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Efficacy of a digital lifestyle intervention on health-related QUAlity of life in non-small cell LUng CAncer survivors following inpatient rehabilitation: protocol of the QUALUCA Swiss multicentre randomised controlled trial

Manuel Weber ,[1,2] Anja Maria Raab ,[1] Kai-Uwe Schmitt ,[1] Gilbert Büsching ,[3,4] Thimo Marcin ,[5] Marc Spielmanns ,[6,7] Milo Alan Puhan ,[2] Anja Frei [2]

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For numbered affiliations see end of article.

Correspondence to
Mr Manuel Weber;
manuel.weber@bfh.ch

ABSTRACT

Introduction Non-small cell lung cancer (NSCLC) survivors suffer from impaired physical and psychological functioning and reduced health-related quality of life (HRQoL) that persist after active treatment ends. Sustaining rehabilitation benefits, promoting a healthy lifestyle and facilitating self-management at home require a multifaceted aftercare programme. We aim to investigate the effect of a 12-week digital lifestyle intervention on HRQoL and lifestyle-related outcomes in NSCLC survivors after completion of inpatient rehabilitation.

Methods and analysis QUAlity of life in LUng CAncer Survivors (QUALUCA) is a multicentre randomised controlled trial that follows a hybrid type 1 design. We randomly allocate participants in a 1:1 ratio to the intervention group (digital lifestyle intervention) or the control group (standard care) using block randomisation stratified by tumour stage and study site. Four accredited Swiss inpatient rehabilitation centres recruit participants. Key inclusion criteria are a diagnosis of NSCLC, an estimated life expectancy of ≥6 months and access to a smartphone or tablet. The 12-week intervention comprises physical activity, nutrition and breathing/relaxation, delivered through a mobile application (app). The primary outcome is the change in HRQoL from baseline (1 week after rehabilitation) to follow-up (3 months after baseline), assessed by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30). Secondary outcomes include body mass index, self-reported physical activity, exercise capacity, risk of low protein intake, appetite, psychological distress, cancer-related fatigue, enablement and self-rated health. Explanatory outcomes in the intervention group include app usability, acceptability, appropriateness, and feasibility of the intervention, experiences and satisfaction with the intervention, and app usage data. We aim to enrol 88 participants. For the main statistical analysis, we will use analysis of covariance, adjusted for baseline measures, stratification variables, age and sex.

Ethics and dissemination The Ethics Committees of the Canton of Zurich (lead), the Canton of Bern and Northwest and Central Switzerland approved the study (2023-00245). We will disseminate study results to researchers, health professionals, study participants and relevant organisations, and through publications in international peer-reviewed journals.

Trial registration number NCT05819346.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ QUAlity of life in LUng CAncer Survivors (QUALUCA) is a multicentre randomised controlled trial with blinded data analysis, which follows a hybrid type 1 design, where the primary focus is on examining the intervention's efficacy while also investigating implementation-related outcomes and process measures.
⇒ Our digital lifestyle intervention was developed by mainly following the Integrate-Design-Assess-Share framework and employing an iterative cocreation approach.
⇒ The use of self-reported outcome measures to assess physical activity and nutrition variables may introduce subjectivity and recall bias.
⇒ This study is limited to non-small cell lung cancer survivors who have completed inpatient rehabilitation but will provide insights into a multifaceted digital lifestyle intervention.

INTRODUCTION

Background and rationale

Lung cancer is the second most diagnosed cancer worldwide[1] and the third most

diagnosed cancer in Switzerland.[2] Individuals with lung cancer have benefited from advances in diagnostic and surgical procedures and more effective medical therapies for lung cancer, which have increased their survival rate over the last decades.[3] However, lung cancer survivors suffer from reduced physical and psychological functioning and a drop in overall health-related quality of life (HRQoL) caused by their cancer, treatments and comorbidities.[4 5] Lung cancer survivors experience symptoms including cancer-related fatigue or dyspnoea, which persist after the end of active treatment.[6] Additionally, individuals living with and beyond lung cancer reported having greater unmet psychological and physiological needs and lower HRQoL than adult survivors of other cancers,[7–9] indicating lung cancer survivors need their health and HRQoL monitored after cancer treatment.[6 10 11] Evidence showed that HRQoL in non-small cell lung cancer (NSCLC) survivors is a clinical outcome that provides vital prognostic information for survival.[12–15]

Lifestyle behaviours, such as physical activity, diet quality and weight management, are key components of tertiary prevention for cancer survivors.[16] Adopting healthy lifestyle behaviours before, during and after cancer treatment can improve physical[17–19] and psychological functioning[18–21] and HRQoL.[17 19 21–24] Pulmonary rehabilitation (PR) is an intervention that can help NSCLC survivors embrace a healthy lifestyle. PR provided to individuals with lung cancer can improve symptoms, tolerance for exercise and quality of life.[25–28] However, rehabilitation patients need an adequate aftercare programme to maintain the gains they made during rehabilitation at home and to develop their capacity to self-manage.[25] To date, there is no multifaceted aftercare programme for NSCLC survivors in Switzerland.

