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DESIGNING A DIGITAL ARTIFACT FOR DATA COLLECTION TO IMPROVE DAILY ADHD MEDICATION

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Research in Progress

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Abstract

Hundreds of millions of persons are affected by Attention-Deficit/Hyperactivity Disorder (ADHD), struggling with lack of concentration, hyperactivity, and emotional regulation. Patients often have the prescription of the same dosage for months to years, and optimizing ADHD medication can be a complex and lengthy trial-and-error process. In this study, we adopt design science methodology to investigate how mobile technologies like smartphones and smartwatches can be used for monitoring and self-reporting data to enable a flexible and personalized pharmacological therapy for ADHD patients on a daily basis. In the initial development of the artifact H-app-y, we focus on patients' self-reporting of emotions in combination with detecting sleep patterns as input in the general psychiatric clinical assessment. It is followed by an investigation about how to add additional input in the iterative development process. We hope that this study can help psychiatrists improve medication and help patients understand themselves better.

Keywords: Design Science, ADHD, Digital Artifact, Affect Model.

1 Background

Global health care systems face many challenges, including the current pandemic, multiresistant bacteria, and a growing and aging population with a range of neuropsychiatric diagnoses. This paper will elaborate on developing an Information System (IS) application for an individualized and improved medication of Attention-Deficit / Hyperactivity Disorder (ADHD), a diagnosis in rising.

Once diagnosed with an ADHD disorder in childhood, many patients continue experiencing disabling symptoms in their adulthood. The estimated prevalence of symptomatic adult ADHD in 2020 was 6.8%, affecting 366 million adults globally (Song *et al.*, 2021). ADHD is associated with a negative impact on quality of life and increased morbidity and mortality rates (Agarwal *et al.*, 2012; Fredriksen *et al.*, 2014; Dalsgaard *et al.*, 2015). The economic impact is estimated to be 266 billion USD in the US alone, where the loss in productivity, personal income (Daley *et al.*, 2019), and education are the most significant cost categories (Doshi *et al.*, 2012).

Although the definition of ADHD focuses on attention-deficit and/or hyperactivity, a component of emotional dysregulation is also suggested, however, the latter is not included in the diagnosis criteria. (Retz *et al.*, 2012; Petrovic, 2015). Cognitive impairment of inhibitory control and executive functions are linked to dysfunction in catecholamine-signaling pathways, primarily in the prefrontal cortex (Purper-Ouakil *et al.*, 2011). Patients with ADHD show deficits in tasks involving executive functions, working memory, inhibitory control, attention control, and cognitive flexibility. By modulating the functional parameters of executive control, catecholamines promote effortful cognition and enhance value-learning and decision-making. The clinical presentation of ADHD is heterogeneous (Purper-Ouakil *et al.*, 2011), regardless of this clinical diagnosis requires symptoms to interfere with or reduce

social, academic, or occupational functioning (McPartland, Law and Dawson, 2016). Potential consequences of untreated clinically significant ADHD include impaired relationships, reduced employment, vulnerability to depression, anxiety, drug abuse, premature death from accident, suicide. Treatments of ADHD can be both pharmacological and non-pharmacological. In the latter case, behavioral therapy, psychoeducation, or exercise, and diet are included (Geffen and Forster, 2018).

To optimize the ADHD medication can be a complex and lengthy trial-and-error process of dosage and timing. To constantly observe and interview the same patient to optimize a daily personalized medication is in real life very difficult. Consequently, many patients have a prescription of the same dosage for months or even years. In this research in progress paper, we adopt design science methodology to investigate how mobile technologies, like smartphones and smartwatches, enabling personal data collection can be used for monitoring and self-reporting to enable a flexible and personalized pharmacological therapy for ADHD patients on a daily basis. The aim of the study is to produce an artifact in the form of a prototype for data collection for personalized pharmacological therapy for ADHD patients.

2 Methodology

The design and construction of applicable solutions to a problem constitute only a small minority of research papers published within IS (Peffers *et al.*, 2007). It involves a rigorous process to design artifacts in order to solve observed problems, contribute to research, evaluate the designs and communicate the results to appropriate audiences (Hevner *et al.*, 2004).

