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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

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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

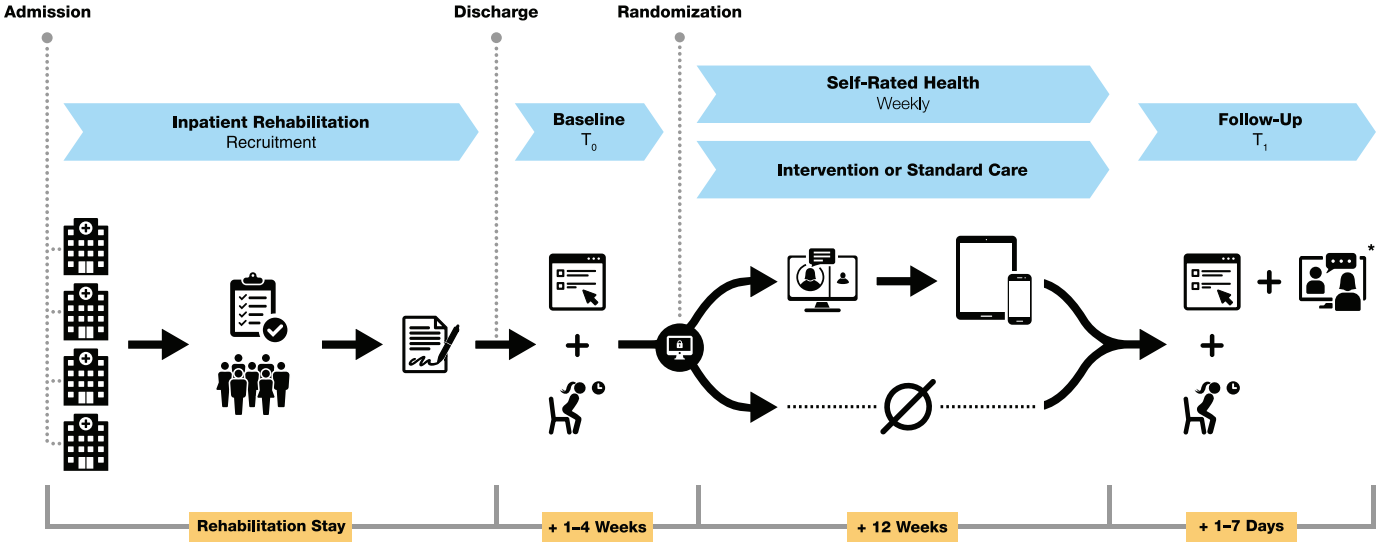

Figure 1 Overview of study procedures. *Intervention group only.

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.

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

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

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.

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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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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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SPIRIT-Outcomes 2022 Checklist (for combined completion of SPIRIT 2013 and SPIRIT-Outcomes 2022 items)[a]

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Administrative information				
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	-	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	-	2
	2b	All items from the World Health Organization Trial Registration Data Set	-	2–17
Protocol version	3	Date and version identifier	-	17
Funding	4	Sources and types of financial, material, and other support	-	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	-	1 + 17
	5b	Name and contact information for the trial sponsor	-	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	-	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	-	N/A
Introduction				
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	-	3–4
	6b	Explanation for choice of comparators	-	
Objectives	7	Specific objectives or hypotheses	-	N/A

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Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	-	4
Methods: Participants, interventions, and outcomes				5
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	-	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	-	5–8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (for specific guidance see TIDieR checklist and guide)	-	14
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	-	6 + 16
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	-	5
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	-	8–13
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
	12.1		Provide a rationale for the selection of the domain for the trial's primary outcome	N/A
	12.2		If the analysis metric for the primary outcome represents within-participant change, define and justify the minimal important change in individuals	N/A
	12.3		If the outcome data collected are continuous but will be analyzed as categorical (method of aggregation), specify the cutoff values to be used	8
	12.4		If outcome assessments will be performed at several time points after randomization, state the time points that will be used for analysis	N/A
	12.5		If a composite outcome is used, define all individual components of the composite outcome	
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	-	12–13
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	-	14
	14.1		Define and justify the target difference between treatment groups (eg, the minimal important difference)	14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	-	13–14
Methods: Assignment of interventions (for controlled trials)				
Allocation:				
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	-	14

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	-	13–14
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	-	15
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	-	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	-	
Methods: Data collection, management, and analysis				
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	-	8–13
	18a.1		Describe what is known about the responsiveness of the study instruments in a population similar to the study sample	8–13
	18a.2		Describe who will assess the outcome (eg, nurse, parent)	8–13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	-	13–16

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	-	15–16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	-	15
	20a.1		Describe any planned methods to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (eg, coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of an outcome)	
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	-	15–16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	-	15–16
Methods: Monitoring				
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	-	16
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	-	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	-	16

SPIRIT | CONSORT OUTCOMES
Reporting Guidelines for Trial Outcomes

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	-	N/A
Ethics and dissemination				
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	-	16–17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	-	17
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	-	13
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	-	13
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	-	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	-	17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	-	17
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	-	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	-	17
	31b	Authorship eligibility guidelines and any intended use of professional writers	-	17

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	-	N/A
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	-	Supplemental material (file 4)
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	-	N/A

[a]It is strongly recommended that this checklist be read in conjunction with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement paper for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license and is reproduced with permission.

[b]Indicates page numbers and/or manuscript location: to be completed by authors.

Please cite as: Butcher NJ, Monsour A, Mew EJ, et al. Guidelines for reporting outcomes in trial protocols: the SPIRIT-Outcomes 2022 extension. JAMA. Published online December 13, 2022. doi:10.1001/jama.2022.21243

QUALUCA STUDY

Supplemental Material | File 2 – Intervention Details

This is a supplemental file to a full manuscript published in *BMJ Open*. For full copyright and citation information see doi: 10.1136/bmjopen-2023-081397.

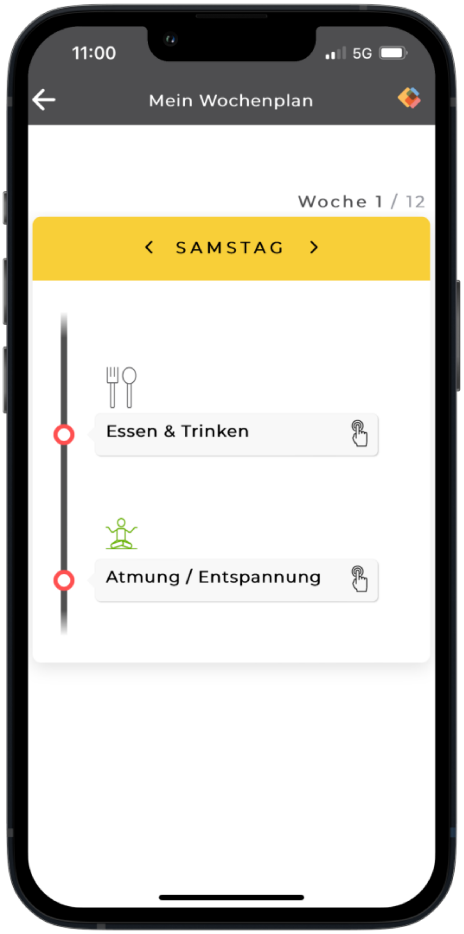
A

B

Figure S1 Screenshots of the mobile application; (A) main menu showing all top-level categories and (B) help and safety view.

QUALUCA STUDY

A



B

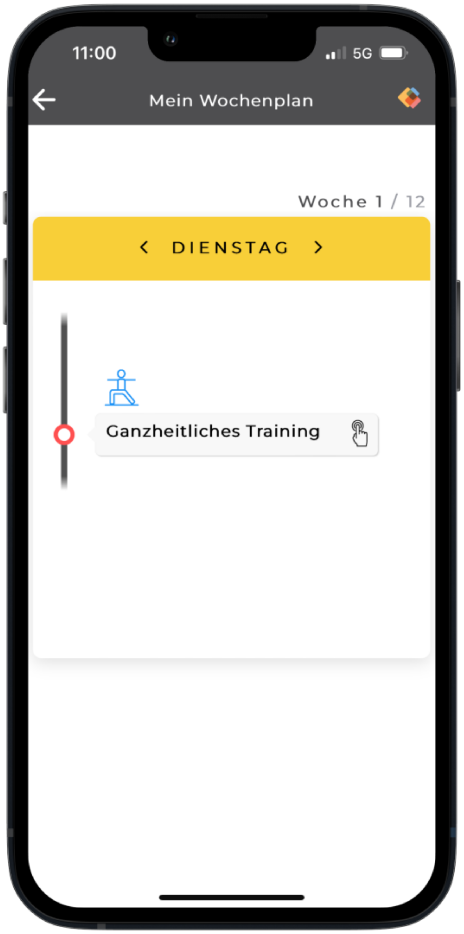


Figure S2 Screenshots of the mobile application; (A) and (B) sample days of the week in the weekly schedule.

