The goal is to make patients and clinicians aware of the current state of the illness with the help of technology [4]. An example is the *Health Buddy* [11], which is used for monitoring patients with schizophrenia who were recently admitted for suicidal behavior. It presents patients with a series of pre-programmed questions about symptoms of depression and suicide, allowing mental health service providers to monitor the patients symptoms. The *Mobile Mood Diary* [16] uses a mobile phone to allow patients to report mood, energy, and sleep levels, which can then be accessed on a website. The *Mobilyze!* system [5] is an example of an intervention system that uses machine learning to predict the cognitive state of the patients from phone sensors and environmental context.

However, most of these health monitoring systems use the collected data solely for visualization purposes, and provides little insight into the nature of the disease. Bipolar and other mental diseases are chronic disorders and patients need to learn to cope with their illness the rest of their lives. There is a great individual variability in the illness in terms of how it affects the individual patient, thus the treatment requires an ongoing process of experimenting with different combinations of medications, combined with learning how to cope with, and reduce, symptoms through awareness and insights into healthy behaviors and routines (e.g. good sleeping habits, avoidance of alcohol, reducing stress, etc.). Therefore, helping patients identify patterns in their behavior and recognizing factors impacting their mental state would provide them with a greater insight into the nature of the disease and helps them cope better. The need for disease insight has also been recognized in other chronic illnesses, such as diabetes [14], but so far the patients have been responsible for making inferences, not the system.

This paper presents an approach to personal health technologies that aims at providing patients with an *insight* into their disease. This is done by collecting self-assessment and sensor

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data on a Smartphone and using this to analyze and present the underlying patterns and correlations to the patient. The paper presents a system implementation of such a disease insight approach designed for patients suffering from bipolar disorder. This work extends previous work on the MONARCA 1.0 system [3, 2] and we thus call this new version MONARCA 2.0. The next section will describe MONARCA 2.0 in more detail and outline the differences between version 1.0 and 2.0. The rest of the paper describes the design and technical implementation of MONARCA 2.0 and outlines how semi-automatic data sampling is used to find correlations between disease symptoms (mood) and data patterns such as activity, sleep, and phone usage. The paper describes how such patterns are used to predict and forecast disease symptoms (mood) and how this is presented to the user to support and improve disease insight. The paper reports on the results of a 6 months trial with 6 patients. This study revealed which data parameters had the highest correlation ranking and hence highest prediction power, as well as provided insight into the usefulness of the system.

BACKGROUND & DESIGN OF MONARCA 2.0

Bipolar disorder is a mental illness characterized by recurring episodes of both depression and mania, and is associated with a high risk of relapse and hospitalization [13]. It is difficult for patients to reflect on their own mood and behavior, and they may only recognize symptoms if they understand the illness and know what to look for. The treatment of bipolar disorder involves management of a patient's daily life and routines. Clinical research has found that routine is the most effective way to reduce symptoms of depression and mania, and prevent relapses which have extreme consequences for the patient's quality of life [8, 9].

MONARCA 1.0 was designed to provide patients with an awareness of how their life and mental state progress [3, 2]. MONARCA 1.0 is a 'classic' personal health technology consisting of a Smartphone app used for collecting data and presenting it to the patient, as well as a web portal that provides access for both patients and clinicians to the data stored in a server-based infrastructure. The main focus of MONARCA 1.0 was on collecting self-assessed data on core parameters such as mood, sleep, medicine compliance, stress, and self-reported activity level. Automatic collection of accelerometer data and phone usage was also collected. This data was presented to the patient in 'raw' format and was hence not subject to any data analysis. The data was used by patients to gain a recounted awareness of the development of their disease and was shared with the clinicians in charge of their treatment. A field deployment of the system showed that patients found MONARCA very useful and easy to use, and the system had a high (87%) 'compliance' rate i.e. patients used the system on a regular basis and the system hence had a high data quality. However, the study also showed areas for improvement, which lead to the design of MONARCA 2.0.

Designing MONARCA 2.0

The design of MONARCA 2.0 continued the user-centered design process applied previously [10, 2, 15], involving patients and clinicians affiliated with a psychiatric clinic at the national university hospital in Denmark. 6 patients and 3 clinicians participated in collaborative design workshops; two-hour sessions held every three weeks for 4 months. All participants had previously participated in the first field trial of the MONARCA system, and had all continued to use the system after the trial period on a regular basis.

Self-assessed Item	1	2	3	4	5	6	7	8	9	10
Activity	5	1	1	2	1	0	0	0	0	0
Sleep	0	3	2	3	1	0	0	1	0	0
Stress	1	2	1	1	1	0	1	2	0	1
Warning Signs	1	0	3	2	0	1	1	0	0	2
Mixed Mood	1	2	0	0	2	0	1	2	2	0
Irritability	1	1	0	0	2	3	1	1	0	1
Alcohol	1	0	1	0	0	2	3	2	1	0
Cognitive Problems	0	0	2	0	2	1	0	1	4	0
Medicine Changed	0	1	0	1	1	0	2	1	3	1
Medicine Taken	0	0	0	1	0	3	1	0	0	5

Table 1. The results of applying Chi-squared correlation evaluator to rank the self-assessed data items according to the patients' mood score. Activity is ranked as the highest for 5 patients, and sleep is ranked as the second highest for 3. In general, Activity, Sleep, Stress, and Warning Signs are the 4 highest ranked items.

The patients involved in the design process thus had extensive experience in using the first version of the MONARCA 1.0 system and has valuable input on how to improve the user interface, the self-assessment data forms, the visualization, etc. – all of which has been incorporated into the design of MONARCA 2.0, as we shall present below.

During the design of MONARCA 1.0, it was important to limit the amount of data items that the patient should self-report in the app. Therefore, a lot of effort went into minimizing the list of self-assessment data items [2]. But during the trial of MONARCA 1.0, a significant amount of self-assessed data had been collected. A natural question then to ask is; which data items were most important in correlation with the main disease parameter, i.e. the mood score? By analyzing the collected data from the trial phase, we could gain some insight into this question, and use this insight in the further design of the system.

Analyzing Self-Assessed Data

In order to understand the correlation between the self-assessed data and the mood score, we analyzed the data from 10 bipolar disorder patients who had used the MONARCA 1.0 system from May 2011 to March 2012. This analysis had two goals; firstly to reveal which items correlate with the mood score, and secondly to uncover how accurately we can estimate and forecast the emotional state (mood score) of the patient, based on self-assessed data. The self-assessed data set included the following items:

- Mood – Highly depressed (-3) to highly manic (3)
- Sleep – Amount of sleep, reported in half hour intervals
- Medicine Taken – Yes/No
- Medicine Changed – Yes/No
- Activity – Highly inactive (-3) to highly active (3)
- Warning Signs – Number of active warning signs
- Mixed Mood – Yes/No
- Irritable – Yes/No

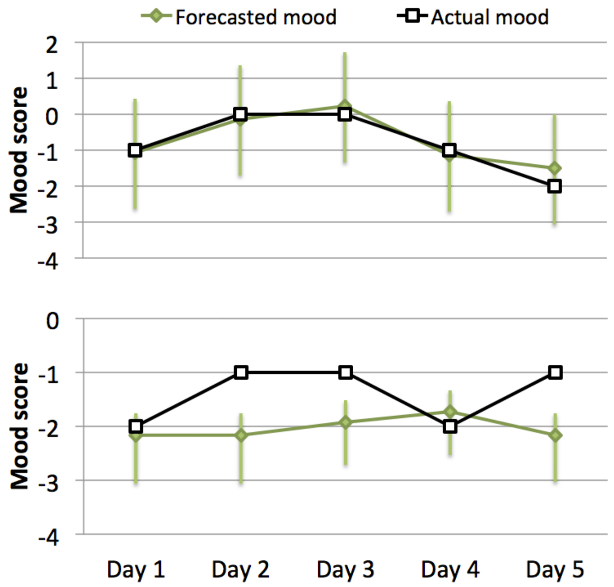

Figure 1. A five days mood forecast for two patients. The horizontal black line is the patient's self-reported mood score and the green line is the predicted values by the model. The vertical green line depicts the 95% confidence interval. The top graph (i) shows a highly accurate forecast, while the forecast in the bottom graph (ii) is less accurate.

- Cognitive Problems – Yes/No
- Stress – No stress (0) to highly stressed (5)
- Alcohol – Number of alcoholic drinks

To answer the first question, we applied the Chi-Squared method to rank the correlations between the mood score and the self-assessed items. The result is shown in Table 1, and reveals that Activity and Sleep are the highest ranked items followed by Stress and Warning Signs Active.

To answer the second question, we applied machine learning techniques to our data set, utilizing best performing learners including linear regression, SVM, additive regression, and model trees. We found that we are able to assess the mood of patients with an average mean absolute error (MAE) of 0.5 compared to the actual mood reported by patients in their self-assessment. For example, if a patient's reported mood score is 1, the inferred value by the model range between 0.5 and 1.5. We also demonstrate that using time series techniques and considering a 95% confidence interval, we can on average estimate the tendency in the mental state with a min MAE of 0.36 and a max MAE of 0.77. Figure 4 shows the forecast results from two patients – one where the forecast was particularly good (top), and one which were less accurate (bottom). The performance of each forecast model depends on the quality of the patients' data, but for 9 out of the 10 patients the majority of the outcome falls within a 95% confidence interval. The explicit details of the machine learning techniques applied in this analysis is submitted for review in a separate publication [7].

DESIGN OF MONARCA 2.0

The initial field trial, the user-centered design phase, and the data analysis suggested that the original MONARCA design could be improved in several ways. In particular, the data analysis of self-assessed data seemed to suggest that it is possible to (i) find correlations between mood and self-assessed data, and (ii) automatically infer the mood as well as estimate the tendency in the emotional state of a patient.

Both of these can be useful in providing patients with a greater *insight* into their disease. The correlation information can help give patients an insight into how their behavior impacts their mood state, both on a past and current basis. We define the features that have the highest correlation with mood as *Impact Factors*, since they are features that affects the patient's mood state. The estimation information can provide patients with insight on the temporal unfolding of their disease. This kind of mood estimation can result in reducing – or possibly even preventing – extreme manic and depressive episodes by faster interventions through the monitoring system.

Another important outcome of the data analysis was that self-reported activity was the highest ranking parameter correlating with mood. With this in mind, it seemed that a natural next step was to ask if activity monitoring could be done automatically by sampling movement and usage data form sensors in the phone, which may provide an indication of a patient's activity level.

In summary, the main design goals of MONARCA 2.0 as compared to MONARCA 1.0 was to improve and incorporate the following components:

User Interface – the user interface of the system (both the phone and the web portal) had to be improved and upgraded, partly based on feedback from the trial of MONARCA 1.0 and the user-centered design process, and partly based on incorporating the new features related to impact factor analysis and mood forecasting.

Data Sampling – the data sampling component of the system had to be significantly improved in order to collect and process a much larger set of data from the phone and its sensors.

Impact Factor Analysis – an impact factor analysis component should continuously calculate correlations between mood and all the collected data, including self-reported as well as automatically sampled data.

Mood Forecasting – a mood forecasting component should continuously train a model that is used for mood prediction on a 5-day horizon.

The following sections describe these four components and explain how self-reported and automatically sampled data is used to pinpoint impact factors and predict mood, and how this is presented and used by the patients and clinicians.

MONARCA 2.0 USER EXPERIENCE

The user experience of MONARCA 2.0 has undergone significant improvements as compared to the first version. The most important improvements to the patient's mobile phone app are; better support for self-reporting of data; support for retrospective reporting of data; and the presentation and management of the new impact factor feedback. On the website the main improvement is that the overview of patients now

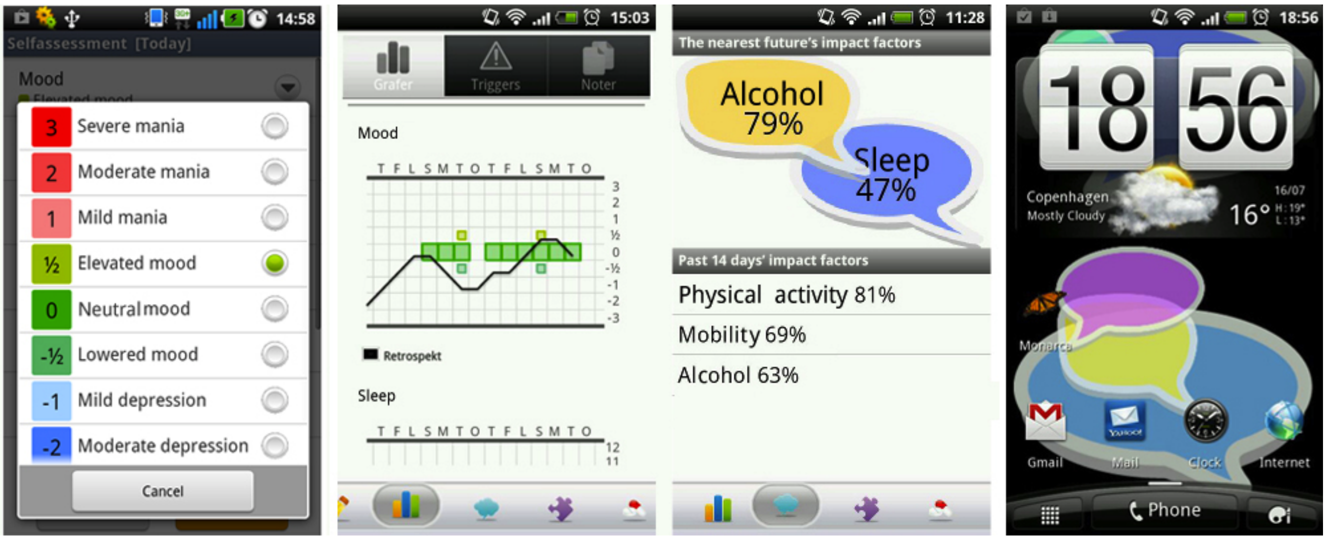

Figure 2. The main MONARCA 2.0 user screens. (i) The new 1/2 point mood scale. (ii) Graphing of mood, mixed mood, and retrospect. (iii) The 'Impact Factors' screen, showing current and past impact factors and their % of magnitude. (iv) The 'Live Wallpaper' displaying impact factors through speech bubbles.

shows the 5-day mood forecast for each patient, as well as a general update of the design with a new css template. Figure 2 shows the main new screens on the Android phone and Figure 3 displays the improved web portal showing the clinician overview screen with impact factors and mood forecasts for a set of patients.

Changes in self-assessment

The design process revealed the need for improving the self-assessment support in the system. There was a request for having a more fine-grained mood assessment by adding 1/2-point mood scores to the existing mood-scale, and having mixed-mood on a scale instead of a yes/no feature. Moreover, the support for personalization was extended allowing for the addition of custom fields to the self-assessment form. Each of these features will be described in detail in the following sections.

Half-point mood scales – the transition from a neutral mood state (0) to 'mild mania' (+1) or 'mild depression' (-1) was too coarse grained. It did not reflect the fact that the patients were able to sense a change that was not yet severe enough to be considered a manic or depressed state, but still significant enough for them to track. Thus, we added the elevated (+1/2) and lowered (-1/2) mood state, as seen in Figure 2(i).

Mixed mood scale – the severity of mixed mood was difficult for the patients to express through the previous simple yes / no option. Thus, mixed mood was transformed into a scale, visually represented by the same preference dialog as the 1/2 point mood scale. The data visualization is depicted in Figure 2(ii) – mixed mood values are represented as small rectangles while the main mood score is still represented as the larger rectangle, enabling the clinicians to understand the span of the mixed mood.

Custom user-defined SA fields – given the great individual variability in bipolar disorder, we experienced the need for enabling SA customization, where the patients could add their personal items to track in the SA. Patients during the design sessions mentioned the need for tracking e.g. anxiety, cups of coffee, minutes of work-out, etc., and thus we have created a SA management feature. Self-assessment comes with a predefined set of items, as previously listed. First the 5 mandatory - *mood, sleep, medicine intake, activity, mixed mood*. The rest of the items can be reordered or excluded from the daily SA, so that if e.g., a patient never drinks, the alcohol field is removed. Furthermore, the patients have the ability to define up to 3 new items of the types Yes/No, Range -3 to 3, Range 0 to 10. The custom items are graphed in the visualization screen, and will show up in the clinician's interface as well. The limitation of a max of 3 custom fields and 3 predefined types is based on the notion of keeping the system simple, as the patients should be able to grasp and cope with the system even when in a severe manic or depressed state.

