Mobile Technology Improves Therapy-Adherence Rates in Elderly Patients Undergoing Rehabilitation—A Crossover Design Study

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Abstract In this publication the results of an empirical study are analyzes regarding the research question if a mobile application on a tablet computer, to support the drug intake and vital sign parameter documentation, affects adherence of elderly patients. For the achievement in the management of patients with hypertension adherence of their medication is essential. Patients with no prior knowledge of tablet computers and a coronary heart disease were included. All Patients were instructed personally into the mobile application "Medication Plan", installed on an Apple iPad™. This study was performed in a crossover design with three sequences. The first sequence is the initial phase, followed by the interventional phase (28 days of using the app system) and at least the comparative phase (28 days of using a paper diary). The interventional and comparative phases were conducted alternately. Altogether, 24 patients (12 male; mean age 73.8 years) were registered. The subjectively assessed adherence (A 14 scale) was 50.0 before the study started (SD 3.44). After the enforcement of both interventions there was a significant increase, which was more pronounced after the intervention phase (54.0,

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SD 2.01) than the comparative phase (52.6, SD 2.49) (for all pairs $p < 0.001$). Furthermore, the medical conditions, or the number of drug intakes per day had no effect on the subjective adherence. For both blood pressure recordings ($p < 0.001$) and medication intake ($p = 0.033$) the obtained logging data showed a significantly stronger adherence for the medication-app than the paper diary system. The majority of participants (n = 22) denoted that they would like to use the medication-app in everyday life and do not need any further assistance. A mobile app for medication adherence strengthened objectively and subjectively metered adherence of elderly users folding rehabilitation.

Keywords Drug therapy · Self-management · Therapy adherence · Elderly patients · Mobile application · Tablet computer

1 Introduction

Management of hypertension is one of the key issues in secondary prevention of ischemic heart disease (IHD), which is among the main causes of death in the Western World [1]. Cardiac rehabilitation of patients with coronary heart disease embrace the risk assessment and management of comorbidities. Furthermore the lifestyle alters and psychosocial support has been shown to reduce mortality [2]. Nevertheless, adherence to self-management and medication is still a challenge, particularly for the management of hypertension and elderly patients with high comorbidity and reduced awareness of their medical condition [3]. The complexity of the daily life, shifting priorities and frequent polypharmacy conducive to patients' inability to deal adequately with their medical conditions. The important risk factors of IHD are known as diabetes, hypertension and dyslipidemia that up to 50 % of patients stop taking the medication during the first year of prescription [4]. Novel strategies are required to better address the needs of elderly and chronically ill patients [5]. To identify their needs, the mobile information technology may offer new system-solutions in future. With more than 1 billion users having access to mobile broadband internet and a rapidly growing mobile app market, stakeholders have high expectations that this technology may improve health care and create it in a new way [6]. Expectations range from overcoming structural barriers, via access in low-income countries to more effective, interactive treatment of chronic conditions. At the moment, previous work suggests that even when sophisticated technology is available, older users (e.g., age 50 and above) think that their initial experiences with medication applications are frustrating and insufficient [7]. To further investigate this issue the Institute of Industrial Engineering and Ergonomics of RWTH Aachen University instigated a study of the iNephro "Medication App", which had previously been developed by the Department of Nephrology and the Institute for Drug Safety, University Hospital Essen. With this study we focused elderly patients with a history of ischemic heart disease folding cardiac rehabilitation.

1.1 Objective

Pre-specified main endpoints of the statistical analysis were the effect on participants' affinity for technology, reported medication compliance/orderliness of self-reliant vital parameter measurements as well as objective adherence which was assessed by the logged interaction protocols.

2 Materials and Methods

2.1 Ethics

The Ethics Committees of RWTH Aachen University as well as the Ethics Committee of the Medical Faculty of Essen University were consulted and ethics approval issued (EK 340/14; respectively 14-5842-BO). To take part in this study all participants needed to provide a written consent. They received a patient information before participating the study. Furthermore, all participants got sufficient time to read and understand the information about objectives, methodology, insurance, data protection etc. The investigator explained the document to the participant and answered their questions. Following participants had to sign a declaration of consent, which declares that they understood everything and take part in the study voluntarily. Afterwards the investigator signed both documents additionally. One copy of each document was given to the patient and the other one was archived by the investigator.