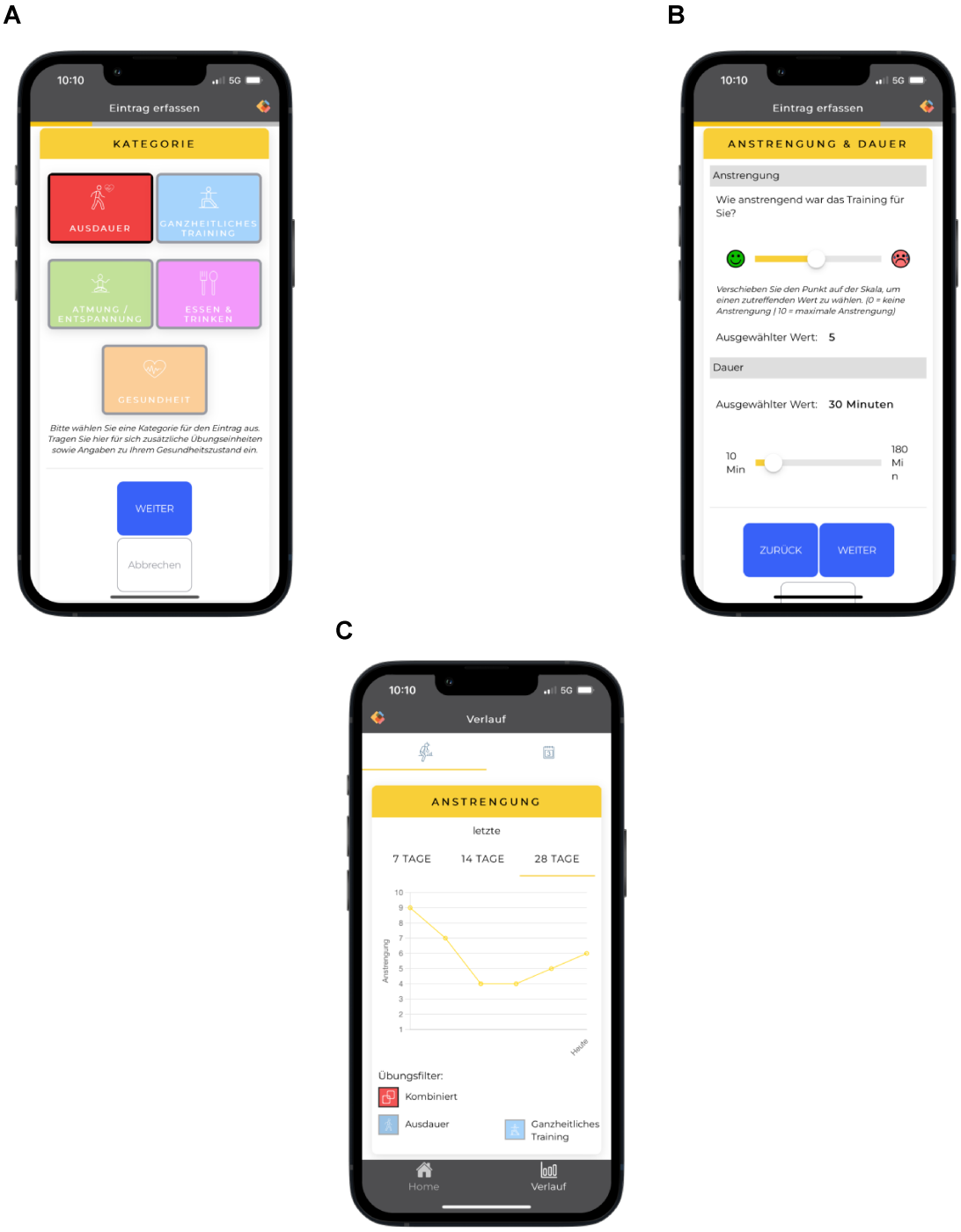


Figure S3 Screenshots of the mobile application; (A) selection of category for diary entries, (B) sample entry of exertion and duration of session, and (C) sample progress tracking.

QUALUCA STUDY

A

B

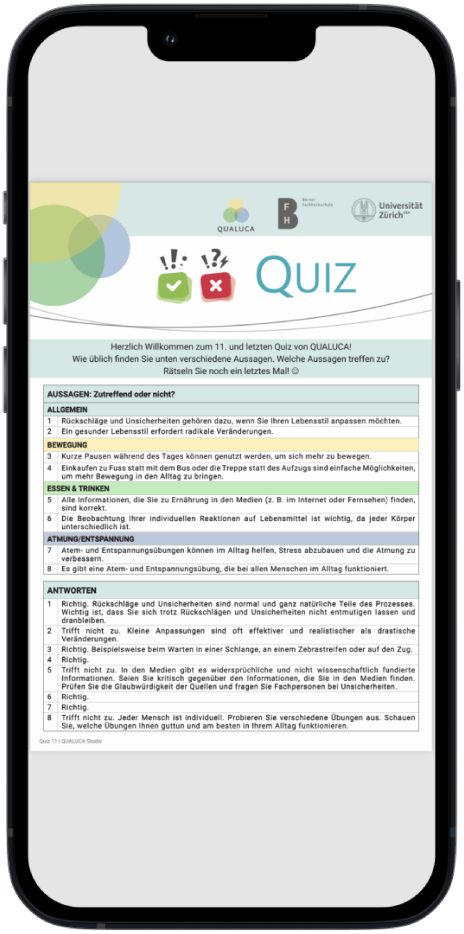


Figure S4 Screenshots of the mobile application; (A) sample newsletter and (B) sample quiz.

QUALUCA STUDY

Table S1 Modalities of the multicomponent exercise training.

	Weeks 1–2	Weeks 3–4	Weeks 5–6	Weeks 7–8	Weeks 9–10	Weeks 11–12
Beginner						
No. of resistance exercises	3	3	3	4	5	6
Sets × reps	2 × 12	2 × 12	2 × 12	2 × 12	2 × 12	2 × 12
No. of balance exercises	1	1	2	2	2	2
Sets × secs	2 × 15	2 × 15	2 × 15	2 × 15	2 × 15	2 × 30
No. of stretching exercises	3	3	3	3	3	3
Sets × secs	1 × 30	1 × 30	1 × 30	1 × 30	1 × 30	1 × 30
Duration of each session [mins]	20	20	15	25	35	35
Intermediate						
No. of resistance exercises	3	4	5	6	6	6
Sets × reps	2 × 10	2 × 10	2 × 10	2 × 10	2 × 10	2 × 10
No. of balance exercises	2	2	2	2	2	3
Sets × secs	2 × 30	2 × 30	2 × 30	2 × 30	2 × 30	2 × 30
No. of stretching exercises	3	3	3	3	3	3
Sets × secs	1 × 30	1 × 30	1 × 30	1 × 30	1 × 30	1 × 30
Duration of each session [mins]	25	20	25	35	35	35
Advanced						
No. of resistance exercises	4	5	6	6	6	5
Sets × reps	2 × 8	2 × 8	2 × 8	2 × 8	2 × 8	2 × 8
No. of balance exercises	2	2	2	2	2	3
Sets × secs	2 × 30	2 × 30	2 × 30	2 × 30	2 × 30	2 × 30
No. of stretching exercises	3	3	3	3	3	3
Sets × secs	1 × 30	1 × 30	1 × 30	1 × 30	1 × 30	1 × 30
Duration of each session [mins]	25	20	30	40	40	40

No, number; reps, repetitions; secs, seconds; mins, minutes.

Table S2 Exercises of the multicomponent training differentiated by level.

	Weeks 1–2	Weeks 3–4	Weeks 5–6	Weeks 7–8	Weeks 9–10	Weeks 11–12
Beginner						
Warm-up (free choice)	Active standing	Active standing	Apple picking	Apple picking	Active standing	Apple picking
	Main joint mobility	Main joint mobility	Full-body joint mobility	Main joint mobility	Full-body joint mobility	Full-body joint mobility
	Full-body joint mobility	Marching[a]	Marching[a]	Marching[a]	Side-to-side step	Side-to-side step
Resistance						
Core	Air wheel[a]	Cat-camel[a]	Scissor chops[a]	Painting (arms)	Cat-camel[a]	Air wheel[a]
				Pelvic tilt[a]	Pelvic tilt[a]	Wall push-ups
Legs	Squats	Sit-to-stand	Calf raises	Hip extension[b]	Hip abduction[b]	Sit-to-stand
					Side lunge[b]	Hip extension[b]
Arms	Biceps curls[a,b,c]	Triceps dips[a]	Arm flutters[a]	Shoulder press[a,b,c]	Rowing[a,b,c]	Arm flutters[a]
						Arm abduction[a,b]
Balance	Single leg stance[b]	Toe taps (stool)	Semi-tandem stance	Single leg stance[b]	Semi-tandem stance	Knee raises
			Knee raises	Eye tracking	Three-way toe taps	Three-way toe taps
Stretching	Neck (posterior)[a]	Standing forward bend[a]	Side bend[b]	Upper body rotation	Cat pose[a]	Standing forward bend[a]
	Dorsal extension[a,b]	Hip flexors[a,b]	Calf (wall)[b]	Dorsal extension[a,b]	Side lunge[a,b]	Hip flexors[a,b]
	Upper arm (wall)[b]	Upper body rotation	Neck (lateral)[b]	Cross-body shoulder stretch[a,b]	Upper arm[b]	Chest (wall)[b]