In this study, we build on theoretical insights from behavioral decision making (Simon, 1987, 1992) and apply the reference process model for conducting design science for information systems by Hevner and co-workers (Hevner *et al.*, 2004). The model describes a framework of design-science research using strategies for understanding, executing, and evaluating the research. Design science has also been successfully applied as a research methodology by Peffers and co-workers (Peffers *et al.*, 2007), who argue that it is necessary to add generally accepted processes to the principles and practice rules. The process includes six steps: problem identification and motivation, the definition of the objectives for a solution, design and development, demonstration, evaluation, and communication.

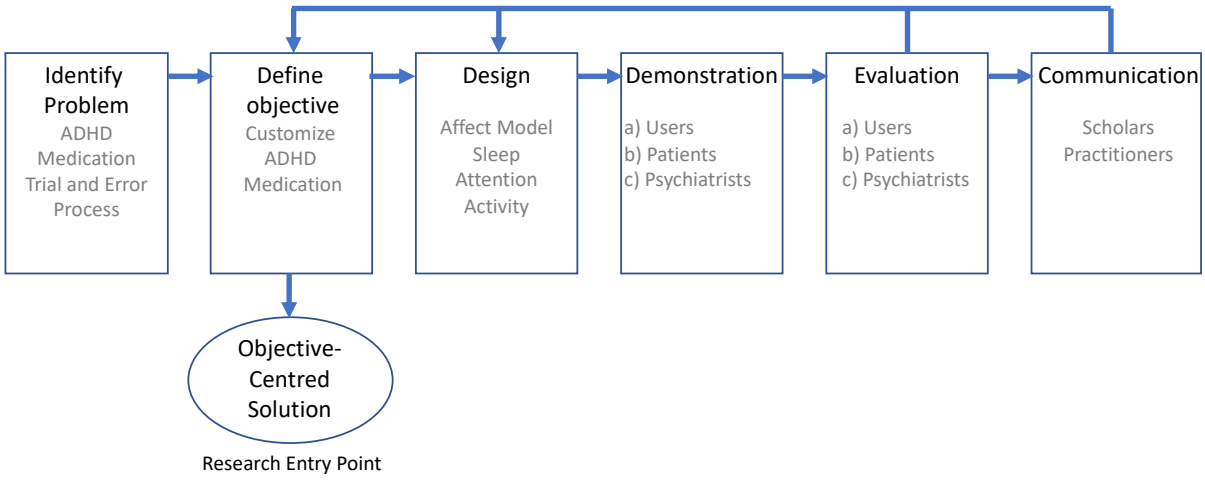

Figure 1. Process Model adopted from Peffer et al. (2007).

In this study, we will use Peffers methodology. The study is performed in collaboration between academia and clinical practitioners within psychiatry and psychology.

3 H-app-y, the App

3.1 Problem Identification – ADHD Medication a Process of Trial-and-Error

ADHD treatments include both non-pharmacological and pharmacological therapies. This study will focus on the latter. The stimulant drugs often used in the pharmacological treatment of ADHD modulate signaling pathways in the prefrontal cortex by increasing the levels of catecholamines, thereby improving the regulation of attention, behavior, and emotion (Arnsten and Pliszka, 2011). However, in clinical practice, obtaining and maintaining a maximal effect without adverse events is often difficult. To optimize the ADHD medication can be a complex and lengthy trial-and-error process of dosage and timing. Firstly, many factors need to be considered: patient's history, genetics, experienced side effects, and unique absorption with individual differences in drug bioavailability. Secondly, the patient's intrinsic dopamine levels exhibit an inter- and intra-daily variation affected by factors such as stress, cognitive workload, sleep, hormone levels, exercise, and diet. The complexity is further increased by the inverted u-shape dose-response relationship between catecholamine levels and prefrontal abilities; too little catecholamines cause fatigue and inadequate treatment response, whereas too much causes stress and a variety of undesired symptoms, i.e. anxiety, fatigue, aggression, and depression (Arnsten and Pliszka, 2011). ADHD medication can be compared with insulin treatment in diabetics. Patients with diabetes sometimes have low blood sugar levels and need to eat sugar. They can also have too high blood sugar levels and need to administer insulin. However, eating sugar when blood sugar levels are high is dangerous, and administering insulin when blood sugar levels are low can be lethal. Contrary to insulin, levels of catecholamines are not measured in psychiatric clinical practice.

