Relationship Between Clinical, Psychological, Physiological, and Technical Parameters and the Use of Digital Tools During Cardiac Rehabilitation Including Home Training

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Table of Contents

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Abstract

Background: Home and telehealth-based interventions are increasingly used in cardiac rehabilitation (CR), a multidisciplinary model of health care. Digital tools such as wearables or digital training diaries are expected to support patients to adhere to recommended lifestyle changes, including physical exercise programmes. As previously published, the EPICURE study analysed the effects of digital tools, i.e., a digital training diary, adherence monitoring, and wearables, on exercise capacity during out-patient CR phase III (OUT-III) which includes an approximately 12-week home training phase. The study encompassed 149 Austrian patients, of which 50 utilized digital tools.

Objective: The present paper takes a deeper look into the EPICURE data to better understand a) the relation between the use of digital tools and various psychological, clinical, and physiological parameters, and b) the relation between these parameters and the improvement of exercise capacity during cardiac rehabilitation.

Methods: For this work, we analysed questionnaires concerning the patients' CR and data acquired by digital tools during CR. On all these parameters we performed two analyses: 1) Comparison of the two groups with and without digital tools and 2) correlation with the change in the maximum workload as achieved during the exercise stress test. If data pre and post OUT-III were available, the change in the respective parameter during OUT-III was determined and group analysis and correlation were applied on a) data pre OUT-III, b) data post OUT-III, and c) the change during OUT-III.

Results: We found significant improvements in quality of life in both groups, with no discernible differences between patients with or without digital tools. Patients with digital tools perceived significantly higher competence during CR, and they anticipated higher cardiac risks if non-adherent to physical activity. Although, the overall subjectively reported adherence was not significantly different in the two groups, specific items differed: Patients with digital tools were significantly less likely not to do their exercises when they were tired and to forget their exercises. Concerning reasons for (non-) adherence, patients with digital tools reported significantly more often to do their exercises because they enjoyed them, whereas they were significantly less likely a) to stop exercising when pain was worse and b) to continue doing their exercises when pain improved. Finally, patients who reported a high level of concrete planning achieved significantly higher improvements in exercise capacity.

Conclusions: We conclude that digital tools can support adhere to exercise training recommendations during facility- as well as home-based out-patient CR. This comprehensive analysis provides valuable insights into the multifaceted impact of digital tools on outpatient cardiac rehabilitation including home training, shedding light on factors influencing patient outcomes and adherence in the evolving landscape of digital health interventions. Clinical Trial: ClincalTrials.gov Identifier: NCT04458727

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Conclusions: We conclude that digital tools can support adhere to exercise training recommendations during facility- as well as home-based out-patient CR. This comprehensive analysis provides valuable insights into the multifaceted impact of digital tools on outpatient cardiac rehabilitation including home training, shedding light on factors influencing patient outcomes and adherence in the evolving landscape of digital health interventions.

Keywords: mHealth; telehealth; cardiac rehabilitation; wearable; adherence; health-related quality of life; intrinsic motivation; self-efficacy; health action process approach.

Introduction

Motivation

Cardiovascular diseases (CVD) are the leading cause of death worldwide [1]. The burden of CVD – in number of disability-adjusted life years (DALYs) and deaths – and especially the CVD burden attributable to modifiable risk factors increase globally. Therefore, countries are recommended to implement cost-effective public health programs and interventions which target modifiable risks, promote healthy aging across the lifespan, and reduce disability and premature death due to CVD [2].

Background

Cardiac Rehabilitation (CR) is a multidisciplinary model of health care that consists of four phases. Phase I starts during in-hospital treatment (IN-I) and focusses on early mobilization. Phase II can either be performed as in-clinic (IN-II) or outpatient (OUT-II) CR, depending on the availability of OUT-II CR and the patient's individual needs and/or preferences. Phase III (OUT-III) can follow both IN-II and OUT-II and consists of weekly visits at outpatient CR facilities. While during phase II patients are being introduced to the management of cardiovascular risk factors and subsequent lifestyle changes, phases III targets at further improving or at least maintaining results of lifestyle changes achieved during phase II [3, 4]. Home- and telehealth-based interventions are increasingly being used in CR, and depending on the chosen cohort, outcomes for home-based rehabilitation may well compare with centre-based CR programmes in terms of hospitalisations, quality-of-life (QoL), and cost [5].

The success of home- and telehealth-based CR is associated with various clinical, psychological, and physiological parameters, that influence and/or are influenced by the patients' adherence to the CR programme. Various studies have analysed the effect of wearables and home-base CR on the QoL. In a recent review including 57 articles, Jones et al. [6] conclude that home-based CR leads to an improved QoL and exercise capacity.

So far, there is little knowledge concerning the relationship of patients' intrinsic motivation and digital tools during home-based CR. In a small-scale study with 23 patients, Lu et al. [7] identified patients' intrinsic motivation as a key facilitator for successful rehabilitation with remote activity sensing. The rehabilitation program, however, did not focus on cardiac patients and none of the patients were reported to have a cardiac disease. Nonetheless, considering the broader context of health behaviour change, which ties in closely with multiple of the above-mentioned CR components, there is a considerable body of research supporting the importance of (intrinsic) motivation [8]. Many current psychological models of health behaviour, such as the Health Action Process Approach (HAPA), place motivation and resulting intentions (motivational phase) as a prerequisites of health behaviour engagement, distinguishing it from a second, volitional phase, which translates intentions into actual behaviour [9]. In the motivational phase, the HAPA proposes risk perception and outcome expectancy as determinants of intentions. Consecutively, action planning, self-efficacy, and action control are proposed to affect the enactment of these health behaviour intentions. Therefore, all of these are promising targets for health interventions [10-12]. Various studies analysed self-efficacy and behavioural driving models during home-based rehabilitation [13-16], indicating that there is a huge potential for addressing psychological drivers in digital technologies used in CR.