Table S2 *Continued.*

	Weeks 1–2	Weeks 3–4	Weeks 5–6	Weeks 7–8	Weeks 9–10	Weeks 11–12
Intermediate						
Warm-up (free choice)	Active standing	Active standing	Apple picking	Apple picking	Active standing	Apple picking
	Main joint mobility	Main joint mobility	Full-body joint mobility	Main joint mobility	Full-body joint mobility	Full-body joint mobility
	Full-body joint mobility	Marching	Marching	Marching	Side-to-side step	Side-to-side step
Resistance						
Core	Air wheel[a]	Air wheel[a]	Scissor chop[a]	Pelvic tilt	Pelvic tilt	Air wheel[a]
		Cat-camel	Cat-camel	Wall push-ups	Cat-camel	Wall push-ups
Legs	Squats	Sit-to-stand	Hip extension[b]	Hip extension[b]	Calf raises	Sit-to-stand
			Hip abduction[b]	Hip abduction[b]	Side lunge[b]	Step up with knee raises
Arms	Biceps curl[b,c]	Triceps dip[a]	Arm flutters[c]	Shoulder press[b,c]	Arm abduction[b,c]	Arm abduction[b,c]
				Bent-over row[b,c]	Bent-over row[b,c]	Arm flutters[c]
Balance	Single leg stance[b]	Tandem stance	Single leg stance[b]	Single leg stance[b]	Tandem stance	Knee raises
	Toe taps (stool)	Toe taps (stool)	Knee raises	Eye tracking	Three-way toe taps	Three-way toe taps
Stretching	Neck (posterior)[a]	Standing forward bend	Side bend[b]	Upper body rotation	Cat pose[a]	Standing forward bend
	Dorsal extension[a,b]	Quadriceps[b]	Calf (wall)[b]	Dorsal extension[a,b]	Side lunge[b]	Quadriceps[b]
	Upper arm[b]	Upper body rotation	Neck (lateral)[b]	Cross-body shoulder stretch[b]	Upper arm[b]	Chest (wall)[b]

Table S2 *Continued.*

	Weeks 1–2	Weeks 3–4	Weeks 5–6	Weeks 7–8	Weeks 9–10	Weeks 11–12
Advanced						
Warm-up (free choice)	Active standing	Active standing	Apple picking	Apple picking	Active standing	Apple picking
	Main joint mobility	Main joint mobility	Full-body joint mobility	Main joint mobility	Full-body joint mobility	Full-body joint mobility
	Full-body joint mobility	Marching	Marching	Marching	Side-to-side step	Side-to-side step
Resistance						
Core	Air wheel[a]	Scissor chop[a,c]	Scissor chop[a,c]	Pelvic tilt	Pelvic tilt	Push-ups[d]
	Cat-camel	Plank[d]	Painting (leg)	Wall push-ups	Hip raises[d]	Side plank[d]
Legs	Squats	Sit-to-stand	Hip extension	Hip extension	Hip abduction[b]	Sit-to-stand
		Calf raises	Hip abduction[b]	Lunges[b]	Side lunge[b]	Step up with knee raises
Arms	Biceps curl[b]	Triceps dip	Arm flutters[c]	Shoulder press[c]	Arm abduction[c]	Arm abduction[c]
			Shoulder press[c]	Bent-over row[c]	Bent-over row[c]	Arm flutters[c]
Balance	Single leg stance[b]	Toe taps (stool)	Single leg stance[b]	Single leg stance[b]	Tandem stance	Knee raises
	Toe taps (stool)	Tandem stance	Knee raises	Eye tracking	Three-way toe taps	Three-way toe taps
Stretching	Neck (posterior)[a]	Standing forward bend	Side bend[b]	Upper body rotation	Cat-camel[d]	Standing forward bend
	Dorsal extension[b]	Quadriceps[b]	Calf (wall)[b]	Dorsal extension[b]	Side lunge[b]	Quadriceps[b]
	Upper arm[b]	Upper body rotation	Neck (lateral)[b]	Cross-body shoulder stretch[b]	Upper arm[b]	Chest (wall)[b]

[a]Chair exercises
[b]Unilateral exercises
[c]Exercises with additional weights (e.g., water bottles)
[d]Floor exercises

Table S3 Overview of nutritional sessions.

	Title	Topic	Type
Week 1			
Session 1	Individual importance of nutrition	Four principles of nutrition and cancer: 1. Do not feel anxious or guilty about diet and cancer 2. There is no one-size-fits-all cancer diet 3. Eat what you like and what is good for you 4. Help your body cope with individual symptoms or side effects by adjusting your diet	Reading (10 min) and exercise (15 min)
Session 2	Nutrition and cancer	Diet after cancer treatment or to prevent a relapse versus diet during cancer treatment	Reading (15 min)
Week 2			
Session 3	Weight management	Differentiation: 1. Symptom-free person 2. Anyone who is experiencing side effects and has already lost weight 3. Anyone who has gained weight because of therapy or medication and needs to take specific measures to control weight gain	Reading (10 min) and exercise (5 min)
Session 4	Aging	Age-related changes (metabolism, muscle mass, and appetite)	Podcast (10 min)
Week 3			
Session 5	Proteins 1	Role and importance of proteins in cancer survivors and sources of proteins	Reading (10 min) and exercise (10 min)
Session 6	Proteins 2	Recommended daily allowance of protein for cancer survivors and sample high-protein meal plan	Reading (10 min) and exercise (5 min)
Week 4			
Session 7	Energy requirement 1	Energy expenditure, energy intake, and energy balance	Reading (10 min)
Session 8	Energy requirement 2	Unintentional weight loss and malnutrition or unintentional weight gain	Reading (10 min)
Week 5			
Session 9	Vitamins	Role and importance of vitamins in cancer survivors and sources of vitamins	Reading (5 min)
Session 10	Minerals	Role and importance of minerals in cancer survivors and sources of minerals	Reading (5 min)
Week 6			
Session 11	Drinking 1	Hydration and cancer survivors	Reading (5 min) and exercise (5 min)
Session 12	Drinking 2	Reasons to drink water and tips for drinking more water	Podcast (10 min) and exercise (5 min)

Table S3 *Continued.*

	Title	Topic	Type
Week 7			
Session 13	Portion sizes 1	Macronutrient ratio based on goals (malnutrition/unintentional weight loss versus unintentional weight gain)	Reading (5 min)
Session 14	Portion sizes 2	Focus on macronutrient ratios for three days	Exercise (10 min)
Week 8			
Session 15	Symptoms and side effects 1	Address common symptoms and side effects	Reading (15 min)
Session 16	Symptoms and side effects 2	Nutrition and mental well-being	Exercise (15 min)
Week 9			
Session 17	Habits and goals 1	Outcome-based habits versus identity-based habits	Reading (10 min) and exercise (10 min)
Session 18	Habits and goals 2	Tiny habits and implementation intentions	Reading (10 min) and exercise (10 min)
Week 10			
Session 19	Tobacco and alcohol	Effects of tobacco and alcohol consumption and tips for quitting smoking	Reading (10 min)
Session 20	Regional and seasonal food	Role and importance of seasonality and regionality	Reading (5 min)
Week 11			
Session 21	Grocery shopping	Tips for grocery shopping	Reading (10 min)
Session 22	Food variety	Role and importance of eating a variety of foods	Reading (5 min)
Week 12			
Session 23	Summary	Key messages	Reading (10 min)
Session 24	Conclusion	Reflecting on the experiences of the past 12 weeks	Exercise (10 min)

Table S4 Overview of breathing and relaxation exercises.

	Breathing[a]	**Relaxation**[b]
Week 1	Coughing with arm support	Introduction body scan (5 min + 20 min)
Week 2	Coach driver's position	Body scan (20 min)
Week 3	Goalkeeper position combined with movement	Body scan (20 min)
Week 4	Thoracic breathing	Introduction seated meditation (5 min + 20 min)
Week 5	Abdominal breathing	Seated meditation (20 min)
Week 6	Flank breathing	Seated meditation (20 min)
Week 7	Pursed lips	Introduction PMR (5 min + 20 min)
Week 8	Arm movement	PMR (20 min)
Week 9	Huffing	PMR (20 min)
Week 10	1-2-3 breathing	Free choice (body scan, seated meditation, or PMR)
Week 11	Air stacking	Free choice (body scan, seated meditation, or PMR)
Week 12	Pranayama breathing (alternate nostril breathing)	Free choice (body scan, seated meditation, or PMR)

[a]Short video exercises (~5 minutes)
[b]Audio track exercises
PMR, progressive muscle relaxation.

