MASTERARBEIT / MASTER'S THESIS

Titel der Masterarbeit / Title of the Master's Thesis

"Effects of a digital mindfulness-based intervention on psychological distress in COPD patients – Preliminary results of a pilot RCT"

verfasst von / submitted by

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angestrebter akademischer Grad / in partial fulfilment of the requirements for the degree of

Master of Science (MSc)

Wien, 2021/ Vienna, 2021

Acknowledgements:

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List of abbreviations

COPD:	chronic obstructive pulmonary disease
MBI:	mindfulness-based intervention
RCT:	randomized controlled trial
GOLD:	Global Initiative for Chronic Obstructive Lung Disease
MBSR:	Mindfulness-based Stress Reduction
MBCT:	Mindfulness-based Cognitive Therapy
HADS:	Hospital Anxiety and Depression Scale, German version
HADS-D:	subscale depressive symptoms of the HADS
HADS-A:	subscale anxiety symptoms of the HADS
FMI-14:	Freiburg Mindfulness Inventory, German short version
SCS-SF:	Self-compassion Scale, German short version
FEV1:	forced expiratory volume in one second
T1:	Baseline measurement
T2:	Measurement after four weeks
T3:	Measurement after eight weeks
T4:	Measurement after four months
T5:	Measurement after six months
EMA:	Ecological Momentary Assessment
CRQ-SAS:	Self-assessment Chronic Respiratory Questionnaire, German version
CAT:	COPD Assessment Test, German version
PHQ-D:	Patients' Health Questionnaire, German version
M:	mean
SD:	standard deviation
n:	number of participants

Abstract

COPD patients not only suffer from physiological aspects of the disease. Also, psychological distress is often part of their burden. Mindfulness-based interventions (MBIs) have been associated with reductions of psychological distress in previous studies. Especially digital interventions, which can be conducted from home, represent a promising approach for COPD patients because of their limited mobility. This thesis discussed three single cases to investigate the effects of a digital MBI on psychological distress and to identify two possible mechanisms of the MBI: mindfulness and self-compassion. The intervention was expected to reduce psychological distress, while mindfulness and self-compassion were expected to mediate this effect. The intervention condition conducted daily mindfulness practices via an app for four weeks. Questionnaires were filled out before the intervention and after four weeks. Results did not show a consistent picture, as psychological distress increased in one case and decreased a little in the other. No change of psychological distress was documented in the control condition. Increased psychological distress could be traced back to stressful life events, adverse effects, and nonadherence, while the small decrease was connected to floor effects. Mediating effects of mindfulness and self-compassion could not be calculated, but a trend to increased mindfulness in the intervention condition could be detected. Self-compassion did not play a role in this intervention. While the thesis brings some light into how and under what conditions digital MBIs might reduce psychological distress in COPD patients, further research is needed to back up these results.

Key words: COPD, mindfulness, psychological distress, self-compassion, single case study

Zusammenfassung

COPD-Patient*innen leiden nicht nur unter den körperlichen Aspekten der Krankheit, auch psychische Probleme sind häufig Teil ihrer Belastung. In bisheriger Forschung konnten achtsamkeitsbasierte Interventionen (MBIs) psychischen Belastung reduzieren. Insbesondere digitale Interventionen, die von zu Hause aus durchgeführt werden können, stellen für COPD-Patient*innen aufgrund ihrer eingeschränkten Mobilität einen vielversprechenden Ansatz dar. In dieser Arbeit wurden drei Einzelfälle untersucht, um die Auswirkungen eines digitalen MBI auf die psychische Belastung bei COPD Patient*innen zu untersuchen und um zwei mögliche Mechanismen des MBI zu identifizieren: Achtsamkeit und Selbstmitgefühl. Erwartet wurde, dass die Intervention die psychische Belastung reduziert, und, dass Achtsamkeit und Selbstmitgefühl diesen Effekt mediieren. Für die Kontrollgruppe wurden keine Veränderungen erwartet. Die Interventionsbedingung führte vier Wochen lang täglich Achtsamkeitsübungen über eine App aus. Vor und nach der Intervention wurden Fragebögen von den Proband*innen ausgefüllt. Die Ergebnisse ergaben kein einheitliches Bild, da die psychische Belastung in einem Fall zunahm, während sie im anderen etwas abnahm. In der Kontrollgruppe wurde keine Veränderung der psychischen Belastung festgestellt. Die Zunahme der psychischen Belastung konnte auf belastende Lebensereignisse, unerwünschte Effekte und Non-Adhärenz zurückgeführt werden, während der geringe Rückgang möglicherweise mit Bodeneffekten zusammenhing. Mediierende Effekte von Achtsamkeit und Selbstmitgefühl konnten nicht statistisch berechnet werden, aber es konnte ein Trend zu erhöhter Achtsamkeit in der Interventionsbedingung festgestellt werden. Selbstmitgefühl spielte bei dieser Intervention scheinbar keine Rolle. Die Arbeit bringt zwar etwas Licht in die Frage, wie und unter welchen Bedingungen digitale MBIs die psychische Belastung von COPD-Patient*innen verringern könnten, doch sind weitere Untersuchungen erforderlich, um diese Ergebnisse zu untermauern.

Schlagwörter: COPD, Achtsamkeit, psychische Belastung, Selbst-Mitgefühl, Einzelfallanalyse

Introduction

Chronic obstructive pulmonary disease (COPD) is a progressive and life-threatening disease of the respiratory system, which is defined by chronic dyspnoea (World Health Organization [WHO], 2021). Previous studies found an increased prevalence of symptoms of anxiety and symptoms of depression, which combined can be referred to as psychological distress, in people with COPD diagnosis (Gudmundsson et al., 2006; Zhang et al., 2011). Psychological distress in turn can worsen the course of COPD, as it has been connected to more frequent and longer hospital stays of affected persons (Jennings et al., 2009; Xu et al., 2008; Ng et al., 2007).

Research on mindfulness and mindfulness-based interventions (MBIs) found a positive relation of MBIs and psychological distress across various populations (Creswell, 2017). Therefore, MBIs might be a possible add-on intervention for COPD patients to help them cope with the psychological aspects of their disease.

However, existing research on effects of MBIs on psychological distress in COPD patients has been scarce and findings have been inconsistent so far (Clari et al., 2020). Although qualitative research has reported great acceptance of MBIs in COPD patients and health care professional, as well as greater acceptance of their illness in COPD patients (Harrison et al., 2016; Malpass et al., 2015), only few quantitative studies found a positive trend of some MBIs on psychological distress (Clari et al., 2020). These results often failed to reach significance. On top of that, MBIs differ between studies, so that results are hardly comparable (Clari et al., 2020). Furthermore, high dropout rates in previous MBI studies with a COPD sample led to less interpretable results (Harrison et al., 2016). The MBI used in this study can be conducted with an app from home, which offers a great advantage for COPD patients as they often have limited mobility (Global Initiative for Chronic Obstructive Lung Disease [GOLD], 2021).

This thesis wants to look further into possible positive effects of daily digital MBIs on psychological distress in COPD patients. Therefore, data of three single cases raised in a pilot randomized controlled trial are discussed. Further, changes of self-compassion and mindfulness are recorded and discussed, to better understand the mechanisms of MBIs as suggested by previous literature (Gu et al., 2015).

Theoretical Background

Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a highly prevalent health problem, which caused 3.23 million deaths globally in 2019 (WHO, 2021). It is a progressive and life-threatening disease of the respiratory system, which is characterized by chronic dyspnoea, often

combined with chronic cough und sputum production (GOLD, 2021). The disease can be divided into four stages, characterised by the severity of airflow limitation (GOLD, 2021). The Global Initiative for Chronic Obstructive Lung Disease (2021) classified these stages into mild (stage I), moderate (stage II), severe (stage III), and very severe (stage IV) COPD. As the disease progresses, sufferers increasingly experience exacerbations (GOLD, 2021). A COPD exacerbation is defined as a sudden worsening of the illness, which leads to great dyspnoea (GOLD, 2021). People experiencing exacerbations therefore have to be hospitalized frequently, which constitutes to a high financial burden of the health system (GOLD, 2021). Although medical treatment can relieve symptoms and reduce the risk of death, COPD is an uncurable disease (GOLD, 2021; WHO, 2021).

One of the main risk factors for developing COPD is smoking (active and passive), but also occupational dust, exposure to air pollution and some genetic predispositions can be risk factors for developing COPD (GOLD, 2021; WHO, 2021). Additionally, COPD can be associated with age and gender, as those of 40 years of age and above, as well as men are of higher risk of falling ill (Buist et al., 2007; Halbert et al., 2006; GOLD, 2021). Landis et al. (2014) however suggested gender differences in prevalence to decrease, due to shrinking gender differences in smoking behaviour.

The Relation of Psychological and Physical Health in COPD Patients

On top of mentioned physical health problems, COPD often comes with a psychological burden, as well. COPD patients often experience low health-related quality of life (Andenæs et al., 2006; GOLD, 2021). Also, an increased prevalence of comorbid depression and anxiety disorders in COPD patients compared to the general population was found in previous literature (Gudmundsson et al., 2006; Willgoss & Yohannes, 2013). Moreover, psychological distress, which combines clinical and subclinical symptoms of anxiety and symptoms of depression, is part of even more COPD patients' everyday lives (Yohannes et al., 2000; Zhang et al., 2011).

The reported prevalence of psychological distress in COPD differs due to methodical differences in various studies. Matte et al. (2016) estimated a prevalence of depression of 27.1% in COPD, while the reported prevalence of anxiety in COPD patients ranges from 10-55% (Willgoss & Yohannes, 2013). As psychological distress also addresses subclinical symptoms of anxiety and depression, the prevalence is probably even higher. For matters of better understanding when discussing previous studies in this thesis anxiety and depression will refer to clinically significant diagnoses, while psychological distress also includes subclinical symptoms of depression and anxiety (e.g., measured by the Hospital Anxiety and Depression Scale; Herrmann-Lingen et al., 2010). Symptoms of anxiety can be for instance having

worrying thoughts and feeling restless or tensed, while depressive symptoms are among others the loss of feeling cheerful and the loss of motivation (Dilling et al., 2016).

Van Manen et al. (2002) found that the prevalence for depression was higher in COPD patients with severe COPD in comparison to patients with mild to moderate COPD. Furthermore, higher psychological distress could be associated with higher severity of COPD (Karadag et al., 2008). This can possibly be explained with the decreased mobility, increased symptom burden, and greater risk of mortality in patients with stage III or IV COPD compared to patients with mild COPD (GOLD, 2021). Psychological distress is further associated with decreased health-related quality of life, which contributes to the psychological burden of affected people (Blakemore et al., 2014).

On top of that, psychological distress has a negative impact on the course of the illness. Thus, COPD patients with depressive symptoms experience significantly more exacerbations, are of higher chance of ever experiencing an exacerbation, and have their first exacerbation earlier than patients without depressive symptoms (Coventry et al., 2011; Jennings et al., 2009; Xu et al., 2008). They also stay significantly longer in the hospital after an exacerbation than patients without depressive symptoms (Ng et al., 2007). Furthermore, the mortality rate of COPD patients after an exacerbation increases with comorbid depressive symptoms (Ng et al., 2007). Comorbid depressive symptoms are additionally associated with less physical functioning, as depressive symptoms in COPD patients predicted poorer performance in a 6-minutes walking task in comparison to COPD patients without depressive symptoms (Spruit et al., 2010).

Equally to symptoms of depression, symptoms of anxiety predicted lower health-related quality of life, poorer exercise performance in a 6-min walking task, increased risk of exacerbations, and a higher chance of hospital readmission after an exacerbation in COPD patients (Eisner et al., 2010; Gudmundsson et al., 2005). Additionally, symptoms of anxiety are connected to dyspnoea in COPD patients, as the gasping for air can be anxiety provoking for affected people (Bailey, 2004). This can further lead to even more breathlessness. Thus, symptoms of anxiety and dyspnoea can become a vicious circle, which is not easy to break through (Bailey, 2004).

Despite these concerning indications, psychological distress is only recently starting to be recognized or considered within the treatment of COPD patients (GOLD, 2021).

Mindfulness

Mindfulness represents a promising approach to cope with the psychological burden of COPD. The concept of mindfulness has its origin in ancient Buddhist philosophy, where it is

referred to as "sati" and is part of the noble eight-folded path leading to the cessation of suffering (Grossman & Van Dam, 2011). Mindfulness research has been an exponentially increasing field of research in the past two decades (Creswell, 2017). In this field of research, a lot of different definitions and concepts of mindfulness have emerged (Creswell, 2017), but an often-replicated definition by Kabat-Zinn (2015) describes mindfulness as a present "moment to-moment, non-judgemental awareness" (p. 1481). Bishop et al. (2004) also suggested that mindfulness mainly consists of these two components: on one side regulating one's attention and on the other side approaching one's experiences with orientation of curiosity, openness, and acceptance.

Besides varying definitions and concepts, two kinds of mindfulness have to be distinguished: trait mindfulness and state mindfulness. State mindfulness describes the moment of being mindful, which is the case during meditation (Kiken et al., 2015). One's state mindfulness can change more quickly than trait mindfulness and can depend on various contextual factors like moods and situations (Kiken et al., 2015). The dispositional trait mindfulness describes the level of mindfulness an individual has even without training, which is relatively stable (Kiken, et al., 2015). These levels variate between individuals (Kiken, et al., 2015). Previous research suggested that trait mindfulness can also be enhanced through mindfulness training comparable to a muscle which can get stronger through the right training (Kiken et al., 2015).

Mindfulness and mindfulness-based interventions have been of such an interest because they have been associated with many positive outcomes on physiological and psychological health (Brown & Ryan, 2003; Creswell, 2017).

Mindfulness-based Interventions and Psychological Distress

MBIs address therapeutic approaches, which focus on teaching a mindful practice. The interventions vary greatly in the way of how mindfulness is taught, as well as to which degree mindfulness is addressed. Furthermore, most MBIs are designed for a specific population. The most commonly used MBI in research is the Mindfulness-Based Stress Reduction program (MBSR; Kabat-Zinn, 1990), followed by the Mindfulness-Based Cognitive Therapy (MBCT; Segal et al., 2013). The MBSR was originally developed to reduce illness-related stress and can be carried out in nonclinical as well as clinical populations, while the MBCT was mainly developed as a relapse prevention for depressive patients (Kabat-Zinn, 1990; Segal et al., 2013). Both programs combine mindfulness practice, such as sitting and walking meditations, with psychoeducational elements, whereby the MBCT adds psychoeducation about depression to the program (Kabat-Zinn, 1990; Segal et al., 2013).

MBSR as well as MBCT can decrease psychological distress but require enough free time and high motivation to participate, as both programs last for eight weeks, and require daily practice of approximately one hour on top of weekly group meetings of two and a half hours (Hofmann et al., 2010; Kabat-Zinn, 1990; Segal et al., 2013). Additionally, part of both programs is one mindfulness day which lasts for six hours (Kabat-Zinn, 1990; Segal et al., 2013). Thus, dropout rates are often relatively high in populations with chromatic diseases (Bohlmeijer et al., 2010; Mularski et al., 2009).

Therefore, Howarth et al. (2019) dealt with the question of how much mindfulness practice was needed for positive changes. When studying previous literature, they found that also brief interventions, which were conducted independently of these programs, were able to lower symptoms of depression and anxiety. In their review, interventions whose single practices lasted no longer than 30 minutes each, were not practiced more than 100 minutes per week, and lasted no longer than four weeks in total were counted as brief interventions (Howarth et al., 2019).

Promising research also found positive effects for MBIs on psychological distress when used in patients with other chronic conditions. Thus, Würtzen et al. (2013) found a significant reduction of anxiety and depression in women with breast cancer after they participated in a MBSR program, with a stronger reduction in higher burdened participants. Also, MBIs seemed to have a positive effect on psychological distress in patients with diabetes or chronic pain in previous research (Foley et al., 2010; Noordali et al., 2017; Veehof et al., 2016).

These positive results lead to the conclusion that MBIs might act as a possible add-on treatment to the pharmacological treatment, which has been dominant in treating COPD patients so far (GOLD, 2021).

Mechanisms of MBIs. Although research on MBIs has increased drastically in the last decades (Creswell, 2017), the underlying mechanisms are still of an ongoing debate (Gu et al., 2015). The importance of understanding how psychological interventions work exactly was discussed by Kazdin (2007). Understanding mechanisms can for instance help to improve interventions, as well as to find suitable patients for a specific intervention and to figure out, which variables could interfere with positive outcomes of an intervention (Kazdin, 2007).

Researchers could identify some brain areas to play a role in the effectiveness of MBIs on psychological distress. Previous research found, for instance, an increase of grey matter concentration in the hippocampus in participants after they had completed an MBSR program (Hölzel et al., 2011). A decrease of grey matter in the hippocampus has further been associated with major depressions in the past (Sheline, 2000). Consequently, when MBIs reduce symptoms

of depression it might be due to changes of the grey matter in the hippocampus. Additionally, an MBSR intervention led to a decrease of amygdala activation in a sample of patients with general anxiety disorder (Hölzel et al., 2013). The amygdala activation has been associated with emotion regulation and anxiety symptoms and could therefore represent another neurological mechanism of MBIs (Hölzel et al., 2013).

However, there are various more theoretical views on possible mechanisms of MBIs. One of the main ones is the stress buffering theory, which states that mindfulness can help to cope with stressors (Creswell & Lindsay, 2014). This theory highlights the changes of perceived stress and stress reactivity after completing an MBI. As stress and especially chronic stress is associated with less physical and mental health, changes of the stress response and of the perception of stress could buffer against physical and mental illnesses (Creswell & Lindsay, 2014). Hölzel and colleagues (2011) on the other hand suggested five different psychological mechanisms of MBIs: attention regulation, body awareness, emotion regulation, change in perspective on the self and self-compassion. Some further emphasized the role of rumination, which can be defined as a "problematic cognitive process in which individuals repetitively focus on symptoms of distress, and on their possible causes and consequences" (Hawley et al., 2014, p. 2) or of mind wandering, which is the "spontaneous mental activity that turns attention from a primary task to the processing of irrelevant information" (Deng et al., 2014, p. 124), when discussing the mechanisms of MBIs (see Deng et al., 2014 and Hawley et al., 2014 for more).

In a meta-analysis, Gu et al. (2015) investigated mechanisms of MBIs through mediation analyses and found a moderate mediating effect of mindfulness, but no significant mediating effect of self-compassion on the association between MBIs and mental health outcomes. This thesis will focus on these two possible mechanisms and will be discussed in the following sections.

Mindfulness as Mediator. Often mindfulness and MBIs have been used synonymously in previous literature. For instance, Hölzel et al. (2011) investigated the research question of how mindfulness works, when actually discussing mechanisms of MBIs. The names of MBIs indicate that mindfulness is the underlying mechanism, but this could not always be confirmed in previous literature (Farver-Vestergaard et al., 2018a; Labelle et al., 2010). On the other hand, Kuyken et al. (2010) found that increased mindfulness mediated the effect of an MBCT on depressive symptoms at follow-up measurements. Gu et al. (2015) compared 12 studies in a meta-analysis, which investigated mindfulness as a mediator between MBIs and symptoms of anxiety and depression. Most of these studies found an effect of mindfulness mediating MBIs

of moderate power, while some of them could not support these results. These inconsistencies could be due to a response shift in the self-assessment of mindfulness, as Grossmann (2008) suggested that participants of MBSR programs get a better understanding of the construct of mindfulness during the intervention. This can lead to a more realistic self-assessment of mindfulness. Thus, participants of the MBSR program could show lower scores in self-report questionnaires, than participants of the control condition. This could also explain why Chan et al. (2015) found decreased scores of mindfulness in participants who had participated in an eight-week MBSR program. Also, varying MBIs in different studies and varying constructs of mindfulness could account for inconsistent results in this domain and further research is highly required (Baer et al., 2019).

To find out if mindfulness mediates the effects of the intervention the mediation model, which has been proposed by Gu et al. (2015) was followed. The mediation model is presented in figure 1.

Figure 1

Mediation Model of Mindfulness
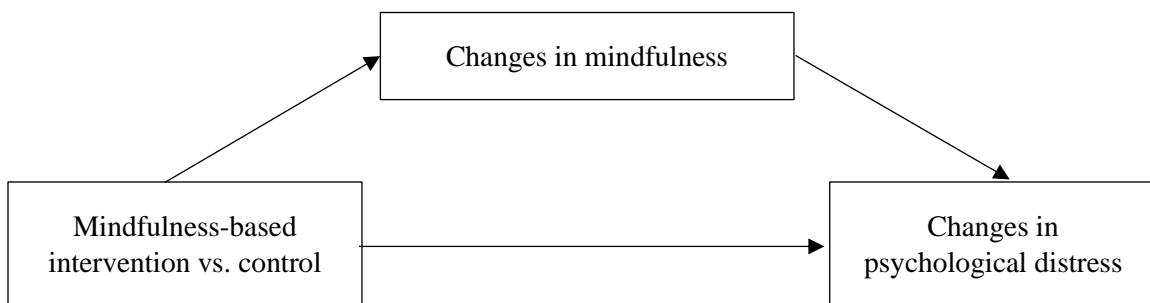
Note: Mediation model with changes in mindfulness as mediating factor between the relationship of mindfulness-based interventions on psychological distress

Self-Compassion as Mediator. Some studies further discussed if self-compassion is one of the key components of MBIs (Hölzel et al., 2011; Gu et al., 2015). Self-compassion is, just as mindfulness, a concept which is originated in Buddhism (Neff, 2003). It is defined as the "ability to hold one's feeling of suffering with a sense of warmth, connection and concern" (Raes et al., 2011, p. 250). Neff (2003) considered three interacting components of self-compassion. These components are self-kindness, which can be understood as the "ability to treat oneself with care rather than harsh self-judgement" (Raes et al., 2011, p. 250), common humanity, which means "recognizing that being imperfect is part of being human" (Raes et al.,

p. 250) and mindfulness. Higher levels of self-compassion have been associated with decreased rumination and perfectionism, as well as reduced symptoms of depression and anxiety in previous research (Leary et al., 2007; Neff, 2003). Moreover, Van Dam et al. (2011) found that self-compassion acted as a more robust predictor of psychological distress, than dispositional mindfulness. Previous literature also showed that MBIs could significantly increase self-compassion in healthcare professionals (Wasson et al., 2020). Some studies found a mediating effect of self-compassion on the effects of MBIs on depressive symptoms and other health outcomes (Kuyken et al., 2010; Sevel et al., 2020), while other could not confirm these results (Bergen-Cico & Cheon, 2014). Bergen-Cico and Cheon (2014) rather found that self-compassion only changed when mindfulness did and concluded that mindfulness is the key component for change of MBIs on the trait anxiety, while self-compassion needed more time than mindfulness to increase.