When implementing digital tools to support CR, user-friendly interfaces are crucial, since poor usability is a main barrier of digital technologies in CR, as recently highlighted by McGowan et al. [17].

The multicentred EPICURE study analysed the effect of digital tools in outpatient cardiac rehabilitation including home training. As previously published [18], 50 out of 149 patients reported to have used digital tools during OUT-III CR. Details concerning the EPICURE study population at baseline (prior to OUT-III CR) are shown in (Table 1). At baseline, patients using digital tools were significantly younger, fitter in terms of the maximum power during ergometry (P_{max}), had a lower BMI and body weight, and reported a higher QoL in all four aspects of the MacNew questionnaire prior to OUT-III.

Table 1. Study population at baseline (prior to cardiac rehabilitation phase OUT-III) as described in [18]. Data are presented as mean ± standard deviation. p-values were calculated with a t-test.

	Without digital tools	With digital tools	*P*
Number of patients (female)	107 (30)	50 (11)	
Age	62 ± 9 y	55 ± 13 y	<.001
Maximum power during ergometry (P_{max})	142 ± 41 W	186 ± 53 W	<.001
Body mass index (BMI)	27.9 ± 4.7 kg/m²	26.4 ± 4.4 kg/m²	.038
Body weight	86 ± 16 kg	82 ± 13 kg	.13
Blood pressure – systolic	118 ± 11 mmHg	120 ± 17 mmHg	.77
– diastolic	77 ± 8 mmHg	75 ± 8 mmHg	.45
Lab – Glucose	105 ± 19 mg/dL	99 ± 30 mg/dL	.23
– Cholesterol – LDL	85 ± 32 mg/dL	77 ± 35 mg/dL	.23
– HDL	48 ± 12 mg/dL	52 ± 12 mg/dL	.043
– Triglycerides	115 ± 53 mg/dL	99 ± 59 mg/dL	.16
Non-smoker / ex-smoker / smoker	28 / 46 / 14	18 / 23 / 1	.06
MacNew – Physical	5.64 ± 0.93	6.15 ± 0.81	.009
– Emotional	5.57 ± 0.91	6.01 ± 0.80	.019
– Social	5.84 ± 0.91	6.23 ± 0.87	.043
– Global	5.68 ± 0.88	6.11 ± 0.76	.017

EPICURE's primary outcomes did not support the hypothesis that the additional use of digital tools like digital diaries and/or wearables during home training lead to further improvement in P_{max} during and after phase III cardiac rehabilitation. So far, the relationship between clinical, psychological, and physiological parameters as recorded in the EPICURE study had not been analysed in detail.

Objectives

The present paper takes a deeper look into the EPICURE data to better understand a) the relationship between the use of digital tools and aforementioned psychological, clinical, and physiological parameters, and b) the relationship between digital tools, psychological, clinical, and physiological parameters and the improvement of exercise capacity during CR. Results are discussed a) in relationship to the primary outcome of the EPICURE study as published in [18] and b) concerning their accordance with the state-of-the-art.

Methods

Dataset

Data were taken from the EPICURE study [18]. During the study, patients were asked to a) answer a questionnaire concerning their CR, and b) to grant access to data acquired during CR. The structure of the analysed data is described in the following.

Quality-of-life (QoL)

We used the German version of the MacNew heart disease health-related QoL questionnaire [19] to assess QoL a) before and b) after OUT-III. MacNew was designed to evaluate how daily activities and physical, emotional, and social functioning are affected by coronary heart disease and its treatment. The questionnaire consists of 27 items concerning three domains (physical limitations, emotional function, and social function), with a maximum score of seven per domain. MacNew is routinely assessed before and after CR by the centres participating in the EPICURE study. Therefore, unlike most other parameters, even differences of QoL pre versus post CR and their relationship to the use of digital tools and to CR outcomes were analysed.

Intrinsic motivation

We used the German version of the Intrinsic Motivation Inventory (IMI) [20] to analyse relations between intrinsic motivation, digital tools, and outcomes of CR. IMI is a standardized multidimensional measurement device intended to assess participants' subjective experience related to a target activity in laboratory experiments. The target activity was defined as “physical activity during the home training phase”. IMI consists of 22 items concerning the categories “interest/enjoyment”, “perceived competence”, “perceived choice”, and “felt pressure and tension”.

Health action process approach

Self-efficacy was determined based on the German version of the Self-Efficacy Scale by Jerusalem and Schwarzer [21]. Additionally, we included the following parts of the health action process approach (HAPA) described by Schwarzer [22] in the questionnaire: Intention, action planning (planning), coping planning (control), outcome expectations, and risk perception. Seven questions concerning intentions prior OUT-III, ten questions concerning concrete planning of physical activity during OUT-III, and six questions concerning control during OUT-III were provided to the participants. Additionally, one question concerning expected health benefits of PA (outcome expectations) and one question concerning expected cardiac risk of non-adherence to PA (risk perception) were retrieved. All these questions were implemented in a four-fold Likert scale.

