Karl Landsteiner Institut für Lungenforschung und Pneumologische Onkologie

Wiener Gesundheitsverbund Klinik Ottakring | Für die Stadt Wien

Wiener Gesundheitsverbund Klinik Floridsdorf | Für die Stadt Wien

universität wien Fakultät für Psychologie

Clinical Study Protocol

SPIROMIND-STUDY

A pilot randomized controlled trial to examine the feasibility and effects of a brief digital mindfulness-based intervention for stable COPD patients

Version 2.0 / 026.04.21

EXECUTIVE SUMMARY

Background: COPD patients frequently experience psychological distress (symptoms of anxiety and depression) as well as psychophysiological symptoms of stress. So far, pharmacological treatments showed only limited effectiveness. Therefore, a need for further treatment options emerges, which was also reported by COPD patients themselves. MBIs were shown to be effective in older and chronically ill populations and appear attractive to stable COPD patients. Hence, the presented study will follow this idea and investigate an app-based mindfulness intervention using ecological momentary assessment (EMA) and psychophysiological measures. This study's primary research objective is to examine a) whether a brief digital mindfulness-based intervention is feasible for stable COPD patients, and b) whether a brief digital mindfulness-based intervention can reduce psychological distress in stable COPD patients. Additionally, this study aims to investigate immediate effects of mindfulness exercises as well as intermediate and long-term effects on other respiratory, psychophysiological and psychological variables.

Methods: This pilot randomized controlled trial intends to include 30 stable COPD patients, who are psychologically distressed and will be randomly assigned to the intervention (app-based mindfulness + treatment as usual) and waitlist control (treatment as usual) condition. The intervention group will be introduced to the intervention in a face-to-face learning phase (single day) conducted by the study coordinator while being hospitalized. Patients in the intervention group will be instructed to practice mindfulness daily using at least one of 4 short exercises (10-15 minutes) over a period of 8 weeks, starting in the hospital and continuing at home. The exercises will be delivered by a software (movisensXS). Additionally, dyspnoea, stress, relaxation, affect and oxygen saturation (assessed by a pulse oximeter) will be assessed before and after each exercise via the software.

Questionnaire data will be collected equally in both groups at 5 measurements: baseline, after 4 weeks, after the intervention (8 weeks) and at follow-up (4 and 6 months). Physiological measures (heart rate variability, electrodermal activity, heart rate) will be conducted at the same 5 measurements, using an ecg and eda sensor (movisens EcgMove4, movisens EdaMove4). Physiological measures will be assessed during the conduction of a cognitive stress test (Stroop-test), as well as before and after the conduction (at rest). Hair cortisol will be collected at baseline, after the intervention (8 weeks) and at follow-up (4 and 6 months). Face-to-face exit interviews will be conducted in the intervention group after 8 weeks to further assess patients' experiences with the intervention.

The primary outcome measures are psychological distress and the intervention's feasibility. The secondary outcome parameters for immediate effects of mindfulness exercises will be dyspnoea, stress, relaxation, affect (anxiety, depression, happiness) and oxygen saturation. The secondary outcome parameters for intermediate and long-term effects are heart rate variability, electrodermal activity, heart rate, health-related quality of life, health status impairment, fatigue, breathlessness catastrophizing, perceived and chronic stress, mindfulness and self-compassion. Additionally, compliance regarding medication-intake, perception of exacerbations, frequency and intensity of exacerbations and hospitalization rate as well as patients' experiences with the intervention are assessed.

Analysis: This study will realize a mixed methods analysis. Differences between conditions as well as moderating and mediating effects will be calculated. The intermediate pre-post effects of mindfulness exercises will be analysed using multi-level analyses (HLM). Interview data will be analysed using thematic analysis.

Discussion: The study aims to assess the feasibility of a brief app-based mindfulness intervention for stable COPD patients who are psychologically distressed and intends to investigate its effects on psychological distress and various other psychological, psychophysiological and respiratory variables. The results of this study could serve as basis for following large-scale RCTs and advance the future implementation of app-based MBIs as add-on treatment in the clinical practice.