To find out whether self-compassion mediates the effects of the intervention on psychological distress, the mediation model proposed by Gu et al. (2015) is used in this thesis (see figure 2).

Figure 2

Mediation Model of Self-Compassion
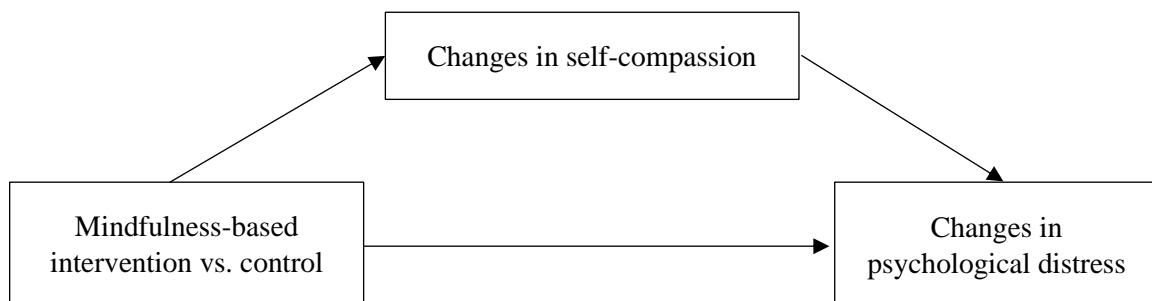
Note: Mediation model with changes in self-compassion as mediating factor between the relationship of mindfulness-based interventions on psychological distress

MBIs in COPD Patients. Despite of these promising theories and results, there has neither been a lot of research on the effects of MBIs on COPD patients so far, nor draw the results of existing research a consistent picture. Qualitative research indicates positive outcomes of MBIs, as COPD patients as well as their healthcare professionals reported a positive attitude towards MBIs as an add-on to their usual treatment in a semi-structured interview study (Harrison et al., 2016). COPD patients following acute exacerbations further expressed their

interest in exercising short MBIs, like breathing meditations and body scans in a recent master's thesis (Tschenett, 2020). A body scan is another mindfulness practice, in which one draws its attention to each part of the body, one after another, while breathing meditations draw attention to the breath. Furthermore, COPD patients reported a greater acceptance of their illness and a greater sense of control over their breathing after participating in an eight-week MBCT program (Malpass et al., 2015).

     Chan et al. (2015) performed a pilot RCT to investigate the effectiveness and feasibility of MBIs in stable COPD patients. The intervention group took part in an eight-week MBSR program, while the control group received treatment as usual. They found a significant change in emotional functioning when excluding participants who attended less than six classes. Psychological distress on the other hand did not significantly differ between both groups. They found a decrease in mindfulness in the intervention group after eight weeks, but it was not significant when excluding participants who attended less than six classes. Despite of these unexpected results, this paper described good feasibility and acceptability for MBIs in COPD patients (Chan et al., 2015).

     In addition, Perkins-Porras et al. (2018) examined, whether a brief mindfulness exercise can decrease psychological distress and breathlessness and improve mindfulness in COPD patients after acute exacerbations. While the control group listened to an audio recording, the intervention group participated in a 10-minute body scan exercise. No significant differences between the intervention condition and the control condition could be found, although there was a positive trend for a reduction of psychological distress in the intervention group compared to the control group (Perkins-Porras et al., 2018). These results might be ascribed to the control condition, in which participants listened to an audio recording, which was also considered as useful and relaxing by participants. On top of that, it should be considered that effects of MBIs might not be seen so quickly, that a three-day intervention would already lead to significant changes, although the meta-analysis of Howarth and colleagues (2019) suggested that often already one-day interventions lead to positive change.

     Another interesting RCT deals with the efficiency of an eight-week MBCT program in COPD patients as an add-on to pulmonary rehabilitation (Farver-Vestergaard et al., 2018b). In the control condition participants only took part in a pulmonary rehabilitation, while the intervention condition additionally attended the MBCT program. They found a significant time x arm effect. Thus, participants out of the intervention condition showed a significantly greater reduction of psychological distress than participants out of the passive control condition after eight weeks of intervention. When assessing symptoms of anxiety and depression separately,

they found a significant effect on symptoms of depression of a medium effect size, but not on symptoms of anxiety. This effect was mediated by self-compassion, while mindfulness did not act as a significant mediator in this study.

Digital MBIs in COPD Patients. Digital health is an emerging and promising field, as it is very economic, and has been feasible and effective when used in health care (Boettcher et al., 2014; Meurer et al., 2019). On top of that, digital MBIs have been able to reduce symptoms of anxiety and depression in patients with anxiety disorders in previous research (Boettcher et al., 2014).

As high dropout rates and nonadherence have been a big problem in research with COPD patients, the digital MBI could be a particularly promising approach for this specific sample (Blackstock et al., 2016; Farver-Vestergaard et al., 2018a; Mularski et al., 2009). Digital interventions might have benefits compared to face-to-face interventions, as COPD patients would not have to make a physical effort to come to MBI classes. Therefore, also non-mobile and very ill patients could take part, which would lead to better adherence in digital MBIs than face-to-face interventions (Farver-Vestergaard et al., 2018a). Especially at times of social distancing during the Covid-19 pandemic, in which data for this thesis were collected, digital interventions had a huge benefit compared to face-to-face interventions, as the risk of infection of participants and study instructors could be minimalized.

To the best of my knowledge there has only been one study so far, investigating the effects and feasibility of a digital MBI in a COPD sample (Farver-Vestergaard et al., 2018a). In this pilot mixed-methods study the sample participated in an eight-week digital MBCT program. The intervention consisted of weekly 120-min videocalls and daily mindfulness practices. The study reported very good adherence and a positive trend for a decrease of psychological distress, although the result failed to reach significance. Results of this pilot study have to be interpreted with caution, as the sample consisted of only eight participants (Farver-Vestergaard et al., 2018a). Thus, further research on the topic of digital interventions especially for clinical populations like COPD patients is highly required.

Aim of the Thesis

As cited literature shows, the effects of MBIs on psychological distress in COPD patients are neither consistent nor fully understood. Therefore, further investigations are highly necessary. Also, digital MBIs have rarely been investigated in COPD samples so far and further research could lead to a huge benefit in treating COPD patients. Hence, this thesis wants to look further into the effectiveness of a digital MBI on reducing psychological distress in COPD patients.

On a secondary level, this thesis wants to discuss two possible mechanisms of MBIs: self-compassion and mindfulness. Understanding underlying mechanisms of psychological interventions is relevant for improving interventions. It can help in selecting suitable patients, and considering variables, which might be important for positive change, and which possibly prevent positive change (Kazdin, 2007). In this field of research, there are still many unresolved questions, as some studies reported significant mediating effects of mindfulness, but no significant mediating effect of self-compassion (Gu et al., 2015), while others reported self-compassion to be a better predictor for positive outcomes of MBIs than mindfulness (Van Dam et al., 2011).

Moreover, most studies dealing with the mechanisms of MBIs concentrate on MBSR or MBCT programs (Gu et al., 2015). Meditation practices without cognitive therapeutic parts or psychoeducational elements might work differently on psychological distress (Chiesa & Malinowski, 2011). To look further into this topic, self-compassion and mindfulness were looked at as possible mediators between the effects of a digital MBI on psychological distress.

Research Question and Hypotheses

Based on the central question of the present thesis, whether daily digital mindfulness-based interventions lead to a reduction of psychological distress (measured by HADS; Herrmann-Lingen et al., 2010) in COPD patients, following hypothesis arise:

H1: Psychological distress decreases significantly more in the intervention condition compared to the control condition over the course of four weeks.

However, according to the authors, the interpretation of the HADS subscales symptoms of depression (HADS-D; Hermann-Lingen et al., 2010) and symptoms of anxiety (HADS-A; Hermann-Lingen et al., 2010) is more meaningful as the interpretation of the sum score of the HADS (Herrmann-Lingen et al., 2010). Thus, this hypothesis was divided into two more specific hypotheses:

H1a: Symptoms of depression decrease more in the intervention condition compared to the control condition over the course of four weeks.

H1b: Symptoms of anxiety decrease more in the intervention condition compared to the control condition over the course of four weeks.

In addition, self-compassion and mindfulness were discussed as possible mechanisms of MBIs. In case of a detected effect of the condition (intervention vs. treatment as usual) on symptoms of anxiety and depression, mindfulness (measured by the German short version of

the Freiburg Mindfulness Inventory; FMI-14; Buchheld, 2000) and self-compassion (measured by the German short version of the Self Compassion Scale; SCS-SF; Hupfeld & Ruffieux, 2011) were planned to be examined as mediators. This leads to following secondary research questions: Does increased mindfulness explain (partly) the effects of MBIs on psychological distress? Does increased self-compassion explain (partly) the effects of MBIs on psychological distress? These hypotheses are based on the mediation models shown in figure 1 and 2. Hypotheses were divided to address both subscales of the HADS (Herrmann-Lingen et al., 2010) separately.

H2: The effect of the condition (intervention vs. waitlist control group) on psychological distress after four weeks is mediated by mindfulness.

H2a: The effect of the condition (intervention vs. waitlist control group) on depressive symptoms after four weeks is mediated by mindfulness.

H2b: The effect of the condition (intervention vs. waitlist control group) on anxiety symptoms after four weeks is mediated by mindfulness.

H3: The effect of the condition (intervention vs. waitlist control group) on psychological distress after four weeks is mediated by self-compassion.

H3a: The effect of the condition (intervention vs. waitlist control group) on depressive symptoms after four weeks is mediated by self-compassion.

H3b: The effect of the condition (intervention vs. waitlist control group) on anxiety symptoms after four weeks is mediated by self-compassion.

Methods

Study Design and Procedure

This master's thesis used data which were collected in the pilot randomized controlled trial of the research project *SPIROMIND*. This project was conducted by the Klinik Ottakring, in Vienna, Austria, and led by Priv.-Doz. Dr. Funk, as well as by the Department for Clinical and Health Psychology at the University of Vienna, Austria, with Univ.-Prof. Dr. Nater as cooperation partner, and by the Klinik Flouridsdorf in Vienna, Austria, with Dr. Valipour as cooperation partner. Study coordinator of the project is Hannah Tschenett, who is a PhD student at the University of Vienna, Austria. The project deals with the question of feasibility and effectiveness of an app-delivered mindfulness-based intervention in stable COPD patients.

Originally planned was a sample of participants, who had been hospitalized because of an acute exacerbation. Because of the Covid-19 pandemic, less COPD participants were

hospitalized in both cooperating clinics during the time of recruitment. Thus, the sample was changed from COPD patients suffering from an acute exacerbation to stable COPD participants.

The new sample was recruited via a list of COPD patients waiting for a respiratory surgery at the Klinik Florisdorf, and via ambulant patients at the Klinik Ottakring. They were screened for matching the eligibility criteria via telephone interviews, conducted by the study coordinator and research assistants. Patients were informed about the study details via telephone. If they were interested and met all eligibility criteria, baseline appointments were made. After the baseline survey, participants were randomly assigned to the intervention or waitlist control condition by the study coordinator. The block randomization method with a 1:1 ratio was used to ensure equal sample sizes in both conditions.

There were three measurements in the waitlist control condition: a baseline measurement (T1) before the intervention started, a second measurement (T2) four weeks into the intervention, and a third measurement (T3) after the intervention (eight weeks). In the intervention condition two more measurements were conducted for follow-up measures: a fourth measurement after four months and a fifth measurement after six months. Due to the lack of time and postponements because of the Covid-19 pandemic, in this thesis only the first two measurements, baseline measurements (T1) and four weeks measurements (T2), could be considered.

Sociodemographic and medical data were collected at baseline (T1), and a screening of common psychological disorders was conducted. Further paper-pencil questionnaire data were collected at baseline (T1), after four weeks (T2), after eight weeks (T3) and after four (T4) and six months (T5) for follow-up measurements. Paper-pencil questionnaires assessed participants' health status impairment, health-related quality of life, perceived stress, fatigue, breathlessness catastrophizing, as well as psychological distress, mindfulness, and self-compassion. Additionally, hair samples were collected at T1, T3, T4 and T5, and a stress test (modified Stroop task) was conducted at all timepoints to investigate changes of cortisol levels as well as changes of heart rate variability in stressful situations. The parent study also investigates immediate effects of the digital MBI on acute perceived stress, dyspnoea, relaxation, affect and oxygen saturation in blood, which are collected via an Ecological Momentary Assessment (EMA) survey via the app right before and after the exercises. See figure 3 for an overview of the parent study process.

Figure 3

Study Procedure of SPIROMIND
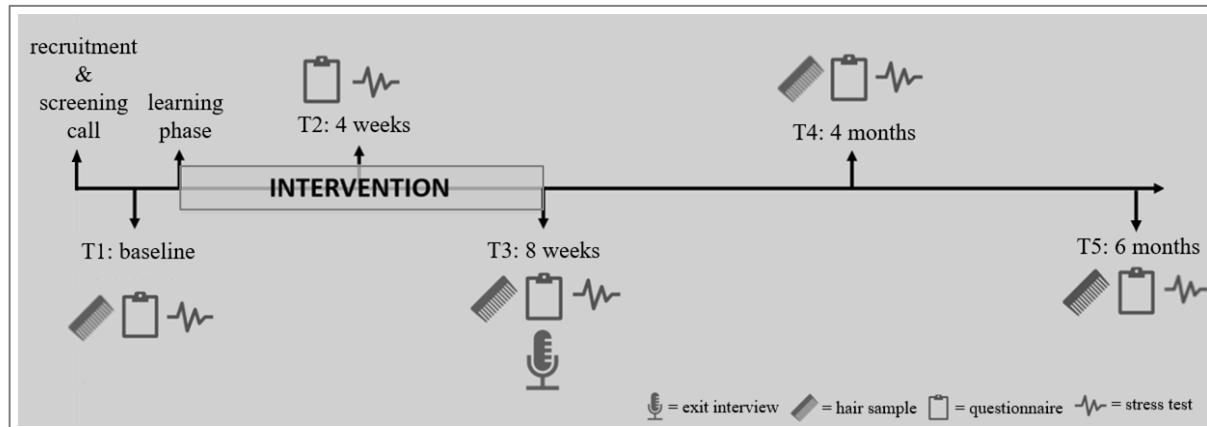
Neither, the data concerning changes of stress through meditation, nor the EMA data were considered in this thesis, except for the amount of practice of participants. For this thesis only paper-pencil questionnaires for assessing psychological distress, mindfulness, and self-compassion at time points T1 and T2 were relevant, as well as baseline data of participants and notes out of weekly telephone calls.

All measurements were implemented in patients' homes in the afternoon between 1pm and 5pm, so outcomes were more comparable. The study was single blinded, as test instructors did not know participants' group allocation. The instruction phase and check-in calls were carried out by a different instructor than the surveys to prevent possible influences of the participants due to the instructor's expectations.

Description of Conditions

In the intervention condition participants were instructed to conduct daily mindfulness exercises over the course of eight weeks on top of their usual medical treatment. They were introduced to the intervention in a face-to-face introductory session, which was conducted by the study coordinator. During this session the study coordinator installed the app on the participants' phones and tested the app in case there was any problem. Participants were then introduced to all four mindfulness exercises, each eleven to 16 minutes long, which were delivered as audio files via the app movisensXS (movisens GmbH, 2020).

The mindfulness exercises included one body scan and three sitting meditations. Although mediations usually use the focus on one's breath to stay focused on the present (Chiesa & Malinowski, 2011), the exercises in this study were adapted, as previous literature suggested, that focusing on parts of the body, which are connected to an illness, can interfere with the meditation, and can lead to feelings of anxiety (Foley et al., 2010). Thus, in these

mindfulness exercises participants were instructed to focus on their heartbeat and warmth in their body instead of their breath. Participants in the intervention condition were instructed to practise at least one of these exercises daily over a period of eight weeks.

The waitlist control group only received their medical treatment as usual during these eight weeks. They were provided with the audio files for the mindfulness exercises after the end of the intervention period (eight weeks).

During the first eight weeks of participation, there were weekly check-in calls, which were conducted by the study coordinator, to discuss open questions or problems and to motivate participants in both conditions.

Description of Exercises

All exercises used in the SPIROMIND study are adaptions of guided meditation exercises out of the MBCT program (Segal et al., 2013). Farver-Verstergaard et al. (2018b) gave their consent to use their adaptions of the original MBCT versions, which were then further adapted by the study coordinator. These last adaptions were based on findings of earlier interviews with COPD patients, which supposed to use short and low threshold MBIs for a sample of COPD patients (Tschenett, 2020).

The body scan exercise is the longest out of the four exercises with a duration of approximately 16 minutes. The body scan can be conducted lying or sitting and is distinguished by a sweeping of attention through the whole body from head to toe, trying to realize what sensations are present in the different body parts without judging them.

All of three sitting meditations last for approximately eleven minutes. They are characterized by sitting straight on a chair and focussing mainly on one of three topics: hearing, body, and heartbeat. The hearing meditation merely uses an open attention towards the surroundings. The heartbeat and body exercise put the focus on the inside. All of them try to heighten attention to the present moment, while trying to stop distractive thinking. See appendix A for the exact contents of the mindfulness exercises.

Ethical Aspects

The study was approved by the ethics committee of the "Wiener Krankenanstaltenverbund", Vienna, Austria (serial number EK 20-177-VK). During the screening, as well as prior to baseline measurements, participants were fully informed about the study, and about participants' rights. Thus, participants were told that they could end their participation at any time without having to give any explanation. Informed consent was signed by participants (see appendix B). Further, all data were pseudonymized, as all participants were represented with a code. Therefore, no data were able to be traced back to the participants.

Participants were told to contact the study coordinator at any time if questions or problems came up.

In the study a waitlist control condition was used, so all participants were allowed to get the intervention after eight weeks if they wanted to. This was considered as important to prevent the ethical dilemma of not providing an intervention to burdened participants, although it might be helpful for them.

To minimize the risk of infecting any of the participants with Covid-19, study instructors were vaccinated before the intervention started. On top of that, study instructors always wore FFP2 face masks during all times of measurements. Further, when participants had to be touched, gloves were worn. Before each measurement, a check for Covid-19 symptoms was conducted by study instructors and participants. Only if instructor and participant showed no symptoms the measurement took place. Furthermore, study instructors were tested with an official Covid-19 antigen rapid test before meeting participants during times of lockdown in Vienna, Austria.

Participants

The study aimed for 30 participants, to have 15 participants in each condition. There are stepped rules of thumb for pilot sample sizes, which recommend a sample size of 15 participants per condition if the targeted standardized difference is of medium size ($0.3 \leq d < 0.7$) and of 90% power (Bell et al., 2018). As at the time of analysis only four participants had completed the second measurement after four weeks, data of only these four participants could be taken into account for this thesis. All participants had a spirometry confirmed COPD diagnosis with a forced expiratory volume in one second (FEV1) below 80%. Further, they were over 40 years of age, to prevent the later onset of an asthma diagnosis. Participants were able to understand German, so they could follow the meditation instructions and questionnaires. All participants reported having the physical and mental capability to take part in a study. They were able to use a smartphone to use the app delivering the intervention. Further, all participants but the pilot participant were psychologically distressed at the time of the screening (measured by the HADS; Herrmann-Lingen et al., 2010; HADS $\geq$ 16, or HADS-D $\geq$ 8, or HADS-A $\geq$ 8). The pilot participant was included into the study to test if all questionnaires worked out and as means of practise for the test instructors. This participant did not meet all eligibility criteria, as she did not score above cut-offs at the HADS (Herrmann-Lingen et al., 2010). This participant was also not randomly put into one of the conditions but participated in the intervention condition. Test instructors were not blinded in this case.

People had to be excluded from trial if they had auditory impairment, an active asthma diagnosis, or any other severe comorbidities, such as heart failure, uncontrolled diabetes, concomitant cancer, stroke, unstable coronary heart disease, or respiratory failure. Participants did not have any history of severe psychological disorders, such as schizophrenia or severe cognitive impairment, either. Furthermore, they did not receive any regular psychosocial treatment during the time of the study, like psychotherapy, or conduct other systematic mind-body practices on a regular basis (at least once a week). A positive Covid-19 test result as well as the participation in another study also would have led to an exclusion of the study. All participants lived in or around Vienna, so that study instructors did not have to drive for more than one hour to get there (see table 1 for a summary of all inclusion and exclusion criteria). Participants did not get any incentives for participating.

Table 1

Full List of Eligibility Criteria

Inclusion criteria

COPD diagnosis according to spirometry (FEV1<80%)

Age ≥ 40

Psychological distress (result from HADS screening: HADS-A ≥ 8 OR HADS-D ≥ 8 OR

　　HADS total score ≥ 16)

Understanding of the German language

Physical and mental ability to participate in the study (patients' assessment)

Ability to use a smartphone (patients' assessment)

Residence in Vienna or surroundings

Exclusion criteria

Active asthma diagnosis

Severe hearing impairment

Severe comorbid physical illness (e.g., heart failure (LVF<35%), unstable coronary artery

　　disease, uncontrolled diabetes, concomitant cancer, stroke, respiratory failure

　　requiring ventilation)

Acute COPD exacerbation

Serious psychological disorder (e.g., severe cognitive impairment, psychotic and

　　associated disorder, borderline personality disorder)

Other health crisis that could interfere with study (e.g., Covid-19)

Regular psychosocial treatment (e.g., psychotherapy)

Regular (at least once a week) other systematic mind-body practice (yoga, progressive

　　muscle relaxation, meditation, autogenic training)

Participation in another clinical study

Note. All eligibility criteria were screened via telephone interviews.

Recruitment

With the starting point on the 29th of March in 2021 COPD patients, who registered for respiratory surgery at Klinik Florisdorf, as well as ambulant patients at Klinik Ottakring, were contacted to ask if they were interested in participating by the study coordinator, cooperation partners and study assistants. Until the 16th of May 2021, when the analysis started, 29 people had been contacted for a telephone screening so far. 20 people were then excluded, because they either were not interested in participating ($n = 5$) or did not fit the eligibility criteria ($n = 14$), as eight persons lived too far away, four persons did not score above cut-off values on the HADS (Herrmann-Lingen et al., 2010), one did not speak German fluently, and one already practices mindfulness on a regular basis. Furthermore, one person unfortunately died before the screening could be completed ($n = 1$). Figure 4 shows the course of recruitment.