Table S5 Overview of newsletter topics during the intervention.

	Overall	Physical activity	Nutrition	Breathing/relaxation
Week 0		Welcome and outline		
Week 1	Introduction and overview	Perceptions of physical activity	Four principles of nutrition and cancer	Frequently asked questions
Week 2	Healthy lifestyle and interactions among physical activity, nutrition, and breathing/relaxation	Types of physical activity (every move counts)	Weight and lung cancer	Perceptions of breathing/relaxation
Week 3	Proteins	Proteins and physical activity	Protein requirement and sources of protein	Proteins and breathing/relaxation
Week 4	Energy and nutrients	Energy and physical activity	Energy requirement (malnutrition/ unintentional weight loss or weight gain)	Energy and sleep
Week 5	Vitamins and minerals	Vitamins, minerals, and physical activity	Vitamins and minerals requirement	Well-being and breathing/relaxation
Week 6	Mindfulness and stress	Training success and muscle memory	Mindful eating and drinking	Mindful breathing/relaxation
Week 7	Dose	Structuring physical activity and regeneration	Macronutrient ratio	Planning of breathing/relaxation exercises
Week 8	Symptoms and side effects	Symptoms, side effects, and physical activity	Symptoms, side effects, and nutrition	Symptoms, side effects, and breathing/relaxation
Week 9	Habits and goals	Physical activity-related tips for good habits and goal setting	Nutrition-related tips for good habits and goal setting	Breathing/relaxation-related tips for good habits and goal setting
Week 10	Collection of topics	Fatigue cycle and physical activity	Tobacco and alcohol consumption	Regulation of emotions
Week 11	Integration into everyday life and motivation	Integration of physical activity into everyday life	Integration of nutrition that meets needs into everyday life	Integration of breathing/relaxation into everyday life
Week 12	Summary and follow-up links	Key messages	Key messages	Key messages

Table S6 Sample weekly schedule.

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Sessions[a]							
Multicomponent training	✓			✓			
Aerobic exercise			✓			✓	
Nutrition		✓			✓		
Breathing/relaxation		✓			✓		
Newsletter							✓
Quiz			✓				

[a]When study participants first log in to the mobile application, they can choose which two days they want to take their multicomponent training, with at least two days in between. Based on this selection, all other sessions are scheduled using a pre-programmed algorithm. One day a week there is no physical practice scheduled (i.e., physical rest).

QUALUCA STUDY

Supplemental Material | File 3 – Interview Topic Guide

This is a supplemental file to a full manuscript published in *BMJ Open*. For full copyright and citation information see doi: 10.1136/bmjopen-2023-081397.

The present document provides an English translation of the original German interview topic guide for the purpose of publication.

Short Interview on Experiences and Satisfaction with the Intervention

INTRODUCTION AND OVERVIEW
▸ Welcome and introduction of the interviewer
INITIAL INSTRUCTIONS
▸ I would like to ask you about your experiences and satisfaction with the QUALUCA program. ▸ Please note that the questions only refer to the QUALUCA program and do not cover the accompanying study (i.e., the surveys you completed or the exercise tests you conducted).
KEY QUESTIONS
1. What did you like best and what did you like least about the whole QUALUCA program?
2. In general, what could we change or improve in the QUALUCA program? In terms of: a. Program contents (physical activity, nutrition, breathing/relaxation) b. The mobile application
3. How did you perceive the amount of information in the QUALUCA program? How did you perceive the variety in the QUALUCA program? Follow-up question: Did you miss anything in the QUALUCA program?
4. What parts of the QUALUCA program motivated and helped you the most in living a healthy lifestyle?
5. Did you follow the QUALUCA program (physical activity, nutrition, breathing/relaxation) as planned or did you modify it? If modified: What did you modify? (e.g., frequency, training duration, intensity, exercises)
6. Have you noticed any changes in your daily life that you attribute to the participation in the QUALUCA program? If so, which ones?
7. The official study ends today. How do you plan to use any new insights and experiences you may have gained from the QUALUCA program in your daily life?

8. On a scale of 1 to 10 (1: lowest / 10: highest), how motivated would you be to continue using the application?
9. On a scale of 1 to 10 (1: lowest / 10: highest), how motivated are you to maintain a healthy lifestyle?
10. What was the main reason or reasons why you decided to participate in the study at the rehabilitation clinic?
11. Is there anything you haven't mentioned yet that you would like to share with us?
CONCLUSION
▸ Summary of the interview ▸ Thank the interviewee ▸ Farewell

OR

OR

Anfrage zur Teilnahme an medizinischer Forschung:

Unterstützung einer gesunden Lebensweise durch ein digitales Programm für Personen mit Lungenkrebs: die QUALUCA Studie

(**QUA**lity of life in **LU**ng **CA**ncer survivors)

Sehr geehrte Dame, sehr geehrter Herr

Wir fragen Sie hier an, ob Sie bereit wären, an unserem Forschungsvorhaben mitzuwirken.

Ihre Teilnahme ist freiwillig. Alle Daten, die in diesem Projekt erhoben werden, unterliegen strengen Datenschutzvorschriften.

Das Forschungsvorhaben wird durchgeführt von Prof. Dr. Kai-Uwe Schmitt (Sponsor) am Departement Gesundheit der Berner Fachhochschule und PD Dr. Anja Frei (wissenschaftliche Leitung) am Institut für Epidemiologie, Biostatistik und Prävention (EBPI) der Universität Zürich. Bei Interesse informieren wir Sie gerne über die Ergebnisse aus dem Forschungsvorhaben.

In einem Gespräch erklären wir Ihnen die wichtigsten Punkte der geplanten Studie und beantworten Ihre Fragen. Damit Sie sich bereits jetzt ein Bild machen können, hier das Wichtigste vorweg. Detaillierte Informationen finden Sie weiter hinten.

Warum führen wir dieses Forschungsvorhaben durch?

- Die gängigen Massnahmen zur Behandlung von Lungenkrebs zielen darauf ab, die Lebensqualität der Betroffenen zu erhalten und zu verbessern. Nach einem Aufenthalt in einer Rehabilitationsklinik fehlt es jedoch an einem krankheitsspezifischen Angebot, das Sie zu Hause nutzen können.
- Eine gesunde Lebensweise hat positive Auswirkungen auf das körperliche und psychische Wohlbefinden. Für viele Menschen mit Lungenkrebs kann es aber aufgrund von Symptomen und Therapien schwierig sein, eine gesunde Lebensweise zu führen.
- In unserem Forschungsvorhaben mit dem Namen QUALUCA wollen wir herausfinden, ob sich eine neu entwickelte Applikation (App) mit Anregungen und Anleitungen zu einer gesunden Lebensweise auf die Lebensqualität auswirkt.

Was muss ich bei einer Teilnahme tun? – Was geschieht mit mir bei einer Teilnahme?

- Wenn Sie sich entscheiden teilzunehmen, werden Sie kurz nach Ihrem Rehabilitationsaufenthalt und drei Monate danach gebeten, verschiedene Fragebogen auszufüllen. Falls Sie eine Waage zu Hause haben, werden Sie gebeten, Ihr Körpergewicht zu Hause zu Beginn und nach drei Monaten zu messen. Ausserdem werden Sie jeweils zu einem Videotelefonat an Ihrem Computer, Tabletcomputer oder Handy eingeladen. Der erste Termin dauert ca. 30

Minuten, der zweite ca. 45 Minuten. Bei diesen Terminen werden Sie gebeten, einige Fragen zu beantworten und einen kurzen, einfachen Fitness-Test durchzuführen.

- Wichtige Aspekte Ihrer Lungenkrebserkrankung und möglichen Zusatzerkrankungen werden aus der Krankenakte Ihrer Rehabilitationsklinik erfasst.
- Nach dem ersten Termin werden Sie zufällig durch ein Computerprogramm in die Interventionsgruppe oder in die Vergleichsgruppe eingeteilt (Chance 50% zu 50%).
- Während drei Monaten werden Sie einmal wöchentlich gebeten, Ihre aktuelle Gesundheit auf einer Skala zwischen 0 und 100 einzuschätzen.
- Teilnehmende der Interventionsgruppe erhalten Zugang zu einem digitalen Programm, das speziell für Personen mit Lungenkrebs entwickelt wurde. Das Programm kann über eine App (Applikation) auf einem Handy und/oder auf einem Tabletcomputer installiert werden. Für eine Einführung in das Programm werden die Teilnehmenden der Interventionsgruppe zu einem weiteren Videotelefonat eingeladen. Während dieses Videotelefonats wird ihnen die Nutzung des digitalen Programms erklärt. Das Programm besteht aus drei Bereichen: Bewegung, Ernährung und Atmung/Entspannung. Die Teilnehmenden verwenden das Programm während drei Monaten. Der Zeitaufwand des Programms ist individuell unterschiedlich, beträgt aber ungefähr drei bis vier Stunden pro Woche. Bewegungseinheiten sind dabei bereits mitgezählt. Das Programm ersetzt keine vorgesehenen Massnahmen, wie z. B. hausärztliche Versorgung, Ernährungsberatung, psychologische Betreuung oder Physiotherapie.
- Teilnehmende der Vergleichsgruppe erhalten zu diesem Zeitpunkt keinen Zugang zum digitalen Programm und nehmen nur an den Datenerhebungen (Fragebogen und Videotelefonat zu Beginn und drei Monate danach) teil. Sie werden am Ende des Forschungsprojekts die Möglichkeit haben, einen Zugang für die Inhalte des digitalen Programms zu erhalten.
- Nach Verlassen der Rehabilitationsklinik müssen die teilnehmenden Personen im Rahmen der Studie weder zurück an die Rehabilitationsklinik noch an die Universität Zürich kommen.

