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eSano – An eHealth Platform for Internet- and Mobile-based Interventions*

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***Abstract*— The prevention and treatment of mental disorders and chronic somatic diseases is a core challenge for health care systems of the 21th century. Mental- and behavioral health interventions provide the means for lowering the public health burden. However, structural deficits, reluctance to use existing services, perceived stigma and further personal and environmental reasons restrict the uptake of these evidence-based approaches. Internet- and mobile-based interventions (IMIs) might overcome some of the limitations of on-site interventions by providing an anonymous, scalable, time- and location-independent, yet evidence-based approach. In order to implement digital mental and behavioral health concepts across the life-span into practice, a technical solution to support the design, creation, and execution of IMIs is needed. However, there are various conceptual, technical as well as legal challenges to implementing a corresponding software solution in the healthcare domain. Therefore, the work at hand (1) identifies these challenges and derives a number of respective requirements, (2) introduces the eHealth platform eSano, a software project developed by an interdisciplinary team of computer scientists, psychologists, therapists, and other domain experts, with the aim to serve as a flexible basis for mental and behavioral research and health care, and (3) provides technical insights into the developed platform and its approach to address the aforementioned requirements.**

I. Introduction

Behavioral risk factors for the development and progression of chronic somatic diseases such as diet, physical activity, and drug use [1] as well as an at least high as ever mental burden of disease [2] stresses health care system resources around the globe. Structural health care system deficits (e.g., lack of resources, fragmented systems), reluctance to use existing services, perceived stigma, and further personal and environmental reasons restrict uptake of evidence-based mental and behavioral health approaches [3]. *Internet- and mobile-based interventions (IMIs)* have the potential to overcome some of the limitations of on-site mental and behavioral health measures by providing a (partially) anonymous, scalable, time- and location independent, yet evidence-based alternative [3], [4].

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Since individually programming every single intervention would be very time and resource consuming and would also require extensive collaboration with software developers for every small change, a more generic approach is desirable. Following the principles of *End-User Development* [5], researchers and health care professionals should be empowered to create their own interventions, which can then be executed on participants' devices without the involvement of a software developer. Furthermore, as shown for eHealth platforms before [6], there are various conceptual and technical challenges to address as well as high legal and ethical healthcare standards and regulations to comply with.

The paper at hand introduces the eHealth platform *eSano*[1], which aims to provide the desired functionality and meet the technical, ethical, and regulatory requirements of internet- and mobile-based interventions, as well as provide the basis to cope with future emerging requirements. It consists of a) a web-based content management system (CMS) to create and design interventions, b) a web-based platform for therapists or other health care professionals providing therapeutic guidance (so-called *eCoaches* [7]), and c) a cross-platform application for patients or other participants to execute the interventions.

The remainder of this work is organized as follows. In Section II, related work on IT infrastructures and platforms delivering IMIs is discussed. Furthermore, in Section III, background information about eMental and eBehavioral health, internet interventions, IMIs and the eSano project are provided. The functional requirements and non-functional requirements for the eSano eHealth platform are described in Section IV. How these requirements are addressed by the proposed approach is outlined in Section V. Finally, the paper is concluded with a summary and an outlook in Section VI.

II. Related Work

IT infrastructures and platforms delivering IMIs and other online treatments have been considered by research and government-funded projects in the past.

The online platform *Iterapi* [8] provides internet-based psychological interventions for a range of mental disorders and other health-related issues and has been used in many randomized controlled trials and outpatient treatments. Each study or treatment has its own website with a custom layout, language, and separated data storage. Interventions include self-help treatment modules with questionnaires, information

[1]sano = health in Esperanto

collection forms (e.g., worksheets or diaries), and a communication system (audio, video and text messages as well as discussion forums). Therapists and editors have access to an administrative area from which they can review and export answers to questionnaires and worksheets, progress with modules, as well as activity logs. In addition, the administration of users and groups can be performed in this area [8].