Retrospect

The retrospect feature allows user to assess their mood in retrospect. The subjective perception of mood can be influence by the mood itself, so in some cases, the lapse of time can help patients assess their mood more accurately. This is especially seen in cases of hypomania. The retrospect feature aims at facilitating this by allowing patients to re-assess a previous mood, adding a retrospect score to the system up to two weeks back in time. The retrospect score in graphed in the mood chart as black line in Figure 2(ii).

Impact Factors

The impact factors screen provides both graphical and textual views of the current and past impact factors, as seen in Figure 2(iii). The current impact factor icons are drawn along with their corresponding text in the upper half of the screen, and past impact factors are displayed below as a simple list view. There can be up to 2 current and 5 past impact factors displayed in the screen. When selecting any of the current or past impact factors, the user is taken to a sub-dialog screen, which displays a detailed textual description of that particular impact factor as well as strategies and actions for self-help, tailored based on the outcome of the forecast component. In this way, the patient gets suggestions about different strategies and actions for self-help according to the assessed mood state.

We designed a Live wallpaper to give the patients a visual insight of their impact factors without forcing them to enter the MONARCA application. It is a mechanism for providing daily feedback to users regarding the impact factors that have the biggest impact on their mood, as explained earlier. The impact factors are visualized of the patient's phone using animated speech bubbles in different colors and sizes, which moves calmly around in the background of the phone's home screen. An example is shown in Figure 2(iv). Each color is color coded according to the colors used in the graphs in the visualization screen. The relative size of the icon on the screen correlates to the magnitude of the impact attributed to that particular factor. Colored speech bubbles were chosen because they are socially neutral, and they symbolize the system trying to say something to the patient. Furthermore, they convey information to the user without compromising their privacy, as would be the case with text. If the patients press the bubbles on the screen, they are immediately taken to the impact factor screen inside the MONARCA application.

Mood Forecasting for patients

The amount of data the system collects through subjective and objective sampling of behavior data from a patient, provides us with the possibility to not only report what happened and why, but also to build models that may predict what will happen – at least to a certain degree. Being able to inform patients about what their future mood state might be if their current behavior continued unchanged, could provide significant insight, both for patients and clinicians, allowing them to be proactive and prevent possible mood swings.

During the design, we explored the area of presenting forecasts to patients, and had in-depth discussions on how mood forecasting could play a role in the feedback to the patient and clinicians. An mock-up Android user interface presenting the mood forecast for patients using a weather forecast metaphor was proposed, but in the end it was rejected by the clinicians mainly due to ethical concerns. The main challenge was that mood forecasting could end up as a self-fulfilling prophecy; patients could become depressed by a forecasted depression. And this again could have significant impacts on the life and wellbeing of a patient, and potentially be life-threading for suicidal patients. The mood forecast hence never became a part of the Android phone UI used by the patients, but was only shown on the clinician's website.

Clinicians Web Portal

The information regarding impact factors and forecasts is presented to clinicians in the web portal. Both are integrated into the overview screen, as seen in Figure 3, and they are also accessible in the detailed patient information, where clinicians

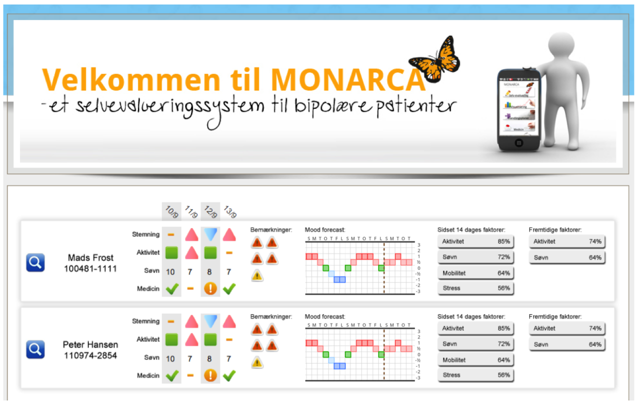

Figure 3. Patient data on the clinician's website. Each line is a patient (name and ID number in the left column), showing mood, activity, sleep, and medicine data for the past 4 days. Then triggers and early warning signs activated, the mood forecast for the next 5 days, and to the far right is the past and present impact factors. An enhancement of the forecast can be seen in Figure 5.

can review the information provided to the patients on strategies and actions for self-help.

TECHNICAL SYSTEM DESIGN

Figure 4 shows the overall architecture and process flow of MONARCA 2.0. This section describes the technical design of the system and the details of the sub-components.

System Architecture

MONARCA 2.0 uses the same technical architecture as MONARCA 1.0 [3] consisting of a server running a CouchDB as the main database, a web application server running the web site, and an Android phone app to be used by the patients. Data sampling and logging takes place on the phone and is transmitted to the CouchDB running on the MONARCA server. On the server, data processing and inference have been implemented as a separate service. This service runs every night, extracts the collected data from the CouchDB, processes the data, and submits the output back into the CouchDB. The processed data, including the calculation of impact factors and the 5-day forecast is then accessible from the phone and the website, as shown in Figure 2 and 5.

Data Logging and Processing

MONARCA 2.0 collects the same self-reported data items as MONARCA 1.0, i.e. the 10 items listed in Table 1. We call this data set the *subjective* data set. MONARCA 2.0 was designed to also collect what we call *objective* data from the phone, which include sensor data from e.g. accelerometers, cell tower ids, and communication logs from the phone.

We use the Funf Open Sensing Framework [1] and integrated this into the MONARCA 2.0 phone app in order to acquire and pre-process the raw sensing inputs. In Funf, the collection and upload of a wide range of data types is done through so-called probes. Each probe is responsible for collecting data from the on-phone sensors, e.g., accelerometer or GPS as well as other information resources such as media files stored on the device, call-logs, application usage, browsing history,

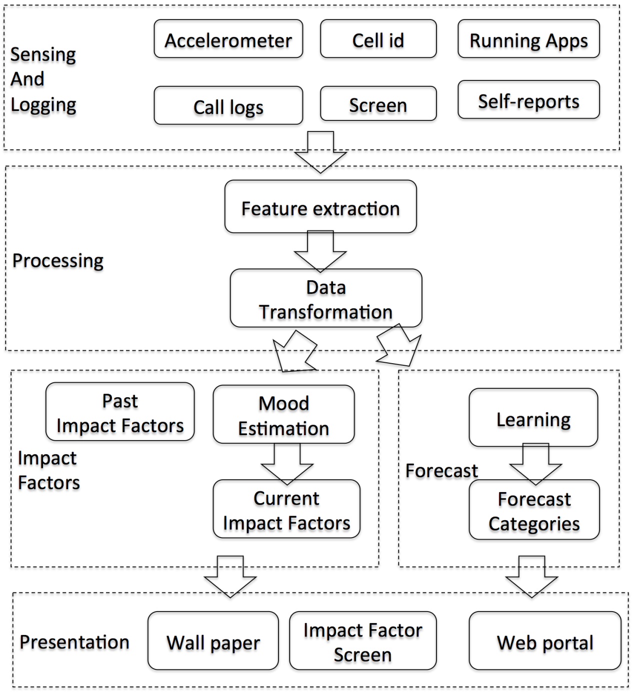

Figure 4. The overview of MONARCA 2.0's main components and process flow.

etc. The data sampling is implemented as a background service, running even if the MONARCA application is not active.

To balance resource consumption (i.e. battery) with optimal sensing frequency, we did a series of iterative tests during the design phase. The following list describes the final design of the data acquisition probes.

- `ActivityProbe` - records how active the user is. It uses the Funf `AccelerometerProbe` data to calculate how many intervals the variance of a device's acceleration is above (hi) or below (low) a certain threshold. It is configured to run every 5 minutes for 20 seconds at 20 Hz.
- `CellProbe` - records ids for the cell tower currently connected to. Configured to run every 5 minutes.
- `ScreenProbe` - records when the screen turns on/off. No configuration needed as the probe acts as a listener of the screen's state.
- `RunningApplicationsProbe` - records the list of currently running applications. Runs every 5 minutes.
- `ApplicationsProbe` - records which applications are installed/uninstalled on the device. Runs every 5 minutes.

Feature Extraction

The Funf probes were used to generate four new 'objective' features: (i) Social Activity, (ii) Physical Activity, (iii) Mobility, and (iv) Phone Usage. These objective features are used in two ways; first they are shown in the visualization screen in the Smartphone application (Figure 2(ii)), providing a status from the past 14 days. Second, they are added to the list of feature attributes that are used for the mood prediction and forecast.

Social Activity

The social activity feature is calculated based on incoming and outgoing calls and text messages. The social incoming (si) and social outgoing (so) feature is generated from the number of incoming and outgoing calls (ic, oc), their duration (id, od), number of incoming and outgoing messages (is, os). These features are then used to build the social activity (sa) feature.

$$sa = si + so, \text{ where}$$
$$si = ic * w + id + is * w$$
$$so = oc * w + od + os * w$$

Incoming and outgoing calls, incoming and outgoing messages are numbers, while durations are calculated in seconds. To balance the weight of the features, we multiply them by a constant value – in our case 10. The value can be calculated using aggregate functions or probability methods. We choose the constant value for simplicity, and since this formula is the same for all data instances, the results are consistent.

Physical Activity

To measure the overall daily physical activity for each patient, we first calculate the level of high (ha) and low activity (la) based on the measurements from the Funf framework which include high and low activity intervals (hai, lai) as well as total activity intervals (ti). We then compute the overall activity rate (ar) by subtracting the low activity rate from the high activity rate which will provide a number between -1 and 1.

$$ar = ha - la, \text{ where}$$
$$ha = hai/ti \;\&\; la = lai/ti$$

Mobility

The mobility feature, called mobility rate (mr), is computed from two raw location features; the number of changes in cell ids (cc) and the total number of identified cell ids (ct) during the day.

$$mr = cc/ct$$

Phone Usage

To measure the phone usage (pu), we look at how many seconds the screen has been turned on (tst), the number of changes in the screen (cs), the number of changes in the running applications on the phone (cra), and the number of changes in the installed applications (cia). We boost the the last 3 by again multiplying them by a constant weight value (w) – in our case 10.

$$pu = tst + cs * w + cr * w + cia * w$$

—- o —-

The generated features produce different values depending on the type and the value of the raw features. A min/max normalization method was used to balance the weight of each feature before training phase. In total, there is now a feature set with 14 different features, consisting of the 10 original subjective and the 4 new objective features. The combined list can been seen in Table 2.

Impact Factor Component

Impact Factors are specific features from the feature list previously mentioned, which the data analysis points out as having a big influence on a patient's mood. This is done to try and provide insights for both the patients and clinicians on what impacts the patients mood, as it can be difficult to spot through simple graphs, which were the only data feedback the patients got in the version 1.0 of the system. Thus, we on a daily basis compute the impact factors related to the current mood – the *current impact factors*, as well as features that have had an impact on the mood over the past 14 days – the *past impact factors*. These factors are shown to the patients in the Android app (see Figure 2(iii)) and to the clinicians on the web site (see Figure 5). By calculating the current impact factors, we inform patients of what features they should be aware of or react to immediately, while the past impact factors serve to provide a retrospective insight into what has influenced their mood historically.

To identify the impact factors (both current and past) and score their impact, we apply three different methods on our data; first we find correlations between each feature and the mood, then we measure the significance of the features wrt. the mood, and finally we measure the information gained from each feature wrt. the mood.

Current Impact Factors

We keep the mood score as continuous values and use prediction methods to estimate the current mood. In our pre-design analysis, we experimented with both individual as well as unified models built from all patients data. Our observation was that although the performance of the individual models varies from patient to patient depending on the size and quality of their data set, in general, they perform slightly better than the unified models. The main reason is that each patient has a different behavior pattern and therefore a model built from a patient's data can more closely predict the mood of that particular person. Hence, in our system, each learner is trained on the data for each patient and individual models are built per learner.

Based on the performance of the learners in the pre-analysis, we choose a combination of basic and meta methods to estimate the mood scores. We use K-nearest neighbors and model trees as well as a set of regression based learners such as linear regression, SVM for regression, and additive regression. Please, note that we do not use the output of the mood estimators directly. The estimated values from the models are only used to identify a mood range that is used for ranking the impact factors, as we will describe below.

To estimate the mood, we use the data collected until the day before ($t - 1$) as our training set, and the data collected on the current day (t) as a test set. We then apply the trained models on the data, compute the residuals from each model, and choose the output of the one where the range between the actual and estimated mood is lowest, and store the range between the two. If the actual mood score is missing, we choose the range between minimum and maximum predicted values. The training set is then filtered based on the mood range, i.e., only instances with mood scores in the mood range are kept.

The new data set is used for parameter ranking. We calculate and normalize the Chi-squared correlation values, the information gain and the significance scores of the parameters. The parameters that are common in at least two evaluators with ranking higher that 25% are selected as the current impact factors. The significance scores provide us with the magnitude of the impact attributed to each individual factor.

Past Impact Factors

The overall method for calculating the past impact factors is the same as the current factors. The difference is that for each patient, we create a data set from the past 14 days instead of only the current day. If there is not enough data from the past two weeks, the algorithm is terminated. In case of mood scores with equal values throughout the 14 days, the time window is extended until two different mood scores are found. The window limit is set to 16 days (one month period in total). Features that are common in at least two evaluators with ranking higher that 25% are selected as past impact factors.

Forecast Component

To estimate the tendency of the mental state, we formulate the problem as a time series forecasting where the value of the variable mood is predicted at a time interval – in our case 5 days. The main difference between the mood estimation, used in the impact factor component, and the mood forecast is that in mood estimation, the mood score is predicted from the models that are built on data which contain actual mood values, while in the forecast component, the data does not contain the actual mood values from the self-assessment.

We address the temporal dependency between data points via additional lagged features which values are computed from the past data points. After transformation, we apply learning algorithms similar to the ones used in the mood estimation, to predict the tendency in the mood state in the form of a 5 days forecast on a daily basis. The mood is forecast on a daily basis 5 days ahead in time by looking at the pattern of the data from the past 14 days. The forecast is shown to the clinicians in their overview screen (Figure 3), where an enhanced section can be seen in Figure 5.

Forecast categories – Based on the forecast mood scores, we calculate the forecast categories which later are used in giving feedback to the patients, as explained in the impact factor part of the design section above. The categories are determined as follows:

1. If at least 2 days values are over 0.5 and none under -0.5, then forecast category $= Manic$
2. If at least 2 days values are under -0.5 and none above 0.5, then forecast category $= Depressed$
3. If values both above 0.5 and below -0.5, then forecast category $= Mixedmood$
4. Else, forecast category $= Neutral$

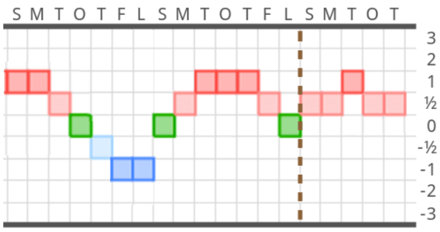

Figure 5. Enhancement of the Mood Forecast from the clinician's patient overview web page, seen in Figure 3. The dotted line represents today; mood scored to the left are self-reported historic data, whereas the 5 days mood scores on the right are forecast.

6 MONTHS FIELD DEPLOYMENT

In order to evaluate MONARCA 2.0, it was deployed for a small 6-month field trial from March to August, 2012, involving 6 patients. The purpose of this study was to verify the redesign of the system, and to investigate if the new data mining functionality would find relevant impact factors and make sensible forecasting. This should prepare for a larger trial with more patients. The use of the system was approved by the Danish National Committee on Health Research Ethics and the security and data handling was approved by the Danish Data Protection Agency. Informed consent was obtained from all patients.