2.2 Participants

The Institute of Industrial Engineering and Ergonomics of RWTH Aachen University adjusted 24 participants via local cardiac-rehab sports groups (phase III rehabilitation). All participants were afflicted with hypertension and coronary heart disease and had experienced myocardial infarction requiring inpatient six-month hospital stay before this study. On average 2.2 (SD 0.9) the following additional chronic conditions were reported: hypertension (n = 14), dyslipidemia (n = 9) and diabetes (n = 9), liver (n = 2) and lung disease (n = 2). All of the 24 participants have been instructed by their physician to take their drugs between twice and six times a day, on average 3.8 drugs (SD 1.4). The consulting physician of the participant requested them to undertake blood pressure readings between once and four times a day (mean 2.0; SD 0.9). All of them are retired and lived autonomously at their homes so none of them needed assistance in activities of daily life. Furthermore, none of the participants had prior experiences with a smartphone or tablet but 14 of them owned a computer and 17 used the internet regularly. We only

accepted participants with a minimum visual acuity of 0.75 using their vision aid, if it was adaptive. Within the group of participants, the sex and age were balanced and used as a control variable. All patients participated voluntarily and their participation had no context with medical treatment. There was no financial compensation given for the participation.

2.3 Apparatus and Inductor Session to User

This usability trial of elderly cardiac patients used the app "Medication Plan" (version 1.3) on a first generation Apple iPad™ (iOS version 5.1.1) in 2014 [8, 9]. Specifications supported regular drug-intake of patients with chronic conditions on polypharmacy (Fig. 1). The home screen of the test iPad was individually modified that only the app "Medication Plan" was available in the dock and all further standard applications were placed in a folder on the second menu page. To ensure that the participants do not delete the app "Medication Plan" itself, we disabled the possibilities to delete applications in the device's restrictions settings. Furthermore, we put a green sticker on the iPad's home button to help the user locating it more easily. The feedback of the users of pre-tests had shown that this facilitated usage (the first generation iPad did not offer the smart cover functionality which turns on the display when you open the cover) acts as an easy visible cue for the orientation on the iPad when the participants wanted to turn it on. For introducing the system we arranged an interactive learning-by-doing tutorial session in which the participants were introduced to the touchscreen usage and the iNephro application. We wanted to enable the user an autonomous exploration of the device by facilitated discoverability. After the physician issued the prescription and individual medication it was entered into the Medication Plan system. We also explained the general concepts of tapping and swiping since none of the participants used a tablet computer or smartphone before. The test subjects were familiarized with the functions of the application (i.e., confirming medication intake and recording blood pressure values) and how to recover if a wrong input has been made. Furthermore, the application "Medication Plan" changed its layout accordingly by rotating the iPad, if the participants prefer the portrait or landscape mode. The personal tutorial session was concluded by a brief test consisting of small series of tasks which should strengthen the knowledge of the participants. Users were asked to turn on the device, to confirm their medication intake, enter blood pressure records and modify the data that was entered into the application "Medication Plan". In addition, the participants received a two-page manual which consists a one page FAQ-like "error treatment" and illustrate how to use the application. The volume of the acoustic pill reminder was set as desired by the users in the test groups but the participants were instructed how to adjust it later on by themselves. The users also received a paper-based notepad to write down any problems or particularly positive

Fig. 1 Creating a medication plan on the smartphone [14]

aspects (e.g., which might have been difficult at first) they encountered when utilizing the system while the study. However, the intervention was not used in the context of a medical treatment and no feedback was given by a doctor on recorded vital signs.

