Digitally Enhanced Recovery: Investigating the Use of Digital Self-Tracking for Monitoring Leisure Time Physical Activity of Cardiovascular Disease (CVD) Patients Undergoing Cardiac Rehabilitation

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Abstract

In this study, we investigate the effects of using smart wearables by patients undergoing cardiac rehabilitation. A field experiment involving 29 patients was designed and participants were either assigned to the study group (N=13 patients who finished the study and used a self-tracking device) or the control group (N=16 patients who finished the study and did not use a device). For both groups data about physiological performance during cardiac stress test was collected at the beginning (baseline), in the middle (in week 6), and at the end of the study (after 12 weeks). Comparing the physiological performance of both groups, the data showed significant differences. The participants in the study group not only maintained the same performance level as during the midterm examination in week 6, they improved performance even further during the six weeks that followed. The results provide evidence for positive effects of digital self-tracking by patients undergoing cardiac rehabilitation on performance of the cardiovascular system. In this way, our study provides novel insight about the effects of the use of smart wearables by chronic disease patients. Our findings have implications for the design of self-management approaches in a patient rehabilitation setting. In essence, the use of smart wearables can prolong the success of the rehabilitation outside of the organized rehabilitation setting.

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Guidelines

Recruite participants from routine rehabilitation groups on the day of their baseline examination. Design the groups for the study to avoid an overlap of study and control group participants in the same routine rehabilitation group to ensure that participants of different groups could not influence each other.

Standard diagnostic processes (in cardiology), like the exercise test for enabling determination of a participant’s maximum exercise capacity, should follow the latest Practice Guidelines for Exercise Testing which provide recommendations about the procedure of testing, the valuation of measured

parameters, possible influences and interruption or termination criteria.

Before start

A consent form has to be signed by the patient and the responsible author after all patient questions were answered satisfactorily; hence the patient completely understands the way in which the study will be conducted, is aware of his rights as a participant, is willing to consent to participation and confirmes that he/she had had enough time to think about whether he/she wishes to participate in the study or not.

Protocol

Method

Step 1.

Select male patients who attend outpatient cardiac rehabilitation phase II (follow-up treatment after early mobilization or hospital stay after an acute cardiac event) randomly and divide them into two groups by a standard software-based random sample generator.

Method

Step 2.

Provide one group of patients, referred to as ‘study group’, with activity trackers for a duration of 12 weeks and ask them to perform a supplementary examination at the end of their observation period. Ask the other group of patients, referred to as ‘control group’, to undergo a supplementary examination 12 weeks after commencement of their rehabilitation without any further intervention (no activity tracking).

Method

Step 3.

To compare improvement of different parameters (e.g., performance of cardiovascular system) between the study and control group, analyze results based on three different examinations ($t1$, $t2$, $t3$). Perform the baseline examination at the beginning (in week 1=$t1$) and the midterm examination at the end (in week 6=$t2$) of the rehabilitation programme. Perform a supplementary examination after 12 weeks (in week 13=$t3$). Therefore, the observation period (period for tracking and monitoring of physical activity) is 12 weeks per participant.

Method

Step 4.

All participants should attend routine cardiac rehabilitation during the first six weeks of the study with heart rate controlled moderate to vigorous physical activity, nutritional education, and psychological support. Exercises are partly supervised at the rehabilitation centre and partly conducted at home. The recommendation and duration of the patients’ medication should not be affected by this field

experiment and therefore remain unchanged. Further, there is no additional medication for reasons related to this study. After the examination six weeks from start participants get medical recommendations for their future lifestyle (including physical activity). For the following six weeks (until the supplementary examination in week 13) the study group participants continue to wear the activity tracker. Thus, for participants in the control group, as in their first six weeks, there is no intervention until the supplementary examination.

Participants

Step 5.

Define inclusion criteria like age (e.g., 40-80), diagnosis of CVD (e.g., ST-elevation myocardial infarction (STEMI), non-ST-elevation myocardial infarction (NSTEMI), percutaneous coronary intervention (PCI) or coronary revascularisation) within the previous 3 months, physical condition (e.g., clinically stable for at least two weeks before the start of the study), ability to participate in the rehabilitation programme (e.g., follow recommendations about physical activity), ability to give informed consent and having a personal computer with access to the Internet at home.

Participants

Step 6.

Define exclusion criteria: e.g., patients are suffering from Parkinson's disease or other medical conditions such as uncontrolled atrial or ventricular dysrhythmias, or they were unable to participate in MVPA due to physical limitations.

Exclude all participants who are unable to complete rehabilitation for medical reasons.

Participants

Step 7.