In this section we discuss the findings from this initial field deployment of MONARCA 2.0, focusing on (i) the general system usage and performance, (ii) the analysis of the data collected and its ability to identify impact factors and forecast mood, and (iii) the patients' and clinicians' feedback on usability and usefulness of using MONARCA 2.0 based on a set of interview during the trial period.

System Usage and Performance

During the field trial, the system collected self-reported data in 511 days and sensor data in 563 days. This gives an total 55.6% uptime of the Android app. In total 1,043 mb of data was collected. In order to gauge the battery consumption of the system, we measured and compared the battery performance over a 24 hour period on 1) an out-of-the-box HTC Desire S phone, 2) a phone with MONARCA 1.0 installed, and 3) a phone with MONARCA 2.0 installed. During the 24 hours, the consumption was respectively 12%, 32%, and 68% of the total battery power. For the measurements to be comparable, the phone was not used in the measurement period. This means that energy consumption will be higher when actually used. But the energy consumption is sufficiently low for the patients to use the phone during a normal day of ca. 16 hours without having to recharge the phone. In the trial, there were a few cases where patients ran out of power, but only when they had used the phone excessively for phone calls. In general, the energy consumption did allow the patients to use the phone throughout a day without the need for recharging.

In the trial of MONARCA 1.0, we tested the adherence rate of the patients' self-reporting, i.e. to what degree a patient would fill in the self-report each day. In the original study we found an adherence rate of 87%, taking into consideration the days where the system was actually working [2]. When performing the same analysis of MONARCA 2.0, we found an adherence rate of 91%, which is slightly better but equivalent. It should be noted that these high adherence rates are in itself a major achievement of the system, since self-reporting typically have very low rates of adherence.

Data features	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Activity	3	1	1	1	0	0	0	0	0	0	0	0	0	0
Stress	1	1	2	0	1	0	1	0	0	0	0	0	0	0
Sleep	0	1	0	3	2	0	0	0	0	0	0	0	0	0
Phone Usage*	1	0	3	0	0	0	1	0	0	0	0	1	0	0
Social Activity*	0	2	0	1	0	0	1	0	1	0	1	0	0	0
Irritability	0	0	0	0	2	2	0	1	1	0	0	0	0	0
Cognitive Problems	0	1	0	1	0	1	1	0	1	0	0	0	1	0
Physical Activity*	1	0	0	1	0	0	1	0	1	1	0	1	0	0
Alcohol	0	0	0	1	0	1	1	2	0	0	0	0	1	0
Warning Signs	0	0	0	0	1	1	0	1	1	1	0	0	1	0
Mobility*	0	0	0	0	0	1	0	2	0	1	1	1	0	0
Mixed Mood	0	0	0	0	0	0	1	1	1	0	0	0	0	3
Medicine Changed	0	0	0	0	0	0	0	1	0	0	2	1	1	1
Medicine Taken	0	0	0	0	0	0	0	0	0	0	0	2	2	2

Table 2. Ranking of the correlation between Impact Factors (features) and the mood score. The objective features are marked with *.

Analyzing the use of the web site, we found that none of the patients logged in. This confirms previous findings that patients do not want to use a web interface; they prefer to have all features on the Smartphone. The clinicians monitoring the patients logged in on a regular basis with 286 logins.

Data Sampling and Analysis

The data (both subjective and objective) collected during the trial was subject to two types of analysis. First, we investigated how data features correlate with the mental state of a patient. Second, we analyzed the performance of the mood forecasting, with a specific focus on how accurate the mood can be inferred using only the objective data set.

Analyzing Impact Factors

We repeated the experiment done during the design phase using the Chi-Squared method on the new data set, now including both objective and subjective features. We applied the method on each individual patient's data, and analyzed the rankings with respect to the mood score as the class.

As shown in Table 2, (self-reported) Activity, Stress, Sleep and Phone Usage are among the 4 highest ranked parameters. For example, Activity is ranked in the top 4 for all 6 patients, and Phone Usage is ranked in the top 4 for 4 out of 6. Although the parameters of Activity, Stress, and Sleep still are amongst the highest ranking, the table also shows that 2 out of 4 objective features, namely Phone Usage and Social Activity are among the parameters that are highly correlated with the participants' mood score.

We repeated the method of inferring mood from the features with the same set of learners used in the design phase analysis. This time, we created two data sets for each patient. The first one include all 14 subjective and objective features, while the second contained only the 4 objective features. We ran the cross-validation on both data sets with the selected learners and compared the output results. From the mood estimation model built with both objective and subjective features, we observed an average min MAE (mean absolute error) of 0.40, while this value from the model built with only objective features is 0.45. Hence, although the combination of objective and subjective features gave slightly better results, we still got a pretty close estimation of the mood using only objective features.

Analyzing Mood Forecast
In order to analyze the mood forecast, we first built models with both subjective and objective features and then compared it with the models built only from objective features. We used the same set of learners as in the design phase analysis, and analyzed how the base learners performed on each data set. The main metric is again the mean absolute error (MAE) between the actual and the forecast value. In order to compare the performance of the two models – the one built with subjective and objective and the one with only objective data – we looked at the MAEs calculated for the 5 days, and computed the minimum and maximum values between them. This helped us determine the closest (minMAE) and the furthermost (maxMAE) predicted mood scores in each model.

We observed that the forecast mood values in the models with only objective data are closer to the actual reported mood scores. In other words, the mean absolute error in 5 days forecast is on average lower than the corresponding value in the models including both subjective and objective data. Figure 6 shows that both minimum and maximum MAEs are lower or equal in the objective models for at least 4 out of 6 patients.

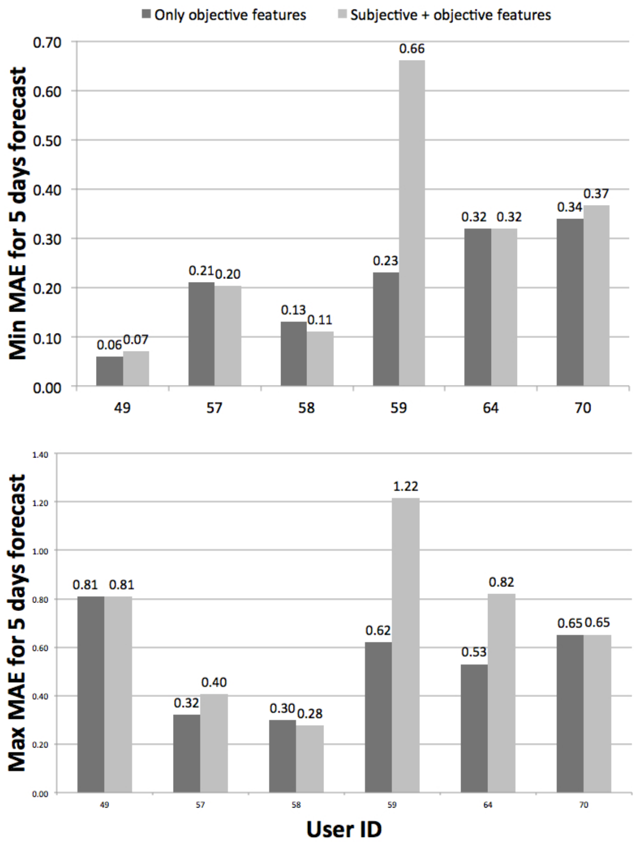

Figure 6. Minimum MAE and maximum MAE for the 5-day mood forecast. For most patients, both minMAE and maxMAE are lower in the 5 days forecast model with only objective features compared to the corresponding model built with both the objective and subjective features.

Feedback from patients and clinicians
When interviewing patient, they reported that the redesign had improved the overall usability and usefulness of the system. For example, they found the improved self-assessment form highly useful, especially the fact that they could add 1/2-point mood score. As stated by patient $P57$; *"the 1/2 point scale allows me to keep track of little details that mean a lot to me; these small changes can be early indicators that something is under way."* Also the personalization of the self-assessment form by adding additional individual features were reported to be key for the patients to manage their disease. However, the limitations in the scale were a limiting factor. As $P59$ stated; *"I would like to keep track of the number of cigarettes I smoke a day, but I cannot enter more that 10. It is annoying that you can't define your own scale."*

Both patients and clinicians appreciated the new objective sensor-based information available in MONARCA 2.0. Patients especially mentioned the benefits of the new objective features. For example, patients reported that it gave them an insight into the circumstances of their disease to see the visualization of the correlation between e.g. social interaction and mood. However, some patients were not completely convinced of the accuracy of the collected data. For example, $P64$ reported that his mobility level was constant whether he was staying in his apartment or traveling long distances with the train.

The structure of the impact factor screen was deemed intuitive by the patients, and the use of colors consistent with the visualization screen made it very coherent. The output fostered a process of reflection, which at times challenged the patients' own insight into their illness, informing them of interconnections which the patients were not aware of. Given the impact factors were built based on the patients' objective and subjective data, there were issues with getting meaningful output when the system did not work properly.

All patients reported that the Live Wallpaper was easy to comprehend and provided a subtle overview of the impact factors generated by the system. The patients did however express difficulties with interacting with the bubbles if their interface were filled with shortcuts and widgets. The phone is becoming a highly personalized tool for many users, and some of the patients reported that the MONARCA wallpaper did not allow them to have other things there. For example, $P58$ reported that she would like to have her newborn baby there, just like her friends.

The clinicians' reactions to the forecast were mixed in the beginning of the trial. They seemed to be hesitant to take actions based on an inferred forecast. For instance, when a patient's forecast pointed towards a depressive state, they did not know if they should call the patient, change their medication, or wait a few days to verify the actual change in the state. They ended up using the forecast as an of indicator to watch, but basically relied on their own clinical experience in handling patients.

CONCLUSIONS

We presented the refinements of the MONARCA system focusing on how this system was designed to convey a *disease insight* to patients. This was based on an approach where the system helps patients to identify patterns in their behavior as well as recognizing factors impacting their mental state. MONARCA 2.0 was tested in a small 6 months field deployment involving 6 patients. This evaluation showed that the system was stable and performed well in real use. The data collected was sufficient to identify the factors impacting the mood of patients, and the subsequent analysis showed that data features related to activity, stress, sleep, and phone usage were those with the highest correlation with the mood score. Patients and clinicians involved in the study reported a high degree of satisfaction with the usefulness and usability of the system.

Through the analysis of the objective sensing from patients' phones during the trial, we observed that by using only these features in our models, we were able to closely estimate the current and future mood state. We also observed that the objective features are strong indicators of the mood. It shows that the new components are a promising approach towards an increased disease insight among bipolar patients. However, we evaluated the system only with a small set of patients, and with an average phone uptime of 55.6%. It is therefore difficult to draw definitive conclusions and should be viewed as a promising initial field trial. Currently we are launching a larger study involving more patients as well as studying the clinical effect of using the MONARCA system.

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Paper 5
Improvements and Challenges in using Personal Health Technologies in Treatment of Bipolar Disorder: Qualitative study.

Mads Frost, Maria Faurholt-Jepsen, Lars Vedel Kessing and Jakob E Bardram. Improvements and Challenges in using Personal Health Technologies in Treatment of Bipolar Disorder: Qualitative study. *Paper submitted for review to the Journal of Internet Interventions (INVENT).*

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Improvements and Challenges in using Personal Health Technologies in Treatment of Bipolar Disorder: Qualitative study

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Abstract

Background: Personal health technologies have been proposed for supporting the treatment of mental illness. This is done through improving symptom detection and activity monitoring, provision of personalized feedback and motivational support, and improving adherence to treatment.

Objective: This study examined how treatment was supported through the use of a personal health system used in treatment of bipolar disorder. It was based on the clinicians' experience aimed at identifying if treatment improved, the challenges it presented, as well as suggestions for improvements.

Methods: The MONARCA Self-Assessment System was deployed at the Clinic for Affective Disorder, Copenhagen, Denmark, in a randomized clinical trial where 35 outpatients and 2 nurses used the system over a period of 2 years. Open ended interviews were conducted with the 2 nurses at the end of the trial, where they discussed their daily use of the system and responded to longitudinal views of implications for treatment through the use of the system. The interviews were recorded, transcribed, and analyzed using common sense analysis.

Results: The study findings suggests that the use of the system increased patients understanding of the disorder. The improved data grounds were valued when used in consultations with patients, and the ability to preform early interventions were facilitated, while the increased focus on preforming these interventions emerged as a challenge for the responsibility of monitoring patients and the liability for intervention. Finally, the study findings proposed improvements for more efficient daily use.

Conclusion: This study provide insight into the opportunities and challenges involved in using personal health technologies in treatment of bipolar disorder. The findings suggests that the system provided possibilities to improve treatment, while it highlight a major challenge that appeared to need further consideration and research

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in order to better cope with this new way of getting data presented. The study supports a first empirical basis to inform the continuous development of personal health technologies for treatment of bipolar disorder.

Keywords: Bipolar disorder, mental illness management, personal health technologies, self-assessment, psychoeducation

1. Introduction

Personal health technologies have been suggested for the management of a wide variety of health-related conditions, such as physical activity [1, 2], healthy eating habits [3], cardiac rehabilitation [4], and the management of chronic illnesses like diabetes [5, 6] and asthma [7]. These types of systems help users by enabling them to monitor and visualize their behavior, keeping them informed about their physical state, reminding them to perform specific tasks, providing feedback on the effectiveness of their behavior, and recommending healthier behavior or actions.

Recent research has focused on personal health technologies used in treatment of mental illness. The use of the systems is reported to improve symptom detection and activity monitoring, provision personalized feedback and motivational support, informs psychotherapy and enhance adherence to treatment [8, 9, 10, 11, 12, 13, 14]. However, prior studies have primarily focused on the clinical effects [15, 9, 16, 17, 18, 19, 20, 21] and the usefulness for the patients [8, 22, 9, 23, 24, 25, 19], while a thorough understanding of the clinicians' perspectives is limited. To our knowledge, only Veerbeek et al. has focused on the clinician's perspectives through their study on a web based system for routine outcome monitoring in old-age psychiatry in the Netherlands [26].

Personal health technologies have been proven as useful in the treatment of mental illnesses. However, to our knowledge, only few systems have actually been adopted into daily clinical use. The success of personal health technologies used in treatment depends upon their effective adaptation and integration into the clinical treatment. The technologies provide clinicians with access to information and resources, and allows for treatment at the right time and place. In addition to providing these capabilities, new technologies also impact the technical, social, organizational, economic, cultural, and political dimensions of work in new and different ways [27]. Observations of technology implementations have shown that a change in technology literally alters roles, strategies, and paths to failure [28]. Thus, the clinicians' experiences, attitudes, and preferences with respect to the use of personal health technologies in treatment of bipolar disorder is the focus of this study.

The study was preformed as part of a randomized controlled trial investigating the clinical effects of using the MONARCA Self-Assessment System in the treatment of bipolar disorder [29]. The trial was conducted at The Clinic for Affective Disorders, Department of Psychiatry, Copenhagen, Rigshospitalet, Copenhagen, Denmark. Ethical approval for the trial was obtained from the Regional Ethics Committee in The Capital Region of Denmark (H-2-2011-056) and The Danish Data Protection Agency (2013-41- 1710). All electronic monitored data was stored at secure servers at It-, Medico- og Telephoneorganization (IMT), in the Capital Region, Copenhagen, Denmark (I-suite number RHP-2011-03).

The design of the MONARCA system was done in a user-centered design process [30, 31] involving patients and clinicians, and the design and its technical implementation has been presented in [32], where much more technical details can be found. In the following sections we try to provide enough background description to inform the understanding of the system and the study setting.