2.4 Study Design

The study was conducted in a crossover design with three sequences: initial phase without assistive systems, interventional phase (28 days of using the app system) and a comparative phase (28 days of using a paper diary). The Interventional and comparative phase were experienced by the users alternately. Furthermore, half of the users were randomly assigned to each group and switched after 28 days (Fig. 2). The environment for this study was the individual participants' home. According to the study design the users were visited at home by the same investigator for three times: initially (when introducing the system) and after using each system. The participants read and filled in the questionnaires on technical affinity

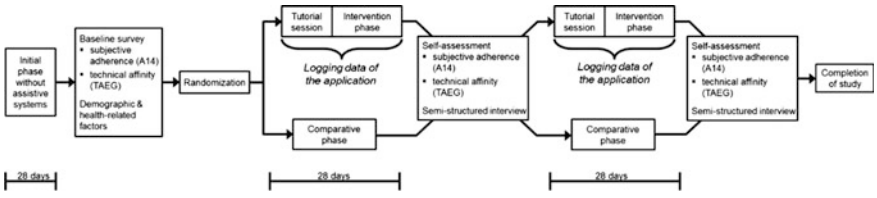

Fig. 2 Different phases of the study and obtained data

and the subjective adherence themselves to minimize the influence of the examiner. If the participant had a query, the examiner gave support and answered all questions. The semi-structured interviews were audio-recorded to enable later analysis, if participant agreed before. Each of the data collection sessions took between 30 min and 2 h, depending on the participants and on the upcoming period (e.g., introduction to use the system or handing out the diary). During the study, all materials and information were given in German language, which is the native language of the participants. After the participants completed the initial questionnaires, the examiner listed medications currently prescribed on a prepared form, based on the patient's self-report. The following data were required: name of the medication, number of intakes per day, and corresponding doses. Prior to the system phase, the examiner entered the participant's specific and individually medication and doses into the app "Medication Plan" on the iPad. Throughout the comparative phase, the participants used a paper diary as a traditional method to record their medication intake and blood pressure values. Logged medication intakes and vital sign parameter recordings were evaluated according to the automatically registered data of the app after interventional phase respectively the diary as a relative indicator for adherence was analyzed after the comparative phase.

2.5 Questionnaires

Initially, the participants completed a questionnaire, which contained items on their demographics and general medication-related questions anonymously. To classify the participants, we categorized them accordingly as novices, intermediates or experts and used an adapted version of the computer literacy scale (CLS) to estimate the existing of technical knowledge and experience [10]. The A 14 questionnaire determined subjective adherence, which contains 14 items on subjective adherence weighted according to a 5 point Likert-scale ranging from "never" to "very often" [11]. Values below 50 are regarded as non-adherent, values between 50 and 56 as adherent (sums ranging between 0 and 56). Finally, for measuring the affinity for technology we used the TA-EG questionnaire [12] consisting of 19 statements on different aspects of technology that are rated on a five point Likert scale from "Do not agree at all" to "Completely agree" designed to assess person's positive attitude, excitement, and trust toward technology. The scores for negative formulated items were poled so that a higher score results a lower rating on the negative aspects of technology. This leads to a consistent representation in which higher scores represent a higher affinity for technology. To get a broader insight into the use of the system, we conducted semi-structured interviews after the participants completed the questionnaires. The semi-structured interviews were designed around central questions including how participants incorporated the system in their daily lives and what they liked or disliked about it [13]. All questions were adapted to harmonize norm based upon ISO 9241.

2.6 Objective Indicators for Technology Adherence

Furthermore, we analyzed all confirmation rates of medication intake, the number of blood pressure records in the system and the data of the paper diaries. We execute a target-performance comparison for comparing the outcome. The target was defined as the number of medications each participant had to take every day multiplied by the days they actually used the system or the diary. An absolute performance was defined as the actual number of confirmations. If one participant had to take more than one unit (i.e., more than one pill) of a single medication at the same point in time/day it was considered as one medication intake ("all or-none") since the application cannot register whether participants only took a subset of a particular medication. To finally confirming medication for the rate of adherence is the ratio of performance and target multiplied by 100 for percentage scale.

2.7 Data Collection and Analysis

Data was double-entered and analyzed using SPSS statistics software version SPSS 21.0 (IBM, U.S.A.). A multi-factorial analysis of variance (ANOVA) with repetitions for the different factor levels of the response variables with a significance level of 0.05 was conducted. Significant findings were additionally analyzed by a post-hoc analysis and the Bonferroni correction to exclude an alpha-error cumulation by paired comparison of mean values. Septicity was assessed by Mauchly's test. In violation of the Mauchly's test, the corrected value according to Greenhouse-Geisser was used.