A successful initiation and maintenance of stimulant drug therapy require knowledge, the ability to analyze collected data, and good communication skills from both the physician and the patient. Furthermore, the dialogue between them needs to be open and frequent. For the patient, it is necessary to have good self-knowledge and be able to identify or recognize mental and physical needs and reactions to the environment and the medication to report critical data to the clinician. On the other hand, the clinician must be experienced and have good psychiatric and pharmacological knowledge, apart from having an aptitude for patient observations and interviews, to help this trial-and-error process forward.

However, to constantly observe and interview the same patient in order to optimize a daily personalized flexible-dose treatment regimen is in real life impossible in today's healthcare. Implications are that patients often have the prescription of the same dosage for extended periods (months to years), and the desired effect of the medication is achieved some days and other days not. Pronounced variability in emotions and affect, in particular those of anxiety, agitation, depression and euphoria which, in our tentative model (see below), corresponds to regions with negative valance and/or high arousal. Ideally, a well-managed pharmacological treatment regimen achieves a stable balance of arousal and positive valance, leading to more functional and desirable emotional states.

In design research science, problem relevance is about finding a solution to an unsolved and important problem (Hevner *et al.*, 2004). Medication of ADHD patients is complex, and considering that hundreds of millions of adults are affected by ADHD globally, the problem has a great impact both socially and medically and is still unsolved.

3.2 Objective – Tailor-Made ADHD Medication

The research entry point of this design research study is an objective-centered solution (Hevner *et al.*, 2004). The clinical psychiatrists' objective in the study is to fine-tune and personalize the dose regimen to the patients' daily needs, compared to the current standard of fixed dose-treatment on a monthly, or in some cases yearly, basis. In a clinical setting, the psychiatrist tries to get an overview of parameters affecting medication like cognitive workload, stress, sleep, exercise, diet, and more. This is achieved by validated assessment interviews and questionnaires (Sheehan *et al.*, 1997; Shankman *et al.*, 2018; Somma *et al.*, 2021). These tools only provide a snapshot of reality and may also be biased by the patient's current emotional state; nonetheless, they act as a foundation for long-term treatment strategies,

not considering the dynamic and ever-changing nature of parameters influencing pharmacological therapy. The latter would require a continuous collection of data. However, as stated, observing and interviewing the patients daily or even on a weekly basis to maintain an optimal treatment regimen is impossible in real life.

3.3 Design – How to Measure Medication Improvements and Impairments

Digital technology can improve data collection, especially with AI, deep neural networks, and machine learning. Smartphones and smartwatches can collect data on important parameters by measuring sleep, activity and exercise, pulse, stress, concentration, and more with little effort from the patient.

Based on the participating psychiatrist's clinical experience (justificatory knowledge (Gregor and Hevner, 2013), we have prioritized getting input on the patients' perception of how well they manage their life as well as their sleep pattern, two key parameters (Asherson *et al.*, 2010; Ramsay, 2017; Wajszilber, Santiseban and Gruber, 2018; Hirsch, Chavanon and Christiansen, 2019; Floros *et al.*, 2021). Design science can be seen as a search process (Hevner *et al.*, 2004) or a test cycle (Simon, 2019). Initially, we will test the affect model to evaluate how well it functions as a support for the psychiatrist's clinical assessment of how well patients handle daily life and perceive their life quality. Today, this clinical assessment is based on the patients' self-reported information and, therefore, his/her own perception. In the next step, we will add data on the patient's sleep pattern to elucidate if and how it contributes to the patient's emotional fluctuations and potential effects on the life quality. In a third step, the psychiatrist can adjust the medication and follow up on the implications on a daily basis. In later stages, we can add additional parameters like cognitive load, exercise, etc. It is a step-by-step process to be able to isolate cause and effect. However, the data collection should also be manageable "*the sheer size and complexity of the solution space will often render the problem computationally infeasible*" (Hevner *et al.*, 2004, p. 89). The aims of the research are satisfactory solutions (Simon, 2019).