The platform *Moodbuster*[2] was originally developed for the treatment of depression [9], but has been expanded into a more generic framework for mental health interventions [10]. Its features include flexible unguided as well as guided self-help treatment modules, ecological momentary assessments (EMA) with automated reminders, mobile (bio) sensor integration (e.g., to measure daily physical activity), and automated feedback based on a reasoning engine. The platform consists of a central database, a web-based platform for patients and therapists and a mobile application. Users can use the mobile application to follow shortened versions of the treatment modules, complete EMA questionnaires, and monitor their progress [9].

The *MindSpot Clinic*[3] is an Australian government-funded service, which provides online assessment and treatment for anxiety, stress, depression and low mood [11]. The features of the "online clinic" include self-report questionnaires, therapist-guided Internet-delivered cognitive-behavioral therapy (iCBT) lessons, automated e-mail reminders, an overview of symptoms, and information about local mental health services. Intervention lessons are composed of text, images and supplementary material [11].

There are other commercial service providers like *Minddistrict*[4], *SilverCloud*[5], and *Online-Therapy.com*[6]. However, no information about their internal technical details are publicly available.

In order to allow for the research of therapeutically guided and unguided IMIs as well as the development and evaluation of innovative Internet- and mobile-based approaches in the fields of mental disorders, chronic somatic diseases and health behaviour risk factors, a flexible eHealth platform was desired that is free from any conflicting commercial goals or boundaries of existing projects and could be adapted to our rapidly changing requirements. Thus, the eSano project presented in the work at hand was launched.

III. Background Information

eMental and eBehavioral health is the use of internet related technologies to support the mental and physical health of people. It relies on internet technologies as an instrument of communication to deliver prevention, treatment, health promotion interventions and other courses. Many benefits can be gained by adopting eMental and eBehavioral health tools, such as a wider scope of delivery, with which people can access such tools from the comfort of their own homes [12]. Another positive aspect are the potentially reduced costs of using eMental and eBehavioral health tools over traditional treatments [13]. Moreover, there is a high potential for flexibility by enabling users to access their treatment at any time, and from any place [3].

One eMental and eBehavioral Health concept that has garnered more and more importance is constituted by *internet interventions*. Internet interventions are typically related to psychotherapy (most often Cognitive Behavior Therapy (CBT)), behavioral medicine and/or health behavior change interventions that have been operationalized and transformed for delivery on the Internet, often with the goal of behavior changes and subsequent symptom improvements [14]. They are usually self-paced, interactive, tailored to the user, and use multimedia content (e.g., images, audio, or video) [14]. Internet interventions can be categorized into Internet-and or mobile-based internet interventions (with or without human support), online counseling (e.g., email, chat, or video-based), and internet-operated therapeutic software (e.g., rule-based expert systems) [15]. In the scope of this work, we will focus on Internet- and mobile-based internet interventions [3], [4].

At its core, IMIs are often based on evidence-based interactive self-help lessons [3]. Moreover, IMIs aim to take full advantage of the technical capabilities of modern mobile devices (e.g., smartphones) by not only allowing users to execute interventions virtually anywhere, but also to incorporate mobile functionalities, such as real-time messaging, feedback, reminders, and other reinforcement automations, as well as the potential to leverage mobile sensing features [16], [17]. IMIs can be implemented with varying degrees of human support ranging from *unguided* self-help modules, with which participants can work on tasks completely independently, to *guided* interventions, with which an accompanying psychologist (eCoach) can provide regular feedback and guidance on the tasks [7]. In addition, IMIs can be carried out as stand-alone approach or integrated in conventional on-site interventions (*blended therapy*) [3].

The effectiveness of IMIs has been shown multiple times in the past [18], [3], [19], [20], [4]. Interventions are thereby particularly effective when guided by an eCoach [7].

In 2017, the Department of Clinical Psychology and Psychotherapy (KLIPS) and the Institute of Databases and Information Systems (DBIS) at Ulm University launched an IT project called eSano with the goal to provide a technological infrastructure for the creation and delivery of generic unguided as well as guided IMIs. The platform is already being used in multiple ongoing studies at Ulm University and its cooperation partners.