Ethics: The study will be conducted in accordance with the Declaration of Helsinki. It will be asked for examination and agreement by the ethics committee of the city of Vienna. Ethics approval for a similar study for COPD patients following acute exacerbations has already been obtained by the ethics committee of the city of Vienna (serial number EK 20-177-VK).

SPONSOR, INVESTIGATOR, MONITOR AND SIGNATURES

Sponsor/or representative (OEL) (AMG §§ 2a, 31, 32)

Karl-Landsteiner-Institut für Lungenforschung und Pneumologische Onkologie

Signature (OEL)	Date

Investigators (AMG §§ 2a, 35, 36)

Prim. Priv.-Doz. Dr. Georg-Christian Funk, Klinik Ottakring, Vienna, Austria (principal investigator)

Signature	Date

Univ.-Prof. Dr. Urs Markus Nater, Department of Clinical and Health Psychology, University of Vienna, Austria

Signature	Date

Dr. Florian Vafai-Tabrizi, Klinik Ottakring, Vienna, Austria

Signature	Date

Hannah Tschenett, B.Sc., Department of Clinical and Health Psychology, University of Vienna, Austria (study coordinator)

Signature	Date

Monitor/ or Representative of CRO (AMG §§ 2a, 33, 34)

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Signature Date

Clinical Trials Centres:

2.Medizinische Abteilung mit Pneumologie, Klinik Ottakring, Vienna, Austria

Abteilung für Innere Medizin und Pneumologie, Klinik Floridsdorf, Vienna, Austria

Associated Departments:

Department of Clinical and Health Psychology, University of Vienna, Austria

CLINICAL STUDY PROTOCOL

TITLE	A pilot randomized controlled trial to examine the feasibility and effects of a brief digital mindfulness-based intervention for stable COPD patients
BACKGROUND	**BACKGROUND:** Multiple reviews showed that symptoms of anxiety and depression (=psychological distress) are significantly more prevalent in COPD patients than in the general population (Matte et al., 2016; Willgoss & Yohannes, 2013). Both correlate with a decrease in health-related quality of life (e.g. Blakemore et al., 2014), but are also associated with other worsened health outcomes, such as a poorer functional status, higher mortality rates and more frequent and longer hospitalisations (e.g. Atlantis, Fahey, Cochrane, & Smith, 2013; Panagioti, Scott, Blakemore, & Coventry, 2014; Pumar et al., 2014). Moreover, breathing problems have been identified as major stressor for COPD patients (Andenæs, Kalfoss, and Wahl, 2006). If stressful events like dyspnoea are experienced frequently, this might determine a maladaptive activation of the bodily stress systems, meaning the autonomous nervous system (ANS) and the hypothalamic-pituitary-adrenal axis (HPA axis), leading to an ongoing dysregulation of these systems and resulting in chronic stress (e.g. Chrousos, 2009). Studies have shown a general sympathetic overactivity of the ANS in COPD patients (Van Gestel, Kohler, & Clarenbach, 2012). Furthermore, COPD is characterized by a systemic inflammatory response manifesting with increased inflammatory cytokines (Singh et al., 2018). As the inflammatory response is regulated by both the ANS as well as the HPA axis (Glaser & Kiecolt-Glaser, 2005), this adds up to the evidence of an ongoing dysregulation of these stress systems in COPD. Such dysregulations, in turn, are known to increase the risk for mental and physical health problems (e.g. Adam et al., 2017). Therefore, it seems crucial to address both, psychological distress and stress, in mental health interventions for COPD patients. In addition, high-quality evidence regarding the effectiveness of pharmacological interventions in reducing symptoms of anxiety and depression in COPD is limited (Cafarella, Effing, Barton, Ahmed, & Frith, 2013), with psychological interventions showing greater treatment efficacy when compared to pharmacotherapy (Usmani, Chahhoud, Esterman, & Smith, 2018). Hence, further psychosocial treatment approaches focusing on the reduction of psychological distress as well as psychophysiological stress responses and dyspnea should be investigated. The results of a recent study conducted by our team underline this necessity, as hospitalized COPD patients reported the need for further treatment options. In our previous study, we were able to show that most hospitalized COPD patients (14/20) would be interested in participating in a mindfulness-based intervention (MBI). Mindfulness is a promising option in the treatment of COPD patients, as it significantly reduced symptoms of stress (psychological and physiological parameters), anxiety and depression in previous studies (Cillessen, Johannsen, Speckens, & Zachariae, 2019; Pascoe, Thompson, Jenkins, & Ski, 2017). Furthermore, mindfulness was beneficial for older adults (Hazlett-Stevens, Singer, & Chong, 2019) and patients with other chronic conditions (Bohlmeijer, Prenger, Taal, & Cuijpers, 2010). Despite the above, the existing evidence on MBIs for COPD patients is very scarce. So far, only eight primary studies examined the effects of MBIs on COPD patients (e.g. Chan, Giardino, & Llarson, 2015). Two of them investigated brief MBIs