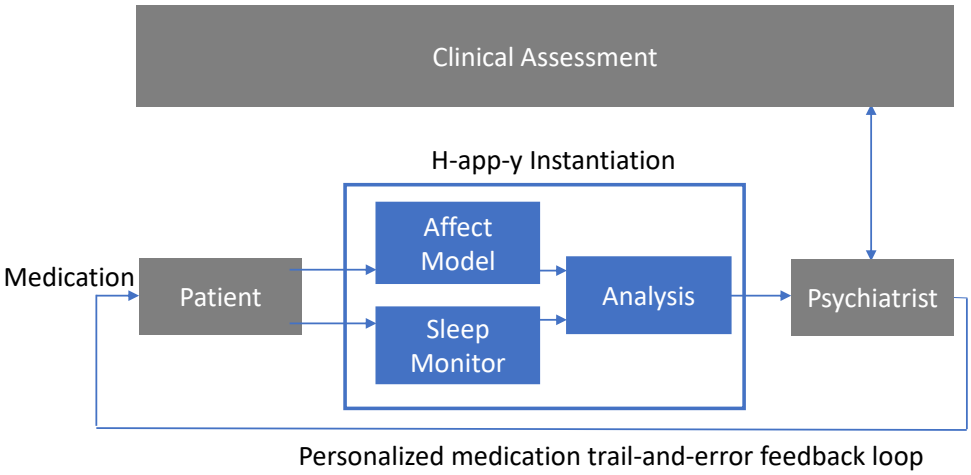

Figure 2. H-app-y, the artifact

3.3.1 The H-app-y App as an Instantiation

By using design science as a methodology, we intend to produce an artifact in the form of a prototype (the realization of the H-app-y App), with constructs (the inputs in the affect model), a model (the affect model expressing the relationships among the constructs) and a method (the algorithms for analysis). However, people or elements of the organization are not included (Hevner *et al.*, 2004).

3.3.2 The Affect Model

As mentioned earlier, one of the criteria for ADHD is that the patient perceives difficulties in daily life. The lack of concentration and poor emotional regulation often impact school or work tasks and

relationships, which in turn have implications on the quality of life. There are standardized questionnaires to measure the severity of ADHD symptoms (ASRS, ADHD-RS-5) and quality of life (BBQ) (Ramsay, 2017) in order to assess and modify the treatment. As lack of concentration is a feature of ADHD, it can become an insurmountable hurdle for the patient to answer these questionnaires several times per week. Furthermore, feedback several times per day is hard to implement. Hence, we have adopted the well-established Circumplex Model of Affect (James A. Russel, 1980) combined with the Geneva Emotion Wheel (Sacharin, Schlegel, and Scherer, 2012). We have also taken inspiration from other scholars measuring affect and self-reporting of arousal and valance (Bradley and Lang, 1994; Barrett *et al.*, 2004; Feidakis, Daradoumis and Caballé, 2011; Kron *et al.*, 2013; Kuppens *et al.*, 2013).

Affect can be described as a combination of arousal (y-axis) and valance (x-axis). Arousal is the state of excitement from highly excited on the top of the y-axis to low and calm on the bottom of the negative y-axis. Valance refers to attractiveness (good or bad), highly positive on the right hand of the x-axis, and very negative on the left hand. To capture the advantage with the Self-Assessment Manikin (Bradley and Lang, 1994) different emotions can then be plotted in this coordinate system as a combination of x,y-values. During the first step in the study, participants will be asked two questions, 1) "How are you feeling right now?" and 2) "How do you feel about your overall life situation?". In the H-app-y application, participants are instructed to use the wheel to mark the applicable emotion to answer the two questions. They will also rate the intensity of the chosen emotion on a visual analog scale (VAS) from 1 to 100. Each emotional statement is represented by a vector from the origin of the coordinate system and the length of the vector is rated 1-100.