Figure 4

Course of Recruitment
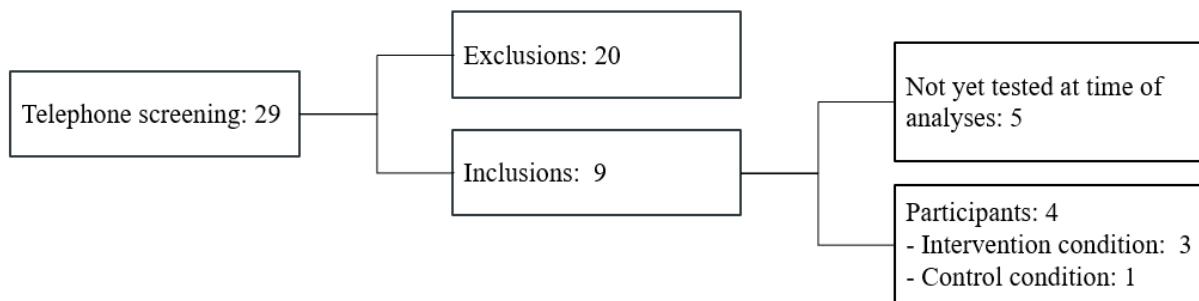
Thus, at time of analysis nine participants had been included so far. Five of these participants had not yet completed the measurement after four weeks of the intervention. Thus, only four participants could be taken into account for this thesis, one of them being the pilot participant. There were three participants in the intervention condition, while one was in the control condition. The recruitment for the superordinated study kept on going until there are 15 participants in each condition.

Measurements

Psychological Distress

Psychological distress was assessed by the German version of the Hospital Anxiety and Depression Scale (HADS; Herrmann-Lingen et al., 2010). The HADS (Herrmann-Lingen et al., 2010) assesses symptoms of depression and anxiety in people with physical health issues

(Herrmann-Lingen et al., 2010). It is the main questionnaire, when assessing psychological distress in patients with somatic diseases (Herrmann-Lingen et al., 2010).

The HADS (Herrmann-Lingen et al., 2010) is a self-assessment questionnaire, which consists of 14 items, seven of them relating to the subscale depression (HADS-D) and seven to the subscale anxiety (HADS-A). Items are assessed on a four-point Likert-scale with varying descriptions. Higher scores in both subscales indicate a higher level of symptoms of depression or anxiety, respectively. Therefore, higher overall scores indicate higher psychological distress, although it has been suggested to focus on interpreting the subscales instead of the sum score (Herrmann-Lingen et al., 2010). It is important to note, that the HADS (Herrmann-Lingen et al., 2010) is not a sufficient measurement for making diagnoses, as it is only a screening tool for symptoms of anxiety and depression (Herrmann-Lingen et al., 2010). These symptoms can also be of subclinical severity. The HADS-A and HADS-D scores are sensitive to change, as in various studies a reduction of the HADS scores could be implemented after an intervention (Friedman et al., 2001; Herrmann et al., 1997).

Items of the anxiety subscale are in accordance with symptoms of the general anxiety disorder (Dilling et al., 2016), e.g., general fears and worries, nervousness, and tension, as well as deficits in relaxation (Herrmann-Lingen et al., 2010). One item addresses heart racing, as it is a main symptom of panic disorders (Herrmann-Lingen et al., 2010). Items of the depression scale are based on symptoms of a depressive episode (Dilling et al., 2016) and address the loss of motivation, joy, and interests (Herrmann-Lingen et al., 2010; see table 2 for sample items).

Both subscales have a cut-off score at 8. Values of 0–7 are indicated as within normal limits, values of 8 or higher indicate a conspicuous score (Herrmann-Lingen et al., 2010). Both subscales were assessed separately, as it is recommended by the authors. The total score was also addressed to report the amount of psychological distress in participants. Criteria of validity are met for clinical and elderly populations (Djukanovic et al., 2017; Herrmann-Lingen et al., 2010). The reliability of subscales anxiety and depression is adequate (see table 2; Herrmann-Lingen et al., 2010).

Table 2

Reliability and Sample Items of the HADS subscales

Scale	Cronbach's α	Sample Item
HADS-A	.80	Mir gehen beunruhigende Gedanken durch den Kopf. (Worrying thoughts go through my mind)*
HADS-D	.81	Ich kann lachen und die lustige Seite der Dinge sehen. (I can laugh and see the funny side of things)*

Note. Reliability was calculated for the German version of the HADS (Herrmann-Lingen et al., 2010). * = Translations are taken from the original English version of the HADS (Zigmond & Snaith, 1983).

Mindfulness

Mindfulness was assessed by the short version of the Freiburg Mindfulness Inventory (FMI-14; Buchheld, 2000). The original long version requires background knowledge in Buddhist philosophy and meditation experiences (Walach et al., 2006). Thus, the short form was used, as it can be used independent of a Buddhist or meditation background. The FMI-14 (Buchheld, 2000) was used in its original language German.

The FMI-14 (Buchheld, 2000) is a self-report questionnaire, which consists of 14 items with a four-point-Likert-scale, ranging from "fast nie" ("almost never") to "fast immer" ("almost always"). It assesses mainly two different facets of mindfulness: presence and acceptance (Walach et al., 2006). A sample item would be, "Ich bin offen für die Erfahrung des Augenblicks" ("I am open to the experience of the present moment").

Higher scores indicate higher mindfulness. The FMI-14 (Buchheld, 2000) is sufficiently reliable, as it holds a Cronbach's α of $\alpha = .86$ (Walach et al., 2006). The FMI-14 is sensitive for change with treatment (Gouda et al., 2016). Although a differentiated view on mindfulness is recommended in some research (e.g., Kohls et al., 2009), for the short form authors do not recommend assessing the subscales separately, because they intercorrelate (Walach et al., 2006). Thus, for this analysis just the total score of mindfulness was considered.

Self-Compassion

Self-compassion was assessed by the German short version of the Self Compassion Scale (SCS-SF) because it is an economic, reliable, and valid questionnaire for assessing self-compassion (Hupfeld & Ruffieux, 2011). The SCS-SF is a self-report questionnaire, which consists of six facets (self-kindness, self-judgment, common humanity, isolation, mindfulness

and over-identification; Hupfeld & Ruffieux, 2011). Subscales of this questionnaires were not assessed separately, because this is not recommended for the short version of the SCS (Raes et al., 2011).

A sample item would be: "Wenn ich eine sehr schwere Zeit durchmache, schenke ich mir selbst die Zuwendung und Einfühlsamkeit, die ich brauche" ("When I'm going through a very hard time, I give myself the caring and tenderness I need"). The original short version of the SCS was developed by Raes et al. (2011) and is in English. The German short version consists of 12 items with a 5-point Likert-scale, ranging from "fast nie" ("almost never") to "fast immer" (almost always"). Cronbach's α of the German SCS-SF is adequate ($α = .87$). Higher scores indicate higher self-compassion. The SCS-SF is supposed to change with treatment (Wasson et al., 2020). Furthermore, Neff (2021) suggested following cut-offs to better interpretate results. Therefore, a mean score of 1.0–2.49 indicates low self-compassion, 2.5–3.5 indicates moderate, and 3.51–5.0 indicates high self-compassion.

Participants' Baseline Health Status

To describe participants health status at the beginning of the intervention various variables were documented. The GOLD stage of COPD severity (GOLD, 2021), as well as the patients' number of past exacerbations in the last year and demographic variables (age, gender and native language) were collected in an patients' interview (see appendix C). Participants' health-related quality of life was measured by the German version of the self-assessment Chronic Respiratory Questionnaire (CRQ-SAS; Schünemann et al., 2003). The CRQ-SAS (Schünemann et al., 2003) measures hereby the self-assessed physical and emotional function, which is divided into dyspnoea, fatigue, emotion, and mastery (Guyatt et al., 1987). The use of the German version of the CRQ-SAS (Schünemann et al., 2003) was made under license from McMaster University, Hamilton, Canada. Participants' COPD specific health status impairment was measured by the COPD Assessment Test (CAT; Jones et al., 2009). Another screening tool for depressive and anxiety disorders represented the German version of the Patients' Health Questionnaire (PHQ-D; Löwe et al., 2002).

Amount of Practice

The amount of daily practice was documented by the app (movisensXS; movisens GmbH, 2020) and was considered for interpreting the results.

Qualitative Information

To better understand context factors of participants' health during the intervention also qualitative information were considered. Therefore, notes from weekly telephone calls were summarized. Table 3 shows all measurements considered in this thesis.

Table 3

Overview of All Variables and Measuring Tools

Variable	Measuring tool
Psychological Distress	Hospital Anxiety and Depression Scale, German version (HADS; Herrmann-Lingen et al., 2010)
Depressive symptoms	Subscale Symptoms of Depression (HADS-D)
Anxiety symptoms	Subscale Symptoms of Anxiety (HADS-A)
Mindfulness	Freiburg Mindfulness Inventory, short version, German version (FMI-14; Buchheld, 2000)
Self-compassion	Self-Compassion Scale, short version, German version (SCS-SF; Hupfeld & Ruffieux, 2011)
Explorative analysis	
Health-related quality of life	Chronic Respiratory Questionnaire, German (CRQ-SAS; Schünemann et al., 2003)
Health status impairment	COPD Assessment Test, German (CAT; Jones et al., 2009)
Depressive and anxiety disorders	Patients' Health Questionnaire, German (PHQ-D; Löwe et al., 2002)
Amount of practice	EMA data (movisensXS; movisens GmbH, 2020)
GOLD stage, demographic variables, amount of previous exacerbations	Patients' interview (see appendix C)
contextual factors	notes from weekly telephone calls

Analysis

Planned was to analyze group differences over time via a two factors ANOVA with repeated measures in SPSS. Between subject factor would have been the condition (mindfulness or treatment as usual) and the within subject factor the time of measurement (baseline T1/four

weeks T2). If the requirements for an ANOVA could not have been met, a non-parametric pendant would have been used. Possible mediating effects of mindfulness and self-compassion would have been analyzed via mediator analysis. According to the Baron and Kenny (1986) causal-steps test, mindfulness and/or self-compassion would act as mediators if four conditions were fulfilled. First, there would be a significant relationship between treatment (MBI) and outcome (psychological distress). Further, there would be a significant relationship of the treatment (MBI) and the mediator (mindfulness/self-compassion), as well as a significant relationship of the mediator (mindfulness/self-compassion) and the outcome (psychological distress), when accounting for the treatment. Last, if a mediation can be accepted, there would be a decrease in the relationship between treatment (MBI) and outcome (psychological distress) when controlling for the mediator (mindfulness/self-compassion).

Since at the time of data analysis only data of four participants were available, an ANOVA or non-parametric pendant could not bring meaningful statistical results. Therefore, single case analyses were performed for three out of all cases. Single case analyses emphasize the individuality of participants. Therefore, single cases will be described in their entirety and effects will be discussed in relation to participants' complexity. IBM SPSS Statistics version 27 was used to prepare the data and for the descriptive analysis of key variables.

Choice of Single Cases

As only four participants had already completed the second measurement after four-weeks of study participation, there was not much choice about which cases to discuss in detail. Data of two participants were quite similar, thus one of them was not further discussed in this thesis. The excluded participant was also the pilot participant, who was included to try out the intervention. She did not fulfil the inclusion criteria of being psychologically distressed at the time of the screening interview, and was not randomly put into the intervention condition, so no blinding was used with this participant. Thus, two participants of the intervention condition and one of the waitlist control condition were chosen for single case analyses.

Data Cleaning

To prepare the data for analyses the values of HADS items (Herrmann-Lingen et al., 2010), FMI-14 items (Buchheld, 2000), and SCS-SF items (Hupfeld & Ruffieux, 2011) were transformed. To build the HADS sum score, HADS-A score, and HADS-D score, items 01, 03, 05, 06, 08, 10, 11, and 13 had to be inverted. For sum scores of the FMI-14 item 13 had to be inverted. For the SCS-SF, items 01, 04, 08, 09, 11 and 12 had to be inverted. When assessing data one missing item could be detected. Case A missed one item on the SCS-SF (Hupfeld & Ruffieux, 2011) at baseline measurement (item 07). The missing item was added through mean

imputation. Therefore, the mean of the SCS-SF (Hupfeld & Ruffieux, 2011) in case A did not change through the imputed score. Besides this one missing item, the data was complete.

Results

Sample Description

The final sample consisted of $N = 3$ participants. Two of them identify as male and one identifies as female. Mean age was 59.67 ($SD = 1.00$; *range = 59–61*). The sample's highest reached educational level was an apprenticeship degree in two cases and an apprenticeship plus master's degree in one case. At time of measurements one case was retired, one was employed and one unemployed.

The sample scored high on the Hospital Anxiety and Depression Scale (HADS; Herrmann-Lingen et al., 2010; $M = 14.00$, $SD = 6.25$, *range = 7–19*), whereby two scored high and one scored low. At baseline the sample scored higher on the depressive symptom scale than on the anxiety symptom scale (HADS-D: $M = 9.67$, $SD = 5.13$, *range = 4–14*; HADS-A: $M = 4.33$, $SD = 1.16$, *range = 3–5*). Anxiety symptoms are in between normal ranges for all participants (< 8). Depression symptoms are salient in two cases (≥ 8).

This is consistent with results from the Patients' Health Questionnaire (PHQ-D; Löwe et al., 2002; see table 4). In the subscale for depressive syndrome (*range = 0–27*) two participants scored very high (> 20) and fulfilled criteria of a major depression (5 items scored 3 or higher), while one participant showed symptoms of a mild depressive disorder (> 5). The self-reported health-related quality of life, measured by the Chronic Respiratory Questionnaire (CRQ-SAS; Schünemann et al., 2003) was relatively low in two cases, but high in one ($M = 81.67$, $SD = 27.30$, *range = 57–111*), while the health status impairment, measured by the COPD Assessment Test (CAT; Jones et al., 2009) was very high in two cases and low in one case ($M = 21.11$, $SD = 11.06$, *range = 11–33*).

Mindfulness measured by the German version of the Freiburg Mindfulness Inventory (FFA-14; Buchheld, 2000) was medium to high in the sample ($M = 2.95$, $SD = 0.42$, *range = 2.64–3.43*).

Self-compassion (SCS-SF; Hupfeld & Ruffieux, 2011) in the sample at baseline can be considered as high (> 3.51; $M = 3.72$, $SD = 0.42$, *range = 3.33–4.17*). Two cases reached high scores (> 3.51) and one reached a moderate score (> 2.5; Neff, 2021). See table 4 for an overview of the participants' starting conditions.

Table 4

Descriptive Statistics of Starting Conditions of All Single Cases at T1

	Case A	Case B	Case C
HADS			
Psychological distress* (0–42)	**19**	7	**16**
Anxiety symptoms* (0–21)	5	3	5
Depressive symptoms* (0–21)	**14**	4	**11**
CAT			
Health status impairment* (0–40)	33	11	20
CRQ-SAS			
Health-related quality of life* (0–125)	57	111	77
PHQ-D			
Depressive Syndrome* (0–27)	**23**	9	**20**
Panic Disorder* (yes/no)	no	no	no
Anxiety Disorder* (yes/no)	no	no	no
FMI-14			
Mindfulness (1–4)	2.79	3.43	2.64
SCS-SF			
Self-Compassion (1–5)	3.67	4.17	3.33

Notes: CAT = COPD Assessment Test (Jones et al., 2009); CRQ-SAS = Chronic Respiratory Questionnaire (Schünemann et al., 2003); HADS = Hospital Anxiety and Depressions Scale (Herrmann-Lingen et al., 2010); PHQ-D = Patients' Health Questionnaire (Löwe et al., 2002). * = higher values represent a stronger expression of the examined variable. () = range. **Scores above Cut-offs.**

Single Cases

Case A

Participant A is 59 years old and identifies as male. He has been living with COPD for 10 years. The participant's mother language is Turkish, but his German was well enough to participate in the study. He lives by himself and does not work. Further, he did not have any experiences with mindfulness or mindfulness-based interventions. He is in GOLD stage IV of COPD and has had five exacerbations during the previous year. Accordingly, case A scored high on the COPD Assessment Test (CAT = 33, range = 0–40), which indicated a highly

impaired health status. Also, his health-related quality of life is low (CRQ = 57; range = 0–125). Additionally, noticeable was his PHQ-D score, as he fit the criteria of a major depression (5 items scored 3 or higher), with a score, which can be considered as very high (≥ 20) on the depressive syndrome scale.

In accordance with that, his psychological distress at baseline was also high (HADS = 19), while he scored higher on the depression subscale (HADS-D = 14) than the anxiety subscale (HADS-A = 5). After baseline measurements, case A was randomly assigned to the intervention condition. Because of public holidays and some technical concerns by the participant, the final instruction day was nine days after the baseline measurement. Thus, he started the intervention the day after that. After another 18 days, the second measurement (T2) took place.

Figure 5 shows changes of psychological distress, composed of changes on the subscales symptoms of depression and symptoms of anxiety from measurements at baseline to T2 after four weeks of intervention. HADS scores increased by 5 points from 19 to 24, which represents an increase of +11.9%. HADS-D increased by 2 points from 14 to 16 (+9.5%) and HADS-A by 3 points from 5 to 8 (+14.3%).

Figure 5

Case A Changes of HADS, HADS-D and HADS-A from T1 to T2
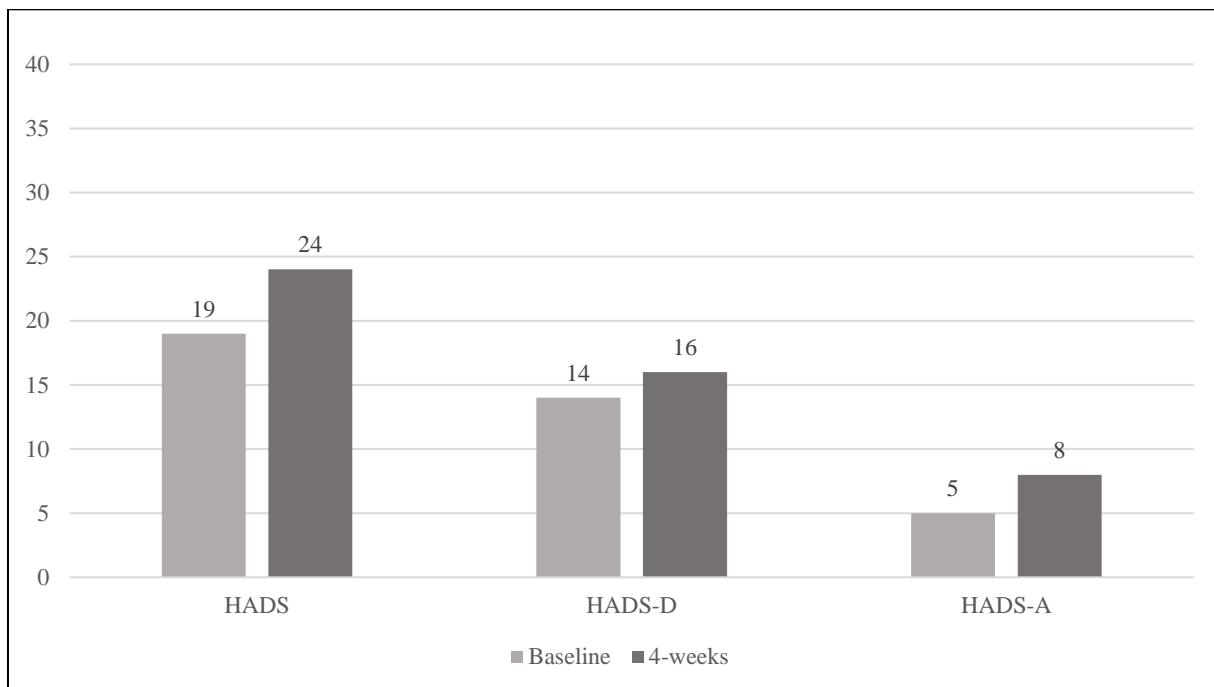
Note. Changes of psychological distress (HADS; Herrmann-Lingen et al., 2010; range = 0–42), divided into changes of symptoms of depression (HADS-D; range = 0–21) and symptoms of anxiety (HADS-A; range = 0–21) from baseline (T1) to 4-weeks measurement (T2) in case A.

Figure 6 shows changes of mindfulness and figure 7 changes of self-compassion from baseline to four weeks measurement. Mindfulness increased slightly by 0.21 points (2.79 to 3.00), which represents an increase of +5.25%. Self-compassion remained the same over both measurements (3.67).

Figure 6

Case A Changes of FMI-14 from T1 to T2
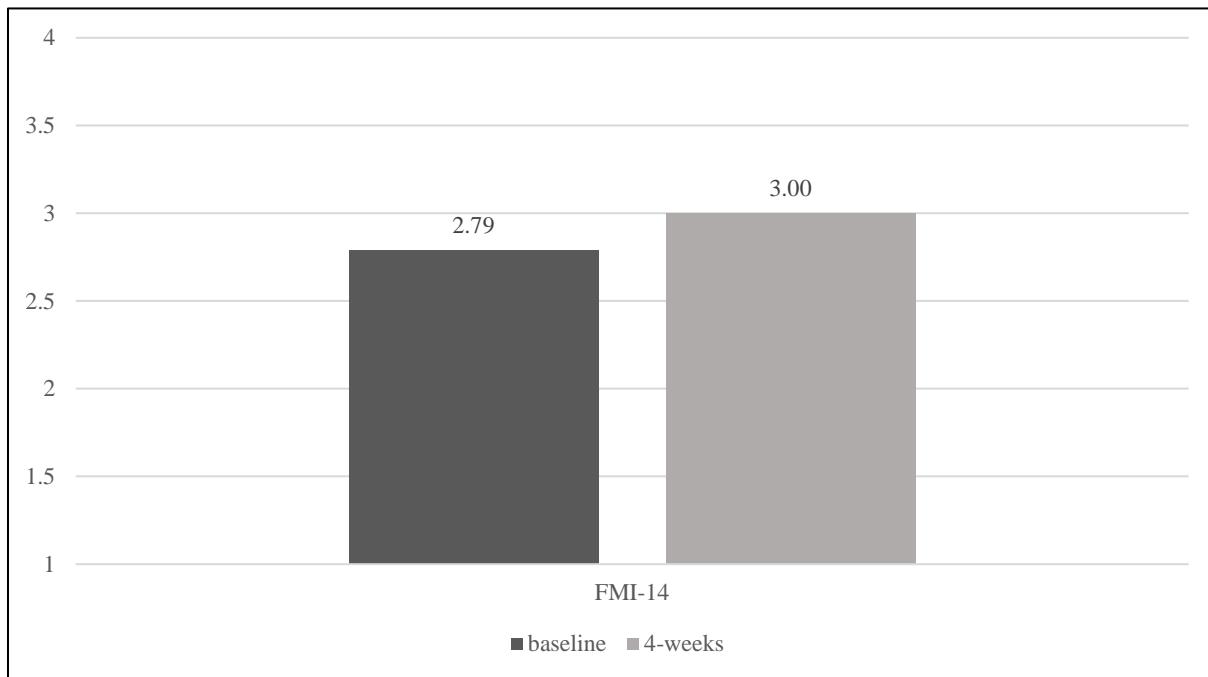
Note. Changes of mindfulness (FMI-14; Buchheld, 2000; range = 1–4) from baseline (T1) to 4-weeks measurement (T2) in case A.