Welcher Nutzen und welches Risiko sind damit verbunden?

Nutzen

- Wenn Sie an der QUALUCA-Studie teilnehmen und der Interventionsgruppe zugeteilt werden, können Sie das digitale Programm über die App (Applikation) während drei Monaten verwenden. Das Programm kann über ein Handy (Smartphone) oder einen Tabletcomputer genutzt werden. Das Programm könnte Sie dabei motivieren und unterstützen, regelmässig körperlich aktiv zu sein, sich gesund und bedarfsgerecht zu ernähren sowie Ihr psychisches Wohlbefinden zu steigern. Insgesamt könnte dies zu einer verbesserten Lebensqualität führen.
- Wenn Sie an der QUALUCA-Studie teilnehmen und der Vergleichsgruppe zugeteilt werden, leisten Sie einen wertvollen Beitrag zur Forschung. Sie können die Programminhalte nach vier Monaten kennenlernen und nutzen.

Risiko und Belastung

- Wir erwarten keine Risiken im Rahmen der Studie. Die Ausübung der Bewegungsübungen könnte bei ungeübten Teilnehmenden zu Beginn etwas Muskelkater verursachen. Dies ist eine natürliche Reaktion des Körpers und wird mit regelmässigem Training deutlich weniger werden bzw. vollkommen ausbleiben.
- Die Teilnahme ist mit einem Zeitaufwand für Sie verbunden.
  - Alle Teilnehmenden: zwei Videotelefonate von jeweils ca. 30 bis 45 Minuten und zweimaliges Ausfüllen von Fragebogen von jeweils ca. 45 Minuten sowie zweimalige Messung des Körpergewichts zu Hause und kurzes wöchentliches Einschätzen der aktuellen Gesundheit auf einer Skala von 0 bis 100
  - Teilnehmende der Interventionsgruppe: ein zusätzliches Videotelefonat zur Erklärung und Installation des digitalen Programms von ca. eineinhalb Stunden, Ausfüllen von gewissen zusätzlichen Fragebogen von ca. 15 Minuten und Beantwortung gewisser zusätzlicher Fragen zu dem Programm im zweiten Videotelefon von ca. 15 Minuten
  - Teilnehmende der Interventionsgruppe: Nutzung des Programms über drei Monate (ca. 3–4 Stunden pro Woche)

Mit Ihrer Unterschrift am Ende des Dokuments bezeugen Sie, dass Sie freiwillig teilnehmen und dass Sie die Inhalte des gesamten Dokuments verstanden haben.

Detaillierte Information

1. Ziel und Auswahl

Unser Forschungsvorhaben bezeichnen wir in dieser Informationsschrift als *Forschungsprojekt*. Wenn Sie an diesem Forschungsprojekt teilnehmen, sind Sie eine *Teilnehmerin* bzw. ein *Teilnehmer*.

Wir wollen mit diesem Forschungsprojekt (= QUALUCA-Studie) untersuchen, ob ein digitales Programm im Anschluss an eine stationäre Rehabilitation die Lebensqualität von Personen mit Lungenkrebs verbessern kann. Ein digitales Programm ist ein Programm, das von überall und zu jederzeit beispielsweise auf einem Handy genutzt werden kann. Die Themen im digitalen Programm der QUALUCA-Studie sind Bewegung, Ernährung und Atmung/Entspannung. Im Rahmen der Studie wird das Programm für drei Monate eingesetzt.

Wir fragen Sie an, da grundsätzlich alle Personen teilnehmen können, die an Lungenkrebs (nicht-kleinzelliges Lungenkarzinom) erkrankt sind, aktuell in einem stationären Rehabilitationsprogramm sind, mindestens 18 Jahre alt sind, die deutsche Sprache gut verstehen und Zugang zu einem Handy (Smartphone) oder Tabletcomputer besitzen.

Nicht teilnehmen können Personen, die wegen körperlicher, kognitiver oder sicherheitsbezogener Gründe aus Sicht der Prüfperson nicht an dem digitalen Programm teilnehmen können. Bei Unklarheiten kontaktieren Sie uns und wir klären eine mögliche Teilnahme gemeinsam ab.

2. Allgemeine Informationen

2.1. Hintergrund

Regelmässige körperliche Aktivität und eine gesunde und bedarfsgerechte Ernährung sind wichtige Bestandteile einer gesunden Lebensweise. Eine gesunde Lebensweise ist wiederum ein wesentlicher Faktor für die Lebensqualität. Aktuelle Untersuchungen zeigen, dass es Personen mit Lungenkrebs schwerfallen kann, eine gesunde Lebensweise zu führen. Dies liegt unter anderem an den Symptomen und Krebsbehandlungen. Ein Aufenthalt in einer Rehabilitationsklinik kann dazu führen, dass Personen mit Lungenkrebs interessiert und motiviert sind, ihre Lebensweise anzupassen. Sobald sie jedoch wieder zu Hause sind, kann es sich schwierig gestalten, eine gesunde Lebensweise in den Alltag zu integrieren. Ein digitales Programm (eine App für Handy

bzw. Computer) kann Personen dabei unterstützen. Obwohl bereits viele digitale Programme verfügbar sind, wurde noch kein Programm speziell für Personen mit Lungenkrebs in der Schweiz entwickelt. Zudem gibt es noch keine Belege dafür, ob ein solches Programm zur Führung einer gesunden Lebensweise für Personen mit Lungenkrebs geeignet ist und dass sich dadurch die Lebensqualität erhalten bzw. erhöhen lässt.

2.2. Aufbau und Dauer des Projekts

Bei diesem Forschungsprojekt handelt es sich um eine sogenannte randomisierte kontrollierte Studie. Randomisiert bedeutet, dass die Studienteilnehmenden zufällig in zwei Studiengruppen eingeteilt werden. Die eine Gruppe erhält die Intervention (= Interventionsgruppe) und die andere Gruppe erhält keine Intervention (= Vergleichsgruppe). Die Zuteilung erfolgt zufällig durch ein Computerprogramm. Das Studienteam besitzt keinen Einfluss auf die Gruppenzuteilung. Die Chance, in eine der beiden Gruppen eingeteilt zu werden, beträgt 50%. Die Teilnahme dauert insgesamt ca. vier Monate.

Personen mit Lungenkrebs werden über vier akkreditierte stationäre Rehabilitationszentren in der Schweiz über die Studie informiert. Wir planen insgesamt 88 Personen mit Lungenkrebs in die Studie aufzunehmen.

Bei allen Studienteilnehmenden werden zu Beginn und nach drei Monaten Datenerhebungen durchgeführt. Alle Personen werden zudem während drei Monaten einmal wöchentlich Ihre aktuelle Gesundheit auf einer Skala von 0 bis 100 einschätzen. Teilnehmende der Interventionsgruppe erhalten zusätzlich zu Beginn ein Videotelefonat zur Einführung und Erklärung des digitalen Programms. Nach Verlassen der Rehabilitationsklinik müssen die teilnehmenden Personen im Rahmen der Studie für die Termine weder zurück an die Rehabilitationsklinik noch an die Universität Zürich kommen.

Wir machen die Studie so, wie es die Gesetze in der Schweiz vorschreiben. Ausserdem beachten wir alle international anerkannten Richtlinien. Die zuständige Ethikkommission hat die Studie geprüft und bewilligt.