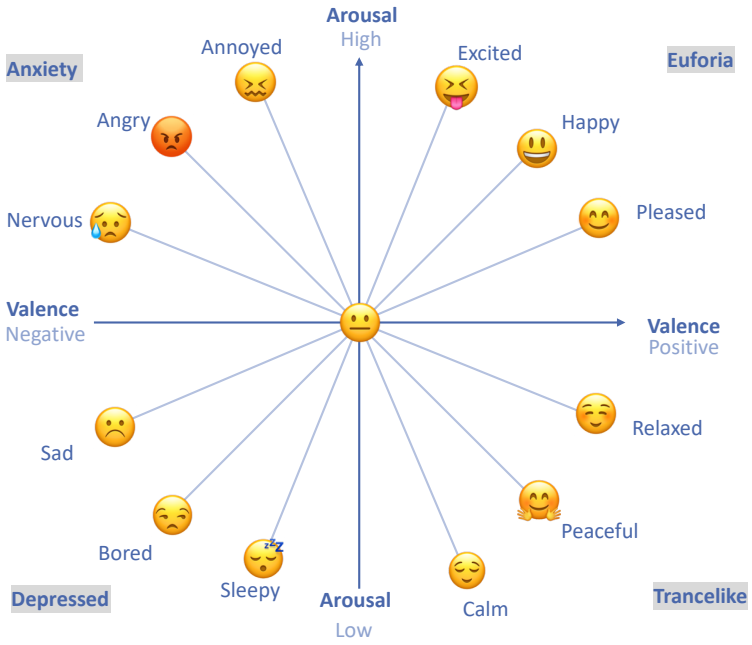

Figure 3. Affect model input interface.

3.3.3 Sleep Monitoring

Sleep will be monitored using readily available consumer-grade smartphones and watches. These devices rely on actigraphy to measure sleep patterns and have shown good performance when combined with publicly available sleep classification algorithms (Roomkham *et al.*, 2019). Following sleep parameters will be used: 1) Total sleep time, 2) Time it takes for a person to fall asleep (sleep onset latency), 3) Time in bed spent asleep (sleep efficiency), 4) Number of awakenings and amount of time spent awake during the night, 5) Time spent in bed after waking up.

3.3.4 Analysis

The psychiatrist will have input from each patient several times per day. By plotting the data points, the psychiatrist can follow clinically useful and important parameters, such as the distribution and variability of emotional states, in a time chart or in cluster analysis. The focus will not be to identify inter-individual differences but to visualize intra-individual variances for each patient over time. Ultimately, the physician will use the information in the clinical assessment to personalize pharmacological treatment to the needs of each specific patient in a flexible dose regimen. It is of utmost importance to note that output from the artifact will be used merely as a tool amongst others to provide information for the psychiatrist's overall assessment and clinical decision.

3.4 Demonstration, Evaluation, and Communication

The development of the H-app-y App is a collaboration between psychiatric practitioners and scholars from different disciplines, including IS, decision-making, and medicine. The demonstration and evaluation of the design science project will be executed in several different steps. At this stage, the involved psychiatrists and scholars have tested different models for self-reporting on life quality and chosen a model that, after minor modifications, appears useful and has the potential to yield an ample amount of input from patients with rapidity and ease. Assessment by self-reporting questionnaires or interviews would require far more questions and answers to obtain the same amount of essential data. Another strength is that not only qualitative data are collected. The quantitative nature of some of the data simplifies statistical analyses. The next step is to evaluate the affect model. The psychiatrists will investigate the value added by the collected data in a clinical setting. Initially, the model will be tested on non-ADHD patients. The iterative process will help in fine-tuning asked questions for self-reporting and applicable constructs and relevant rating scales. The relevant emojis to each emotion will also be evaluated. The advantage of emojis is that many ADHD patients have concentration deficits, reading difficulties, and co-occurring disabilities such as dyslexia. The emojis are a good complement for more intuitive communication, "*design evaluation should include an assessment of the artifactís style*"(Hevner *et al.*, 2004, p. 86). In a second step, the model will be tested on ADHD patients for further elaboration. In a third step, data collection of sleep patterns will be added. We are currently in the process of ethical approval, and the psychiatrists will finally evaluate the H-app-y App as a tool in the clinical trial and error process to fine-tune the medication. After ethical approval, the evaluation will be an iterative process where traditional clinical work, including interviews and questionnaires, will be compared with the effect when using H-app-y. After adjustments and validation, a case-control study will be executed. The iterative evaluation process is described in Figure 4.