Figure 7

Case A Changes of SCS-SF from T1 to T2
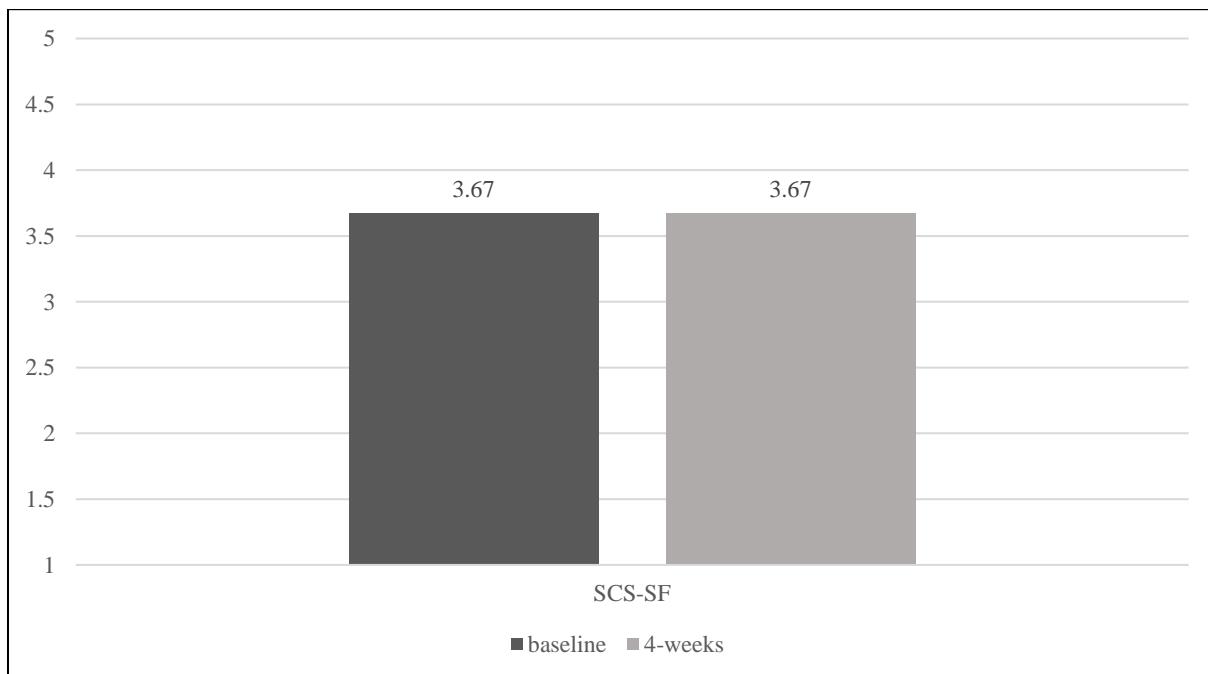
Note. Changes of self-compassion (SCS-SF; Hupfeld & Ruffieux, 2011; range = 1–5) from baseline (T1) to 4-weeks measurement (T2) in case A.

Case A reported in weekly telephone calls about his high social and financial burden. During week two of the intervention, he reported a worsening of symptoms. Week four was according to the participant especially distressing, as his sister got a cancer diagnosis, and the participants was not able to visit her, because she lives in Turkey. The participant's health status and financial situation would hinder him to travel there. His high distress was the reason he gave for pausing the intervention after day 20. As case A practised the exercise twice on one day, in summery case A practised mindfulness 12 times over the course of four weeks, as shown by EMA data.

Case B

Case B is 61 years old and identifies as female. She has been diagnosed with COPD for 12 to 15 years and is currently in GOLD stage III. She lives by herself, as she is widowed, and is retired. Case B has made some experiences with mindfulness meditations. Besides her COPD diagnosis, the participant also suffers from an anxiety disorder, for which she takes medications (Xanor). Her last exacerbation was six months ago. Her health status impairment is medium to high at baseline (CAT = 11; range = 0–40). Her health-related quality of life is high (CRQ = 111; range = 0–125). In line with these results, her psychological distress is low (< 16), with low symptoms of depression (< 8) and anxiety (< 8; HADS = 7; range = 0–41; HADS-D = 4; range = 0–21; HADS-A = 3; range = 0–21). Also, on depression and anxiety scales of the PHQ, case B showed normal results. Her HADS results were lower at baseline than during her screening (HADS = 11; HADS-D = 9; HADS-A = 2).

After baseline measurement, case B was randomly assigned to the intervention condition. The instruction day took place the day after the baseline measurement. The four weeks measurement took place 27 days after the instruction day.

Figure 8 shows changes of psychological distress from T1 to T2. HADS scores decreased 3 points from 7 to 4, which represents a decrease of -7.1%. Changes of subscales are also presented in figure 8, from T1 to T2 anxiety symptoms decreased 1 point (-2.4%) and depression symptoms decreased 2 points (-4.8%).

Figure 8

Case B Changes of HADS, HADS-D and HADS-A from T1 to T2
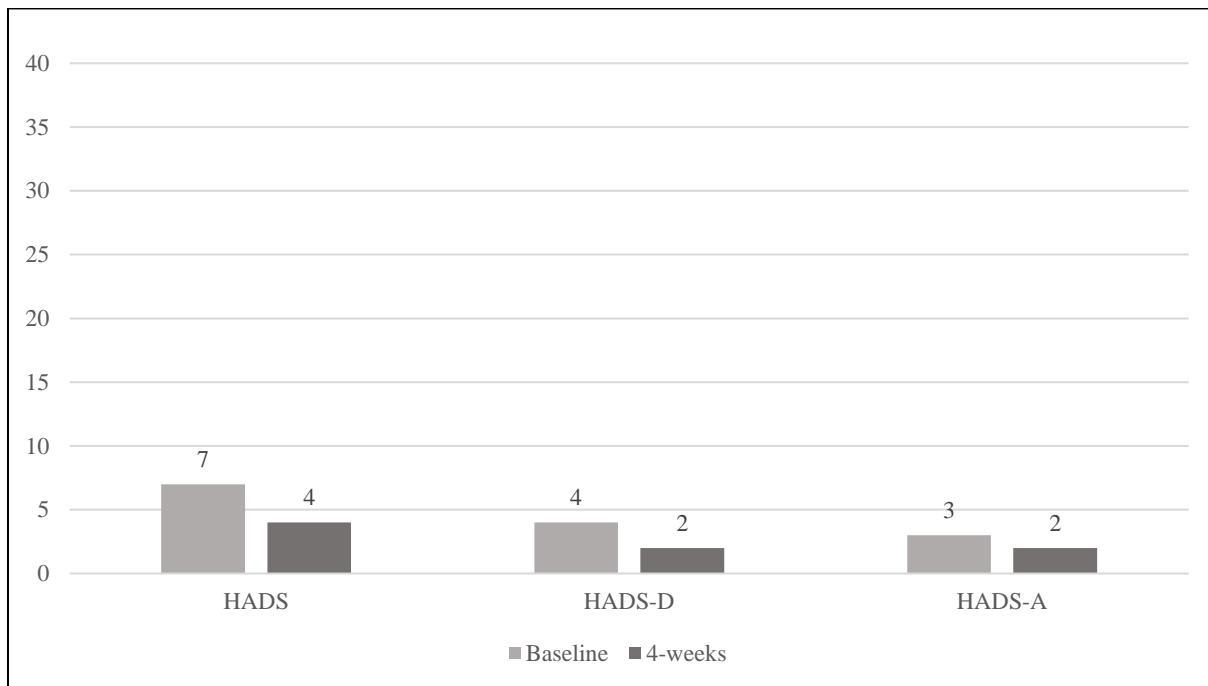
Note. Changes of psychological distress (HADS; Herrmann-Lingen et al., 2010; range = 0–42), divided into changes of symptoms of depression (HADS-D; range = 0–21) and symptoms of anxiety (HADS-A; range = 0–21) from baseline (T1) to 4-weeks measurement (T2) in case B.

Figure 9 presents changes of mindfulness and figure 10 changes of self-compassion after 4 weeks of intervention. The mindfulness of case B increased by 0.28 points (3.43 to 3.71), which represents an increase of +7%, while her self-compassion decreased by 0.5 points (4.17 to 3.67), which indicates a decrease of -10%.

Figure 9

Case B Changes of FMI-14 from T1 to T2
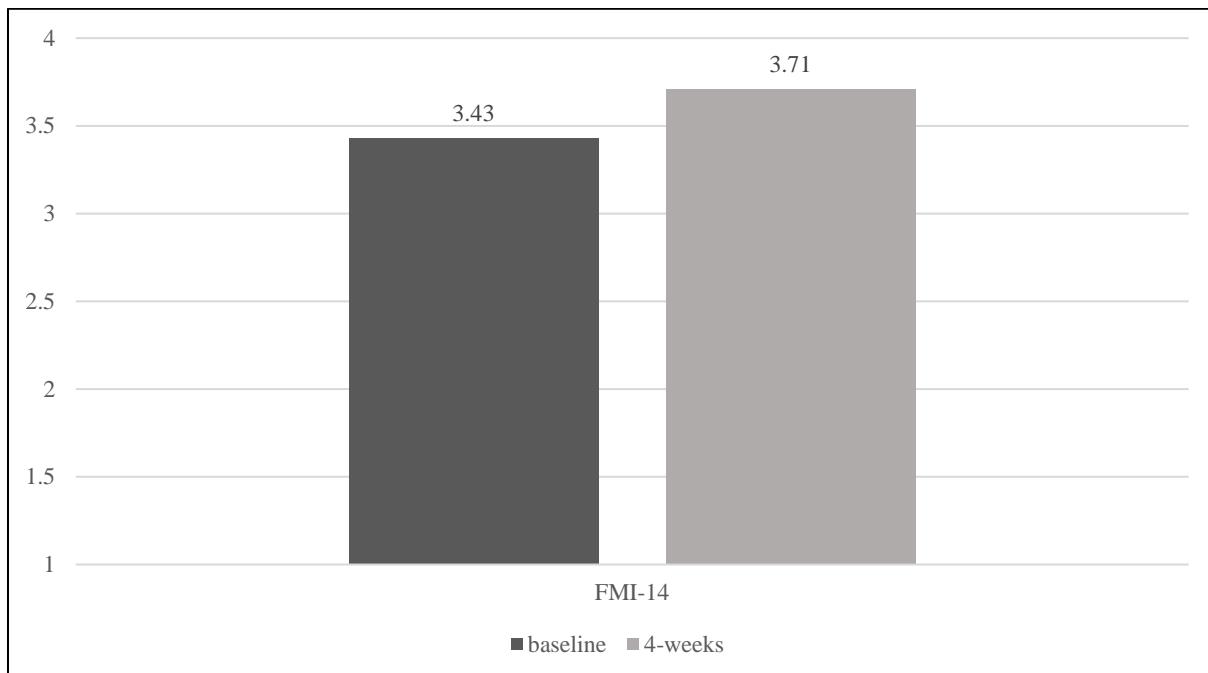
Note. Changes of mindfulness (FMI-14; Buchheld, 2000; range = 1–4) from baseline (T1) to 4-weeks measurement (T2) in case B.

Figure 10

Case B Changes of SCS-SF from T1 to T2
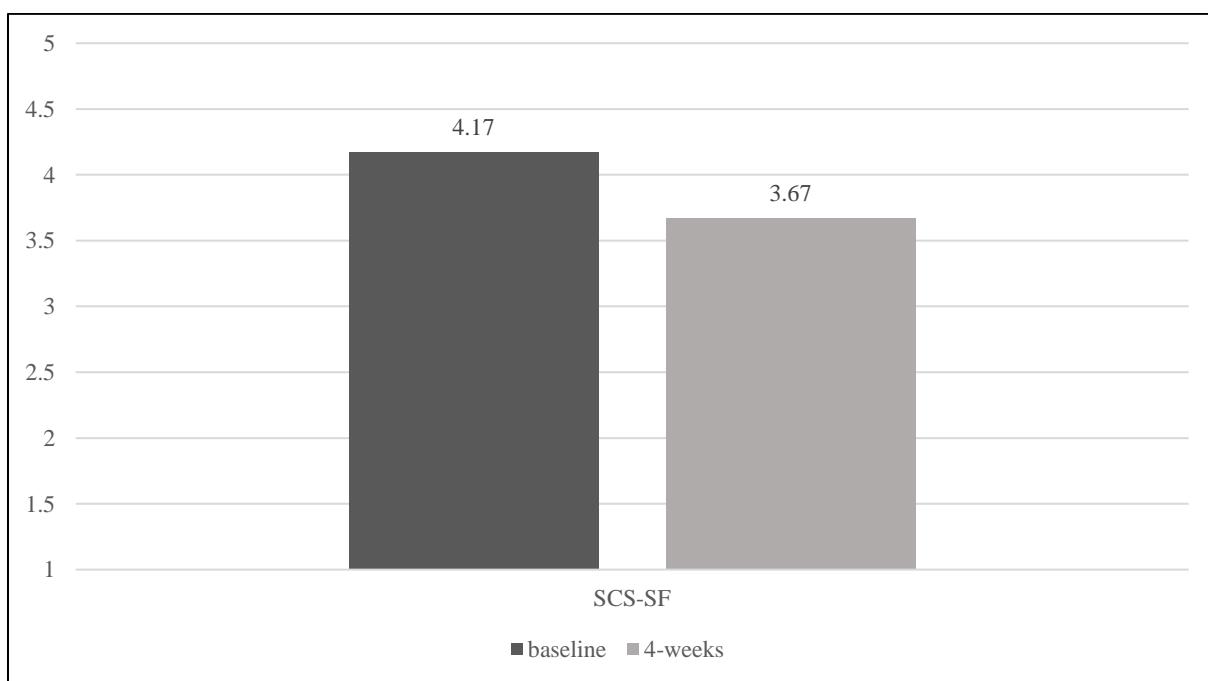
Note. Changes of self-compassion (SCS-SF; Hupfeld & Ruffieux, 2011; range = 1–5) from baseline (T1) to 4-weeks measurement (T2) in case B.

Case B reported in weekly telephone calls, that her health was better than before the intervention. Further, she stated that she had no problems with the practices, and she even used them, when she was in a bad mood.

EMA data showed that case B started the intervention the day after the instruction day and continued practicing mindfulness meditations every day for 27 days until the second measurement after four weeks (T2).

Case C

Case C is 59-years old and identifies as male. He lives with his wife and is employed. He has had no experiences in mindfulness meditations so far. Case C has had his COPD diagnosis for seven years and is currently in GOLD stage III of the disease. He has never had an exacerbation, but his health status impairment is still high (CAT = 20; range = 0–40). Also, his health-related quality of life is relatively low (CRQ = 77; range = 0–125; see table 4). At baseline, his psychological distress is high, with higher symptoms of depression compared to anxiety (HADS = 16; range = 0–41; HADS-D = 11; range = 0–21; HADS-A = 5; range = 0–21). In line with these results, his results of the PHQ reported the presence of a major depression (5 or more items scored 3 or higher; item 2i also counts when 2 or higher) and his score on the depressive syndrome subscale was very high (≥ 20; see table 4). In summary, case C is highly burdened by his disease, physically and mentally.

Case C was randomly assigned to the waitlist control condition. Thus, he did not practice any mindfulness meditations until the end of measurements.

T1 and T2 were exactly 27 days apart from each other. Figure 11 shows changes of psychological distress, divided into symptoms of depression and anxiety from T1 to T2. His psychological distress remained the same over the course of 4 weeks, while the subscales changed 1 point in different directions. The depression symptom score decreased 1 point (-4.8%), while the anxiety symptom score increased 1 point (+4.8%).

Figure 11

*Case C Changes of HADS, HADS-D and HADS-A from T1 to T2*
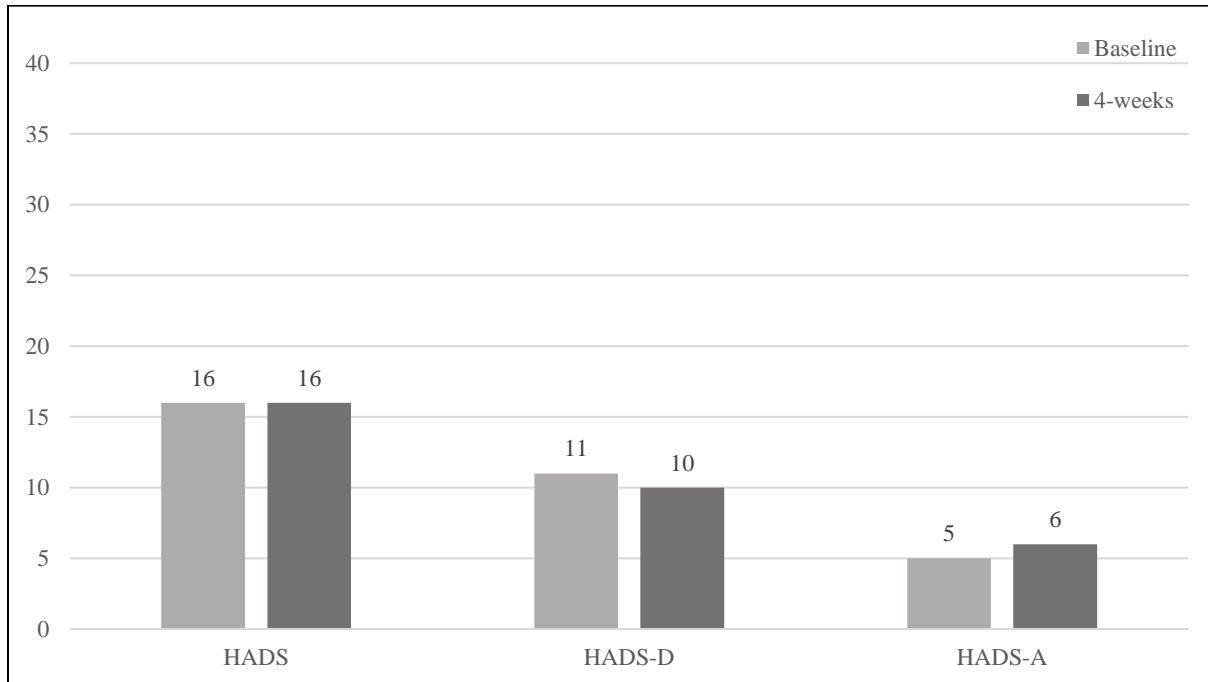
Note. Changes of psychological distress (HADS; Herrmann-Lingen et al., 2010; range = 0–42), divided into changes of symptoms of depression (HADS-D; range = 0–21) and symptoms of anxiety (HADS-A; range = 0–21) from baseline (T1) to 4-weeks measurement (T2) in case C.

Figure 12 shows how mindfulness and figure 13 how self-compassion changed in case C from T1 to T2. The mindfulness of case C decreased by 0.14 points (2.64 to 2.5), which represents a decrease of 3.5%. His self-compassion decreased by 0.5 points (3.33 to 2.83), which represents a decrease of 10%.

Figure 12

Case C Changes of FMI-14 from T1 to T2
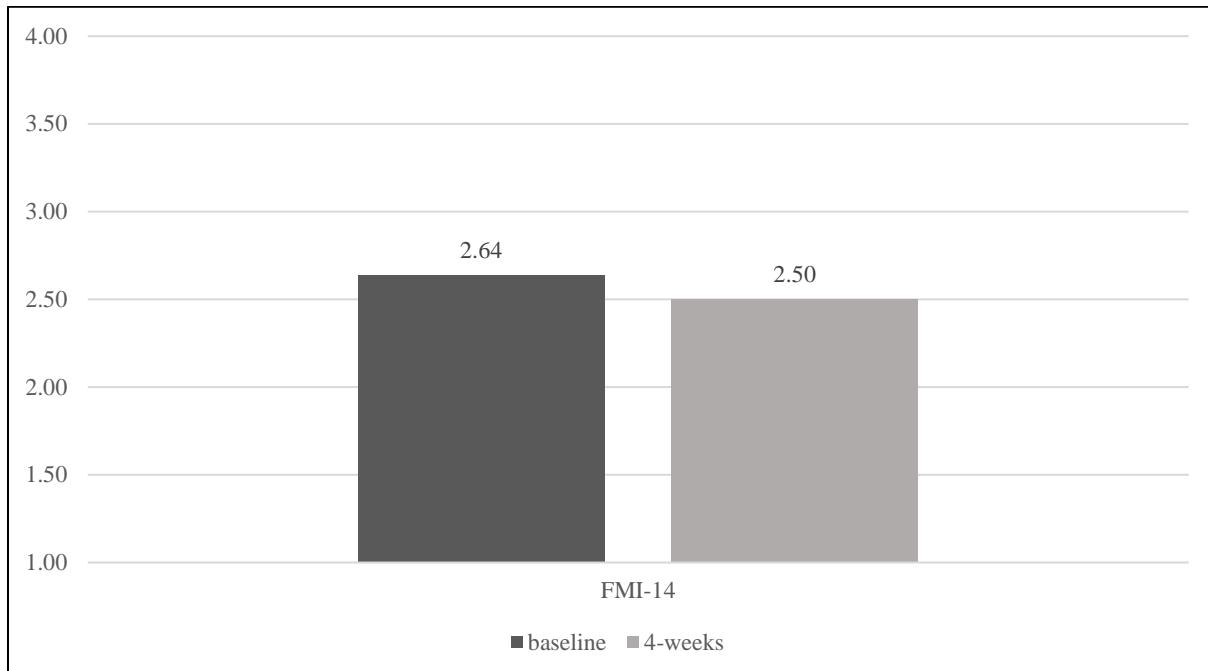
Note. Changes of mindfulness (FMI-14; Buchheld, 2000; range = 1–4) from baseline (T1) to 4-weeks measurement (T2) in case B.

