

Understanding Patients and Mental Health during the COVID-19 Pandemic thru a Psychological Lens: Needs, Resources and Implications

by

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a Thesis submitted in partial fulfillment of the requirements for the degree of

Doctor of Philosophy in Psychology

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Acknowledgments

First of all, I would like to express my sincerest appreciation to and would like to thank my PhD supervisor, Prof. Dr. Sonia Lippke, for the continuous support, guidance, understanding, and encouragement that allowed me to learn and develop into the researcher that I am today. I would also like to thank Prof. Dr. Adalbert F. X. Wilhelm for his support throughout the past years. Finally, thank you to Dr. med. Alina Dahmen for the encouraging discussions and her constant support.

I would also like to thank the Innovation Fund of The Federal Joint Committee (G-BA) and the Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit who funded the TeamBaby project and the ASAP project and, thus, a large part of this research. Further, I would like to express my gratitude to the Dr. Becker Klinikgruppe, specifically to Dr. Petra Becker and Carina Kolb, who supported further parts of this dissertation.

I also want to thank all of my co-authors as well as colleagues, Christina Derksen, Lukas Kötting, Dr. Martina Schmiedhofer, and Johanna Dietl for their support in writing these five papers. Thank you also to our student assistants and interns, Nathalie Linda Herzog-Petropaki, Jing Liu, Nerma Pasic, Grace Wire, and Katharina Schiffer for their support in proofreading and editing.

Finally, I would like to say my biggest thanks and gratitude to my parents and my brothers. Thank you for your constant emotional and financial support, for your understanding, and for your trust in my decisions. To my friends: Thank you for encouraging talks and ensuring time for breaks.

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List of Abbreviations

ANCOVA: Analysis of covariance

ANOVA: Analysis of variance

ANX: Anxiety

ASE: Action self-efficacy

CBT: Cognitive Behavioral Therapy

CCAM: Compensatory Carry-Over Action Model

CES-D: Center for Epidemiologic Studies-Depression scale

CFA: Confirmatory factor analysis

CFT: Communication-focused therapy

CG: Control group

CHO: Curriculum Hannover Online

COVID-19: coronavirus disease 2019

CPDI: COVID-19 Peritraumatic Distress Index

DEP: Depression

DiGAs: Digital health applications

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

DT: Diagnosis and treatment

DV: Dependent variable

DVG: Digitales Versorgungsgesetz (digital supply act)

eCBT: Electronically delivered cognitive behavioral therapy

EFIs: Engagement-facilitation interventions

e-Mental health: Electronic mental health

EFA: Exploratory factor analysis

EM Imputation: Expectation-maximization-algorithm

ETL: Evolutionary Theory of Loneliness

FIML: Full information likelihood method

FW: Financial worries

GAD-2: 2-item Generalized Anxiety Disorder Scale

GAD-7: 7-item Generalized Anxiety Disorder Scale

GKV: General health insurance

HAPA: Health Action Process Approach

HC: Hygiene and communication among health care professionals

HO: Household-related worries

HW: Health-related worries

HYG: Hand hygiene

IC: Information and communication with patients

iCBT: Internet-delivered cognitive behavior therapy

ICD-10: International Classification of Disease-10 (ICD-10) manual

ICF: International Classification of Functioning, Disability, and Health

IDEAS: Integrate, Design, Assess and Share method

IG1: Intervention group one

IG2: Intervention group two

IMB: Information-Motivation-Behavioral skills method

IMIs: Internet- and mobile-based interventions

INT: Intention

IV: Independent variable

KP: Knowledge and operational procedures

M1: Mediator 1

M2: Mediator 2

MANCOVA: Multivariate analysis of covariance

MDMA: Synthetic amphetamine

mHealth: mobile health

MERS-CoV: Middle East Respiratory Syndrome Coronavirus

MMRM ANCOVA: mixed-model repeated measures analysis of covariances

MSE: Maintenance self-efficacy

OE: Outcome expectancies

OMS: Output Management System

pAEs: Preventable adverse events

PHQ-2: 2-item Patient Health Questionnaire

PHQ-4: 4-item Patient Health Questionnaire

PHQ-9: 9-item Patient Health Questionnaire

PL: Planning

PP: patient participation

PPAEAT: Perceptions of Preventable Adverse Events Assessment Tool

PREMs: Patient-reported experience measures

PROMs: Patient-reported outcome measures

PS: Patient safety

PSM: Propensity score matching

PSS: Perceived stress scale

PSS-4: 4-item Perceived stress scale

RCT: Randomized control trial

RES: Resources

RISK: Risk perception

RTW: Return to work

SARS: Severe acute respiratory syndrome

SARS-CoV-1: Severe acute respiratory syndrome coronavirus type 1

SARS-CoV-2: Severe acute respiratory syndrome coronavirus type 2

SC: Satisfaction with communication

SEM: Structural equation modeling

SUP: Social support

T1: First time point (6 weeks before the start until the first day of rehabilitation)

T2: Second time point (after rehabilitation)

TAM: Technology Acceptance Model

TC: Time constraints

TPB: Theory of planned behavior

TTM: Transtheoretical Model of Behavior Change

UCLA Loneliness Scale: University of California, Los Angeles Loneliness Scale

QI: Quality improvement

VIF: Variance inflation factor

WHO: World Health Organization

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Abstract

Different crises, such as the COVID-19 pandemic, have been associated with changes related to daily interaction, social interconnectedness, mental health, and support structures as well as the provision of (mental) health care treatment options. Psychology can describe such changes and explain them to some extent. Overall, the COVID-19 pandemic has shown to be interrelated with several negatively associated reactions (i.e., changes in well-being, increased worries and concerns, changes in health-related behaviors) for the individual due to the necessary mitigation strategies imposed by governmental regulations. Further, increased symptoms related to (di)stress, loneliness, depression, and anxiety have been noted. Besides, the COVID-19 pandemic has been associated with changes in (mental) health care, which is imperative for psychologists and psychologically interested health care providers. Yet, the psychological reaction and mechanisms related to a perceived change in mental health, the associated consequences for patient care and mental health in crises, as well as the implementation and evaluation of contemporary compensatory support measures, lack an evaluation in the context of (mental) health care. Therefore, the overarching goal of this dissertation was to examine psychological well-being by considering constructs such as patient safety, stress, loneliness, depression, and anxiety during the COVID-19 pandemic. Furthermore, this dissertation aimed to disentangle the psychological mechanisms, reactions, and consequences for individuals during crises. In addition, this thesis aimed to provide evidence for the effectiveness of digital support systems to compensate for a possible deterioration or chronic development of mental health. These aims were evaluated within an interdisciplinary research setting of health psychology, rehabilitation psychology, and clinical psychology applying selected methodological approaches. Such main approaches were a psychometric evaluation a questionnaire, structural equation modeling, propensity score matching, longitudinal mix-models analyses, or longitudinal serial mediation modeling. As an overall psychological theoretical foundation for this dissertation, a model, describing triggering situations (S), the organism (O), reactions on a behavioral, cognitive, emotional, and physiological level (R), as well as the contingency (K), and short-term as well as long-term consequences (C), has been adapted to the context of the COVID-19 pandemic. This model has been named the SORKC model which has been frequently used in the area of clinical psychology to describe the development of a psychological disorder. This dissertation extended the scope of the SORKC model to an individual and system level approach to describe the interrelations of the COVID-19 pandemic with psychological variables and mechanisms related to mental health.

More specifically, to gain an overall understanding of potentially threatening situations in the health care context (i.e., focusing on a system level), Chapter 3 aimed to define triggers of preventable adverse that pose a threat to own patient safety by employing a questionnaire. While previous studies have identified areas of preventable adverse events from the perspective of health care professionals, the uniqueness of this thesis is that it offers a first insight into patient-defined areas of possible triggers of preventable adverse events (*Chapter 3*). The developed questionnaire was evaluated concerning its psychometric properties in the primary health care setting and tested concerning its robustness to changes in mental health. As the definition of (patient) safety in health care settings along with potential triggers of preventable adverse events remained open, this was therefore examined in *Chapter 3* along the system reaction level.

The *second aim* of this dissertation was to shed light on the processes that are involved in performing and maintaining effective and protective measures against a COVID-19 infection. Several preventative measures, such as wearing a face mask, keeping the required distance of 1.5 meters, regular airing, or practicing hand hygiene behavior, are effective in reducing the possibility of an infection as well as the transmission of the virus. Of these behaviors, hand

hygiene was chosen as the evaluated health behavior due to the following reasons: Firstly, a lack of or ineffective performance of hand hygiene behavior has been conceptualized as a potential trigger that may lead to the occurrence of preventable adverse events in the primary health care sector (*Chapter 3*). Secondly, hand hygiene behavior has been recommended as a rather cost- and time-effective health behavior that has the potential to prevent a COVID-19 infection and mitigate the spread of the virus. While several other studies have examined hand hygiene behavior during the COVID-19 pandemic, this Chapter extends the scope by offering a unique examination of social-cognitive processes that describe hand hygiene behavior as a health behavior during the COVID-19 pandemic (i.e., a health-threatening crisis). Chapter 4 evaluated hand hygiene behavior along the Health Action Process Approach (HAPA), which has been known as a well-established theoretical framework for explaining health behavior change. It was examined whether the social-cognitive variables (i.e., self-efficacy, outcome expectancies, risk perception, intention, and planning) were able to explain changes in hand hygiene behavior over and above the mental health status. The uniqueness of this approach was that invariances between groups (i.e. individuals with and without a reduced mental health status) could be examined through latent means. Further, it was evaluated whether the mental health status was predictive of changes in hand hygiene behavior. Thereby, Chapter 4 provided an insight into the psychological mechanisms related to the performance and maintenance of hand hygiene behavior. Concerning the proposed adaption of the SORKC model, Chapter 4 was able to explain reactions to the COVID-19 pandemic on a behavioral level.

The COVID-19 pandemic is associated with a decrease in mental health for most individuals. Literature has suggested that specifically individuals with a pre-existing limited mental health condition are at higher risk of a chronic development of psychological symptoms. However, what previous evidence is missing, is a comparison between individuals from the general population and individuals with a pre-existing mental health condition to determine

changes in psychological mechanisms. Hence, *Chapter 5* investigated the following areas of interest: (a) differences in the experienced psychological symptoms such as stress, loneliness, depression, and anxiety, (b) differences in COVID-19-related worries and concerns, and (c) intention to use digital support measures evaluated based on the HAPA framework in the context of mental health care, and (d) the change in reported psychological symptoms for individuals with a pre-existing mental health condition (i.e. psychosomatic rehabilitation patients). *Chapter 5* offered a unique direct examination of two groups of individuals by applying propensity score matching. Hence, *Chapter 5* provided an understanding of the psychological mechanisms relevant to the formation of an intention. Further, this chapter has laid the basis for the development of digital interventions as a higher intention to use digital trainings as well as partaking in digital interventions was associated with a significant reduction in reported psychological symptoms. Based on the results, *Chapter 5* was able to describe additional psychological reactions on the cognitive level as well as consequences with regard to changes in mental health as well as the necessity to implement digital support measures.

During the COVID-19 pandemic, symptoms such as distress associated with a possible COVID-19 infection, loneliness associated with quarantining, voluntary physical or social distancing, and symptoms of depression and anxiety were frequently reported. Despite previous evidence partially examining the proposed variables during the COVID-19 pandemic, research is lacking on their interrelation. To explain the relationship between the variables, Chapter 6 turned toward the Evolutionary Theory of Loneliness (ETL) as a theoretical baseline. The ETL has been able to demonstrate that loneliness serves as a signaling function against a possible threat. However, what this theory is lacking is an extension of the proposed variables and the appreciation of maintaining and sustaining factors of psychological disorders. Consequently, *Chapter 6* examined this research gap. Uniquely, *Chapter 6* was able to demonstrate the interrelation of the variables by highlighting the mediating role of anxiety and loneliness in the

association between distress and depression. Thereby, the results provided insight into a possible extension of the ETL by highlighting the vicious circle between the variables in the development and maintenance of a depressive disorder as one of the most prevalent disorders during the COVID-19 pandemic.

As suggested in *Chapter 5*, the use of digital trainings or interventions has been shown to support symptom reduction in psychosomatic rehabilitation patients. However, the psychological mechanisms and the effectiveness of those digital trainings in the setting of psychosomatic rehabilitation warranted further research. Therefore, *Chapter 7* adds to *Chapter 5* by evaluating the effectiveness of digitally supplemented interventions in addition to traditional face-to-face therapy processes before and during a psychosomatic rehabilitation treatment. The Compensatory Carry-Over Action Model (CCAM) as a psychological model, can describe the association between mental health and factors contributing to changes in mental health. Accordingly, the CCAM can provide a theoretical basis for explaining behavior change (i.e., changes in depression, anxiety, loneliness, and stress) based on the level of participation in digitally supported trainings in addition to traditional face-to-face therapy. Results of *Chapter 7* underlined the importance to support individuals with a pre-existing mental health condition in a multidisciplinary and interdisciplinary manner by integrating digital approaches into more traditional face-to-face therapeutical approaches. Results of *Chapter 7* inform the consequences of the adapted SORKC model.

Overall, the results of the dissertation provided an understanding of (mental) health care from the perspective of patients. Results were aggregated on an integrative cross-level, multifactorial-probabilistic, and bio-psycho-social vulnerability stress model that was based on the adaption of the SORKC model. The proposed final model assumed that vulnerabilities (i.e., pre-existing mental health limitations) and protective factors (i.e., social support or access to treatment options) predict how a crisis is perceived on a reactional level (i.e., behavioral,

cognitive, emotional, and system level). Therefore, results from *Chapters 3 to 6* contributed to an understanding of behavioral, emotional, and cognitive reactions associated with a crisis. These reactional levels furthermore were associated with consequences and are discussed in *Chapters 5 to 7*. Results of this thesis proposed that modifiable variables acted as a buffer in the relationship between reactions and consequences. These modifiable variables include the increase of functional coping strategies, behavior change techniques, access to (digital) treatment options, and fostering of emotional competencies.

To conclude, the findings of this dissertation contributed to a greater understanding of psychological mechanisms evaluated by reactions and related consequences associated with the COVID-19 pandemic. Based on the results several implications could be drawn: The results called for further theoretical advancements and evaluations of patient safety and related constitutes from the perspective of the patient. Further, to reduce the number of potentially preventable adverse events, interventions in form of trainings are needed to encourage communication skills, coping responses, and confidence to speak up, thereby, strengthening the modifiable variables part of the adapted SORKC model. In addition, to increase hand hygiene behavior in hospitals but also in everyday life settings as a preventive measure, further interventions should be developed to promote behavior change. Further, digital interventions should be developed based on theory and tailored to the needs of the individual in the area of mental health care, specifically, psychosomatic rehabilitation.

Overall, results have highlighted an association between the COVID-19 pandemic and changes in mental health and well-being for individuals with and without a pre-existing mental health condition. Therefore, low-threshold interventions are warranted that act as a support system, foster effective coping strategies, and create a sense of belonging, thereby, counteracting potential negative consequences associated with the COVID-19 pandemic. Results of this dissertation call for an adaption of the (mental) health care treatment process

Abstract

adjusted to the specifications of the COVID-19 pandemic as well as to changes in treatment advancements while considering the needs of patients and psychological mechanisms related to behavior change.

Krisensituationen, wie die COVID-19-Pandemie, sind mit vielen Veränderungen des täglichen Lebens verbunden. Dazu gehören zwischenmenschlicher Umgang, allgemeine Verschlechterung des psychischen Wohlbefindens, sowie Vorbeugung psychischer Erkrankungen. Der Bereich der Psychologie, besonders die Bereiche Gesundheitspsychologie, klinische Psychologie und Rehabilitationspsychologie, ermöglichen bis zu einem gewissen Grad die Beschreibung und Erklärungen solcher Veränderungen. In früheren Studien konnte bereits gezeigt werden, dass die COVID-19-Pandemie bedingt durch notwendige und behördlich auferlegte Verhaltensmaßnahmen vermehrt mit (Di)Stress, Einsamkeit, Depression oder Angst assoziiert ist. Die COVID-19-Pandemie als Krisensituation steht jedoch nicht nur im Zusammenhang mit Veränderungen der psychischen Gesundheit, sondern auch mit Veränderungen von Versorgungsstrukturen und -adhärenz: Die Patientenversorgung während der COVID-19-Pandemie ist durch gehäufte Therapieabbrüche oder Unterbrechungen von notwendigen Behandlungsmaßnahmen im somatischen und psychischen Verzögerungen und Verschiebungen von Vorsorgeuntersuchungen sowie Mangel an Personal oder Schutzausrüstung als Reaktion auf die Herausforderungen der Pandemie gekennzeichnet. Es fehlt jedoch ein Verständnis psychologischer Reaktionen auf die COVID-19-Pandemie, was sowohl für Psychologen als auch für psychologisch interessierte Gesundheitsdienstleister von Relevanz ist. Zudem wurden bis zum aktuellen Zeitpunkt psychologische Konsequenzen und deren Prädiktoren im Rahmen der COVID-19-Pandemie für die Patientenversorgung sowie für die Vorsorge psychischer Erkrankungen noch nicht evaluiert. Darüber hinaus fehlt es an Untersuchungen hinsichtlich der Wirksamkeit und den damit assoziierten psychologischen Mechanismen von digitalen Unterstützungsmaßnahmen, die zur Verbesserung der Patientenversorgung/-unterstützung beitragen könnten. Somit besteht das übergenordnete Ziel dieser Dissertation in der Untersuchung des mentalen Gesundheitsstatus im Bereich der

Patientensicherheit und Gesundheitsversorgung anhand von häufig berichteten psychischen Symptomen wie Stress, Einsamkeit, Depression und Angst während der COVID-19-Pandemie. Zunächst wurden psychologische Mechanismen, Reaktionen und Konsequenzen für den Einzelnen in Krisensituationen untersucht. Des Weiteren betont diese Arbeit die Notwendigkeit der Integration von digitalen Unterstützungsmöglichkeiten in traditionellere Face-to-Face Behandlungsstrukturen, um mögliche Verschlechterungen oder Chronifizierungen von psychischen Symptomen trotz coronabedingten Therapieunterbrechungen oder -abbrüchen zu kompensieren. Zusätzliche digitale Therapieansätze ermöglichen eine Sicherstellung der (psychischen) Versorgung während Krisensituationen. Deren Wirksamkeit wurde hinsichtlich Symptomveränderung von depressiven Symptomen und Angstsymptomen sowie von wahrgenommenem Stress und wahrgenommener Einsamkeit im Kontext der psychosomatischen Rehabilitation evaluiert. Sämtliche Forschungsfragen dieser Dissertation wurden einer interdisziplinären, gesundheitspsychologischen, aus rehabilitationspsychologischen und klinisch psychologischen Perspektive unter Anwendung ausgewählter methodischer Ansätze evaluiert. Verwendete methodische Ansätze waren die psychometrische Auswertung eines entwickelten Fragebogens, neu Strukturgleichungsmodellierung, Propensity Score Matching, longitudinale Analysen gemischter Modelle und longitudinale serielle Mediationsmodellierung.

Als wesentliche psychologische und theoretische Grundlage dieser Dissertation wurde ein Modell genutzt, das auslösende Situationen (S), den Organismus bzw. biologischsomatische Bedingungen eines Individuums (O), Reaktionen auf Verhaltensebene, kognitiver Ebene, emotionaler Ebene oder physiologischer Ebene (R), die Kontingenz, welche regelhafte und zeitliche Zusammenhänge zwischen auslösenden Situationen, Reaktionen und Konsequenzen bedingt (K) und sowohl kurzfristige als auch langfristige positive und negative Konsequenzen (C) beschreibt. Dieses Modell ist als sogenanntes SORKC Modell bekannt und

wird häufig im klinisch psychologischen Bereich genutzt, um die Faktoren, die zur Entstehung und Aufrechterhaltung von psychischen Störungen führen, zu beschreiben und deren interkorrelative Prozesse zu erklären. In dieser Dissertation wird der Ansatz des SORKC Modells um eine individuelle Ebene und eine Systemebene erweitert. Damit sollen Zusammenhänge der COVID-19-Pandemie als eine Krisensituation mit psychologischen Variablen und Mechanismen evaluiert werden.

Um allgemeines Verständnis von Patientensicherheit potentiell gesundheitsgefährdenden Situationen (d. h. Konzentration auf Systemebene) zu erlangen, zielte Kapitel 3 darauf ab, Auslöser oder sogenannte Trigger von vermeidbaren unerwünschten Ereignissen mittels eines Fragebogens zu identifizieren. Der entwickelte Fragebogen und dessen Inhalte wurden hinsichtlich der psychometrischen Eigenschaften in der primären Gesundheitsversorgung evaluiert. In vorherigen Studien konnte gezeigt werden, dass psychische Erkrankungen mit einer veränderten Wahrnehmung und Beurteilung von Faktoren der eigenen Patientensicherheit assoziiert sind. Dies lässt sich darauf zurückführen, dass Individuen mit einer depressiven Erkrankung oder einer Angststörung häufiger maladaptive Bewältigungsfähigkeiten in bedrohlichen Situationen aufzeigen. Dementsprechend wurde untersucht, ob psychische Symptome, wie depressive Symptome oder Angstsymptome, mit einer veränderten Wahrnehmung und Beurteilung von vermeidbaren unerwarteten Ereignissen assoziiert sind. Somit wurde die sogenannte Robustheit gegenüber Veränderungen der psychischen Gesundheit getestet. Da die Definition der (Patienten-) Sicherheit im Gesundheitswesen zusammen mit potenziellen Auslösern vermeidbarer unerwünschter Ereignisse aus Patientenperspektive laut jetzigem Forschungsstand nicht adäquat definiert ist, wurden diese in Kapitel 3 entlang der Systemreaktionsebene untersucht. Folgende fünf übergeordnete Themen konnten, bezogen auf vermeidbare unerwünschte Ereignisse aus Patientensicht, hierbei definiert werden: (a) Information und Kommunikation mit Patienten, (b)

zeitliche Limitationen des medizinischen Personals, (c) Diagnostik und Behandlungsabläufe, (d) Einhaltung der Hygiene, Kommunikation innerhalb des medizinischen Personals und (e) Wissensstand und Arbeitsabläufe. Es zeigte sich, dass der neu entwickelte Fragebogen gute psychometrische Eigenschaften aufweist und sich robust gegenüber Veränderungen der psychischen Gesundheit verhält.

Ein weiteres Ziel dieser Dissertation war die Beleuchtung der Prozesse, die mit der Durchführung und Aufrechterhaltung wirksamer Schutzmaßnahmen gegen eine COVID-19-Infektion verbunden sind. Neben verschiedenen präventiven Verhaltensweisen zur Eindämmung des Coronavirus (z. B. Abstand halten, Tragen einer Mund-Nasen-Maske, regelmäßiges Lüften) hat sich Handhygiene aus mehreren Gründen als bewertetes Gesundheitsverhalten etabliert: (1) ein fehlendes oder mangelhaftes Handhygieneverhalten wurde als potenzieller Auslöser definiert, der mit der erhöhten Wahrscheinlichkeit von vermeidbaren unerwünschten Ereignissen assoziiert ist (Kapitel 3), und (2) das Handhygieneverhalten ist als ein eher kosten- und zeiteffektives Gesundheitsverhalten bekannt, welches eine mögliche COVID-19 Infektion verhindern und die Ausbreitung des Virus reduzieren kann. Während mehrere bereits publizierte Studien das Handhygieneverhalten während der COVID-19-Pandemie untersucht haben, erweiterte Kapitel 4 den jetzigen Forschungsstand, indem es eine erste Untersuchung sozial-kognitiver Prozesse bietet, die das Handhygieneverhalten als Gesundheitsverhalten beschreiben. In Kapitel 4 wurde darüber hinaus das Handhygieneverhalten entlang des Health Action Process Approach (HAPA) analysiert, das als etablierter theoretischer Rahmen für die Erklärung von Gesundheitsverhaltensänderungen bekannt ist. Es wurde untersucht, ob die sozial-kognitiven Variablen (d. h. Selbstwirksamkeit, Ergebniserwartungen, Risikowahrnehmung, Intention und Planung) Veränderungen im Handhygieneverhalten über den psychischen Gesundheitszustand hinaus erklären konnten. Ergänzend wurde untersucht, ob der psychische Gesundheitszustand

Veränderungen im Handhygieneverhalten vorhersagen kann. Dabei gab Kapitel 4 einen Einblick in die psychologischen Mechanismen, die mit motivationalen und volitionalen Faktoren des Handhygieneverhaltens zusammenhängen. Im Hinblick auf die in dieser Arbeit vorgeschlagene Anpassung des SORKC-Modells konnte Kapitel 4 Reaktionen auf der Verhaltensebene während der COVID-19-Pandemie erklären. Zentrales Ergebnis war, dass das HAPA Modell zur Beschreibung und Erklärung des Handhygieneverhaltens mit seinen motivationalen und volitionalen Faktoren geeignet ist. Die Variable Planung konnte die Intentions-Verhaltens-Lücke schließen beziehungsweise überwinden. Zudem hat sich gezeigt, dass Veränderungen in der psychischen Gesundheit nicht mit Veränderungen in sozial-kognitiven Variablen und Handhygieneverhalten assoziiert sind.