	in COPD inpatients (Perkins-Porras et al., 2018; Tan et al., 2019). To summarize the few results, MBIs appeared to be feasible and attractive to COPD patients and showed a trend for being effective in the improvement of anxiety and depression symptoms (Farver-Vestergaard, O'Toole, et al., 2018) and dyspnea (Tan et al., 2019). Perceived or psychophysiological stress responses have been considered in only two studies, which found no effects on perceived stress and inflammatory stress markers (Farver-Vestergaard, O'Toole, et al., 2018; Mularski et al., 2009). Only one study investigated a digital MBI (Farver-Vestergaard, O'Connor, et al., 2018), which had very high attendance rates but found only trends in improvement of psychological distress. However, digital interventions seem to be especially promising for COPD patients, as they are often limited in their mobility and therefore seek for interventions feasible for the conduction at home. Moreover, digital health applications have become of particular interest and importance since the onset of the ongoing Covid19-pandemic. To summarize, well-designed, high quality studies are needed to confirm the beneficial effects of MBIs on psychological distress and dyspnea, but also to further investigate the effects on perceived and psychophysiological stress. This is crucial to enable an evidence-based use of MBIs in clinical settings. **PRESENT STUDY:** The presented pilot and feasibility randomized controlled trial will investigate a mindfulness-based ecological momentary intervention (EMI) applicable in the daily life of COPD patients. The intervention is adapted to patients' needs and limitations, which were assessed in our previous study and were found to be crucial for patients' adherence. This will be the first study to examine an app-based mindfulness EMI for COPD patients. The study will use an ecological momentary assessment (EMA) design, which allows real-time measures in the patients' daily life. Previous research showed EMA to be more valid and sensitive in investigating dynamic psychological aspects (e.g. affective variables). Moreover, it was able to detect therapeutic effects earlier and minimized retrospective biases compared to standard questionnaire assessments (Ebner-Priemer & Trull, 2009). The delivery via an app was chosen to improve adherence and to suit patients' difficulties regarding mobility. Additionally, this allows to provide a personalized intervention, as different exercises can be chosen based on patients' preferences and needs. Furthermore, mobile health is an emerging and promising field, which is both economic and feasible when used in health care. In addition, as personalized medicine is a growing field of interest and holds great potential, the presented study aims to identify treatable traits and patients who benefit most from the intervention. Finally, this study will examine the effects of mindfulness on psychophysiological stress markers (e.g. heart rate variability), which play an important role in COPD (Andreas, Haarmann, Klarner, Hasenfuß, & Raupach, 2014). It is well known that physiological and psychological stress symptoms can be reduced by MBIs (Pascoe et al., 2017). Yet, this effect has poorly been studied in COPD patients to date.
OBJECTIVES	**Primary Research Questions** • Is a brief digital mindfulness-based intervention feasible for stable COPD patients?