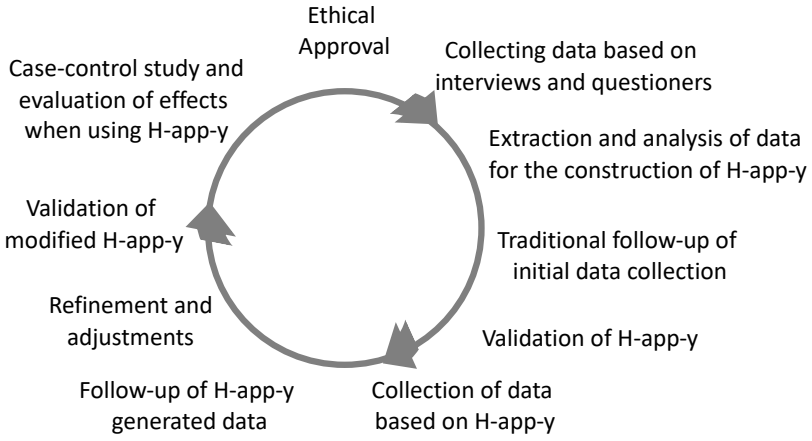

Figure 4. Iterative evaluation process.

We expect that one of the key challenges will be demonstrating validity and reliability. Interpretation of emojis can very well and most likely do exhibit an interpersonal variability (low reliability); however, this is of less concern in clinical practice. More importantly, one should establish a common baseline or

interpretation between each patient and the psychiatrist. The patient and clinician need to agree on the interpretation and meaning of a specific emoji for that particular patient enabling the physician to effectively track and identify symptoms that need to be acted on. The psychiatrist in this project will focus on 1) variability of emotional state (especially variability between high and low valence) and 2) extreme emotional states, i.e.euphoria (high arousal and valance), anxiety (high arousal and low valance), and depression (low arousal and low valance). Focusing on the variability in valence and the extreme states are likely to improve validity. We believe that in the evaluation, the number of emotion states can be reduced by bundling the emotion states in some of the quadrants, for example, happy and peaceful. To clarify, a psychiatrist is less interested in whether the patient is happy or pleased since this is a desirable state, and the differentiation will not have an impact on treatment. On the other hand, it is important to differentiate whether a patient is angry or nervous. For example, the latter one could be a sign of too inadequate or excessive dosage, depending on when these emotions occur in relation to drug ingestion.

The quality and efficiency of the artifact must be evaluated. This is a constant development and evaluation process. A heuristic design solution opens the question of how goodness is measured. One way is to compare the produced solution with those constructed by humans for the same problem situation (Hevner *et al.*, 2004). This process will be executed in close collaboration with the involved practicing psychiatrists. We hope that this research can help psychiatrists collect more information and potentially be more data-driven. Clinical judgments are based on experience and are often intuitive decisions. Many studies have shown that simple checklists or algorithms can be superior to clinical decisions (Meehl, 1986; Kahneman, 2011). However, an artifact or an algorithm does not need to be better than the best psychiatrists; in many cases, performing better than the worst will significantly improve the lowest level. In the strive for research rigor, good enough can be satisfactory, "*in an attempt to be mathematically rigorous, important parts of the problem may be abstracted or assumed away"*(Hevner *et al.*, 2004, p. 88)

In the communication of this research, we highlight the H-app-y application's importance to scholars in psychology and psychiatry, IS-oriented audiences, and practitioners like psychiatrists and psychologists. We reiterate the call for more cross-over research between academia and practitioners, not only in the design science domain, "*practitioners to take advantage of the artifacts' benefits. It enables researchers to build a cumulative knowledge base for further extension and evaluation*." (Hevner *et al.*, 2004, p. 90).