IV. Requirements

In collaboration with domain experts (e.g., psychologists, computer scientists, regulatory consultants) and gained experiences with other similar projects in the field [6], a number of requirements were derived and continuously adapted for the eSano eHealth platform.

[2]https://www.moodbuster.science (accessed: 2021-01-21)
[3]https://mindspot.org.au (accessed: 2021-01-21)
[4]https://www.minddistrict.com (accessed: 2021-01-21)
[5]https://www.silvercloudhealth.com (accessed: 2021-01-21)
[6]https://www.online-therapy.com (accessed: 2021-01-21)

The functional requirements are listed in Tables I and II, including the provision of a user identity, a role system, groups, generic interventions, a customizable intervention configuration, generic diaries, guidance, a preview for CMS editors and eCoaches, chat messages between different users on the platform, and automatic reminders. The non-functional requirements are listed in Table III, including safety, security & privacy, availability, performance & scalability, offline availability, interoperability, multilingualism, modularity, maintainability & extensibility, and an open-source software development approach.

TABLE I
MOST IMPORTANT FUNCTIONAL REQUIREMENTS OF THE ESANO EHEALTH PLATFORM (PART 1)

ID	Title	Description
FR1	User Identity	There should be authentication and authorization mechanisms allowing only privileged users (c.f. Role System) to access the CMS and eCoach platforms. All users should only be able to access their own data or data to which they have been granted access.
FR2	Role System	There should be a role system in order to allow certain users to access different areas of the platform (e.g., roles for content editors, eCoaches and admins).
FR3	Groups	There should be the option to group users (content editors, eCoaches, participants) and content (interventions, diaries) in order to implement studies and enable isolated work environments for privileged users.
FR4	Generic Interventions	The platform should enable the composition of generic interventions for content editors (using end-user development), which can then be assigned by eCoaches and executed by participants. Interventions should be structured into modules (called *lessons*, e.g., *Psychoeducation: development of anxiety* [21]), and these in turn into pages. Each lesson/page can contain different static multimedia elements (e.g., headline, text, image, audio, video) as well as interactive elements (e.g., questions). Content might only be displayed under certain conditions (*conditional content*, e.g., if a question was answered with a certain option).
FR5	Intervention Configuration	The process of interventions should be configurable. For each lesson it should be definable whether it should be unlocked a) always, b) after completion of the previous lesson, c) at a specific date & time, or d) manually by the eCoach (see Guidance).

TABLE II
MOST IMPORTANT FUNCTIONAL REQUIREMENTS OF THE ESANO EHEALTH PLATFORM (PART 2)

ID	Title	Description
FR6	Generic Diaries	The platform should enable the composition of generic diaries for content editors, which can then be assigned by eCoaches and executed by participants. Diaries can contain the same elements as an intervention lesson, but can be completed as often as desired.
FR7	Guidance	Participants might be assigned to an eCoach. This eCoach should then be able to assign interventions and diaries to the participant, access the given answers and provide feedback in form of text messages. Additionally, the eCoach might change the intervention configuration and manually unlock new lessons.
FR8	Preview	The intervention and diary contents should be viewable in a preview in the CMS and eCoach platform that simulates in what way the content shall look like in the participant app, but allows to skip content through lessons.
FR9	Chat Messages	There should be the option for users of the platform to communicate via chat messages (e.g., eCoaches with their participants).
FR10	Automatic Reminders	The platform should offer the ability to automatically remind users of the platform and notify them about certain activities via emails and push notifications. For example, participants should be reminded to finish their lessons or read feedback from their eCoach.