Self-reported adherence to the exercise program

Patients were asked to answer 17 questions concerning their adherence to CR, which were based on the Exercise Adherence Rating Scale (EARS) [23]. Eleven out of the 17 questions concerned reasons for non-adherence, while the remaining six questions focussed on adherence. EARS was translated to German and slightly adapted according to the study needs (see figures in chapter 3.4 for the detailed questions). As compared to the original EARS which applies a 5-fold Likert scale, binary responses (yes / no) were implemented.

Objective adherence measures from digital diaries

For all patients, we analysed whether access to data from any CR supporting tool was available. In three out of five participating CR facilities, access to digital diary data could be established, based on the following two tele-rehabilitation services:

- The Heartfish App (hearfish GmbH, Wien, Austria) supports medical training therapy (MTT), which can be applied to various clinical settings, such as CR, cancer, multiple sclerosis, etc. Heartfish was used in one of the five CR facilities.
- The AIT Telehealth Service (AIT Austrian Institute of Technology GmbH, Vienna, Austria) is a web-based service supporting rehabilitation, disease management programs, and tele-monitoring in multi-disciplinary care settings for various indications such as diabetes, stroke, heart failure, dermatology, etc. [24-27]. The AIT Telehealth Service was used in two of the five CR facilities.

Some patients used other digital tools. However, no access to those data could be established. The following parameters which were available in both systems were calculated for each patient for each week:

- Number of activities per week
- Active time per week [min]
- Mean heart rate during exercise [bpm]
- Number of recorded steps per week

Even if telehealth records of some patients were available for longer time periods, only data relating to activities during OUT-III were analysed. We analysed a) if the parameters differed between patients using different tools (AIT Telehealth System versus Heartfish), b) if the respective parameters correlated with ΔP_{max}, and c) if the respective parameters correlated with the self-reported adherence.

System Usability Scale

We used the System Usability Scale (SUS) [28] to assess usability of the tools used during CR for those patients who reported to have used digital tools. The SUS is a widely used tool to measure usability, which contains 10 items implemented in a five-fold Likert scale.

Statistical Analysis

The maximum mechanical power P_{max} [W] as achieved by patients during the exercise stress test at their regular assessments in the study centres pre and post OUT-III was analysed. The difference ΔP_{max} [W] between P_{max} at the end of OUT-III minus P_{max} at the beginning of OUT-III was determined. If no data from the assessment prior to OUT-III was available, data from the assessment post phase II was taken instead.
For each of the parameters described in chapter 2.1, we performed two analyses:

1) Comparison of the two groups with and without digital tools
2) Correlation with ΔP_{max}

For the correlation with ΔP_{max} the groups defined by the digital tools were not regarded, hence only one r per parameter was calculated. Where data for both, pre and post OUT-III, were available, the change in the respective parameter during OUT-III was determined and group analysis and correlation were applied on a) data pre OUT-III, b) data post OUT-III, and c) the change during OUT-III.
Normal distribution of the data was tested by the Shapiro-Wilk test. A student t-test was applied to test for global differences between pre- to post CR (dependent t-test) and for differences between the

groups (independent t-test). A value of alpha <.05 was considered significant. Where appropriate, we applied ANCOVA statistics to correct for confounders. Changes pre versus post CR were analysed with boxplots and two-tailed t-tests based on matched pairs. The correlation coefficients r were calculated using Pearson's correlation coefficient and the significance of the influence was calculated using ANCOVA. If not stated otherwise, the cofounders considered in the ANCOVA were the age, P_{max}, body mass index, and the global MacNew score, all measured at the start of OUT-III.

Ethics

The EPICURE study protocol was approved by the ethics committee of Upper Austria (vote nr. 1165/2019) and registered at ClincalTrials.gov (Identifier: NCT04458727). All participants received oral and written information prior to the study entry and provided written informed consent to participate in this study. All data were recorded in a pseudonymised way and anonymity was ensured for all participants during presentation of the findings.

Results

Quality of life (QoL)

As illustrated in (Table 2), the QoL according to the global MacNew score, significantly improved in patients without (*P=.004*) as well as patients with digital tools (*P=.012*). A significant increase in the physical sub-questionnaire has been identified for the group without (*P < .001*) and with digital tools (*P=.043*). The group with digital tools showed a significant improvement concerning the emotional QoL subsection (*P=.002*) while the group without digital tools achieved a significant increase in the social QoL score (*P=.004*).

Table 2. Mean ± standard deviation of the quality-of-life as reported by the MacNew questionnaire (mean per sub-category, 1…strongly disagree, 7… strongly agree). The number of data points available for each analysis is shown in brackets. Sub-categories (physical, emotional, and social) and global scores pre and post OUT-III cardiac rehabilitation including home training, as well as the difference between pre and post OUT-III are shown (p-value pre vs post). Differences between the groups with and without digital tools are provided (p-value between groups).