1.1. The MONARCA Self-Assessment System

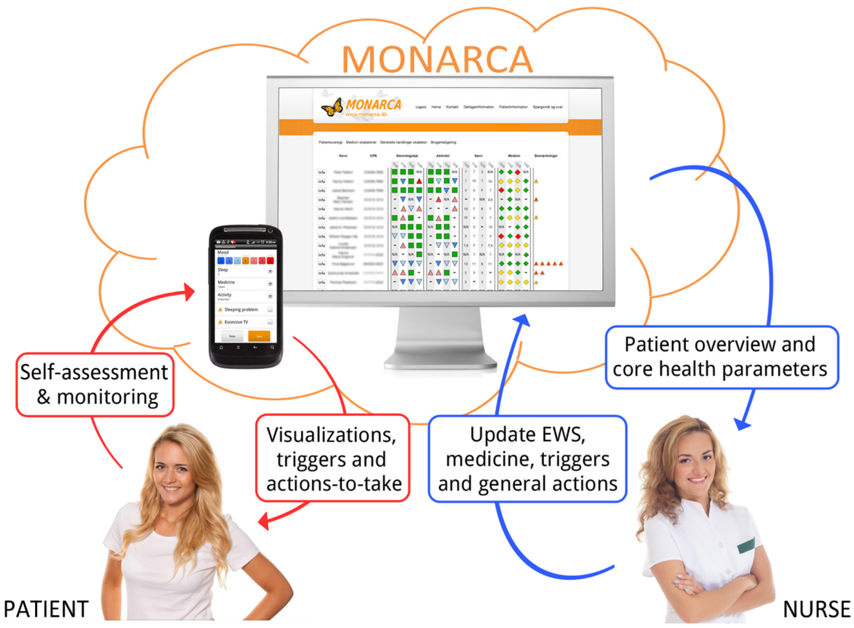

Figure 1: Patient - Clinician loop through the system.

The system consists of two main parts; an Android Smartphone application used by the patients, and a website used by patients as well as clinicians. The system contains 5 core aspects supporting treatment; (i) daily self-assessment of parameters such as mood, sleep, alcohol, (ii) automatic data sampling from sensors in the Smartphone, (iii) historical overview of self-assessed and sensed data, (iv) coaching & self-treatment based on customizable triggers, detection of early warning signs, and general actions, and (v) support contact between the patient and the clinician through data sharing. Through the loop of monitoring and feedback between the patient and the clinicians, they can use the data to determine adherence to medication, investigate illness patterns and identify early warning signs for upcoming affective episodes, or test potentially beneficial behavior changes. The loop is depicted in Figure 1. It supports an upstream treatment approach, allowing for prompt intervention based on the information from daily self-assessments. Figure 2 provides an overview of the different features in the system along with a short description, relating to the aspects mentioned above.

Feature	Description
Self-Assessment	*Primary*; Mood, Sleep, Activity, and Medicine. *Secondary*; Mixed mood, Cognitive problems, Irritability, Alcohol, Stress, Menstruation and a Note. *Personal*; Early warning signs.
Sensor based data collection	*Physical Activity*; Sampled through the accelerometer every 5 minutes. *Social Activity*; Number of in- and outgoing text messages and phone calls, as well as length of calls.
General Actions	General actions, also known as action plans, contains personalized information regarding how the patient can manage the disorder. It focuses on the manic and depressed state, and each cover three aspects; "How to help myself", "Things that help", and "Others can help me by..".
Medication	Medication provides an overview of a patient's regular and p.r.n. medication, along with detailed information on each prescribed drug.
Triggers	Triggers are monitoring the submitted self-assessment data based on a user defined set of rules, e.g. sleeping less than 6 hours 3 night in a row. If a trigger is activated, the patients receive personalized strategies and actions for self-help and clinicians are notified in the Dashboard.
Early Warning Signs	Early warning signs (EWS) are personal signs of an impending episode, which are configured specifically to the patient. If an EWS is activated, the patient receive personalized strategies and actions for self-help and clinicians are notified in the Dashboard.
Action To Take	Actions To Take is a generalization of the feedback the patients receive from both Triggers, Early Warning Signs, and General Actions.

Figure 2: An overview of the features in the MONARCA system and their description.

1.1.1. Android Phone Application

The overview of the interfaces of the application can be seen in Figure 3. On a daily basis, an alarm on the Smartphone reminds the patient to fill out the self-assessment (Figure 3(i)). As described in Figure 2, the self-assessment is divided into 3 overall sets of parameters. First the *primary* parameters, which must to be entered on a daily basis. The core parameter is the patient's mood, which the patients rate on a 7-point scale spanning from highly depressed (-3) to highly manic $(+3)$. Secondly the *secondary* parameters, which are useful supplement to the mandatory parameters, and are also required for the patients to fill in. Finally the *personal* parameters, which are user-defined early warning signs the patients can create together with their clinician. A self-assessment can be modified throughout a day, but is closed at midnight and can not be changed hereafter. If a patient forgets to fill in the self-assessment all together, it is possible to go back two days in time and fill it in. When a self-assessment is saved, the application presents the patients with an overview of the data from the past 14 days (Figure 3(ii)). Besides the self-assessment, the Smartphone continuously samples data automatically through different sensors in the phone. There are 2 different types of sensor data; Physical and Social Activity. They are described in detail in Figure 2.

Furthermore, the application provides patients with personalized context-appropriate clinical responses on the data through triggers and early warning signs, and helps patients manage their general actions (Figure 3(iii)), as well as their prescribed medication (Figure 3(iv)). In the development of the system, a lot of effort have gone into designing the application as concise and simple as possible. This means the use of the system only requires the patients to fill in a self-assessment once a day, which only takes approximately 10 seconds. The main reason for using a Smartphone application is that the phone is almost always with the patient [33]. This is useful not only for the automated data collection, but also for collecting the self-assessment data since a Smartphone is much easier available compared to paper based mood charts or a web browser [8].

Figure 3: The MONARCA Android application user interface. (i) Self-Assessment; (ii) Visualizations; (iii) Actions to take; (iv) Medicine; and (v) Settings.

1.1.2. Website

The system is available to patients and clinicians through a website. Patients can review their personal data and configure the system. When clinicians enter the system, they get a dashboard providing an overview of their patients and how they are doing. The dashboard is shown in Figure 4. The overview is supported through displaying the

5

core parameters of mood, activity, sleep, and medicine adherence as well as notifications, all from the last 4 days. From the dashboard, the clinicians can select individual patients and review their data in more detail, configure the settings by updating prescribed medication, personalized general actions as well as create triggers and early warning signs.

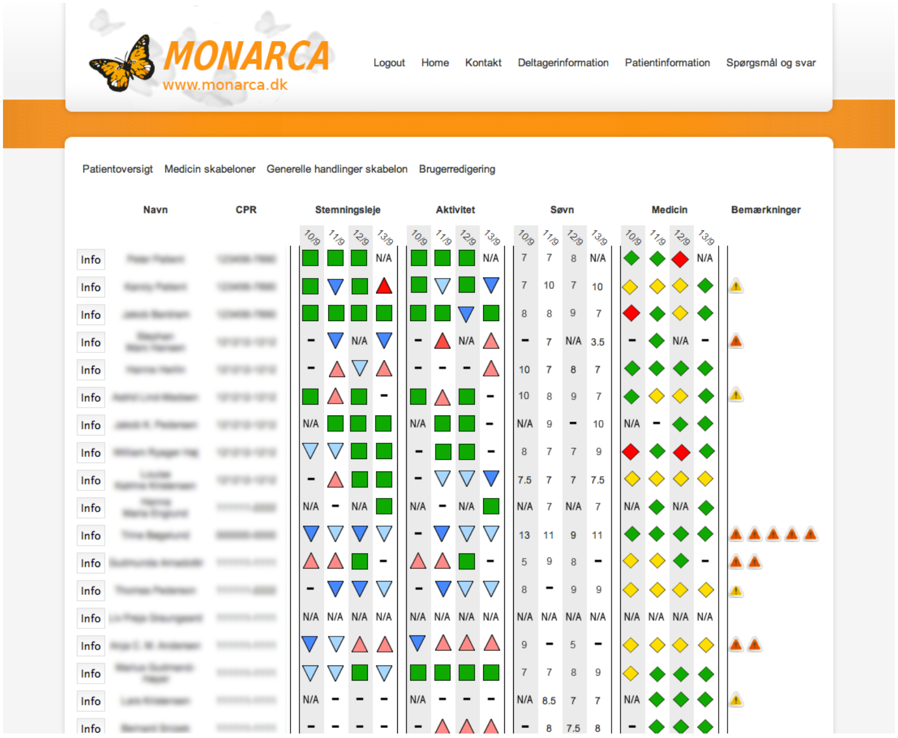

Figure 4: Website - The Clinician Dashboard. Each line is a patient (name and ID number in the left column), showing mood, activity, sleep, and medicine data for the past 4 days. To the far right is an indication of Triggers and Early Warning Signs activated.

1.2. Study settings

The study is based on the use of the MONARCA system in a randomized clinical trial, as previously mentioned. The trial was preformed at the Clinic for Affective Disorder, Department of Psychiatry, Copenhagen, Rigshospitalet, Copenhagen, Denmark from September 2011 to September 2013. Patients with bipolar disorder are referred to the clinic from secondary health care when a diagnosis of a single mania or bipolar disorder is made for the first time or if occurrence of treatment resistance, i.e. persistent affective symptoms or recurrences despite treatment in standard care. The treatment model the system is located within is an optimised pharmacotherapy [34] and psychological treatment of bipolar disorder, where the aim of the use of the system is to support the psychoeducation based treatment process the patients are going through [35].

Parameter	When to contact the patient
	(-1) registrered in 3 consecutive days
Mood	(+1) registrered in 2 consecutive days
	(+2) or (-2) registrered 1 day
Sleep	Changes of at least 1 hour compared to usual in 3 consecutive days
Medicine	Medication not taken or taken with change in 2 consecutive days
	(-1) registrered in 3 consecutive days
Activity	(+1) registrered in 2 consecutive days
	(+3) or (-3) registrered 1 day
Mixed mood	Registered in 3 consecutive days
Cognitive problems	Registered in 3 consecutive days
Stress	Registered in 3 consecutive days
Alcohol	More than 2 drinks in 3 consecutive days

Figure 5: An overview of the parameters and when the nurse should react. They should only react if change happened without any known reason.

Psychoeducation seeks to empower patients with tools that allow them to be more active in their therapy process. There is no unifying theory behind psychoeducation in bipolar disorder, as it is a simple pragmatic program [36]. However, psychoeducation uses elements from cognitive behavioral therapy (CBT) and interpersonal therapy (IPT), and aims at improving the treatment outcome of patients with bipolar disorder as well as enhancing the prevention of future episodes by delivering information-based behavioural training aimed at adjusting patient lifestyle and strategies of coping with bipolar disorder, including enhancement of illness awareness, treatment adherence, avoidance of potentially harmful behavior, and early detection of relapses [37]. The treatment model is documented in [35], where more details can be found.

A study nurse from the clinic with experience with bipolar disorder was assigned to the patients allocated to the active intervention arm of the trial and attended to the psychoeducative part of the treatment, while a doctor would attend to the pharmacotherapy. A total of 35 patients from the active arm completed the randomized clinical trial. The nurse would review the dashboard every morning, overseeing the patient data. If there were anything irregular about the data, the nurse would write a text message to the patient with a suggestion to a later point in the day where she could call the patient. The rules for contact were defined prior to the trial, and can be found in Figure 5

The patient then either approved the call, or cleared up the issue through the reply. If the patient did not reply, the nurse would confer with the patient's primary doctor about his or her experience with the patient, and the nurse would then contact patient through a phone call. If the patient did not answer, and the nurse was concerned with the patient, she would contacts the relatives. Finally, if nothing else provided results, the nurse would go to the home of the patient. When the nurse had a patient scheduled for a consultation, she would go through the data in the system just before the consultation. During the consultation, the data would be used in the conversation with the patient if the topic fell within areas where the system contained information. Possible changes to *Actions to take* were entered in the system in collaboration with the patient, ensuring that they agreed on the content.

2. Methods

2.1. Participants

In total there were two study nurses. One primary study nurse - hereon referred to as $nurse1$ - a female, age 44, who have been working with mental illness the past 15 years, and a secondary study nurse - hereon referred to as $nurse2$ - a female, age 43, who have been working with mental illness the past 8 years.

2.2. Data sources

This study is focused around the two study nurses and their work with the system in the randomized controlled trial. There were no interviews with doctors involved in the treatment, as it was the nurses who handled the use of the system during the trial. Thus, the data from the study comprises of post-trial open-ended unstructured interviews with the two study nurses. Through the interviews, the nurses discussed their daily use of the system and responded to longitudinal views of implications for treatment. The interviews were of 171 and 62 minutes length.

2.3. Data Analysis

The interviews were analyzed using Kvale's first two levels of conversation analysis; self-perception and critical common sense understanding [38]. The interviews were audio recorded and key verbatim quotes were transcribed. The quotes from the transcribed interviews were initially coded by key terms and phrases. Following the initial coding, labels were attached to quotes which appeared to indicate important material in relation to the research questions. Hereafter the analysis progressed in an iterative fashion to develop a set of themes (parent and subthemes) that captured the essence of the interviews.

3. Results

3.1. Thematic Analysis

3 key themes emerged from the common sense analysis of the interviews, with several sub-themes. The themes were classified as (3.2) Improved treatment; (3.2.1) Patient focused improvements, (3.2.2) Clinician focused improvements, (3.2.3) Enabling faster intervention, (3.3) Challenges; (3.3.1) High patient focus, (3.3.2) Responsibility for patients, and (3.3.3) Liability for intervention, and finally (3.4) Suggestions for improvements. All themes are outlined below, together with some essential verbatim quotes.

3.2. Improved treatment

3.2.1. Patient focused improvements

The nurses found that the use of the system improved the patients' adherence to reporting their self-assessment compared to a paper based approach.

> *"With the system, the patients can't get away with not filling in their self-assessment compared to paper based assessments. If they don't fill it in for a couple of days, they would be contacted and asked if everything is okay"* $[nurse1]$

The use of the system was found to provide accurate day-by-day information. Not only in terms of it being truthful, but also in the perception and categorization of the employed scales across patients was found to be consistent.

> *"The patients have a tendency to lie to themselves about how they are doing, but by forcing them to actually report this daily, makes them more open minded and truthful about their illness"* $[nurse1]$

> *"The patients have had a remarkably good knowledge of the -3 +3 mood scale, which have been consistent both across patients, but also in general the patients have been very truthful about their scores"* $[nurse1]$

The nurses found that the system assisted patients in monitoring their illness, supporting the process of understanding the impact of their actions and behavior by visualizing the collected data in a manner which generated reflection.

> *"For the patients, the biggest eye-opener have been in regards to their alcohol intake and their activity level, and how much it actually impacts their illness. Of course this is explained in the psychoeducation process, but the correlations is just so much more obvious and imminent when they visually can see the correlations from the graphs"* $[nurse1]$

3.2.2. Clinician focused improvements

The system was perceived as useful as a reference point during consultations with the patient. This was due to the system contained readily information on the patients data history, which is useful in the reflexive process of understanding cause and effects. Moreover, the use of data as the basis for the conversation eased an otherwise difficult conversation with patients who struggle with sharing personal experiences.

> *"It [the system] provides an overview, for both the patient and the clinician. It is a great point of departure for the conversation with the patient - a much better basis"* $[nurse1]$

> *"I have used the system as a reference point during my consultations with the patients. When the patient indicated problems on given days, we were able to go through the data on the preceding days and find possible causes for the problem"* $[nurse1]$

"In my conversations with the patient, I always depart from the data in the system. It is a great ice-breaker that you don't need to question the patient, the conversation is carried and facilitated by the data. This is especially useful in the cases where patients who are either in denial of something being wrong, or patients who are having a hard time talking about themselves and their experiences" $[nurse2]$

The system also served as a collaboration tool between the patient and the nurse, improving the presence of both General Actions and Early Warning Signs. This was found especially useful when the nurses did not know the patients well.

"It is a really nice feature with the treatment plans and the personalized feedback the patients get in the system. Especially with patients you don't know well yet, as you then know what have been recommended and how you should advice the patient in case of problems" $[nurse2]$

The nurses found that the treatment improved, but the nurses also pointed out that this improvement was not caused by the system alone, but highly facilitated by the use of the data in the conversation with the nurse.

"It is not solely the numbers and graphs that provides cause and effect. It functions as the basis for the conversation. The data is present in the mind of the clinician, but it is the conversation between the patient and the clinician which unravels why the data looks the way it does. The conversation puts forth a lot more information than what the system is able to track" $[nurse1]$

3.2.3. Enabling faster intervention

The daily collection of data allowed for the nurse to keep track of the patients. This allowed for a faster intervention whenever the patient data starts to change.