Figure 13

Case C Changes of SCS-SF from T1 to T2
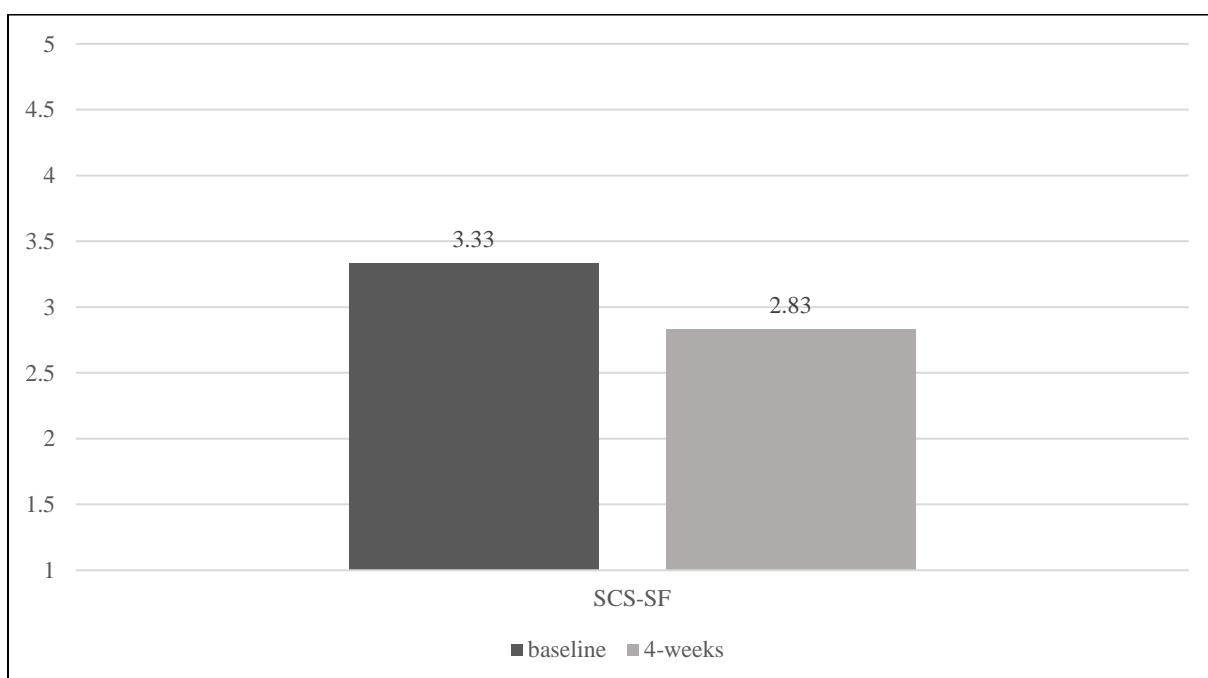
Note. Changes of self-compassion (SCS-SF; Hupfeld & Ruffieux, 2011; range = 1–5) from baseline (T1) to 4-weeks measurement (T2) in case C.

Case C reported in the weekly telephone calls, that especially the fourth week was very stressful, as his wife had a suspected heart attack and had to be picked up by a helicopter and was hospitalized. No EMA data exist of case C, as only the intervention condition used the app to collect data.

Explorative Analysis

To better understand the effects of chosen single cases, also changes of single items of the HADS were looked at.

When assessing the change of single items of HADS-A in case A, it stands out that items 3, 5, and 9 worsened over the course of four weeks (see table 5). These items represent symptoms of general fears and worries, as well as tension.

When assessing the HADS-D, items 4 and 14 worsened, which cover symptoms for loss of joy and interest, while item 8 improved (see table 5). Item 8 asks here for loss of motivation.

In case B different items of the HADS-A changed from T1 to T2. Items 1 and 9 improved, which address nervousness and tension, while item 11 worsened, which stands for a deficit in relaxation (see table 5).

On the HADS-D two items decreased (see table 5). Items 4 and 12 address the loss of joy, so if the score on these items decreased it stand for less loss of joy after four weeks of intervention.

On the HADS-A of case C item 3 increased, thus is general fears and worries got stronger in this domain. The rest of the items stayed the same. On the HADS-D two symptoms improved, as item 4 and 8 decreased. These items can be connected to the loss of joy and motivation. One item (item 6) increased, which is also connected to loss of joy.

Table 5

Changes of Single Items of the HADS in All Single Cases

HADS Item	Case A		Case B		Case C	
	T1	T2	T1	T2	T1	T2
Anxiety subscale						
Item 01	1	1	1	0	1	1
Item 03	1	2	0	0	0	1
Item 05	0	1	0	0	1	1
Item 07	2	2	0	0	1	1
Item 09	1	2	1	0	0	0
Item 11	0	0	0	1	2	2
Item 13	0	0	1	1	0	0
Depression subscale						
Item 02	2	2	1	1	1	1
Item 04	2	3	1	0	2	1
Item 06	2	2	0	0	0	1
Item 08	3	2	1	1	3	2
Item 10	2	2	0	0	2	2
Item 12	2	2	1	0	2	2
Item 14	1	3	0	0	1	1

Discussion

Summary of Results

The aim of the thesis was to examine whether a daily digital mindfulness-based intervention (MBI) reduces psychological distress (symptoms of anxiety and depression) in COPD patients after four weeks of intervention. Furthermore, the thesis wanted to detect mindfulness and self-compassion as possible underlying mechanisms of the MBI.

Because of very low numbers of results of participants at time of analysis ($N = 4$), single case analyses of three cases were conducted instead of planned statistical analyses to answer research questions. Two of them participated in the intervention condition and one in the waitlist control condition.

Single case analyses could not show a consistent picture, as one case participating in the intervention condition showed higher symptoms of anxiety and depression, which could indicate possible adverse effects (Cebolla et al., 2017), while the other participant showed a

small reduction of symptoms of anxiety and depression after four weeks of intervention, which might have been influenced by floor effects. The single case participating in the waitlist control condition showed no change of psychological distress after four weeks, although symptoms of anxiety increased slightly, while symptoms of depression decreased, as it would have been expected.

The question whether mindfulness or self-compassion mediate the effect of MBIs on psychological distress cannot be answered with single case analyses. But it the possibility of mediating effects was discussed following some steps of the causal-steps method (Baron & Kenny, 1986). Thus, mindfulness increased in both cases of the intervention condition, while it decreased in the control condition. This could be an indicator for possible positive relationship between MBIs and mindfulness. A positive relation of mindfulness and psychological distress on the other hand could only be assumed in case B, but not in case A. Regarding self-compassion, there seemed to be no connection to the MBI or psychological distress, as self-compassion stayed the same in case A (intervention condition), and decreased in case B (intervention condition) and C (control condition), while it would have been expected to increase in the intervention condition and stay the same in the waitlist control condition.

As effects could not be statistically calculated, thus results of this thesis should not be overvalued. All results could be coincidental and cannot to be generalized.

Discussion of Results

Hypothesis 1

The main research question was to detect positive effects of MBIs on symptoms of anxiety and depression. As the results variate between the cases, outcomes of three single cases will be discussed separately, because the results are better understood in the context of each case.

Case A. Symptoms of anxiety as well as depression of case A increased over the course of four weeks, as the scores of case A at baseline measurement (T1) were lower than after four weeks (T2) of the intervention. This result is contrary to previous literature, suggesting that MBIs reduces symptoms of anxiety and depression (Hofmann et al., 2010; Howarth et al., 2019). There are different explanations, which could account for these unexpected results, and which will be discussed in this section.

First, it must be mentioned that case A only practiced the intervention 12 times on 11 days. Thus, the adherence of this participant was very bad, which could be traced back to the delayed introductory session (due to holidays and technical problems), as well as his psychological wellbeing. The health status of case A reflect a high burden by his disease at T1.

He was at GOLD stage IV of COPD, which represents a very severe COPD (GOLD). His health status impairment (measured by CAT; Jones et al., 2009), as well as symptoms of anxiety and depression (measured by HADS; Herrmann-Lingen et al., 2010) were very high at baseline, while his health-related quality of life (measured by the CRQ-SAS; Schünemann et al., 2003) was low. During weekly telephone calls, case A also reported how he was very distressed and experienced a worsening of COPD symptoms since the baseline measurement. As his psychological state worsened drastically during the third week of intervention, he stopped carrying out the meditation exercises, as he could not motivate himself to do anything. Thus, it leads to the conclusion that even digital MBIs might not be feasible for very burdened COPD patients. Mularski and colleagues (2009) also reported bad adherence and high dropout rates in participants with moderate to severe COPD and concluded that MBIs are not feasible for very burdened COPD participants. Also, Blackstock et al. (2016) discussed the nonadherence of COPD patients in various treatments. They found symptom burden, as well as depression to be factors associated with less adherence.

Therefore, nonadherence is a relevant factor, when discussing the results of case A, as the amount of practice influences positive outcomes of MBIs. Results from a meta-analysis showed a small but significant effect of the amount participants practiced mindfulness at home on psychological distress when conducting an MBSR or MBCT (Parsons et al., 2017). Case A only practiced on around 44% of the days during the intervention. It has been suggested to only interpret results when participants took part in more than four out of eight weekly sessions (Gu et al., 2015; Kazdin, 2007). This would be comparable to at least 13 days of practice out of possible 27 days. Thus, the negative changes of his psychological distress could be attributed to the fact, that he did not practice enough. This would be in line with results from Perkins-Porras et al. (2018), who could not find a significant decrease of psychological distress after only one meditation unit. This leads to the conclusion that more frequent practices might be needed to lead to positive change and would explain why the intervention did not reduce symptoms of depression or anxiety in case A. On the other hand, Howarth et al. (2019) found that already one session of an MBI can have positive effects on depressive and anxiety symptoms. Also, this would not explain why the psychological distress of case A increased over the course of four weeks.

The increase of psychological distress could also indicate adverse effects of MBIs, which have been discussed in more recent research. Adverse or unwanted effects of MBIs, such as greater emotional pain, greater self-criticism as well as more anxiety and depression, have been documented to occur more frequently when practicing mindfulness alone (Cebolla et al.,

2017). A recent study examined adverse effect in a meditation-naïve sample over the course of a 21-day MBI (Aizik-Reebs et al., 2021). They found that most participants (87%) experienced adverse effects at least once while meditating. Anxious mood was the momentary adverse effect which was reported the most. Also, this study found no association between the momentary adverse effects and long-term adverse effects and concludes that positive change of MBIs might be nonlinear and especially when beginning to meditate also distressing feelings can come up. Cebolla and colleagues (2017) also found that 39% of adverse effects were only temporarily and only 1% of participants stopped meditating as a result of the negative effects they had experienced (Cebolla et al., 2017). Results of case A could indicate the possibility of adverse effects, but as this was not part of my hypothesizes, this conclusion should be interpreted with caution and requests further research. Also looking into associations with adverse effects, like meditating alone, could help to prevent negative effects after an MBI in the future.

Another reason for the increase of depressive and anxiety symptoms after four weeks could possibly be the stressful life event case A experienced during the intervention. Case A reported that he was told about his sister's cancer diagnosis before the second measurement. The change of health of a family member has been classified as the 11th most distressing event on the Social Readjustment Rating Scale (SRRS) by Holmes and Rahe (1967). Moreover, Yu et al. (2018) found that stressful life events like the disease of a family member led to increased symptoms of anxiety and depression in COPD patients. Lu et al. (2012) even found the increase of depressive symptoms after a stressful life event to be much higher in COPD patients than in other samples. Thus, the increase of psychological distress could be accounted to the stressful life event case A experienced.

The assessment of single item changes as part of an explorative analysis can underline the theory of a relation of higher psychological distress to stressful life events. For instance, item 3 "I get a sort of frightened feeling as if something awful is about to happen" (translation from original version of the HADS; Zigmond & Snaith, 1983) increased from T1 to T2 in case A. This could be due to the experience of learning about his sister's cancer diagnosis. Case A could have referred to that fact and maybe the fear that his sister might die. The increase of the score in item 5 "worrying thoughts go through my mind" (translation from original version of the HADS; Zigmond & Snaith, 1983) can also be connected to that event, as well as his reported worries about financial problems.

Case B. Symptoms of anxiety and depression of case B decreased slightly after four weeks of intervention. This is in line with Farver-Vestergaard et al. (2018b) results, showing a significant decrease of psychological distress after an MBCT and pulmonary rehabilitation program.

As Puhan et al. (2008) suggested a minimal difference of 1,5 points on each subscale to be a relevant difference of the HADS, the reduction of depressive symptoms of case B can be interpreted as a relevant reduction (2 points). The reduction of symptoms of anxiety (1 point) would not be considered as a relevant reduction according to Puhan et al. (2008). The small reduction of psychological distress in case B can be traced back to floor effects. A floor effect is the result of an insufficient distinction in the lower regions of a measuring scale. Thus, stronger improvements could not be displayed by the HADS questionnaire in this case, because there is nothing below 0 you can choose. Previous research found floor effects to be problematic in all items of the HADS in an elderly sample (Djukanovic et al., 2017). When assessing changes of single items of the HADS, it is noticed that most items were answered with 0 on a 5-point Likert scale. Hence, the floor effect is a very likely reason for the reduction of symptoms of anxiety and depression being so small in case B.

To prevent possible floor effects, only participants with higher HADS scores (HADS ≥ 16, and/or HADS-D ≥ 8, and/or HADS-A ≥ 8) were planned to be included. Case B could be included, as her HADS score during the screening was above cut-off (HADS = 11, HADS-D = 9, HADS-A = 2). Even though at the time of baseline measurements her HADS score was below the cut-off (HADS = 7, HADS-D = 4, HADS-A = 3). As the screening was only used for the inclusion and exclusion of participants, scores of the screening cannot be further interpreted.

Another possible confounding variable in case B might be the medication against her anxiety disorder (Xenor), as this possibly affected HADS results. As case B took the medication regularly during the whole intervention, no changes of the HADS should be traced back to the medication, but the generalization of the results is further narrowed. The intervention could therefore lead to different results in COPD patients, who do not take medication against anxiety disorders.

However, the adherence of case B was very good, as she practised meditation exercises every day for 27 days in total. This fits the assumption made for case A, that the amount and regularity of mindfulness practise is an important factor for positive change of MBIs (Parsons et al., 2017).

Case B also differs from case A, as case B had some previous experiences with mindfulness already. Sedlmeier and colleagues (2012) reported in a meta-analysis confounding

variables of the effect of MBI. They found that the experience of meditators seemed to play a role on the effectiveness of MBIs. This influence was especially strong I the first four years of experience and lost its significance, when meditators had ten or more years of meditation experience. Thus, the mindfulness experiences of case B could account for some of the positive change of symptoms of depression after the intervention.

Case C. The psychological distress of case C remained the same after participating in the waitlist control condition for four weeks. Although the score of the depressive symptoms decreased slightly (-1 point) and anxiety symptoms increased slightly (+1 point), the changes of 1 point in each score would not be considered as a relevant change according to Puhan et al. (2008). These results fit the underlying theory of this thesis, as we would have expected psychological distress to stay the same without intervention.

When considering the contextual factors of case C, it seems surprising that his psychological distress stayed the same at first sight, as case C reported in weekly telephone calls how his wife had a suspected heart attack a few days before the second measurement took place. She had to be picked up by a helicopter as no ambulances were available at the time. As stressful life events have a negative impact on anxiety and depressive symptoms in COPD patients, psychological distress would have been expected to increase just like in case A (Yu et al., 2018). On the other hand, case C told how this was not the first time of his wife experiencing a heart attack and thus, the event might not have been as distressing for the participant. Also, case C might have better coping mechanisms of stressful life events than case A and therefore not show an increase of psychological distress.

Just as case A, also case C reported an increase of item 3 "I get a sort of frightened feeling as if something awful is about to happen" (translation from original version of the HADS; Zigmond & Snaith, 1983). This increase can be traced back to his experience. This experience would have been very frightening and could account for the increase of the feeling that something awful is about to happen.

This case as well as the other cases is a single case, thus we have to consider that the results can also be completely coincidental.

In Summary. Considering hypothesis 1 the single cases showed an inconsistent picture. Case A had higher psychological distress at T2, which can be traced back to nonadherence of this participant. This in turn could be associated with his high symptom burden. The increase of psychological distress could be connected to stressful life events or adverse effects of MBIs, which should be investigated further, as research in this domain is very scares. Results of case B show the expected trend of decreasing psychological distress, but the change was very small.

Case B showed very good adherence, and the small decrease could be explained by floor effects. Future research should only include patients with higher psychological distress, as it is planned in the parent RCT study, so that changes can be detected. Case C showed no change of psychological distress as was expected, although he also experienced stressful life events. Individual differences in coping with stressful situations could account for that and could possibly be a subject of future studies. All results are preliminary and request further research.

Hypotheses 2 and 3

My secondary research questions addressed possible mechanisms of MBIs. Previous literature found increased mindfulness and self-compassion across treatment to mediate the effect of a MBCT on depressive symptoms at follow-up measurements (Kuyken et al., 2010). According to the Baron and Kenny (1986) causal-steps test, mindfulness and self-compassion would act as mediators if some conditions were fulfilled, the first of them being a significant relationship between the condition (MBI) and the outcome (symptoms of anxiety and depression). As this relationship cannot be seen as significant, the interpretation of results of hypotheses 2 and 3 should be seen as explorative. If mindfulness and self-compassion were increased after four weeks of intervention in the intervention condition, while they did not change in the control condition, and if the variables changed in the opposite direction as psychological distress, this could indicate possible mediating effects, although this could not be seen as a prove for mediating effects.

Thus, for these explorative analyses the paths between the MBI and mindfulness/self-compassion, and mindfulness/self-compassion and psychological distress were explored. As all results can be coincidental and mediating effects could be just one of many explanations for changes, these results and interpretations have to be considered with caution. All single cases will be discussed separately.

Case A. The mindfulness of case A increased from baseline (T1) to the second measurement after four weeks (T2). This result fits the theory that MBIs increase mindfulness (Kiken et al., 2015). It could also indicate that mindfulness is a possible mechanism of MBIs, as it has been discussed in previous literature (Gu et al., 2015). Another indicator for possible mediating effects of mindfulness on changes of psychological distress, would be if both scores changed in opposite directions. We expected psychological distress to decrease in the intervention condition, while mindfulness increased. This was not the case in case A, as both, psychological distress and mindfulness increased. Case A therefore does not support findings of previous literature, which found a mediating effect of mindfulness (Kuyken et al., 2010). It seemed to be in line with contrary findings of Labelle et al. (2010). Although Labelle and

colleagues (2010) found the first two steps of the causal-steps method to come true, the third did not. Thus, they concluded, that mindfulness did not mediate the association between changes of depressive scores and the MBI. That mindfulness increased but psychological decrease increased as well could underline the previously stated theory of adverse effects. Thus, the intervention did work properly, because mindfulness increased, but psychological distress increased. This association should be investigated in future research.

Self-compassion of case A remained the same from first (T1) to second (T2) measurement. This is an unexpected result, as we expected self-compassion to increase in the intervention condition, as it was indicated by Gu et al. (2015).

That the intervention could not increase self-compassion could be explained with the nonadherence of case A, which has been discussed earlier. As Bergen-Cico and Cheon (2014) found that self-compassion only increased after an MBI when mindfulness did and also needed more time, the four weeks of intervention, as well as the little practice of case A might not have been enough time for self-compassion to change.

The results of case A did not support findings of previous literature, in which self-compassion mediated the effect of MBIs on psychological distress (Kuyken et al., 2010), but in future research only participants who took part in more than half of the intervention practices should be included (Kazdin, 2007).

Case B. As well as in case A, mindfulness of case B increased over the course of four weeks. In this case mindfulness and psychological distress change in opposite directions, as we would have expected it if mindfulness was a mediator of the MBI in the study. Thus, while mindfulness increased after four weeks of the intervention, psychological distress decreased. Interestingly mindfulness did not increase more than in case A, although the adherence of case B was much better than in case A. The change of mindfulness in case B being quite small could be due to ceiling effects, as the self-assessed mindfulness of case B was already high (3.41) to begin with. After four weeks of intervention case B reported a score of 3.71 out of the maximum score of 4. Ceiling effect in this case are very likely.

Although results of case B could indicate a mediating effect of mindfulness on the association between the intervention and decreased psychological distress, the results cannot be seen as prove for this effect. Thus, it is possible that the intervention increased mindfulness and decreased psychological distress, but there is no mediating effect of mindfulness. Therefore, future studies are needed to investigate this connection further by using a greater sample size to statistically calculate mediation effects of mindfulness on the connection between MBIs and psychological distress in COPD patients.

Further explorative analyses suggest looking into subscales presence and acceptance of the FMI-14 (Buchheld, 2000). Although authors did not recommend assessing subscales separately because both subscales intercorrelate (Walach et al., 2006), Kohls et al. (2009) found the subscale acceptance of the FMI-14 (Buchheld, 2000) to be more strongly associated with the reduction of psychological distress than the subscale presence. Single case B seems to underline these suggestions, as the items associated with the acceptance subscale increased more than those associated with the presence subscale. As these are only explorative results, this should be interpreted with caution. Future research should look further into a connection of MBIs and the acceptance subscale of the FMI-14 (Buchheld, 2000).

Self-compassion unexpectedly decreased in case B after four weeks. As case B showed very good adherence and decreased depressive and anxiety symptoms, increased self-compassion would have been expected. Further, previous literature suggested self-compassion to better predict positive changes of MBIs than mindfulness (Van Dam et al., 2011). This case does not support previous findings, as it seems like mindfulness is better connected to the outcome in this study than self-compassion. As previously addressed, self-compassion could need more time to change than only four weeks of intervention (Bergen-Cico & Cheon, 2014).

That self-compassion was lower after the intervention than before (T1 = 4.17; T2 = 3.67) could be due to the response shift, which was mentioned in the context of mindfulness questionnaires (Grossmann, 2008). The response shift would hereby describe the phenomenon that scores in self-assessment questionnaires decrease, because of a better understanding of the construct self-compassion through the intervention, but this would be contrary to the finding that response shift only occurs when the MBI includes psychoeducation.

Results of case B cannot answer the question, whether self-compassion mediates the effect of the intervention on psychological distress, and further research will be needed to get a better understanding of the underlying mechanisms of MBIs.