		Without digital tools	With digital tools	*P* between groups
Physical	Pre	5.64 ± 0.93 (74)	6.15 ± 0.81 (32)	.024
	Post	5.92 ± 0.82 (63)	6.38 ± 0.80 (13)	.037
	Pre vs. post	<.001 (62)	0.043 (13)	.21
Emotional	Pre	5.57 ± 0.91 (74)	6.01 ± 0.80 (32)	.014
	Post	5.71 ± 0.95 (63)	6.40 ± 0.70 (13)	.002
	Pre vs. post	0.15 (62)	0.002 (13)	.94
Social	Pre	5.84 ± 0.91 (74)	6.23 ± 0.87 (32)	.07
	Post	6.11 ± 0.84 (63)	6.42 ± 0.79 (13)	.06
	Pre vs. post	0.004 (62)	0.84 (13)	.78
Global	Pre	5.68 ± 0.88 (74)	6.11 ± 0.76 (32)	.029
	Post	5.91 ± 0.85 (63)	6.39 ± 0.73 (13)	.017
	Pre vs. post	0.004 (62)	0.012 (13)	.53

The change of the global QoL pre vs. post OUT-III for both groups is illustrated in (Figure 1). Although both groups improved, no significant differences in the improvement between the two groups were found according to the ANCOVA analysis, neither for MacNew global nor for any of the sub-categories.

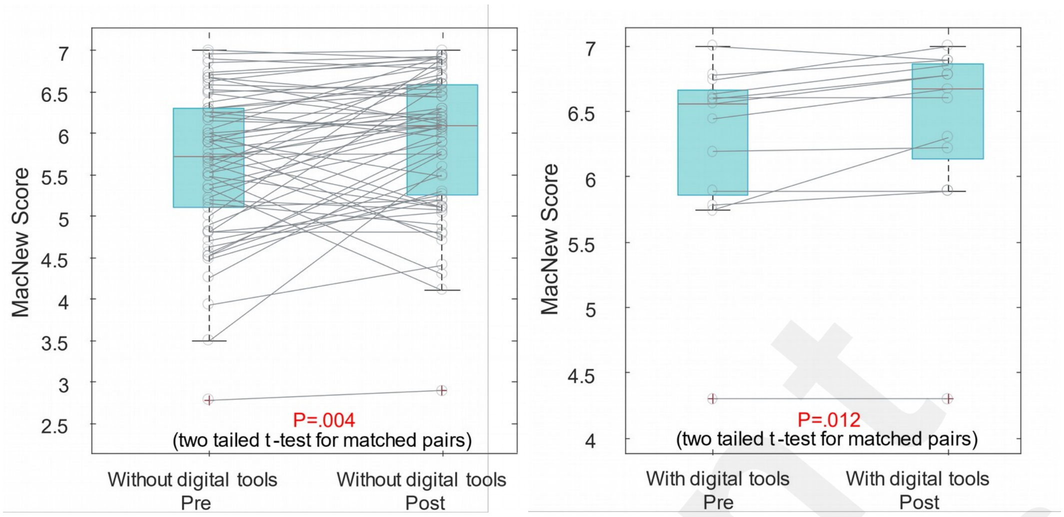

Figure 1. Quality-of-life according to the global MacNew score pre vs. post OUT-III for patients without digital tools (left) and with digital tools (right), illustrated as boxplots with matched pairs. Markers pre and post which are connected by lines correspond to one and the same patient.

As shown in (Table 3), there were no correlations between changes in QoL scores and ΔP_{max}.

Table 3. Pearson's correlation coefficient *r* (p-value calculated via ANCOVA) between changes of quality-of-life in sub-categories physical, emotional, and social as well as the global overall score as reported by the MacNew questionnaire and the change in exercise capacity ΔP_{max}.

	Correlations with ΔP_{max}	
	r	*P*
ΔPhysical	0.20	.16
ΔEmotional	0.09	.84
ΔSocial	0.18	.28
ΔGlobal	0.19	.20

Intrinsic motivation scale (IMS)

(Table 4) shows results per sub-section of the IMS as well as the aggregated score over all four categories. A significant difference in the item group concerning perceived competence was found between patients with versus without digital tools (*P=.049*). No significant correlation with ΔP_{max} was identified (*P=.57*). Additionally, the IMS score for interest/enjoyment and the total IMS score showed borderline significant differences between the groups. In all significant/borderline significant cases, the group with digital tools achieved higher scores.

Table 4. Mean ± standard deviation of the Intrinsic Motivation Scale (IMS, 1…strongly disagree, 5…strongly agree) and differences between the groups and Pearson's correlation coefficient *r* (p-value calculated via ANCOVA) between the IMS and change in exercise capacity ΔP_{max}.

	Influence of the group			Correlation with ΔP_{max}	
	Without digital tools	With digital tools	*P*	r	*P*
Interest/enjoyment	2.58 ± 0.83	3.16 ± 0.68	.08	0.27	.41
Perceived choice	3.15 ± 0.78	3.49 ± 0.69	.50	0.20	.39
Perceived competence	2.58 ± 0.78	3.24 ± 0.78	.049	0.23	.57
Felt pressure and tension	2.80 ± 0.84	3.10 ± 0.91	.66	0.06	.31
Total	2.77 ± 0.62	3.25 ± 0.57	.09	0.25	.74

Health action process approach

As summarized in (Table 5), we did not identify a significant difference between the patients without and with digital tools concerning the self-efficacy (*P* =.95). Additionally, there was no significant correlation between self-efficacy and the change in exercise capacity ΔP_{max} (*P=.16*). We did not identify any significant differences between patients without and with digital tools regarding the intention, control, and planning scores. However, the planning score was significantly correlated with ΔP_{max} (*P*=.039, *r=0.14*). (Table 5) also shows results concerning the patients' expected health benefit of PA (outcome expectations) and cardiac risk of non-adherence to PA (risk perception). Borderline significance (*P=.06*) was found between outcome expectations and ΔP_{max}. Patients with digital tools reported to expect significantly higher cardiac risks, if they were inadherent to PA (*P=.028*).