Digital health interventions (DHIs), such as digital lifestyle interventions, may be useful aftercare programmes, as they may ease cancer survivors' transition from a clinical setting (eg, rehabilitation) to home.[29] DHIs for cancer survivors can provide location-independent and time-independent, cost-effective, safe and scalable assistance.[30–32] They can encourage cancer survivors to self-manage their health[33 34] and may also help them cope with the side effects of cancer and its treatment, leading to an improved HRQoL.[31 35] To effectively accomplish these ends, DHIs for cancer survivors should be tailored to the specific needs of survivors.[36–40] Likewise, DHIs should be developed through collaboration between health professionals and potential users to increase the likelihood that DHIs will be effective and that users will be empowered to use them.[39 41–43]

Aims

Based on the current state of research and the lack of a multifaceted aftercare programme for NSCLC survivors in Switzerland, we developed a digital lifestyle intervention delivered via a mobile application (app) targeting physical activity, nutrition and breathing/relaxation. Our primary aim is to assess the efficacy of this digital lifestyle intervention on HRQoL in NSCLC survivors who have completed inpatient rehabilitation. Our secondary aims comprise investigating the effect of the intervention on body mass index (BMI), self-reported physical activity, exercise capacity, risk of low protein intake, appetite, cancer-related fatigue, psychological distress, enablement and self-rated health. We will also evaluate explanatory outcomes within the intervention group, including app usability, feasibility, appropriateness, and acceptability of the intervention, experiences and satisfaction with the intervention, and app usage data.

METHODS

Design

The QUAlity of life in LUng CAncer Survivors (QUALUCA) study is a multicentre, randomised, parallel-group controlled trial. We randomly allocate study participants to the intervention group (digital lifestyle intervention) or the control group (standard care). The study follows a hybrid type 1 design, meaning that the primary focus is on testing the intervention (efficacy) while the secondary focus is to examine implementation-related outcomes and process measures.[44] This study protocol has been prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trial (SPIRIT) Outcomes 2022 extension[45] of the SPIRIT 2013 statement[46]; the checklist can be found in online supplemental file 1.

Study setting

Study participants are recruited from four accredited inpatient rehabilitation centres located in Switzerland (Berner Reha Zentrum, Klinik Barmelweid, Zürcher RehaZentren–Klinik Wald and Klinik Davos).

Eligibility criteria

To be eligible for study inclusion, individuals must meet the following inclusion criteria:

- Aged ≥18 years.
- Diagnosed with NSCLC.
- Estimated life expectancy of ≥6 months, as determined by local investigators or responsible health professionals.
- Undergoing inpatient rehabilitation.
- Knowledge of German to understand study material and assessments.
- Access to a smartphone or a tablet with an integrated camera that can connect to the internet (Apple iOS ≥13 or Google Android ≥10 operating system).
- Written informed consent.

Individuals are not eligible for study inclusion if they meet any of the following exclusion criteria:

- Unable to provide informed consent.
- Not being able to participate in the intervention due to physical, cognitive or safety reasons, as determined by local investigators or responsible health professionals.

Intervention

The overall purpose of the intervention is to maintain participants' HRQoL by enabling and empowering them to adhere to international lifestyle guidelines for (lung) cancer survivors. Participants assigned to the intervention group receive access to a lifestyle app after completing inpatient rehabilitation, through which the intervention is delivered. The app can be downloaded from the Apple Store or Google Play Store using a smartphone or a tablet (online supplemental figures S1–S4). The app was developed in collaboration with *Skyscraper Software* (Feldbrunnen-St Niklaus, Switzerland). The three core components of the intervention are physical activity, nutrition and breathing/relaxation. Except for a comprehensive online onboarding at the beginning, the intervention is self-managed.

Apart from the additional digital lifestyle programme that the participants either receive (intervention group) or not (control group), the present study does not interfere with or change any other planned treatments (eg, physiotherapy, immunotherapy). Participants assigned to the control group receive access to the content of the digital lifestyle programme after their 3-month follow-up assessments.

Development and theoretical frameworks

The Integrate-Design-Assess-Share framework[47] mainly guided the interdisciplinary study team in developing the intervention.