"With the system, you are given an additional tool to use in the treatment, which can provide you with a lot more insights into how the patient is doing. This allows you to react a lot faster on their state changes, which enables you to help the patient before they get really ill and needs to be hospitalized" $[nurse1]$

"Using the system supports a much faster intervention compared to earlier, where you would only see the patients when they walk in the door. It is very rewarding being able to help and make a difference for these patients, preventing that they get really ill" $[nurse2]$

3.3. Challenges

3.3.1. High patient focus

Through the use system of the system, the focus on the collected data yielded a higher awareness of the patients, and how they were doing. This was especially caused by the dashboard, which the nurse would review on a daily basis. The use of the dashboard enabled the nurse to get a fast overview of all the patients. This allowed for an easy identification of the patients in need of attention, supporting an early intervention. However, the nurses found that the increased focus by displaying all the patients each time they entered the system, also created a side effect of increased concern for the patients.

> *"You go from seeing the patient when they walked in the door to every time you turn on the screen"* $[nurse2]$

> *"It forces me to relate to how the patients are doing. There is a big difference between them popping out on the screen compared to them lying as a journal in the filing cabinet. You feel more responsible. When you see changes on the screen, you feel obligated to do something. It causes a lot more worry for the patients, but again, it also works in the opposite way, that you can see that things are going in the right direction, which can be reassuring when you have made treatment changes"* $[nurse1]$

3.3.2. Responsibility for patients

The continuous stream of patient data increased the nurse's awareness and focus on the patients' progression. The patients were told that the nurse would react if a patient's data would start to change. Thus the nurses had a hard time letting go, as the patients were relying on the nurse to act accordingly.

> *"When I am monitoring patients, I have a hard time letting go, as it is my responsibility. An example is that if you can see a patient has changed for the worse on a Friday. Not so much that you fear for their life, but still significantly. You are not able to get in touch with the patient, so what do you then do? Should you stay late, call the relatives, go to the patients house, or should you go home for the weekend knowing that something might be wrong - and you are responsible? It is very frustrating and a real stress factor"* $[nurse2]$

> *"I checked the system on my days off, just to make sure the patients are doing fine. Even though it is my day off, I still feel responsible for them, and I would feel really bad if something happened, even though it is not my responsibility"* $[nurse1]$

3.3.3. Liability for intervention

Even though clear rules for when to contact the patients based on their data were defined prior to the study. The findings suggest that these rules were not always adequate. Especially when the nurse didn't know the patient well.

> *"We have the standard rules for when to contact a patient, but you have more contact with the patients when you don't know them - you want to make sure that nothing is wrong. I feel very comfortable texting with the patients - it's a very un-intrusive way to assess what is going on. However,*

I tend to call the patients which I don't know well, just to make sure" $[nurse2]$

The lack of response when contact was initiated, was very troublesome for the nurse, as it left a void. The reason why the patient did not respond was not transparent, and left the nurse with difficult choices on how to handle the situation, which could be very time consuming.

> *"What if the patient does not respond, what should you then do? Go see them at their home? Should you contact the relatives and worry them, even though it might be for nothing? The whole process takes a long time, especially when you don't know the patient well. If you know the patient, you usually know their rhythms and routines, and thus the reason for their actions. But when you don't know the patient, it creates a lot of anxiety. It requires you to spend a lot of time reading up on the patient in the patient record, in order to figure out what to do and how to act"* $[nurse1]$

This issue of contact was also the case if there had been no connection between the server and a patient's phone. It could be that the patient had forgotten to turn on the phone, it had run out of power, the internet connection was down, or the phone was broken or stolen. However, it could also be that the patient was ill and did not want to turn on the phone, or simply could not. In any case, the nurses did not know the cause of this lack of data, and the effect of being the one monitoring the patients made the nurses insecure.

> *"The problem is not that the patients rate themselves as being ill, but if the don't register at all, you can't keep up with what is going on. The uncertainty makes you insecure"* $[nurse1]$

3.4. Suggestions for improvements

Through the use of the system, the nurses uncovered different aspects that they perceived would improve the use of the system. First of all adding the patients' stress score to the dashboard would make it more useful. Even though the 4 primary features were defined by clinicians in the design of the system, the nurses found stress to be one of the best indicators of problems.

> *"Activity is important as an overall item to keep track of for the patients, but is not very informative on the dashboard where you want to assess the patients' current state. Here stress would be much more suited, as this clearly indicates whether or not the patient is doing fine"* $[nurse1]$

> *"Activity on the dashboard have not been so informative. I would add stress there instead, as it says a lot about how the patient is doing"* $[nurse2]$

Furthermore, the system lacked the ability to tailor it to the individual patient. Bipolar disorder is known to have generalizable parameters important for all patients to keep track of. However, there is a need for tracking individual parameters, which highly relevant for the patient, but not for the general population. Also a more nuanced scale was suggested to assess the mood, to better keep track of minor changes.

"Like you can add early warning signs in the system, it would be good if you could add personal parameters to track in the self-assessment as well, as they are important for the individual patient" $[nurse1]$

"It would have been nice with 1/2 point mood scores, such as (+0.5) and (-0.5), it gives a better insight into the smaller changes" $[nurse1]$

Lastly, one of the nurses also had a possible solution to how to overcome the previously mentioned issue regarding the problematic patient focus caused by the use of the dashboard.

"One way of handling this could be to drop the use of the dashboard and have the system create warning notifications based on the patients data. This way you would not need to see all patients every time you logged in, but only the patients you needed to" $[nurse2]$

4. Discussion

This study explores the use of personal health technologies in treatment of bipolar disorder, and it is the first report from the perspective of the clinician. The study shows that using personal health technologies in treatment is possible and feasible, and the nurses in the study found that the use improved the treatment process.

The results of the interviews showed, that the nurses found the use of the system provided a high adherence to patients' reporting of self-assessments on a daily basis. Prior research show that a high adherence to self-reporting is crucial in efficient psychoeducation [39, 40], and treatment non-adherence is found to be a major factor in relapse and poor outcomes for patients with bipolar disorder. It has been speculated that the promotion of treatment adherence may explain, at least in part, the positive outcomes of psychoeducational approaches [41], which is also evident in these findings. The use of the system is core in building disease awareness and insights, and thus adherence to the use of personal health technologies is key to their success.

Not only was the adherence to treatment and self-assessment perceived as high, the reported data was also found to be very truthful and accurate. These are some of the problems the usual self-assessment charting suffers from, with low adherence rates and unreliable retrospective entries [14, 22, 42]. The daily self-assessments is further perceived by the nurses to generate awareness, as well as support the insight for the patients. Helping patients to develop an awareness and insight of the relationships between behaviour and the disease, improves the outcome of the treatment [43, 44, 45]. Especially improving disease awareness is vital for an effective treatment of bipolar disorder [46, 47], while promoting insight and good strategies for coping with their risk situations, is important for patients in their long-term management of the disease [48, 49]. However, as the nurses pointed out, the improvement of the treatment was not caused by the system alone, but highly facilitated through the use of the data in the conversation between the patient and the nurse, to improve the patient's understanding of the behavior and the effects of their disease. Thus, the data was also useful for the nurses in the consultation with the patient, as they were much better informed through the data in the system, making the process easier, while it also highlighting additional areas for discussion during the consultation.

The system further allowed for an upstream treatment approach, supporting early intervention when a patient's state started changing. Research show that enhancing early detection of relapses and thereby prevent future episodes is important for successful outcomes [36, 46, 37, 44, 50]. The nurses perceived this as very helpful for the patients, creating a trust that someone would help them if they got ill. This was also found rewarding for the nurses, being able to reach out and help the patients when relapses occur.

However, this focus on the patients as well as the trust the patients had in getting help, is key to the challenges the nurses found in the use of the system. The improved focus the system created challenged the nurses in how to handle the improved awareness of how the the patients were doing, making it difficult to let go, and not worry for the patients. Even though clear rules were created prior to the study, difficult questions would arise when the nurse could see a patient's data started to change. When was the change enough to react on, and when could they wait and see what happened the following day? These challenges described by the nurses should be seen as a form of moral distress. Moral distress been defined as a painful feelings and/or psychological disequilibrium that occurs in situations where the appropriate action to take is known to the nurse, but is unable to act upon it [51]. This, together with the nurses views on the parameters displayed in the dashboard, requesting that activity should be switched out with stress, suggest that the knowledge on how to use the data from self-assessments in determination of relapses, might not be optimal. The system is an expansion of the paper based self-assessments, and can be seen as an improved, electrified version. In regular treatment, patients use paper based self-assessments, which they fill out at home and bring to the clinic when they have an appointment. Thus, it is used for a retrospective analysis, just as described by the nurses in the use of the current system during consultations. However, the self-assessment have never been used to monitor the patients health state and acted as the ground for early intervention, and thus the nurses anxiety is partly founded in the realization that they are not entirely sure of what data they should be concerned with, other than the obvious mood rating. Guidelines on when the nurses should contact the patients were created, but the findings suggest that these should be revisited. Previous research have further suggested a contrasting list of symptoms to track in terms of early intervention [50, 52] compared to the data collected in the MONARCA system. This could inform an improved basis for early intervention, given its specialized purpose.

Finally, the nurses suggested the ability to have personalized parameters for each patient included into the self-assessment, as patients have individual parameters important to track in relation to their illness. They also suggested a refined mood scale, which providing a more nuanced view of the disease. These suggestions are similar to what patients proposed in the first pilot trial of the system [8]. A different solution to the issue of the high focus on the patients is proposed by $nurse2$ in removing the dashboard, and replacing it with a clinical decision support system [53]. The idea is to have the system automatically spawn notifications to the clinicians according to a predefined set of rules – such as the ones already defined for when the nurses should react. This would relieve the nurses from *"seeing the patients each time they turned* *on the screen"*. However, seen in the light of the current experience with the use of the system, more research is needed to better define the exact parameters and rules before such a system would be successful.

The results enlighten the perspectives on use of personal health systems in treatment of bipolar disorder, but should be interpreted with caution at this stage. They are based on a small sample of patients and nurses, and it reports based on a randomized clinical trail. However they do suggest a potential benefit for the use of personal health technologies used in treatment of bipolar disorder. The length of the trial does give merit to the strength, while reporting from a fully integrated system in daily clinical use would have been preferred.

5. Conclusions

As mentioned in the beginning of the paper, there has in recent years been an increasing tendency to apply personal health technologies for therapeutic interventions and patient education targeted patients with mental illness. In the design of such interventions, the specific problems, needs, and consequences of clinicians should be carefully considered, and this study supports a first empirical basis to inform the continuous development of personal health technologies for treatment of bipolar disorder.

From the study it is evident that the use of personal health technology in the treatment of bipolar disorder improved the process. It furthermore found that the use of the system increased clinicians' awareness of their patients and their state, allowing for more focused treatment and faster interventions. However, it also posed challenges in terms of the nurses' experience of responsibility and liability for treatment and interventions.

Contributors

MF conducted the interviews and performed the analyses. MF wrote the first draft of the manuscript. All authors contributed to and have approved the final manuscript.

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Statement on Conflicts of Interest

LVK has within the last three years been a consultant for Lundbeck and Astra Zenica. MFJ has been a consultant for Eli Lilly. MF and JEB have no competing interests.

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Paper 6
Increasing Awareness, Insight and Adherence in Treatment of Bipolar Disorder through Personal Health Technology: Pilot Study

Mads Frost, Maria Faurholt-Jepsen, Afsaneh Doryab, Lars Vedel Kessing and Jakob E Bardram. Increasing Awareness, Insight and Adherence in Treatment of Bipolar Disorder through Personal Health Technology: Pilot Study. *Paper submitted for review to the Journal of Medical Internet Research (JMIR).*

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of which I am a co-author, will form part of the PhD dissertation by

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who made a

☒ major

☐ proportional

☐ minor

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of which I am a co-author, will form part of the PhD dissertation by

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who made a

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☐ proportional

☐ minor

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Co-Author Statement

I hereby declare that I am aware that the work in the paper

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of which I am a co-author, will form part of the PhD dissertation by

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☒ major

☐ proportional

☐ minor

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Increasing Awareness, Insight and Adherence in Treatment of Bipolar Disorder through Personal Health Technology: Pilot Study

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Abstract

Background: Psychoeducation is proven as efficient in the treatment of patients suffering from bipolar disorder [1, 2]. The approach of psychoeducation is to (i) help the patient to develop an awareness and insight of the relationships between behaviour and the disease [3, 4, 5], (ii) to provide prompt assistance when a problem arise [6], and (iii) to enhance early detection of relapses and thereby prevent future episodes [1, 7, 8, 4, 9]. Central to psychoeducation is patient engagement and self-reporting of mood and behavioural data. High adherence to self-reporting and engagement is crucial in efficient psychoeducation [10, 11, 12].

Objective: This study examine the use of a personal health system in psychoeducative treatment of patients suffering from bipolar disorder. The objective is to examine to what degree the system; (i) supports disease awareness and insight, (ii) prompts treatment when problems emerge, and (iii) is able to detect future mood changes. The study further measure patient adherence to the use of the system.

Methods: We deployed the MONARCA system [13] at the Clinic for Affective Disorder, Copenhagen, Denmark, in a single-arm feasibility trial where 18 outpatients suffering from bipolar disorder used the system for 19 weeks. Data from the use of the system was logged and analysed. Questionnaires focusing on disease awareness and insight, and prompt assistance were issued to patients, together with follow-up interviews at the end of the trial.

Results: The results of the study shows that patients use the system daily, when available. The average adherence rate for the system is 88%. Patients agreed that the system improve disease awareness and insight; scores are $\tilde{x} = 2.00$; $iqr = 3.00$ on a 7-

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point Likert scale (1 is best). The patients further agree that the system provide prompt assistance; scores are $\tilde{x} = 3.00$; $iqr = 3.00$. The average mean absolute error of the system's mood forecast compared to patients' self-assessed mood is 0.28, measured on a mood scale from -3 to $+3$. However, the accuracy in determining manic or depressive episodes is less accurate, with an accuracy of 8% compared to the patient's mood score, while the accuracy increases to 42% if the 1st neighboring scores is included.

Conclusion: Based on patient feedback, the study finds that personal health technologies, such as the deployed MONARCA system, are useful tools in supporting psychoeducative treatment of patients suffering from bipolar disorder. The patients have a high adherence rate to the use of the system, and it is found to help patients to an increased awareness and insight into the relationship between behaviour and their disease.

Keywords: Bipolar Disorder, Therapeutics, Technology, Validation Studies

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1. Introduction

Bipolar Disorder is a common and complex mental disorder, which accounts as one of the most important causes of disability worldwide for patients at age 15-44 years [14], and in its broadest sense, bipolar disorder has a community lifetime prevalence of 4% [15]. It is a long-term and chronic disease characterized by manic episodes of elevated mood and overactivity intersperse with periods of depression and with need for treatment over many years [16].It is associated with high morbidity and disability [17] as well as with a high risk of relapse and hospitalization [18].

A number of personal health technologies have been suggested for the management of a wide range of conditions. Research has targeted behavior change such as physical activity [19, 20], healthy eating habits [21], cardiac rehabilitation [22], and the management of chronic illnesses like diabetes [23, 24] and asthma [25]. Recent research has started to focus on mobile phone systems for mental illness like depression [26, 27, 28, 29], borderline personality disorder [30], and more general-purpose mobile phone systems for mood charting to be used in Cognitive Behavioral Therapy (CBT) has been suggested [31, 32, 33, 34].

Personal health technologies hold promise for helping patients to monitor their symptoms and mood patterns, recognize behavioral trends and early warning signs (EWS), and to handle their medication [35]. Such personal technologies can – based on self-reported and automatically collected sensor data – provide timely feedback to the patient and thereby increase the awareness of the disease, and by continued use, assist in the clarification process of creating insights into the illness progression. Personal health technologies further have the potential to apply machine learning techniques that can monitor and learn to recognize a patient's circumstances and state, and supply personalized context-appropriate clinical responses [13]. These features align with psychoedcation, a treatment form used towards different mental illnessses, such as bipolar disorder [1, 2]. The aim of psychoeducation is to help the patient by engaging and empowering the patient in the treatment process. This is commonly done through self-reporting of mood and behavioural information, intended to develop an awareness and insight of the relationships between behaviour and their disease [3, 4, 5]. This engagement further target the identification of risk situations and early detection of relapses [1, 7, 8, 4].