Case C. Case C is representing the waitlist control condition in this thesis. Without intervention I would have expected mindfulness and self-compassion to remain the same, as they have been suggested to be relatively stable constructs, which can be enhanced through MBIs (Kiken et al., 2015; Neff & Germer, 2013). Interestingly mindfulness and self-compassion decreased in case C after four weeks. The change of mindfulness (-3.5%) is the smallest out of all single cases. Thus, the small change of mindfulness might reflect the usual variations from day to day, which can be dependent on moods and situations (Kiken et al., 2015). The decrease of self-compassion (-10%) of case C was unexpected, as it would have

been expected to stay the same without intervention. Future studies should investigate variables, which can be associated with decreasing self-compassion, as research on this has been lacking.

In Summary. The discussion in research whether self-compassion and/or mindfulness mediate the effect of MBIs on psychological distress cannot be resolved through single case analyses, as no statistical evaluation was possible. Explorative analyses of changes of mindfulness and self-compassion indicate that the digital MBI used in the study could increase mindfulness but not self-compassion. The direction of change of mindfulness was as expected, as mindfulness increased in case A and case B. Mindfulness decreased slightly in case C, which might reflect the usual variations from day to day (Kiken et al., 2015).

When discussing mindfulness, we mentioned the response shift, which states how learning about mindfulness can negatively affect scores on self-report questionnaires because of a new understanding of the items (Grossmann, 2008). The results of this thesis did not show a response shift, which could be due to the differing MBI used in this study. As mentioned before, MBSR and MBCT are the most common MBIs used in research. These programs also use psychoeducation, in which they teach mindfulness explicitly, which was kept to a minimum in the intervention used in this study. Therefore, mindfulness practice might not lead to a response shift, but the explicit knowledge about mindfulness does. Future research should consider using MBIs without the psychoeducation parts of the MBSR and MBCT programs, when investigating changes of mindfulness to prevent possible response shifts.

The decrease of self-compassion in case C is as high as in case B. Although both cases took part in different conditions and had different contextual situations, they both reported a decrease of self-compassion by 10%. These results indicate that changes of self-compassion could negatively be influenced by something other than the intervention. On the other hand, starting conditions and contextual factors of single cases B and C were very different from another. Therefore, this thesis cannot make any suggestions on which variables might have influenced the decrease of self-compassion in these two cases. Future studies should look further into possible moderating and mediating effects of MBIs on self-compassion.

Strengths and Limitations

The main strength of the parent study is the new approach of an app-based mindfulness-based intervention for COPD patients. As emphasized earlier the intervention, which was completely conducted at participants' homes (measurements and interventions), represents a huge benefit for often non-mobile or at least mobile restricted participants (Farver-Vestergaard et al., 2018a). Especially at times of the Covid-19 pandemic this approach was much safer for high-risk participants. The approach is also cost- and time-efficient for participants and test-

instructors, as participants did not have to travel anywhere and the intervention lasted no longer than 16 minutes, and test-instructors only explained the intervention once and then participants could perform the intervention by themselves. On the other hand, this setting also holds a limitation, as mindfulness practice alone has been associated with more frequent adverse effects in previous literature (Cebolla et a., 2017).

That the MBI mainly consisted of mindfulness meditation practices represents another advantage of the study. In most studies about MBIs, MBSR and MBCT programs are used, but they consist of many different parts (psychoeducation, different meditation practices; Kabat-Zinn, 1990; Segal et al., 2013). Thus, in these studies detected effects cannot be traced back to mindfulness meditation only. Also, as mentioned earlier, the explicit knowledge about mindfulness can lead to response shift in participants when assessing self-assessed mindfulness (Grossmann, 2008). In the MBI of the present thesis, no response shift was detected as the intervention promoted implicit rather than explicit knowledge about mindfulness.

On the other side, the deviation of the intervention to other studies reduces the comparability with them. As mentioned before, research on mindfulness and MBIs differ greatly, due to differing operationalization of the construct mindfulness and various MBIs used in research, such as MBSR and MBCT programs or different types of meditations (Chiesa & Malinowski, 2011). This contributes to a field of research with inconsistent results (for a discussion about the differences between MBIs see Chiesa & Malinowski, 2011).

Single case analyses can offer a broader insight into possible confounding variables, as qualitative information about contextual factors can be included in the analysis and the complexity of individual cases can be taken into account. Especially for young fields of research, such as the effects of digital MBIs in COPD samples, it is advantageous to look closely into single cases to figure out why the intervention did or did not work for these individuals. This can help with developing future studies, when considering problems, which came up, such as nonadherence, very high or very low symptom burden. Thus, in can help to decide, which participants should be excluded in future studies.

Single case analyses also hold some disadvantages, as results of single case analyses cannot be generalized, as the risk of coincidental results is very high. Thus, if different cases were chosen, results could have shown a completely different picture. Moreover, chosen single cases did not seem to be representable, which further narrows the possibility of generalization. Case A showed nonadherence, as he conducted the MBI only 12 times instead of 27-times over the first four weeks of intervention. Furthermore, case B showed a low HADS baseline score, which amplifies the risk of floor effects (Djukanovic et al., 2017). For mentioned reasons, both

cases out of the intervention condition would have been excluded if more data had been available by the time of analysis.

Also, because of the delay of the start of the study due to the Covid-19 pandemic, only data after four weeks of the intervention could be included. Therefore, all results have to be considered as preliminary, and a different outcome after the complete intervention is possible.

However, the current thesis contributes to the very promising field of research on digital MBIs in a COPD sample and might help to improve future study designs.

Prospects

For future research findings of this thesis should be considered. Thus, future studies investigating digital MBIs should collect data about adverse effects of MBIs. These have not often been documented in past studies and rely mostly on qualitative, retrospective interviews (Cebolla et al., 2017). Adverse effects occur in 87% of meditators new to mindfulness practices (Aizik-Reebs et al., 2021). Therefore, adverse effects should be considered when investigating effects of MBIs, especially when participants have no experiences with mindfulness practices and practise by themselves, to find out how to prevent adverse effects in MBIs.

When using the Hospital Anxiety and Depression Scale (Herrmann-Lingen et al., 2010) in a COPD sample in the future, researchers should ensure that participants show symptoms of anxiety and depression above cut-offs (≥ 8). Otherwise, the risk of floor effects is high, as the HADS (Herrmann-Lingen et al., 2010) cannot detect positive changes, if participants are not psychologically distressed to begin with. Floor effects have been documented to occur frequently in the HADS when used in an elderly sample (Djukanovic et al., 2017).

On the other hand, findings of this thesis suggest that MBIs might not be feasible for very psychologically distressed participants. COPD participants have stood out with nonadherence and high drop-out rates in past research (Mularski et al., 2009). This rate is even higher in COPD patients with depression and high symptom burden (Blackstock et al., 2016). Although the new approach of an app based MBI offers an advantage for this sample over analogue ones, future research should investigate what aspects could further motivate participants with high psychological distress to carry out the complete intervention.

Future research on MBIs should further investigate underlying mechanisms, as they have remained undetected so far. Mediation analyses are a valid method to detect possible mechanisms, which could help to improve interventions, finding suitable patients for a specific intervention and figuring out, which variables could interfere with positive outcomes of MBIs (Kazdin, 2007). In this regard, self-compassion should be further investigated. Although self-compassion has been suggested to be one of the underlying mechanisms of MBIs, self-

compassion decreased in two of three single cases in this thesis. Most research in the field of self-compassion concentrates on the positive effect of self-compassion on many health outcomes (e.g., Barnard & Curry, 2011), but also factors, which can reduce self-compassion should be further investigated.

For more valid results in the field of research on digital MBIs, future studies should include bigger sample sizes. It will only be possible to perform statistical analyses and find possible mediating effects of mindfulness and self-compassion using bigger sample sizes. A bigger sample size would also make results easier to generalize. On the other hand, single case analyses offer the benefits of including contextual factors of participants, thus future studies could also use mixed methods models and integrate qualitative and quantitative research.

Conclusion

The thesis brought more insight into the field of digital MBIs and psychological distress in the population of COPD patients. Results of this thesis led to the conclusion that adherence plays a role in the effectiveness of MBIs on psychological distress in COPD patients. To shed light into the connection between symptom burden and adherence, more research is needed in the future. When adherence is given, the MBI used in the parent study seems to be able to reduce symptoms of anxiety and depression, which could have been enhanced through experiences with mindfulness. Small effects can be traced back to floor effects. As there are many variables, which could have influenced the results of single cases, no valid conclusion can be drawn from these results. Further research will be necessary to do so. As this thesis only presented preliminary result of a RCT, more valid results should follow.

To figure out whether mindfulness and self-compassion acts as mediators in the relation of MBIs and psychological distress, future research with a bigger sample would be needed to statistically calculate results. Preliminary results of this thesis lead to the conclusion that self-compassion was not influenced by the digital MBI, but negatively influenced by something other which was present in the intervention and control condition. Future research should look into variables, which can lead to decreased self-compassion. Mindfulness on the other hand seemed to play a role in MBIs, as mindfulness increased in the intervention condition and remained nearly the same in the control condition. The association with psychological distress cannot be made through single cases and should be investigated further.

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Appendices

Appendix A. Mindfulness Exercises (original German version)

Mindfulness with Focus on the Heartbeat

1. [Glocke]

2. Nehmen Sie eine bequeme aufrechte Sitzhaltung ein, auf einem Stuhl mit einer geraden Lehne oder auf einem Hocker, sodass sich Ihre Wirbelsäule selbst aufrichten kann.

3. Erlauben Sie Ihrem Rücken, eine aufrechte und bequeme Haltung einzunehmen. Stellen Sie Ihre Füße flach auf den Boden, die Beine abgewinkelt nebeneinander. Wenn möglich, schließen Sie sanft Ihre Augen.

4. Bringen Sie Ihre Aufmerksamkeit zu den Empfindungen Ihres Körpers, so, wie Sie jetzt gerade hier sitzen. Richten Sie Ihre Aufmerksamkeit auf die Empfindungen von Berührung und Druck in Ihrem Körper, da wo er in Kontakt mit dem Boden oder Ihrer Unterlage ist. Spüren Sie den Kontakt Ihrer Füße mit dem Boden, den Kontakt mit etwas Festem, Stabilem, Beständigem, egal, was sonst gerade in Ihrem Körper oder Geist passiert. Untersuchen Sie diese Empfindungen für ein paar Momente.

5. Bringen Sie nun Ihre Aufmerksamkeit zu Ihrem Herzschlag und werden Sie sich dessen bewusst. Vielleicht spüren Sie das Schlagen des Herzens direkt…im Brustraum vielleicht. Wenn Sie Ihren Herzschlag im Moment nicht fühlen können, seien Sie sich einfach bewusst, dass Ihr Herz schlägt.

6. Der Herzschlag ist unser lebenslanger Begleiter, und versorgt unseren Körper zu jeder Zeit mit Energie und Wärme – egal, ob wir uns dessen bewusst sind, oder nicht. Stellen Sie sich vor, wie mit jedem Herzschlag – ähnlich einem Fluss – Energie und Wärme in Ihrem Körper verbreitet wird. Vom Herz ausgehend, hinauf durch die Schultern, den Nacken und den Kopf. Hinaus in die Arme und Hände. Und hinunter in den Bauchraum, die Beine, und die Füße.

7. Richten Sie nun Ihre Aufmerksamkeit auf die Empfindungen der Energie und Wärme in Ihrem Körper.

8. Wie fühlt sich der Fluss von Energie und Wärme – ausgehend von Ihrem Herzschlag - an? Vielleicht wie eine Welle durch bestimmte Bereiche des Körpers? Vielleicht wie eine pochende Empfindung? Vielleicht flatternd oder kribbelnd? Warm? Es gibt hier kein richtig oder falsch. Entdecken Sie einfach neugierig, wie es sich für Sie gerade anfühlt.

9. Vielleicht können Sie den Herzschlag in Ihrem Körper gerade nicht fühlen, und falls das so ist, ist das vollkommen in Ordnung. Dann nehmen Sie einfach wahr „Ich kann den Herzschlag in meinem Körper gerade nicht fühlen".

10. Werden Sie sich der sich ständig verändernden Empfindungen des Herzschlages in Ihrem Körper bewusst, von Moment zu Moment.

11. 11. Lassen Sie Ihre Erfahrung – so gut es Ihnen möglich ist – einfach Ihre Erfahrung sein, ohne dass sie anders sein müsste, als sie ist. Es gibt nichts, das verändert werden müsste. Nehmen Sie Ihren Herzschlag einfach wahr und stellen Sie sich vor, wie Ihr Herzschlag Energie und Wärme in alle Bereiche Ihres Körpers strömen lässt, Moment für Moment.

12. Früher oder später wird Ihr Geist vom Fokus auf den Herzschlag abschweifen und sich in Gedanken, Planen, Tagträumen – oder was auch immer – verlieren. Das ist vollkommen in Ordnung – unser Geist tut das nun mal.

13. Sobald Sie merken, dass Ihre Aufmerksamkeit nicht mehr bei Ihrem Herzschlag ist, nehmen Sie dies einfach wahr – somit sind Sie zurückgekommen und sich einmal mehr Ihrer Erfahrung bewusst! Vielleicht möchten Sie kurz zur Kenntnis nehmen, wo Ihr Geist gerade gewesen ist, ohne dies bewerten oder verändern zu wollen. Kommen Sie dann mit Ihrer Aufmerksamkeit wieder zu den Empfindungen des Herzschlages in Ihrem Körper zurück.

14. Vielleicht erforschen Sie, wo im Körper Sie den Herzschlag und die verbreitete Energie und Wärme am deutlichsten spüren können. Vielleicht ist das ein Pochen in Ihrem Kopf? Ein Kribbeln in den Händen? Eine Welle in den Füßen oder Beinen? Oder eine Empfindung irgendwo anders.

15. Füllen Sie diesen Teil Ihres Körpers mit Aufmerksamkeit. Erforschen Sie die Empfindungen in diesem Bereich. Wie fühlt es sich in diesem Bereich an? Pochend, überspannt, warm? Ändern sich die Empfindungen von Moment zu Moment, oder bleiben Sie gleich?

16. Jedes Mal, wenn Ihre Gedanken abschweifen, nehmen Sie dies einfach wahr, erkennen an, wo Ihr Geist hingewandert ist, und begleiten ihn sanft zurück zu dem Bereich des Körpers, an dem Sie Ihren Herzschlag am deutlichsten spüren können.

17. Erinnern Sie sich daran, dass das Ziel dieser Übung nicht ist, Gedanken loszuwerden oder zu verändern, sondern die Aufmerksamkeit auf das zu lenken, was auch immer in diesem Moment da ist, und die Aufmerksamkeit wieder und wieder auf die aktuellen Erfahrungen und Empfindungen zurückzubringen, egal, wo Ihr Geist hingewandert ist.

18. Für die letzten Momente dieser Übung breiten Sie die Aufmerksamkeit auf den ganzen Körper aus und spüren Sie die Empfindung des Herzschlages und die verbreitete Energie und Wärme im gesamten Körper. Hinauf durch die Schultern, den Nacken und den Kopf. Hinaus in die Arme und Hände. Hinunter durch den Bauchraum, die Beine, und die Füße. Erinnern wir uns nochmals daran, dass egal, was gerade in unserem Leben passiert, der

Herzschlag unser ständiger Begleiter ist, der unserem gesamten Körper zu jeder Zeit Energie und Wärme liefert.

19. Wenn Sie so weit sind, beginnen Sie den Körper wieder zu bewegen, genauso, wie es Ihnen jetzt im Moment guttut. Dann öffnen Sie allmählich wieder die Augen, und beenden die Übung.

20. [Glocke]

Mindfulness with Focus on the Body

1. [Glocke]

2. Nehmen Sie eine bequeme aufrechte Sitzhaltung ein, auf einem Stuhl mit einer geraden Lehne oder auf einem Hocker, sodass sich Ihre Wirbelsäule selbst aufrichten kann.

3. Erlauben Sie Ihrem Rücken, eine aufrechte und bequeme Haltung einzunehmen. Stellen Sie Ihre Füße flach auf den Boden, die Beine abgewinkelt nebeneinander. Wenn möglich, schließen Sie sanft Ihre Augen.

4. Bringen Sie Ihre Aufmerksamkeit zu den Empfindungen Ihres Körpers, so, wie Sie jetzt gerade hier sitzen. Richten Sie Ihre Aufmerksamkeit auf die Empfindungen von Berührung und Druck in Ihrem Körper, da wo er in Kontakt mit dem Boden oder Ihrer Unterlage ist. Spüren Sie den Kontakt Ihrer Füße mit dem Boden, den Kontakt mit etwas Festem, Stabilem, Beständigem, egal, was sonst gerade in Ihrem Körper oder Geist passiert. Untersuchen Sie diese Empfindungen für ein paar Momente.

5. Bringen Sie nun Ihre Aufmerksamkeit zu Ihrem Herzschlag und werden Sie sich dessen bewusst. Vielleicht spüren Sie das Schlagen des Herzens direkt…im Brustraum vielleicht. Wenn Sie Ihren Herzschlag im Moment nicht fühlen können, seien Sie sich einfach bewusst, dass Ihr Herz schlägt.

6. Der Herzschlag ist unser lebenslanger Begleiter, und versorgt unseren Körper zu jeder Zeit mit Energie und Wärme – egal, ob wir uns dessen bewusst sind, oder nicht. Stellen Sie sich vor, wie mit jedem Herzschlag – ähnlich einem Fluss – Energie und Wärme in Ihrem Körper verbreitet wird. Vom Herz ausgehend, hinauf durch die Schultern, den Nacken und den Kopf. Hinaus in die Arme und Hände. Und hinunter in den Bauchraum, die Beine, und die Füße.

7. Richten Sie nun Ihre Aufmerksamkeit auf die Empfindungen der Energie und Wärme in Ihrem Körper.

8. Wie fühlt sich der Fluss von Energie und Wärme - ausgehend von Ihrem Herzschlag - an? Vielleicht wie eine Welle durch bestimmte Bereiche des Körpers? Vielleicht wie eine

pochende Empfindung? Vielleicht flatternd oder kribbelnd? Warm? Es gibt hier kein richtig oder falsch. Entdecken Sie einfach neugierig, wie es sich für Sie gerade anfühlt.

9. Vielleicht können Sie den Herzschlag in Ihrem Körper gerade nicht fühlen, und falls das so ist, ist das vollkommen in Ordnung. Dann nehmen Sie einfach wahr „Ich kann den Herzschlag in meinem Körper gerade nicht fühlen".

10. Werden Sie sich der sich ständig verändernden Empfindungen des Herzschlages in Ihrem Körper bewusst, von Moment zu Moment.

11. Während Sie sich im Hintergrund immer noch bewusst sind, dass Ihr Herzschlag Energie und Wärme durch den Körper fließen lässt, ändern Sie Ihren primären Fokus und richten Sie ihn auf den Körper als Ganzes. Nehmen Sie die sich ändernden Empfindungen im Körper bewusst wahr. Sie spüren vielleicht das Pochen des Herzschlages durch den Körper, wie das Herz den gesamten Körper mit Energie und Wärme füllt, wie der Herzschlag alle Bereiche und Winkel des Körpers erreicht.

12. Der Geist wird immer wieder von den Empfindungen des Körpers abschweifen – das ist ganz normal und zu erwarten. Wenn Sie merken, dass Ihre Aufmerksamkeit von den Körperempfindungen abgeschweift ist, nehmen Sie einfach sanft wahr, wo Ihr Geist gerade war, bei welchen Gedanken, und dann richten Sie Ihre Aufmerksamkeit wieder freundlich zurück auf Ihren Körper als Ganzes.

13. Lassen Sie die Dinge möglichst einfach und widmen Sie sich sanft den tatsächlichen Empfindungen in Ihrem ganzen Körper, von einem Moment zum nächsten.

14. Während Sie sitzen, können manche Empfindungen unter Umständen besonders intensiv werden, z.B. Schmerzen im Rücken, in den Knien oder den Schultern, und vielleicht stellen Sie fest, wie diese Empfindungen die Aufmerksamkeit wiederholt auf sich ziehen – weg von Ihrem angestrebten Fokus auf den Körper als Ganzes. Vielleicht möchten Sie diese Zeiten nutzen, um damit zu experimentieren, sich absichtsvoll dafür zu entscheiden, die Haltung zu verändern, oder still zu bleiben und den Fokus Ihrer Aufmerksamkeit bewusst in diesen Bereich intensiver Empfindung zu bringen. Wenn Sie still bleiben, dann können Sie, so gut es Ihnen möglich ist, mit sanfter Aufmerksamkeit die genauen Muster von Empfindungen an dieser Stelle in allen Einzelheiten erforschen: Wie fühlt sich diese Empfindung genau an? Wo genau befindet sie sich? Verändert sie sich mit der Zeit oder variiert sie von einer Stelle des stark empfundenen Bereiches zur nächsten? Versuchen Sie, nicht so sehr darüber nachzudenken und einfach wahrzunehmen. Vielleicht möchten Sie auch den Herzschlag als Instrument verwenden, um in diesen Bereich tiefer hineinzufühlen, und zu spüren, wie Energie und Wärme in diesen Bereich transportiert werden.

15. Wann immer Sie merken, dass Sie aufgrund der Intensität der Körperempfindungen oder aus irgendeinem anderen Grund von der achtsamen Wahrnehmung des Augenblickes „fortgetragen" werden, verbinden Sie sich wieder mit dem Hier und Jetzt, indem Sie Ihre Aufmerksamkeit auf die Empfindung des Körpers als Ganzes richten. Wenn Sie sich auf diese Weise gesammelt haben, lassen Sie ihre Aufmerksamkeit sich erneut ausdehnen, sodass es die Empfindungen im ganzen Körper einschließt.

16. Bringen Sie nun für die letzten Momente der Übung Ihren Fokus zurück auf das Herz, welches Energie und Wärme durch den ganzen Körper strömen lässt. Erinnern wir uns nochmals daran, dass egal, was gerade in unserem Leben passiert, der Herzschlag unser ständiger Begleiter ist, der unserem gesamten Körper zu jeder Zeit Energie und Wärme liefert.

17. Wenn Sie so weit sind, beginnen Sie den Körper wieder zu bewegen, genauso, wie es Ihnen jetzt im Moment guttut. Dann öffnen Sie allmählich wieder die Augen, und beenden die Übung.

18. [Glocke]

Mindfulness with Focus on the Hearing

1. [Glocke]

2. Nehmen Sie eine bequeme aufrechte Sitzhaltung ein, auf einem Stuhl mit einer geraden Lehne oder auf einem Hocker, sodass sich Ihre Wirbelsäule selbst aufrichten kann.

3. Erlauben Sie Ihrem Rücken, eine aufrechte und bequeme Haltung einzunehmen. Stellen Sie Ihre Füße flach auf den Boden, die Beine abgewinkelt nebeneinander. Wenn möglich, schließen Sie sanft Ihre Augen.