Table 5. Mean ± standard deviation of health action process approach scores (Self-efficacy: sum of 10 items, each item 1…strongly disagree, 4…strongly agree; all other parameters: mean per category, 1…strongly disagree, 4…strongly agree) per group and difference between group including p-value and Pearson's correlation coefficient r (p-value calculated via ANCOVA) between the scores and change in exercise capacity ΔP_{max}.

	Influence of the group			Correlation with ΔP_{max}	
	Without digital tools	With digital tools	*P*	r	*P*
Self-efficacy	31.80 ± 3.91	32.20 ± 5.55	.95	0.08	.16
Intention	3.33 ± 0.49	3.46 ± 0.50	.92	0.11	.36
Control	3.22 ± 0.59	3.51 ± 0.52	.21	0.17	.13
Planning	2.90 ± 0.57	3.15 ± 0.62	.10	0.14	.039
Outcome expectations	3.75 ± 0.54	3.88 ± 0.33	.82	0.13	.06
Risk perception	2.95 ± 0.83	3.31 ± 0.85	.028	0.02	.57

Subjective adherence questionnaire

As shown in (Figure 2), patients with versus without digital tools significantly differed in five out of 17 EARs related questions.

Concerning adherence-related items, patients without digital tools reported to do their exercises significantly less often when tired (item 9). Patients with digital tools reported forget to do their exercises significantly less often (item 15).

Concerning reasons for none-adherence, item 12 (“I do my exercises because I enjoy them”) was significantly more important in patients with digital tools. Pain-related items were more important in the group without digital tools (item 14 and item 17), although high scores of item 14 represent low adherence, while high scores for item 17 relate to high adherence.

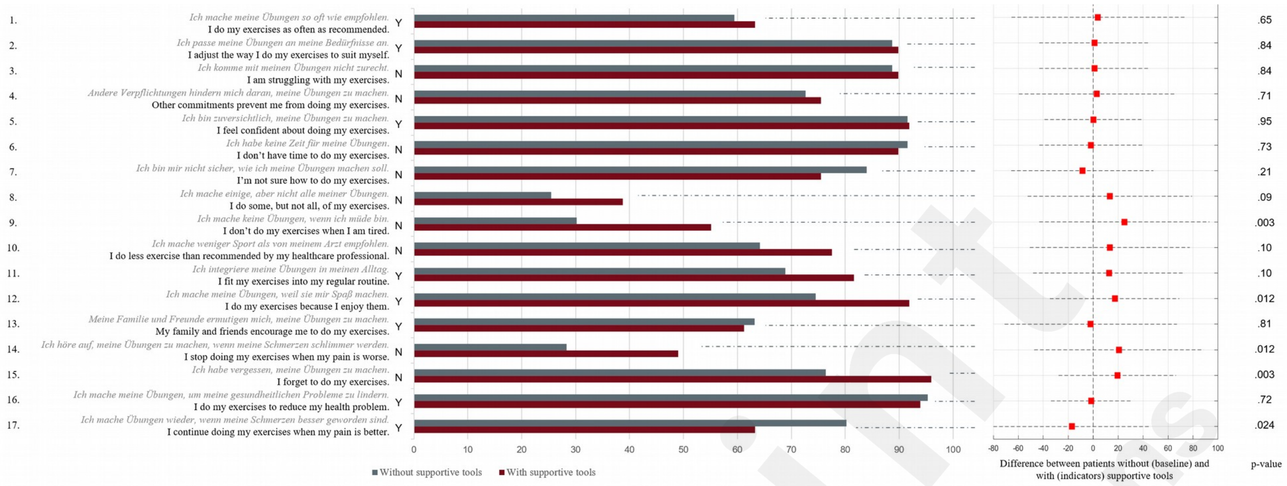

Figure 2. Results of the subjective adherence questionnaire per group with the original questions in German (grey) and the English translation (black).
Left: Percentage of patients per group, answering with Yes / No as indicated beside the bars. Yes / No are aligned alternatingly, depending on positive / negative phrasings of the respective questions, so that end-to-end bars relate to positive behaviour. Right: The difference of the score per item between patients with versus without digital tools, including the corresponding p-value.

(Table 6) shows that the overall EARs related score as well as the adherence as calculated by items 1, 3, 8, 10, 11, and 15 resulted in no significant difference between the patients without and with digital tools. Neither of the scores significantly correlated with ΔP_{max}.

Table 6. Mean ± standard deviation of the adherence related score (items 1, 3, 8, 10, 11, and 15) and the overall subjective adherence questionnaire score (sum of selected items, 0…no, 1…yes), compared between the groups and Pearson's correlation coefficient r (p-value calculated via ANCOVA) between the scores and the change in exercise capacity ΔP_{max}

	Influence of the group			Correlation with ΔP_{max}	
	Without digital tools	With digital tools	*P*	r	*P*
Adherence-related score	3.79 ± 1.71	4.38 ± 1.58	.57	0.01	.27
Overall score	11.80 ± 2.74	12.80 ± 2.79	.50	0.07	.21

Objective adherence measures from digital training diaries

For 17 out of 27 patients who registered for Heartfish, and for 10 out of 16 patients who registered for the AIT Telehealth Service, detailed home-training data were available. The remaining 16 patients were excluded from the following analysis.