Die COVID-19-Pandemie ist und war für die meisten Menschen mit einer Veränderung oder auch Verschlechterung der psychischen Gesundheit verbunden. Potenzielle Risikofaktoren wurden wie folgt definiert: Veränderungen in der menschlichen Interaktion, freiwillige oder obligatorische Quarantäne, mangelnder Zugang zu benötigten Strukturen der allgemeinen Versorgung und Unterstützung, Veränderungen im Arbeitsleben sowie Veränderungen in Bezug auf die familiäre und finanzielle Situation. In dieser Arbeit konnte gezeigt werden, dass insbesondere Personen mit einer bereits bestehenden psychischen Erkrankung ein höheres Risiko hinsichtlich einer Chronifizierung der Symptome aufwiesen. Was jedoch in der bisherigen Literatur fehlt, ist ein Vergleich zwischen psychisch gesunden und psychisch erkrankten Individuen, um Veränderungen in psychologischen Mechanismen darzustellen.

Als drittes Ziel wurde in *Kapitel 5* die wahrgenommene Belastung in beiden definierten Gruppen (d. h. Personen aus der Allgemeinbevölkerung und psychosomatischen Rehabilitationspatienten) während der COVID-19-Pandemie untersucht. Dabei wurden folgende Forschungsfragen analysiert: (a) Unterschiede in den erlebten psychischen

Symptomen wie Stress, Einsamkeit, Depression und Angst, (b) Unterschiede in COVID-19bedingten Sorgen und Bedenken, (c) Intention, digitale Unterstützungsmöglichkeiten zu verwenden, um eine Verschlechterung der psychischen Gesundheit zu reduzieren beziehungsweise zu kompensieren und (d) die Veränderung der berichteten psychologischen Symptome von Individuen mit einer psychischen Erkrankung (d. h. von psychosomatischen Rehabilitationspatienten). Kapitel 5 bot somit eine einzigartige Untersuchung zwischen zwei unterschiedlichen Gruppen von Individuen (d. h. psychisch gesunde und psychisch erkrankte Personen) in Bezug auf psychologische Symptome, Sorgen und Bedenken durch Anwendung von Propensity Score Matching. Außerdem konnten in diesem Kapitel die Ergebnisse zur Intention der beiden Gruppen, die digitalen unterstützenden Maßnahmen während der COVID-19-Pandemie zu nutzten, dargestellt werden. Diese digitalen Unterstützungsmodalitäten beruhten auf der theoretischen Grundlage des HAPA Models. Zudem konnte Kapitel 5 zeigen, dass eine höhere Intention, digitale Trainings zu nutzten sowie an diesen teilzunehmen, mit einer Verringerung der berichteten psychologischen Symptome einherging. Erkenntnisse dieses Kapitels gaben Einblicke in die psychologischen Mechanismen und Grundlagen von digitalen Interventionen. Basierend auf diesen Ergebnissen konnten in Kapitel 5 psychologische Reaktionen auf kognitiver Ebene beschrieben werden. Die Ergebnisse dieses Kapitels gaben zudem einen Einblick in mögliche Konsequenzen bei der Bewertung von Veränderungen der psychischen Gesundheit (a) durch die COVID-19-Pandemie und durch Unterstützungsmaßnahmen. Zentrale Befunde waren, dass psychosomatische Rehabilitationspatienten stärkere Symptome hinsichtlich Depression, Angst, Stress und Einsamkeit wahrgenommen haben sowie mehr Sorgen um die eigene Gesundheit und den Haushalt berichteten. Finanzielle Sorgen spielten jedoch eine untergeordnete Rolle. Zudem gaben psychosomatische Rehabilitationspatienten eine höhere Intention an, digitale Unterstützungsmaßnahmen zu nutzen. Es konnte auch gezeigt werden, dass sich die

wahrgenommenen psychischen Symptome während des Verlaufs der Rehabilitation reduzierten.

Während der COVID-19-Pandemie wurde häufig von Symptomen wie Distress, Einsamkeit, Depression und Angst berichtet, die mit den Veränderungen des täglichen Miteinanders und der strukturellen Veränderungen assoziiert sind. Trotz früherer Studien, die die psychischen Symptome während der COVID-19-Pandemie partiell untersucht haben, fehlt es an Forschung über ihre Beziehung zueinander. Um die Beziehung zwischen den Variablen zu erklären, beschäftigte sich Kapitel 6 mit der Evolutionary Theory of Loneliness (ETL) als theoretische Grundlage. Nach Auffassung der ETL dient die wahrgenommene Einsamkeit als Signalfunktion gegenüber einer möglichen Bedrohung. Was dieser Theorie jedoch fehlt, ist eine Erweiterung um die genannten psychischen Variablen und die Berücksichtigung von aufrechterhaltenden Faktoren einer psychischen Erkrankung. Folglich untersuchte Kapitel 6 diese Forschungslücke. Zentraler Befund des sechsten Kapitels war, dass die Beziehung zwischen Distress und Depression durch Angst und Einsamkeit mediiert wurde. Dabei gaben die Ergebnisse Aufschluss über eine mögliche Adaption und Erweiterung der ETL, indem sie die Abwärtsspirale hinsichtlich der Entstehung und Aufrechterhaltung einer depressiven Störung, eine der häufigsten Erkrankungen, während der COVID-19-Pandemie aufzeigten. Die Ergebnisse dieses Kapitels konnten somit psychologische Reaktionen auf emotionaler Ebene beschreiben sowie die Konsequenzen im Zusammenhang mit notwendigen Anpassungen der (psycho)therapeutischen Behandlungsansätze und -pläne darlegen.

Wie in *Kapitel 5* dargestellt konnte die Nutzung digitaler Interventionen die Symptomreduktion von psychosomatischen Rehabilitationspatienten unterstützen. Dieses Ergebnis stimmt mit vorhandenen Studien überein, die digitale therapeutische Unterstützungsmöglichkeiten zusätzlich zur traditionellen Face-to-Face-Therapie untersuchten. Die Evaluation der psychologischen Mechanismen und die Wirksamkeit dieser digitalen

Trainings im Rahmen der psychosomatischen Rehabilitation bedarf jedoch weiterer Untersuchungen. Kapitel 7 ergänzte somit Kapitel 5. Hier wurde die Wirksamkeit von digitalen Interventionen zusätzlich zu traditionellen Face-to-Face Therapie vor und während einer psychosomatischen Rehabilitationsbehandlung evaluiert. Diese digitalen Interventionen zielten darauf ab, nicht nur die Hauptdiagnose beziehungsweise die Hauptsymptome, sondern auch die aufrechterhaltenden Faktoren zu behandeln. Das Compensatory Carry-Over Action Model (CCAM) diente als psychologisches Modell, das den Zusammenhang zwischen psychischer Gesundheit und Faktoren, die zu einer Verbesserung derer beitragen, beschreiben kann. Somit ist es dem CCAM gelungen eine theoretische Grundlage für die Erklärung von Verhaltensänderungen (d. h. Veränderungen von Depressionen, Angstzuständen, Einsamkeit und Stress) zu liefern, die auf dem Ausmaß der Teilnahme an digital unterstützten Trainings zusätzlich zur traditionellen Face-to-Face Therapie basieren. Die Ergebnisse von Kapitel 7 unterstrichen die Notwendigkeit, Menschen mit einer bereits bestehenden psychischen Erkrankung interdisziplinär zu unterstützen, indem digitale Ansätze in traditionellere therapeutische Ansätze integriert wurden. Die Besonderheit von Kapitel 7 war die Erkenntnis, digitale Unterstützungssysteme vor und während des (psycho)therapeutischen Behandlungsprozesses langfristig zu einem besseren psychischen Wohlbefinden beitragen konnten, indem sie konstruktive Bewältigungsfähigkeiten, kommunikative Fähigkeiten und eine allgemeinen Verbesserung des Selbstwertgefühls und des Selbstvertrauens unterstützten. Die Ergebnisse von Kapitel 7 zielten auf den Bereich der Konsequenzen des angepassten SORKC-Modells ab. Wesentliches Ergebnis war, dass die Behandlungen, die im Rahmen einer psychosomatischen Rehabilitation angeboten wurden, zu einer Verbesserung hinsichtlich der Symptome Depression, Angst, Einsamkeit und Stress führte. Zudem konnte gezeigt werden, dass die Teilnahme an allen drei angebotenen zusätzlichen digitalen Therapiemaßnahmen eine wirksame Symptomreduzierung besonders hinsichtlich Depression und Angst unterstützte.

Weitere Faktoren, die mit einer Symptomreduzierung assoziiert waren, lauten wie folgt: bessere wahrgenommene Kommunikation zwischen Patienten und dem medizinischen Personal sowie Zufriedenheit mit den gesamten Rehabilitationsprozess.

Insgesamt führten die Ergebnisse der Dissertation zu einem besseren Verständnis der (psychischen) Gesundheitsversorgung aus Sicht der Patienten. Die Ergebnisse wurden in dem Konzept eines integrativen ebenen-übergreifenden, multifaktoriell-probabilistischen und biopsycho-sozialen Vulnerabilitätsstressmodell zusammengefasst, das auf der Anpassung und auf Erweiterungen des SORKC-Modells basiert. Das endgültige Modell geht davon aus, dass das Ausmaß an Vulnerabilität (d. h. bereits bestehende Einschränkungen der psychischen Gesundheit) sowie protektive Faktoren (d. h. soziale Unterstützung oder Zugang zu Behandlungsmöglichkeiten) prognostizieren können, wie eine Krise auf den verschiedenen Ebenen, also Verhaltensreaktion, kognitive Reaktion, emotionale Reaktion und Systemebene wahrgenommen wird. Die Ergebnisse aus Kapiteln 3 bis 6 tragen somit zum Verständnis der Reaktionen bei, die mit einer Krisensituation auf mehreren Reaktionsebenen verbunden sind: Verhaltensreaktionen (d. h. Veränderungen des Handhygieneverhaltens), emotionale Reaktionen (d. h. Stress und Angst) und kognitive Reaktionen (d. h. Sorgen und Bedenken) sowie Reaktionen auf Systemebene (d. h. Veränderungen der Patientensicherheit). Diese Reaktionsebenen waren zudem mit Konsequenzen, wie Veränderungen der psychischen Gesundheit und Veränderungen in der (psychischen) Gesundheitsversorgung, verbunden und wurden in Kapiteln 5 bis 7 evaluiert und diskutiert.

Die Ergebnisse dieser Arbeit erweitern die ursprüngliche Annahme des SORKC Models um eine sogenannte modifizierbare Variable, die als Zwischenschritt oder als Puffer in der Beziehung zwischen Reaktionen und Konsequenzen agiert. Durch diese können potentiell negative Konsequenzen kompensiert werden. Mit dieser modifizierbaren Variable sind unter anderem die Zunahme funktioneller Bewältigungsstrategien, Verhaltensänderungstechniken,

der Zugang zu (digitalen) Behandlungsmöglichkeiten und die Förderung emotionaler Kompetenzen verbunden. Somit lässt sich sagen, dass die Ergebnisse dieser Dissertation zu einem besseren Verständnis der psychologischen Mechanismen beitragen, die durch Reaktionen auf mehreren Ebenen (d. h. Verhaltens-, emotionale, kognitive und Systemebene) bewertet werden. Auch wurden die Konsequenzen aus den Reaktionen unter Berücksichtigung der modifizierbaren Variablen im Rahmen der COVID-19-Pandemie betrachtet. Diese weisen einen hohen Stellenwert bei mehreren Implikationen für zukünftige Forschung und praktische Anwendungen auf. Theoretische Grundlagen sollten erweitert werden. Patientensicherheit und die damit verbundenen Trigger oder auslösenden Situationen aus Sicht des Patienten sollten adäquat bewertet werden. Um die Anzahl potenziell vermeidbarer unerwünschter Ereignisse zu reduzieren, sind Interventionen in Form von Schulungen erforderlich, Kommunikationsfähigkeiten zu verbessern, weitere Bewältigungsstrategien zu entwickeln und Selbstvertrauen, mögliche Fehler in der eigenen Versorgung anzusprechen, zu stärken. Dies kann durch die modifizierbare Variable aus dem angepassten SORKC Model unterstützt werden. Um das Händehygieneverhalten im Krankenhaus sowie auch im Alltag präventiv zu verbessern, sollten niederschwellige Interventionen für Patienten und Menschen aus der Allgemeinbevölkerung entwickelt werden, um Veränderungen im Verhalten der Menschen zu erreichen. Inhalte dieser Interventionen sollten anhand der sozial-kognitiven Variablen des HAPA Models entwickelt werden.

Da die Ergebnisse dieser Dissertation gezeigt haben, dass digitale Interventionen, als Addition zur traditionellen Face-to-Face Therapie, die Wirksamkeit psychosomatischer Rehabilitationsbehandlungsprogramme erhöhen, sollten weitere digitale Interventionen für den Bereich der psychosomatischen Rehabilitation entwickelt werden. Dementsprechend empfehlen die Erkenntnisse dieser Arbeit, Interventionen zu implementieren, die auf Theorie und Bedarfsanalysen basieren, um eine Anpassung an den einzelnen Patienten und dessen

psychische Erkrankung zu gewährleisten. Diese digitalen Interventionen sollten nicht nur während, sondern auch vor (d. h. in Form der Vorbereitung) und nach dem Behandlungsprozess angeboten werden (d. h. zur Rückfallprophylaxe).

Zusammenfassend haben die Ergebnisse einen Zusammenhang zwischen der COVID-19-Pandemie und Veränderungen der psychischen Gesundheit von Personen ohne und mit bereits bestehenden psychischen Erkrankungen aufgezeigt. Erkenntnisse dieser Dissertation wurden anhand des angepassten SORKC Modells analysiert. Dafür wurden Ergebnisse aus Kapiteln 3 bis 6 als Verhaltensreaktionen, kognitive Reaktionen, emotionale Reaktionen und Reaktionen auf Systemebene auf die COVID-19-Pandemie als eine Krisensituation untersucht und interpretiert. Zudem wurden Konsequenzen der Reaktionen in Kapitel 5 bis 7 evaluiert und modifizierbare Variable als Puffer für negative Konsequenzen definiert. Die Ergebnisse betonen die Förderung der modifizierbaren Variable zur Aufrechterhaltung beziehungswiese Reduzierung negativer Konsequenzen aus der COVID-19-Pandemie auf den psychischen Gesundheitsstatus von Menschen mit und ohne bereits bestehender psychischer Erkrankung. Um dies sicherzustellen, bedarf es niedrigschwelliger, teils auch digitaler Interventionen, die als Unterstützungssystem agieren können sowie effektive Bewältigungsstrategien und Verhaltensänderungen fördern können.

Chapter 1: General Introduction

The coronavirus pandemic has led to many disruptions in daily living across the globe. Increases in adversities such as infection, illness, and even a possibility of death from the disease have been reported to result from the virus itself but also from containment and mitigation strategies. In addition to changes in daily living, the pandemic has challenged many individuals and groups with the need to adapt and cope with changes, due to the coronavirus disease 2019 (COVID-19) pandemic as well as with the consequences of the pandemic. Psychological understanding concerning how individuals with and without a limited mental health status react to, and are affected by, the pandemic has so far been understudied. In addition, psycho-social coping strategies and support measures that aid with challenges and uncertainties due to the COVID-19 need to be examined in terms of psychological processes and mechanisms. This thesis will examine the needs, resources, as well as implications of the COVID-19 pandemic by acknowledging psychological mechanisms within the context of health psychology, rehabilitation psychology, and clinical psychology. To that end, *Chapter 1* will provide an overview of relevant topics in the literature concerning the COVID-19 pandemic. Chapter 2 will provide an overview of the research aims and the overall framework of the present thesis.

1.1. Ensuring Patient Safety Before and During the COVID-19 Pandemic

The COVID-19 pandemic has posed a sudden challenge to many health care systems. As a response to the crisis, health care systems such as hospitals, stationary rehabilitation clinics, or ambulatory therapy settings, had to implement instant changes within a rapid time frame and to reflect on roles, processes, and procedures related to patient safety (PS) and quality improvement (QI). Patient safety has been defined as a critical component of quality in health care which has increasingly recognized the importance of continuous improvements in the quality of care processes for patients. Accordingly, a strong safety culture in health care settings

has been associated with the prevention or reduction of (preventable) adverse events (pAEs; DiCuccio, 2015; Fan et al., 2016; Reis et al., 2018).

According to the World Health Organization (WHO), unsafe care in health care settings has been highly related to patient morbidity and mortality, not only in Germany but around the world (World Health Organization & World Alliance for Patient Safety Research Priority Setting Working Group, 2008). According to a recent study by Cheraghi-Sohi et al. (2021), independent reviewers found patient safety incidents in consultations in the United Kingdom occurred 4.3% of the time. Even though this percentage seems to be rather low, the high numbers of daily contacts with primary health care suggest that several million patients may be at risk of preventable harm each year. However, when examining data from the German ambulatory health care sector, only limited data have been analyzed and published on the frequency of (preventable) adverse events.

Literature reviewed by the German Coalition for Patient Safety examined data on all hospitalized patients (i.e., in-patients and out-patients) in 2007 with a focus on identifying possible experienced adverse events, preventable adverse events, as well as experienced treatment errors and deaths due to preventable adverse events. Their results showed a frequency of 5%-10% of patients experiencing adverse events of which 2%-4% can be termed preventable. Furthermore, 1% of patients had experienced treatment errors and 0.1% of patients died as a consequence of preventable adverse events (SVR, 2007). However, rarely has the focus been directed toward the needs and the perspective of the patient when evaluating patient safety. During the past decade, the patient role in health care has become more prominent. A shift from a rather passive role toward an active and informed participant in one's own health-related choices and decisions has been noted. This concept has been termed patient participation (PP) and is in line with the maxim "Nothing about me without me." (Sacristán et al., 2016).

Literature has shown that recognizing and integrating PP into PS is of utmost importance for an effective definition and identification of potential pitfalls to patient safety, as well as for the promotion of safer care in health care settings (Ringdal et al., 2017). Therefore, Geraedts and colleagues undertook the effort to retrospectively examine the prevalence of patient safety problems in ambulatory care settings in Germany. Out of their sample, 1422 respondents (14%) reported patient safety problems. Their results highlight, on the one hand, the relatively high percentage of patients safety problems (which call for improvements in the ambulatory health care sector) and, on the other hand, highlight the valuable contribution of and the necessity to include patients and their reports in the analyses of patient safety problems (Geraedts et al., 2020). Still, so far, little is known about how to integrate patients in the process of being an active agent in their safety and the factors relevant to the decision to participate as active agents.

Previous literature has stated that predictors of the intention to participate may be the sense of control, one's ability to perform safety-related behaviors, and the acknowledgment of the benefits of patient safety-related behaviors in anticipation of positive outcome expectancies (Bishop et al., 2015; Davis et al., 2015). However, current literature has rarely identified and examined common domains of triggers of preventable adverse events (i.e., situations that have the potential to lead to preventable adverse events; Ricci-Cabello et al., 2015). Therefore, study 1 has focused on the development of a questionnaire assessing triggers of preventable adverse events significant for patient safety from the perspective of patients (*Chapter 3*).

When the severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) became a significant factor in health care settings all over the world, it quickly impacted and interrupted several aspects of patient and medical care. To support the maxim "Stop the Spread" (Desai & Patel, 2020), health care settings changed the focus from treating all patients to limiting or restricting access to hospitals and rescheduling appointments to control the spread of the virus, thereby attempting to reduce the potential transmission of infection. However, the

consequences included the lack of and unavailability of necessary treatment and preventative examinations, and in the worst case, patients died, sometimes alone, without sufficient care (Silvera et al., 2021). The strain on health care systems increased demands in times of stress (i.e., during the COVID-19 pandemic), and their associations with (preventable) adverse events have been well documented in the literature. Aspects that have led to additional challenges in providing adequate patient care include the following: The uncertainty at the beginning of the COVID-19 pandemic, the shortage of personnel, the redeployment of health care workers to different wards outside their specialization, the transfer of health care workers from different institutions, as well as the shortage of necessary treatment equipment and protective equipment (Alagha et al., 2021). As well as the challenges for health care systems and health care workers, patients reported rising fear or anxiety of taking advantage of preventative examinations due to the risk of infection (Gens-Barberà et al., 2021). It may be postulated that the COVID-19 pandemic as an obstacle to care would mean that individuals did not receive treatment for illnesses or postponed treatments, attended fewer preventative medical checkups, or did not receive basic medical care, thus, posing as a risk factor for individual health and patient safety.

1.2. Preventing the Spread of the Coronavirus

On the 30th of January 2020, the WHO declared the spread of the COVID-19 disease a public health emergency (World Health Organization, 2020a). Research on the spread of the virus has shown that the transition occurs from human to human (Rothe et al., 2020). Therefore, public health behavior strategies to prevent the spread of the virus such as quarantining, social or physical distancing, mask-wearing behavior, regular airing, and hand hygiene behavior were put into place to mitigate the transmission of the virus.

Quarantining, which involves (self-)isolation or limiting the mobility of people to travel from country to country by closing borders, can prevent the human-to-human spread of the disease by disrupting or breaking the chain of viral transmission (Wilder-Smith & Freedman,

2020). Further, social or physical distancing was introduced as a mitigation strategy. Social distancing has the function to reduce human-to-human communication in larger population groups. Social or physical distancing involved adhering to a minimum distance of 1.5 m between individuals in public and closed spaces. Literature has shown that this form of preventive measure may be useful especially when the direct relationship between infected persons is not clear (Mahase, 2020).

However, it needs to be stressed that for both quarantining as well as physical and social distancing, unpleasant experiences may be perceived by those undergoing the necessary containment measures. Several authors have examined the impact of quarantining and social and physical distancing on the mental health and well-being of individuals. Brooks and colleagues, for example, have shown that the separation from loved ones, the uncertainty of the status and the progression of the infection, as well as potential boredom and restrictions of rights may have noteworthy effects on personal well-being and mental health (Brooks et al., 2020). In addition, several studies have highlighted the increase in mental issues and the consequent decrease in mental well-being and psychological health due to quarantining measures (Brooks et al., 2020; Wang et al., 2021; Xiao, 2020). Specifically, literature has shown that quarantining and social isolation can precipitate psychological disorders such as depression and anxiety. In addition, quarantine is associated with increased feelings of stress. These feelings, in turn, may exacerbate feelings of uncertainty, fear, and anxiety (Jain et al., 2020). Furthermore, when having to isolate from loved ones paired with the fear of transmission, individuals are prone to experiencing post-traumatic distress which could lead to worse mental well-being in the long run. Shown risk factors that make individuals more susceptible to experiencing post-traumatic distress are self-quarantining as well as isolation, fear of being socially discriminated due to the infection as well as witnessing other individuals developing health threatening symptoms and potentially dying (Nesterko et al., 2020).

The effectiveness of wearing face masks to reduce the spread of infections transmitted from human to human has been studied for a long time. Evidence suggests that wearing face masks helped to mitigate the spread of previous epidemics such as the severe acute respiratory syndrome in 2003 or influenza (Chu et al., 2020; Greenhalgh et al., 2020; Howard et al., 2021; Prather et al., 2020). In six federal states in Germany, face masks were made mandatory between 1st of April and 10th of April 2020 before a compulsory introduction of face masks in all federal states of Germany between the 20th of April and 29th of April 2020. Specific predictors of adherence to face mask-wearing behavior have been defined: sociodemographic factors and strict mask-related policies associated with mask usage in public settings. However, contrary to the expectations, social behaviors considered risky are not significant predictors of effective face mask-wearing behavior but were, rather, associated with lower adherence (Badillo-Goicoechea et al., 2021).

Next to the required containment behaviors (i.e., keeping the distance of 1.5 m between individuals, avoiding mass gatherings or larger masses, wearing face masks in open and public settings), according to the German Law of Infection prevention Law, Section 28a and 28b, performing hand hygiene behavior has only been recommended and occasionally enforced by policies for specific institutions (i.e., hospitals or elderly homes; IfSG, 2000). According to the World Health Organization, practicing hand hygiene with alcohol-based hand sanitizers or washing hands with soap and water has been established as one of the most effective and low-cost strategies to prevent the spread and transmission of COVID-19 (World Health Organization, 2020b). The study by Chiu et al. (2020) has shown that combining multiple preventive health behaviors such as hand hygiene behavior, face mask-wearing behavior, and physical distancing has been associated with a decrease in respiratory infections during the COVID-19 pandemic.

Previous evidence has shown that several predictors are necessary for performing and maintaining effective hand hygiene behavior: (a) the perceived susceptibility or risk perception towards a potential infection, (b) the belief in the effectiveness of hand hygiene behavior and own capabilities to reduce the probability of a potential infection, (c) the intention to perform effective hand hygiene behavior, and (d) prioritization of own health as well as subjective norms, as well as (e) planning (Clark et al., 2020; Dwipayanti et al., 2021; Gaube et al., 2021; Liddelow et al., 2021; Zhang et al., 2020). Ranasinghe and colleagues have shown that symptoms of depression were associated with an increased likelihood of poor hand hygiene (Ranasinghe et al., 2016). During the COVID-19 pandemic, several studies have highlighted the increased burden of the restriction measures, such as staying at home or physically distancing from others, increased hand hygiene behavior, or face mask-wearing behavior. Studies have shown that prolonging those restriction measures has led to the exacerbation of pre-existing mental health disorders or a general increase of symptoms related to depression or anxiety (Fiorillo & Gorwood, 2020). Islam et al. have investigated the association between depressive symptoms in conjunction with COVID-19 preventive measures. Their results found that higher depression rates were found among individuals who rarely, or not at all, engage in preventive measures such as hand hygiene practices (Islam et al., 2021). Furthermore, Richey et al. (2019) highlighted that generalized anxiety is related to motivational deficits. As socialcognitive variables (i.e., outcome expectations, self-efficacy, risk perception, intention or planning), as well as the mental health status of individuals, seems to play a role in how or whether hand hygiene behavior is performed and maintained, Chapter 4 investigates whether hand hygiene behavior can be explained by the social-cognitive variables or whether the mental health status of individuals needs to be considered over and above the social-cognitive variables.