A recent umbrella review found strong evidence that credible sources, goals and planning, feedback and monitoring and personalisation components increase the effectiveness of DHIs targeting the prevention and management of non-communicable diseases.[48] Additionally, most of the interventions that use apps to improve physical activity, sedentary behaviour and diet showed significant improvements in behavioural and health outcomes when including goal setting, self-monitoring and performance feedback.[49] Therefore, our intervention is mainly based on the following behaviour change technique clusters according to the taxonomy by Michie *et al*[50]: goals and planning, feedback and monitoring, shaping knowledge, repetition and substitution, comparison of behaviour and natural consequences.

Content

The development of the interventional content was based on available literature, current guidelines and recommendations of international institutions (eg, American Institute for Cancer Research[51] and European Society for Clinical Nutrition and Metabolism[52]), and an iterative cocreation approach. The cocreation approach involved potential users (ie, NSCLC survivors) as well as highly experienced health professionals and researchers with various backgrounds and expertise including oncology, pulmonology, physiotherapy, sports science, nutrition and dietetics, psychology, nursing and medical informatics. At the beginning of the development, we conducted an interdisciplinary workshop with experienced health professionals working with NSCLC survivors. The goal of the workshop was to gather insights and experiences from health professionals to tailor our lifestyle intervention for NSCLC survivors.

Onboarding

Comprehensive onboarding via video call (90 min) takes place at the beginning of the intervention. A study team member conducts the onboarding and discusses the following with the participants:

- Instructions about installing and using the app and its features.
- Importance of following study guidelines for adherence.
- Safety issues.

Physical activity

The 'physical activity' component consists of instructional exercise training videos focusing on strength, balance and flexibility. Given the lack of specific guidelines for lung cancer survivors,[53 54] the exercise modalities follow physical activity recommendations in international oncology guidelines.[51 55 56] Resistance exercises in our intervention cover the upper limbs, lower limbs and core. Each session includes a warm-up (5 min), followed by whole-body exercise training (15–45 min), and concludes with a cool-down involving three stretching exercises (5–10 min) (online supplemental file 2 tables S1 and S2). All exercises can be easily performed at home or anywhere else, requiring only a chair and additional weights (eg, water bottles). This multicomponent exercise training is scheduled twice a week (24 sessions over 12 weeks).

The app provides recommendations for aerobic exercises twice a week (24 sessions over 12 weeks), starting with 15 min (week 1) and gradually increasing to 45 min (week 12). Aerobic exercise recommendations follow aerobic training zones including rating of perceived exertion (5–6) (modified Borg CR10 Scale[57]) and age-predicated maximum heart rate (HR_{max}) (60–80% of HR_{max}). Equations 1 and 2 show estimating formulas for age-predicted HR_{max} in patients with lung disease.[58]

$$HR_{max} = 183 - 0.76 \times age \text{ (intake of beta blocker)} \quad (1)$$

$$HR_{max} = 210 - 0.91 \times age \text{ (no intake of beta blocker)} \quad (2)$$

Participants can choose aerobic exercises that suit them best. The app provides sample activities for each session such as biking, swimming, cleaning windows or mowing the lawn.

Nutrition

The 'nutrition' component offers information and tips on nutrition in the context of cancer. It also includes exercises and podcasts aimed at integrating appropriate dietary practices into daily routines. Two sessions per week (24 sessions over 12 weeks) of 5–25 min each are scheduled for this area (online supplemental file 2 table S3).

Breathing/relaxation

The 'breathing/relaxation' component comprises videos demonstrating breathing exercises and audio recordings of relaxation exercises. A total of 12 breathing exercises and three relaxation exercises are part of the intervention (online supplemental file 2 table S4). One breathing exercise and one relaxation exercise are scheduled each week (24 sessions over 12 weeks).

Newsletter and quiz

A newsletter is released once a week, providing new lifestyle-related information in the context of cancer and integrating previously learnt content. Health and lifestyle quizzes are made available once a week to reinforce knowledge acquisition (online supplemental file 2 table S5).

Features

The app provides the following features:

- Personalised weekly schedule: the app features a weekly schedule showing planned sessions from Monday to Sunday, with direct access to session content (online supplemental file 2 table S6).
- Diary: participants can create diary entries at any time. Participants should make a diary entry if they are unable to complete a session, for instance, if they are sick.
- Feedback and notifications: the app automatically sends motivational messages as participants enter data or complete sessions. Push notifications occur at the beginning (completion of self-rated health assessment), middle (reminder to keep using the app) and end (release of the weekly newsletter) of each week.
- Session completion: participants can record sessions as completed in the app, even if they complete them on a different day of the current week.
- Progress tracking: after each multicomponent training and aerobic exercise session, participants are asked to rate their perceived exertion using the modified Borg CR10 Scale and to record the duration of the session. Participants can monitor their Borg CR10 values and exercise durations over 12 weeks.
- Support: participants can reach out to the study team via the app's contact form for assistance or questions.
- Supplementary web access: participants can also access all videos, audio files, newsletters and quizzes through a simple web page.

