SUPPLEMENT

Original article

Using a smartphone application maintains physical activity following pulmonary rehabilitation in COPD patients: a randomised controlled trial

Marc Spielmanns[1,2*], Rainer Gloeckl[6] ,Inga Jarosch[6], Daniela Leitl[6,7], Tessa Schneeberger[6,7], Tobias Boeselt[3], Stephan Huber[4], Pawandeep Kaur Bollinger[4], Bernhard Ulm[5], Claudia Müller[4], Jonas Bjoerklund[4], Sabine Spielmanns[1], Wolfram Windisch[2], Anna-Maria Pekacka-Egli[1], and A. Rembert Koczulla[6,7]

[1]Pulmonary Medicine, Zurich RehaCenter Clinik Wald, Faltigbergstrasse 7, 8636 Wald, Switzerland. [2]Department of Pneumology; Cologne Merheim Hospital; Kliniken der Stadt Köln gGmbH Witten/Herdecke University, Faculty of Health/School of Medicine, Germany. [3]Department of Pulmonary Rehabilitation, Philipps-University of Marburg, German Center for Lung Research (DZL), Marburg, Germany. [4]Fa. Kaia Health GmbH, Siegfriedstr.8, 80797 Munich, Germany. [5]Unabhängiges statistische Beratung Bernhard Ulm, Landsberger Strasse 147, D-80339 Munich, Germany. [6]Department of Pulmonary Rehabilitation, Philipps-University of Marburg, Member of the German Center for Lung Research (DZL), Marburg, Germany. [7]Institute for Pulmonary Rehabilitation Research, Schoen Klinik Berchtesgadener Land, Schoenau am Koenigssee, Germany.

Corresponding author: Marc Spielmanns, MD
Pulmonary Medicine and Sleep Medicine Center,
Zurich RehaCenter Clinik Wald, CH-8636 Wald-ZH, Switzerland
spielmanns@me.com; Tel: 0041 55 256 6821

Overview

- Figure S6: Contents of the KAIA COPD App
- Figure S7: Smartphone with the KAIA COPD App and Polar A370® Watch
- Table S7: Intervention subgroup analysis (n=13, "Frequent-App-User" IG, intervention subgroup vs. control group, CG) from baseline to visit 8
- Safety endpoints
- Table S5: Adverse and severe adverse events in the intervention (IG) and control group (CG)
- **Table S8: Overview of achieved and set physical activity goals**
- **Table S9: Results of the intervention group in comparison to the minimal clinically important differences**

Inclusion and exclusion criteria

Inclusion criteria

- Diagnosis of COPD was defined as forced expiratory volume in 1 s/forced vital capacity (FEV1/FVC) < 70% predicted, FEV1< 80% predicted after bronchodilation, with or without chronic symptoms (such as cough and sputum production) corresponding to GOLD stage II–IV COPD patients who are willing and can sign the informed consent form for the use of their pseudonymised clinical data within the scope of the present interventional trial.
- Patients with COPD who have completed a comprehensive inpatient pulmonary rehabilitation program for an average duration of 3 weeks (which is a common concept in Germany).
- Completion of the screening period and fulfilment of the randomisation criteria as defined by the protocol.
- Ability to use a smartphone and smartphone apps.
- Willingness to wear an activity tracker during the 6-month study period.
- Age ≥ 40 years
- Familiar with German language to understand the study material, assessments, and contents of the COPD app.

Exclusion criteria

- Patients unable to adhere to the exercise training program due to physical, cognitive, or safety reasons, as judged by the investigators, such as lower limb joint surgery

within the preceding 3 months, unstable cardiac diseases, predominant neurological limitations, and planned surgical or other interventions disturbing the study intervention.

- Significant psychiatric disorders, legal incapacity, or limited legal capacity.
- Patient participation in another clinical trial with an investigative medication within 30 days prior to the study entry.
- Patients already using the KAIA COPD app.

Randomisation and allocation concealment

Allocation concealment was maintained during the study, as the randomisation lists were kept separate from study sites, and only after confirmation of informed consent of a participant, group allocation was communicated to the study sites. Randomisation was performed by generating blocks of varying sizes stratified by participating sites.

Sleep parameters

Sleep data for the endpoints sleep efficiency (in %) and total sleep time (in hours) were measured by the Polar A-370 watch and extracted for all participants.

Screening period

During the recruitment period, all COPD patients admitted to PR who were interested in participating in clinical trials were screened for eligibility and informed about the on-going study by verbal and written information provided by the Principal Investigator or his Deputy. After obtaining informed consent, participants were instructed to wear an activity tracker for at least 20 h each day, followed by four 20-min structured training sessions. Training sessions were conducted to educate the participants on the use of the study equipment and to perform the necessary assessments, which were sent via the provided smartphone. After an initial screening period of 7-14 days, eligibility was judged by the local investigators based on the inclusion/exclusion criteria (participants regularly wearing the activity tracker and completing the training program). When participants fulfilled these requirements, they were deemed eligible for the study.