(Table 7) shows the correlation between the objective adherence measures obtained from the uploaded tele-rehabilitation data and the change in exercise capacity ΔP_{max}. Since objective adherence measures were only available for patients with digital tools, no comparison between patients with and without digital tools is provided. Instead, data are grouped according to the tele-rehabilitation service used (Heartfish / AIT Telehealth Service). For each measure, the mean ± standard deviation over all patients of the respective data – aggregated per week – are presented. For the ANCOVA analysis of the objective adherence measures, only the systolic blood pressure was identified as a confounder between the Heartfish and AIT Telehealth Service patients.

Table 7. Mean ± standard deviation of the parameters of the digital training diaries and Pearson's correlation coefficient r (p-value calculated via ANCOVA) between the parameters and change in exercise capacity ΔP_{max}.

Digital training diary parameter				Correlation with ΔP_{max}	
	Heartfish (N=17)	AIT Telehealth Service (N=10)	*P*	r	*P*
Mean number of activities per week	3.05 ± 1.65	2.37 ± 1.83	.25	-0.05	.80
Mean active time per week [min]	165 ± 114	300 ± 220	.09	-0.15	.39
Mean number of steps per week	49,250 ± 34,560	33,210 ± 30,560	.22	0.02	.91
Mean per week of the mean heart rate during exercise [bpm]	115 ± 11	105 ± 13	.014	0.28	.16

No significant difference between Heartfish (N=17) and the AIT Telehealth Service (N=10) was identified, regarding the number of active days per week (a day with at least one logged activity) (*P=.25*), the active time throughout the week (sum of all logged activity durations) (*P=.09*) and the number of steps per week (*P=.22*). We did, however, identify a significant difference between Heartfish and the AIT Telehealth Service regarding the heart rate during exercise (*P=.014*).

The objective adherence measures correlated with the subjective adherence score (EARs) as shown in (Table 8). The number of activities per week and the weekly active time both showed significant correlation with the overall EARs score (*P=.044* and *P=.022* respectively).

Table 8. Pearson's correlation coefficient r (p-value calculated via ANCOVA) between the parameters of the digital training diaries and the adherence specific and overall subjective adherence questionnaire.

	Subjective adherence questionnaire			
Objective adherence measures	Adherence related score		Overall score	
	r	*P*	r	*P*
Mean number of activities per week	0.28	.15	0.39	.044
Mean active time [min]	0.30	.06	0.40	.022
Mean number of steps per week	0.32	.12	0.36	.08
Mean per week of the mean heart rate during exercise [bpm]	0.25	.18	0.05	.79

System Usability Scale

As can be seen in (Table 9) the usability measured with the SUS scale did not show a significant difference between the tele-rehabilitation services (*P* =.98). Additionally, we did not identify a significant correlation between the SUS score and ΔP_{max} (*P*=.32) or the type of used tool and ΔP_{max} (*P*=.11).

Table 9. Mean ± standard deviation of the System Usability Scale (SUS) scores (10 items, 1…strongly disagree, 5…strongly agree, mapped to a scale from 0-100, see [28]) and of the change in exercise capacity ΔP_{max} depending on the telehealth services. Additionally, Pearson's correlation coefficient r (p-value calculated via ANCOVA) between SUS and ΔP_{max} is provided.

	Difference between the groups				Correlation with ΔP_{max}	
	Heartfish (N=26)	AIT Telehealth Service (N=10)	Others (N=13)	*P*	r	*P*
SUS score	74.7 ± 17.9	76.2 ± 21.9	75.0 ± 18.6	0.98	0.11	0.48
ΔP_{max} [W]	16.3 ± 14.2	24.6 ± 27.0	14.0 ± 18.2	0.43	-	-

Discussion

Principal Results

In this work we analysed the secondary hypotheses of the EPICURE study (primary outcomes have been published previously [18]), i.e., the effects of digital tools in outpatient CR including home training.

Our main findings are that, according to the MacNew questionnaire, QoL improved significantly during OUT-III CR, with similar improvement in patients without and with digital tools. Further, we found that patients with or without digital tools significantly differed in the following aspects:

- Patients' perceived competence during CR was significantly higher in patients with as compared to patients without digital tools.
- Patients with digital tools reported significantly more often to expect an increased risk for future cardiac events if they were not adequately physically active in the future.
- Patients with digital tools were significantly less likely "not to do their exercises when they are tired" and to "forget to do their exercises". Concerning reasons for (non-) adherence,

patients with digital tools significantly more often reported to do their exercises because they enjoyed them. Additionally, patients with digital tools were significantly less likely a) to stop exercising when pain got worse and b) to continue doing their exercises when there was a relieve in pain. However, the subjectively reported overall adherence was not significantly different in the two groups.

- Patients who reported a high level of concrete planning to perform exercise training during CR achieved significantly higher improvements in ΔP_{max}.

Comparison with Prior Work

The previously published EPICURE paper [18] summarized that, overall, exercise capacity improved both in patients with and without digital tools. When comparing changes with t-tests, patients with digital tools improved significantly more than patients without digital tools. However, this change did no longer reach statistical significance when correcting for confounders with an ANCOVA analysis. In the present paper, wherever suitable, p values were based on ANCOVA corrected for confounders.