Different levels and tracks

On first login, all study participants are required to enter certain information (age, sex, height, weight, weight 3 months ago and food intake). Based on this information and the overall assessment (ie, clinical data and professional expertise) of the study team member responsible for onboarding, a preprogrammed algorithm assigns study participants to a specific level or track. The 'physical activity' component has three levels of difficulty: beginner, intermediate and advanced. The lowest level mainly comprises chair exercises. The highest level includes floor exercises (eg, side plank) that require participants to be able to get down to the floor and back up on their own. The 'nutrition' component operates on two levels using the Nutritional Risk Screening (NRS)[59] score to determine participants' risk of malnutrition. Based on their score, participants are classified into either the low-risk track (<3) or the high-risk track (≥3) for malnutrition. The 'breathing/relaxation' component has one track for all participants.

After the first and sixth weeks, the app asks participants how they feel about the intensity of the training (too high, just right, too low). Based on their response, the level is adjusted or maintained.

Outcomes

The primary and secondary outcomes are assessed at baseline (T_0) and 3-month follow-up (T_1) (figure 1). Self-rated health is additionally assessed weekly between T_0 and T_1. Explanatory outcomes are assessed at 3-month

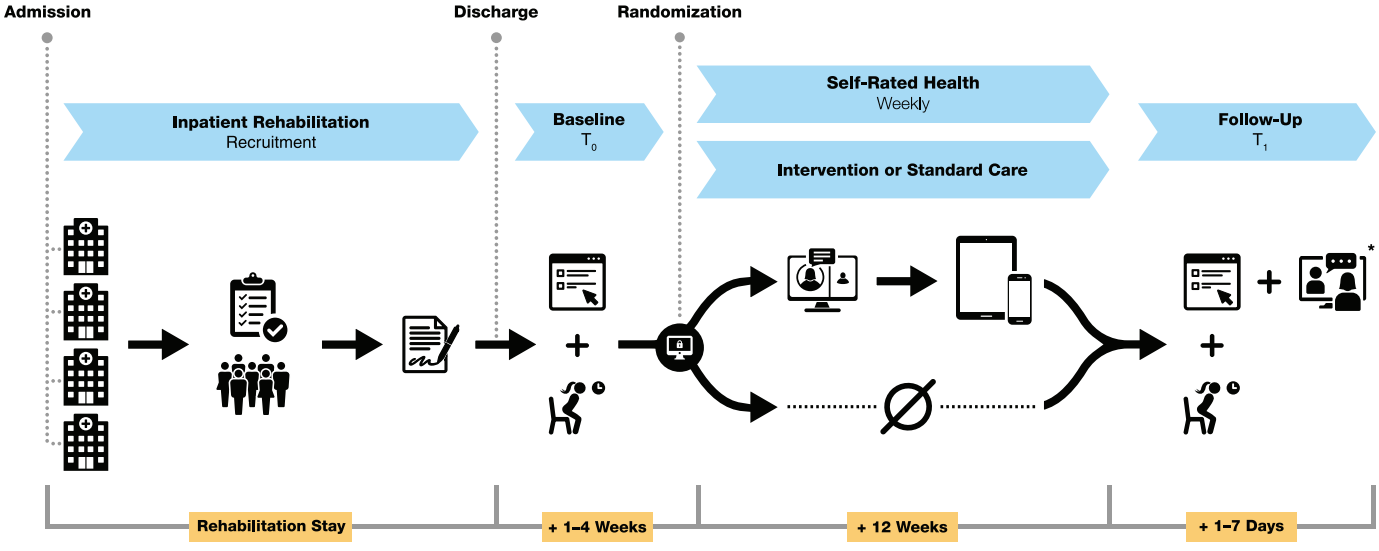

Figure 1 Overview of study procedures. *Intervention group only.