Table S6: Study schedule in detail

Data to be recorded	Screening-Period (V1) (duration 8-10 days) **Enrolment / Allocation**		V2 / Baseline (day 5-8)	V3 30 ± 5 days	V4 60 ± 5 days	V5 90 ± 5 days	V6 120 ± 5 days	V7 150 ± 5 days	V8 180 ± 5 days
Informed Consent	X								
Inclusion, exclusion and randomization criteria	X		X						
Demographic Data	X								
Medical History	X								
COPD Treatment History	X								
Adverse Events / Severe Adverse Events	X	X	X	X	X	X	X	X	X
Compliance Check		X	X	X	X	X	X	X	X
Telephone-Call				X	X	X	X	X	X
Email-Link sent to the participant			X	X	X	X	X	X	X
Exacerbations	X		X	X	X	X	X	X	X
Physical Activity Tracker	X	X	X	X	X	X	X	X	X
COPD-App usage		X	X	X	X	X	X	X	X
Individual Goals			X	X	X	X	X	X	X
CAT			X			X			X
HADS			X			X			X
CRQ			X			X			X
Feeling-Thermometer			X	X	X	X	X	X	X

One-Minute Sit-to-stand Test			X			X			X
Satisfaction with the App			X			X			X
Concomitant Medication / Change in medication	X		X	X	X	X	X	X	X

CAT, COPD Assessment Test; CRQ, Chronic Respiratory Questionnaire; HADS, Hospital Anxiety and Depression Score; V, visit; App, application

Detailed study schedule

Study period

Every 2 weeks, a follow-up phone call was made by the study staff and ePROs regarding exacerbations, safety (adverse events [AEs] or severe adverse events [SAEs]), device deficiencies, and patient feedback were collected. No medications were prohibited during the study. Any change in concomitant medication was recorded during regular follow-up phone calls. Daily steps were automatically collected by the activity tracker and were imported into the study-specific electronic case report form (eCRF) system. Participants in the IG were supplied with a smartphone and access to the application together with the activity monitor, while the CG was supplied with a smartphone (without the app) and activity monitor. The smartphone was used in both groups to synchronise daily step data and collect questionnaires as described above. All study-related equipment was collected from the participants at the end of the study period.

Description of the KAIA COPD App

The KAIA COPD-App is a multiplatform smartphone application developed by KAIA Health Software GmbH (Munich, Germany) and a CE-marked class I medical device in Europe. It is indicated for self-management and exercise training in COPD patients. The software is available on the Apple App Store (iOS) and the Google Play Store. The app provides daily exercises according to the resulting user profile from a selection of relevant disciplines in PR, i.e., psychology, physiotherapy, and patient education, as recommended by

international medical guidelines. Furthermore, users have to confirm that they are physically able to perform the exercises and that they have no contraindications to exercise therapy.

The daily exercises include the following elements:

• Physical exercises for strength and mobility training delivered in short videos.
• Patient education based on established patient guidelines.
• Mindfulness techniques for disease coping.

The user is presented with one exercise per category each day but can choose whether he or she wants to complete one, two, or all three elements. The physical exercises were developed by the company and external advisors to be suited for COPD patients, teachable via videos, and completed without additional training. The KAIA algorithm tailors both the duration and the selection of the exercises to the specific user. Daily physical training includes exercises focused on exercise tolerance and muscle function. The exercises are taught by video tutorials. A countdown timer informs about the duration of the exercise. A standard exercise unit consists of five units, but this may vary. The participants rate the exercises daily on difficulty. The exercises alternate between mobilizing and strengthening exercises. Selection, frequency of training, duration of training sessions, and intensity are based on recommendations of the current guidelines.

Figure S7: Contents of the KAIA COPD App

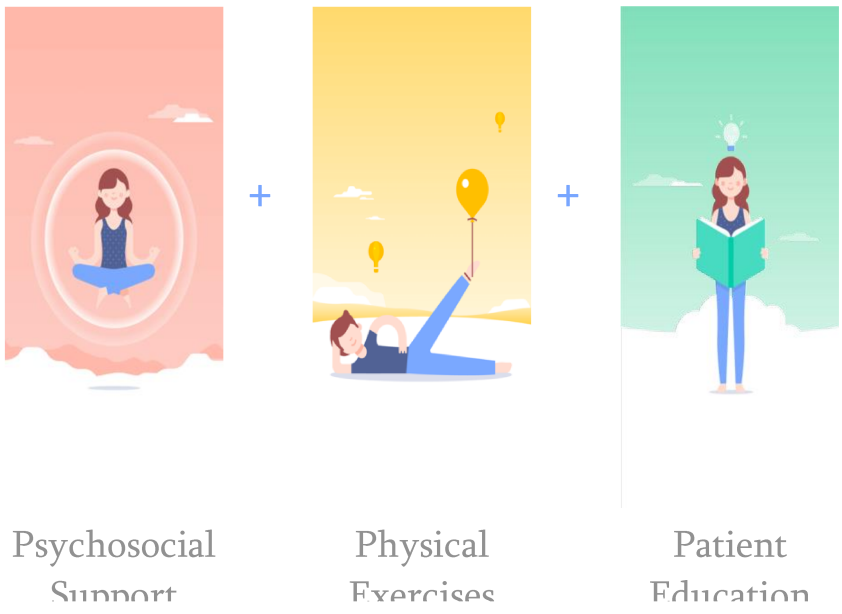

Figure S8: Smartphone with the KAIA COPD App and Polar A370® Watch

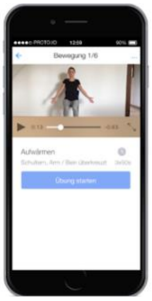

Table S7: Intervention subgroup analysis (n=13, "Frequent-App-User" IG, intervention subgroup vs. control group, CG) from baseline to visit 8