3 Results

3.1 Subjective Adherence

The mean subjectively assessed adherence before the study without supporting system was 50.02 (SD 3.44), after the interventional phase (medication-app) 53.96 (SD 2.01) and after the comparative phase (paper diary) 52.60 (SD 2.49). Furthermore, the inferential analysis of the three measurement points proofs, if there is a significant effect of the respective type of intervention ($F = 31.662$; $df = 1.613$; $p < 0.001$; Fig. 3) with a medium effect size of $\omega^2 = 0.07$ [20]. Post hoc pairwise analysis with Bonferroni correction showed significant differences between both interventions ($p = 0.02$) and in comparison to the initial phase (both $p < 0.001$). The effect on adherence was more pronounced after medication-app intervention than after the paper diary. The individual medical conditions and therapy were represented by the quantity of chronical diseases ($F = 2.494$; $df = 3$;

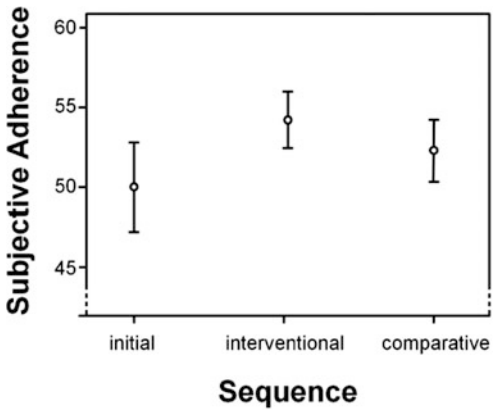

Fig. 3 Subjective adherence of the participants after initial, interventional and comparative phase

$p = 0.106$), number of drug intakes per day (F = 0.994; df = 4; $p = 0.627$) as well a number of vital parameter readings (F = 1.583; df = 3; $p = 0.515$) no effect could be identified.

3.2 Objective Adherence

The analysis of the logging data of the application and the documented medication intake of the paper system with regard to blood pressure recordings (F = 27.404; df = 1; $p < 0.001$) showed a significantly stronger adherence for the medication-app system than the paper diary system with a medium effect size of $\omega^2 = 0.09$ (Fig. 4). Intaking the medication per day (F = 0.072; df = 4; $p = 0.980$) and the number of chronic diseases (F = 2.521; df = 3; $p = 0.244$) as a well as

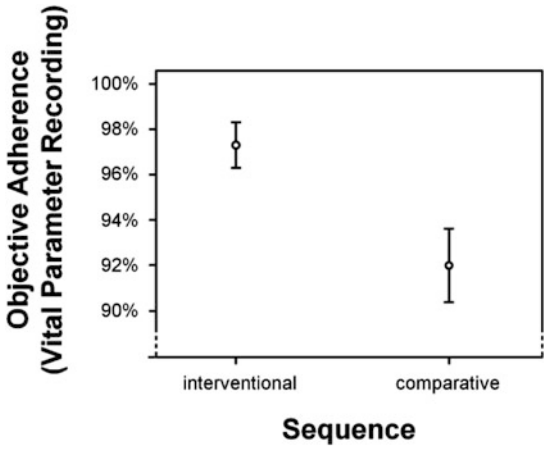

Fig. 4 Analysis of blood pressure documentation

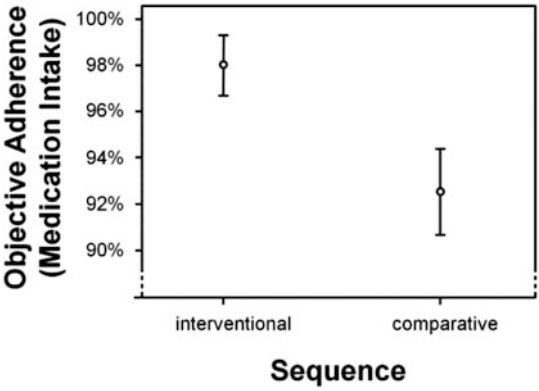

Fig. 5 Analysis of medication intake

required blood pressure readings (F = 0.641; df = 3; $p = 0.700$) did not affect the "recording" adherence for blood pressure monitoring.