In this study, we examine the use of a Smartphone-based self-assessment system called MONARCA. The system is developed through an iterative development process, informed by both patients and clinicians, to inform and support an psychoeducation based treatment process. This is done through collection of behavior data from patients through a combination of user-inputted self-ratings and automated sensor based sampling. The system visualize these data, and provide tailored feedback including coping strategies and actions for self-help. The collected data is furthermore replicated to servers at the hospital, allowing clinicians to monitor the patients, enabling fast interventions as well as better informs consultations. The system further pilot an automated data analysis. This consist of both a correlation analysis of what impacts the patients illness, as well as a daily forecast of the patients' future mood state.

The use of the technology is evaluated based on a 19 week single arm field trial of the MONARCA system. The outcome of the study is to examine if the use of the system supports the psychoeducation based treatment through; (i) an improved disease awareness and insight, (ii) prompt treatment when problems emerge, and (iii) the ability to forecast patients' mood and detect future mood state changes. Finally, it examines patients' adherence to the use of the system. It does not target clinical effects of the system, as this is not feasible in a short term deployment of 19 weeks, with the small sample size of 18 patients, and without the use of a control group.

2. Treatment and System Background

The design of the MONARCA system is done in a user-centered design process [36, 37] involving patients and clinicians affiliated with Clinic for Affetive Disorder, Psychiatric Centre Copenhagen, Denmark. The system deployed and studied in this article is the 2nd version of the system, also known as MONARCA 2.0. The system's design and technical is described elsewhere [13]. However, the following section provide background description of the treatment setting, the MONARCA system, and the mood forecast.

2.1. Treatment Setting

The MONARCA system is designed to be used by patients in an optimised pharmacotherapy and psychological treatment of bipolar disorder [2]. Psychoeducation seeks to empower patients with tools that allow them to be more active in their therapy process. There is no unifying theory behind psychoeducation in bipolar disorder, as it is a simple pragmatic program [1]. However, psychoeducation uses elements from cognitive behavioral therapy (CBT) and interpersonal therapy (IPT), and aims at improving the treatment outcome of patients with bipolar disorder as well as enhancing the prevention of future episodes. This is done by delivering information-based behavioural training aimed at adjusting patient lifestyle and strategies of coping with bipolar disorder, including enhancement of disease awareness, treatment adherence, avoidance of potentially harmful behavior, and early detection of relapses [8]. Furthermore, the prediction and prevention of episodes through psychoeducation by recognizing patients' early warning signs – symptoms indicative of an oncoming episode – has proven to have a high long-term effect [6, 38].

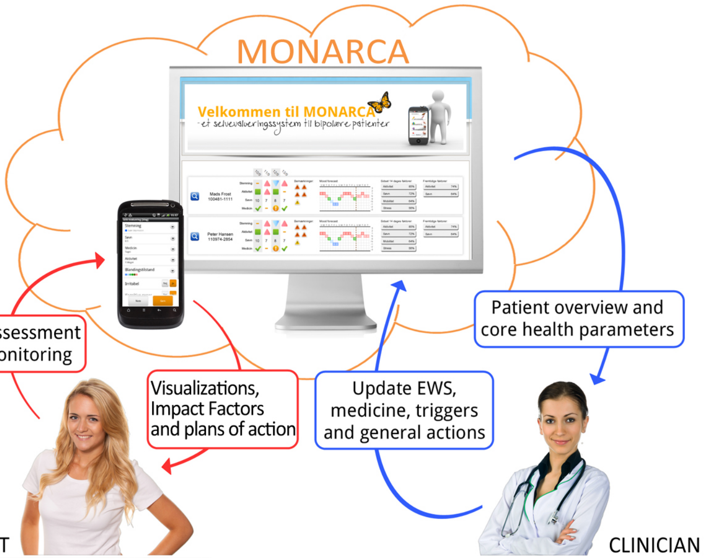

Figure 1: The role of the MONARCA system in the psychoeducational treatment of a bipolar patient.

2.2. *The MONARCA System*

Treatment is supported through a loop of monitoring and feedback between the patient and the clinician via the system, as illustrated in Figure 1. The MONARCA system consists of two main parts; an Android Smartphone application used by the patients, and a web portal used by patients and the clinicians. The system has six main features designed to support psychoeducational treatment; (i) daily self-assessment of parameters such as mood, sleep, alcohol; (ii) automatic data sampling from sensors in the Smartphone; (iii) historical overview of self-assessed and sensed data; (iv) coaching and self-treatment advise based on customizable triggers, detection of early warning signs, and general actions; (v) automatic data analysis to calculate impact factors and forecast patients' mood; and (vi) support data sharing between the patient and the clinician via the web portal.

The system allow patients and their clinicians to use the data to determine adherence to medications, investigate illness patterns, identify early warning signs for upcoming affective episodes, or test potentially beneficial behavior changes. It can help patients implement effective short-term responses to risk situations and preventative long-term habits, by increasing their disease insight. It supports an upstream treatment approach, allowing for prompt intervention through the information from daily self-assessments, and even further by the forecast of patients' mood. Figure 2 provides an overview and description of the system's features.

Feature	Description	View P	View C	Edit P	Edit C
Self-Assessment	*Primary*; Mood, Sleep, Activity, and Medicine.	X	X		
	Secondary; Mixed mood, Cognitive problems, Irritability, Alcohol, Stress, Menstruation and a Note.	X	X	X	
	Personal; Early warning signs and up to 3 custom user-defined items through predefined scales.	X	X	X	
Sensor based data collection	*Physical Activity*; Sampled through the accelerometer every 5 minutes.	X	X		
	Social Activity; Number of in- and outgoing text messages and phone calls, as well as length of calls.	X	X		
	Mobility; Monitoring the number of times the phone changes the cell tower it is connected to.	X	X		
	Phone Usage; How much the phone is used, e.g. how long the screen is turned on, etc.	X	X		
Impact Factors	Impact Factors are computed daily through a correlation analysis based on the collected data, pointing out which collected data has the biggest impact on a patient's mood. Feedback is provided along with the impact factors, focusing on strategies and actions for self-help on each factor.	X	X		X
Forecast	A forecast of patients' mood 5 days ahead in time is computed daily, based on the collected data. The outcome of the forecast is shown only to the clinician in the overview screen.		X		
General Actions	General actions, also known as action plans, contains personalized information regarding how the patient can manage the disorder. It focuses on the manic and depressed state, and each cover three aspects; "How to help myself", "Things that help", and "Others can help me by..".	X	X	X	X
Medication	Medication provides an overview of a patient's regular and p.r.n. medication, along with detailed information on each prescribed drug.	X	X	X	X
Triggers	Triggers are monitoring the submitted self-assessment data based on a user defined set of rules, e.g. sleeping less than 6 hours 3 night in a row. If a trigger is activated, the patients receive personalized strategies and actions for self-help and clinicians are notified in the overview screen.	X	X	X	X
Early Warning Signs	Early warning signs (EWS) are personal signs of an impending episode, which are configured specifically to the patient. If an EWS is activated, the patient receive personalized strategies and actions for self-help and clinicians are notified in the overview screen.	X	X	X	X
Plans of Action	Plans of action is a generalization of the feedback the patients is receiving from both Impact Factors, General Actions, Triggers, and Early Warning Signs.				

Figure 2: An overview of the features in the MONARCA system and their description, along with a indication of viewing and editing rights for both patients (P) and clinicians (C).

2.2.1. *Android Phone Application*

Figure 3 shows the main screens of the Android MONARCA app. A daily alarm reminds the patient to fill in the self-assessment form (Figure 3(2)). As described in Figure 2, the self-assessment form is divided into three overall sets of parameters. The *primary* parameters include mood, sleep duration, experienced activity level, and adherence to medicine prescriptions. The patient scores his or her mood on a 9-point scale spanning from highly depressed (-3) to highly manic $(+3)$, including $(+0.5)$ and (-0.5) point scores. Daily self-assessment is considered done when these four parameters has been reported by the patient. The *secondary* parameters included parameters like mixed mood, irritability, stress, and menstruation. These parameters can be tailored to the specific patient as needed (e.g. based on stage of disease or gender). The secondary parameters are optional to fill in. Finally, the *personal* parameters are user-defined parameters, which the patients can create together with their clinician. Examples included specifying personal early warning signs (EWS) for a patient or personal behavioral patters to watch out for.

The self-assessment form can be filled and changed throughout a day, but is closed at midnight and can not be changed hereafter. If a patient forgets to fill in the self-assessment all together, it is possible to go back two days in time and fill it in. However, the system records (and hence visualizes) that data has been filled in retrospectively.

Besides the self-assessment, the Smartphone continuously samples behavioral data from different sensors in the phone. This data is aggregated and processed to reflect four types of patient behavior; physical activity, social activity, mobility, and phone usage (see Figure 2). Self-assessed and automatically sampled data is visualized and accessible on the phone, as shown in Figure 3(3).

Based on a correlation analysis on the sampled data, the system calculates daily 'Impact Factors' that show which of the reported data parameters (i.e. 'Factors') has the greatest impact on the patient's mood. This is visualized on the phone as colored 'speech bubbles' as shown in Figure 3(4).

The system also keeps track on 'Triggers', early warning signs (EWS), and 'Actions-to-take' (Figure 3(5)). Triggers are are simple user-defined rules that monitors data over time. For example, a rule can be defined to trigger if a patient sleeps less than 5 hours 3 days in a row. Actions-to-take are personalized description of actions that the patient can take when a trigger and/or EWS occurs. For example, if he or she is not sleeping enough, actions that ensure better sleep hygiene can be useful. Finally, the system keeps track of the patient's prescribed medication, and allow him or her to report to what degree the medication is taken (Figure 3(6)).

In the design of the system, significant effort have gone into designing the application as concise and simple as possible. This means the use of the system only requires the patients to fill in the primary self-assessment parameters once a day, which only takes approximately 10 seconds. The main reason for using a Smartphone is that the phone is almost always with the patient [39]. This is useful not only for the automated data collection, but also for collecting the self-assessment data since a phone is much easier available compared to paper based mood charts or a web browser [40].

2.2.2. Web Portal

The system is available to patients and clinicians through a web portal. Patients can review their personal data and configure the system. Clinicians have a 'Dashboard' (Figure 4) which provides them with and overview of the patients they are responsible for. For each patient, the dashboard shows how the patient is doing on the four primary parameters of mood, activity, sleep, and medicine adherence for the last 4 days, and it shows if there are any triggers or early warnings signs. It also shows the mood graph of the patient, including a 5-day mood forecast. Finally, it shows the patient's impact factors.

From the dashboard, the clinician can select a patient and review his or her data in more details on a separate page (not shown). This page is also used to update data, like prescribed medication, and to personalize the patient's triggers, early warning signs, and descriptions of actions-to-take.

2.2.3. Mood Forecast

The amount of data the system collects from each patient enables the possibility to not only report what happened and why, but also to build models that may predict what

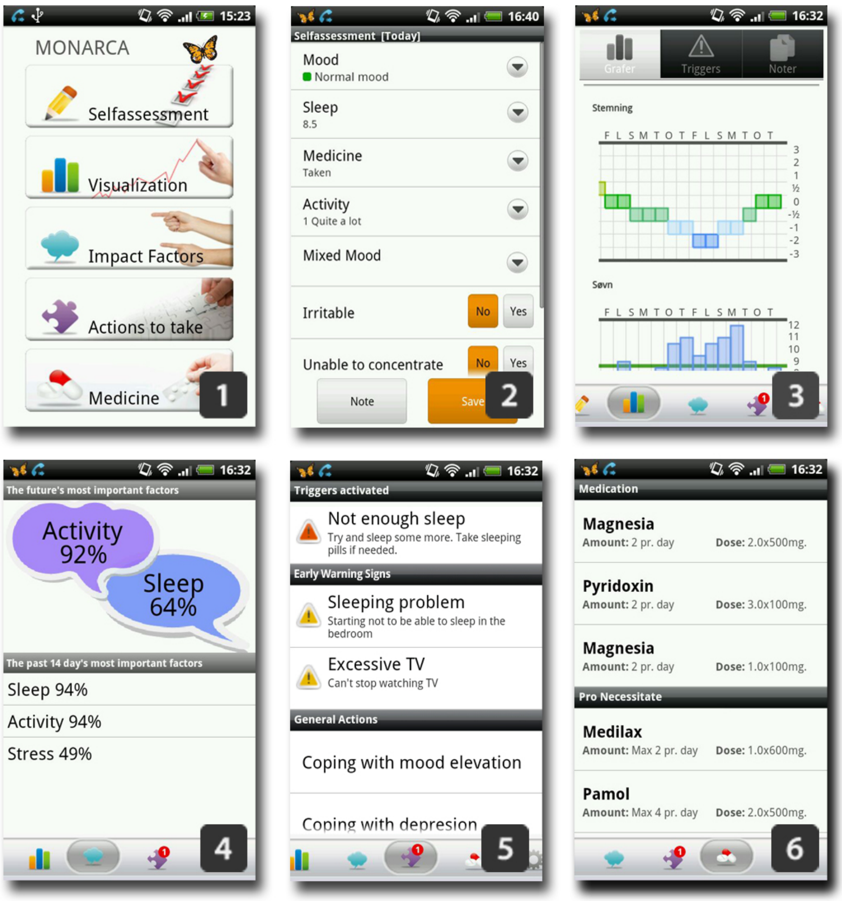

Figure 3: The MONARCA Android application user interface. (1) Menu; (2) Self-Assessment; (3) Visualizations; (4) Impact Factors; (5) Plans of Action; and (6) Medicine

will happen – at least to a certain degree. Being able to inform clinicians of patients' future mood state provide significant information, allowing clinicians to be proactive and prevent possible manic or depressive episodes.

To estimate the tendency of the mental state, the system preforms a time series forecast, where the patients' mood is predicted for the coming 5 days. The mood forecast is computed on a daily basis by looking at the pattern of the data from the past 14 days, evaluated based on a personalized model generated on the full data history of each patient. The outcome of the forecast is a floating point number for each forecast day, and this number is rounded to the nearest category in the 9-point mood scale. The mood forecast is only shown to the clinicians – not the patient. The forecast is shown in the dashboard (Figure 4).

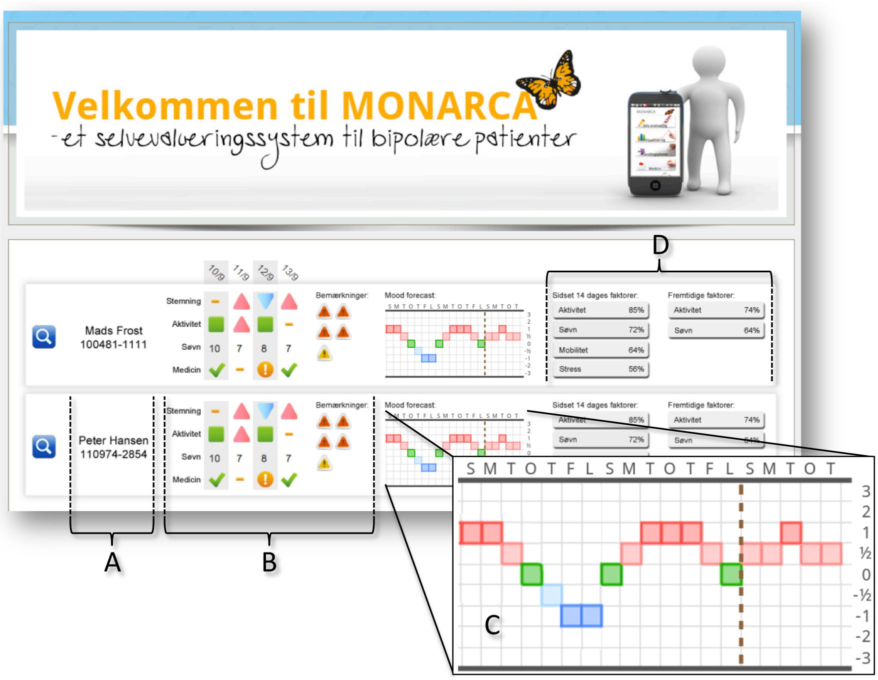

Figure 4: The Clinician Dashboard – Each block highlights cores data from a patient: (A) Patient name and social security number; (B) data on mood, activity, sleep, medicine, triggers, and early warning signs for the past 4 days; (C) a graph visualizing historical as well as forecasted mood scores; and (D) impact factors. An enlargement of the mood graph is inserted. The dotted line represents today; mood scored to the left are self-reported historic data, whereas the 5 days mood scores on the right is the mood forecast.