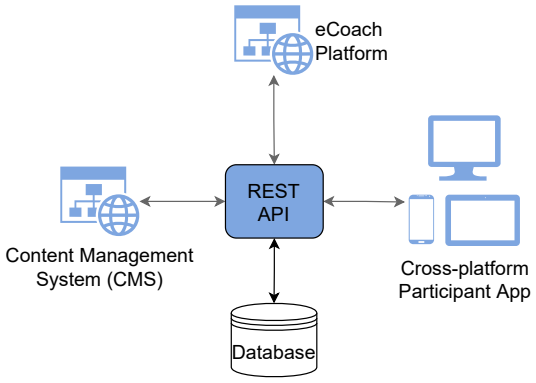

Fig. 1. Architecture of the eSano eHealth platform

V. APPROACH

The eSano eHealth platform attempts to provide a software solution that addresses the requirements described previously. The following describes how the software architecture as well as the data model of the platform are composed. Furthermore, the guidance-related features are described in more detail. Finally, the process of developing and validating the software in regulated environments is addressed.

A. Software Architecture

eSano is mainly composed of three applications that rely on one central backend, as shown in Fig.1. Intervention content is designed and created by domain experts in the web-based *Content Management System (CMS)*. The interventions can then be published to the web-based *eCoach platform*. eCoaches can manage their participants and assign interventions to them. Participants are then able to work on these interventions in the cross-platform *Participant Application* (web-based, Android, iOS). During the execution of an intervention, therapeutic guidance can be provided by the eCoach. All applications are built with web technologies, using frameworks such as Laravel (PHP), Vue.js (JavaScript/TypeScript), Angular (JavaScript/TypeScript), and Ionic (JavaScript/TypeScript) and use HTML, CSS, and SASS to display content to its users. The communication between the three applications and

TABLE III

MOST IMPORTANT NON-FUNCTIONAL REQUIREMENTS OF THE ESANO EHEALTH PLATFORM

ID	Title	Description
NR1	Safety, Security & Privacy	The platform should meet high safety, security and data protection standards. This includes development under consideration of the EU General Data Protection Regulation (GDPR) and the Medical Device Regulation (MDR). The software validation process should be oriented towards relevant standards and guidance documents (e.g., IEC 62304 [22]). All confidential data should be stored securely and transmitted in encrypted form. User data and credentials should be stored separately from application data. Health risks should be identified and addressed early and transparently presented to users. A security model should exist for the entire platform.
NR2	Availability, Performance & Scalability	The platform should always be available for its users, if possible. There should be no noticeable performance drops at higher load. Scalability aspects for mHealth platforms [23] should be considered.
NR3	Offline Availability	If possible, the mobile participant app should also be usable when there is no internet connection (or more generally: no connection to the backend). All data should be stored on the device and synchronized with the backend, if necessary.
NR4	Interoperability	The platform should provide good interoperability with other (external) systems. This includes the implementation of common data exchange format standards and communication protocols as well as the provision of uniform, understandable and well-documented interfaces.
NR5	Multilingualism	The platform should be available in multiple languages at the same time. The language of the applications as well as the content should be configurable by the user.
NR6	Modularity, Maintainability & Extensibility	The platform should be modular, so that it can be easily maintained and extended to meet future changing or new requirements.
NR7	Open-Source	The software should be open-source. Any software developments and used software libraries should be under licenses which allow everyone to use, study, change, and redistribute the software.

the backend is based on the use of the *Representational State Transfer (REST)* architecture. The overall communication is encrypted end-to-end with TLS and transmitted via Hypertext Transfer Protocol Secure (HTTPS). The separation of the eSano platform into three independent applications provides several benefits, e.g., each application can be developed independently with completely different toolsets based on its specific requirements. Moreover, errors in one application do not necessarily affect the other applications, which makes the platform more resilient and simplifies maintenance because these errors can be isolated from the rest of the platform.