The documentation of medication intake showed significantly stronger adherence (F = 361.349; df = 1; $p = 0.033$) while using the medication-app (small effect size $\omega^2 = 0.05$), in relative to the paper system (Fig. 5). Similar to the influence on the blood pressure recording, the documentation of medication intake was not affected by the number of chronic diseases (F = 1.882; df = 2; $p = 0.458$), medication intake/day (F = 11.748; df = 4; $p = 0.215$) and the number of required blood pressure readings (F = 3.138; df = 3; $p = 0.388$).

3.3 Technical Affinity

Technical affinity differentiate significantly after each intervention (F = 13.538; df = 2; $p = 0.003$). The correlation had a medium effect size of $\omega^2 = 0.07$. Further, paired testing showed significant differences between all values (naive vs. tablet-experienced: $p < 0.001$; naive vs. paper diary-experienced: $p = 0.043$, tablet-experienced vs. paper diary-experienced: $p = 0.002$). As expected, the 28 day intervention phase with assistance through the tablet computer had the strongest impact of technical affinity.

Computer literacy of the participants, which was assessed by means of the computer literacy scale (CLS) [16] were positively associated with technical affinity (F = 4.504; df = 2; $p = 0.028$) with a small effect size of $\omega^2 = 0.03$. While the difference between expert and novice is significant ($p = 0.021$), no significant difference could be detected between novice and intermediate ($p = 0.262$) and intermediate and expert ($p = 0.784$).

3.4 Impact of Comorbidities on Usage

The user, which suffer from hypertension were significantly more adherent (small effect size $\omega^2 = 0.05$) for the functionality of vital sign documentation than the other ones ($F = 480.720$; $df = 1$; $p = 0.036$) ($\omega^2 = 0.05$), while there was no significant effect on confirmation of medication intake compared to the other participants without this condition ($F = 35.98$; $df = 1$; $p = 0.131$). Other conditions like diabetes and dyslipidemia did not affect the technical adherence.

3.5 Interviews on User Experience

In structured interviews the vast majority of participants (n = 22) denoted, that they would like to use the medication-app in everyday life, without needing any further assistance. A Few of the participants (n = 2) felt that the system of the medication app would overly control them, while 20 reported that they did not feel that way. Most participants (n = 21) stated that they think that the system was useful for them and a large proportion (n = 18) said they would propose the system to other people. All of the test persons said that the size of the user interface elements was appropriate and that they liked the touch-screen interface and appreciated its precise use. Furthermore, three of the participants noted that "for me, the displayed information could be half of its current size" while almost half of test subjects (n = 11) were comfortable with the font size: "…also suitable for elderly, the numbers are nice and big". All participants liked to use the native iOS picker that displays numerals which are used to enter the blood pressure values. Most of the participants (n = 19) preferred this method over using a keyboard or an on-screen keyboard because it was faster especially since the last entered values were pre-selected. Two mentioned that this method was "fun" and "nice". One of the participants had a red-green color deficiency but had no problems telling apart the different colors of the status of the medication intake (i.e., red, green, and blue). N = 14 users said it was "fun using the system". Another participant denoted "The application and its structure are super". Only minor problems were reported, e.g. two participants forgot how to confirm all of the medication of one single moment of intake and another participant said he struggled twice with how to confirm his medication that he had to take late in the evening but did not confirm before the next day since the app always auto-switches to the current day. Four participants accidentally deleted one of their blood pressure records. All users spent between 1 and 6 min per day using the Medication Plan system app. Only three of them required the manual provided for additional help. Most of the participants (n = 19) preferred using the tablet computer in portrait mode, three of them had no preference. More than a half (n = 13) used the diagram function of the blood pressure values, four used it from time to time and six did not use the diagram function at all. Test persons who used the diagram function summed up that "It is useful to spot

peaks", "It is easy to see whether it is a random outlier or a trend", "It is much clearer than looking at the numbers". Three said they did not use the function at all because they were not able to interpret them: "I took a look but I don't know what to do with it. Without my doctor, I'm not able to explain this graph". One person said that he would like to see the exact moment he confirmed his medication intake.