Give detailed information in the form of an introductory face-to-face conversation (duration approximately 30 minutes) to all participants. The conversation should be about the purpose and procedure of the study, benefits and risks to the participants, effects on medication and lifestyle, expected symptoms, side effects or injuries, information about premature termination of participation, use of data and results, costs of participation, reimbursement of costs and remuneration, and contact details for further inquiries.

Additionally, give information to all participants in written form in easily understandable language.

Examinations

Step 8.

Perform an examination of the participants' physiological performance at the beginning ($t1$), in week 6 ($t2$), and after 12 weeks ($t3$).

Therefore, conduct a graded exercise test (cardiac stress test) on an electronically braked cycle ergometer or treadmill. The exercise test enables the determination of a participant's maximum exercise capacity.

Examinations

Step 9.

Use individual ramp protocols according to the latest national guidelines and international recommendations. To ensure comparability of measures of *t*1, *t*2 and *t*3, these should be kept identical for all participants during the different examinations.

Examinations

Step 10.

Monitor heart rate continuously by a conventional 12 lead ECG with ten electrodes.

Examinations

Step 11.

Measur blood pressure manually with a standard medical measuring device.

Examinations

Step 12.

Let participants perform maximum capacity exercise testing until exhaustion or until individual ECG termination criteria were reached. Chose testing protocols lasting 8-12 minutes to the peak of exercise depending on the participant's physical status and capacity. For the test, after an initial warm-up phase with unloaded pedalling, the work rate during progressive uninterrupted exercise should be regularly increased after an adequate time interval in each level until the participant's maximum work rate (power given in W) is reached.

Examinations

Step 13.

For comparison of the participants' physiological performance between examination *t*1, *t*2 and *t*3 and between the study and the control groups use values like the maximum power given in W achieved by the participants during the cardiac stress test and their calculated relative performance as a percentage (representing their actual performance during the cardiac stress test in relation to their individual target values).

Monitoring PA

Step 14.

The tracking and monitoring of study group participants' leisure time physical activity should be performed by using a common consumer smart wearable device (e.g., a bracelet-shaped, wrist-worn 3D accelerometer) with a storage capacity of at least 7 days. The device should allow for easy navigation via the display. Technical support should be ensured in advance by the national representative of the manufacturing company.

Monitoring PA

Step 15.

Distribute activity trackers to participants on the day of *t*1 and ask them to return them on the day of *t*3.

Monitoring PA

Step 16.

Ask participants to wear the device on their non-dominant wrist, if possible, 24 hours a day and seven days a week, to regularly charge the (rechargeable) battery via computer (USB) or charging unit, and to regularly synchronize the automatically collected activity data by using a provided software.

Monitoring PA

Step 17.

Provide important information about display views, features and functions, memory capacity, charging and operating time, communication and technical specifications of the device, as well as system requirements for the software and web service, to the participants during the introductory conversation.

Monitoring PA

Step 18.

To ensure that the device is comfortable to wear, individually customise the bracelet size to the wrist size of all participants. Give a copy of the user manual to all participants.

Monitoring PA

Step 19.

Because of the limited storage capacity of the device, data needs to be synchronised with a computer about once a week to enable ongoing tracking. Data is automatically generated by participants while wearing the activity tracker. For synchronizing data with a computer, ask participants to download and install the synchronising software on their own PC or laptop. As some of the elderly people were not quite familiar with this kind of process, it should be explained to them in detail. Additionally, provide a copy of an installation guide with step-by-step instructions (including screenshots). If needed prepare user accounts for all participants in advance. Set up activity trackers, update them to the latest software version, and connected them to the accounts.

Monitoring PA

Step 20.

Set privacy preferences of the web service to the most private level. Give personal login data to access the pre-set accounts to participants immediately after they had agreed to participate in the study.

Monitoring PA

Step 21.

If possible connect participants accounts to a special coaching account held by the study authors. This

enables the authors to precisely monitor all synchronised activity data of participants. Inform participants that only the authors and medical staff have access to their activity data and that all personal information such as full name and date of birth is subject to medical confidentiality. For statistical purposes and analysis all data must be anonymised to a study reference number so that it could not be traced to an individual based on published results of the study.

Monitoring PA

Step 22.

Advice participants to try to raise their awareness about their own physical activity behaviour, to set realistic and achievable personal goals (such as total daily steps, less overall time spent sitting, or just being more active than the day before).

Monitoring PA

Step 23.

Check every three days whether participants were synchronising their activity data regularly. If anyone’s data is missing for more than five days, participants should be contacted (personally, by phone, or per e-mail), receive a reminder to synchronise data, or should be asked whether there were any problems (e.g., with synchronisation or use of the device).

Warnings

All measures have to be performed by a medical doctor or a trained exercise physiologist (under supervision of a medical doctor, to deal with any emergencies).