3. Methods

The MONARCA system was deployed in a single-arm feasibility trial for a total of 19 weeks. As this is a test of a novel intervention, a single arm trial testing feasibility rather than efficacy is an appropriate design [41].

3.1. Ethical considerations

The study was approved by the Regional Ethics Committee in The Capital Region of Denmark (H-2-2011-056) and The Danish Data Protection Agency (2013-41-1710). All electronic data from the Smartphones were stored at a secure server at IT department in the Capital Region, Copenhagen, Denmark (I-suite number RHP-2011-03). Written and oral information about the study was presented to all eligible patients before informed consent was obtained. All patients were free to withdraw their consent for participating in the study at any time without this interfering with their treatment at the clinic. All Smartphones were provided by the MONARCA project. Patients used their own SIM card, and economic costs due to data traffic from the study were refunded.

3.2. Participants

All participants were recruited from The Clinic of Affective Disorder, Psychiatric Centre Copenhagen, Rigshospitalet, Denmark from August - October 2012. The Clinic of Affective Disorder covers a recruitment area of the Capital Region, Denmark corresponding to 1.4 million people and treats approximately 100 patients suffering from bipolar disorder per year with integrated psychopharmacological and psychological interventions. Inclusion criteria were and age between 18-60 years and a bipolar disorder diagnosis according to ICD-10 using Schedules for Clinical Assessment of Neuropsychiatry (SCAN (15)). Exclusion criteria were unwillingness to use the MONARCA Smartphone as the primary cell phone, inability to learn the necessary technical skills for being able to use the Smartphone, lack of Danish language skills, and pregnancy. A total of 21 patients were approached, whereof 18 accepted to join the trial. No patients dropped out of the trial.

Following referral to the MONARCA pilot study, the patients were screened for meeting the inclusion criteria and none of the exclusion criteria. After inclusion in the study patients received a MONARCA Android Smartphone and were instructed to use the MONARCA application throughout the trial period.

3.2.1. Human Support

A nurse reviewed the patients data on a daily basis, Monday to Friday, while no one looked at the data during the weekends. If the patients' data in the system caused concern, the nurse would consult with the patients' regular doctor before contacting the patients via text message or phone call. A total of 8 patients were contacted by the nurse based on changes in their data with a total of 11 contacts, while no patients were hospitalized during the trial. The nurse would only contact the patients if there were problems, and did not prompt them to use the system.

3.3. Outcome Measures

The study examines the use of a personal health system supporting a psychoeducative treatment process of patients suffering from bipolar disorder. The objective is to examine to what degree the system; (i) supports disease awareness and insight, (ii) prompts treatment when problems emerge, and (iii) can detect future mood changes. The study further measures patient adherence to the use of the system.

To answer (i) and (ii), the patients assessed 20 statements in a questionnaire at the end of the trial, based on a 7-point Likert scale from 'Strongly Agree' (1) to 'Strongly Disagree' (7). The statements are a subset of a larger questionnaire [40], and the specific statements and their scores can be seen in Figure 6 while the full questionnaire is available on request. The outcome of the questionnaire is further informed by individual follow-up interviews with all patients, where they described their use of the system and responded to longitudinal views of their experiences. The interviews were audio recorded and analyzed using Kvale's first two levels of conversation analysis; self-perception and critical common sense understanding [42].

To answer (iii), forecast data values and actual self-assessed mood scores were extracted from the system database and processed in Excel. Through comparing the historical sequence of mood forecasts with the actual mood values provided through the self-assessments, the construction of the forecast error is created as the difference, and thereby allowing for the calculation of the mean absolute error. The early detection of episodes is is likewise calculated in Excel through the generation of a confusion matrix of the summarized 5 day forecast, which unveils the performance in determining manic or depressive episodes.

Finally, the adherence to the system is calculated by the number of filled in daily self-assessments, extracted from the system database.

4. Results

The left column of Figure 5 shows the list of enrolled participants and their demographic background. A diverse set of patients was recruited with different gender (5 male, 13 female); age (spanning from 20 to 52); and occupation.

4.1. Support of Disease Awareness and Insight

The ability of the system to create and support awareness and insight during the trial scored $\tilde{x} = 2.00; iqr = 3.00$. The patients found that especially the visualization of the collected was highly useful ($Q6.1 - \tilde{x} = 1.00; iqr = 1.00$), making it easy for the patients to understand the data ($Q6.2 - \tilde{x} = 1.50; iqr = 2.00$). Further, the general use of the system made the patients notably aware of their illness ($Q1.2 - \tilde{x} = 1.50; iqr = 1.00$). However, the items found less helpful were the impact factors, which did not provide much insight to the patients ($Q13.3 - \tilde{x} = 4.00; iqr = 4.00$), as well as the medication overview was not perceived as particularly useful in making the patients aware of their medication ($Q7.2 - \tilde{x} = 4.00; iqr = 4.00$).

Qualitative comments were consistent with increasing awareness and insight, and an improved self-management through the use of the system. In the interviews, the patients agree that the use of the system and the daily self-assessments is useful approach to be aware of how they are doing, as $P17$ states that is it due to:

> *"It provided insights into the disease and what I did – and did wrong – on a daily basis to get a more stable life, by monitoring factors that are important for me and my disease"* [$P17$]

This view on insights was also supported $P18$, who argued that

> *"The fact that I can control my disease - or at least be more aware of the it - and more aware of myself; how much I am sleeping, what I am doing, and how that impacts my disease"*[$P18$]

Some patients reported that initially, the increased awareness on own behaviour, life style and illness could be annoying and needless – especially when they felt that they were doing fine. Nevertheless, in the long run, the awareness process allowed for greater insights, which they reported was important to them. As $P12$ put it:

> *"I is not always positive that you have to focus so much on the illness every day. In the beginning, I felt it very annoying that I had to this self-assessment every day as I couldn't see what I should use it for. It only made*

Participants	Gender	Age	Occupation	# days participated	# days reporting data	# self-assessment days	% general adherence	% adherence (run. system)
P1	M	30	University student	80	53	30	38	57
P2	F	51	Unemployed	117	62	56	48	90
P3	F	36	Full-time employee	122	97	95	78	98
P4	F	35	Full-time employee	125	90	83	66	92
P5	F	39	Unemployed	76	59	42	55	71
P6	F	52	Disability pensioner	131	116	103	79	89
P7	M	24	University student	131	116	113	86	97
P8	M	36	Sick leave	120	76	67	56	88
P9	M	23	Full-time employee	106	72	57	54	79
P10	F	32	Part-time employee	89	71	71	80	100
P11	F	28	University student	109	85	72	66	85
P12	F	41	Sick leave	131	121	111	85	92
P13	F	30	Full-time employee	96	89	82	85	92
P14	M	33	Unemployed	121	98	82	68	84
P15	F	20	High school student	126	79	49	39	62
P16	F	22	High school student	122	97	95	78	98
P17	F	39	Full-time employee	115	90	84	73	93
P18	F	22	Unemployed	106	67	59	56	88
Avr.		33		112	85	75	66	88

Figure 5: Patients in the MONARCA trial. From left: participation ID; demographic data; and usage data from the 19 weeks trial of the MONARCA system.

Questions		MIN	Q1	MEDIAN	Q3	MAX	IQR
Disease Awareness and Insight		**1.00**	**1.00**	**2.00**	**4.00**	**7.00**	**3.00**
- 1.1	This system enabled me to manage my illness	1.00	2.00	3.50	4.00	6.00	2.00
- 1.2	The system provided me with awareness of my disease	1.00	1.00	1.50	2.00	4.00	1.00
- 1.4	The use of the Smartphone application helped me to better manage my illness	1.00	1.25	2.50	3.75	6.00	2.50
- 1.6	The system made me think about my lifestyle	1.00	1.25	2.00	3.00	7.00	1.75
- 2.4	Self-assessment made me aware of what I'm doing	1.00	1.25	2.00	2.00	5.00	0.75
- 4.3	I got an improved awareness of my early warning signs	1.00	1.00	2.00	3.00	5.00	2.00
- 6.1	The visualizations of data gave me a good overview of my data	1.00	1.00	1.00	2.00	6.00	1.00
- 6.2	The appearance of visualizations made it easy for me to decipher my data	1.00	1.00	1.50	3.00	6.00	2.00
- 7.2	The medicine overview made me aware of my medication	1.00	2.00	4.00	6.00	7.00	4.00
- 13.3	The impact factors provided me more insight into my illness	1.00	2.00	4.00	6.00	7.00	4.00
- 14.1	The sensor data made me more aware of what I'm doing	1.00	2.00	3.00	3.75	6.00	1.75
Prompt Treatment		**1.00**	**1.00**	**3.00**	**4.00**	**7.00**	**3.00**
- 3.1	Triggers helped me keep track of my data	1.00	2.00	3.00	4.50	7.00	2.50
- 3.2	Triggers helped to respond to fluctuations I was not aware of	1.00	3.00	4.00	5.00	7.00	2.00
- 5.1	Plans of action were easily available on the phone	1.00	1.00	1.00	3.25	4.00	2.25
- 6.3	The visualizations made it easy for me to find contexts and meanings	1.00	1.25	2.00	3.00	7.00	1.75
- 10.3	If I got ill, I got faster help from the clinic by using the system	1.00	2.00	4.00	5.25	7.00	3.25
- 10.4	The system was useful in the treatment at the clinic	1.00	1.00	2.00	4.00	7.00	3.00
- 13.6	The impact factors gave me useful feedback on my disease	1.00	2.00	3.00	6.00	7.00	4.00
- 13.7	The impact factors made me better able to handle my illness	1.00	2.00	4.00	5.00	7.00	3.00
- 16.4	The clinic knew how to use my data in the treatment	1.00	2.00	3.00	4.75	7.00	2.75

Figure 6: Results of Disease Awareness and Insight, and Prompt Treatment from the questionnaire, measured using a 7-point Likert scale from ‘Strongly Agree’ (1) to ‘Strongly Disagree’ (7). An explanation of the features used in the questionnaire can be found in Figure 2.

> *it more aware that I was ill. But when you can see the illness progression over time, then it becomes usable.... Because it is a difficult disease to live with and you need a lot of attention to what you do, and your life style, in order to live a good life with it. MONARCA is good at providing an overall impression of how things are going, and that many things impact the mood. This is something you need to be aware of, always — every day”*[$P12$]

This issue is also touched upon by $P5$, who stated that

> *“In retrospect, it [the system] suddenly makes a lot more sense to me, and it is now that I can really see that ’hmm.. it did help a little here and it did make a difference there’. I have been extremely happy with it from the start, as it is like having yourself in your pocket”*[$P5$]

4.2. Aiding Prompt Treatment

If problems starts to arise, the system provides assistance to the patient in two ways. Firstly through personalized triggers, EWS, and actions-to-take, and secondly by the nurse contacting patients if their data shows problematic patterns.

Overall, patients found triggers ($Q3.1 - \tilde{x} = 3.00; iqr = 2.50$), general actions ($Q5.1 - \tilde{x} = 1.00; iqr = 2.25$), and impact factors ($Q13.6 - \tilde{x} = 3.00; iqr = 4.00$) to be useful. Feedback from the patients revealed that these personal feedback mechanisms were perceived as helpful, both in terms of illuminating problem areas as well as in providing useful strategies to help with the problem. As $P6$ explained in the interviews, *"I was able to adjust my life based on feedback from the system and thereby get a more stable mood"*.

If the nurse identified problematic patterns in the reported data, she would contact the patient. This connection to the clinic was considered useful (Q10.4 - $\tilde{x} = 2.00; iqr = 3.00$), and the patients felt that the clinician knew how to use the data in the treatment (Q16.4 - $\tilde{x} = 3.00; iqr = 2.75$). Qualitative comments confirmed the importance of this connection between the patient and the clinic. The system is perceived as a sort of 'safety net', since patients trust that clinicians will react if they get ill. As $P14$ puts it: *"It is like running around wearing a life jacket; you get help if you need it"*. During the trial, 8 patients were contacted by the nurse, who reacted based on reported data in the system. This was described by one of the patients ($P2$) as:

> *"I got contacted by the clinic in the period where I got depressed. The clinician was very observant regarding my data which I felt was extremely nice. It was a very positive experience, as I know how fast things [the mood] can change"*[$P2$]

This point of interaction between the patient and the clinician mediated by the system is also touched upon by $P5$ who states that

> *"The system cannot treat bipolar disorder alone, but it can be a helping factor. And it is in this, the interesting part lies. In the collaboration between the patient and the clinician, it [the system] can make the patient more independent — instead of having to call the psychiatrist all the time, having to explain that things are not right in the head"*[$P5$]

4.3. Forecasts

The MONARCA system automatically compute a daily forecast of patients' mood as a floating point number. This number is rounded to the nearest category in the 9-point mood scale before being displayed to the clinician in the dashboard (Figure 4). The analysis of this forecast data and its accuracy is done in two ways. First, the raw output from the algorithm (the floating point number) is compared to the actual mood score. This provides an mean absolute error of the forecast. Then a confusion matrix of the forecast is calculated, which visualize the accuracy of the forecast in discrete depressed or manic mood categories.

4.3.1. Forecast Accuracy

Figure 7 shows the accuracy in terms of mean absolute errors (MAE) for each patient in the 5-day forecast period. On average, the mood forecasts were accurate having a MAE for each daily forecast in the range of $0.3 - 0.4$, i.e. less than one score wrong, even on the 5-day forecast.