3. Ablauf

Sie werden während ca. vier Monaten an dieser Studie teilnehmen. In einem ersten Gespräch in Ihrer Rehabilitationsklinik informieren wir Sie über die Studie und die Ein- und Ausschlusskriterien. Wir geben Ihnen am Ende des Gesprächs die detaillierte Studieninformation mit der Einwilligungserklärung ab. Anschliessend haben Sie mindestens 24 Stunden Zeit, sich für eine Teilnahme zu entscheiden. Bei allfälligen Fragen zur Studie können Sie sich jederzeit an die zuständige Studienperson in Ihrer Rehabilitationsklinik wenden. Wenn Sie sich für eine Teilnahme entscheiden, unterschreiben Sie die Einwilligungserklärung gleichzeitig mit der zuständigen Studienperson in Ihrer Rehabilitationsklinik. Wenn Sie unterschrieben haben, erfassen wir wichtige Aspekte Ihrer Lungenkrebserkrankung und allfälliger Zusatzerkrankungen aus der Krankenakte Ihrer Rehabilitationsklinik. Eine Studienperson der Universität Zürich wird anschliessend Kontakt mit Ihnen aufnehmen, um ein Datum für das erste Videotelefonat zu vereinbaren.

Die Abbildung 1 zeigt eine Übersicht des gesamten Ablaufs der Studie.

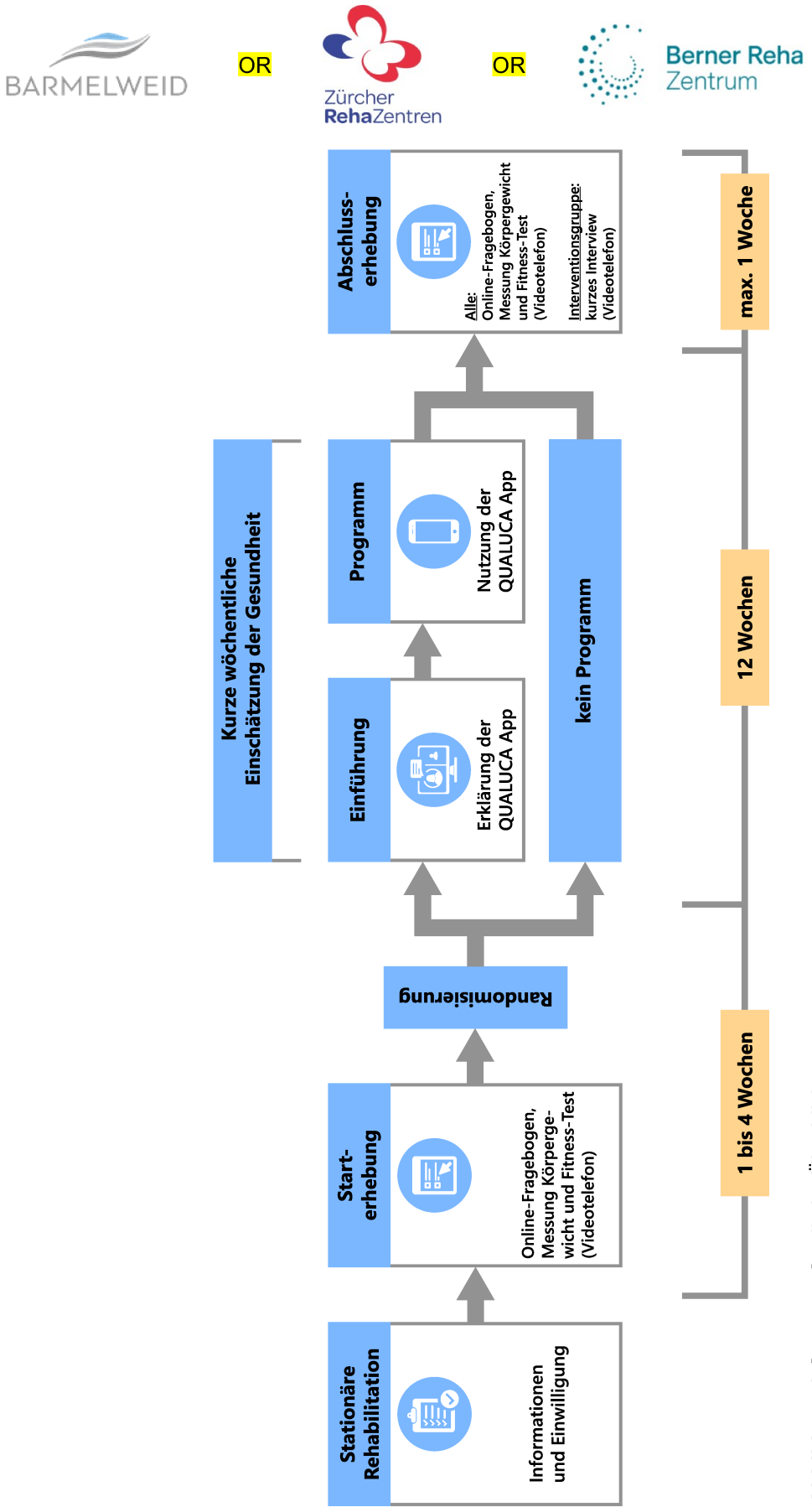


Abbildung 1 Gesamte Studie im Überblick.

3.1. Online-Fragebogen und Messung des Körpergewichts zu Beginn

Wenn Sie sich für eine Teilnahme entscheiden, werden Sie einen persönlichen Link per E-Mail zu mehreren Fragebogen erhalten, die Sie direkt über den Computer, den Tabletcomputer oder das Handy (Smartphone) ausfüllen können. Die Fragebogen beinhalten Fragen zu Lebensqualität, körperlicher Aktivität, Ernährung, psychischem Wohlbefinden und Rauchgewohnheiten. Das Beantworten dieser Fragebogen nimmt ca. 45 Minuten in Anspruch. Falls Sie eine Waage zu Hause haben, werden Sie gebeten, Ihr Körpergewicht zu messen und zusammen mit den Fragebogen einzutragen. Die Fragebogen sowie die Messung des Körpergewichts sollten Sie bis zum ersten Videotelefonat-Termin erledigt haben.

3.2. Videotelefonat zu Beginn (kurzer Fitness-Test)

Das erste Videotelefonat dauert etwa 30 Minuten und sollte etwa eine Woche nach dem Verlassen der Rehabilitationsklinik stattfinden. Sie benötigen dazu ein Gerät mit einer integrierten Kamera und einer aktiven Internetverbindung (z. B. Handy, Tabletcomputer, Laptop). Im Videotelefonat vergewissert sich die zuständige Studienperson, dass Sie die per E-Mail zugeschickten Fragebogen bereits ausgefüllt haben. Zudem werden Sie im Videotelefonat vor Ihrer Kamera den 1-Minuten Sitz-Steh-Test absolvieren. Die Studienperson wird Sie anleiten. Für den Test benötigen Sie nur einen Stuhl ohne Armlehne. Beim 1-Minuten Sitz-Steh-Test werden Sie gebeten, innerhalb von einer Minute so oft wie möglich von einem Stuhl aufzustehen und sich wieder hinzusetzen. Die zuständige Studienperson wird dabei die Anzahl der geleisteten Wiederholungen zählen.
Nach dem ersten Videotelefonat werden Sie zufällig der Interventionsgruppe oder der Kontrollgruppe zugeteilt. Dies erfolgt durch ein Computerprogramm. Das Studienteam besitzt keinen Einfluss auf die Gruppenzuteilung.

3.3. Bekanntmachung der Gruppenzuteilung

Kurz nach dem ersten Videotelefonat werden wir Sie telefonisch und per E-Mail über die Gruppenzuteilung informieren.

3.4 Einschätzung der aktuellen Gesundheit während drei Monaten

Vergleichsgruppe: Während drei Monaten werden Sie einmal wöchentlich einen Link per E-Mail erhalten. Dieser Link führt Sie zu einer Skala, auf der Sie Ihre aktuelle Gesundheit zwischen 0 und 100 einschätzen sollen.
Interventionsgruppe: Während drei Monaten werden Sie einmal wöchentlich in der App (Applikation) gebeten, Ihre aktuelle Gesundheit auf einer Skala zwischen 0 und 100 einzuschätzen.

3.5. Online-Fragebogen und Messung des Körpergewichts nach drei Monaten

Drei Monate nach dem ersten Videotelefonat erhalten Sie wie zu Beginn der Studie einen Link per E-Mail zu mehreren Fragebogen. Die Fragebogen beinhalten wiederum Fragen zu Lebensqualität, körperlicher Aktivität, Ernährung und psychischem Wohlbefinden. Ausserdem gibt es Fragen zu Behandlungen und Unterstützung, die Sie während den vergangenen drei Monaten erhalten bzw. genutzt haben. Das Beantworten dieser Fragebogen nimmt ca. 45 Minuten in Anspruch. Falls Sie eine Waage zu Hause haben, werden Sie gebeten, Ihr Körpergewicht zu messen und zusammen mit den Antworten der Fragebogen einzutragen. Die Fragebogen sowie die Messung des Körpergewichts sollten Sie bis zum zweiten Videotelefonat-Termin erledigt haben.