B. Data model & representation

A simplified Entity Relationship (ER) model diagram is shown in Fig. 2. The main entity in the diagram is the study

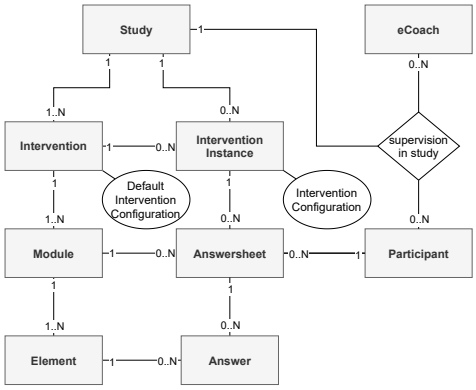

Fig. 2. Simplified entity-relationship model (ERM) of the eSano data model

entity. It can be seen that almost every other entity is a descendent of it, either directly or indirectly. An eCoach can be a supervisor for a specific participant in a study and a study can have one or more supervisors and participants. Furthermore, interventions are grouped under studies, where any intervention can belong to one study. These interventions hold the different modules that were designed in the CMS and each module could contain one or more elements (e.g., headline, text, image, audio, video). Additionally, the default intervention configuration is stored together with the intervention (see Section V-C). The *Intervention Instance* represents a specific instance of an intervention that has been adjusted to suit the specific needs of each participant. This includes the intervention configuration (see Section V-C) as well as the current progress of the participant within the respective intervention. An eCoach can create an instance of an intervention and modify it so that it works according to the needs and requirements of a certain user and then this instance can be assigned to this participant. Whenever a participant goes through a module and submits answers, these answers are stored in an answersheet. This can be seen in Fig. 2 with the entity *Answersheet*, where an answersheet can contain multiple answers and can belong to exactly one module.

As outlined in Section V-A, RESTful interfaces are used to exchange data between different applications of the eSano platform. In this process, the requested entities are transformed into the *JavaScript Object Notation (JSON)*, which is a human-readable and easy-to-understand format, but can also be directly processed by many JavaScript-based clients. Since the interfaces are independent of the data storage, it is possible to extend the API with additional interfaces and data formats to serve other needs and applications in the future.

C. Guidance

eSano offers therapists and other domain experts a number of choices and a significant degree of freedom when supervising the users of the platform. Communication between participants and their supervisors can easily be initiated by both parties. Whenever a participant finishes a module, a notification is sent to the user's supervisor. From the eCoach platform, the supervisor can go through the answers of

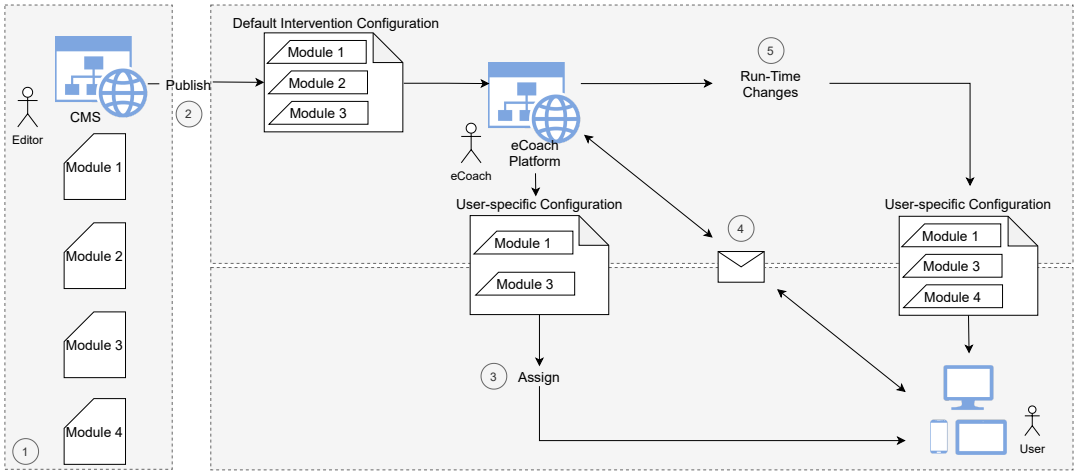

Fig. 3. Guidance process in eSano that spans the different subsystems

the user and, when needed, also provide suitable feedback. Additionally, when there is a need for a module to be repeated, the supervisor can simply run such a command. On top of that, modules can be added to the intervention and can also be removed or exchanged for other modules. This flexibility helps therapists, healthcare providers and researchers to supervise their participants closely and to easily update the modules, if the situation or therapy progress requires it.