Table 1 Schedule of the study procedures and assessments

Study contacts	Screening/information	Inclusion	T_0: baseline assessments	Intervention or standard care	T_1: follow-up assessments
Time	**Inpatient rehabilitation**	**Inpatient rehabilitation**	**7–14 days after rehabilitation**	**12 weeks**	**14 weeks±7 days after baseline assessments**
Oral and written study information	✓				
Inclusion/exclusion criteria	✓	✓			
Written informed consent		✓			
Participant characteristics		✓	✓		
Clinical data		✓			
Primary outcome					
HRQoL (Global Health Status) (EORTC QLQ-C30)			✓		✓
Secondary outcomes					
HRQoL (functional and symptom scales) (EORTC QLQ-C30)			✓		✓
Lung cancer-specific HRQoL (EORTC QLQ-LC29)			✓		✓
BMI (self-reported height and weight)			✓		✓
Self-reported PA (modified GSLTPAQ)			✓		✓
Exercise capacity (1 min STS test)			✓		✓
Risk of low protein intake (Pro55+)			✓		✓
Appetite (SNAQ)			✓		✓
Psychological distress (PHQ-4)			✓		✓
Cancer-related fatigue (BFI)			✓		✓
Enablement (shortened PEN-13)			✓		✓
Self-rated health (EQ VAS)			✓	✓ (weekly)	✓
Explanatory outcomes					
Treatments/support since discharge					✓
App usability (MAUQ)					✓ (IG only)
Acceptability, appropriateness and feasibility (AIM, IAM, FIM)					✓ (IG only)
Short semistructured interview					✓ (IG only)
Mobile app tracking				✓ (IG only)	

AIM, Acceptability of Intervention Measure; BFI, Brief Fatigue Inventory; BMI, body mass index; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EORTC QLQ-LC29, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Lung Cancer 29; EQ VAS, EuroQol Visual Analogue Scale; FIM, Feasibility of Intervention Measure; GSLTPAQ, Godin-Shephard Leisure-Time Physical Activity Questionnaire; HRQoL, health-related quality of life; IAM, Intervention Appropriateness Measure; IG, intervention group; MAUQ, mHealth App Usability Questionnaire; 1 min STS, 1-minute Sit-to-Stand; PA, physical activity; PEN-13, Patient Enablement Scale-13; PHQ-4, Patient Health Questionnaire-4; Pro55+, Protein Screener 55+; SNAQ, Simplified Nutritional Appetite Questionnaire.

follow-up, and except for postdischarge treatments and support, only in intervention group participants (table 1).

The following participant characteristics, if available, are obtained from the clinical information systems of the rehabilitation centres: demographics, BMI, tumour stage, subtype of NSCLC, medication, oxygen under rest or load, Cumulative Illness Rating Scale,[60] performance status,[61] 6 min walk test distance, NRS score, forced expiratory volume in 1 s as a percentage of predicted (FEV_1 % predicted), FEV_1 % forced vital capacity, length of PR,

reasons for PR, participation objective at admission to PR and whether participants received individual nutritional therapy and/or individual psychological therapy during PR.

If participants had surgery before PR, the type of surgery and length of acute hospital stay are recorded.

Participants' education levels and the following additional self-reported behavioural data are assessed using a self-administered survey at baseline: smoking status and pack-years, weekly alcohol units, daily use of digital devices and intake of nutritional supplements.

Primary outcome

The primary endpoint is the change in HRQoL from baseline (1 week after rehabilitation) to follow-up (3 months after baseline), assessed using the Global Health Status Scale of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30)[62] (Cronbach's α=0.86[63]). The score comprises two 7-point Likert-type scales that are combined using linear transformation to 0–100 according to the official scoring manual.[64] The EORTC QLQ-C30 is a reliable and valid measure of HRQoL in cancer survivors that is internationally used.[62 64]

Secondary outcomes

HRQoL (functional and symptom scales)

The five functional scales, three symptom scales and six single-symptom items of the EORTC QLQ-C30 are composed of the remaining 28 items of the instrument.

Lung cancer-specific HRQoL

The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Lung Cancer 29,[65 66] the updated and validated supplementary lung cancer-specific module of the EORTC QLQ-C30, is used to assess lung cancer-specific HRQoL. In total, this lung cancer-specific module consists of five multi-item symptom scales and five single-symptom items.

Body mass index

The BMI is computed based on self-reported weight and height measurements, providing insights into participants' nutritional status.[67]

Self-reported physical activity

Physical activity is quantified using a modified version of the Godin-Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ).[68 69] Participants report their weekly frequency and average duration of minutes spent on light, moderate and strenuous leisure-time activities during the preceding week (T_0 and T_1) and before rehabilitation (T_0 only). The intended scoring system for the GSLTPAQ is the Leisure Score Index (LSI), which is derived using the following formula: LSI=(frequency of light×3)+(frequency of moderate×5)+(frequency of strenuous×9).[69] This formula combines the frequencies of different activity intensities, assigning weights based on metabolic equivalents to calculate the overall LSI score. The GSLTPAQ is widely used in oncology research[70] and has been frequently employed in previous studies involving lung cancer survivors.[71]