3.6. Videotelefonat nach drei Monaten (kurzer Fitness-Test)

Für das abschliessende Videotelefonat nach drei Monaten werden alle Teilnehmenden beider Gruppen wieder vom Studienteam eingeladen. Für diesen Termin sind 45 Minuten vorgesehen. Während des Videotelefonats absolvieren beide Gruppen erneut den 1-Minuten Sitz-Steh-Test. Ausserdem werden Ihnen Fragen zu Ihrer Gesundheit in den vergangenen drei Monaten gestellt. Falls Sie der Kontrollgruppe zugeteilt wurden, werden wir Ihnen nach Abschluss des Videotelefonats auf Wunsch einen Zugang zu den Programminhalten mitteilen.

3.7. Programmeinführung und digitales Programm (nur Interventionsgruppe)

Falls Sie der Interventionsgruppe zugeteilt wurden, werden wir mit Ihnen bei der Kontaktaufnahme zur Bekanntmachung der Gruppenzuteilung einen Termin für ein zusätzliches Videotelefonat vereinbaren. Dieses Videotelefonat sollte so zeitnah wie möglich stattfinden. Bei diesem Videotelefonat wird Sie eine Studienperson in das Programm einführen. Das heisst, die Studienperson wird mit Ihnen zusammen die App (Applikation) installieren und Ihnen die Nutzung des Programms erklären. Zudem wird sie mit Ihnen Sicherheitsaspekte besprechen. Für dieses Videotelefonat sind eineinhalb Stunden vorgesehen.

Sie können das strukturierte digitale Programm während drei Monaten nutzen. Dieses Programm kann Ihnen dabei helfen, regelmässig körperlich aktiv zu sein, sich gesund und bedarfsgerecht zu ernähren und Ihr psychisches Wohlbefinden zu steigern. Das Programm wurde speziell für Personen mit Lungenkrebs durch verschiedene Gesundheitsfachpersonen sowie Wissenschaftlerinnen und Wissenschaftler entwickelt. Durch das Gespräch mit der Studienperson zu Beginn wird das Programm individuell auf Sie zugeschnitten. Der Bereich *Bewegung* enthält ein sich über drei Monate aufbauendes Bewegungsprogramm. Es beinhaltet sowohl Kraft-, Beweglichkeits- und Gleichgewichtsübungen als auch Empfehlungen für Ausdauertrainings. Sie benötigen dazu nur einen Stuhl und herkömmliche Flaschen (z. B. PET-Flaschen). Der Bereich *Ernährung* zeigt Ihnen einfache und gesunde Rezepte. Ausserdem lernen Sie, welche Nahrungsmittel für Sie gesund sind und wie viel Sie von welchen Nahrungsmitteln konsumieren sollten. Der Bereich *Atmung/Entspannung* beinhaltet auf Sie abgestimmte Atmungs- und Entspannungsübungen, die Sie überall ohne Material durchführen können. Die App (Applikation) ermöglicht es Ihnen ausserdem, sich Ziele zu setzen, Ihren Fortschritt zu beobachten und einen strukturierten Wochenplan zu den verschiedenen Aktivitäten zu erstellen. Der Zeitaufwand des Programms ist individuell unterschiedlich, beträgt aber ungefähr drei bis vier Stunden pro Woche. Das Programm ersetzt jedoch keine vorgesehenen Massnahmen, wie z. B. hausärztliche Versorgung, Ernährungsberatung, psychologische Betreuung oder Physiotherapie.

Falls Sie der Kontrollgruppe zugeteilt wurden, nehmen Sie nur an den Datenerhebungen teil und erhalten kein Programm. Nach Abschluss des zweiten Videotelefonats werden wir Ihnen jedoch auf Wunsch gerne einen Zugang zu den Programminhalten ermöglichen.

3.8. Zusätzliche Online-Fragebogen nach drei Monaten (nur Interventionsgruppe)

Falls Sie der Interventionsgruppe zugeteilt wurden, werden wir Ihnen nach drei Monaten einen zusätzlichen Link per E-Mail mit mehreren Fragebogen zusenden. Die Fragebogen beinhalten Fragen zu Ihrer Zufriedenheit und Ihren Erfahrungen mit dem digitalen Programm. Das Ausfüllen dieser Fragebogen dauert ca. 15 Minuten.

3.9. Kurzes Interview nach drei Monaten (nur Interventionsgruppe)

Falls Sie der Interventionsgruppe zugeteilt wurden, werden wir Sie nach drei Monaten zu Ihren Erfahrungen befragen. Dies geschieht im selben Videotelefonat, in dem Sie den kurzen Fitness-Test durchführen. Das Interview wird ca. 15 Minuten dauern.

4. Nutzen

Wenn Sie bei dieser Studie teilnehmen und der Interventionsgruppe zugeteilt werden, können Sie ein strukturiertes digitales Programm nutzen. Dieses Programm wurde speziell für Personen mit Lungenkrebs entwickelt und soll Sie dabei unterstützen, eine gesunde Lebensweise zu führen. Das Programm kann Sie dabei unterstützen regelmässig körperlich aktiv sein, sich gesund und bedarfsgerecht zu ernähren und Ihr psychisches Wohlbefinden zu steigern. Dies wiederum kann zu einer verbesserten Lebensqualität führen. Es kann aber auch sein, dass die Teilnahme keinen persönlichen Nutzen mit sich bringt.

Wenn Sie an der QUALUCA-Studie teilnehmen und der Vergleichsgruppe zugeteilt werden, leisten Sie einen wertvollen Beitrag zur Forschung. Ausserdem können Sie die Programminhalte nach vier Monaten kennenlernen und nutzen.

Die Ergebnisse der Studie könnten wichtig und nutzbringend für andere Personen sein, die die gleiche Krankheit haben.

5. Freiwilligkeit und Pflichten

Sie nehmen freiwillig teil. Wenn Sie nicht an dieser Studie teilnehmen oder später Ihre Teilnahme zurückziehen wollen, müssen Sie dies nicht begründen. Ihre Teilnahme ist unabhängig von Ihrer medizinischen Behandlung/Betreuung.
Wenn Sie an dieser Studie teilnehmen, bitten wir Sie:

- die vereinbarten Termine einzuhalten,
- die Fragebogen jeweils ehrlich und möglichst vollständig zu beantworten und den kurzen Fitness-Test bestmöglich durchzuführen,
- uns vorab zu informieren, wenn Sie einen vereinbarten Termin verschieben müssen.

6. Risiken und Belastungen

Wir erwarten keine Risiken im Rahmen der Studie. Die Ausübung der Bewegungsübungen könnte bei ungeübten Teilnehmenden zu Beginn etwas Muskelkater verursachen. Dies ist eine natürliche Reaktion des Körpers und wird mit regelmässigem Training deutlich weniger werden bzw. vollkommen ausbleiben.

7. Andere Behandlungsmöglichkeiten

Sie müssen nicht an dieser Studie teilnehmen. Sie können alternativ das Gespräch über Ihre Lebensweise und mögliche Anpassungen mit ärztlichen/therapeutischen Fachpersonen Ihrer Wahl suchen.

8. Ergebnisse

Das Forschungsteam wird Ihnen am Ende der Studie eine Zusammenfassung der Gesamtergebnisse zukommen lassen.

9. Vertraulichkeit von Daten

9.1. Datenverarbeitung und Verschlüsselung

Für diese Studie werden Daten zu Ihrer Person und Gesundheit erfasst und bearbeitet, teilweise in automatisierter Form. Bei der Datenerhebung werden Ihre Daten verschlüsselt. Verschlüsselung bedeutet, dass alle Bezugsdaten, die Sie identifizieren könnten (Name, Geburtsdatum etc.), gelöscht und durch einen Code ersetzt werden. Personen, die keinen Zugang zu dieser Schlüssel-Liste haben, können keine Rückschlüsse auf Ihre Person ziehen. Die Schlüssel-Liste bleibt immer am Institut für Epidemiologie, Biostatistik und Prävention der Universität Zürich und ist passwortgeschützt auf einem sicheren Server gespeichert. Zugriff auf die Liste besitzen nur wenige, ausgewählte Fachpersonen des Rehabilitationszentrums und der Universität Zürich, und zwar nur, um Aufgaben im Rahmen der Studie zu erfüllen. Diese Personen unterliegen der Schweigepflicht. Sie als teilnehmende Person haben das Recht auf Einsicht in Ihre Daten.

9.2. Datenschutz

Alle Vorgaben des Datenschutzes werden streng eingehalten. Es ist möglich, dass Ihre Daten in verschlüsselter Form, zum Beispiel für eine Publikation, übermittelt werden müssen und anderen Forschenden zur Verfügung gestellt werden können.

9.3. Datenschutz bei Weiterverwendung

Ihre Daten könnten für die Beantwortung von anderen Fragestellungen zu einem späteren Zeitpunkt wichtig sein oder später an eine andere Datenbank in der Schweiz oder ins Ausland für noch nicht näher definierte Untersuchungen (Weiterverwendung) versandt und verwendet werden. Diese andere Datenbank muss die gleichen Standards einhalten wie die Datenbank zu dieser Studie.