4 Discussion and Future Research Plans

We argue that this research develops a new solution for already known problems (improvements) (Gregor and Hevner, 2013). However, despite that the problem of making daily adjustments of ADHD pharmaceutical treatment is identified, daily adjustments are not applied in a clinical application since daily monitoring of patients is virtually impossible. Hence, we argue that for the practicing clinician, this research has the potential for a new solution to a new problem (invention research contribution). From a medical perspective, just concluding that adjustments in daily dose are needed is a contribution itself. The H-app-y artifact is, to our knowledge, one of the first attempts to use IS, including recent development in artificial intelligence, in striving to improve ADHD medication. We expect to add new knowledge on tailor-making medication (contributing to the knowledge base) and give feedback on how the medication is perceived by the patients in a new way (contributing to the environment) (Hevner *et al.*, 2004).

We believe that potential research contributions can be made in the form of both a viable artifact (the H-app-y App) but also contributions at a more general (i.e., abstract) level (Gregor and Hevner, 2013) where the artifact includes an overall method (what to measure, like variability in emotions and extreme states of emotion), constructs (inputs in the affect model) and design principles for measuring affect, arousal and valence. Our hypothesis, based on the participating clinical psychiatrists' kernel (justificatory) knowledge, is that the affect model can be a satisfactory proxy for emotions and the patient's perception of being able to manage attention and activity. We hope that this study can help not only psychiatrists but also patients to better understand themselves, and if there is a biological lack of

catecholamines, medication can be needed. However, this is both interpersonal (differs from person to person) and intrapersonal (from time to time in the same individual). It all depends on when the patient perceives that daily life is not working.

Being able to collect long-term data series from patients with the H-app-y artifact could potentially be used in other areas of mental healthcare to adjust and plan therapy and treatments. Interesting research areas could be to compare a patient's self-perception of an emotional state with the perception of family and friends. Understanding differences between different persons' perceptions could potentially be part of, for example, family or couples' therapy. In self-therapy, just the mere documentation of being happy or relaxed can be a valuable reminder for patients when valence is low, and life seems gloomy.

In new and emerging applications of technology, the artifact itself represents an experiment (Hevner *et al.*, 2004). This H-app-y App is an experiment and an iterative process. We plan several phases of development for future research.

1) With new AI-based technologies, we can collect and analyze more data. Smartphones and smart wearables like watches can monitor sleep, activity, pulse, and much more. As input for the analysis, we will start with affect model for self-reporting, then add sleep. We will investigate how to add additional input in the iterative development process. We also look forward to researching how to detect deviations in attention and activity by AI tools since this could give an early indication of the need for intervention. Reinforcement Learning (RL), a subtype of Machine Learning (ML), has shown promising results when being applied to dose-optimization of the drug Heparin (Nemati, Ghassemi and Clifford, 2016). RL has also been trialed in controlling anesthetics in an ICU-setting (Padmanabhan, Meskin and Haddad, 2015) and optimal individualized lung cancer treatment (Zhao et al., 2011). RL algorithms could potentially be constructed to perform a given task by learning a specific policy based on a pre-set objective, such as maximizing the time a patient is in a certain pattern of desired emotional state by proposing an optimal dosage of ADHD medication. Optimal individualized dosage-proposal could potentially be achieved by reinforcement, in this case by the patients' continuous reporting of emotional state. By setting values to different patterns of emotional states, we could potentially construct a function that yields a maximum reward when the given objective is achieved, instructing the algorithm to maximize the long-time reward. Additional important parameters such as sleep, physical activity, and diet could be included to enable a dynamic proposal of the lowest therapeutical dose. This needs to be done within a set framework under the psychiatrist's supervision.

2) In the initial setup, we focus on how psychiatrists can improve pharmacological treatment. In our following study, we will investigate how this tool can support therapists and psychologists in optimizing non-pharmacological therapies.

Since a wide range of important parameters about individuals can be measured and collected with little effort with smartphones or other smart tools, ethical issues need to be addressed. Independent of how and when this artifact is used in the future, the personal integrity of each and every user needs to be protected, and the question of how and where the information is handled and stored should be carefully paid attention to.

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