1.3. Corona Worries

Research has shown that infection outbreaks may be associated with several psychological, as well as social, impacts. On an individual basis, individuals are more likely to perceive fear for their health and the health of loved ones and to express concerns regarding safety, or financial worries (Taylor, 2019). The COVID-19 pandemic demonstrates a unique situation in human history that has allowed countries to warn individuals before the occurrence of potential danger and to prepare the health care systems for a possible epidemic or pandemic. However, literature has shown that the COVID-19 pandemic also represents a period of uncertainty leading to an increased perception of worries and reported concerns (Lauri Korajlija & Jokic-Begic, 2020). In the following, the frequently reported corona worries and concerns will be explored further. Additionally, a comparison between the general population and individuals with a pre-existing limited mental health status will be drawn, as previous evidence has suggested that individuals with and without a limited mental health status may perceive different worries or concerns (Kämpfen et al., 2020).

1.3.1. Frequently Reported Corona Worries during the COVID-19 Pandemic

The coronavirus pandemic has led to many disruptions in daily living across the globe. Increases in the experience of adversities such as infection, illness, and even a possibility of death from the disease have been reported to arise from the virus itself but also from containment and mitigation strategies. These include financial challenges due to a possible loss of employment or a reduction in income due to changes in savings strategies, challenges in the delivery of foods and daily produces, medication, and adverse experiences in the domestic context such as abuse (Chung et al., 2020; Dorn et al., 2020; The Lancet, 2020; Usher et al., 2020; Wright et al., 2020).

More specifically, many reported worries or concerns experienced during the COVID-19 pandemic focused on the topics of health and well-being, receiving adequate and appropriate medical care, (personal) finances and job status, travel restrictions, balancing work, and caring for children or dependents, and media coverage (Gawrych et al., 2021; Moore & Lucas, 2021; Van Rheenen et al., 2020). A study by Gawrych et al. (2021) investigated COVID-19-related worries at the beginning or initial stage of the coronavirus pandemic. Most common reported worries centered around the fear of the death of loved ones, a severe course of illness of loved ones, a failure of the health care system as a consequence of the pandemic, followed by financial and health worries at an individual level as well as at a social level, unavailability of resources and daily goods as well as worries about the prospect of quarantining and isolation. In addition, Moore and Lucas (2021) highlighted that individuals perceived increased worries about a possible contagion with COVID-19, their financial status, the general economy, and the political impact of the COVID-19 pandemic (Moore & Lucas, 2021).

Evidence give rise to concern that experiencing adversities may have long-lasting impacts on psychological as well as physical health (Holmes et al., 2020; McKee & Stuckler, 2020). Further, it should also be noted that it is not merely the direct experience of the mentioned stressors but also worries about experiencing those potential stressors that may be negatively associated with health and well-being, both psychologically as well as physiologically (Kubzansky et al., 1997; Rief et al., 2012; Szabó, 2011). Therefore, *Chapter 5* evaluates the frequency of different perceived corona worries and concerns.

1.3.2. Perception of Worries: Comparison Between the General Population and Individuals with a Pre-Existing Limited Health Status Regarding the COVID-19 Pandemic

Emerging evidence shows that the coronavirus pandemic increasingly poses a threat to mental well-being as the pandemic has brought about profound changes in activities related to daily life and may lead to additional stressors, such as the concerns and fears of the disease itself or the mitigation strategies implemented by the authorities as well as economic and financial consequences (Blix et al., 2021). These additional stressors may be challenging for many individuals and increase the strain on mental health. However, it needs to be stressed that concerns, worries, or stressors may be perceived differently as some groups may experience more stressors that pose a danger to mental well-being than other groups. Evidence has shown that individuals, who perceive a greater strain, tend to be diagnosed with previous mental health or a neurological disorder (González-Sanguino et al., 2020). This is in line with the assumption that the COVID-19 pandemic leads to more negative feelings associated with worry (Liu, 2020; Reynolds et al., 2008). Worry, according to Sibrava and Borkeovec (2006), has been defined as a form of repetitive negative thinking. It is considered to be future-oriented and involves thoughts and images of certain and possible negative outcomes (Sibrava & Borkovec, 2006). Worrying has been termed as a form of cognitive avoidance to prepare for potential arising threats and negative outcomes, such as those associated with the COVID-19 pandemic (Sibrava & Borkovec, 2006). However, the perception of stress-related emotions, cognitions, behaviors, as well as responses is intensified and prolonged when exposed to worrisome thoughts and images over a longer period (Stange et al., 2014), suggesting that worry may be an important mechanism in the relationship of stress and stress-related mental health problems (Eisma et al., 2017; Ottaviani et al., 2016) such as depression and anxiety.

Pieces of evidence from studies have shown that many individuals experience worry in some form at least once during their lives. However, the experience of worry may be pathological for some individuals as worries may be excessive and uncontrollable, consequently leading to increased feelings of distress and impairment (Barlow, 2002). Considering the evidence in the literature, worry seems to be a maintaining factor for several mental disorders. In addition, worry may be regarded as a transdiagnostic process that is related to numerous other pathologies (Barlow et al., 2004; McEvoy et al., 2013). However, whether individuals with a pre-existing and without a pre-existing mental health disorder perceived a

difference in the intensity and the relevance as well as in the content of those worries is a research question that will be discussed as part of this thesis (*Chapter 5*).

1.4. Mental Health and COVID-19

According to World Health Organization the effects of the coronavirus disease 2019 will have profound and long-lasting consequences on mental health and well-being (World Health Organization, 2020d). According to the evidence, the changes in mental health and wellbeing will not only affect those who have been infected with the coronavirus disease but will extend beyond those (O'Connor et al., 2021). The WHO has expressed concerns that mitigation strategies and containment measures such as self-isolation, quarantining, and physical or social distancing have changed daily activities, routines, and livelihoods of individuals that, in the long run, may increase perceptions of loneliness, anxiety, feelings of depression, insomnia, harmful consumption of drugs and alcohol, self-harm or even suicide (World Health Organization, 2020c). In the following, this thesis will explore the emergence of mental health issues as a consequence of the COVID-19 pandemic and will explore the differences in the mental health status between the general population and individuals with a pre-existing limited mental health status (*Chapter 5*). Thereby, it is also necessary to shed light on factors preventing a deterioration of the mental health status such as social support, a positive family climate, and family functioning, mindfulness and psychological flexibility, and a refocusing on positive outcomes (Gloster et al., 2020; Rossell et al., 2021).

1.4.1. A Psychological Approach to Understanding Effects of the COVID-19 Pandemic

Several approaches and theoretical perspectives have been used to explain responses and challenges to mental health and well-being during the COVID-19 pandemic. The mindfulness-based approach, for example, is well-suited for coping with mental health challenges as well as coping with short-term and long-term associations of the pandemic and mitigation measures (Antonova et al., 2021).

Mindfulness has been conceptualized as paying attention to specific and individual purposes, focusing on the present, and being non-judgmental (Kabat-Zinn, 2005) while practicing self-compassion in the face of negative thoughts and feelings. Individuals are encouraged to be observers without judging or reacting to negative feelings or thoughts thereby practicing decentering. The concept of decentering has frequently been associated with Cognitive Behavioral Therapy (CBT) as learning to decenter has been associated with preventing relapse concerning a depressive disorder (Fresco et al., 2007). Therefore, interventional approaches based on CBT should be offered to individuals to prevent a deterioration of their mental health status irrespective of a pre-existing limited mental health by practicing mindfulness as an emotion regulatory strategy (Chambers et al., 2009).

The *psychodynamic approach* is another approach or strategy that can explain COVID-related psychological responses. According to evidence, it has been shown that emotion regulation plays a central role in stress management and in adapting to changing situations and circumstances thereby helping individuals with discharged feelings and thoughts associated with the COVID-19 pandemic (Prout et al., 2020; Walker & McCabe, 2021). Therefore, the psychodynamic approach has been shown to moderate emotional reactions by enhancing adaption and resilience in stressful times (Aafjes-van Doorn et al., 2020; Békés et al., 2020). As the COVID-19 pandemic has been associated with a state of uncertainty and perceived distress, the psychodynamic approach may be able to support emotional regulation and management of perceived stress to prevent the rise of possible factors involved in the pathogenesis of psychological disorders (Di Giuseppe et al., 2019; Sardella et al., 2020).

According to the psychodynamic approach, individuals may activate unconscious mechanisms and psychological strategies to defend against uncertainty, stress, and anxiety related to the awareness of internal conflicts. Through the use of high-adaptive defense mechanisms an increased awareness of one's feelings related to difficult experiences, such as

those during the COVID-19 pandemic, may be elicited which may be associated with improved adjustment and resilience. The use of low-adaptive or immature adaptive responses may have been associated with less effective and rather maladaptive cognitive and relational dysfunctions. Therefore, interventions are necessary to train adaptive and mature defense mechanisms to improve or at least stabilize psychological well-being and adjustment (Giuseppe et al., 2020; Prout et al., 2019, 2020).

1.4.2. Possible Mental Health Issues as a Consequence of the COVID-19 Pandemic

The COVID-19 pandemic has concerned all individuals of all ages with profound changes in life and interaction (Cheng et al., 2021; Voitsidis et al., 2020) and requires a certain degree of individuals to deal with new challenges as well as to cope with the "new normal". Studies examining past epidemics such as the severe acute respiratory syndrome coronavirus type 1 (SARS-CoV-1) epidemic in 2003 or the Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in 2012 reported an increase in anxiety disorders, depression as well as posttraumatic stress disorders (Vindegaard & Benros, 2020). Evidence has shown that not only health-threatening but also financial and economic losses can pose threats to mental health and well-being as noted during the financial crisis in the United States between 2007 and 2008 (Forbes & Krueger, 2019). Forbes and Krueger showed that individuals affected by at least one major loss or impact such as finance, work, or housing displayed a higher probability of developing a mood or anxiety disorder (Forbes & Krueger, 2019). As the COVID-19 pandemic affects different areas of life, the pandemic may be considered a multidimensional stressor. According to previous evidence in the literature, five characteristics of the COVID-19 pandemic as a stressor have been defined: (1) The COVID-19 pandemic and related consequences are of global concern; (2) several individuals consequences and changes are interrelated with multiple life domains that pose as threats to mental health; (3) loss of control or helplessness may be experienced; (4) the systematic impact of COVID-19 on multiple domains of sociality; (5) limited access to protective measures (i.e., treatment measures or support systems and groups) during the COVID-19 pandemic (Brakemeier et al., 2020; Gruber et al., 2021). Hence, due to the multidimensional character of the COVID-19 pandemic, almost all individuals are affected at least to some extent by changes and require a certain amount of flexibility to cope with experienced stressors. However, according to the vulnerability-stressmodel when stressors and demands experienced during the COVID-19 pandemic exceed one's resources, paired with a pre-existing vulnerability, a risk for mental health problems such as depression, anxiety disorders or post-traumatic disorders arises (Marin et al., 2011; Smoller, 2016).

Studies, especially from countries with high infection rates at the beginning of the COVID-19 pandemic such as China, highlight a positive association between an increase in the prevalence of infection and an increase in depressive and anxious symptoms (Xie et al., 2020; Zhou et al., 2020). A study by Wang and colleagues assessed the psychological impact on the general population during the COVID-19 pandemic. Out of all surveyed individuals, 54% considered the impact of the pandemic between moderate to severe; 29% of respondents reported having moderate to severe anxiety symptoms; 17% perceived depressive symptoms to be moderate to severe (Wang et al., 2020). Overall, Sønderskov et al. (2020) revealed a general lower psychological well-being in the population during the COVID-19 pandemic compared to before.

A key term that is a protective factor for mental health is *psychological resilience*. Resilience has been understood to be a psychological mechanism supporting adjustment processes with coping flexibility being a central element of resilience (Lam & McBride-Chang, 2007). As resilience and coping flexibility have shown to be protective mechanisms in preventing the deterioration of mental health, the *theory of coping flexibility* will be used to demonstrate how different coping styles may be associated with mental health issues.

According to the theory of coping flexibility, effective coping, on the one hand, represents individuals' sensitivity to different situational demands part of changing environment, and on the other hand, demonstrates the flexibility and variability to develop and adjust different specific coping strategies to meet changing demands (Cheng et al., 2014).

Specifically, the adjustment process is defined by whether individuals turn to problemfocused coping strategies by deploying direct actions as part of perceived controllable but stressful situations or whether they turn to emotion-focused coping strategies such as distraction in perceived uncontrollable situations (Cheng et al., 2014). However, previous pieces of evidence have shown that inflexible coping styles have been associated with an increase in psychological symptoms. By comparing individuals with and without a decreased mental health status concerning their coping flexibility and coping style, the differences become evident. For individuals without a pre-existing mental health issue, heightened anxiety levels, such as those experienced during the COVID-19 pandemic, are characterized by an illusion of control (i.e., having the perception of having control over life events). Thus, those individuals tend to predominantly deploy problem-focused coping strategies (Cheng et al., 2021). Compared to individuals without a pre-existing mental health disorder, individuals with a pre-existing mental health disorder such as depression have been shown to perceive a sense of learned helplessness (Gan et al., 2006). Instead of experiencing perceived control over uncertain or stressful situations, those individuals tend to view situations and events beyond their control and, thus, deploy emotion-focused coping strategies (Cheng & Chau, 2019). Based on the differences in coping styles in stressful situations between individuals with and without a limited mental health status, this thesis will further explore differences in mental health between the general population and individuals with a pre-existing limited mental health status during the COVID-19 pandemic.

1.4.3. Protective Factors and Positive Aspects of the COVID-19 Pandemic on Mental Health

Despite the negative impact of the COVID-19 pandemic on mental health and well-being for some individuals, protective factors need to be examined as not all individuals, especially those without a pre-existing mental health limitation, reported a decrease in mental health and well-being. Therefore, this section will shed some light on possible protective factors. Evidence has shown that social support, a positive family environment, refocusing on positive outcomes that may provide individuals with a sense of agency, focusing on positive emotions or problem-focused coping (e.g., planning), and positive coping strategies (e.g., positive reframing) have shown to be protective factors against a deterioration of mental health and well-being (Agha, 2021; Gloster et al., 2020; Rossell et al., 2021). In addition to the above presented risks, however, the positive aspects of the pandemic should also be mentioned. Accordingly, it has been reported that only 27% of all participants did not perceive positive aspects and experiences from the period of corona restrictions and mitigation measures. Other participants reported positive experiences associated with increased mental health and well-being such as slowing down everyday life or focusing on important aspects of life (Brakemeier et al., 2020).

Rothmüller reported that some individuals who acknowledged the positive aspects of the COVID-19 pandemic also revealed more committed partnerships or marriages with deepened intimate relationships (Rothmüller, 2020). On another positive note, a reduction in drug and substance abuse has been reported. The reduction of risk factors and tempting situations, especially for gambling and drinking alcohol, could be associated with a decrease in consumption behavior. Evidence of a decline in the use of synthetic amphetamine (MDMA) and cocaine can be found in the Global Drug Survey (Winstock et al., 2020), which was attributed, among other things, to the lack of consumption opportunities outside the home and the limited contact with consumption partners. In rare cases, relatives reported positive effects

when there was a decrease in substance use and a strengthening of positive interaction patterns within the family (Bischof et al., 2020).

1.4.4. General Population vs. Individuals with a Pre-Existing Limited Mental Health Status

Several studies have highlighted elevated rates and symptoms of depression, anxiety, and perceived stress as well as post-traumatic stress resulting from the COVID-19 pandemic (Rogers et al., 2020). However, for individuals with a pre-diagnosed mental health disorder, symptoms may worsen (i.e., due to the prolongation of the restriction and mitigation strategies; Ettman et al., 2020). In addition, those already susceptible to a mental health disorder due to increased perception of stressors and a heightened vulnerability before the COVID-19 pandemic may develop psychological disorders as a consequence (Van Rheenen et al., 2020). MacDonald et al. (2022) revealed in a nationwide survey that across a span of 12 months depressive and anxiety symptoms were more likely to be reported by adults who also reported increased stress associated with the COVID-19 pandemic or who perceived greater uncertainty and loneliness. From a psychological perspective, these differences between the general population and individuals with a pre-diagnosed mental health disorder may be explained along with the vulnerability-stress model. The vulnerability-stress model assumes specific and individual vulnerabilities, such as pre-existing mental health disorders that predict or predispose one to psychopathological responses. In addition, it has been suggested that mental illnesses may manifest when the personal threshold for tolerating increased stress is exceeded in times of increased experienced stress such as during the COVID-19 pandemic (Bendau et al., 2021; Goh & Agius, 2010). Therefore, according to the vulnerability-stress model, there is a predisposed or genetic predisposition to developing a psychological disorder. With the addition of increased perceived stress or other psychological stressors (i.e., increased worries), mental illnesses and disorders may develop. According to the model, to normalize the perception of stress or to adapt to the stressors, constructive coping strategies and mechanisms are necessary. However, it needs to be mentioned that when stressors are perceived as uncontrollable, coping mechanisms become overwhelmed and individuals may be more prone to experience mental distress. If this status is prolonged for a longer period of time, the development of serious or even chronic mental health disorders may be the consequence. Consequently, concerning the COVID-19 pandemic, reasons for why and how individuals experience reduced mental health may well be explained along with the vulnerability-stress model (Bendau et al., 2021; Goh & Agius, 2010). To gain a better understanding of the different stressors perceived between individuals with and without a pre-diagnosed mental health disorder (i.e., psychosomatic rehabilitation patients), this thesis will further examine the prevalence and incidence of common experiences of psychological symptoms or disorders such as depression, anxiety, stress, and loneliness before and during the COVID-19 pandemic and will perform a comparison between the general population and between individuals with a pre-existing mental health disorder.

Prevalence and Incidence of Depression and Anxiety Before the COVID-19 Pandemic. Depression and anxiety disorders are two of the most common psychological disorders (Kandola et al., 2019; NVL, 2015). According to evidence in the literature, varying prevalence and incidence rates have been reported both internationally and nationally. Thakur et al. (2020) revealed a prevalence of anxiety and depression in 2015 of about 32.6% and an incidence rate for both depression and anxiety of 3.6 per 100 in 2015 in US American veterans. According to a systematic review and meta-analysis by Barker et al. (2019), an average prevalence of an anxiety disorder was estimated at 19.1% and 14.3% in children, adolescents, and young adults with life-limiting health conditions.

Two further studies evaluated the prevalence rates before COVID-19 of clinically significant generalized anxiety and depressive symptoms in young adults without any

limitations or previous disabilities and found a prevalence rate for anxiety at 11.6% (Tiirikainen et al., 2019) and depression at 12.9% (Lu, 2019). According to the World Health Organization, the world prevalence of depression and anxiety has been reported to be 4.4% for depression and 3.6% for anxiety. Specifically, the prevalence in Germany has been reported to be 5.2% for depressive disorders and 5.8% for anxiety-related disorders in 2015 (World Health Organization, 2017). According to recent reports by the Robert Koch-Institute, the risk of developing a lifetime prevalence of depression in Germany is on average 9.2% and therefore higher than in most other European countries (Robert Koch-Institut, 2019). However, it needs to be stressed that the incidence rates have largely been underreported in literature and are very dependent on the sample being examined (Barker et al., 2019).

Prevalence and Incidence of Depression and Anxiety During the COVID-19 Pandemic. Several studies have begun to explore the prevalence and incidence rates of depression and anxiety disorders during the COVID-19 pandemic. Results have shown a substantial increase in anxiety disorders. Several systematic reviews and meta-analyses revealed an average prevalence of 25% to 21.8% for anxiety and 26.9% for depression (Bareeqa et al., 2021; Santabárbara et al., 2021). However, it needs to be stressed that the average prevalence values largely depend on the measurement instrument used as well as the point of time during the COVID-19 pandemic at which data was collected. Next to the increase in the prevalence of mental health disorders, another worrying finding for a study by Puccuinelli et al. (2021) revealed increased incidence rates for both depression and anxiety of 30% and 23% respectively. However, more research is necessary to evaluate the current prevalence and incidence rates at different points in time during the COVID-19 pandemic.

The COVID-19 Pandemic Affecting Both the General Population and Individuals with a Pre-Existing Mental Health Status. Increasingly, evidence in literature has shown a strong association between the COVID-19 pandemic and changes in mental health and a

subsequent increase in experienced anxiety and depression (Rajkumar, 2020). Since the beginning of the pandemic, studies have shown increases in incidences of reported depression and anxiety. Between late January 2020 and early February 2020, a study by Wang et al. (2020) reported that 28.8% of the examined sample perceived moderate to severe anxiety symptoms. Additionally, 16.5% of the participants reported moderate to severe depressive symptoms.

Moreover, a later survey conducted between March 2020 and May 2020 reported even higher incidences of depression, anxiety, and stress. 65.6% of the participants reported clinically significant levels of the mentioned variables (Tso & Park, 2020). These findings suggest that the prolongation of the coronavirus pandemic may consequently lead to an increase in incidences associated with mental health disorders. According to experts, it is expected that the prolongation of the pandemic will have even more detrimental effects or will exacerbate latent or pre-existing mental health conditions (Druss, 2020; Pfefferbaum & North, 2020).

Increased fear and stress resulting from the additional burden of epidemics or pandemics are associated with every aspect of life in both earlier research and present research. Evidence suggests that epidemics and pandemics can have traumatic experiences for some individuals and may lead to distress and consequently to increased psychological symptoms (Hahn, 2020). The outcomes of the coronavirus pandemic and the associations with mental health have been suggested to be different according to whether individuals had a prior mental health disorder. Specifically, the emotional response, perceived control, and the differently employed comping mechanisms (i.e., problem-focused coping or emotional-focused coping) might be more indicative of changes in mental health in the vulnerable group (The Lancet, 2020; Yao et al., 2020b). A common factor of individuals with a limited mental health status is a reduced social network. Hence, the containment measures of the COVID-19 pandemic, which focused in parts on physical and social distancing, travel restrictions, and quarantining, could have posed unprecedented additional stressors to individuals with a pre-existing limited mental health

status (Druss, 2020). Despite a reported increase in symptoms for both groups (i.e., with and without a prior mental health diagnosis), evidence has reported no significant exacerbation of symptoms for individuals with pre-existing high and severe levels of symptoms. Symptoms, related to depression, anxiety, worry, loneliness, and (di-) stress increased more in individuals with no or a mild to a moderate chronic mental health disorder, which could call for an increased need for the provision of mental health care services (Pan et al., 2021).

To sum up, on the one hand, most evidence suggests that the general public showed increased symptoms of depression, anxiety, stress-related to the COVID-19 pandemic, and loneliness as a result of additional psychosocial stressors. Besides the associations of the COVID-19 pandemic, potential benefits such as the reduction in social pressure as well as the exposure to psychosocial stressors were highlighted (HSE, 2021; The Children's Society, 2020). On the other hand, individuals with a pre-existing mental health disorder have indicated increased symptoms related to depression and anxiety as well as post-traumatic stress and insomnia (Hao et al., 2020). Additionally, physical distancing has reduced the possibility of partaking in as well as the availability of support networks (i.e., family, social and psychiatric support). As individuals with a pre-existing mental health diagnosis are at risk of socioeconomic disadvantages, they are at risk for both direct and indirect negative consequences associated with the pandemic (Kozloff et al., 2020). Considering all factors together, it may be postulated that individuals with pre-existing mental health disorders are generally at a higher risk of chronic development or worsening of symptoms in the long run.

However, so far literature and pieces of evidence are relatively scarce on the direct comparisons between individuals with and without a pre-existing mental health disorder. Hence, this research gap will be examined in *Chapter 5*. Furthermore, the relationship between the variables distress experiences as part of the COVID-19 pandemic, anxiety, loneliness, and depression remains of interest and will be explored in *Chapter 6*.

1.4.5. The Need for Effective Communication.

Next to the examination of how the COVID-19 pandemic interrelated with the mental health status and well-being of individuals with and without a pre-existing mental health condition, factors contributing to changes in mental health also need to be considered. Communication, such as risk and crisis communication, has played an essential role in how the public responds to health emergencies (Reynolds & Seeger, 2005). According to the evidence, crisis communication has the beneficial function of being cost-effect and being able to address multifaceted issues (Coombs, 2010). However, for crisis communication to be effective in the media or also in the health care context, certain communication skills are required. According to Rider and Keefer, communication needs to focus on interpersonal relations. Hence, it has been suggested that for communication to be effective, it is important to communicate clearly and accurately and provide the individual with sufficient information. Effective communication also needs to consider the individual's situation (Rider & Keefer, 2006).

Specifically, in the health care context, the focus of effective communication (i.e., such as during psychotherapy sessions) has been deemed important. It has been shown that a cooperative working atmosphere or a therapeutic alliance with a patient may only be achieved, once effective communication strategies have been employed. In addition, for patients, such as psychosomatic rehabilitation patients, to improve their mental health status, they need to be encouraged and trained to use effective communication strategies to first reflect on and understand maladaptive cognitions, emotions and behaviors before applying effective coping skills (Söllner et al., 2007). However, the association between the perceived effectiveness of communication and improvements in mental health has so far not been assessed in the psychosomatic rehabilitation context. Hence, *Chapter 7* will perform such an evaluation.

1.4.6. There is no Glory in Prevention

Several mitigation strategies have been imposed by the German government to prevent the spread of the COVID-19 virus. However, until now there has been some degree of uncertainty about whether those containment measures were too extensive or maybe just right. During an interview in 2020, Christian Drosten drew attention to the so-called prevention paradox by saying "There is no glory in prevention", meaning that no glory will be achieved despite successful prevention strategies. Geoffrey Rose was the first to introduce this paradox in a study examining prevention strategies for coronary heart disease in which he states that preventive measures that may be beneficial to the entire population, may be of little benefit to the individuals and vice versa (Rose, 1985).