OR

OR

Für diese eventuelle Weiterverwendung Ihrer verschlüsselten Daten bitten wir Sie, ganz am Ende dieses Dokuments eine weitere Einwilligungserklärung zu unterzeichnen. Diese zweite Einwilligung ist unabhängig von der Teilnahme an dieser Studie und selbstverständlich freiwillig.

9.4. Einsichtsrechte bei Kontrollen

Die zuständige Ethikkommission kann die korrekte Durchführung der Studie kontrollieren. Das Forschungsteam muss dann Ihre Daten für solche Kontrollen offenlegen. Alle müssen absolute Vertraulichkeit wahren.

10. Rücktritt

Sie können jederzeit von der Studie zurücktreten. Die bis dahin erhobenen Daten werden in diesem Fall noch verschlüsselt ausgewertet.

Nach der Auswertung werden Ihre Daten auf Ihren Wunsch hin anonymisiert. Die Schlüsselzuordnung wird vernichtet, so dass danach niemand mehr erfahren kann, dass die Daten ursprünglich von Ihnen stammten. Dies dient vorrangig dem Datenschutz.

11. Entschädigung

Wenn Sie an dieser Studie teilnehmen, bekommen Sie dafür keine Entschädigung. Es entstehen Ihnen oder Ihrer Krankenkasse keine Kosten durch die Teilnahme.

12. Haftung

Die Universität Zürich, die die Studie veranlasst hat und für die Durchführung verantwortlich ist, haftet für Schäden, die Ihnen im Zusammenhang mit den Forschungshandlungen (z. B. Datenerhebungen) entstehen könnten. Die Voraussetzungen und das Vorgehen dazu sind gesetzlich geregelt. Sollten Sie durch die Teilnahme an dieser Studie einen Schaden erleiden, so wenden Sie sich bitte an das Forschungsteam.

13. Finanzierung

Die Studie wird mehrheitlich durch die *Lungenliga Schweiz* finanziell unterstützt.

14. Kontaktpersonen

Sie dürfen jederzeit Fragen zur Studienteilnahme stellen. Auch bei Unsicherheiten wenden Sie sich bitte an:

Prüfperson:
PD Dr. med. Marc Spielmanns
Zürcher RehaZentren | Klinik Wald
Faltigbergstrasse 7
8636 Wald

OR

PD Dr. med. Marc Spielmanns
Zürcher RehaZentren | Klinik Davos
Klinikstrasse 6
7272 Davos Clavadel

OR

Gilbert Büsching
Klinik Barmelweid AG
5017 Barmelweid

OR

OR

OR

Dr. Thimo Marcin
Berner Reha Zentrum AG
Schwendi 299
3625 Heiligenschwendi

Studienmitarbeiter:
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Universität Zürich (Institut für Epidemiologie, Biostatistik und Prävention)
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PD Dr. Anja Frei
Institut für Epidemiologie, Biostatistik und Prävention
Universität Zürich
Hirschengraben 84
8001 Zürich

OR

OR

Einwilligungserklärung

Schriftliche Einwilligungserklärung zur Teilnahme an einer klinischen Studie
Bitte lesen Sie dieses Formular sorgfältig durch. Bitte fragen Sie, wenn Sie etwas nicht verstehen oder wissen möchten. Für die Teilnahme ist Ihre schriftliche Einwilligung notwendig.

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Titel der Studie:	Unterstützung einer gesunden Lebensweise durch ein digitales Programm für Personen mit Lungenkrebs: die QUALUCA Studie
Verantwortliche Institution:	Prof. Dr. Kai-Uwe Schmitt Berner Fachhochschule Departement Gesundheit Akademie-Praxis-Partnerschaft Insel Gruppe Murtenstrasse 10 3008 Bern
Ort der Durchführung:	Zürcher RehaZentren | Klinik Wald Faltigbergstrasse 7 8636 Wald OR Zürcher RehaZentren | Klinik Davos Klinikstrasse 6 7272 Davos Clavadel OR Klinik Barmelweid AG 5017 Barmelweid OR Berner Reha Zentrum AG Schwendi 299 3625 Heiligenschwendi und zu Hause
Prüfperson am Studienort: Name und Vorname in Druckbuchstaben:	PD Dr. med. Marc Spielmanns OR Gilbert Büsching OR Dr. Thimo Marcin

OR

OR

Teilnehmerin/Teilnehmer: Name und Vorname in Druckbuchstaben: Geburtsdatum:	

- Ich wurde von der unterzeichnenden Prüfperson mündlich und schriftlich über den Zweck, den Ablauf der Studie, mögliche Vor- und Nachteile sowie über eventuelle Risiken informiert.
- Ich nehme an dieser Studie freiwillig teil und akzeptiere den Inhalt der mir ausgehändigten schriftlichen Information. Ich hatte genügend Zeit, meine Entscheidung zu treffen.
- Meine Fragen im Zusammenhang mit der Teilnahme an dieser Studie sind mir beantwortet worden. Ich behalte die schriftliche Information und erhalte auf Wunsch eine Kopie meiner schriftlichen Einwilligungserklärung.
- Ich bin einverstanden, dass die Rehabilitationsklinik, in der ich aktuell behandelt werde, Daten zu meiner Person und meiner Gesundheit an die Universität Zürich (Institut für Epidemiologie, Biostatistik und Prävention) im Rahmen dieser Studie weitergeben darf. Ausserdem bin ich einverstanden, dass die Rehabilitationsklinik die Kontaktdaten zu meinem Notfallkontakt an die Universität Zürich (Institut für Epidemiologie, Biostatistik und Prävention) im Rahmen der Studie weitergeben darf.
- Ich bin einverstanden, dass die zuständigen Fachleute der Projektleitung und der zuständigen Ethikkommission zu Prüf- und Kontrollzwecken in meine unverschlüsselten Daten Einsicht nehmen dürfen, jedoch unter strikter Einhaltung der Vertraulichkeit.
- Ich weiss, dass meine gesundheitsbezogenen und persönlichen Daten nur in verschlüsselter Form zu Forschungszwecken für diese Studie weitergegeben werden können. Die Projektleitung gewährleistet, dass der Datenschutz nach Schweizer Standard eingehalten wird.
- Ich kann jederzeit und ohne Angabe von Gründen von der Studienteilnahme zurücktreten. Meine weitere medizinische Behandlung ist unabhängig von der Studienteilnahme gewährleistet. Die bis zum Rücktritt erhobenen Daten werden noch im Rahmen der Studie ausgewertet.
- Die Haftpflichtversicherung der Universität Zürich kommt für allfällige Schäden auf.
- Ich bin mir bewusst, dass die in der Informationsschrift genannten Pflichten einzuhalten sind.

Ort, Datum	Unterschrift Teilnehmerin/Teilnehmer

Bestätigung der Prüfperson: Hiermit bestätige ich, dass ich dieser Teilnehmerin/diesem Teilnehmer Wesen, Bedeutung und Tragweite der Studie erläutert habe. Ich versichere, alle im Zusammenhang mit dieser Studie stehenden Verpflichtungen gemäss in der Schweiz geltenden Rechts zu erfüllen. Sollte ich im Verlauf der Studie von Aspekten erfahren, welche die Bereitschaft der Teilnehmerin/des Teilnehmers zur Studienteilnahme beeinflussen könnten, werde ich sie/ihn umgehend darüber informieren.

Ort, Datum	Name und Vorname der Prüfperson in Druckbuchstaben Unterschrift der Prüfperson

OR

OR

Einwilligungserklärung für Weiterverwendung von Daten in verschlüsselter Form

BASEC-Nummer:	2023-00245
Titel der Studie:	Unterstützung einer gesunden Lebensweise durch ein digitales Programm für Personen mit Lungenkrebs: die QUALUCA Studie
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Ich erlaube, dass meine verschlüsselten Daten aus dieser Studie für die medizinische Forschung weiterverwendet werden dürfen. Die Daten werden in einer Datenbank gelagert und für zukünftige, noch nicht näher definierte Forschungsprojekte auf unbestimmte Zeitdauer verwendet.

Ich habe verstanden, dass die Daten verschlüsselt sind und der Schlüssel sicher aufbewahrt wird. Die Daten können im In- und Ausland an andere Datenbanken zur Analyse gesendet werden, wenn diese dieselben Standards wie in der Schweiz einhalten. Alle rechtlichen Vorgaben zum Datenschutz werden eingehalten.

Ich entscheide freiwillig und kann diesen Entscheid zu jedem Zeitpunkt wiederzurücknehmen. Wenn ich zurücktrete, werden meine Daten anonymisiert. Ich informiere lediglich die Projektleitung und muss diesen Entscheid nicht begründen.

Ort, Datum	Unterschrift Teilnehmerin/Teilnehmer

Bestätigung der Prüfperson: Hiermit bestätige ich, dass ich dieser Teilnehmerin/diesem Teilnehmer Wesen, Bedeutung und Tragweite der Weiterverwendung von Daten erläutert habe.

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