Subgroup analyses in [18] revealed that digital training diaries in combination with heart rate monitoring during training or activity trackers significantly improved the exercise capacity compared to patients without digital training diaries and additional monitoring or tracking. However, in the current paper no significant correlation between ΔP_{max} and the objective adherence measures obtained from the digital training diaries, heart rate monitors and activity trackers was identified (see Table 7).

Jones et al. [6] reported that digital tools resulted in a significantly higher improvement of QoL for the home-based compared to the centre-based CR group. Although we identified a significant improvement in both groups, no significant difference in the improvement of the QoL between patients with or without digital tools was found. In both groups, QoL was already high before OUT-III CR, with a mean of 5.68 (without) and 6.11 (with digital tools) out of 7.00 possible points. These high QoL scores prior to OUT-III in combination with a small sample size of patients with MacNew data pre and post OUT-III, especially in the group with digital tools (n=13), might explain the difference between Jones et al. and our results.

The higher IMS scores in the group with digital tools are in line with Lu et al. [7], who identified patients' intrinsic motivation as a key facilitator for successful rehabilitation of chronically ill/on the verge of being chronically ill patients with remote activity sensing. Our results indicate that digital tools can also help to motivate cardiac patients, without exposing patients to additional distress. However, since IMS was asked retrospectively, patients who knew that they were adherent may have been influenced by this knowledge when retrospectively evaluating their motivation prior to the program. Therefore, and since there is only little literature on this topic so far, prospective studies might be indicated to get a deeper insight into the relationship between intrinsic motivation and digital tools during CR.

Unlike a previous study by Salah Eldin Saad et al. which showed significant differences in self-efficacy [29], our study indicates that self-efficacy neither differed between patients with and without digital tools, nor was there a significant correlation with the achieved change in exercise capacity. In part, this result can be explained by the retrospective nature of the EPICURE study. However, the relationship between self-efficacy, digital tools and outcome of CR might further be studied in the future.

The change in exercise capacity ΔP_{max} correlated significantly with the level of planning, as retrieved from ten items in a respective questionnaire (Table 5). No significant difference between patients with and without digital tools was identified. Additionally, there was no significant difference or correlation concerning the intention and control dimension of the questionnaire. As Scholz et al. suggested, planning predicts behavior when intention scores are high [10], which was confirmed by our findings that showed a significant correlation between the planning score and ΔP_{max}.

The outcome expectation showed a marginally significant influence on ΔP_{max}, therefore, it might be beneficial to strengthen the patients' expectation during OUT-III rehabilitation.

Even though the risk perception did not influence the outcome ΔP_{max} we identified a significant difference between patients with and without digital tools. Since patients with digital tools had a higher score on the risk question this might be an indicator that patients who are more aware of their risk are more willing to participate in home-based CR.

Results from the exercise adherence questionnaire revealed that the use of digital tools in CR is associated with higher exercise adherence and to support patients to do their exercises even when they are tired. Additionally, patients with digital tools reported more often to do their exercises because they enjoy them. This is in line with the results from the IMS questionnaire, which also showed higher interest and enjoyment scores in the group with digital tools. Differences in the IMS scores did, however, not reach statistical significance. Since the data were analysed retrospectively, people who decided to use digital tools might have been more motivated in general and, therefore, better in adhering to their exercise plans.

Significant differences in the subjective adherence scores related to pain are expected to be caused by different baseline characteristics concerning pain the two groups. However, since pain itself was not recorded in our study, these results might require further analyses in the future.

For patients using digital tools, objective adherence scores were analysed, where accessible, which resulted in no significant difference between the type of tool that was used and the usability scores or the achieved improvement in exercise capacity. Both analysed tools (Heartfish, AIT Telehealth Service) showed high usability. However, usability scores did not significantly correlate with the change in exercise capacity.

In their recent study, Serves et al. [30] reported a mismatch between patients' perceptions of their physical activity and actual level of activity. This is in line with our results: although we identified a significant correlation between subjective and objective adherence scores, the correlation was moderate only (up to 0.40).

The mean number of steps per week did not correlate with the subjectively reported adherence scores. This might be either caused by incomplete step counting (e.g., patients wearing the sensor only during exercises) and/or by the subjective questionnaire, which focused on exercises, not weekly steps. Also, no correlation between subjectively reported adherence scores and the mean heart rate during exercises was identified. However, the mean heart rate per week during exercise [bpm] differed significantly between the two tools we had access to (Heartfish and AIT Telehealth Service). Since the tools were used in different centers, we expect that the difference was not related to the tools but to the patient group or CR plan in the respective centers.

Since the study design was retrospective except for the questionnaires, patients were not randomised, but grouped according to their response to an item in the questionnaire that asked whether they used digital tools or not. However, during analysing the objective adherence measures from the tele-rehabilitation systems, five patients (0 from Heartfish and five from the AIT Telehealth Service) who did obviously use but reported not to have used a digital diary were identified. Nevertheless, in accordance with the initial group definition, group assignment was kept based on the patients' answer even in these cases. In addition, there were of course several patients that reported to have used digital tools, although no data in Heartfish or the AIT Telehealth Service were found. These patients were expected to have used other services / wearables / etc. Due to these reasons, the group with digital tools was quite heterogeneous, which needs to be kept in mind when interpreting our results.