This notion can easily be transferred to the COVID-19 pandemic and the associated mitigation strategies. According to an international comparison between different restriction strategies by Gibney in 2020, countries such as Germany and Austria have employed relatively aggressive mitigation strategies compared to Sweden, the United Kingdom, and the Netherlands. In addition, Germany and Austria, in comparison to France, Italy, and Spain, have employed those strategies relatively early on during the pandemic, resulting in lower deaths per capita (Gibney, 2020). Research is currently trying to evaluate these results to make informed policy changes (Ruiz et al., 2021; Xiao, 2021). Hence, with regard to the current thesis, the social-cognitive behaviors of hand hygiene behavior, an effective mitigation strategy that has frequently been promoted along with the AHA-L rules in Germany (Nohl et al., 2021; World Health Organization, 2009), will be evaluated in *Chapter 4*.

1.5. Digital Approaches to Provide Support

Individuals with a pre-existing mental health disorder have reportedly perceived reduced access to support systems, experienced earlier discharges from psychiatric units or wards as well as a discontinuation of psychotherapeutic treatment (Chevance et al., 2020; Hao

et al., 2020; Yao et al., 2020a). However, to provide continuous support for those individuals during the COVID-19 pandemic, the state of art in mental health care had to drastically change. As a consequence, for individuals with a pre-existing mental health disorder, health care services have increasingly adopted electronic mental health (e-Mental health) tools, which have been shown to provide a solution for continuous high-quality mental health care while following all containment and mitigation strategies (Riva & Wiederhold, 2020; Zhou et al., 2020). Thus, this thesis will focus on the necessity and importance of providing continuous treatment for individuals with a pre-existing limited mental health status and will consider motivational and intentional factors relevant for the continuation of treatment. Further, social and environmental factors that may hinder or support psychotherapeutic treatment processes will be examined while considering digital therapeutical supplements to traditional face-to-face therapy.

1.5.1. The Necessity of Providing Continuous Treatment Options

The continuation of psychological treatment and access to essential psychological support has become more evident and more important during the COVID-19 pandemic, which has been characterized by disruptions in the provision of mental health care (Feijt et al., 2020). According to NeJhaddadgar and colleagues, the disruptions in mental health care have disproportionally affected those individuals with pre-existing mental health problems (NeJhaddadgar et al., 2020). However, especially for those individuals with mental health disorders before the pandemic, a new traumatic experience such as the COVID-19 pandemic can increase and aggravate distress and may trigger new symptoms (i.e., anxiety-related symptoms) and stimulate earlier traumatic experiences (Ronen-Setter & Cohen, 2020). To prevent a relapse or the worsening of psychological symptoms, continuous treatment is necessary. One option to ensure continuous treatment for individuals with a pre-existing mental

health disorder is the use of digital therapeutic elements such as internet- and mobile-based interventions in psychotherapy (IMIS; Lin & Baumeister, 2015).

1.5.2. Mental Health Care and Psychotherapy

As the transmissibility of the COVID-19 virus via direct personal contacts hinders direct face-to-face contact in mental health care, there is a common agreement to offer and use e-Mental health options to provide a continuation of care. Hence, the use of e-Mental health has rapidly become the "new normal" during COVID-19 (Martinez-Martin et al., 2020). Mental health offers and services conducted via the internet have been known as e-therapy, internet-based therapy, or online counseling and have integrated two "therapy worlds" into one: the more traditional form of face-to-face therapy together with digital elements either as a standalone form of therapy or as an integration (Wells et al., 2007).

Per definition e-Mental health has been defined as "mental health services and information delivered or enhanced through the internet and related technologies. It includes all technology-enabled therapies, including internet-based programs, mobile phone applications, telehealth, and informational websites" (page 475, Stone & Waldron, 2019). Previously, the uptake of e-Mental health tools has often been reluctant and limited. However, since the COVID-19 pandemic resulted in a sharp global shift and has increased the focus on digitalization, e-Mental health has shown to be an important tool to ensure and provide care. (Vis et al., 2018; Wind et al., 2020). To compensate for the limitations in access to therapeutic support created by the COVID-19 pandemic, it has become apparent that alternative treatment formats, such as remote sessions via telephone, internet, or the introduction of so-called Digital Health Applications (DiGAs) have received greater positive reception (Wright & Caudill, 2020). As a consequence, in addition to face-to-face therapy sessions, online services have been increasingly offered and utilized to ensure a continuing and ongoing treatment that aligns with hygiene guidelines (Kapoor et al., 2020).

Already since 01.04.2019, it has been possible for psychotherapists to bill the video consultation as a therapeutic session, but only for a maximum of 20% of patients. Due to the digital turnaround in the context of the coronavirus pandemic, the National Association of Statutory Health Insurances (Kassenärztliche Bundesvereinigung) decided on 25.03.2020 that to ensure adequate care for patients who are in quarantine or have previous health concerns, but also to not expose elderly people to a risk of infection, a psychotherapeutic consultation hour, as well as the probationary talks, are possible via video phone call and the restriction to a maximum of 20% of patients was suspended (BPtK, 2020).

In the field of e-Mental health offerings, there is a wide range of digital media used in the prevention, treatment, or rehabilitation of mental disorders (Baumeister et al., 2018; Ebert & Baumeister, 2020). In this context, online-only therapy is a self-directed intervention program with a set treatment protocol (Eichenberg, 2021). However, the type of intervention offered can be adjusted to the personal preferences of the person being treated. There are different levels of e-Mental health options that range from self-directed or unguided self-help to guided self-help. These interventions are mostly cognitive-behaviorally oriented and are especially suitable for the treatment of depression as well as anxiety disorders (Stein et al., 2018). In addition, mental health interventions delivered digitally have shown to be a lower-cost alternative compared to traditional face-to-face therapy (Zhang et al., 2014).

Another variation of online therapy is "blended therapy." A combination of various digital treatment modules and face-to-face therapy modules (Eichenberg, 2021). Again, there are different options for digital offerings. These offerings can be guided or unguided and incorporated into treatment. One format of blended therapy that has been frequently examined in literature is internet- and mobile-based interventions (IMIs). IMIs have been used as an additional tool running alongside psychotherapy and serve to support the actual therapeutical

progress. Besides, therapy concepts part of IMIs can be reviewed or reworked, which leaves the psychotherapist more time for focused therapy content.

For psychotherapists, IMIs provide important information regarding the diagnosis or recognition of crises. This information can be collected via questionnaires (Baumeister et al., 2018; Ebert & Baumeister, 2020). If IMIs are used for support, there are two applicable options. Either IMIs may replace a psychotherapy session, or they serve to enhance psychotherapeutic progress in addition to the traditional face-to-face psychotherapy sessions. As suggested, the best use of IMIs to improve psychotherapeutic outcomes (Baumeister et al., 2018; Ebert & Baumeister, 2020) is to incorporate these digital offerings into face-to-face therapy processes. For this purpose, questionnaires, videos, or short exercises can be used to strengthen the patient's problem-solving resources. However, for e-Mental health options, such as IMIs to be effective, individual social and environmental factors need to be considered.

1.5.3. Considering Individual Barriers Concerning the Psychotherapeutic Treatment

e-Mental health interventions have shown to be relevant for those individuals considered to be at risk for developing a serious mental health disorder or for those with a mild-to-moderate symptom expression (Donker et al., 2015). Evidence has shown that e-Mental health interventions are often as effective as traditional face-to-face therapy and have the potential to reduce or lower key barriers such as reducing costs, time, and accessibility as well as stigma (Batterham et al., 2015). For e-Mental health options to be effective, individual barriers need to be identified and considered. It has been shown that e-Mental health interventions have been promising in providing effective support for individuals. Nevertheless, non-completion, non-adherence, or drop-out are relatively high (Clarke et al., 2015; Grist et al., 2019).

Despite the many reported advantages of e-Mental health interventions such as that online treatments can be administered remotely, provide more flexibility for both the patient and the therapist, reduce the stigma or provide early and quick support in regions where therapeutical help may not be readily available, several barriers that are associated with dropout and non-adherence need to be considered, too (Erbe et al., 2017; Lindhiem et al., 2015).

According to several studies, common barriers to the uptake of e-Mental health included a lack
of general education on the availability of such treatment options, the increased costs associated
with hardware and internet access (i.e., not every individual even in Germany has access to a
laptop/ tablet or the internet), and the additional time demands (i.e., such as with IMIs; Waller
& Gilbody, 2009). In addition, individuals have reported concerns with data security or reported
general anxiety about using the internet. Furthermore, some individuals were concerned about
the e-Mental health tool itself (Batterham et al., 2015; Ebert et al., 2015; Waller & Gilbody,
2009). Next to the environmental factors, individual factors also need to be considered.
Individuals with limited internet health literacy or with generally limited literacy (Erbe et al.,
2017) may be overwhelmed in completing e-Mental health modules on their own.

e-Mental health interventions require a certain degree of introspection and the ability to self-reflect. Hence, individuals lacking those skills may not profit from digital interventions and are more likely to drop out. In addition, previous negative experiences with digital e-Mental health interventions may inhibit the uptake of new digital interventions or traditional face-to-face therapy overall potentially leading to a deterioration of their symptoms (Marks et al., 2004). Therefore, based on the aforementioned pitfalls of e-Mental health interventions, interventions such as IMIs should be tailored to the specific needs of patients, adapted to their previous therapeutical progress, and accompanied by occasional traditional face-to-face contact with psychotherapists to support adaptation to prevent drop-out and non-adherence.

1.5.4. The Need to Foster Motivation

Initial patient motivation, among other factors known to be associated with individual cognitive behavioral therapy, is considered vital for the continuation of treatment and the subsequent outcome and success (Vogel et al., 2006). Typical characteristics of individuals with

a limited health status include a loss of motivation and apathy (Wilson et al., 2007). Another study has highlighted that individuals with increased levels of psychological symptoms tend to show lower intentions specifically concerning help-seeking behavior (Wilson et al., 2005). Evidence indicates that patients who show an increase in motivation during therapy perceived the greatest symptom reductions, and reported a better therapeutic alliance as well as greater adherence to treatment compared to those individuals lacking motivations (Hunter et al., 2014; Lombardi et al., 2014; Simpson & Zuckoff, 2011). Hence, strategies need to be developed to foster intention and motivation to improve and continue with therapy. Therefore, it has been suggested to employ engagement-facilitation interventions (EFIs) as well as to consider consumer involvement. EFIs aim to increase patient engagement both in the uptake as well as in the maintenance and adherence to therapy. According to the EFIs, this may be achieved by addressing common factors associated with the acceptability and barriers of digital interventions (Donkin & Glozier, 2012).

Whereas the EFIs aim to increase engagement, involvement strategies focused on choosing appropriate tasks based on the skills of consumers, such as psychosomatic rehabilitation patients. Consumer involvement has been deemed necessary to foster the intention concerning uptake and adherence by tailoring the content as well as by assessing the appropriateness of the content to complement one's capabilities (Bovaird, 2007; Suomi et al., 2017). The current literature calls for specific tailoring of digital health interventions such as e-Mental health interventions to the individual and environmental factors as well as to the psychological diagnosis to improve intention and motivation, thereby, ensuring uptake and adherence. In later parts of this thesis, variables associated with intention and maintenance will be examined (*Chapters 5 and 7*).

1.6. Therapeutic Changes during the COVID-19 Pandemic

As previously stated, psychotherapeutic changes for out-patient care included shifting from the traditional face-to-face therapy setting toward the implementation or integration of digital components (i.e., IMIS) into mental health care processes. Several studies have examined the effectiveness of such digital or e-Mental health interventions. Results have demonstrated that the integration of such digital components has been successful in symptom reduction and therapeutic progress (Domhardt et al., 2020; Ebert et al., 2018). However, literature and studies on the integration of digital components into inpatient treatment settings, such as medical psychosomatic rehabilitation, are lacking. Hence, this thesis will, as a first step, provide an overview of the digital tools that have the potential to be integrated into the rehabilitation context.

Chapter 5 and Chapter 7 will, on the one hand, evaluate whether integrating different digital components in the form of blended therapy increases symptom reduction and, on the other hand, will evaluate the effectiveness of the inclusion of digital treatment programs into traditional face-to-face programs. Psychosomatic rehabilitation patients represent a sub-group of individuals with pre-existing mental health problems which may have been specifically neglected during the COVID-19 pandemic due to the mitigation and containment strategies imposed on hospitals and rehabilitation clinics. According to imposed regulations, if patients choose an uptake of a psychosomatic therapy program, they may be faced with changes and difficulties during their stay such as contact regulations (i.e., having no or only a limited number of visitors, limited contact with fellow patients, increased hygiene measures and smaller group sizes during therapy). However, if left untreated (i.e., deciding against a rehabilitation stay), an aggravation of experienced symptoms as well as of the overall psychological status may be experienced (Dahmen et al., 2021). Providing continuous treatment for individuals with a pre-existing mental health condition, such as in psychosomatic rehabilitation settings, has been

particularly challenging. Besides the general difficulty in providing psychosomatic rehabilitation (for example they tend to be regionally bound), other challenges include long wait times, limited capacities, and a reduced available number of qualified personnel. These challenges have been amplified during the COVID-19 pandemic. Health care priorities in Germany have shifted since early March 2020 toward the premises of (a) preventing infections and slowing down the spread of the COVID-19 virus and (b) ensuring sufficient care, including the provision of a large number of intensive care beds to severely ill individuals infected with the SARS-CoV-2 virus. As a consequence of these changes, only a few rehabilitative treatment options and services were available to individuals with chronic illnesses, such as those with psychological disorders. One reason for the limited availability was the partial mandatory closure of most rehabilitation clinics for inpatient treatment but also due to the reduced capacity of personnel available for the treatment of patients. Additionally, the initial lack of protective equipment and the shortage of hygiene measures has reduced the therapeutic capacities available to patients. These changes in the provision of care result in challenges for individuals with pre-existing limited mental health such as (a) a lack of treatment, improvement, stabilization, and relapse prevention for psychosomatic and psychological patients and (b) a feared possibility that postponed interventions may lead to chronic developments with potentially serious consequences for mental health and well-being such (Gutenbrunner et al., 2020). To compensate for those limitations and restrictions in the treatment process of psychosomatic rehabilitation patients, digital tools provide an option in the context of a psychosomatic rehabilitation setting to close the gap between adversities experienced by patients and to ensure adequate care (Kobelt et al., 2011). Hence, it may be recommended that psychosomatic rehabilitation clinics start to integrate digital elements into the therapy process.

1.6.1. Content of a Medical Psychosomatic Rehabilitation Treatment Program

According to the regulations for rehabilitation treatment programs in Germany, the main focus of the rehabilitation system is on reintegration and support of participation along the lines of the biopsychological model. According to data by Bengel et al. (2003), 60% of diagnosed mental health disorders may have a chronic course. As a consequence of this, impairments at the workplace or in daily functioning have been found. Compared to psychiatric wards which tend to treat patients with severe and chronic mental health disorders, psychosomatic rehabilitation settings tend to take the stance of a multidisciplinary and interdisciplinary therapy setting fostering return to work and social participation. By offering therapy along the lines of occupational therapy, physical therapy, psychoeducation, musical therapy, and individual and group psychotherapy, skills relevant for reintegration as well as return to work are being trained (Scheidt, 2017; Zipfel et al., 2016).

1.6.2. Implementation of Digital Treatment Options during a Medical Psychometric Rehabilitation Stay

Several studies have examined the integration of blended therapy at different stages of the rehabilitation process: before, during, and after the rehabilitation stay itself (Becker et al., 2016). First attempts to integrate digital elements and digital support in the rehabilitation process have been made by Curriculum Hannover Online (CHO). CHO online is a rehabilitation aftercare program that follows a guideline for group interventions (Gao et al., 2021; Kobelt & Grosch, 2005). A further internet- and mobile-based intervention that has been used in the support after a rehabilitation stay is DE-RENA which focuses on supporting patients in their return to daily life, consolidating individual rehabilitation goals, and preventing relapse (Schmädeke et al., 2019). However, studies that evaluate the implementation and effectiveness of digital elements prior to and during a psychosomatic rehabilitation stay are lacking. Hence, *Chapters 5* and 7 will focus on these topics of interest.

1.7. Research Gaps: Understanding Patient Safety and Mental Health Care

The previously presented literature conceptualized the background of this PhD thesis. The current section will now point out gaps in theory as well as in practice which this dissertation aims to close. All research gaps will center around fostering and improving a common understanding of patient safety and patient care with a focus on mental health and well-being. According to the above-mentioned literature, patient safety has gained more prominence during the recent decade (i.e., Cheraghi-Sohi et al., 2021). It has been shown that patient engagement (i.e., empowering the patient to be an active agent in engaging in informed decision processes concerning own health and well-being) has been frequently recognized as an essential aspect of patient safety (Geraedts et al., 2020). Still, however, studies have mainly focused on defining patient safety from the perspective of health care professionals and disregarded the patient perspective. Hence, instruments to quantitatively assess factors that may pose a danger to patient safety, so-called triggers, need to be developed from the perspective of a patient. In addition, as more and more individuals are affected by the COVID-19 pandemic and experience a decrease in mental health (i.e., evaluated by changes in symptoms related to depression and anxiety), instruments need to be robust to changes in mental health.

After acknowledging that the patient plays an integral part in ensuring patient safety, patients need to be integrated into actively participating in ensuring their safety (Geraedts et al., 2020). For that, one of the most common factors associated with threats to patient safety, specifically during the COVID-19 pandemic, is a lack of hand hygiene (Wilder-Smith & Freedman, 2020). Therefore, patients need to be educated on how to perform effective hand hygiene which has been acknowledged by previous evidence in the literature. However, what has been missing is a theoretical contribution examining the mechanisms and social-cognitive variables that lead to the formation of intention and maintenance to perform effective hand hygiene behavior. It has been shown that individuals with depressive symptoms have been

demonstrated to have motivational deficits (Fervaha et al., 2016; Raskin et al., 2012). In addition, individuals with an anxiety disorder are more prone to increased adherent and dysfunctional safety behaviors (i.e., excessive hand hygiene behavior). In the case of the COVID-19 pandemic, it has been found that individuals with increased anxiety or with a diagnosed anxiety disorder paid more attention to hygiene behavior and the consequent implementation of mitigation recommendations. Nevertheless, those individuals did tend to engage in dysfunctional ways, leading to a decoupling of recommendations to an anxious state. Hence it may be assumed that concerning the COVID-19 pandemic, perceived fear and anxiety may reinforce and maintain dysfunctional behaviors (Kohler et al., 2021; Maner & Kenrick, 2010). However, so far, literature has not examined whether factors associated with a decreased mental health status may be able to explain effective hand hygiene practices or whether social-cognitive variables, such as self-efficacy, outcome expectancies, risk perception, intention, or planning, can explain hand hygiene behavior as a health behavior.

The COVID-19 pandemic has contributed to changes in mental health and well-being and has at worst led to an increase or aggravation of psychological disorders. However, the literature is missing comparative investigations on the impact of the COVID-19 pandemic on individuals with and without a pre-existing limited mental health status. In addition, even though some studies have evaluated commonly experienced worries and concerns associated with the COVID-19 pandemic, no study was able to draw a direct comparison between both groups: individuals with and without a pre-existing limited mental health status. As the consequence of an increased psychological strain and due to limited access to mental health care during the coronavirus pandemic, the intention to use digital supplements to improve mental health and well-being will be evaluated between the general population and individuals with a limited mental health status.

Evidence has shown that individuals with a pre-existing limited mental health status are particularly vulnerable to a deterioration of their mental health status (e.g. Fiorillo & Gorwood, 2020). Accordingly, this group of individuals has reported higher health-related worries and concerns compared to the general population, an increase in distress associated with the coronavirus disease, an increase in perceived fear and loneliness as well as depression. However, so far, no study has focused on the directionality and the relationship between these variables to make informed decisions on treatment plans by recognizing and acknowledging the interrelation between these symptoms and possible sustaining and maintaining factors.

To provide continuous treatment options for patients with a pre-existing limited mental health status, evidence has suggested implementing digital aspects into therapy processes (Lin & Baumeister, 2015). However, so far literature is lacking evaluations concerning the effectiveness of digital interventions incorporated into the traditional treatment process of psychosomatic rehabilitation patients. Hence, this thesis will focus on determining the effectiveness of implementing digital interventions before and during the rehabilitation stay into traditional face-to-face treatment processes.

1.8. An Overview of Theoretical Frameworks

1.8.1. Modeling Behavior Change

Evidence has shown that a critical element in behavior change in individuals with a limited mental health status is to elicit intention or motivation to perform changes (Wilson et al., 2005). Accordingly, it may be suggested that the perceived psychological strain needs to be high enough to evoke those changes. Models considering behavior changes have frequently been used in health psychology concerning health-related behaviors such as physical activity or healthy eating (Lippke et al., 2021; Lippke, 2014; Prochaska et al., 1992; Schwarzer, 2008; Schwarzer et al., 2011). Increasingly, however, have those models found more acceptance in the field of rehabilitation and clinical psychology (Krämer et al., 2014; Zarski et al., 2018).

Thus, in the following section of this dissertation, the two models, namely the Health Action Process Approach and the Compensatory Carry-Over Action Model (CCAM), will be presented.

Single behavior change theory: The Health Action Process Approach. The Health Action Process Approach (HAPA; Schwarzer, 2008) has been known as a social-cognitive model specifying motivational and volitional components and determinants of health behavior changes. According to Schwarzer, the HAPA model, known as a hybrid model, is divided into two phases: the motivational phase and the volitional phase. Whereas the motivational phase focuses on the formation of an intention, the volitional phase concentrates on maintaining the desired behavior. According to the literature and evidence on the HAPA, three social-cognitive variables are necessary for the formation of an intention to perform a certain health-related behavior. These include self-efficacy, outcome expectancies, and risk perception. As per definition, self-efficacy is the belief in own capabilities that are necessary to perform the desired behavior. Outcome expectancies, either positive or negative, are individual beliefs about a certain outcome of a performed behavior. Lastly, risk perceptions, which describe the subjective perception about one's susceptibility towards a possible threat, make up the motivational phase. For an intention to be formed, however, all three variables need to be perceived as relevant (Schwarzer, 2008; Schwarzer et al., 2011).

Planning has been integrated into the HAPA model as an intermediate step between the motivational and volitional phase (i.e., between intention and maintenance of the subsequent behavior). Therefore, planning is assumed to bridge the intention-behavior gap and hence assumes the function of a mediator variable. According to the intention-behavior gap, however, even if individuals hold strong intentions to perform the desired behavior, without sufficient planning capabilities the intention may not be translated into actual behavior. To successfully bridge the gap, individuals are required to make action plans focusing on when, how, and where

the desired behavior will be performed, as well as coping plans, which refer to strategies employed to cope with challenges. Therefore, for individuals to move from the motivational phase to the volitional phase, they need to possess the ability to combine intentions with the desired outcome behavior by planning and activating self-regulatory behaviors that ensure maintenance of the behavior without relapsing to previous old habits (Schwarzer, 2008; Schwarzer et al., 2011; *Chapter 4 and Chapter 5*).

Multiple behavior change theory: The Compensatory Carry-Over Action Model. So far, most models relevant to health psychology, have only addressed one health-related behavior. The Compensatory Carry-Over Action Model (CCAM), however, aims to address multiple health-related behavior changes (Lippke, 2014). The CCAM describes processes and associated mechanisms by connecting one health behavior and its determinants to further health behavior and its determinants, respectively. The applicability and validity of the CCAM have been shown in several health-related areas such as physical activity, healthy eating (Lippke, 2014), harmful behaviors such as smoking (Joveini et al., 2020) as well as problematic internet use (Gao et al., 2020). According to the CCAM, health behavior may be interrelated in terms of compensating for one another, thus, implying compensatory health beliefs. Compensatory health beliefs have been defined as the compensation of negative and unhealthy behavior by engaging in healthy behavior (Rabiau et al., 2009). Hence, the CCAM draws on model structures from the HAPA as well as from the Compensatory Health Beliefs Model with different social-cognitive variables for single health behaviors and extends the perception from single to multiple health behaviors (Lippke, 2014). According to evidence, the CCAM has been shown to integrate well-being as a higher level-goal of individuals into the model structure. Hence, higher-level well-being goals may play a significant role in psychological mechanisms underlying changes in health behaviors, which have also been related to mental health and wellbeing (Lippke et al., 2021).

In conclusion, social-cognitive models have been shown to explain health behavior changes and interrelations between multiple health-related behaviors. In addition, models have been used as a basis for informing interventions and trainings in health care not only limited to health psychology but also in fields relevant to rehabilitation and clinical psychology. Therefore, this thesis draws in parts on the HAPA (*Chapter 4*) to examine the applicability of the model structure in the context of hand hygiene as a health-related behavior. In, addition the HAPA has been used in *Chapter 5* to examine the intention to use digital interventions in the prevention and treatment of a reduced mental health status. Furthermore, the CCAM (*Chapter 7*) has been applied to explain how adaptions to the psychosomatic rehabilitation process (i.e., the integration of digital trainings to support goal attainment and foster communication) are associated with changes in mental health and well-being.