	• Can a brief digital mindfulness-based intervention reduce psychological distress in stable, but psychologically distressed, COPD patients (using the "Hospital Anxiety and Depression Scale")? **Secondary Research Questions** • What are the immediate effects of a short mindfulness exercise for stable COPD patients on dyspnea, acute perceived stress, relaxation, affect and oxygen saturation? • What are the effects of daily short mindfulness practice for stable COPD patients on patients' stress level and stress reactivity (heart rate variability, electrodermal activity), when being exposed to a cognitive stressor (Stroop-test)? • What are the effects of daily short mindfulness practice for stable COPD patients on patients' dealing with the exposure to a cognitive stressor (Stroop-Test)? Are there effects on anxiety, panic, acute perceived stress, relaxation, affect and oxygen saturation? • What are the intermediate and long-term effects of daily short mindfulness practice for stable COPD patients on health-related quality of life, health status impairment, fatigue, breathlessness catastrophizing, perceived stress, mindfulness and self-compassion? • Does the compliance regarding medication differ between the groups due to the intervention? • How do patients experience the intervention? • How often do patients meditate by using the app? How long? When? Do they prefer a specific mindfulness exercise? • Which patients benefit the most from the intervention (moderating factors, e.g. age)? • Do mindfulness and self-compassion mediate the intermediate and long-term effects on psychological distress?
DESIGN / PHASE	• pilot and feasibility study • randomized controlled trial including follow-up • two treatment arms: intervention + treatment as usual (TAU) vs. waitlist (TAU) • ecological momentary assessment (EMA) study • ecological momentary intervention (EMI) study (app-based) • prospective and experimental • mixed methods analysis • multi-centred
STUDY PLANNED DURATION	6 months (8 weeks intervention + follow-up)
CENTER(S)/ COUNTRY(IES)	Respiratory unit of the "Klinik Ottakring", Vienna, Austria Respiratory unit of the "Klinik Floridsdorf", Vienna, Austria
PATIENTS / GROUPS	**Groups:** 1. Intervention group: mindfulness exercises + TAU 2. Waitlist control group: TAU **Sample size:** 30 COPD patients (15 patients in each group)

	Sampling method: screening of all eligible patients during survey period, inclusion of all eligible interested patients **Blinding:** single blinding (of assessors) **Allocation:** equal treatment allocation via block randomization

ETHICS	• patients' written informed consent
	• pseudonymisation of patients:
	  ○ Patients' personal data is noted on 2 documents: the *patients' information* (name, birth date, code) and the *patients' contact details* (name, birth date, address, phone number, email address, code). These documents are safely stored in a locked cupboard in the Klinik Ottakring, Vienna, Austria. Only members of the research team have access to the cupboard's key.
	  ○ After the screening, the patient is given a unique reference code (continuous numerical code starting from 01). In the following, only this numerical code will be used to allocate the data to the patient.
	  ○ The allocation of the patients' personal data to their numerical code will only be possible using either the *patients' information* or the *patients' contact details.*
	• pseudonymised data analysis
	• provision of mindfulness intervention to waitlist control group after study completion
	• examination and agreement by the ethics committee of the "Wiener Krankenanstaltenverbund", Vienna, Austria

INCLUSION CRITERIA	• spirometry confirmed (FEV1<80%) COPD diagnosis
	• psychological distress (as assessed by the Hospital Anxiety and Depression Scale):
	  ○ HADS-A ≥ 8 OR
	  ○ HADS-D ≥ 8 OR
	  ○ HADS total score ≥ 16
	• age ≥ 40 years
	• ability to understand German
	• physical and mental capability to attend the intervention, judged by the treating physician
	• life expectancy > 6 months as judged by treating physician
	• ability to use a smartphone

EXCLUSION CRITERIA	• auditory impairment • active asthma diagnosis • any other known severe comorbidities such as heart failure (LVF<35%), uncontrolled diabetes, concomitant cancer, stroke, unstable coronary heart disease, respiratory failure • history of/current severe psychological disorder (e.g. schizophrenia, severe cognitive impairment) • current acute exacerbation of COPD • any other relevant acute health crisis interfering with the study intervention (e.g. Covid-19) • receiving any psychosocial treatment (e.g. psychotherapy) • regular other systematic mind-body-practice
STUDY PERIODS	**Period 1:** individual mindfulness practice at home (baseline – 8 weeks) **Period 2:** Follow-up (3 months and 6 months)