Limitations

Most questionnaire data were recorded at the time of study entry of the patients, i.e., post OUT-III. Therefore, except for those questionnaires that were routinely recorded during CR (e.g., MacNew prior to OUT-III), all questions dealing with data before the end of OUT-III need to be interpreted

with care, since the answers might have been influenced by the patients' experiences during OUT-III and different answers might have been given in a prospective setting.
During sample number calculations in the study preparation phase, we assumed that approx. 50% of patients would report to have performed CR with and without digital tools, respectively. However, questionnaire data revealed that approx. one third did and two thirds did not use digital tools, which reduced the power of our analyses. Since especially the number of patients using digital tools was rather low, additional studies with larger sample size may be indicated. For future work, a prospective study is warranted that randomizes patients to either a group with or without digital tools, preferably including stratification on those baseline parameters that were found to have significant influence on CR outcomes, i.e., age, P_{max}, BMI, body weight, and QoL.

Conclusion

We conclude that digital tools used during out-patient CR phase III including home-training can increase perceived confidence and improve joy during CR. Additionally, digital tools can help to not forget exercises and to do the exercises even when tired. Concrete planning is correlated with better improvement in exercise capacity and should be fostered during phase III CR.

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Conflict of Interest

Author Karl Mayer is employed by heartfish GmbH and CARDIOMED Kardiologisches Rehabilitationszentrum GmbH and holds 20 % shares in both companies.
Author Norbert Mürzl is employed by Cardio Vital Wels.
Author Christoph Puelacher is employed by Reha Innsbruck, REHAmed-tirol GmbH and holds 100% of the company's shares.
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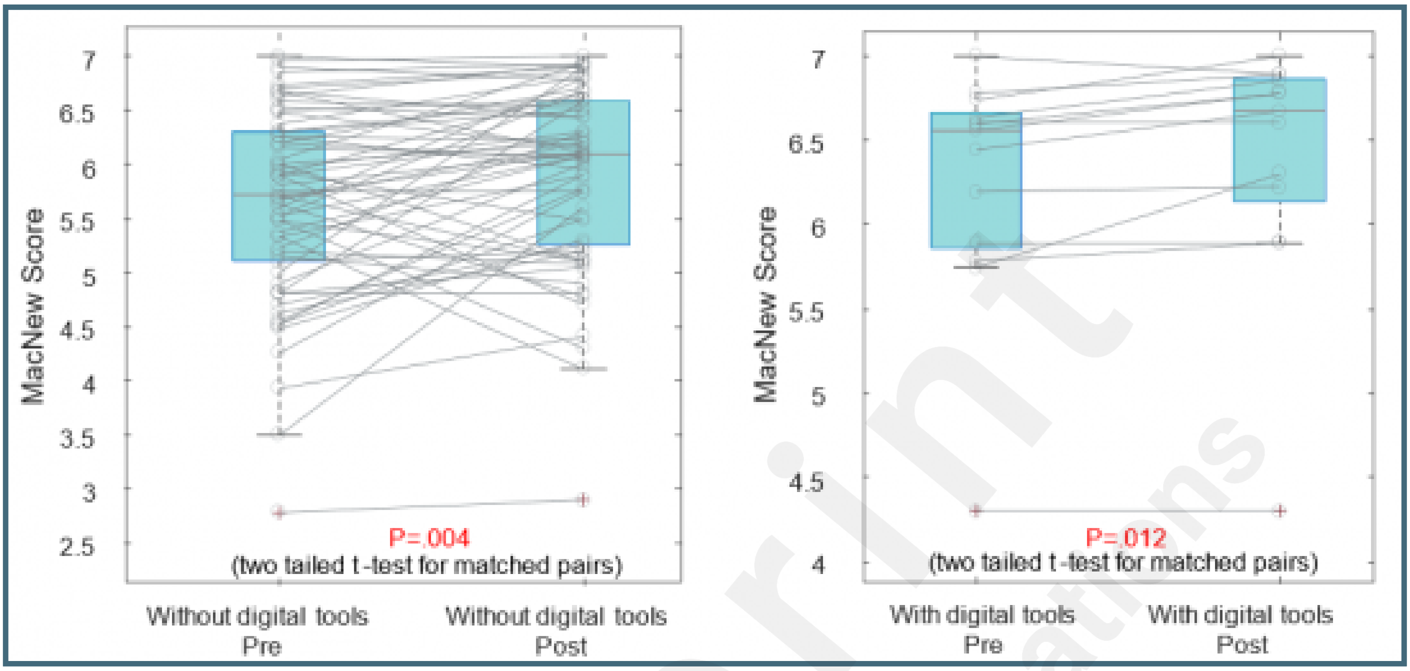
Supplementary Files

Figures

Quality-of-life according to the global MacNew score pre vs. post OUT-III for patients without digital tools (left) and with digital tools (right), illustrated as boxplots with matched pairs. Markers pre and post which are connected by lines correspond to one and the same patient.



Results of the subjective adherence questionnaire per group with the original questions in German (grey) and the English translation (black). Left: Percentage of patients per group, answering with Yes / No as indicated beside the bars. Yes / No are aligned alternatingly, depending on positive / negative phrasings of the respective questions, so that end-to-end bars relate to positive behaviour. Right: The difference of the score per item between patients with versus without digital tools, including the corresponding p-value.