1.8.2. The Evolutionary Theory of Loneliness and an Extension to the Theory

According to evidence in the literature, changes in mental health as a consequence of changes in daily life due to the COVID-19 pandemic have been shown. These changes in mental health include, besides others, increased perception of loneliness, anxiety, and depression (Gallagher et al., 2021; Li et al., 2021; McPherson et al., 2021; Megalakaki et al., 2021; Wang et al., 2020). As the COVID-19 pandemic may represent a traumatic event, specifically for individuals with a limited mental health, the Evolutionary Theory of Loneliness (ETL) will be used to determine the interrelations between experienced traumatic distress, anxiety, loneliness, and depression (Cacioppo & Cacioppo, 2018). The ETL provides a theoretical explanation of how loneliness emerges, is maintained, and may interrelate with physiological and mental health symptoms over time. As perceived loneliness is considered to be associated with experiences of physical pain, loneliness has been termed as a signaling function that needs may not be fulfilled (Cacioppo & Hawkley, 2009). *Chapter 6* provides an extension to the ELT by assuming an interplay between distress associated with the COVID-19 pandemic that may

Chapter 1

consequently lead to an increased perception of anxiety. The increased perceived anxiety symptoms, in turn, may elicit a withdrawal from social contacts, thus, increasing perceived loneliness. As loneliness is a sustaining and central element of depression, prolonged feelings of loneliness may in the long run also increase symptoms associated with depression, thus, leading to a vicious circle. However, as the interrelation and the directionality have not been previously examined, this dissertation will refer to results from *Chapter 6*.

Chapter 2: Research Aim and the Overall Goal of the

Dissertation, Research Questions, and Related Hypotheses

1.1. Psychological Lens of this Dissertation

The COVID-19 pandemic can be termed as a multifactorial crisis that is assumed to be perceived by individuals as an intolerable and difficult experience. It has been known that psychological factors play a role in how individuals experience and cope with the consequences of the COVID-19 pandemic, which includes maladaptive behaviors or coping strategies, experienced emotional distress, or defensive responses (James & Gilliland, 2001). Several theories, frameworks, and models have aimed to explain different reactions and the consequences of the COVID-19 pandemic, as a crisis, on governmental policies, on the social level, and the individual level. For example, the system level approach assumes governmental changes and policies (i.e., mental health promotion and mental health policies) on the macrolevel, primary health care infrastructures and support systems as well as effective and safe care processes and community support networks on the meso level, and individuals with a chronic condition or a pre-existing mental health issue on the micro level (Stabler et al., 2021). Accordingly, to compensate for the proposed challenges at the different levels due to the COVID-19 pandemic, coordinated responses with feedback loops between the three levels should be performed. Hence, the macro level should be concerned with a rapid adjustment of policies, setting priorities, and targeting resources to ensure multisectoral responses; on the meso level, it has been recommended to develop partnerships, and provide integrated and inclusive support systems to ensure quality in care and continuous support; concerning the micro level perspective, vulnerable groups should be identified, support should be offered, and structures in daily life should be adapted to the needs of those individuals.

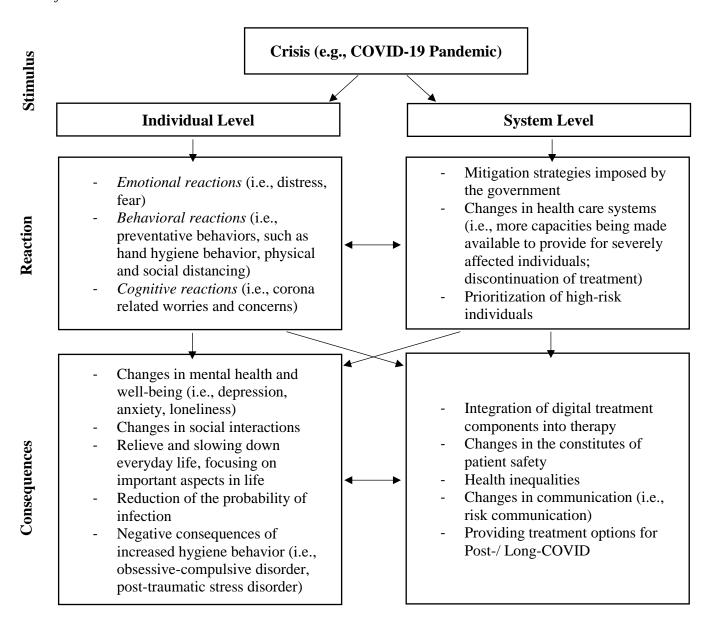
The *biopsychosocial model* provides another integrated perspective on understanding the COVID-19 pandemic (Engel, 1977). According to the model, determinants of health, disease, or well-being depend on the dynamic interaction between the following entities: biological, psychological, and social factors. Applying the biopsychosocial model to the COVID-19 pandemic, the coronavirus represents the biological aspect of the model. The psychological factor has been described with common experiences reported during the COVID-19 pandemic, such as fear, anxiety, depression, loneliness, stress, panic, or in the worst case suicidal attempts. Concerning the social factor, the respective entity concerns social aspects that are associated with changes in individuals, groups, and communities. Hence, focusing on economic, cultural, domestic, and socioeconomic variables (Jadoo, 2020).

The *stress system model* has in previous literature been adapted to the context of the COVID-19 pandemic (Coyne & Downey, 1991). Accordingly, the COVID-19 pandemic represents the function of a stressor that leads to a stress response on a psychological, behavioral, and physiological level. This process is mediated by different modifiable variables such as awareness, coping style, social support, and personality traits. Together, these factors contribute to health or disease (Shi et al., 2020).

However, what all models are lacking is an integrated understanding of how the COVID-19 pandemic triggers reactions on the behavioral, emotional, and cognitive level, that lead to consequences associated with mental health and well-being. Therefore, the current dissertation will adapt the *SORKC model*, which has been previously used and well established in the field of clinical psychology, to explain the development and maintenance of dysfunctional behaviors and psychological illnesses (Kanfer & Saslow, 1969). Originally, the SORKC model has been differentiated into five variables: the stimulus, the organism, the reaction or response, the contingency, and the consequence. This thesis proposed that the original version of the SORKC model may be helpful as a conceptual framework to explain the overall consequences

of the COVID-19 pandemic because it reflects a relatively complete account of how situations, changes in regulations, and resources interact in shaping responses to the COVID-19 pandemic, which may bring about consequences for health and well-being (Kanfer & Saslow, 1969). As the COVID-19 pandemic, however, is rather multidimensional than unidimensional, this thesis will examine the COVID-19 pandemic on an individual as well as system level while applying a simplified version of the SORKC model by focusing on patient care and mental health care (Figure 1).

Figure 1. SORKC Model Adapted to the Purpose of Explaining Reactions and Consequences of the COVID-19 Pandemic as a Crisis Situation.



Consequently, this dissertation proposes that the COVID-19 pandemic, as a crisis, has the function of a trigger (stimulus) that leads on the individual level to a behavioral reaction (i.e., such as hand hygiene or physical and social distancing as a mitigation strategy), to emotional reactions (i.e., perceived distress and threat or fear), and cognitive reaction (i.e., worries and concerns). As a consequence, greater negative reactions would be more likely to be associated with a worse mental health status characterized by symptoms of depression, anxiety, and loneliness and reduced uptake and partaking in preventative treatments. On the positive side, increased feelings of relief and perceptions of safety due to mitigation strategies may be experienced. However, in the long-term (i.e., prolongation of a crisis), a chronic development of mental health symptoms poses a possible threat to mental health and wellbeing. In addition, changes in social connectedness, social interaction, and treatment possibilities need to be considered as another long-term consequence. Further, due to the initial reaction to postponing preventative examinations, a rise in serious and threatening medical conditions may be experienced. On the system level, reactions include imposed mitigation strategies and time-limited contact restrictions as part of governmental rules and regulations, changes in health care systems, and health care provision for individuals. All these reactions resulting from the COVID-19 pandemic as a crisis on a system level lead to consequences for health care concerning the following aspects: integration of digital treatment components into therapy, changes in the understanding of constitutes of patient safety as well as the acknowledgment of health inequalities resulting from reactions towards the crisis of the COVID-19 pandemic, as well as changes in communication and the introduction of new treatment options.

To examine the COVID-19 pandemic as a crisis along with the adapted SORKC model on the individual as well as the system level, this dissertation will examine the reactions based on the COVID-19 pandemic (study 1, study 2, study 3, study 4) as well as its consequences

(study 3, study 4 and study 5). Therefore, the following research questions will be examined within the present dissertation:

- 1) How do patients conceptualize their patient safety and what are potential triggers that may lead to preventable adverse events posing a danger to patient safety (study 1)?
- 2) Modeling behavior change: Can hand hygiene as a health behavior be explained by health behavior change models and does the mental health status of individuals need to be considered over and above social-cognitive variables part of the health behavior change model (study 2)?
- 3) How do the general population and individuals with a pre-existing limited mental health status compare concerning (a) psychological symptoms experienced during the COVID-19 pandemic, (b) experienced worries and concerns experienced resulting from changes to everyday life due to the impact of the pandemic (c) and to what extent do individuals of both groups intend to use digital supplements to either prevent a deterioration of the mental health status or a worsening of pre-existing symptoms (study 3)?
- 4) How do frequently experienced symptoms during the COVID-19 pandemic, such as perceived distress, anxiety, loneliness and depression interrelate (study 4)?
- 5) To what extent are digital interventions integrated into existing rehabilitation treatment structures a valuable addition in reducing symptoms also in the long run concerning their effectiveness? Do digital interventions contribute to rehabilitation success during the COVID-19 pandemic indicated by a symptom reduction in depression, anxiety, loneliness, and stress (study 5)?

This thesis includes five empirical papers. In particular, these five studies consider the following objectives:

To define patient safety and the constitutes of patient safety in the primary health care context from the perspective of patients, study 1 aimed to develop and assess the psychometric

properties of a questionnaire designed to evaluate triggers that may potentially lead to preventable adverse events. The study was conducted among patients in primary health care settings. Additionally, the study included an evaluation of whether the questionnaire was equally applicable for individuals with symptoms of anxiety and depression, hence, examining whether the questionnaire shows to be robust against effects on mental health. Data were evaluated in a cross-sectional manner (*Chapter 3*). This study focused on research question 1. Therefore, study 1 provides a theoretical foundation to define patient safety in the primary health care context. So far, no previous study was able to define and conceptualize patient safety from the perspective of the patients with the use of a questionnaire. *Chapter 3*, consequently, provides a foundation for understanding changes in constitutes of patient safety (i.e., reactions on the system level due to the COVID-19 pandemic) that in turn understand and inform changes to primary prevention, secondary prevention, and mental health care.

Study 2 was conceptualized as a two-study paper by examining two data sets concerning (a) factors relevant for performing effective hand hygiene behavior and (b) examining mental health as a predictor for hand hygiene compliance. It firstly evaluated whether effective hand hygiene behavior could be described based on the *Health Action Process Approach*. Therefore, this study examined whether the collected data fitted the assumed model structure of the HAPA well by applying a structural equation modeling approach. In addition, the study examined whether the mental health status of the recruited study participants (i.e., anxiety and depression) or the social-cognitive variables part of the HAPA may be indicative of better maintenance in hand hygiene behavior. Data were collected cross-sectionally from patients who had previously been admitted to a hospital either as an outpatient or an inpatient. Secondly, study 2 examined whether mental health factors (i.e., depression and anxiety) were associated with changes in compliance (i.e., from non-compliance to compliance and vice versa) concerning hand hygiene behavior. Therefore, data were examined longitudinally from patients from psychosomatic

rehabilitation clinics pre-and post-rehabilitation stay (*Chapter 4*). This study evaluated the research question, of whether social-cognitive variables (i.e., self-efficacy, outcome expectancies, intention, and planning) can explain hand hygiene behavior over and above the mental health status of individuals. In addition, mental health as a possible predictor of hand hygiene compliance and changes in compliance was evaluated. This study adds to the general understanding of the HAPA model being able to explain hand hygiene behavior. However, as previous literature has failed to show the intention-behavior gap concerning hand hygiene behavior, this study aims to do so. In addition, it has largely been understudied whether the mental health status of individuals is predictive of compliance and changes in compliances concerning hand hygiene. Hence, this study aims to close this research gap by relying on longitudinal data. *Chapter 4* adds information to the reactional level of the proposed adaption of the SORKC model.

Literature has been missing on the reactions and consequences of the COVID-19 pandemic of individuals with and without a pre-existing mental health condition in direct comparison. Study 3, therefore, examines the association between the COVID-19 pandemic and the mental health status (i.e., depression, anxiety, loneliness, stress) of individuals from the general population and individuals with a pre-diagnosed mental health condition. The intention to make use of digital apps or interventions was compared between the general population and the individuals with a pre-diagnosed mental health condition. Lastly, the relationship between the intention to use digital interventions as well as the perceived usefulness of those offered before and during a rehabilitation stay in association with pre-to-post-symptom expression (i.e., depression, anxiety, stress, loneliness) in psychosomatic rehabilitation patients has been examined. Comparisons between the general population and psychosomatic rehabilitation patients were performed with cross-sectional data. Evaluations on the changes in perceived symptom intensity were performed with longitudinal data collected pre-and post-rehabilitation

stay (*Chapter 5*). Chapter 5 evaluated the research question: How do the general population and individuals with a pre-existing limited mental health status compare concerning (a) psychological symptoms experienced during the COVID-19 pandemic, (b) experienced worries and concerns experienced resulting from changes to everyday life due to the impact of the pandemic (c) and to what extent do individuals of both groups intend to use digital supplements to either prevent a deterioration of the mental health status or a worsening of pre-existing symptoms (study 3)? Hence, this study evaluated factors along with the proposed reactional level as well as the consequences of the COVID-19 pandemic. Results of study 3 can provide a rationale for necessary changes in health care provision by connecting the reactional level with proposed consequences due to the COVID-19 pandemic, thereby, providing the baseline for *Chapters 6 and 7*.

As study 3 was able to show a deterioration of the mental health status specifically for individuals with a pre-existing mental health disorder, study 4 of this dissertation investigated the relationship between distress, anxiety, loneliness, and depression. Symptoms of anxiety and perceived loneliness were treated as serial mediators in the positive association between perceived distress and depression. It was assumed that higher perceived distress was to predict higher experienced symptoms of depression through the serial mediation pathway of higher symptoms of anxiety and loneliness. Data were collected from psychosomatic patients and evaluated in a longitudinal manner (i.e., pre-and post-rehabilitation stay; *Chapter 6*). This study evaluated how frequently experienced symptoms during the COVID-19 pandemic, as shown in study 3, such as perceived distress, anxiety, loneliness, and depression interrelated. Therefore, study 4 extends the understanding of reactions and consequences due to the COVID-19 pandemic concerning the adapted version of the SORKC model.

Study 5 builds on findings from studies 3 as well as 4 and evaluates the effectiveness of digital trainings provided in addition to the regular rehabilitation treatment program (i.e., faceto-face treatment) before and during the psychosomatic rehabilitation stay. It was proposed that digital interventions integrated into existing rehabilitation treatment structures add a valuable addition in reducing symptoms also in the long run concerning their effectiveness (i.e., by reducing perceived symptoms of depression, anxiety, loneliness, and stress). It was assumed that individuals participating in all digital interventions before and during the rehabilitation stay, would show the highest improvements along symptoms related to depression, anxiety, stress, and loneliness and report a greater rehabilitation success, compared to those individuals only participating in digital trainings before the rehabilitation stay as well as compared to patients deciding against the participation in any digital interventions. In addition, the interrelation between perceived quality of communication, which has been termed a central factor in the improvement of symptoms, and rehabilitation satisfaction and success was evaluated in study 5. Data were collected and examined in a longitudinal fashion (i.e., pre-and post-rehabilitation; Chapter 7). Therefore, Chapter 7 provides an examination of the reactions and consequences of the COVID-19 pandemic on the individual level by giving recommendations for and integrating with the proposed system level of the adapted SORKC model. Table 1 provides an overview of the included studies, their rationale, the proposed research questions as well as the added value.

 $\textbf{Table 1.} \ \textit{Overview of the Presented Studies including their Rationale, Research Questions, and Added Value.}$

Study	Rational of the study	Research question	Added value
Study 1 (Chapter 3)	 Systematic literature and evidence are missing on understanding patient safety from the perspective of the patient. No quantitative evaluation tools are available that assess potential triggers of preventable adverse events. 	 What are potential triggers that may lead to preventable adverse events posing a danger to patient safety? Is mental health associated with different perceptions of preventable adverse events? 	examine triggers of preventable adverse events from the perspective of patients.
Study 2 (Chapter 4)	 Previous literature has failed to show the role of planning in explaining the intention-behavior gap concerning hand hygiene behavior according to the HAPA. The predictive role of mental health concerning hand hygiene and compliance has rarely been examined. 	explained by health behavior change models such as the HAPA model?	hygiene behavior by examining the intention-behavior gap.
Study 3 (Chapter 5)	 The COVID-19 pandemic has consequences on overall health and wellbeing which has been pronounced for individuals with a pre-existing mental health diagnosis. The direct differences between the general population and individuals with a pre-existing limited health condition will be examined. 	concerning: (a) psychological symptoms, (b) experienced worries and concerns (c) and the intention to use digital supplements to prevent a deterioration of the mental health status?	• Direct comparisons between the two groups on the reactions and consequences of the COVID-19 pandemic have so far not been performed concerning worries and concerns, changes in mental health, and the intention to use digital tools and interventions to support health and well-being during the COVID-19 pandemic.

Study	Rational of the study	Research question	Added value
Study 4 (Chapter 6)	 It may be assumed that distress is the initial reaction whereas anxiety, loneliness, and depression may be consequences of the COVID-19 pandemic as a crisis. The exact relationship between these variables has not been examined so far. 	How do frequently experienced symptoms during the COVID-19 pandemic, such as perceived distress, anxiety, loneliness and depression interrelate?	• Adds information on the understanding of the relationship and mediating factors between perceived distress, anxiety, loneliness, and depression.
Study 5 (Chapter 7)	• Examination of the effectiveness of digital interventions in addition to the regular, face-to-face, rehabilitation treatment.	 Does taking part in digital interventions lead to a reduction in psychological symptoms? Differences in effectiveness of partaking in none, some, and all digital interventions concerning symptom reduction. 	intervention included before and into the psychosomatic rehabilitation process.

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Chapter 3: Development of the Perceptions of Preventable Adverse Events Assessment Tool (PPAEAT): Measurement Properties and Patients' Mental Health Status

Keller, F. M., Derksen, C., Kötting, L., Schmiedhofer, M., & Lippke, S. (2021).

Development of the perceptions of preventable adverse events assessment tool

(PPAEAT): Measurement properties and patients' mental health status.

International Journal for Quality in Health Care, 33(2), mzab063.

https://doi.org/10.1093/intqhc/mzab063

Development of the Perceptions of Preventable Adverse Events Assessment Tool:

Measurement Properties and Patients' Mental Health Status

Abstract

Background

Patient-centered care and patient involvement have been increasingly recognized as crucial elements of patient safety. However, patient safety has rarely been evaluated from the patient perspective with a quantitative approach aiming at making patient safety and preventable adverse events measurable.

Objectives

The objectives of this study were to develop and evaluate the psychometric properties of a questionnaire assessing patient safety by perceived triggers of preventable adverse events among patients in primary health care settings while considering mental health.

Methods

Two hundred and ten participants were recruited through various digital and print channels and asked to complete an online survey between November 2019 and April 2020. Exploratory factor analysis was performed to identify domains of triggers of preventable adverse events affecting patient safety. Furthermore, a multi-trait scaling analysis was performed to evaluate internal reliability as well as item-scale convergent—discriminant validity. A multivariate analysis of covariance evaluated whether individuals below and above the symptom threshold for depression and generalized anxiety perceive triggers of preventable adverse events differently.

Results

The five factors were information and communication with patients, time constraints of health care professionals, diagnosis and treatment, hygiene and

communication among health care professionals, and knowledge and operational

procedures. The questionnaire demonstrated a good total and subscale internal

consistency ($\alpha = .90$; $\alpha = .75$ to $\alpha = .88$); good item-scale convergent validity with

significant correlations between .57 and .78 (p < .05; p < .01) of all items with their

associated subscales and satisfactory item-scale discriminant validity between .14 and .55

(p > .05) with no significant correlations between the items and their competing subscales.

The questionnaire was further revealed to be a generic measure irrespective of patients'

mental health status. Patients older than 50 years of age perceived a significantly greater

threat to their safety compared to patients below that age.

Conclusion

The developed Perceptions of Preventable Adverse Events Assessment Tool

(PPAEAT) exhibits good psychometric properties, which supports its use in future

research and primary health care practice. Further validation of the PPAEAT in different

settings, languages, and larger samples is needed. The results of this study need to be

considered when assessing patient safety in the context of health care research.

Keywords: Patient Safety, Preventable Adverse Events, Mental Health

Disorders, Age, Psychometric Properties

Introduction

Research into human factors in health and *patient safety* in primary care settings has increasingly gained importance, especially concerning the *patient perspective* (Giardina et al., 2018). Patient safety is a central goal of health care (The Joint Commission, 2020) and has been defined as the absence of adverse events. Sandars and Esmail reported in their review that the occurrence of patient safety incidents in primary care settings is between 5 and 80 per 100 000 consultations in Australia and the USA (Sandars & Esmail, 2003). Several studies have determined key domains of patient safety and defined areas of re-occurring *preventable adverse events* (*pAEs*; Lippke et al., 2019; Ricci-Cabello et al., 2017; Verstappen et al., 2015). Commonly agreed domains were diagnosis and treatment, organization of health care, human factors of health-care professionals, teamwork and effective communication between health-care professionals, the patient role and patient-provider communication as well as the environment and (technical) equipment in care settings (De Vries et al., 2008).

pAEs as relevant factors of patient safety have been defined as a potentially harmful result of care that fell below the standard expected in a certain setting (Brennan et al., 1991). Most knowledge on the prevalence of pAEs in hospital settings has been obtained from *retrospective reviews of patient records, formal incident reporting, or case studies* (Forster et al., 2003; Hernan et al., 2015; Spencer & Campbell, 2014). While these results often show the pAE or negative consequence itself, they rarely highlight the potential processes or triggers that lead to pAEs.

Former research highlighted the importance of assessing the needs of patients and what matters most to patients concerning own safety (Santana et al., 2020). If patient needs are not properly understood, this missing knowledge can pose an additional threat to patient safety. Patients may experience considerable trauma because of pAEs and their

inadequate management (Guijarro et al., 2010). Therefore, patient involvement needs to be considered more systematically to reduce errors as well as to increase transparency about what constitutes patient safety while also providing tailored treatment options (Busch et al., 2020; Verstappen et al., 2015). While there has already been some research into qualitative evaluations of patient safety, there is still a lack of understanding concerning the patients' experience in care settings and quantitative research on triggers of pAEs has been limited (Ricci-Cabello et al., 2015).

Literature has proposed that mental health in terms of *generalized anxiety* and *depression* can be associated with several illnesses and various health-related processes such as the burden of physiological medical symptoms (Meneghetti et al., 2017), treatment, recovery as well as readmission (Tully et al., 2008). However, a big gap remains in the current literature on whether and how patients' anxiety and depressive symptoms are associated with the perception of their safety.

Thus, the *research objectives* of this study are to close this research gap by (1) developing a questionnaire that assesses perceived triggers of pAEs in health care settings from the patient perspective, (2) evaluating the psychometric properties in terms of the factor structure of the questionnaire as well as reliability and item-scale convergent-discriminant validity, and (3) determining whether the questionnaire is a generic measure and, thus, appropriate for patients with and without clinical psychological symptoms.

Methods

Procedure

Participants were recruited through various channels such as press releases, social networks, and study homepages. Data were collected anonymously with the online survey tool Unipark between November 2019 and April 2020. The survey lasted for 10 min. All

participants were informed about the purpose of the survey and provided online informed consent.

Instruments

Patient Safety and Preventable Adverse Events – Questionnaire Development

Items assessing *triggers of preventable adverse events* (*pAE*) derived from literature research of reviews, syntheses, incident and case reports, patient-reported outcome measures (PROMs), and patient-reported experience measures (PREMs), which measure the outcomes of patient health and the experience about a caring process (Elder & Dovey, 2002; Forster et al., 2003; Jacobs et al., 2020; Ricci-Cabello et al., 2017; Verstappen et al., 2015). An item pool of 47 items assessing potential triggers was developed and refined by two chief medical officers and doctors from the field of gynecology and obstetrics, psychologists as well as quality management staff with over 15 years of work experience from two university hospitals. After initial piloting and adaption, participants were asked to estimate whether they have experienced triggers of pAEs during their last hospital visit (1 = "completely disagree", 2 = "somewhat disagree", 3 = "somewhat agree", 4 = "completely agree"). Higher average ratings denote a more common threat to patient safety.

Depressive Symptoms

The PHQ-9 is the depression module of the Patient Health Questionnaire, which is a self-administered questionnaire assessing each of the nine Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria for depression on a 4-point Likert scale from 0 ('not at all') to 3 ('nearly every day'). A sum score of \geq 10 depicts the cutoff value with a sensitivity of 88% and specificity of 88%. The scale has a Cronbach's alpha of .89 in care settings (Kroenke et al., 2001).

Generalized Anxiety Symptoms

The GAD-7, a self-report measure of generalized anxiety disorder symptoms, measures seven items based on the seven DSM-5 criteria on a 4-point Likert scale from 0 ('not at all') to 3 ('nearly every day'). A sum score of \geq 10 represents the cutoff value and provides a sensitivity of 89% and specificity of 82%. Primary validation estimated a Cronbach's alpha of .86 (Spitzer et al., 2006).

Socio-Demographic and Additional Information

Additional data included patients' age, sex, and last admission as an inpatient or outpatient to a hospital. All variables were treated as categorical variables.