4. Bringen Sie Ihre Aufmerksamkeit zu den Empfindungen Ihres Körpers, so, wie Sie jetzt gerade hier sitzen. Richten Sie Ihre Aufmerksamkeit auf die Empfindungen von Berührung und Druck in Ihrem Körper, da wo er in Kontakt mit dem Boden oder Ihrer Unterlage ist. Spüren Sie den Kontakt Ihrer Füße mit dem Boden, den Kontakt mit etwas Festem, Stabilem, Beständigem, egal, was sonst gerade in Ihrem Körper oder Geist passiert. Untersuchen Sie diese Empfindungen für ein paar Momente.

5. Bringen Sie nun Ihre Aufmerksamkeit zu Ihrem Herzschlag und werden Sie sich dessen bewusst. Vielleicht spüren Sie das Schlagen des Herzens direkt…im Brustraum vielleicht. Wenn Sie Ihren Herzschlag im Moment nicht fühlen können, seien Sie sich einfach bewusst, dass Ihr Herz schlägt.

6. Der Herzschlag ist unser lebenslanger Begleiter, und versorgt unseren Körper zu jeder Zeit mit Energie und Wärme – egal, ob wir uns dessen bewusst sind, oder nicht. Stellen Sie sich

vor, wie mit jedem Herzschlag – ähnlich einem Fluss – Energie und Wärme in Ihrem Körper verbreitet wird. Vom Herz ausgehend, hinauf durch die Schultern, den Nacken und den Kopf. Hinaus in die Arme und Hände. Und hinunter in den Bauchraum, die Beine, und die Füße.

7. Richten Sie nun Ihre Aufmerksamkeit auf die Empfindungen der Energie und Wärme in Ihrem Körper.

8. Wie fühlt sich der Fluss von Energie und Wärme - ausgehend von Ihrem Herzschlag - an? Vielleicht wie eine Welle durch bestimmte Bereiche des Körpers? Vielleicht wie eine pochende Empfindung? Vielleicht flatternd oder kribbelnd? Warm? Es gibt hier kein richtig oder falsch. Entdecken Sie einfach neugierig, wie es sich für Sie gerade anfühlt.

9. Vielleicht können Sie den Herzschlag in Ihrem Körper gerade nicht fühlen, und falls das so ist, ist das vollkommen in Ordnung. Dann nehmen Sie einfach wahr „Ich kann den Herzschlag in meinem Körper gerade nicht fühlen".

10. Werden Sie sich der sich ständig verändernden Empfindungen des Herzschlages in Ihrem Körper bewusst, von Moment zu Moment.

11. Früher oder später wird Ihr Geist vom Fokus auf den Herzschlag abschweifen und sich in Gedanken, Planen, Tagträumen – oder was auch immer – verlieren. Das ist vollkommen in Ordnung – unser Geist tut das nun mal. Sobald Sie merken, dass Ihre Aufmerksamkeit nicht mehr bei Ihrem Herzschlag ist, nehmen Sie dies einfach wahr und nehmen Sie zur Kenntnis, wo Ihr Geist gerade gewesen ist, ohne dies bewerten oder verändern zu wollen. Kommen Sie dann mit Ihrer Aufmerksamkeit wieder zu den aktuellen Empfindungen zurück.

12. Verlagern Sie nun Ihre Aufmerksamkeit von den Körperempfindungen weg zum Hören. Bringen Sie Ihre Aufmerksamkeit zu Ihren Ohren und lassen Sie Ihre Wahrnehmung sich öffnen und ausdehnen, sodass Sie empfänglich sind für Geräusche, während sie entstehen, wo auch immer sie entstehen.

13. Sie brauchen nicht nach Geräuschen zu suchen oder nur auf bestimmte Geräusche zu hören. Stattdessen öffnen Sie einfach Ihren Geist, so gut es Ihnen möglich ist, sodass er für die Wahrnehmung von Geräuschen aus allen Richtungen empfänglich ist, in dem Moment, in dem sie entstehen – Geräusche in der Nähe oder in der Ferne, Geräusche von vorne, hinten, von der Seite, von oben oder unten. Öffnen Sie sich für den ganzen weiten Raum zwischen den Geräuschen um Sie herum. Nehmen Sie sowohl offensichtliche als auch feine Geräusche bewusst wahr, und auch den Raum zwischen den Geräuschen sowie die Stille.

14. Betrachten Sie die Geräusche, so gut es Ihnen möglich ist, einfach als Empfindungen. Wenn Sie merken, dass Sie über die Geräusche nachdenken, nehmen Sie – so gut es Ihnen möglich

ist – wieder Kontakt auf mit dem direkten Wahrnehmen ihrer sinnlichen Eigenschaften – den Mustern der Tonlage, der Klangfarbe, der Lautstärke, der Dauer - anstatt mit ihrer Bedeutung oder ihrem Sinn.

15. Wann auch immer Sie bemerken, dass Ihre Aufmerksamkeit nicht mehr auf die Geräusche des Augenblickes fokussiert ist, würdigen Sie sanft, wohin Ihr Geist gewandert ist, und richten Sie dann ihre Aufmerksamkeit wieder auf die Geräusche, so wie sie von einem Moment zum nächsten entstehen und wieder vergehen.

16. Bringen Sie nun für die letzten Momente der Übung Ihren Fokus zurück auf das Herz, welches Energie und Wärme durch den ganzen Körper strömen lässt. Erinnern wir uns nochmals daran, dass egal, was gerade in unserem Leben passiert, der Herzschlag unser ständiger Begleiter ist, der unserem gesamten Körper zu jeder Zeit Energie und Wärme liefert.

17. Wenn Sie so weit sind, beginnen Sie den Körper wieder zu bewegen, genauso, wie es Ihnen jetzt im Moment guttut. Dann öffnen Sie allmählich wieder die Augen, und beenden die Übung.

18. [Glocke]

Body Scan

1. [Glocke]

2. Legen Sie sich ausgestreckt auf Ihrem Rücken hin, oder setzen Sie sich auf einen Stuhl mit einer Rückenlehne, an die Sie sich anlehnen können. Machen Sie es sich bequem, an einem Ort, an dem es warm ist und Sie ungestört sind. Wenn möglich, schließen Sie Ihre Augen. Spüren Sie den Kontakt Ihrer Füße mit dem Boden, den Kontakt mit etwas Festem, Stabilem, Beständigem, egal, was sonst in Ihrem Körper und Geist gerade passiert.

3. Nehmen Sie sich ein paar Augenblicke Zeit, um Ihren Herzschlag wahrzunehmen – vielleicht fühlen Sie ihn direkt, in der Brustregion, oder irgendwo anders im Körper, oder Sie stellen ihn sich einfach vor. Wenn Sie so weit sind, richten Sie Ihre Aufmerksamkeit auf die Empfindungen in Ihrem Körper, vor allem die Berührungen und Druck, dort, wo Ihr Körper in Kontakt mit der Unterlage ist. Stellen Sie sich vor, wie mit jedem Herzschlag – ähnlich einem Fluss – Energie und Wärme in Ihrem Körper verbreitet wird. Lassen Sie den Körper etwas tiefer in die Unterlage sinken und nehmen Sie sich ein paar Momente, um die Empfindungen Ihres Herzschlages wahrzunehmen.

4. In dieser Übung werden Sie Ihre Aufmerksamkeit der Reihe nach auf die verschiedenen Bereiche des Körpers richten und, so gut es Ihnen möglich ist, die Empfindungen in diesen Bereichen erforschen.

5. Nachdem Sie die Empfindungen im Brustraum wahrgenommen haben, lassen Sie den Fokus Ihrer Aufmerksamkeit das linke Bein hinunterwandern, bis hinein in den linken Fuß und zu den Zehen des linken Fußes. Richten Sie die Aufmerksamkeit der Reihe nach auf jeden einzelnen Zeh des linken Fußes und erforschen Sie mit sanftem Interesse die Qualität der Empfindungen dort; vielleicht spüren Sie den Kontakt zwischen Ihren Zehen, ein Kitzeln, Wärme oder auch gar keine bestimmte Empfindung.

6. Wenn Sie so weit sind, spüren Sie oder stellen Sie sich vor, wie, ausgehend von Ihrem Herzen, Energie und Wärme verströmt wird, hinunter bis in das linke Bein, den linken Fuß, und hinaus in die Zehen des linken Fußes. Fahren Sie damit – so gut es Ihnen möglich ist – ein paar Momente fort, spüren sie oder stellen Sie sich vor, wie Ihr Herzschlag Energie und Wärme in Ihre Zehen fließen lässt. Vielleicht spüren Sie den Fluss als einen Puls, ein Kribbeln, oder was immer Sie gerade wahrnehmen. Vielleicht ist es schwierig, ein Gefühl dafür zu entwickeln, üben Sie einfach, so gut es Ihnen möglich ist, auf spielerische Weise.

7. Wenn Sie nun bereit sind, lassen Sie den Fokus auf die Zehen los und richten Sie Ihre Aufmerksamkeit auf die Empfindungen Ihrer linken Fußsohle – eine sanfte, interessierte Wahrnehmung der Fußsohle, der Ferse, dem Fußrücken. Experimentieren Sie mit dem Gefühl des Flusses von Energie und Wärme in diesem Bereich, während Sie die Empfindungen des gesamten linken Fußes erforschen.

8. Dann lassen Sie Ihre Aufmerksamkeit vom Fluss der Energie und Wärme weiterwandern, in die linke Wade, das Schienbein, das Knie, und schließlich auf den oberen Bereich des linken Beins. Bringen Sie den gegenwärtigen Körperempfindungen in jedem Bereich, so gut es Ihnen möglich ist, die gleiche sorgfältige Aufmerksamkeit und das gleiche sanfte Interesse entgegen. In jedem Bereich spüren Sie oder stellen Sie sich vor, wie Energie und Wärme in diesen Bereich fließen, ausgehend vom Herzen.

9. Wenn Sie Anspannungen oder andere intensive Empfindungen in einem bestimmten Teil des Körpers wahrnehmen, können Sie sich vorstellen, wie der Fluss von Energie und Wärme in diesen Bereich strömt und diese somit lösen oder Sie diese loslassen.

10. Von Zeit zu Zeit wird der Geist unweigerlich von Ihrem Körper abschweifen. Das ist vollkommen normal. Unser Geist tut das nun mal. Sobald Sie es bemerken, nehmen Sie es zur Kenntnis, nehmen Sie einfach wahr, wohin Sie mit Ihrem Geist gewandert sind, und dann kehren Sie mit Ihrer Aufmerksamkeit wieder sanft zu dem Körperteil zurück, dem Sie sich gerade zuwenden wollten.

11. Wandern Sie nun mit Ihrer Aufmerksamkeit hinunter durch das rechte Bein bis hin zu den Zehen. Erforschen Sie in gleicher Weise die Empfindungen in Ihren Zehen und spüren Sie – so gut es Ihnen möglich ist – das Gefühl von Energie und Wärme in diesem Bereich.

12. Dehnen Sie Ihre Aufmerksamkeit nun auf den gesamten rechten Fuß aus. Und wandern Sie mit Ihrer Aufmerksamkeit weiter in die rechte Wade, das Schienbein, das Knie, und schließlich in den oberen Bereich des rechten Beins. Erforschen Sie Ihre Empfindungen mit sorgfältiger Aufmerksamkeit und sanftem Interesse.

13. Bringen Sie Ihre Aufmerksamkeit nun zu Ihrem Becken. Spüren Sie die Empfindungen, ohne etwas bewerten oder verändern zu wollen.

14. Richten Sie Ihre Aufmerksamkeit nun sanft auf den unteren Rücken und den Bauchraum. Nehmen Sie wahr, welche Empfindungen in diesem Moment da sind.

15. Wandern Sie nun mit Ihrer Aufmerksamkeit in den oberen Rücken und den Brustraum. Spüren Sie das Gefühl von Energie und Wärme in diesem Bereich, ausgehend von Ihrem Herzschlag.

16. Wann immer Sie bemerken, dass Ihr Geist abschweift, nehmen Sie es sanft zur Kenntnis, und dann kehren Sie mit Ihrer Aufmerksamkeit wieder zu dem Körperteil zurück, dem Sie sich gerade zuwenden wollten.

17. Lassen Sie Ihre Aufmerksamkeit nun durch Ihre Arme in Ihre Hände und Finger wandern. Nehmen Sie die Empfindungen in jedem einzelnen Ihrer Finger wahr. Dann richten Sie Ihre Aufmerksamkeit auf die Handflächen, die Handrücken, und schließlich die gesamte Hand.

18. Wandern Sie mit Ihrer Aufmerksamkeit nun weiter über die Handgelenke, die Unterarme, die Ellenbogen, die Oberarme, bis hin zu den Schultern. Nehmen Sie wahr, wie sich diese Bereiche des Körpers im Moment anfühlen.

19. Wandern Sie mit Ihrer Aufmerksamkeit nun weiter zum Hals und Nacken, und nehmen Sie sanft Ihre Empfindungen wahr.

20. Schließlich bringen Sie Ihre Aufmerksamkeit zu Ihrem Kopf und Gesicht. Erforschen Sie Ihre Empfindungen in Ihrem Kiefer, dem Kinn, den Lippen, den Wangen, der Nase, den Augen, den Ohren, der Stirn. Spüren Sie – so gut es Ihnen möglich ist – das Gefühl von Energie und Wärme in diesen Bereichen.

21. Seien Sie sich für die letzten Momente dieser Übung Ihres Körpers als Ganzes bewusst, und spüren Sie, wie der Herzschlag Energie und Wärme durch Ihren gesamten Körper fließen lässt.

22. Wenn Sie so weit sind, beginnen Sie den Körper wieder zu bewegen, genauso, wie es Ihnen jetzt im Moment guttut. Dann öffnen Sie allmählich wieder die Augen, und beenden die Übung.

23. [Glocke]

Appendix B. Informed Consent for Participants (original German version)

SPIROMIND-STUDY

Eine Pilotstudie zur Untersuchung der Machbarkeit und Effektivität einer digitalen Achtsamkeitsintervention für COPD-Patient*innen

Sehr geehrte Patientin, sehr geehrter Patient!

Wir laden Sie ein an der oben genannten klinischen Interventionsstudie teilzunehmen. Die Aufklärung darüber erfolgt in einem ausführlichen Gespräch.

Ihre Teilnahme an dieser Studie erfolgt freiwillig. Sie können jederzeit ohne Angabe von Gründen aus der Studie ausscheiden. Die Ablehnung der Teilnahme oder ein vorzeitiges Ausscheiden aus dieser Studie hat keine nachteiligen Folgen für Ihre medizinische Betreuung.

Klinische Interventionsstudien sind notwendig, um verlässliche neue medizinische Forschungsergebnisse zu gewinnen. Unverzichtbare Voraussetzung für die Durchführung einer klinischen Interventionsstudie ist jedoch, dass Sie Ihr Einverständnis zur Teilnahme an dieser Studie schriftlich erklären. Bitte lesen Sie den folgenden Text als Ergänzung zum Informationsgespräch mit Ihrem Arzt sorgfältig durch und zögern Sie nicht Fragen zu stellen.

Bitte unterschreiben Sie die Einwilligungserklärung nur

- wenn Sie Art und Ablauf der klinischen Interventionsstudie vollständig verstanden haben,

- wenn Sie bereit sind, der Teilnahme zuzustimmen und

- wenn Sie sich über Ihre Rechte als Teilnehmer an dieser klinischen Interventionsstudie im Klaren sind.

Zu dieser klinischen Interventionsstudie, sowie zur Patient*inneninformation und Einwilligungserklärung wurde von der zuständigen Ethikkommission eine befürwortende Stellungnahme abgegeben.

1.   Was ist der Zweck dieser Studie?

Der Zweck dieser klinischen Interventionsstudie ist die Untersuchung der Fragestellung, ob Achtsamkeitsübungen, die über eine App durchgeführt werden können, für COPD-Patient*innen machbar und nützlich sind. Zudem wird untersucht, ob die Durchführung von Achtsamkeitsübungen positive Veränderungen für COPD-Patient*innen in Bezug auf verschiedene Belastungen bringt (wie z.B. Stress, psychische Belastung, Atemnot,…).

2.   Wie läuft die Studie ab?

Diese Studie wird vom **Karl-Landsteiner Institut für Lungenforschung und Pneumologische Onkologie (Standorte: Klinik Floridsdorf, Klinik Ottakring)** durchgeführt. Es werden

insgesamt **30 Personen** daran teilnehmen. Ihre Teilnahme an dieser klinischen Studie wird **6 Monate** dauern.

Im Rahmen dieser klinischen Studie werden Patient*innen, die Achtsamkeitsübungen durchführen, mit einer so genannten Wartelistengruppe verglichen. Die Wartelistengruppe führt die Übungen erst nach **6 Monaten Wartezeit** aus. In den ersten 6 Monaten erhält die Wartelistengruppe keine zusätzlichen Behandlungen. Welcher Gruppe Sie zugeteilt werden (**Wartelistengruppe**: Behandlung wie bisher für 6 Monate, danach Achtsamkeitsübungen ODER **Achtsamkeitsgruppe**: Behandlung wie bisher + Achtsamkeitsübungen für 6 Monate) ist zufallsbedingt. Die Wahrscheinlichkeit, in die Wartelistengruppe zu kommen, beträgt 50%.

Wichtig ist, dass Sie sowohl in der Achtsamkeitsgruppe als auch in der Wartelistengruppe Ihre medizinische Standardbehandlung weiterhin erhalten. **Die Teilnahme an dieser Studie hat keine Auswirkungen auf Ihre medizinische Behandlung.** Eine Reihe von Untersuchungen und Eingriffen werden im Zuge Ihrer Behandlung durchgeführt, gleichgültig, ob Sie nun an dieser klinischen Studie teilnehmen oder nicht. Diese werden von Ihrem Prüfarzt im Rahmen des üblichen ärztlichen Aufklärungsgespräches mit Ihnen besprochen.

Folgende Maßnahmen werden ausschließlich aus Studiengründen durchgeführt:

Wartelistengruppe UND Achtsamkeitsgruppe:

Vor **Beginn der Studie** werden einmalig Daten zu Ihrer Person (z.B. Alter, Wohnsituation,…) und medizinische Daten (z.B. andere Erkrankungen, Häufigkeit von Atemkrisen…) mittels Fragebögen von Ihnen erfragt. Zudem werden psychologische und medizinische Daten (konkret: psychische Belastung, Stress, gesundheitsbezogene Lebensqualität, gesundheitsbezogene Beeinträchtigungen, Erschöpfung, Achtsamkeit, Selbst-Mitgefühl, Katastrophisieren von Atemnot) mittels Fragebögen erhoben. Es wird auch eine Haarprobe entnommen (Strähne vom Hinterkopf) und es werden psychophysiologische Messungen mittels Brustgurt (Erfassung der Herzrate und Herzratenvariabilität) und Armband (Erfassung der Elektrodermalen Aktivität) durchgeführt.

Zudem werden die oben genannten Erhebungen (mit Ausnahme der medizinischen Daten und der Daten zu Ihrer Person) nach **4 und 8 Wochen** sowie nach **4 und 6 Monaten** wiederholt. Dazu werden Sie von wissenschaftlichen Mitarbeiter*innen bei Ihnen zu Hause besucht, welche Ihnen die entsprechenden Materialien (Fragebögen, Brustgurt, Armband) vorbeibringen und die Haarprobe entnehmen.

Außerdem werden Sie im Laufe des **Studienzeitraumes (8 Wochen) wöchentlich** von wissenschaftlichen Mitarbeiter*innen **angerufen**, um zu eventuelle Probleme besprechen zu können.

Achtsamkeitsgruppe:

Sind Sie in der Achtsamkeitsgruppe, wird Ihnen nach Ihrer Einwilligung und der Erhebungen vor Studienbeginn die Intervention genauestens erklärt. Ein*e wissenschaftliche*r Mitarbeiter*in wird mit Ihnen gemeinsam die **App** installieren, mit welcher Sie die Achtsamkeitsübungen durchführen können. Zudem wird der/die Mitarbeiter*in mit Ihnen eine Übung ausprobieren. Von nun an werden Sie gebeten für die folgenden **8 Wochen täglich mindestens eine von vier Achtsamkeitsübung** durchzuführen, welche Sie frei wählen können. Die Übungen dauern zwischen **10 und 15 Minuten**.

Direkt vor und nach der Durchführung der Übung werden Ihnen **7 kurze Fragen** gestellt (zu den Themen: Atemnot, Stress, Entspannung, Stimmung). Zudem werden Sie gebeten, vor und nach der Achtsamkeitsübung Ihre **Sauerstoffsättigung** im Blut zu messen und einzutragen (mittels Finger-Pulsoximeter).

Im Rahmen dieser Studie werden Sie Achtsamkeitsübungen durchführen, die Ihnen über eine App zur Verfügung gestellt werden. Die Übungen sind von einer Person angeleitet und sind in Form von **Audiodateien** verfügbar. Sie können sich also über die App die Übungen anhören und sie währenddessen durchführen. Die App enthält außer der Beantwortung der genannten Fragen und den Achtsamkeitsübungen als Audiofiles keine weiteren Funktionen.

Für die Durchführung der Studie erhalten Sie für den Studienzeitraum als Leihgabe (falls Sie dies nicht selbst besitzen) ein Smartphone und ein Finger-Pulsoximeter. Zudem erhalten Sie ein Manual, das Sie bei der Durchführung unterstützen soll.

Nach den 8 Wochen erhalten Sie alle 4 Übungen als Audiodateien und können diese nach Belieben weiterhin durchführen.

Wartelistengruppe:

Sind Sie in der Wartelistengruppe, findet die Einführung in die **Achtsamkeitsintervention nach 6 Monaten** statt. Dazu wird ein*e wissenschaftliche*r Mitarbeiter*in Sie zu Hause besuchen, Ihnen die Intervention genauestens erklären und eine Übung mit Ihnen ausprobieren. Sie erhalten alle 4 Übungen als Audiodateien und können diese nun nach Belieben durchführen (über das Smartphone, Laptop, ect.). Zudem erhalten Sie ein Manual, das Sie bei der Durchführung unterstützen soll.