Exercise capacity

Functional exercise capacity is assessed using the 1-minute Sit-to-Stand (1 min STS) test.[72] The outcome of the 1 min STS test is the number of complete STS movements that participants can perform in 1 min. We also assess dyspnoea and leg fatigue before and after the test using the modified Borg CR10 Scale,[57 73] ranging from 0 (indicating no leg fatigue or dyspnoea at all) to 10 (indicating maximal leg fatigue or dyspnoea). The 1 min STS test has demonstrated strong validity, reliability and responsiveness in measuring exercise capacity among patients with chronic obstructive pulmonary disease with a minimal important difference of three repetitions.[74 75]

Risk of low protein intake

The risk of low protein intake is assessed using the Protein Screener 55+,[76] a validated 10-item instrument developed to estimate the probability of low protein intake among community-dwelling older adults.

Appetite

Appetite is assessed using the Simplified Nutritional Appetite Questionnaire (SNAQ),[77] which consists of four items that participants rate on a 5-point Likert-type scale. Item scores are summed to calculate the total SNAQ score.

Psychological distress

Psychological distress is assessed using the short form of the Patient Health Questionnaire-4 (PHQ-4),[78] which comprises two items for depression and two items for anxiety. The PHQ-4 is a reliable and valid ultrabrief tool for the general population.[79] The total score can range from 0 to 12, with a score above the cut-off of 6 indicating a higher risk for anxiety and depression.[80]

Cancer-related fatigue

Cancer-related fatigue is assessed using the Brief Fatigue Inventory (BFI),[81] a widely recognised and well-validated self-administered instrument for measuring clinically relevant fatigue.[81–83] The BFI was constructed to assess the severity and impairment from fatigue in nine questions. Severity and impairment levels are rated using the 11-step numerical rating scales, with higher scores indicating greater intensity and impairment.[83]

Enablement

Enablement is quantified by a shortened version of the German Patient Enablement Scale-13,[84] comprising five items (1, 2, 6, 11 and 13) that have been deemed pertinent and valuable for the present study. These five items are rated on a 5-point Likert-type scale, and a total score ranging from 5 to 25 is calculated.

Self-rated health

Self-rated health is assessed using the EuroQol Visual Analogue Scale (EQ VAS) of the European Quality of Life-5 Dimensions.[85] The EQ VAS is a vertical VAS ranging from 0 (worst imaginable health) to 100 (best imaginable health).

Explanatory outcomes

In both the intervention and the control group any treatments and support (eg, chemotherapy, physiotherapy, nutritional counselling) participants may have received since their discharge from rehabilitation and its duration is assessed at 3-month follow-up.

The app usability is assessed using the reliable and validated mHealth App Usability Questionnaire (MAUQ).[86] The MAUQ version for stand-alone apps comprises 18 items on three subscales that are rated on a 7-point Likert-type scale. The MAUQ has demonstrated a strong correlation with the widely used System Usability Scale,[86] which is a standardised questionnaire frequently employed for evaluating perceived usability.[87] In a recent validation study of the German version of the MAUQ, an internal consistency of Cronbach's α=0.93 demonstrated high reliability.[88]

To measure implementation outcomes, the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM) and Feasibility of Intervention Measure (FIM)[89] are used. These measures consist of four items each that are rated on a 5-point Likert-type scale. The German versions of AIM, IAM and FIM have shown reliability and validity (Cronbach's α=0.91–0.97).[90]

A brief semistructured interview using an interview topic guide is conducted during the online follow-up appointment to assess participants' experiences and satisfaction with the intervention (online supplemental file 3).

Usage data is automatically tracked within the app used by the intervention group. These data include the number of active days, number of completed sessions, diary entries, changes in difficulty level and the rate of perceived exertion (Borg CR10 Scale) as well as the duration of exercise sessions.

Recruitment and participant timeline

The study team members at the rehabilitation centres approach eligible individuals during their rehabilitation stay and inform them about the study, its purpose, procedures, potential benefits and risks. Individuals are provided with a participant information sheet and a consent form (online supplemental file 4). Individuals can sign a second written informed consent regarding the reuse of data in pseudonymised form for other research projects. This second consent is voluntary and independent of participation in the present study. On obtaining a valid and signed written informed consent, we schedule baseline assessments. We conduct baseline measures (T_0) within a timeframe of 7–14 days after discharge from inpatient rehabilitation. Online questionnaires are administered via Research Electronic Data Capture (REDCap) and the 1 min STS test is conducted via a video call with a study team member. After the completion of baseline measures, participants are randomised. For participants allocated to the intervention group, we schedule the online onboarding. We conduct randomisation and onboarding within a period of 0–14 days after baseline, and follow-up assessments (T_1) between 13 and 15 weeks after baseline assessments. The short semistructured interview in the intervention group at follow-up is conducted during the same online appointment as the 1 min STS test.