Data Analysis

Missing values were imputed via multiple imputations within SPSS Version 26. Five datasets were created and combined via the Output Management System (OMS procedure) into one dataset. Firstly, an *exploratory factor analysis* (EFA) was carried out to determine factor structure and factor loadings. Three sequential steps were taken. Step 1 involved identifying the number of meaningful factors to retain based on the scree plot and the percentage of (common) variance explained by a given factor with an eigenvalue of above 1. Factors that appeared to be meaningful were retained for rotation. Promax (oblique) rotation was applied during Step 2 on the retained factors. Oblique rotation was chosen and considered appropriate because the factors retained for further analyses were constructs of the overall construct of patient safety and, thus, reasoned to be significantly correlated with one another. Identification and interpretation of the factor loadings of relevant items retained were performed in Step 3. Item loadings > .40 were used for interpretation purposes. Hence, 27 items were eliminated for the analysis due to low item loadings.

As part of the multi-trait scaling analysis, internal consistency and reliability of the scales were examined by assessing the item-scale correlation to test whether the item was correlated with the hypothesized scale. An item-scale correlation of < .40 was considered low so the item was removed from the respective scale. An item internal consistency value of \geq .40 can, thus, be considered satisfactory. A narrow range of item-scale correlation within each defined scale was used as an assessment to confirm the choice between the item and hypothesized scale. A range of < .20 was defined as acceptable. A Cronbach's alpha value between 0.70 and 0.90 was considered satisfactory (Streiner, 2003).

Furthermore, item-concurrent and item-divergent validity were analyzed by employing a multi-trait scaling analysis. The multi-trait scaling analysis allows for the following assumptions to be tested simultaneously: (1) Item-subscale consistency (correcting for overlap), (2) equality of item-scale correlation, and (3) item-scale convergent-discriminant validity. Item-subscale consistency considers the correlations between an item and the subscale score computed from all other items associated with the same subscale by assessing Cronbach's alpha (correcting for overlap). By this, an inflation of the item-scale correlation is avoided. Next to the test of item-subscale consistency, the second assumption is considering the equality of item-scale correlations. This requires items of the same subscale to contribute roughly equal proportions of information to the total subscale score. Item-scale convergent-discriminant validity assesses whether an item measures what it is supposed to measure, but also the extent to which an item is associated with other competing subscales that it is not supposed to be associated with. Item-scale discriminant validity was analyzed by evaluating Pearson's correlation coefficient. Concerning item-scale discriminant validity, the standard significance level used to compare two correlations is considered to be two standard errors (standard errors of a correlations coefficient represented by 1 divided by the square root of the total sample size).

In addition, *multivariate analyses of covariance (MANCOVA)* were performed to test for differences in perceived patient safety between mentally healthy and non-healthy groups of patients with depressive as well as symptoms of generalized anxiety. All data analysis was carried out using IBM SPSS Version 26.

Results

Participants

Two hundred and ten participants completed an online questionnaire. One hundred and forty-four participants (68.6%) were female, and 19 (9.0%) did not indicate their gender. The participants varied in age from 18 to over 60 years old. Sixty-eight (32.4%) participants indicated that they were admitted to the hospital during the last year, 75 (35.7%) during the last one to five years, and 51 (24.3%) five or more years ago. One hundred and fifty-nine (75.7%) participants revealed no depressive symptoms while 51 (24.3%) participants showed depressive symptoms according to the threshold by Kroenke and colleagues (2001). One hundred and seventy-eight (84.8%) participants reported no symptoms of generalized anxiety whereas 32 (15.2%) reported symptoms above the threshold according to Spitzer and colleagues (2006).

Exploratory Factor Analysis

The original missing data analysis revealed missing data of 4.65%. As a summated rating score for each subscale cannot be estimated with the same degree of confidence with missing data, multiple imputations were performed before the analyses on missing data concerning measures of pAEs. All 47 items were subjected to the exploratory factor analysis. After oblique rotation, 20 items were retained in the analysis with a factor loading of \geq .40 with the respective factor (Table 2).

Table 2. Exploratory Factor Analysis - Factor Loadings and Explained Variance (N = 210).

Scale I = Information and communication with patients IC1 Not informed about procedure beforehand .72 IC2 Not sufficiently informed about medications and side effects IC3 Not adequately informed about treatment procedure .65 IC4 Not sufficiently informed overall .64 Scale 2 = Time constraints .88 TC1 A lack of health care professionals available .84 TC2 Long waiting times .84 TC3 Many delays .77 TC4 A lack of time of health care professionals .69 TC5 The health care professionals seemed .64 emotionally burdened .64 Scale 3 = Diagnosis and treatment DT1 Diagnoses were made too late .83 DT2 Diagnoses were made too late .83 DT3 The treatment proposed was not sufficient .80 DT4 Diagnoses were made too hastily .80 Scale 4 = Hygiene and communication among health care professionals .80 HC1 Lack of hand hygiene among health care professionals .66 HC2 Conflicts among the hospital staff .71 </th <th>Scale/</th> <th>Label</th> <th>1</th> <th>2</th> <th>3</th> <th>4</th> <th>5</th>	Scale/	Label	1	2	3	4	5
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Note. Abbreviations: IC = Information and communication with patients, TC = Time constraints, DT = Diagnosis and treatment, HC = Hygiene and communication among health care professionals, KP = Knowledge and operational procedures.

Five factors could explain 70.3% variance. Items on the first factor (4 items) represented *information and communication with patients*; items on the second factor (5 items) represented the *time constraints* of health care professionals, items on the third factor (4 items) represented *diagnosis and treatment* process, items on the fourth factor (3 items) highlighted *hygiene and communication among health care professionals* and the fifth factor (4 items) centered around *knowledge and operational procedures*.

Item Descriptive Statistics

Table 3 depicts mean scores with standard deviations and frequency distributions of average answer patterns of the 20 items. The frequency distribution expresses the degree of agreement with potential triggers of prevalent adverse events. The most commonly perceived threat to patient safety was found within the factor of time constraints of health care professionals with an average mean of M = 2.77 (SD = 0.73). Knowledge and operational procedures were perceived by patients to pose a rather uncommon threat to patient safety (M = 1.79, SD = 0.65). For item means per factor see Table 3.

Table 3. *Item Statistics and Frequency Distributions* (N = 210).

Scale/ Item	Mean	SD	Response values frequency						
Ttem			1	2	3	4			
Scale $1 = Information$ and communication with patients $(M = 2.20; SD = 0.85)$									
IC1	2.22	0.80	39	95	66	10			
IC2	2.23	0.98	61	60	68	21			
IC3	2.06	0.81	57	89	58	6			
IC4	2.29	0.79	31	99	68	12			
Scale 2	Scale 2 = Time constraints $(M = 2.77; SD = 0.73)$								
TC1	3.05	0.90	14	38	81	77			
TC2	2.97	0.91	17	39	88	66			
TC3	2.74	0.94	25	52	86	47			
TC4	2.52	0.89	30	68	85	27			
TC5	2.56	0.90	32	56	95	27			
Scale 3	Scale $3 = Diagnosis$ and treatment ($M = 1.85$; $SD = 0.92$)								
DT1	1.79	0.90	111	63	23	13			
DT2	1.83	0.93	99	59	40	12			
DT3	1.95	0.92	85	59	57	9			
DT4	1.83	0.92	96	65	37	12			
Scale 4	= Hygiene	and com	municati	on am	ong h	ealth care professionals ($M = 2.30$;			
SD = 0.9	*								
HC1	2.10	0.96	66	79	44	21			
HC2	2.33	0.92	45	72	72	21			
HC3	2.47	0.85	28	76	85	21			
Scale 5 = Knowledge and operational procedures ($M = 1.79$; $SD = 0.65$)									
KP1	1.87	0.85	84	78	40	8			
KP2	1.80	0.81	86	89	27	8			
KP3	1.89	0.77	71	94	42	3			
KP4	1.64	0.80	113	65	27	5			

Note. IC = Information and communication with patients, TC = Time constraints, DT =

Diagnosis and treatment, HC = Hygiene and communication among health care professionals, KP = Knowledge and operational procedures. Response values on a 4-point Likert scale. 1='completely disagree', 2='somewhat disagree', 3='somewhat agree' and 4='completely agree'.

Multi-Trait Scaling Analysis

Results of the multi-item correlation matrix are shown in Table 4. Each row in the matrix contains Pearson's correlations between the score for an item and all five hypothesized item groupings. Each column contains correlations between the total score for one subscale and all items in the matrix.

Results concerning *item-subscale consistency* reveal that all items on all five factors show a value of \geq .40 with the respective subscale, hence meeting the assumption of item-subscale consistency. All five subscales meet the criteria for the assumption of the *equality of item-scale correlations*. As shown in Table 4, the range of all item-scale correlations within each defined scale was lower than the previously defined value of < .20. Furthermore, *item-convergent validity* (item scale correlation \geq .40) and *item-scale discriminant validity* (an item-own scale correlation higher than the correlation with the other competing subscales) were termed as sufficient as all items had higher correlations with their hypothesized own scales than with the other competing scales (see Table 4).

Table 4. Correlation Matrix Showing the Relationship of each Item to its Subscale Corrected for Overlap and to the Other Subscale (N=210).

Item	Scales							
Name	1	2	3	4	5			
Scale 1 =	Scale $I = Information$ and communication with patients $(M = 2.20; SD = 0.85)$							
IC1	.72***	.29	.46	.44	.53			
IC2	.64***	.32	.47	.48	.47			
IC3	.68**	.35	.47	.42	.55			
IC4	.70**	.45	.45	.46	.52			
$Scale\ 2 =$	Time cons	traints (M	= 2.77; SD	0 = 0.73)				
TC1	.26	.76***	.14	.28	.23			
TC2	.27	.66***	.14	.21	.17			
TC3	.32	.70***	.25	.34	.26			
TC4	.53	.69***	.33	.38	.39			
TC5	.32	.63***	.23	.46	.31			
Scale 3 =	Scale $3 = Diagnosis$ and treatment ($M = 1.85$; $SD = 0.92$)							
DT1	.47	.15	.78***	.31	.37			
DT2	.47	.25	.75***	.38	.40			
DT3	.51	.27	.70***	.37	.32			
DT4	.47	.26	.73***	.36	.50			
Scale $4 = Hygiene$ and communication among health care professionals ($M = 2.30$;								
SD = 0.91	*							
HC1	.46	.17	.32	.57**	.42			
HC2	.40	.46	.36	.61***	.42			
HC3	.49	.40	.33	.58**	.46			
Scale 5 = Knowledge and operational procedures ($M = 1.79$; $SD = 0.65$)								
KP1	.47	.35	.40	.39	.70***			
KP2	.54	.23	.30	.38	.61**			
KP3	.47	.34	.37	.54	.63**			
KP4	.51	.16	.43	.39	.59**			

Note. All correlations were statistically significant (p < .05). Two or more than two standard errors were used as a significance level for comparing each item-subscale with its subscale and competing subscale. *** Item-subscale correlation was significantly higher for the associated subscale than for the competing subscale at p < .01; ** Item-subscale correlation was significantly higher for the associated subscale than for the competing subscale at p < .05.

Reliability and Correlation Between Subscales

Results from Table 5 reveal acceptable Cronbach's alpha coefficients between .75 and .88, which are below the recommended acceptable maximum value of .90 and above the suggested value of .70. Furthermore, all correlation coefficients between two subscales are consequently lower than their reliability coefficients. All correlations among subscales were significantly related to each other (p < .01). The total internal consistency proved to be good ($\alpha = .90$).

Table 5. *Scale Internal Consistency - Reliability* (N = 210).

Scale	IC	TC	DT	НС	PK
IC	(.84)				
TC	.42	(.78)			
DT	.56	.27	(.88)		
HC	.55	.41	.41	(.75)	
KP	.62	.34	.47	.53	(.81)

Note. Scale internal consistency reliability (Cronbach's alpha coefficient) is presented in the diagonal. IC = Information and communication, TC = Time constraints, DT = Diagnosis and treatment, HC = Hygiene and communication, KP = Knowledge and Procedures.

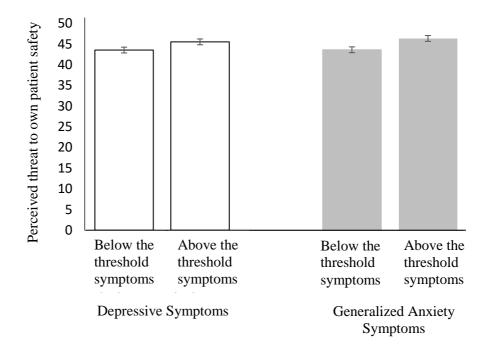
All correlations between scales represented non-diagonally are statistically significant p < .01

Multivariate Analyses of Covariance with Depression and Generalized Anxiety

To examine whether participants below and above the threshold for generalized anxiety and depressive symptoms differed in their perception of triggers of *pAEs*, multivariate analyses were performed controlling for gender, age, and last hospital visit. Results indicate generic patterns regarding perceived triggers of pAEs in participants

below and above the threshold for depressive symptoms (F(5,182) = 0.57, p = .72) as well as generalized anxiety symptoms (F(5,182) = 0.86, p = .51; Figure 2).

Figure 2. Perceived Threat to own Patient Safety by the Mental Health Status of Patients.



Note. Perceived threat to patient safety is expressed as mean scores. Error bars represent standard errors.

However, triggers of pAEs differed concerning age groups (F(1,191) = 15.62, p < .001). Patients below the age of 50 years perceived a significantly lower threat to their patient safety (M = 42.06, SD = 10.89) compared to participants above that age (M = 48.28, SD = 9.18).

Discussion

Statement of principal findings

The current study with 210 participants aimed to develop a questionnaire assessing potential triggers of preventable adverse events that indicate patient safety concerns from the patient perspective. Therefore, psychometric properties were investigated. As a secondary aim, we evaluated whether the PPAEAT questionnaire is robust against the effects of the mental health status. The results of the present study provide evidence for the psychometric properties (internal consistency, reliability, and item-scale convergent–discriminant validity) of the Perceptions of Preventable Adverse Events Assessment Tool (PPAEAT; see Appendix 1, Table 23 and 24) assessing perceived triggers of pAEs that is useful for both patients with and without symptoms of depression and generalized anxiety.

The factor structure identifies five different areas of pAEs from the patient perspective: information and communication with patients, time constraints of health care professionals, diagnosis and treatment, hygiene and communication among health care professionals, and knowledge and operational processes. These areas of patient safety have been considered crucial in previous literature reviews or qualitative analyses, also providing further evidence for the face validity of the proposed PPAEAT questionnaire (Elder & Dovey, 2002; Jacobs et al., 2007; Makeham et al., 2008). Furthermore, this questionnaire was robust against the effects of the mental health status. The results support the reliability and validity of this PPAEAT questionnaire with good psychometric properties concerning internal consistency, item-scale convergent and item-scale discriminant associations, and concurrent validity.

Interpretation within the context of the wider literature and implication

This study bridges the research gap regarding the lack of patient involvement, especially concerning their mental health status and their perceptions about patient safety,

hence being an important contribution to the fields of health care services research and clinical psychology. It has been shown that patients can provide good insights into adverse care processes that potentially endanger patient safety (Unruh & Pratt, 2007). Potential risks might be preventable by providing health care professionals with the necessary information on how to reduce triggers (Hernan et al., 2015; Unruh & Pratt, 2007). Therefore, from a practical viewpoint, it is important to evaluate indicators of patient safety from the patient perspective as they can help to ensure quality standards in hospitals (Baxter et al., 2018). Additionally, the results contribute to the understanding of patient-centered care, which is addressing patients concerning their personal context and needs. As a consequence, patient-centered care is associated with improved adherence and self-care (Epstein & Street, 2011). In that light, a lack of attention and explanation given by health care professionals may negatively impact patients' assessment of clinicians' knowledge and communicative behavior as well as operational procedures (Epstein & Street, 2011).

This PPAEAT questionnaire proves to be generic for the assessment of perceived pAEs, as individual perceptions of triggers do not differ concerning the mental health status. The only factor associated with perceived patient safety was age. Participants below the age of 50 years perceived lower threats to their safety than those above. This is in line with literature stating that around the age of 50 years, the importance and awareness of preventative medical examinations rise due to a higher need for preventive examination (Glenn et al., 2020). Higher awareness of prevention may lead to a heightened awareness of patient safety threats as well. However, the exact link between age and awareness of triggers concerning pAEs needs to be investigated in the future.

As previously developed or applied measures in health care settings frequently only assess patient experience or satisfaction with care (Burt et al., 2017) and may not

provide additional information based on system-level factors that may be interrelated with patient safety (Giles et al., 2019), the current PPAEAT questionnaire provides a generic tool for clinical practices to routinely evaluate patient safety concerning quality management aspects and system-level factors relevant for patient safety.

Limitations

Possible limitations of this study include that this PPAEAT questionnaire was specifically designed to assess perceived triggers of pAEs in hospital settings limiting the generalizability to other health care settings such as general practices or rehabilitation centers. Future research should, therefore, evaluate this questionnaire not only in clinical hospital settings but also in medical surgeries and other health-care-related areas. Furthermore, we need to be cautious in the interpretation of the concurrent validity, as we did not compare the newly developed questionnaire to an already existing and well-established assessment tool. Furthermore, developing a short version of this 20-item questionnaire would increase the response rate from patients in health care settings. Since the questionnaire was evaluated with an online sample, the replication of these results in an offline setting is warranted. Moreover, the current perspective was only examined from the patient perspective; thus, the accompanying persons' viewpoint should be accounted for in future studies. The health care professionals' perspective could also be added in a dyadic fashion.

Conclusion

Overall, this study provides support for a generic, reliable, and valid tool that measures perceived triggers associated with patient safety in health care settings, irrespective of gender, last admission as a patient, or mental health status. Further research should be undertaken to understand application possibilities in different health care settings and the limitations of the Perceptions of Preventable Adverse Events Assessment

Tool (PPAEAT). The results of this study need to be considered when assessing patient safety, e.g. by using the presented PPAEAT questionnaire, and in the context of health care research.

Authors' contribution

F.M.K., C.D., L.K., M.S., and S.L. have contributed to the development of this paper. F.M.K., C.D., and L.K. are research students supervised by S.L.; F.M.K. wrote the first and final draft of this paper. C.D., L.K., and S.L. have contributed to the conception and design as well as the drafting process, and M.S. contributed to the discussion. All authors have read and approved the final manuscript.

Ethics and Other Permission

Approval was granted as part of the research project ethical approval from the Ethics Committee at Jacobs University Bremen. All study participants provided written informed consent for participation (ClinicalTrials.gov Identifier: NCT03855735).

Funding

This work was supported by the Innovation Fund of the Federal Joint Committee as part of the research project 'TeamBaby-Communication and patient safety in gynecology and obstetrics' [01VSF18023].

Conflict of Interests

All authors report no conflict of interest.

Acknowledgments

We would like to thank Nathalie Linda Herzog-Petropaki for proofreading a previous version of this manuscript. We also appreciate the support by Jing Liu for supporting us with language editing and proofreading.

Data availability statement

The data underlying this article will be shared upon reasonable request to the corresponding author.

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Chapter 4: Changes in and Compliance with Hand Washing
Behavior Interrelating with Patients' Mental Health Status:

Application of the Health Action Process Approach

Keller, F. M., Derksen, C., Kötting, L., Dahmen, A., & Lippke, S. (2022). Changes in and Compliance with Hand Washing Behavior Interrelating with Patients'

Mental Health Status: Application of the Health Action Process Approach.

Psychology & Health, Under Review.

Social-Cognitive Determinants of Patients' Hand Hygiene Behavior and the Role of Mental Health: Application of the Health Action Process Approach

Abstract

Objective:

Patients' effective hand hygiene helps to reduce health care-associated infections and prevents the spread of nosocomial infections and communicable diseases, such as COVID-19. This study aimed to describe effective hand hygiene behavior based on the Health Action Process Approach (HAPA) and to examine whether the mental health status or rather processes of social-cognitive variables may be associated with increased compliance with hand hygiene behavior.

Methods and Measures:

Data were collected cross-sectionally from participants who had previously been admitted to a hospital (N = 279; study 1) and longitudinally from psychosomatic rehabilitation patients (N = 1073; study 2). Changes in compliance in hand hygiene behavior, social-cognitive variables of the HAPA, and mental health status were examined.

Results:

The trimmed HAPA framework fitted the data well ($\chi^2 = 27.1$, df = 12, p < .01, CMIN/df = 2.26, CFI = .97, RMSEA = .08). In the multi-group structural equation modeling, model invariances emerged. Mental health was not a significant predictor for changes in compliance with hand hygiene behavior.

Conclusion:

The trimmed HAPA framework was revealed to be a generic framework for explaining social-cognitive processes of hand hygiene behavior. Helping individuals to perform and be compliant with hand hygiene by intention formation

and bridging the intention-behavior gap by planning and self-efficacy was revealed to be feasible irrespective of the participants' mental health status.

Keywords: Hand Hygiene; Compliance; Health Action Process Approach;Mental Health; Depression, Generalized Anxiety

Introduction

The prevention of communicable diseases and infections is key for overall population health and patient safety, especially in susceptible populations (Gaube et al., 2021). The prevention and containment of viruses and infections have been of particular importance during the current COVID-19 pandemic (Abdelrahman, 2020). In comparison to other preventative measures, especially hygiene behaviors, maintenance of hand hygiene behavior has been rather low, thus calling for a better understanding of the reasons for the lack in performance and maintenance (Jabbari et al., 2020). In general, more risk perceptions (fearing an infection) and more outcome expectancies (knowing why to perform the target behavior) are related to more preventative behavior (Dahmen et al., 2021). However, one important finding is that highly elevated fear leads to a decreasing likelihood of performing hand hygiene behavior (Lippke et al., 2022). Furthermore, the role of mental health needs to be considered when examining hand hygiene behavior. Literature has shown that psychosomatic patients appear more compliant with preventive measures, specifically hand hygiene, but also experience more fear of a potential infection than the general population (Lippke et al., 2022). However, it is not clear whether the patients' mental health status may be the reason for their higher fear of an infection and better hygiene behavior or, rather, other social-cognitive processes. To date, research has rarely investigated the association between mental health and hand hygiene behavior, which will be the main aim of the current study. Thus, the present study will investigate whether hand hygiene behavior can be explained by the Health Action Process Approach (HAPA) and whether the mental health status needs to be regarded over and above the HAPA variables.

Since little is known about patients' hand hygiene behavior in hospitals, this study aims to examine patients' hand hygiene and its determinants (Bellissimo-Rodrigues et al.,

2016; Sande-Meijide et al., 2019). This is especially important as many patients are not sufficiently aware that they can actively participate in hand hygiene and thus protect themselves, and others, from infections. While 85% of people state that they disinfect or wash their hands at home after going to the toilet, this is only true for about 70% of hospitalized patients (Barker et al., 2014). Observational studies have shown varying hand hygiene rates ranging from 56% of patients in hospital wards (Randle et al., 2010) to 84% of patients always, or usually, cleaning their hands after visiting the toilet and 72% before eating (Srigley et al., 2020). However, the probability to suffer from an infection can be higher in hospitals. It is crucial to understand barriers to good hand hygiene in hospitals in detail to effectively increase compliance (Scheithauer & Lemmen, 2013).

Especially during the COVID-19 pandemic, hand hygiene behavior has gained more awareness and attention. Concerning recommendations and regulations by the government in form of containment measures, individuals were encouraged to frequently disinfect or wash their hands. Previous research conducted during the SARS pandemic in 2002 and 2003 examined elements relevant to adopting and maintaining effective hand hygiene behavior. Results suggested that to reduce the spread of a virus, a behavioral change in hand hygiene behavior and associated health behaviors is necessary (Hamilton et al., 2020).

Hand Hygiene and Social-Cognitive Theories

Several theories of social cognition have been used to provide an understanding of determinants of health-related behaviors such as hand hygiene behavior. The theory of planned behavior (TPB) as a classical and fundamental health behavior theory (Sheeran et al., 2017) and the Transtheoretical Model of Behavior Change (TTM) have widely been

used to explain and predict health behaviors (Hashemzadeh et al., 2019). However, both have been unsuccessful to overcome the intention-behavior gap. Consequently, to overcome this gap, the Health Action Process Approach has been adopted as the theoretical foundation for the present study. The HAPA is an effective model for explaining health behavior change in a variety of settings (Schwarzer, 2008; Srigley et al., 2015). The model differentiates between the pre-intentional and post-intentional phases. The pre-intentional phase includes motivational factors necessary for the formation of an intention such as outcome expectancies, risk perceptions, and self-efficacy. Afterward, the intention to perform the desired behavior is reinforced by post-intentional or volitional factors. The main two factors include (1) planning: which is divided into action planning and coping planning, and (2) self-efficacy: which enables individuals to act on their intentions (Hamilton et al., 2020; Schwarzer, 2008). Both action and coping planning act as mediators between the formed intention and the consequent behavior (Schwarzer, 2008).

The HAPA model, as a dual-phase model of behavior, poses the most comprehensive model therefore it will be used as a theoretical basis for the present study. Previous studies have already tested the HAPA model, or its determinants, in explaining behavior change in association with preventative behaviors during the COVID-19 pandemic (Lao et al., 2021; Lin et al., 2020). Gaube et al. (2021) were able to apply a modified version of the HAPA to examine hand hygiene behavior. However, according to their results, self-efficacy, action control, and planning were not able to fully bridge the intention behavior gap. Therefore, this study will replicate previous studies by highlighting the important role of planning in overcoming the intention-behavior gap. In addition, what previous studies have not acknowledged, is the possible association between mental health and preventative measures (i.e., hand hygiene) in the context of

the HAPA. Therefore, the current study will evaluate the HAPA determinants in the

context of hand hygiene by also acknowledging the role of symptoms of depression and

anxiety.