Participants	% adherence	# mood score changes in consecutive days	Average absolute mood change in consecutive days	Precision Day 1			Precision Day 2			Precision Day 3			Precision Day 4			Precision Day 5			Precision All Days		
				MAE	MIN MAE	MAX MAE	MAE	MIN MAE	MAX MAE	MAE	MIN MAE	MAX MAE	MAE	MIN MAE	MAX MAE	MAE	MIN MAE	MAX MAE	MAE	MIN MAE	MAX MAE
P1	57	13	1.19	0.72	0.74	0.77	0.79	0.63	1.08	0.98	0.71	1.24	0.97	0.76	1.36	1.16	0.83	1.56	0.92	0.73	1.20
P2	90	13	0.77	0.65	0.06	1.12	0.65	0.06	1.08	0.74	0.35	1.23	0.74	0.40	1.17	0.71	0.32	1.21	0.70	0.24	1.16
P3	98	9	0.55	0.04	0.08	0.05	0.04	0.20	0.04	0.08	0.08	0.16	0.08	0.46	0.07	0.04	0.25	0.06	0.06	0.21	0.07
P4	92	16	0.53	0.18	0.15	0.46	0.15	0.43	0.14	0.46	0.13	0.47	0.16	0.43	0.15	0.09	0.14	0.24	0.21	0.26	0.29
P5	71	21	0.52	0.60	0.24	0.66	0.97	0.00	0.97	0.68	0.13	0.73	0.41	0.32	0.47	0.34	0.30	0.37	0.60	0.25	0.64
P6	89	47	0.76	0.50	0.41	0.66	0.51	0.42	0.74	0.52	0.48	0.63	0.52	0.40	0.77	0.65	0.73	0.54	0.54	0.49	0.67
P7	97	42	0.57	0.22	0.41	0.22	0.26	0.41	0.25	0.23	0.39	0.26	0.22	0.38	0.26	0.23	0.27	0.27	0.23	0.37	0.25
P8	88	7	0.50	0.10	0.47	0.07	0.12	0.40	0.08	0.11	0.37	0.08	0.12	0.24	0.10	0.13	0.42	0.11	0.12	0.38	0.09
P9	79	2	0.50	0.03	0.04	0.04	0.02	0.02	0.02	0.01	0.00	0.02	0.03	0.00	0.03	0.01	0.00	0.02	0.02	0.01	0.03
P10	100	48	0.64	0.55	0.59	0.65	0.67	0.82	0.31	0.50	0.58	0.42	0.58	0.61	0.56	0.74	0.58	0.80	0.61	0.63	0.55
P11	85	25	0.70	0.43	0.51	0.44	0.42	0.42	0.48	0.44	0.45	0.45	0.43	0.46	0.43	0.44	0.57	0.34	0.43	0.48	0.43
P12	92	48	0.52	0.32	0.29	0.36	0.33	0.26	0.40	0.36	0.25	0.46	0.36	0.31	0.45	0.36	0.41	0.35	0.35	0.30	0.41
P13	92	21	0.52	0.22	0.15	0.46	0.32	0.30	0.37	0.40	0.42	0.36	0.45	0.47	0.34	0.46	0.47	0.45	0.37	0.36	0.40
P14	84	4	0.50	0.02	0.02	0.03	0.01	0.01	0.03	0.03	0.00	0.03	0.03	0.00	0.03	0.11	0.00	0.11	0.04	0.00	0.04
P15	62	16	0.78	0.48	0.55	0.42	0.50	0.24	0.69	0.48	0.25	0.71	0.48	0.37	0.57	0.52	0.50	0.58	0.49	0.38	0.60
P16	98	38	0.63	0.33	0.33	0.37	0.49	0.55	0.34	0.51	0.54	0.36	0.56	0.59	0.29	0.58	0.61	0.27	0.50	0.52	0.33
P17	93	3	0.50	0.07	0.18	0.05	0.08	0.42	0.06	0.09	0.46	0.07	0.08	0.44	0.06	0.08	0.44	0.06	0.08	0.39	0.06
P18	88	0	0.00	0.00	0.00	0.00	0.02	0.00	0.02	0.01	0.00	0.01	0.01	0.00	0.01	0.00	0.00	0.00	0.01	0.00	0.01
Avr.				0.30	0.29	0.38	0.35	0.31	0.39	0.37	0.31	0.43	0.35	0.37	0.40	0.37	0.38	0.41	0.35	0.33	0.40

Figure 7: An overview of the precision from the 5 day forecast by comparing the forecast values with the actual self-assessed mood scores: From left: Participation ID, self-assessment adherence percentage, the number of self-assessed mood score changes in consecutive days, the average mood score change in consecutive days, and the overview of precision for the five day forecast; MAE = Mean Absolute Error, MIN MAE = Minimum Mean Absolute Error, and MAX MAE = Maximum Mean Absolute Error

When analyzing the data in detail, the forecast is more precise when patients are stable, i.e. with less mood swings. For example, patient $P18$ reports no mood swings and the system hence have a very precise prediction of his or her mood (Max MAE is 0.02). The number of mood swings (e.g., when a patient is continuously changing between two scores next to each other, such as (-1) and (-2)), have an impact, since the system will forecast the patient to be somewhere in the middle. For example, $P10$ has a total of 48 mood state changes in the self-assessments, where the system has a mean precision score of 0.61 in all 5 days. We also see that when patients have a lot of missing data, the accuracy of the system declines. An example is $P5$ who has a low adherence rate of 71%. Patients who make sudden change in mood state (e.g., goes from (-2) to $(+2)$ from one day to another) likewise challenge the accuracy. For example, $P1$ has an average absolute mood change of 1.19 in consecutive self-assessments, which means that the patient on average leaps more than 1 full point on the mood self-assessment on two days next to each other.

4.3.2. Determining Manic or Depressive Episodes

In machine learning, a confusion matrix (also known as a contingency table or an error matrix) is a specific table layout that visualize the performance of classification and forecast algorithms. Figure 8 shows the confusion matrix from the forecast, and it summarizing the output of the 5-day forecast. Each column of the matrix represents the mood forecast, while each row represents the actual self-assessed mood. For instance, if we take the -2 forecast value column, we see that in 11 cases the forecast was correct. We further see that in 15 cases the actual value were -1, and in 5 cases -0.5.

From the confusion matrix we observe several things. Overall, the forecast has a precision of 57%, i.e the mood forecast is correct 57% of all cases (the diagonal in Figure 8). In general, the algorithm forecast a neutral mood state for the patients; 69% of all cases is forecasted to neutral (0) and 96% of the cases are forecasted between -0.5 and $+0.5$. We can observe that the system is highly accurate when forecasting the patients neutral state (between $(+0.5)$ and (-0.5)), with an accuracy of 96%. However, we also see that the system preform rather poorly on forecasting mood states above $(+0.5)$ and under (-0.5), with an accuracy of 8% If we include the 1^{st} neighboring scores, the accuracy increases to 42%.

It should be noted, however, that out of the total 1555 self-assessments done in the trial, only 148 scored below (-0.5) and 8 scored above $(+0.5)$. Hence, only $\sim$10% of the self-assessed mood scores fell outside the neutral category. As such, the algorithm had very little training data outside the neutral range, which explains it consistent forecasting in the same range.

4.4. Adherence to the use of the system

Figure 5 presents the number of days each patient have used the system, number of days it has reported sensor data, and the number of days the patient filled in the self-assessment. If the telephone is turned on and the MONARCA app is installed, the phone will automatically sample sensor data. Thus, we see that, on average, sampling was done 85 out of 112 days and the application was hence working 76% of the trial period. The average adherence rate for all 18 patients over the 112 days is 66%. However, if we only look at the days where the system was actually working, where the

Forecast

Actual	-3	-2	-1	-0.5	0	0.5	1	2	3
-3	**0**	0	1	1	3	0	0	0	0
-2	1	**11**	21	53	66	2	4	0	0
-1	0	15	**49**	226	265	17	2	1	0
-0.5	0	5	58	**349**	532	53	4	0	0
0	0	0	115	648	**2851**	58	4	0	0
0.5	0	0	10	43	194	**9**	0	0	0
1	0	0	2	2	32	4	**0**	0	0
2	0	0	0	0	0	0	0	**0**	0
3	0	0	0	0	0	0	0	0	**0**

Figure 8: The summed confusion matrix for the 5 day mood forecast. Each column of the matrix represents the rounded instances of the mood forecast, while each row represents the instances of the actual self-assessed mood.

patients were able to make fill in a self-assessment (85 instead of 112), the adherence rate is 88$\%$.

5. Discussion

5.1. Improving Disease Awareness and Prompt Feedback

Improving disease awareness is vital for an effective treatment of bipolar disorder [7, 43]. Having patients monitor their mood while promoting insight and good strategies for coping with their risk situations, is important for patients in their management of the disease [44, 6]. This study has showed, that a personal health technology like the MONARCA system can foster such disease awareness and insight. The system was used on a daily basis, and helped patients to quickly and easily enter cores parameters on mood, stress, activity, etc. In general, patients agreed that the use of the system helped them manage their disease and provided them with a better awareness of their disease. In particular, the patients reported that self-reporting of data combined with automatically sensing of data on their physical and social activity made them more aware of the relationships between behavior and disease.

Overall, the so-called ‘Impact Factors’ – i.e. correlation analysis between mood and specific behavior parameters – was found less useful. But this was subject to the largest disagreement amongst patients. The questions related to impact factors ($Q13.3, Q13.6, Q13.7$) had a very large distribution ($min/max = 1/7, iqr = 3 - 4$). Hence, some patients found this correlation analysis highly useful, whereas others found it not useful at all. During our interviews, we investigated these results and found, that patients who found impact factor analysis useful confirmed our design hypothesis; the impact factor analysis helped them identify patterns of their behavior over time that had an influence on their mood. On the other hand, patients who did not find it useful reported that the impact factor analysis did not take into account parameters that was important for them, and that data sensing at time was very inaccurate. For example, some patients reported that the biggest impact on their mood often were related to overall social issues, which the system did not capture. For example, personal problems in the family or a high work load at work. Others reported that the automatic data sampling were inaccurate. For example, physical activity sensing did not capture activity when the phone was not with them, and social activity did not capture activity on social media like Facebook and Snapchat. Therefore, reporting that a low activity level has an impact on mood might not be correct; it might just be a result of missing activity data.

Enabling patients to receive prompt treatment when experiencing early symptoms of relapse is associated with high clinical outcomes [6], while delayed treatment initiation is linked with an adverse impact on many clinical variables, including poorer social adjustment, more hospitalisations, increased risk of suicide, and a increased rates of comorbidities [45, 46, 47]. This study has showed, that a personal health technology used as part of a psychoeducational setup can mediate prompt treatment. On the phone, data visualizations, personalized triggers, early warnings signs, and actions-to-take provided contextual and prompt feedback to the patient. Patients reported that data visualizations and automatic triggers were very useful for keeping track of the development of their disease and to take actions based on this. Patients also reported that the system's support for maintaining continuous contact with the nurse at the clinic was very useful. This was perceived as a way the system facilitated prompt attention from the clinic when early symptoms were detected.

5.2. Adherence

Building disease awareness and insights rely on continuous and sustained self-reporting and reflection. Paper-based self-assessment is known to suffers from a range of problems, such as low adherence rates, unreliable retrospective completion, and time intensive data entry [31, 33, 48]. The MONARCA system provides much more valid day-by-day self-assessment data, which is assured by only allowing patients to fill in self-assessment data on the day, and if data is reported back in time (up to two days back), this is marked in the system. This study showed an adherence rate to self-assessment on 88%. Other studies have shown similar adherence rates. For example, in a study of the ChronoRecord, 80% of the patients had an adherence rate over 90% [49], and the Mobile Mood Diary system showed an 65% adherence [33], which, however, was tested in a much longer period and may suffer from long-term effects.

Hence, adherence to self-assessment is crucial to the benefit of a personal health technology such as the MONARCA system. Based on the experience from this study, we would argue that high adherence to self-assessment and use of a personal health technology comes from three aspects. First, a strong focus on the usability of the system enabling the patients to report data even when impaired by manic or depressive symptoms. Deliberately designing for contextualized reminders and only requiring the patient's attention for 10 seconds a day entering the self-assessment, keeps self-reporting simple and relevant. Second, patients could see that self-reported data was used actively by the system in terms of identifying early warning signs and analyzing impact factors. In this way, data was not only used passively for visualization and historical storage, but was used on a daily basis as a feedback mechanisms for the patient while using the phone. In this way, there was a continuous and closed feedback loop between the system and the patient (as illustrated in Figure 1), which demonstrated to the patient, that the quality and validity of data was important for increased disease insight and hence treatment. Third, patient would also see that self-reported data was used by the clinic in their outpatient treatment. The nurse at the clinic would monitor the incoming data, and contact the patient if disturbing trends were identified. One such disturbing trend was obviously if a patient stopped reporting data. Moreover, when the a patient would see a psychiatrist, data form the system would be used as the starting point of the consultation. Thus, data validity becomes important for the quality of this consultation.

5.3. Mood Forecasting

Recent technological advances in small embedded sensors in e.g. Smartphones and Smartwatches, low-power processing, and progress in activity modeling and recognition, have all enabled personal health technologies to gather and process a wide range of relevant information regarding patients and their disease. This growing sophistication of data collection and system architectures presents opportunities for forecasting individual patient's future health state [50]. To our knowledge, the approach taken in the MONARCA system is the first attempt at forecasting mood state of mentally ill patients. Mood forecasting enables proactive illness management, but the data quantity and quality challenges the accuracy. Our mood forecast results were, on the one hand, quite accurate having a mean absolute error (MAE) in the range of $0.3 - 0.4$, i.e. significantly below one mood score. On the other hand, the confusion matrix analysis showed a low precision on 57%, i.e. that a significant amount of mood forecasts would be in the wrong category. If we, however, define the neutral category to include -0.5 and $+0.5$, precision is increased to 96%. On the other hand, only 8% of forecast outside this neutral area is correct.

These results in the determination of manic or depressed episodes is caused by several issues. First, the available data is primarily from neutral patients. Only $\sim$10% of the self-assessed mood scores fell outside the neutral category. Thus, the algorithm had very little training data outside the neutral categories. Second, the system and algorithm may need to be optimized to include tracking of other or more specific disease parameters and symptoms. Research by Moriss et. al. [9] suggest a much more detailed checklist of early warning symptoms to track in terms of early intervention. Examples include questions on 'Feeling high', 'Ideas flowing too fast', and 'Feeling strong or powerful'. Moriss et. al. lists 18 of the more common early warning symptoms in the manic prodromes and 22 in the depressive prodromes, but writes that the list is not exhaustive. A detailed tracking of these parameters, which have show to correlated with mood swings, might improve the precision of the mood forecasting. However, such detailed self-assessment were never the design goal of the MONARCA system and may contradict with the desire of designing a simple and very easy-to-use application for the patient. Finally, it is still unclear whether bipolar disorder is appropriate for mathematical forecasting methods. There might not be underlying patterns in the development of mood, which can be modeled and recognized by computers.

These are all open research questions that needs to be further addressed and it is, therefore, still an open question if mood forecasting is feasible. But in this research we have presented results that provide some initial evidence that mood forecasting might be a useful approach in the treatment of mentally ill patients.

6. Limitations and Future Work

We evaluated the system with a small set of patients, and although the study hold evidence for short-term adherence and effect, we cannot claim that the results can be replicated with a larger group of participants for a longer period of time. The study is based solely on patients' experiences with the use of the system, as the perspective of clinicians' use of the system is reported in a separate publication. Further, the MONARCA system provides a multilevel intervention comprising ecological momentary assessment and intervention. Factorial designs will be required to isolate the specific contributions of each of the features of the MONARCA system [51, 52]. Next steps beyond this pilot stage are larger randomized controlled trials to further demonstrate the clinical effect of the system. Furthermore, to improve on the effectiveness of mood forecasting, a better understanding of optimum predictive algorithms such as automated approaches that detect patterns and correlations (data mining and artificial intelligence) versus algorithms that incorporate investigator hypotheses and iterative feedback (structured and learning models) should be pursued.

7. Conclusion

This paper has reported from a 19 week field deployment and study of the MONARCA system, used by 18 patients suffering from bipolar disorder. From a treatment perspective, the system provides a platform for disease awareness and insights, which supports the goal of psychoeducation by empowering the patients to have a proactive attitude and help them to develop an awareness and understanding of bipolar disorder, while providing methods for episode reduction and prevention. The study showed that patients found the system very useful in (i) developing an awareness and insight into the relationships between behavior and the disease, (ii) providing prompt assistance when a problem arise, and (iii) enhancing early detection of relapses and thereby prevent future episodes. Clinical research have found evidence that these aspects are core in the treatment of bipolar disorder, and the treatment effects of the system hence correlate with improved outcomes from previous findings in clinical research.

The study also presented an analysis of a method for forecasting the mood of a patient. The study showed that the system was able to estimate a patient's future mood 5 days ahead in time with a high accuracy, while the discrete detection of mood scores were less precise.

In summary, there is much to be learned about the potential roles and effectiveness of personal health technologies in treatment of bipolar disorder. The study presented here should provide some confidence that personal health technologies are feasible, acceptable, and can be used to inform and support a psychoeducation-based treatment. Psychoeducation is a treatment form not only practiced with bipolar disorder, but applied on many different types of mental illnessess [53, 54, 55, 56]. Thus, personal health technologies like the MONARCA system hold promise for supporting the general psychoeducative based treatments across mental illnesses, and we hope that the presented work inspire future work in these areas.

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Contributors

MF, MFJ, JEB, and LVK conceived the trial. LVK, MFJ, and MF authored the protocol. MF, AD, and JEB were the designers of the MONARCA system and handled all technical matters. MF recruited the patients, preformed the interviews and performed the analyses. MF wrote the first draft of the manuscript and JEB revised it. All authors have approved the final manuscript.

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Statement on Conflicts of Interest

LVK has within the last three years been a consultant for Lundbeck and Astra Zenica. MFJ has been a consultant for Eli Lilly. MF, AD and JEB have no competing interests.

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