Change from Baseline to Visit 8	**Frequent-App-User (IG)**	**CG**	**p-value**	**test**
n	13	30		
Change in steps (median [IQR])	1092 [-1036, 2318]	-1173 [-3813, -94]	0.006	nonnorm
Change in CAT (median [IQR])	-3.00 [-10.00, -1.00]	5.00 [0.00, 7.00]	<0.001	nonnorm
Change in STST (median [IQR])	5.00 [0.00, 9.00]	2.00 [-4.00, 8.00]	0.191	nonnorm
Change of CRQ Dyspnea subdomain (median [IQR])	0.20 [0.00, 0.60]	-0.80 [-1.60, -0.25]	0.001	nonnorm
Change of CRQ Fatigue subdomain (median [IQR])	0.00 [-0.25, 0.50]	-0.75 [-1.50, 0.00]	0.029	nonnorm

Change of CRQ Emotional Function subdomain median [IQR])	-0.43 [-0.57, 0.00]	-0.29 [-1.14, 0.29]	0.754	nonnorm
Change of Mastery subdomain (median [IQR])	0.25 [0.00, 0.50]	-0.25 [-1.00, 0.25]	0.026	nonnorm
Change of total CRQ (median [IQR])	0.02 [-0.22, 0.26]	-0.49 [-1.19, 0.08]	0.015	nonnorm
HADS-A (median [IQR])	0.00 [-2.00, 1.00]	0.00 [-1.00, 3.00]	0.223	nonnorm
HADS-D (median [IQR])	0.00 [-2.00, 2.00]	1.00 [0.00, 5.00]	0.055	nonnorm

"Frequent App User" was defined as a participant using the application at least four times a week for at least 70% of the weeks during the study.

Abbreviations: CAT, COPD Assessment Test; CRQ, Chronic Respiratory Questionnaire; HADS, Hospital Anxiety and Depression Score; HADS-A, score for the Anxiety Domain of the HADS; HADS-D, score core for the Depression Domain of the HADS; STST, One-Minute Sit-to-Stand Test

Safety endpoints

The overall number of AEs and SAEs reported during the study is shown in Table S5. There was no detectable difference between the groups in both overall AEs (p=0.54) and SAEs (p=1.00). No SAEs were related to the study intervention. No participants died during the observational period. The most frequent AEs reported were COPD exacerbations, chest infections, myalgia, and localised dermatitis. There was no significant difference in the distribution of AEs. While 117 device deficiencies were recorded, according to the definitions in the study protocol, no serious device deficiencies leading to AEs or SAEs occurred (Table S5).

Table S5: Adverse, severe adverse events, and device deficiencies in the intervention (IG) and control group (CG)

	IG	CG	p-value
Adverse Events (n)	53	44	0.53
Severe Adverse Events (n)	10	9	1.00
COPD Exacerbations (n)	17	12	
Chest infections (n)	2	5	
Myalgia (n)	5	0	
Dermatitis, localized (n)	0	4	
Device Deficiencies (n)	N/A	117	
Serious Device Deficiencies (n)	N/A	0	

N, number; p-value indicates the result of a Chi-square test; N/A not applicable

Physical activity goals

Table S8: Overview of achieved and set physical activity goals

Weeks where activity goals were identified n (%)	773 (100)
Weeks where activity goals were reached n (%)	455 (58.9)

n, number

Table S9: Differences for outcome parameters between intervention group and control group at visit 8 in comparison to the minimal clinically important differences (MCID)

Assessment	Result	MCID
Steps per day	+1911	+600-1100 [S1]

CAT points	-4.59	-2 (-3)[S2]
HADS-A points	-0.91	-1.7 [S2]
HADS-D points	-2.35	-1.5 [S2]
CRQ		
-Dyspnea points	+0.85	+0.5 [S3]
-Fatigue points	+0,78	+0.5 [S3]
-Emotional functioning points	+0.6	+0.5 [S3]
STST repetitions	+3,21	+3 [S4]
Feeling thermometer degrees	+7.5	+5 [S5]

CAT, COPD Assessment Test; CRQ, Chronic Respiratory Questionnaire; HADS, Hospital Anxiety and Depression Score; HADS-A, score for the Anxiety Domain of the HADS; HADS-D, score core for the Depression Domain of the HADS; STST, One-Minute Sit-to-Stand Test

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