MEASUREMENTS	**Paper-pencil data collection** (baseline, 4 weeks, 8 weeks, 4 months, 6 months)**:** psychological distress, perceived stress, health related quality of life, health status impairment, fatigue, mindfulness, self-compassion, breathlessness catastrophizing **Psychophysiological data collection** (baseline, 4 weeks, 8 weeks, 4 months, 6 months)**:** heart rate variability, electrodermal activity (before, during and after the conduction of a cognitive task (Stroop-test)) **EMA data collection** (daily for intervention period of 8 weeks)**:** • pre-meditation (event-based): dyspnea, acute perceived stress, relaxation, anxiety, depression, happiness, oxygen saturation (pulse oximeter) • post-meditation (event-based): dyspnea, acute perceived stress, relaxation, anxiety, depression, happiness, oxygen saturation (pulse oximeter)

STUDY TIME-LINE	**Recruitment:**
	• pulmonary ambulances of the Klinik Ottakring and Klinik Floridsdorf
	• previously hospitalized COPD patients in the Klinik Ottakring and Klinik Floridsdorf
	• invitation to the intervention via telephone call or personal invitation in the pulmonary ambulance (flyer and oral information)
	• invitation to the intervention via posting a flyer on social media (Facebook)
	
	Telephone-Screening:
	• screening for inclusion and exclusion criteria
	
	Period 1 (patients' home)
	
	<u>Day 0:</u>
	• Informed consent
	• Baseline data collection
	  ○ Sociodemographic and medical data
	  ○ Paper-pencil data collection
	  ○ Chronic stress (collection of hair sample)
	  ○ Psychophysiological data collection
	
	<u>Day 1:</u>
	• Introductory and learning phase (face-to-face)
	• Installation and testing of app, explanation of intervention, conduction of all mindfulness exercises in the presence of study investigator
	• From now on: Individual daily meditation + daily EMA data collection
	• Possibility of consulting the study coordinator in person and if necessary, discussing/solving problems in period 1
	
	<u>Intermediate (4 weeks):</u>
	• Paper-pencil data collection (+ hospitalization and exacerbation rate)
	• Psychophysiological data collection
	
	<u>Exit (8 weeks):</u>
	• Paper-pencil data collection (+ hospitalization rate, exacerbation rate, credibility/expectancy)
	• Psychophysiological data collection
	• Short exit-interview (telephone)

	Period 2 (follow-up) Follow-up 1 (4 months): • Paper-pencil data collection (+ hospitalization and exacerbation rate) • Psychophysiological data collection • Chronic stress (collection of hair sample) Follow-up 2 (6 months): • Paper-pencil data collection (+ hospitalization and exacerbation rate) • Psychophysiological data collection • Chronic stress (collection of hair sample) • Post-monitoring interview

INTERVENTION	**Daily short mindfulness exercises delivered via app**
	• App provides 4 audio-files of guided mindfulness exercises
	• Length: 10-15 minutes
	• Mindfulness exercises:
	  ○ Body awareness meditation (Body-scan)
	  ○ Sitting meditation: awareness of the heartbeat
	  ○ Sitting meditation: awareness of the body
	  ○ Sitting meditation: awareness of sounds
	
	Dose: Patients can choose individually between exercises
	
	Daily practice: instructions to practice at least once each day, either in the morning or the evening (patients choose in the beginning if they prefer meditating in the morning or in the evening)
	
	Additional practice: additional meditations are possible and encouraged (it is advised to practice when experiencing respiratory problems, feeling distressed, feeling stressed or whenever considered to be beneficial)