3.   Was sind Achtsamkeitsübungen und Achtsamkeit?

Achtsamkeitsübungen können als Form der Meditation oder Entspannungsübungen gesehen werden. Achtsam sein heißt Momente bewusst zu erleben und die Aufmerksamkeit auf das Hier und Jetzt zu lenken. Dabei wird bewusst auf Erfahrungen, Gedanken und Gefühle, die in diesem Moment wahrgenommen werden, geachtet, ohne diese zu bewerten. Die Fähigkeit, achtsam zu

sein, hat jede*r bereits in sich. Achtsamkeit kann wie ein Muskel verstanden werden. Mit Achtsamkeitsübungen kann dieser Muskel trainiert werden.

4.   Worin liegt der Nutzen einer Teilnahme an der klinischen Interventionsstudie?

Mit der regelmäßigen Durchführung von Achtsamkeitsübungen über einen längeren Zeitraum ist es möglich, dass sich psychische und/oder körperliche Beschwerden in Bezug auf Ihre Krankheit verbessern. Zudem wird Ihnen eine Möglichkeit geboten, mit welcher Sie auf einfachem und schnellem Weg zu Hause zu mehr Entspannung finden können. Möglicherweise können Sie mittels Achtsamkeitsübungen lernen, mit Atemkrisen und den Herausforderungen einer chronischen Erkrankung wie COPD besser umgehen zu können.

Es ist jedoch auch möglich, dass Sie durch Ihre Teilnahme an dieser klinischen Studie keinen direkten Nutzen für Ihre Gesundheit ziehen können.

5.   Gibt es Risiken, Beschwerden und Begleiterscheinungen?

Für die Durchführung von Achtsamkeitsübungen sind keine Risiken, Beschwerden oder Begleiterscheinungen bekannt.

6.   Zusätzliche Einnahme von Arzneimitteln?

Die Teilnahme an dieser Studie hat **keine** Auswirkungen auf Ihre medizinische Behandlung. Daher werden Sie weiterhin alle Arzneimittel und medizinische Behandlungen einnehmen bzw. durchführen können.

7.   Hat die Teilnahme an der klinischen Studie sonstige Auswirkungen auf die Lebensführung und welche Verpflichtungen ergeben sich daraus?

Durch die Teilnahme an der Studie ergeben sich **keine** sonstigen Auswirkungen auf die Lebensführung oder etwaige Verpflichtungen.

8.   Entstehen für die Teilnehmer Kosten?

Durch Ihre Teilnahme an dieser klinischen Studie entstehen für Sie **keine** zusätzlichen Kosten.

9.   Wann wird die klinische Studie vorzeitig beendet?

Sie können jederzeit auch ohne Angabe von Gründen, Ihre Teilnahmebereitschaft widerrufen und aus der klinischen Studie ausscheiden ohne dass Ihnen dadurch irgendwelche Nachteile für Ihre weitere medizinische Betreuung entstehen.

10.   In welcher Weise werden die im Rahmen dieser klinischen Interventionsstudie gesammelten Daten verwendet?

Bei den Daten, die über Sie im Rahmen dieser klinischen Studie erhoben und verarbeitet werden, ist grundsätzlich zu unterscheiden zwischen

1) jenen personenbezogenen Daten, anhand derer Sie direkt identifizierbar sind (z.B. Name, Geburtsdatum, Adresse, Bildaufnahmen...),

2) pseudonymisierten (verschlüsselten) personenbezogenen Daten, bei denen alle Informationen, die direkte Rückschlüsse auf Ihre Identität zulassen, durch einen Code (z. B. eine Zahl) ersetzt bzw. (z.B. im Fall von Bildaufnahmen) unkenntlich gemacht werden. Dies bewirkt, dass die Daten ohne Hinzuziehung zusätzlicher Informationen und ohne unverhältnismäßig großen Aufwand nicht mehr Ihrer Person zugeordnet werden können und

3) anonymisierten Daten, bei denen eine Rückführung auf Ihre Person nicht mehr möglich ist.

Der Code zur Verschlüsselung wird von den verschlüsselten Datensätzen streng getrennt und nur an Ihrem Prüfzentrum aufbewahrt.

Zugang zu Ihren nicht verschlüsselten Daten haben der Prüfarzt und andere Mitarbeiter des Studienzentrums, die an der klinischen Studie oder Ihrer medizinischen Versorgung mitwirken. Die Daten sind gegen unbefugten Zugriff geschützt. Zusätzlich können autorisierte und zur Verschwiegenheit verpflichtete Beauftragte des Karl-Landsteiner Institut für Lungenforschung und Pneumologische Onkologie (Prim.Priv.-Doz.Dr.Georg-Christian Funk) sowie Beauftragte von in- und/oder ausländischen Gesundheitsbehörden und jeweils zuständige Ethikkommissionen in die nicht verschlüsselten Daten Einsicht nehmen, soweit dies für die Überprüfung der ordnungsgemäßen Durchführung der klinischen Studie notwendig bzw. vorgeschrieben ist.

Eine Weitergabe der Daten, insbesondere an den Sponsor und seine Vertragspartner, erfolgt nur in verschlüsselter oder anonymisierter Form. Auch für etwaige Publikationen werden nur die verschlüsselten oder anonymisierten Daten verwendet.

Sämtliche Personen, die Zugang zu Ihren verschlüsselten und nicht verschlüsselten Daten erhalten, unterliegen im Umgang mit den Daten der Datenschutz-Grundverordnung (DSGVO) sowie den österreichischen Anpassungsvorschriften in der jeweils gültigen Fassung.

Im Rahmen dieser klinischen Studie ist keine Weitergabe von Daten in Länder außerhalb der EU vorgesehen.

Sie können Ihre Einwilligung zur Erhebung und Verarbeitung Ihrer Daten jederzeit widerrufen. Nach Ihrem Widerruf werden keine weiteren Daten mehr über Sie erhoben. Die bis zum Widerruf erhobenen Daten können allerdings weiter im Rahmen dieser klinischen Studie verwendet werden.

Aufgrund der gesetzlichen Vorgaben haben Sie außerdem, sofern dies nicht die Durchführung der klinischen Studie voraussichtlich unmöglich macht oder ernsthaft beeinträchtigt, das Recht auf Einsicht in die Ihre Person betreffenden Daten und die Möglichkeit der Berichtigung, falls Sie Fehler feststellen.

Sie haben auch das Recht, bei der österreichischen Datenschutzbehörde eine Beschwerde über den Umgang mit Ihren Daten einzubringen (www.dsb.gv.at).

Die voraussichtliche Dauer der klinischen Studie beträgt 1 Jahr. Die Dauer der Speicherung Ihrer Daten über das Ende der klinischen Studie hinaus ist durch Rechtsvorschriften geregelt.

11.   Aufbewahrung von Proben und Daten

Nach dem Ende der Studie möchten wir die übrigen Proben und Daten gerne für weitere Forschungsprojekte auf dem Gebiet der klinischen Psychologie und Medizin verwenden. Für jedes dieser Forschungsprojekte wird zuvor die Zustimmung der Ethikkommission eingeholt. Die Studienbezogenen Daten werden in der Klinik Ottakring für 15 Jahre archiviert. Die Haarproben werden in mehreren Schritten analysiert, wobei in der Regel ein Großteil der jeweiligen Probe verbraucht wird. Etwaige Reste können für mögliche zukünftige Analysen für mehrere Jahre aufbewahrt werden. Sie können jederzeit verlangen, dass Ihre Proben und Daten vernichtet werden. Verantwortlich für die Lagerung und Vernichtung der Proben ist Prim.Priv.-Doz.Dr. Georg-Christian Funk.

12.   Möglichkeit zur Diskussion weiterer Fragen

Falls Sie Fragen zum Umgang mit Ihren Daten in dieser klinischen Studie haben, wenden Sie sich zunächst an Ihren Prüfarzt oder dessen wissenschaftliche Mitarbeiter*innen. Diese können Ihr Anliegen ggf. an die Personen, die beim Sponsor oder am Studienzentrum für den Datenschutz verantwortlich sind, weiterleiten.

Datenschutzbeauftragte/r des Prüfzentrums:

Prüfarzt: Prim.Priv.-Doz.Dr. Georg-Christian Funk

Karl-Landsteiner Institut für Lungenforschung und Pneumologische Onkologie

███████████

████████████████████

Datenschutzbeauftragte der 2. Medizinischen Abteilung mit Pneumologie mit Ambulanz der Klinik Ottakring:

OÄ Dr. Karin Schmid-Scherzer

████████████

██████████████████████

Für weitere Fragen im Zusammenhang mit dieser Studie stehen Ihnen Ihre Studienärzte und wissenschaftliche Mitarbeiter*innen gern zur Verfügung.

Name der Kontaktperson: Hannah Tschenett

Erreichbar unter: ██████████████████████████████

Für den Bedarfsfall finden Sie nachfolgend die Kontaktdaten der für Wien zuständigen Patient*Innenanwaltschaft:

Wiener Pflege-, Patientinnen- und Patientenanwaltschaft

Ramperstorffergasse 67

1050 Wien

Tel.: 01/5871204

Fax: 01/5863699

E-Mail: post@wpa.wien.gv.at

13.   Kurzzusammenfassung

- **Um welche Krankheit geht es in der Studie?**

  In dieser Studie geht es um Patient*innen mit der chronisch obstruktiven Lungenerkrankung.

- **Was sind Achtsamkeitsübungen?**

  Achtsamkeitsübungen sind eine Art der Meditation, bei welcher man sich bewusst auf den aktuellen Moment und das Hier und Jetzt konzentriert.

- **Bei welchen Krankheiten sind Achtsamkeitsübungen bereits eingesetzt worden?**

  Achtsamkeitsübungen haben bereits positive Wirkungen bei anderen chronischen Erkrankungen (z.B. chronischer Schmerz) gezeigt, aber auch bei verschiedenen psychischen Erkrankungen wie Depression, stress-bezogenen Symptomen oder auch in der Allgemeinbevölkerung.

- **Wie viele Personen werden an der Studie teilnehmen?**

  30 Patient*innen

- **Warum bin ich geeignet für eine Teilnahme?**

  Alle CODP-Patient*innen, die Interesse an einer Studienteilnahme haben und die Ein- und Ausschlusskriterien erfüllen, sind für die Teilnahme geeignet.

- **Was erwartet mich, wenn ich teilnehme, und was ändert sich im Vergleich zu meiner vorgesehenen "normalen" Behandlung?**

Wenn Sie teilnehmen, werden Sie in den nächsten **6 Monaten** 5x gebeten Fragebögen auszufüllen, Ihnen wird 4x eine Haarsträhne entnommen und es wird 5x eine physiologische Messung (Brustgurt, Armband) durchgeführt.

In der **Achtsamkeitsgruppe** werden Sie für 8 Wochen mindestens einmal täglich eine 10-15-minütige Achtsamkeitsübung mittels einer App durchführen, die Sie selbst wählen können.

In der **Wartelistengruppe** erhalten Sie die Achtsamkeitsintervention nach 6 Monaten.

Sie müssen für die Studie zu keinen Visiten ins Krankenhaus gehen. Alle Erhebungen finden bei Ihnen zu Hause statt. Ihre „normale" medizinische Behandlung verändert sich durch die Studienteilnahme nicht.

- **Wie lange dauert die Studie für mich?**

  Die Studie dauert 8 Wochen. Erhebungen finden an 5 Zeitpunkten innerhalb von 6 Monaten bei Ihnen zu Hause statt (vor Studienbeginn, 4 Wochen, 8 Wochen, 4 Monate, 6 Monate).

- **Welche Vorteile habe ich möglicherweise von einer Teilnahme?**

  Es ist möglich, dass sich psychische und/oder körperliche Beschwerden in Bezug auf Ihre Krankheit verbessern.

- **Was sind die Risiken und Unannehmlichkeiten, die damit verbunden sind?**

  Für die Durchführung von Achtsamkeitsübungen sind keine Risiken bekannt.

Alle persönlichen Daten werden streng vertraulich behandelt. Die Teilnahme an dieser klinischen Interventionsstudie erfolgt freiwillig und kann jederzeit widerrufen werden. Bitte lesen Sie die gesamte Patienteninformation sorgfältig durch!

14.   Einverständniserklärung

Name der Patientin / des Patienten in Druckbuchstaben:

…………………...…………………………………………………….…………

Geb.Datum: 		Code:..

Ich erkläre mich bereit, an der klinischen Interventionsstudie *„SPIROMIND-STUDY - Eine Pilotstudie zur Untersuchung der Machbarkeit und Effektivität einer digitalen Achtsamkeitsintervention für COPD-Patient*innen"* teilzunehmen.

Ich bin von Projektmitarbeiter*innen ausführlich und verständlich über die Studie, Achtsamkeitsübungen, mögliche Belastungen und Risiken, sowie über Wesen, Bedeutung und Tragweite der klinischen Studie, sowie die sich für mich daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text dieser Patientenaufklärung und Einwilligungserklärung, die insgesamt 9 Seiten umfasst, gelesen. Aufgetretene Fragen wurden mir

vom Prüfarzt verständlich und genügend beantwortet. Ich hatte ausreichend Zeit, mich zu entscheiden. Ich habe zurzeit keine weiteren Fragen mehr.

Ich werde den ärztlichen Anordnungen, die für die Durchführung der klinischen Prüfung erforderlich sind, Folge leisten, behalte mir jedoch das Recht vor, meine freiwillige Mitwirkung jederzeit zu beenden, ohne dass mir daraus Nachteile für meine weitere medizinische Betreuung entstehen.

Beim Umgang der im Rahmen der SPROMIND-Studie erhobenen Daten werden die Bestimmungen des Datenschutzgesetzes 2000 beachtet. Alle Personen, die auf Grund ihrer beruflichen Tätigkeit Zugang zu diesen Daten haben, sind - unbeschadet anderer gesetzlicher Verpflichtungen - gemäß § 15 DSG 2000 an das Datengeheimnis gebunden.

Nach dem DSG 2000 sind „personenbezogene Daten" Angaben über Studienteilnehmer*innen, durch die deren Identität bestimmt oder bestimmbar ist. Unter „indirekt personenbezogenen Daten" versteht das DSG 2000 Daten, deren Personenbezug derart ist, dass die Identität der Studienteilnehmer/-innen mit rechtlich zulässigen Mitteln nicht ermittelt werden kann.

Ich stimme zu, dass meine im Rahmen und zum Zweck dieser Studie ermittelten personenbezogenen Daten (Name, Anschrift, Alter, Daten zur Person und medizinische Daten) verarbeitet werden und in indirekt personenbezogener (pseudonymisierter bzw. verschlüsselter) Form an alle Forschungsmitarbeiter*innen zum Zweck der Datenauswertung übermittelt werden.

Mir ist bekannt, dass zur Überprüfung der Richtigkeit der Datenaufzeichnung Beauftragte der zuständigen Behörden, der Ethikkommissionen und des Auftragsgebers der Prüfung beim Prüfarzt Einblick in die Daten nehmen dürfen.

Mir ist auch bekannt, dass ich meine Zustimmung zur Datenverwendung ohne Angabe von Gründen und ohne nachteilige Folgen für meine medizinische Behandlung jederzeit widerrufen kann, wobei ein Widerruf grundsätzlich die Unzulässigkeit der weiteren Verwendung der Daten bewirkt, sofern nicht andere gesetzliche Vorschriften oder überwiegende berechtigte Interessen die Datenverwendung weiterhin zulässig machen.

Darüber hinaus bin ich für den Fall, dass ich aus der Studie ausscheide oder die Studie beendet wird, damit einverstanden, dass etwaige Restproben für weitere Forschungsprojekte auf dem Gebiet der klinischen Psychologie und Medizin verwendet werden. Für jedes dieser Forschungsprojekte wird zuvor die Zustimmung der Ethikkommission eingeholt. Die studienbezogenen Daten werden in indirekt personenbezogener Form in der Klink Ottakring für 15 Jahre archiviert. Etwaige Reste der Haarproben können für mögliche zukünftige Analysen für mehrere Jahre aufbewahrt werden.

Mir ist bekannt, dass ich jederzeit verlangen kann, dass meine Proben vernichtet werden. Verantwortlich für die Lagerung und die Vernichtung der Proben ist Prim.Priv.-Doz.Dr. Georg-Christian Funk.

Eine Kopie dieser Patienteninformation und Einwilligungserklärung habe ich erhalten. Das Original verbleibt beim Prüfarzt.

....

(Datum und Unterschrift des Patienten / der Patientin)

....

(Datum, Name und Unterschrift des verantwortlichen Arztes)

(Der/Die Patient*in erhält eine unterschriebene Kopie der Patient*inneninformation und Einwilligungserklärung, das Original verbleibt im Studienordner des Studienarztes.)

Appendix C. Patients' Interview (original German version)

MEDIZINISCHE DATEN – PATIENT*INNENBEFRAGUNG

Datum der Patient*innenbefragung: _____

Alter (in Jahren): _____

Geschlecht:
    o männlich   o weiblich   o anderes

Gewicht (in kg):_____   **Größe** (in m): _____   **BMI**: _____

Dauer der Erkrankung (in Jahren): _____

Stadium der Erkrankung:
    o I   o III
    o II   o IV

Lag oder liegt bei Ihnen eine <u>komorbide körperliche Erkrankung</u> neben Ihrer Lungenerkrankung vor?
    o nein   o ja, früher   o ja, derzeit (akut und/oder chronisch)

Wenn ja, um welche Erkrankung/en handelt/e es sich dabei? (Mehrfachantworten möglich)
    o Diabetes   o Koronare Herzerkrankung
    o Periphere Gefäßerkrankungen   o Kardiale Arrhythmien
    o Lungenkrebs   o Osteoporose
    o Bronchiektasie   o Refluxösophagitis
    o Obstruktive Schlafapnoe
    o Sonstiges:
    _____

Zusätzliche Informationen:
_____
_____
_____
_____

Lag oder liegt bei Ihnen eine diagnostizierte psychische Störung vor?
    o nein   o ja, früher   o ja, derzeit (akut und/oder chronisch)

Wenn ja, um welche Form/en der <u>psychischen Störung</u> handelt/e es sich dabei? (Mehrfachantworten möglich)
    o Depression   o Posttraumatische Belastungsstörung
    o Angststörung   o Zwangsstörung

o Störung der Gedächtnisfunktion   o Substanzmissbrauch/-abhängigkeit

o Essstörung   o Persönlichkeitsstörung

o Sonstiges:

_____

Zusätzliche Informationen:

_____

_____

_____

_____

Gesamtanzahl der eingenommenen Medikamente:

_____

Auflistung aller Medikamente inklusive Dosierung und evtl. zusätzliche Informationen
(falls den Patient*innen bekannt):

Präparat (Firma)	Dosierung (Darreichungsform)	Zusätzliche Informationen

Haben Sie bereits eine der folgenden Therapien/Behandlungen für Ihre Lungenerkrankung erhalten? (wenn ja, bitte entsprechende ankreuzen)

JA	Therapie/Behandlung	Anzahl, wie oft Sie diese Therapie/Behandlung bereits erhalten haben
o	Ventilimplantation	
o	Dampfablation	
o	Coilimplantation	
o	Atemphysiotherapie	
o	Andere:	
o	Andere:	
o	Andere:	

Erhalten Sie eine Sauerstofftherapie?
     o   nein   o   ja

Haben Sie bereits an einer pulmonalen Rehabilitation teilgenommen?
     o   nein   o   ja

Wenn ja, wie oft?
_____

Wenn ja, wo?
_____

EXAZERBATIONEN:
„Hatten Sie innerhalb der letzten 12 Monate eine vorübergehende Verschlechterung Ihrer Atmung, die zu einem Arztkontakt oder einem stationären Aufenthalt geführt hat?"

Hatten Sie schon einmal eine CODP-Exazerbation (=Atemkrise)?
     o   nein   o   ja

Letzter stationärer Aufenthalt aufgrund einer Exazerbation (in Monaten):
_____

Häufigkeit von Exazerbationen (unabhängig davon, ob diese stationär oder ambulant behandelt wurden): _____

Haben Sie geraucht oder rauchen Sie derzeit?
     o   nein   o   ja, früher   o   ja, derzeit

Wenn Sie früher geraucht haben, seit wie vielen Jahren rauchen Sie nicht mehr?
_____

Wenn ja, wie viele Jahre haben Sie in Summe geraucht? _____

Wenn ja, durchschnittliche Anzahl der gerauchten Zigaretten pro Tag:
_____

DEMOGRAPHISCHE DATEN

Muttersprache:
- o Deutsch
- o andere: _____

Familienstand:
- o keine Partnerschaft
- o verheiratet
- o Lebensgemeinschaft/Partnerschaft
- o geschieden
- o verwitwet

Haben Sie Kinder?
- o nein
- o ja: _____ (Anzahl)

Wohnsituation:
- o alleine
- o mit Partner*in
- o betreute Institution
- o Wohngemeinschaft

Wie viele Personen leben ständig in Ihrem Haushalt, Sie eingeschlossen?
 Insgesamt _____ Personen

Werden Sie zu Hause von einer anderen Person betreut?
- o nein
- o ja

Wenn ja, von wem?
- o Familienmitglied
- o mobile Krankenschwester
- o Andere:
  _____
- o Heimhilfe
- o Tages-Pflegehilfe

Zusätzliche Informationen zur Betreuungssituation:
_____
_____
_____
_____

Höchste abgeschlossene Ausbildung:
- o Grund-/Volksschule
- o Hauptschule
- o Handels- oder Fachschule
- o Lehre
- o Lehre mit Meisterprüfung
- o Matura/Abitur
- o Diplomlehrgang
- o Bachelor
- o Magister/Master
- o Dr./Ph.D. oder höher

Berufsgruppe (Mehrfachantworten möglich):
- o in Ausbildung
- o Arbeiter*in/Facharbeiter*in
- o Angestellte*r/Beamte*r
- o in Karenz/Mutterschutz/Elternzeit
- o Hausfrau/Hausmann
- o in Pension/Rente

o   selbstständig/ freiberuflich tätig   o   nicht erwerbstätig

Wenn Sie berufstätig sind oder waren, in welchem Bereich arbeiten/arbeiteten Sie?
_____

_____

Haushaltseinkommen (monatlich, netto):
- o < 1250€
- o 1250€ - 1750€
- o 1750€ - 2250€
- o 2250€ - 3000€

- o 3000€ - 4000€
- o 4000€ - 5000€
- o >5000€

Hatten Sie bereits Kontakte zu Psycholog*innen, Psychotherapeut*innen oder Psychiater*innen?
- o nein   o ja

Wenn ja, welche bzw. in welchen Situationen?
_____

_____

Haben Sie bereits Erfahrungen mit verschiedenen Entspannungsübungen (z.B. Progressive Muskelrelaxation, Autogenes Training), Meditation, Yoga oder Achtsamkeit gemacht?
- o nein   o ja

Wenn ja, welche?
_____