Screening and recruitment will continue until the target sample size is achieved. We expect an enrolment period of up to 24 months. Recruitment has started in August 2023. The anticipated end date for the study is December 2025.

Participants may withdraw from the study for any reason at any time. When an individual's withdrawal request is limited to discontinuation of the interventional component of the research project, data collection will continue as scheduled.

Sample size

The sample size calculation was based on analysis of covariance (ANCOVA) to compare the change in the EORTC QLQ-C30 (Global Health Status Scale) from baseline to follow-up. The sample size for the ANCOVA was determined using a two-step method proposed by Borm *et al*.[91] First, the sample size (n) was calculated as if a t-test on the follow-up score was conducted, and then one additional individual per group was added. Second, the number of participants was multiplied by a 'design factor' of $(1–r^2)$, where r denotes the correlation coefficient between baseline and follow-up scores, to obtain the total number of participants required for the ANCOVA. In this study, a conservative estimate was used with r=0.4, resulting in a 'design factor' of 0.84. To detect a change of 15 points $(\mu_i - \mu_c)$ in the EORTC QLQ-C30, which corresponds to a moderate change from the patient's perspective,[92 93] and assuming a standard deviation (σ) of 23,[94 95] a total of 66 participants are needed to achieve a power of 80% at a significance level of 5% (two sided) (equations 3 and 4). Considering an anticipated dropout rate of 25%, the study aims to include a required total sample size (N) of 88 participants.

$$\delta = \frac{|\mu_i - \mu_c|}{\sigma} \quad (3)$$

$$N = \left(\frac{4\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2}{\delta^2} + \frac{Z^2_{1-\frac{\alpha}{2}}}{2} \right) \left\{1 - r^2\right\} \quad (4)$$

Allocation

Study participants are randomly allocated (1:1 ratio) to either the intervention (digital lifestyle intervention) or control group (standard care) by a study team member at Bern University of Applied Sciences (BFH) using block randomisation with varying block sizes of 2–4, stratified

by rehabilitation centre and tumour stage (I/II vs III/IV). Randomisation is performed in REDCap using allocation tables that were generated by an external biostatistician from the Epidemiology, Biostatistics and Prevention Institute (EBPI) at the University of Zurich. The biostatistician created a list of random numbers in R using the package 'blockrand'.[96] The lists are not accessible to the study team members who have contact with study participants, allowing for complete allocation concealment.

Blinding

Except for the 1 min STS test, outcome measures encompass online questionnaires. The outcome assessors performing the 1 min STS test online with participants are aware of their group allocation. To minimise potential measurement bias, we employ standard operating procedures and ensure thorough training of the assessors.

To maintain the blinding of group allocation during statistical analyses, a senior researcher from EBPI who has no interaction with the study participants will extract the final data set from REDCap and randomly assign group names as 'A' and 'B'.

Due to the nature of the intervention, participants cannot be blinded.

To prevent control group participants from using the mobile app or website, intervention group participants receive an activation code. Without this code, they are not able to access the intervention materials. Intervention group participants are specifically instructed not to share the code.

Data management

Study data are collected and managed using REDCap electronic data capture tools[97 98] hosted at the University of Zurich (EBPI). REDCap is a secure, web-based software platform designed to support data capture for research studies. Password-protected accounts are created for authorised study team members and the level of database access granted to each member depends on their respective role(s) within the study. The data of the app are hosted and saved in the infrastructure and on protected servers of *Skyscraper Software*.

Statistical methods

Baseline characteristics of the study participants and explanatory outcomes will be summarised using frequencies and percentages for categorical data. Numerical data will be presented as means and SDs or medians and IQRs.

ANCOVA will be used to analyse the primary outcome and determine between-group differences at follow-up, adjusting for covariates. Covariates will be selected a priori and include baseline values of the outcomes, stratification variables (ie, rehabilitation centre and tumour stage), age and sex. We will use Q-Q plots to assess the distribution of residuals, and transformations will be considered if the assumptions of linear regression are violated. The same regression-based approach will be applied to analyse continuous secondary outcomes.

Interviews will be analysed using conventional content analysis with data-driven category development.[99]

We will analyse all available data sets. For participants lost to follow-up, the data already collected will be retained.

Results will be examined both with and without adjustment for multiple comparisons using the Holm method[100] to control the probability of type I error rate.

We will follow the intention-to-treat principle for the main analyses.

Sensitivity analyses will include multiple imputation and per protocol analysis. We define adherence to the protocol as completing at least six sessions per week for at least 70% of the weeks during the study, with 1 week consisting of 10 sessions (120 sessions total). If participants have health conditions that prevent them from completing sessions, we will not count those sessions.