CONTROL CONDITION	Waitlist control group (receiving treatment as usual during the intervention period) (same collection of psychophysiological, psychological and biological data, except for the intervention-related measures right before and after the intervention)
INCENTIVES	Weekly “checking-in calls”
CONCOMITANT MEDICATION	Allowed (but must be monitored)
PRIMARY OUTCOME VARIABLES	**Feasibility** (exit interview, drop-out-rate) **Intermediate and long-term effects of daily mindfulness practice:** • Psychological distress (Hospital Anxiety and Depression Scale)
SECONDARY OUTCOME VARIABLES	**Immediate effects of mindfulness exercises:** • Acute perceived stress (visual analogue scale) • Dyspnea (Borg Dyspnea Scale) • Relaxation (Likert scale based on MDBF) • Affect (anxiety, depression, happiness; based on HADS) • Oxygen saturation in blood (Pulse Oximeter)

	Intermediate and long-term effects of daily mindfulness practice: • Heart rate variability, heart rate (chest belt) • Electrodermal activity (EDA-sensors) • Chronic stress (hair-cortisol) • Chronic stress (Perceived Stress Scale) • Health related quality of life (Chronic Respiratory Questionnaire) • Health status impairment (COPD-Assessment Test) • Fatigue (Multidimensional Fatigue Inventory) • Mindfulness (German Version of Freiburg Mindfulness Inventory – Freiburger Fragebogen zur Achtsamkeit) • Self-compassion (Self Compassion Scale) • Breathlessness Catastrophizing (Breathlessness Catastrophizing Scale) **Further outcomes:** • Compliance regarding medication • Perception of exacerbations (exit interview) • Hospitalization rate • Frequency and intensity of exacerbations
STATISTICAL METHODOLOGY	**Primary hypotheses:** It is hypothesized that the digital MBI will be feasible in the ambulant setting. Furthermore, it is assumed that the digital intervention will reduce psychological distress. The feasibility of the study will be examined using descriptive analyses, looking deeper into drop-out-rates, recruitment, adherence and patients' personal factors. **Statistical analyses:** Groups (intervention vs. waitlist) will be compared regarding subjective variables (e.g. psychological distress), biological variables (hair cortisol levels), and physiological responses of the autonomous nervous system (heart rate variability, electrodermal activity) to the mental stressor using analyses of variance (ANOVAs) with repeated measurement. These analyses test for main effects of time (within subject factor) and group (between subject factor) as well as their interaction effect. In case the requirements of ANOVAs are not met, a non-parametric pendant will be used. Furthermore, mediating (e.g. mindfulness) and moderating (e.g. age, gender, disease severity) effects will be analysed. For the analysis of the EMA data in the intervention group, multilevel modelling will be used to fit the nested data structure. A two-level model (level 1 = within persons, level 2 = between persons) will be used, with all the assessed subjective variables (e.g. momentary stress) nested on level 1 due to multiple measurements. Pre-post effects of the assessed subjective variables will examine the immediate effects of the MBI. Telephone exit interviews will be recorded and analysed using thematic analysis and a mixed methods approach.
DATA MANAGEMENT	**Paper-pencil-data:** • **Digitalization:** As data are collected on different sites by student research assistants, data will firstly be transported to the Department of Clinical and Health Psychology, University of Vienna, Austria. There, data will be digitalized.