The Current Study

To our knowledge, only one study, so far, has aimed to evaluate the hand hygiene

behavior of patients specifically along with the HAPA model. Despite being able to show

that hand hygiene behavior could be explained by most of the social-cognitive variables

in the HAPA model, their results were not able to show that planning mediated the

intention-behavior gap which is an essential assumption of the HAPA model (Gaube et

al., 2021). In addition, the role of mental health in explaining changes along social-

cognitive variables, as well as maintenance and compliance or non-compliance with hand

hygiene behavior has, so far, not been examined. Therefore, the scope of the present paper

will attempt to (1) identify that the HAPA can explain the most variance in hand hygiene

behavior of patients (study 1), (2) examine whether planning mediates the intention-

behavior gap (study 1), (3) examine the role of mental health concerning social-cognitive

variables of the HAPA as well as in hand hygiene behavior and compliance (study 1 and

study 2).

Materials and Methods

To answer these hypotheses two samples were recruited: people from the general

population as a cross-sectional online sample (study 1) and patients from four

psychosomatic rehabilitation clinics for the longitudinal analyses (study 2).

Study 1: Cross-sectional Study

Procedure and Participants

Participants (N = 279) were recruited through press releases, social networks, and study homepages and invited to answer an online survey. Data were collected anonymously between November 2019 and June 2020 in Germany in three waves before SARS-CoV-2 (n = 97), during the first lockdown (n = 85), and after lockdown measures were reduced (n = 97)¹. All participants were informed about both the purpose of the survey and data security measures and all were asked to indicate informed consent. The study was approved by the Ethics Committee Jacobs University Bremen (ClinicalTrials.gov registration number: NCT03855735).

Participants who had previously (in the last 5 years)² been admitted to a hospital as either an inpatient or an outpatient completed the online questionnaire (194 [69.5%] female, 16 [5.7%] missing). Age ranged from 18 to over 60 years. 206 (73.8%) participants revealed no depressive symptoms, while 42 (15.1%) participants showed depressive symptoms according to the threshold by Kroenke and colleagues (2001). 224 (80.3%) participants revealed no symptoms of generalized anxiety, whereas 33 (11.8%) revealed symptoms above the threshold according to Spitzer and colleagues (Spitzer et al., 2006).

Measures

For an overview of all items used see Appendix 2 (Tables 25 to 36).

¹ No significant differences were found for social-cognitive variables and mental health variables between the three measurement timepoints except for resources and support (see Appendix 3).

² No significant differences were found for social-cognitive variables and mental health symptoms (i.e., depression and anxiety) with regard to time between hospital visit and partaking in the survey (see Appendix 4).

Socio-Demographic Information. Socio-demographic data included patients' age and sex. Age was assessed in five categories ("younger than or 29 years old", "30 to 39 years old", "40 to 49 years old", "50 to 59 years old", and "60 years and older"). Sex was categorized into two groups ("men" and "women").

Hand Hygiene Behavior and HAPA Constructs. The questionnaire used to investigate social-cognitive variables of the HAPA model (Gholami & Schwarzer, 2014) was adapted for hand hygiene behavior in primary health care settings. Risk perception was assessed using a single item on a seven-point Likert scale on which 1 indicated 'Significantly below average' and 7 'Significantly above average'. Action self-efficacy (a = .87) was investigated by four items on a six-point Likert scale from 1 'Not at all' to 6 'Completely'. Outcome expectancies ($\alpha = .83$) were measured using five items on a sixpoint Likert scale from 1 'Not at all' to 6 'Completely'. Intention ($\alpha = .68$), as well as action planning ($\alpha = .92$) and coping planning ($\alpha = .78$), were assessed using two questions each on a six-point Likert scale, where 1 indicated 'Not at all' and 6 'Completely'. However, according to the literature, action and coping planning have frequently been combined as "planning", increasing the content validity of the predictor. Hence, planning ($\alpha = .86$) was used as a general construct for the following analysis (Caudroit et al., 2011; Chiu et al., 2012). Maintenance self-efficacy ($\alpha = .91$) was assessed by three items on a six-point Likert scale from 1 'Not at all' to 6 'Completely'. Composite means scores for all HAPA constructs were computed. Measures of hand hygiene behavior were adapted from the recommendations provided by the "Clean Hands Campaign" (Reichardt et al., 2009). Hand hygiene behavior was measured by twelve items on a five-point Likert scale (1- 'Never'; 5- 'Always'; $\alpha = .87$) on how they behaved concerning how they perform hand hygiene behavior in daily life.

Mental Health Status. Symptoms of depression were assessed by the *PHQ-9*, which is the depression module of the Patient Health Questionnaire. It assesses symptoms of depression on each of the nine DSM-5 criteria on a four-point Likert scale from 0 'Not at all' to 3 'Nearly every day' by asking patients to think about the past two weeks. For analysis and evaluation purposes, composite mean scores were computed. A sum score of ≥ 10 depicts the cut-off value for the symptom threshold. Cronbach's alpha was .89 in primary care settings (Kroenke et al., 2001).

The GAD-7, a self-report measure of generalized anxiety disorder symptoms, was used to determine the symptom threshold of generalized anxiety. The seven items, based on the seven DSM-5 criteria, were measured on a 4-point Likert scale from 0 'Not at all' to 3 'Nearly every day'. The questionnaire requires patients to think about the past two weeks. A sum score of ≥ 10 represents the cut-off value for the symptom threshold for symptoms of generalized anxiety. Primary validation estimated a Cronbach's alpha of .86 (Spitzer et al., 2006).

Data Analysis

A bivariate correlation table, including all HAPA variables, was used to examine correlations between the social-cognitive variables and hand hygiene behavior. Furthermore, structural equation modeling (SEM) with latent variables was performed to test whether the HAPA fitted the data, as well as to examine whether planning mediated the behavior-intention gap. For SEM fit indices including chi-square (χ^2), degrees of freedom (df), chi-square to df ratio (CMIN/df), p-values for χ^2 -Test, Comparative Fit Index (CFI), and Root Mean Square Error of Approximation (RMSEA) were evaluated. A model is evaluated to have a good fit to the data if the following fit indices have been fulfilled: a CFI and TLI with values higher than .90 and a value of below .08 concerning the RMSEA (Tabachnick et al., 2019). As the χ^2 statistic is considered to be dependent

on the sample size, the χ^2/df ratio was used as a goodness-of-fit criterion for this paper. As suggested by Bollen and Long (1993), χ^2 should not be larger than 2-5 times of the degrees of freedom. The model with the best-fit indices was used for multi-group structural equation modeling to test for invariances across subsamples. Differences in the HAPA constructs and hand hygiene behavior between individuals below and above the symptom threshold for psychological symptoms were analyzed by latent means.

Missing Data. The amount of missing data per item was below 5% for both samples. Participants with missing data on the social-cognitive variables were included in the analysis if they had at least one non-missing data point under the assumption of missing (completely) at random. Missing data were imputed via the full information likelihood method (FIML) in AMOS v. 28.

Study 2: Longitudinal Study

Procedure and Participants: Longitudinal Study

Participants (N=1073) were recruited through four psychosomatic rehabilitation clinics from the Dr. Becker clinic group between July 2020 and August 2021. Data collection was performed longitudinally with two measurement timepoints. Data was collected from six weeks until the first day of the rehabilitation treatment and up to 12 weeks post-rehabilitation treatment. All participants were informed about the purpose of the study as well as associated data security measures on the clinic's study portal. Ethical approval for the study was obtained by the Ethics Committee at Jacobs University Bremen (protocol code 2020_09 and date of approval: 25 June 2020; ClinicalTrials.gov Identifier: NCT04453475). In total, n = 1073 participants took part in the study at both timepoints (before rehabilitation and after rehabilitation). Patients' age, measured in categories, ranged from 18 to above 60 years. 697 (65.4%) patients reported being female.

Measures

Hand Hygiene Behavior. Measures for socio-demographic information were the same as in the cross-sectional study. Participants from the psychosomatic rehabilitation clinics (longitudinal study) were asked to answer a stage item assessing the intention to perform hand hygiene behavior on a 5-point Likert scale. Answers were dichotomized as "non-compliant" (1-3) and "compliant". Changes in compliance were calculated by subtracting the stage before rehabilitation from the stage after rehabilitation.

Mental Health Symptoms. To measure depressive symptoms during the past, the PHQ-2 was administered which is part of the Patient Health Questionnaire-4 (PHQ-4) with two items (Kroenke et al., 2003) on a 4-point Likert scale from 0 'not at all' to 3 'nearly every day'. A scale sum score of \geq 3 (T1 Spearman's rho = .83; T2 Spearman's rho = .85) depicts the cut-off value between the normal range and a probable case of depression (Löwe et al., 2005). The PHQ-2 was used as a measure of symptom intensity.

In addition, the generalized anxiety index was examined via the GAD-2 which is a questionnaire part of the PHQ-4 (Löwe et al., 2010). The GAD-2 encompasses two items measuring symptoms of generalized anxiety during the past two weeks on a 4-point Likert scale from 0 'not at all' to 3 'nearly every day'. A sum score of \geq 3 (Kroenke et al., 2007) serves as the cut-off value between the normal range and a possible case of a generalized anxiety disorder (T1 Spearman's rho = .80; T2 Spearman's rho = .83). Compared to the GAD-7, the GAD-2 was only used as a measure of symptom intensity.

Data Analysis

To evaluate whether mental health (i.e., depression and generalized anxiety) played a role in changes in compliance from being non-compliant concerning performing hand hygiene behavior to being complaint, the change was evaluated by a binary logistic regression analysis controlling for gender and age. For patients progressing from non-compliant to compliant, a '1' was coded. Conversely, for patients regressing a '-1' was

coded. Concerning patients who did not change in their compliance, a '0' was coded. Odds ratio with a 95% confidence interval was used to report the effect size estimate. Additionally, Wald static was used as an indicator of the significance of each regression coefficient in the binary logistic regression. All of the analyses were conducted using IBM SPSS v.28 and AMOS v.28.

Results

Study 1

Scale Internal Consistency and Correlations between Constructs

Table 6 shows bivariate correlations between the social-cognitive variables for participants.

Table 6. Correlations between Health Action Process Approach (HAPA) Constructs, Hand hygiene Behavior, and Mental Health Status of N = 279 Participants.

	α	М	SD	ASE	OE	RISK	INT	MSE	PL	RES	SUP	HYG	DEP	ANX
ASE	.87	19.13	4.28	-										
OE	.83	24.61	3.83	.41**	-									
RISK	_1	3.16	1.33	20**	.03	-								
INT	.68	10.04	1.87	.55**	.50**	08	-							
MSE	.91	19.58	3.99	.56**	.48**	08	.55**	-						
PL	.86	12.43	5.34	.40**	.38**	14**	.40**	.28*	-					
RES	.81	20.28	5.03	.27**	.34**	.03	.21**	.26**	.16**	-				
SUP	.92	5.82	3.15	.27**	.30**	.05	.24*	.06	.33**	.44**	-			
HYG	.87	48.12	7.98	.39**	.32**	20**	.52**	.44**	.36**	.22**	.12*	-		
DEP	.86	5.89	4.75	08	03	04	.01	03	.01	12	07	07	-	
ANX	.85	4.70	3.82	08	03	08	.03	10	.01	05	10	01	48**	-

Note. HAPA variables: ASE = Action Self-Efficacy, OE = Outcome Expectancies, RISK = Risk Perception (single-item), INT = Intentions, MSE

= Maintenance Self-Efficacy, PL = Planning, RES = Resources, SUP = Social Support, HYG = Hand Hygiene Behavior, DEP = Depression,

ANX = Anxiety

 α = Cronbach's alpha, *p < .05, **p < .01, M = Mean, SD = Standard deviation

¹Risk perception was examined via a single item. Therefore, no Cronbach's alpha can be provided.

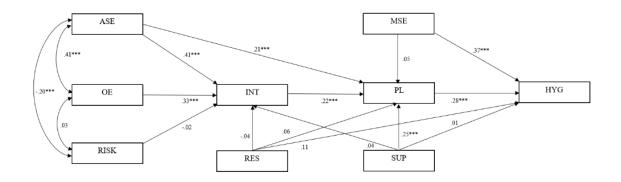
N = 279

Structural Equation Modeling

N = 279

To examine links between HAPA variables, a structural equation modeling was performed (see Figure 1). The hypothesized model was a poor fit with the proposed data according to the literature (Barrett, 2007; Hu & Bentler, 1999). Fit indices for the model were as follows: $\chi^2 = 339.20$, df = 19; p < .001, CMIN/df = 17.85, CFI = .53, RMSEA = .25. Standardized estimates for each path are reported in Figure 3.

Figure 3. Structural Equation Modeling of the Full Health Action Process Approach.



Note. HAPA variables: ASE = Action Self-Efficacy; OE = Outcome Expectancies, RISK = Risk Perception; INT = Intentions; MSE = Maintenance Self-Efficacy; PL = Planning, RES = Resources, SUP = Social Support, HYG = Hand Hygiene Behavior

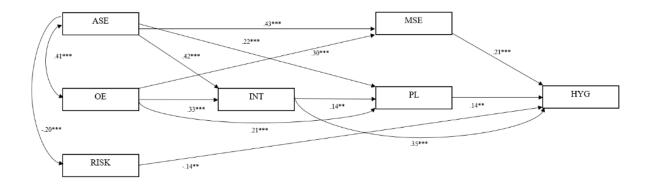
Intention $R^2 = 39.5\%$; Planning $R^2 = 19.8\%$; Hand Hygiene $R^2 = 21.6\%$

The values reported represent the standardized estimates of each path in the model. Significant path at ***p < .001, **p < .01, *p < .05.

Considering age and gender, as well as depressive and generalized anxiety symptoms as covariates, modifications proposed by AMOS lead to a final adaption of the HAPA framework with a reasonably good fit: $\chi^2 = 27.1$, df = 12, p < .01, CMIN/df = 2.26, CFI = .97, RMSEA= .08. The standardized estimates for each path in the trimmed HAPA framework are

reported in Figure 4. All paths were significant at either p < .01 or p < .001 ranging between β = -.20 and β = .43. All covariates revealed to be non-significant (except for symptoms of generalized anxiety) were associated with hand hygiene behavior, β = -.16, p < .05.

Figure 4. Structural Equation Modeling of the Trimmed Health Action Process Approach.



Note. HAPA variables: ASE = Action Self-Efficacy; OE = Outcome Expectancies, RISK = Risk Perception; INT = Intentions; MSE = Maintenance Self-Efficacy; PL = Planning; HYG = Hand Hygiene Behavior

$$N = 279$$

Intention $R^2 = 39.3\%$; Planning $R^2 = 23.5\%$; Hand Hygiene $R^2 = 33.2\%$

The values reported represent the standardized estimates of each path in the model. Age, gender, depressive symptoms, and symptoms of generalized anxiety were included as covariates. Significant path at ***p < .001, **p < .01, *p < .05.

Latent Mean Differences Across Mental Health Status

To test for potential differences in the HAPA constructs from the trimmed HAPA framework (Figure 4) between patients above and below the symptom threshold for generalized anxiety as well as for depression, a three-step multi-group analysis was conducted applying (1) an unrestricted model, (2) a semi-restricted model, and (3) a fully restricted model. All were subsequently compared with the χ^2 difference indices according to Yuan and Bentler (2004).

Concerning depression, indices indicated a good fit for the unrestricted, semi-restricted, and full-restricted models (Table 7). Hence, χ^2 -difference tests between the unrestricted and semi-restricted model ($\chi^2(12) = 11.29$, p = .501) and between the semi-restricted and fully restricted model ($\chi^2(15) = 11.38$, p = .734) were performed and did not reach significance. Results confirmed measurement invariance and allowed for group comparison. This suggests structural equivalence (Yuan & Bentler, 2004) and states that for patients above and below the symptom threshold for depression, the HAPA constructs were equivalent concerning their structural pattern and their magnitude. Therefore, no differences were detected concerning the symptomatology of depression in the pattern of relationships.

Table 7. Model Fit Indices for the Unrestricted Model, the Semi-Restricted Model, and the Fully Restricted Model for the Multi-Group Mental Health Status Model for Individuals Below and Above the Symptom Threshold for Depression (N = 279).

Indices	Unrestricted model	Semi-restricted	Fully restricted
		model	mode
χ^2 – Test of model fit	40.49	51.77	63.15
df	16	12	27
$\frac{df}{\chi^2}$	<i>p</i> <.01	<i>p</i> <.01	p < .05
CFI	.94	.94	.95
TLI	.85	.92	.95
Model 1 Delta TLI	-	07	09
RMSEA (90% CI)	.08	.06	.04

Note. df=degrees of freedom, χ^2 = Chi square, CFI = comparative fit index, TLI = Tucker-

Lewis Index, RMSEA = root mean squared error of approximation

About symptoms of anxiety, indices again indicated a good fit for the unrestricted, semi-restricted, and full-restricted model (Table 8). Hence, a χ^2 -difference test between the unrestricted and semi-restricted model ($\chi^2(12) = 10.884$, p = .543) and between the semi-restricted and fully restricted model ($\chi^2(15) = 23.17$, p = .082) was performed and did not reach significance. Results confirmed measurement invariance and allow for group comparison. This

suggests structural equivalence (Yuan & Bentler, 2004) and indicates that, for patients above and below the symptom threshold for generalized anxiety, the HAPA constructs were equivalent concerning their structural pattern and also in terms of their magnitude. This indicates that no differences were detected concerning the symptomatology of generalized anxiety in the pattern of relationships.

Table 8. Model Fit Indices for the Unrestricted Model, the Semi-Restricted Model, and the Fully Restricted Model for the Multi-Group Model of Individuals Below and Above the Symptom Threshold for Generalized Anxiety (N = 279).

Indices	Unrestricted model	Semi-restricted model	Fully restricted model
χ^2 – Test of model fit	29.75	40.63	63.80
df	16	12	27
$\frac{df}{\chi^2}$	p=.020	p=.062	p=.013
CFI	.97	.97	.97
TLI	.92	.95	.95
Model 1 Delta TLI	-	03	03
RMSEA (90% CI)	.06	.04	.04

Note. df=degrees of freedom, χ^2 = Chi square, CFI = comparative fit index, TLI = Tucker-

Lewis Index, RMSEA = root mean squared error of approximation

With the results showing that factor loadings and covariances were invariant across individuals below and above the symptom threshold for depression as well as anxiety, the assumption for latent mean analysis was met. Therefore, it was analyzed to determine if the latent means of the HAPA constructs of the trimmed framework were different across individuals below and above the symptom threshold for depression and generalized anxiety. To estimate the latent mean differences between groups, the group below the symptom threshold for depression and generalized anxiety operated as a reference group. The latent mean was fixed to zero, against which the latent means of the other group were compared. The latent mean for

the other group, above the symptom threshold for depression and generalized anxiety, was freely estimated.

Table 9. *Latent Mean Analysis: Mean Estimates, Standard Error, and Critical Ratio (N = 279).*

	ASE	OE	RISK	INT	MSE	PL	HYG
With symptoms of depression							
in comparison to the							
reference group without							
depressive symptoms							
Mean estimate (ME)	-0.194	-0.090	-0.137	0.049	-0.239	0.050	0.016
Standard error (SE)	0.163	0.126	0.238	0.154	0.150	0.282	0.018
Critical ratio (CR)	-1.252	-0.715	-0.576	0.320	-1.159	0.177	0.907
p	.233	.475	.565	.749	.110	.859	.365
With symptoms of anxiety in							
comparison to the reference							
group without symptoms of							
anxiety							
Mean estimate (ME)	-0.227	-0.102	-0.310	0.068	-0.072	0.127	-0.043
Standard error (SE)	0.212	0.136	0.242	0.176	0.168	0.294	0.029
Critical ratio (CR)	-1.073	-0.752	-1.280	0.384	-0.429	0.433	-1.466
p	.283	.452	.201	.701	.668	.665	.143

Note. HAPA variables: ASE = Action Self-Efficacy; OE = Outcome Expectancies, RISK =

Risk Perception; INT = Intentions; MSE = Maintenance Self-Efficacy; PL = Planning; HYG = Hand Hygiene Behavior

Analysis of latent means of HAPA constructs revealed no significant differences between individuals below the symptom threshold and above the symptom threshold for depression and generalized anxiety (Table 9).

Study 2 Changes in compliance and its predictors

To analyze whether mental health was a predictor in changes concerning compliance or non-compliance in hand hygiene behavior, data from the longitudinal sample of psychosomatic

rehabilitation patients was used. Table 10 shows the distribution and transitions of compliance with hand hygiene behavior from before to after rehabilitation.

Table 10. *HAPA Stage Distributions and Transitions of the Longitudinal Sample* (N = 1058).

Time 2 (after rehabilitation)								
Non-compliance Compliance Total								
Time 1	Non-compliance	25 (2.4)	30 (2.8)	55 (5.2)				
	Compliance	47 (4.4)	956 (90.4)	1003 (94.8)				
	Total	72 (6.8)	986 (93.2)	1058 (100)				

Note. Numbers in parentheses represent percentages of N = 1058.

Stages of compliance did differ significantly regarding hand hygiene behavior. F(1,1064) = 2152.79, p < .01: those compliant had an average compliance score of 4.80 (SD = 0.40) compared to non-compliant patients (M = 2.11; SD = 0.76). Patients progressing from non-compliance to compliance showed an increase in hand hygiene behavior (T1 M = 2.20, T2 M = 4.67). Those regressing displayed a decrease in hygiene behavior (T1 M = 4.53, T2 M = 2.09). Hence, the transition from non-compliance to compliance and vice versa has shown to be consistent with behavior changes such as the increase or decrease in hand hygiene behavior.

At post-assessment, significant differences in hand hygiene behavior between patients being compliant and non-compliant were found, F(1,1064) = 2152.79, p < .01. Those compliant had an average compliance score of 4.79 (SD = 0.41) compared to those being non-compliant patients (M = 2.00; SD = 0.80).

Table 11. Summary of Results from the Binary Logistic Regression Analysis and Descriptive Data for Mental Health Variables and Control Variables Predicting Changes in Compliance in Hand Hygiene Behavior (n = 71).

Predictors	Wald	OR	95%	P-Value	Remaining in		Change	in		
			CI_{OR}		baseline		complia	nce		
					compliance					
					M	SD	M	SD		
Change in co	Change in compliance: remaining non-compliant (0) versus progression (1)									
Depression	1.03	1.36	0.75-2.48	.31	2.79	1.14	3.27	1.89		
Anxiety	0.32	0.84	0.45-1.57	.58	2.84	1.25	3.10	1.69		
Change in co	Change in compliance: remaining compliant (0) versus regression (1)									
Depression	1.14	1.15	0.89-1.48	.29	3.45	1.66	3.83	1.61		
Anxiety	0.05	0.97	0.75-1.26	.84	3.61	1.67	3.82	1.35		

Note. CI_{OR} = 95% confidence interval of the odds ratio (OR).

The results of the binary logistic regression indicate that neither symptoms of depression, nor generalized anxiety, were significant predictors of change in compliance. Odds ratios, Wald statistics, and descriptive data are summarized in Table 11.

Discussion

The current study aimed to evaluate, as part of study 1, whether the social cognitive variables part of the HAPA model were associated with hand hygiene behavior. In addition, we aimed to examine whether the HAPA framework fits hand hygiene behavior and its processes by evaluating the intention-behavior gap. In addition, this study examined the role of hand hygiene behavior in examining the maintenance of, and compliance with, hand hygiene behavior. Our results support the hypothesis as all variables (except for risk perception) were positively correlated with each other. Risk perception was negatively correlated with action self-efficacy, intention, maintenance self-efficacy, planning, and hand hygiene behavior.

Further, risk perception was negatively correlated with depression and anxiety despite the results not being significant.

The second aim of study 1 was to test whether the model structure of the HAPA is applicable to hand hygiene behavior tested by structural equation modeling. The first attempt to fit the HAPA to the data revealed a poor fit according to commonly accepted fit indices (Browne & Cudeck, 1992). This, however, is not surprising as models with a good fit found in literature often are incomplete and do not include all of the HAPA constructs.

The final attempt to fit the data to a model revealed significant paths and acceptable fit indices. Still, the latest model needs to be treated with caution as the model fit was not perfect according to the RMSEA (Shi et al., 2020). However, as Kenny et al. (2015) suggested, sample size and degrees of freedom also need to be looked at when interpreting RMSEA. Hence, models with small sample sizes and low degrees of freedom tend to display an elevated RMSEA. Therefore, considering all fit indices, we can assume that the proposed model fits our data. This is in line with literature as the HAPA model has been used previously to explain health care workers' hand hygiene as well as to inform successful interventions (von Lengerke et al., 2019). In a recent study, Gaube and colleagues found that the HAPA model (although not explaining the highest amount of variance) could explain patients' and visitors' hand hygiene (Gaube et al., 2021). Hence, based on previous evidence, it seems that hand hygiene behavior is a health behavior developing in a dynamic process that is fairly similar between health care workers, the general public, and patients. Therefore, the process of performing hand hygiene along the HAPA may be described as follows: In the motivational phase, outcome expectancies and action self-efficacy were associated with intention. These results indicate that improving beliefs about the beneficial effects of performing good hand hygiene might be promising when motivating patients to become more active concerning their hand hygiene. Contrary to the hypothesized structure of the HAPA, risk perception was not associated with intention. Risk perception does not seem to be significantly associated to practice good hand hygiene in the context of the HAPA model. This is in line with other studies in the area of physical activity (Schwarzer et al., 2007; Zhang et al., 2019). These last findings have suggested that risk perception may not be sufficient to form an actual intention to change health behavior (Schwarzer et al., 2011) and may instead, be a distal predictor of hand hygiene behavior (Chiu et al., 2012).