4 Discussion

The study at hand is the first one to describe a medication-app versus paper-diary intervention to support therapy adherence in a crossover design amongst cardiac patients. Forgetfulness is stated quite often as a reason for unintentional non-adherence, which this study demonstrates. In addition, this study suggests—as other technology intervention studies—that it maybe is a benefit to enhance therapy adherence in future. Thus far in most cases text-messaging has been used to help e.g. aid tobacco cessation, improve physical activity and stimulate weight management efforts and improve diabetic control among countless other applications [14]. Studies with various clinical contexts and integrated text-messaging services report a revised medication adherence [15]. In this context it is interesting to mention that our participants had no experience with mobile devices before this study. However, this is conspicuous since the situation in the generation segment 60+ in neighboring countries is essentially different. For example in Switzerland, more than half of the population with the age between 55 and 69-years uses mobile communication technology [16]. Germany stays behind Spain, Italy, Canada, the US, or the United Kingdom in general usage of smartphones, even with disregarding age [17]. Previous studies confirmed that the lack of acceptance within the target group causes the below average utilization of such applications [18]. On the other hand, we demonstrated that after a relatively short introduction the participants could handle a mobile device quite certain and did not need further assistance. Our results give additional awareness into what has been termed the "digital divide" [19], an expression coined by developers, which implies, that in comparison with the younger generation the elderly generation is less likely to make extensive use of digital technology [20, 21]. It is important to mention that all patients lived autonomously at their home and none was in need of further assistance for activities of daily life, which suggests that they were not severely cognitively affected. All patients were responsible for their own self-management and needed no help by other ones. One critical point of using technology with elderly people is that maybe older adults are unable or have problems to use technology if they have cognitive disturbances. Our research results are contrary to this kind of criticism because the appropriate population for technology are those patients who can manage their illnesses on their own. One may expect that the driver for acceptance is the technology to offer a "relative advantage" over the status quo (Diffusion of Innovation

Model; [22]) and less demographic characteristics of the user [23]. Together with our research results that the technical intervention improves subjective drug adherence, one may reasoned that that the use of applications like "Medication Plan" may improve drug-therapy and -safety.

4.1 Limitations

In this study, the medication intake simply had to be confirmed via the users' iPad. Although a patient's report (confirmation) does not necessarily mean that the patient took the medication essentially. It was also possible, that conversely a participant forgot to report an intake. However, the shown method is very similar to pill counting which gives an objective and quantifiable insight into the level of adherence. Furthermore, assessing adherence for blood pressure recording is slightly different because it could happen that participants may take more records each day than actually arranged. For instance, a participant would still comply an adherence rate of 100 %, if he had to take one record each day and actually took two records on one and none the next day. To eliminate this factor, the adherence was calculated for every single day, capped at the rate of 100 % and then averaged. An additional restriction is the duration of the study, which was carried out within 56 days per user. Other mobile phone researches report that weights users place on user experience and enjoyment of use decrease within a period of five months. However, the weight referring to usability increases. In addition, the objective adherence was acutely high and it was conspicuous that the smart device intervention improved adherence over the already high adherence on the paper diary. Adherence was probably higher with using both applications (the diary and the tablet), caused of the measurement reactivity. However, that either of these conditions is really an intervention. In the following phase of research, medication adherence should be controlled by using electronic monitoring methods such as monitored pill bottles (e.g., MEMS cap), so that the correspondence of objectively monitored medication adherence with self-reported medication taking behavior using the app could be verified. Obviously, these suggestions are for the future and beyond the scope of this study at hand.

4.2 Interpretation

Adherence still illustrates a multi-dimensional problem and cannot be solved solely by Apple's promise "there is an app for that" as it introduced its App Store in 2008. With this study, we demonstrated that a mobile application for medication adherence increased objectively and subjectively measured adherence. However, it is compared with a baseline and a paper diary intervention in elderly users undergoing phase III cardiac rehabilitation. Patients, whose average age was over 70, indicated

an empathy to continue the using of the app. Furthermore, the app was amended with a face-to-face initial training stage and did not require any further technical support. The clinical implication is, that mobile technology, combined with an offline support, can be an effective tool for supporting adherence to medication with elderly populations. These users, which are not technology-savvy, can be conquered by a training phase, which promise that the tools can be spread and utilized over time in cardiac rehabilitation and patient care in general, if sufficient technological support is provided for patients.

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