	For this process, data will be safely stored in a locked cupboard in the Department of Clinical and Health Psychology, University of Vienna, Austria. Only members of the research team have access to the key. • **Final storage of physical data:** The study coordinator will transport the physical data safely to the Klinik Ottakring, Vienna, Austria, where the data is finally stored in a locked cupboard. Only members of the research team have access to the key. • **Storage of digital data:** Digital data will be stored on the share server of the research team led by Prof. Urs Markus Nater (University of Vienna, Austria). A project folder "39 SPIROMIND" was created for the data storage. Each person's access to the folder must be approved by Prof. Urs Markus Nater and must be activated by the department's IT team. Only members of the SPIROMIND research team have access to the folder. Additionally, data will be stored on the study coordinator's server of the Klinik Ottakring, Vienna, Austria, and on the study coordinator's server of the Department of Clinical and Health Psychology, University of Vienna, Austria. • **Analysis:** Data will be analysed using the software IBM SPSS Statistics, version 24, and the software R, version 3.4.2. **EMA data:** • **Access to data:** Data are stored on the study's private account of the software MovisensXS. Only members of the research team have access to the account. • **Storage of data:** Data will be exported from MovisensXS and stored on the share server of the research team led by Prof. Urs Markus Nater (University of Vienna, Austria). A project folder "39 SPIROMIND" was created for the data storage. Each person's access to the folder must be approved by Prof. Urs Markus Nater and must be activated by the department's IT team. Only members of the SPIROMIND research team have access to the folder. Additionally, data will be stored on the study coordinator's server of the Klinik Ottakring, Vienna, Austria, and on the study coordinator's server of the Department of Clinical and Health Psychology, University of Vienna, Austria. • **Analysis:** Data will be analysed using the software IBM SPSS Statistics, version 24, the software R, version 3.4.2, and HLM. **Physiological data:** • **Access to data:** Data will be exported from the devices using the Movisens Data Manager. This will be conducted by the student research assistants. • **Storage of data:** Data will then be stored on the share server of the research team led by Prof. Urs Markus Nater (University of Vienna, Austria). A project folder "39 SPIROMIND" was created for the data storage. Each person's access to the folder must be approved by Prof. Urs Markus Nater and must be activated by the department's IT team. Only members of the SPIROMIND research team have access to the folder. Additionally, data will be stored on the study coordinator's server of the Klinik Ottakring, Vienna, Austria, and on the study coordinator's server of the Department of Clinical and Health Psychology, University of Vienna, Austria. • **Analysis:** Data will be analysed using the software Movisens Data Analyser (Base + Cardio/HRV), IBM SPSS Statistics, version 24, and the software R, version 3.4.2. **Biometric data (hair samples):** • **Collection:** As data are collected on different sites by student research assistants, data will firstly be transported to the Department of Clinical and

	Health Psychology, University of Vienna, Austria. There, data will be safely stored in a locked cupboard in the Department of Clinical and Health Psychology, University of Vienna, Austria, until data will be analysed. Only members of the research team have access to the key. • **Biometric analysis:** A member of the research team will safely transport the data to the biochemical laboratory of the Faculty of Psychology, Vienna, Austria, where the data will be analysed by researchers unrelated to the SPIROMIND study. The biochemical laboratory ensures safe storage of the data. • **Final storage of biometric data:** The study coordinator will transport the biometric data safely to the Klink Ottakring, Vienna, Austria, where the data is finally stored in a locked cupboard. Only members of the research team have access to the key. • **Storage of digital data:** Digital data will be stored on the share server of the research team led by Prof. Urs Markus Nater (University of Vienna, Austria). A project folder "39 SPIROMIND" was created for the data storage. Each person's access to the folder must be approved by Prof. Urs Markus Nater and must be activated by the department's IT team. Only members of the SPIROMIND research team have access to the folder. Additionally, data will be stored on the study coordinator's server of the Klinik Ottakring, Vienna, Austria, and on the study coordinator's server of the Department of Clinical and Health Psychology, University of Vienna, Austria. • **Analysis:** Digital data will be analysed using the software IBM SPSS Statistics, version 24, and the software R, version 3.4.2. **Qualitative data:** • **Collection:** Data will be collected using a recorder. • **Storage**: Data (audio-files) will be stored on the share server of the research team led by Prof. Urs Markus Nater (University of Vienna, Austria). A project folder "39 SPIROMIND" was created for the data storage. Each person's access to the folder must be approved by Prof. Urs Markus Nater and must be activated by the department's IT team. Only members of the SPIROMIND research team have access to the folder. Additionally, data will be stored on the study coordinator's server of the Klinik Ottakring, Vienna, Austria, and on the study coordinator's server of the Department of Clinical and Health Psychology, University of Vienna, Austria. • **Analysis:** Data will be analysed using the softwares f4transcript and f4analyse.
DATA SECURITY	All WIGEV external members of the research team consented to sign the "datenschutzrechtliche Verpflichtungserklärung des WIGEV". The study coordinator of the Karl Landsteiner Institute for Lung Research and Pneumological Oncology stores these documents in the Klinik Ottakring.

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