The potential impact of missing data on the results will be assessed using multivariate imputation by chained equations with 50 imputed data sets. However, we expect few missing data due to ongoing monitoring.

We will use R software[101] to perform analyses.

Monitoring and quality assurance

External monitoring is not required for this study with minimal risk. A study team member from BFH conducts two monitoring visits at the rehabilitation centres involved. Monitoring visits involve the monitor assessing protocol adherence and data accuracy in REDCap. The first visit occurred after the first participant was enrolled, and the second visit will occur at the study's end.

Harms

In our study, a serious adverse event (SAE) is defined as any untoward medical occurrence that:

- Results in death or is life threatening.
- Requires inpatient hospitalisation or prolongation of existing hospitalisation.
- Results in persistent or significant disability or incapacity.

SAEs are assessed during the online follow-up appointment. SAEs potentially related to the intervention will be reported to the lead national ethics committee within 15 days.

Patient and public involvement

We consulted the patient advisory board of the University Hospital of Bern (Inselspital) and lung cancer survivors throughout the development of the intervention and the app. An initial mock-up test of a web-based lifestyle app was conducted with six patients from the patient advisory board. The patients provided feedback on the app's interface, navigation and usability. Additionally, we performed short semistructured interviews with four lung cancer survivors undergoing inpatient rehabilitation to better understand their needs and perspectives. Once all the features of the app had been implemented, we conducted a prototype test with six patients from the

advisory board and three lung cancer survivors contacted through a national lung cancer survivors' patient organisation. They tested the app for a week and provided valuable feedback that was used to improve the app.

ETHICS AND DISSEMINATION

This study was registered at ClinicalTrials.gov in April 2023 (identifier: NCT05819346). All national ethics committees of the involved sites—the Ethics Committee of the Canton of Zurich (lead agency), the Ethics Committee of the Canton of Bern and the Ethics Committee Northwest and Central Switzerland—reviewed and approved this study (project ID: 2023-00245; protocol version and date: v1.1, 4 April 2023). Any protocol modification will be communicated to the local principal investigators and the study team and approved by the ethics committees.

Signed written informed consent forms are stored securely in locked file cabinets in areas with limited access at the rehabilitation centres. Forms, logs and any other listings that link participant ID numbers to other identifying information are stored on secure and local databases with limited access. All local databases are secured with password-protected access systems.

We will disseminate study results to researchers, health professionals, study participants and relevant organisations, and through publications in international peer-reviewed journals. Pseudonymised data will be made available on reasonable request after the main results have been published. The privacy of each subject and confidentiality of their information will be preserved in reports and publication of data.

Eligibility for authorship of final publications is based on the four criteria recommended by the International Committee of Medical Journal Editors.

Author affiliations
[1]Academic-Practice-Partnership between School of Health Professions at Bern University of Applied Sciences and University Hospital of Bern, Bern, Switzerland
[2]Epidemiology, Biostatistics and Prevention Institute, University of Zurich, Zurich, Switzerland
[3]Barmelweid Academy, Klinik Barmelweid, Barmelweid, Switzerland
[4]Department of Therapeutics, Klinik Barmelweid, Barmelweid, Switzerland
[5]Berner Reha Zentrum, Rehabilitation & Sports Medicine, Insel Group, University Hospital of Bern, University of Bern, Heiligenschwendi, Switzerland
[6]Department of Pulmonary Medicine, Zürcher RehaZentren – Klinik Wald and Klinik Davos, Wald & Davos, Switzerland
[7]Faculty of Health, Department for Pulmonary Medicine, Witten/Herdecke University, Witten, Germany

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Contributors All authors conceived the RCT. MW wrote the first draft of both the study protocol and this manuscript. AMR, K-US, MAP and AF provided methodological expertise. GB, TM and MS provided critical review as well as clinical and methodological expertise. MW, AMR, GB, TM, MS and AF developed the intervention. All authors read, contributed to and approved the final version of this manuscript.

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ORCID iDs
Manuel Weber http://orcid.org/0000-0002-5866-9618
Anja Maria Raab http://orcid.org/0000-0002-4139-2173
Kai-Uwe Schmitt http://orcid.org/0000-0003-3439-9323
Gilbert Büsching http://orcid.org/0000-0002-1014-6033
Thimo Marcin http://orcid.org/0000-0001-7229-5985
Marc Spielmanns http://orcid.org/0000-0003-4541-6977
Milo Alan Puhan http://orcid.org/0000-0003-4721-1879
Anja Frei http://orcid.org/0000-0002-7134-1000

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