The workflow of the guidance process is described in Fig. 3. Domain experts can use the CMS to ① create and design an intervention with a number of modules (e.g., for depression or anxiety [21]). They can then decide which modules shall be included in the *intervention default configuration*, how these modules should be unlocked (i.e., always, after completion of the previous module, at a specific date and time, or manually by the eCoach), and in which order they should be processed by the user. Once the default configuration of the intervention is set up, the intervention can be ② published, so that it is accessible from the eCoach platform. At this point, an eCoach (e.g., a therapist) can further modify the default configuration of the intervention into a *user-specific configuration* using the eCoach platform and then ③ assign it to a participant. This stage helps eCoaches to tailor the intervention to the individual needs and therapy plan of each participant. After an intervention has been assigned to a participant, it can be accessed from the participant app. As described in Section V-A, the participant app is a cross-platform application, so users can access their interventions through both a web browser and a mobile device. While the user is working through the modules of the intervention, the eCoach can supervise this process and monitor the progress by checking the activities as well as the given answers of the user. The eCoach can then ④ provide feedback to the participant based on the user's progress, and the user is also able to contact the eCoach whenever needed. Moreover, the eCoach has the option to further ⑤ apply run-time changes to the user-specific configuration, e.g., by adding another module from the intervention repository as indicated by Fig 3, which helps to make the process more flexible and more responsive to new developments in the user's needs and requirements.

D. Software development & validation process

The platform is developed tailored to the requirements of the German Medical Devices Act and the Medical Device Regulation (MDR). Thus, the software development, documentation and validation processes take into account the IEC 62304 [22] (safety class B), the GAMP5 [24] (category 4), the General Principles of Software Validation [25] of the FDA, as well as the Pharmaceutical Inspection Cooperation Scheme (PIC/S) 11-3 [26]. Requirements are documented in detail and updated on an ongoing basis. Risks regarding patient safety, data integrity, and product functionality are assessed and rated in terms of their severity and estimated frequency of occurrence. For each risk, mitigation measures are taken, documented and continuously monitored. The software is not released until all risks are within acceptable levels. Validation of all requirements is performed and documented for every release of the platform that is used in regulated environments.

Furthermore, the platform is currently being used in the three-armed multicenter cluster-randomized controlled non-inferiority trial PSYCHOnlineTHERAPY [21] to assess its feasibility and usability. The study compares two implementations of blended psychotherapy with CBT. 75 outpatient psychotherapists are recruited and each of them asked to include 12 patients with depressive or anxiety disorders, yielding a total sample size of N = 900.

VI. Summary & Outlook

In this work, we introduced eSano, an eHealth platform for Internet- and mobile-based interventions. The functional and non-functional requirements, which were elaborated in collaboration with various domain experts, were described. Furthermore, several aspects of the approach that have been selected for the eSano platform in order to cope with these requirements were highlighted. In this context, the software

architecture and data model of the platform were described. In addition, the guidance process was outlined in more detail. Finally, the software development and validation process used in order to cope with legal requirements and guidelines in regulated environments of the healthcare domain was described.

As eMental and eBehavioral Health in general and internet interventions in specific are gaining more and more attention and acceptance, and the research in this field is advancing, new innovative eHealth and mHealth approaches will emerge on the one hand. On the other hand, they are required with respect to many needs of the 21th century. Furthermore, technological advances are opening up even more possibilities, e.g., chatbots that mimic therapeutic conversations [27], [28] or *just-in-time interventions* that intervene at the moment of need by analyzing sensor and other contextual information captured by mobile devices [17]. The respective software solutions, in turn, must on the one hand be able to deal flexibly with these changing requirements and adapt accordingly. On the other hand, software in regulated environments must comply with legal regulations, which leads to increased documentation and validation efforts that prevent rapid changes. In the future, it is planned to split the eSano project into a validated version intended for regulated environments and one version that allows for flexible changes used for cutting-edge research.

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