However, for effective maintenance and performance to occur, necessary self-regulatory strategies, such as planning, need to be shown in the volitional stage. Therefore, it has been assumed that planning bridges the intention-behavior gap, thus ensuring the maintenance of hand hygiene. Similar to the results by Gaube et al. (2021), our results have shown a direct link between intention and the desired behavior. However, their study lacks results showing that planning was able to bridge the intention-behavior gap. Hence, the present study is the first to show that, for hand hygiene behavior of patients to be maintained, planning has the function to bridge the intention-behavior gap. Nevertheless, the present study did not include or acknowledge other self-regulatory skills, automatism, and action control as part of this study. Hence, integrating those variables should be regarded in future research.

Further, we aimed to investigate in study 1 whether individuals below or above the symptom threshold for depression and generalized anxiety differed on the social-cognitive determinant regarding hand hygiene according to the trimmed HAPA framework. Results revealed no statistically significant differences in latent means nor with the interrelations of the variables. This suggests that the trimmed HAPA may be a generic framework for explaining social-cognitive processes of hand hygiene behavior irrespective of patients' mental health status. Based on the results, it may be postulated that mental health may not be a factor associated with better or worse hand hygiene performance but, rather, social-cognitive variables may need to be considered. This is in line with previous studies examining compliance to hand hygiene behavior in the general population, as well as in psychosomatic rehabilitation patients, indicating that both groups of participants display good hand hygiene behavior when either,

possessing greater fear of an infection or being more susceptible to anxiety (Dahmen et al., 2021; Lippke et al., 2022). In addition, the systematic review by Farholm and Sørensen (2016) suggested no differences in motivational mechanisms between the normal population and individuals with mental illnesses. However, our results need to be treated with caution due to the small sample size of individuals displaying symptoms of depression and generalized anxiety.

Finally, as part of study 2, we aimed to investigate whether symptoms of depression and generalized anxiety were predictive of a change in compliance in hand hygiene behavior in psychosomatic rehabilitation patients. Our results indicated that neither symptoms of depression, nor generalized anxiety, were predictive of a regression or a progression concerning compliance with hand hygiene behavior. Firstly, these findings confirm results from the general population that compliance with hand hygiene behavior is independent of mental health status (Lippke et al., 2022). However, contrary to the previous assumption that a reduced mental health status would be associated with poorer compliance with hand hygiene behavior, the present results did not find such effects. A possible reason for the non-significant results might be that there are no significant changes in motivation to perform the hygiene behavior between individuals with and without a mental health illness (Farholm & Sørensen, 2016). Another possibility is that hand hygiene may be a stable construct irrespective of mental health status. For example, individuals who were compliant with hand hygiene behavior before the pandemic also were compliant during the pandemic and vice versa (Guzek et al., 2020), which may also explain the absence of any differences based on the three data collection points (see Appendix 3). Therefore, non-compliant individuals need to be encouraged to perform adequate hand hygiene. One way to do so may be to implement interventions that foster planning and selfefficacy measures, helping to overcome the intention-behavior gap (Tan et al., 2018).

Limitations and Future Directions

The current study has some limitations. All variables examining hand hygiene behavior were (retrospective) self-report measures collected at one point in time within the general population. This was done to replicate previous research (e.g., Reyes Fernández et al., 2016) and to assess data during the COVID-19 pandemic. However, recall bias and social desirability need to be considered when interpreting participants' responses. To overcome this limitation, the handwashing behavior of patients should be observed by trained observers or tracked by technical devices. Still, even with testing for differences in time between hospitalization and participation in the survey (concerning the self-reporting of hand hygiene behavior), no significant differences were found. This suggests that even though self-reporting biases and social desirability should be acknowledged, reported hand hygiene behavior has remained stable. Additionally, mental health was examined by a validated questionnaire but not via a diagnosis according to the International Classification of Disease-10 (ICD-10) manual. Furthermore, mental health symptoms might have been exacerbated by the COVID-19 pandemic (e.g., through increasing uncertainty, and reduced social contacts). Due to this potential, the expression of depressive symptoms, or symptoms of generalized anxiety, may be confounded by the current situation and should be considered in future research.

A further methodological limitation may be that this study used data from a cross-sectional study to investigate hand hygiene processes in the general population. Using structural equation modeling on cross-sectional data does not reflect the dynamic nature of underlying processes over time and thus violates model assumptions. However, testing for differences in (1) HAPA variables, (2) part of the final adapted HAPA model, and (3) depression and generalized anxiety, have shown no significant differences across the three measurement waves suggesting relatively stable constructs irrespective of situational context. It is recommended that future research should validate the results from the trimmed HAPA model in the form of a prospective or experimental study i.e., a randomized controlled trial to determine causal effects

conclusively. Prospective behavioral measures, especially for the main outcome of hand hygiene, should be applied.

Another limitation is that only a few participants with symptoms of depression (n = 42)and generalized anxiety (n = 33) could be included in this study from the general population, thus, compromising the statistical power. Nevertheless, the findings of this cross-sectional study and longitudinal examination can contribute to the understanding of the current state of hand hygiene adherence of patients and provide a basis for designing interventions to improve psychological aspects related to hand hygiene. Results indicate that the following should be considered when designing interventions: encouragement for the patients, regardless of their mental health status, to create hand washing plans for specific situations. In this regard, digital tools could be employed to function as reminders of plans and reminders of past successes. The present results indicate that social-cognitive variables and self-regulatory processes are necessary determinants for effective hand hygiene behavior. Therefore, to make patients more aware of the necessity and to support them by reducing the need for self-regulatory processes, hospitals should be encouraged to promote hand hygiene behavior throughout the health care facilities with visible posters or dispensers at accessible and visible locations as shown in studies by Hobbs et al. (2016). In addition, to increase the intention to perform hand hygiene behavior, visual, auditory, and dynamic videos should be employed to encourage patients to clean their hands which have shown to be effective in other hospitals (Gaube et al., 2018). Furthermore, individuals need to be made more aware of the potential risks associated with reduced hand washing behavior and compliance. Literature has shown that, in general, and irrespective of mental health status, individuals report more compliance if they are aware of the potential risks (Lippke et al., 2022). Hence, communication in the public media and hospitals (i.e., on leaflets or posters) needs to be clearer and more objective while focusing on the risks.

Conclusion

In conclusion, the present study investigated the process of change in hand hygiene behavior. Findings were largely consistent with previous literature on the generalizability of the HAPA framework in the context of health behavior change even though the proposed adaption of the HAPA should be examined in more depth in the future. It was found that the intention to wash or sanitize hands is crucial for the resulting hand hygiene behavior. Furthermore, planning was able to close the intention-behavior gap concerning performing effective hand hygiene. Including additional constructs such as action control, self-regulation, and automatisms might further explain hand hygiene behavior and deepen the current understanding. Regarding the crucial role of self-efficacy, intention, and planning: these constructs should be targeted in future interventions with patients to decrease the risk of communicable diseases in hospitals. This should be considered when designing interventions, especially as most initiatives still mainly draw on risk perception which was not related to the intention and, instead, had a detrimental effect on the behavior of hand hygiene. Thus, it would be better to take a resourceoriented approach while communicating and targeting self-efficacy, outcome expectancies, intention, and planning to improve behavior sustainably. Testing interventions for patients and visitors in rigorous research designs such as randomized control trials (RCT) with a high sample size needs to be a research focus to target hospital hygiene more broadly. Furthermore, the trimmed HAPA proved to be a generic framework for explaining social-cognitive determinants of hand hygiene behavior regardless of the mental health status of patients. In addition, mental health was revealed to not be a predictor of changes in compliance concerning hand hygiene behavior, indicating that interventions can be beneficial for patients with and without mental health symptoms since the underlying process appears to be similar. Further, these findings indicate that interventions should focus on social-cognitive predictors rather than on the role of mental health with regard to hand hygiene behavior. Drawing on the actual findings, helping individuals to perform hand hygiene by intention formation and bridging the intention-behavior

gap by planning and self-efficacy was revealed to be feasible independent of mental health status.

Acknowledgments

We would like to thank the Dr. Becker clinics Möhnesee, Norddeich, Juliana, and Burg for supporting us with the data collection and Grace Wire for proofreading a previous version of this manuscript.

Declaration of Interest

We have no known conflict of interest to disclose.

Funding

This work was supported by The Federal Joint Committee (G-BA) as part of the research project "TeamBaby – Safe, digitally supported communication in obstetrics and gynecology" [01VSF18023].

Data Availability

The data that support the findings of this study are available on request from the corresponding author, FMK, only. The data are not allowed to be made publicly available due to the privacy and data security reasons of research participants.

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Chapter 5: Psychosomatic Rehabilitation Patients and the

General Population During COVID-19: Online Cross-sectional
and Longitudinal Study of Digital Trainings and Rehabilitation

Effects

Keller, F. M., Dahmen, A., Derksen, C., Kötting, L., & Lippke, S. (2021). Psychosomatic Rehabilitation Patients and the General Population During COVID-19: Online Crosssectional and Longitudinal Study of Digital Trainings and Rehabilitation Effects. *JMIR Mental Health*, 8(8), e30610. https://doi.org/10.2196/30610

COVID-19 Pandemic and Mental Health: Digital Trainings to Support Psychosomatic Rehabilitation Patients

Abstract

Background:

The COVID-19 pandemic has largely affected people's mental health and psychological well-being. Specifically, individuals with a pre-existing mental health disorder seem more impaired by lockdown measures posing as major stress factors. Medical rehabilitation treatment can help people cope with these stressors. The internet and digital apps provide a platform to contribute to regular treatment and conduct research on this topic.

Objective:

Making use of internet-based assessments, this study investigated individuals from the general population and patients from medical, and psychosomatic rehabilitation clinics. Levels of depression, anxiety, loneliness, and perceived stress during the COVID-19 pandemic, common COVID-19—related worries, and the intention to use digital apps were compared. Furthermore, we investigated whether participating in internet-delivered digital trainings before and during patients' rehabilitation stay, as well as the perceived usefulness of digital trainings, were associated with improved mental health after rehabilitation.

Methods:

A large-scale, online, cross-sectional study was conducted among a study sample taken from the general population (N = 1812) in Germany from May 2020 to April 2021. Further, a longitudinal study was conducted making use of the internet among a second study sample of psychosomatic rehabilitation patients at two measurement time points—before (N = 1719) and after (N = 1719) rehabilitation—between July 2020 and April 2021. Validated questionnaires and adapted items were used to assess mental health and COVID-19–related worries. Digital

trainings were evaluated. Propensity score matching, multivariate analyses of covariance, an exploratory factor analysis, and hierarchical regression analyses were performed.

Results:

Patients from the psychosomatic rehabilitation clinics reported increased symptoms concerning depression, anxiety, loneliness, and stress (F(4,2028) = 183.74, p < .001, $\eta_p^2 = .27$) compared to the general population. Patients perceived greater satisfaction in communication with health care professionals (F(1,837) = 31.67, p < .001, $\eta_p^2 = .04$), had lower financial worries (F(1,837) = 38.96, p < .001, $\eta_p^2 = .04$), but higher household-related worries (F(1,837) = 5.34, p = .02, $\eta_p^2 = .01$) compared to the general population. Symptoms of depression, anxiety, loneliness, and perceived stress were lower post rehabilitation (F(1,712) = 23.21, p < .001, $\eta_p^2 = .04$) than prior to the rehabilitation. Psychosomatic patients reported a higher intention to use common apps and digital trainings (F(3,2021) = 51.41, p < .001, $\eta_p^2 = .07$) than the general population. With regard to digital trainings offered prior and during the rehabilitation stay, the perceived usefulness of digital rehabilitation goal trainings was associated with decreased symptoms of depression ($\beta = -.14$, p < .001), anxiety ($\beta = -.12$, p < .001), loneliness ($\beta = -.18$, p < .001) and stress post rehabilitation ($\beta = -.19$, p < .001). Participation in digital group therapy for depression was associated with an overall change in depression (F(1,725) = 4.82, p = .03, $\eta_p^2 = .01$) and anxiety (F(1,725) = 6.22, p = .01, $\eta_p^2 = .01$) from pre to post-rehabilitation.

Conclusion:

This study validated the increased mental health constraints of psychosomatic rehabilitation patients in comparison to the general population and the effects of rehabilitation treatment. Digital rehabilitation components are promising tools that could prepare patients for their rehabilitation stay, could integrate well with face-to-face therapy during rehabilitation treatment, and could support aftercare.

	Keywords:	Mental	Health;	COVID-19;	Medical	Rehabilitation;	Psychosomatic				
Rehabilitation; Internet-Delivered Digital Trainings											

Introduction

Mental Health and the COVID-19 Pandemic

The COVID-19 pandemic has led to rapid changes in the lives of people all over the world, thus affecting both physical health as well as mental health and well-being (Shigemura et al., 2020). Worries about one's health, the health of family and friends, as well as worries associated with the future are indicative of decreased mental health and psychological well-being. Hence, for many individuals, the COVID-19 pandemic evoked feelings of uncertainty, social isolation due to contact regulations, stress reactions, symptoms of depression and anxiety, and general fear of the virus (Balkhi et al., 2020; Liu et al., 2020). In case of prolonged concerns or worries, individuals are at risk of developing serious mental health disorders (Fiorillo & Gorwood, 2020).

A study by Wang et al. asked respondents to assess the psychological impact of the COVID-19 pandemic on their mental health. Results highlighted that 54% of the respondents rated the psychological impact of the COVID-19 pandemic as moderate to severe. Further, 29% estimated own anxiety symptoms to be between moderate and severe, and 17% estimated symptoms of depression as moderate to severe (Wang et al., 2020). Another study by Sønderskov et al. revealed lower psychological well-being in the general public compared to before the COVID-19 pandemic (Sønderskov et al., 2020). Recent studies from the United States highlighted the worldwide increase in depressive symptoms as well as in symptoms of anxiety, which occurred about three times more frequently during the COVID-19 pandemic than before. Research has indicated that pre-existing mental health conditions may worsen due to COVID-19 (Ettman et al., 2020; Twenge & Joiner, 2020).

The conjectured decrease in mental health worldwide may be explained by two developments associated with the ongoing course of the COVID-19 pandemic. On the one hand, the ramifications associated with the COVID-19 pandemic, such as uncertainties,

unemployment, short-term employment, or social isolation, may pose a mental health threat. A cross-national comparison of Norway, the United Kingdom, the United States, and Australia found that secure employment status was associated with lower levels of loneliness and mental health distress as well as higher levels of well-being and quality of life during the early social distancing requirements of the pandemic (Ruffolo et al., 2021). Correspondingly, returning to work during the pandemic was associated with low levels of psychiatric problems (Tan et al., 2020).

On the other hand, the way most people live, work, study, socialize, or travel has been abruptly disrupted or shifted online. The associated containment measures, such as quarantining and physical distancing, restrict people in their freedom but are necessary to control the disease's spread. Literature has shown that quarantining or physically distancing oneself from others may lead to problems associated with decreased mental health status (Chatterjee et al., 2020). It can precipitate feelings related to fear, anger, anxiety, or even panic about possible negative outcomes and is associated with increased perceived loneliness and boredom.

The World Health Organization (WHO) has also expressed concerns concerning the mental health and psychological well-being of individuals due to containment measures. According to the WHO, restrictions may interfere with people's daily activities and routines and may consequently lead to an increased perception of loneliness, depression and anxiety, insomnia, substance misuse, self-harm, or even suicidal behavior (World Health Organization, 2020). It has been shown that increased loneliness and reduced interactions due to social distancing are risk factors for several mental health disorders, such as depression, anxiety, and schizophrenia. Especially for women, young people, and those living with young children, mental health problems have increased over time (Pierce et al., 2020).

COVID-19 and Patients with Pre-Existing Mental Health Disorders

Literature on the impact of the 2003 severe acute respiratory syndrome (SARS) outbreak and the COVID-19 pandemic underlined more negative feelings associated with worry (Liu,

2020; Reynolds et al., 2008). Worry, which can be defined as an attempt to engage in mental problem solving or to deal with outcome uncertainty under some circumstances (Borkovec & Costello, 1993), is a central feature of anxiety disorders (American Psychiatric Association, 2013) and is associated with depressive rumination (Watkins et al., 2005). Several studies have identified worries associated with the COVID-19 pandemic, such as health-, future-, or employment-related worries, and their associated consequences, such as sleep hygiene, drinking behavior, changes in social interactions, or changes in physical exercise (Barber & Kim, 2021; Van Rheenen et al., 2020).

For patients with a pre-existing mental health disorder or a decreased perception of well-being, lockdown measures are major stress factors affecting daily routine and social rhythms. A study by van Rheenen et al. examined the mental health status of individuals with a mood disorder during the COVID-19 pandemic in an Australian sample as compared to individuals without a prior mood disorder. Their results underlined that distress in response to the COVID-19 pandemic is highlighted in individuals with a mood disorder (Van Rheenen et al., 2020). Patients with a pre-existing mental health disorder increasingly reported worries related to infecting themselves or infecting others (Dahmen et al., 2021).

COVID-19 and Psychosomatic Medical Rehabilitation

A population that has been especially concerned by the COVID-19 pandemic because of pre-existing mental health problems comprises psychosomatic patients in medical rehabilitation. They may be afraid of visiting a doctor and receiving inpatient treatment in a hospital; on the other hand, they report worsening physical and mental well-being (Dahmen et al., 2021). This development aggravates the already worrisome situation of psychosocial and psychosomatic rehabilitation programs, causing patients to remain untreated. If they decide to use medical services, they are confronted with many changes in therapy programs: due to contact regulations and hygiene measures, as well as the general lack of therapists in health care

systems, it is necessary to develop and establish internet-based programs and trainings as one component of therapy as well as digital support systems and platforms.

Due to the pandemic and, accordingly, its restrictions, resources had to be re-allocated and therapies had to be paused, which caused a decrease in the availability of on-site services (Drwal et al., 2020). Particularly for older people, the fear of infection can prevent hospital or rehabilitation stays (Hau et al., 2020). Possible solutions can be home-based or telehealth rehabilitation programs (Bryant et al., 2020; Drwal et al., 2020), or shifting parts of the rehabilitation treatment to online preparation in the form of a home-based telehealth intervention. This is especially innovative because, during the past several years, patients have frequently been prepared for rehabilitation as well as treated during the rehabilitation stay with written material. While the focus has increasingly shifted toward online trainings and interventions as the basis of psychotherapy, which are considered emerging technologies in health care and therapy, so far this is rather rare in the German rehabilitation system with its focus on inpatient treatment of "chronic psychosomatic conditions at risk of resulting in longterm sick leave and disability" (Scheidt, 2017, p. 79). Such interventions and trainings are independent of time and location. They can, therefore, be used in preparation for a rehabilitation stay (Becker et al., 2016), during a rehabilitation stay to supplement and support in-person therapy (Zwerenz et al., 2015), as well as for aftercare and stabilization processes (Hennemann et al., 2018; Zwerenz et al., 2013).

Digital interventions and trainings allow for adherence to hygiene measures as well as allow for therapeutic services to be offered on a large-scale basis. In addition, patients may be offered digital treatment options if they refrain from entering a rehabilitation stay due to worries and fears associated with the current COVID-19 pandemic, such as their own health and well-being or worries associated with losing their work placement (Van Rheenen et al., 2020). Several studies have examined the usefulness of electronically delivered cognitive behavioral therapy (eCBT), which has proven to be effective in the treatment of anxiety and depression

compared to regular in-person therapy (Alavi et al., 2020; Sztein et al., 2018). However, it remains to be evaluated whether digital trainings and therapies are useful measures to reduce symptoms of anxiety, depression, loneliness, and perceived stress in psychosomatic rehabilitation patients and how they can be implemented in practice. A crucial aspect of digital or mobile health (mHealth) interventions is the users' acceptance, often operationalized as perceived usefulness and ease of use. Both constructs determine the current or future usage and, thus, pose an important prerequisite for possible intervention effects (Davis, 1989). Both perceived usefulness and ease of use should, therefore, be considered in mHealth interventions.

The Health Action Process Approach

Drawing on the Health Action Process Approach (HAPA; Schwarzer, 2008; Schwarzer et al., 2011), which is separated into motivational and volitional phases, higher intentions, planning, as well as self-regulatory strategies are needed to perform a health behavior change. During the motivational phase, an intention is formed, and after the formation, self-regulatory strategies ensure that the target behavior is realized and maintained as part of the volitional phase. Therefore, planning bridges the gap between intentions and the respective behavior (Schwarzer et al., 2011). Literature has shown that the HAPA as a theoretical basis for digital trainings and interventions in the sector of care after psychosomatic rehabilitation has proven to be an effective model in explaining behavior change with consequent improvements in mental health (Schmädeke et al., 2019). Especially for psychosomatic rehabilitation patients diagnosed with a pre-existing affective disorder, it is necessary to specifically promote competencies, such as formulating intentions, action plans, as well as coping plans, and foster the development of outcome expectancies. Hereby, patients can increase their own control over their actions and can be supported employing digital trainings and interventions to change from a situation-focused orientation, which is considered typical for depression, to an action-focused orientation (Kuhl, 2001). Future research is necessary with regard to the HAPA being implemented in digital trainings and interventions for psychosomatic rehabilitation patients.

Goal of this Study

Based on the described background, we posed several research questions to understand worries and associated consequences regarding the COVID-19 pandemic in different populations, especially medical, and psychosomatic rehabilitation patients, using internet technology:

- 1. What differences are there in the expression and perception of psychological variables such as depression, anxiety, loneliness, and perceived stress between the general population and patients assigned to medical, psychosomatic rehabilitation clinics? The patients were diagnosed with a mental illness and were, thus, hypothesized to be at a higher risk for an exaggeration of their illness due to the pandemic, as shown above.
- 2. Which worries are associated with the current COVID-19 pandemic and are there differences in the perception between the two groups? We hypothesized that individuals from the psychosomatic rehabilitation group experienced more worries concerning the pandemic.
- 3. Is medical, psychosomatic rehabilitation treatment effective in terms of a decrease in symptomatology for depressive symptoms, symptoms of anxiety, loneliness, and perceived stress?
- 4. Do the general population and patient groups intend to make use of internet-delivered treatment components?
- 5. Is there a relationship between the usage, as well as perceived usefulness, of digital trainings that are offered before as well as during the rehabilitation stay in association with the intensity of mental health symptoms (e.g., depression) of patients after their medical rehabilitation?

By testing these research questions, we aimed to close the research gap in evaluating mental health and COVID-19-related worries between the general population and

psychosomatic rehabilitation. Furthermore, this study assessed the usefulness of internetdelivered trainings and their association with the mental health status of psychosomatic rehabilitation patients in Germany. To our knowledge, this has not been done before systematically. It is warranted to implement not only innovative but also effective internetdelivered interventions in the provision of medical services.

Methods

Overview

The study was conducted as part of the project "Anhand-COVID19 – Offer to achieve treatment and rehabilitation goals in compliance with hygiene and social-distancing rules" (ClinicalTrials.gov Identifier: NCT04453475), which is supported by the Dr. Becker clinic group. In addition, data collection and analyses on the general population were part of the research project "TeamBaby – Safe, digitally supported communication in obstetrics and gynecology" (ClinicalTrials.gov Identifier: NCT03855735), which is funded by the German Innovation Fund (Project No. 01VSF18023) of The Federal Joint Committee (G-BA).

First Sample: Recruitment and Procedure of the General Population

Data were collected anonymously through a nationwide recruitment campaign, press releases, social media posts, and the study home page of the TeamBaby project. No market research company or public sample was involved; however, the sample might have been selective. For data collection purposes, the software tool Unipark was used. The nationwide cross-sectional survey aimed to examine worries and coping mechanisms during the COVID-19 pandemic. All participants were informed about the purpose of the survey beforehand and provided online informed consent. Participants from the general population were not offered any form of compensation for participation. Data collection from the general population took place between May 2020 and April 2021. The time to complete the survey took, on average,

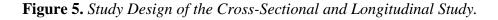
15.18 minutes (SD = 11.50). Ethical approval for the online survey for the general population was given by the Ethics Committee at Jacobs University Bremen on September 17, 2019.

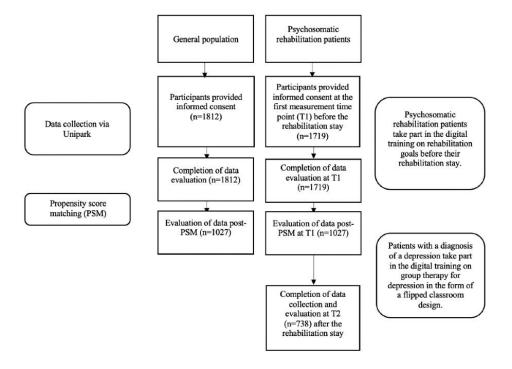
Second Sample: Recruitment and Procedure of Psychosomatic Rehabilitation Patients

The second group of participants were recruited through four psychosomatic clinics from the Dr. Becker clinic group and attended regular treatment at the recruiting clinics, consisting of psychological and physical interventions (i.e., individual and group psychotherapy, physiotherapy, or occupational therapy) as part of the incoming process for their rehabilitation stay. The German rehabilitation system focuses not on curation but reintegration and social participation. "Interventions in rehabilitation include psychoeducation, physical training, psychotherapy, and the training of skills particularly concerning working ability" (Scheidt, 2017, p. 81 Participants from the four psychosomatic clinics were informed about the study in writing on the hospital group's original online portal. Therefore, only patients who had access to this digital portal via smartphone, tablet, or computer before the start of rehabilitation were included. Participation was only possible after the patients had read the participation information and had given their informed consent in writing; data were pseudonymized. Rehabilitation patients were not offered any form of compensation for their participation in the online study.

The online survey at the psychosomatic clinics was administered between July 2020 and April 2021. Data collection at the rehabilitation clinics was longitudinal and took place at two time points: 6 weeks before the start until the first day of rehabilitation (T1) and after their rehabilitation stay (T2). All four participating medical, psychosomatic rehabilitation clinics that took part in this study and supported the recruitment of participants provided psychosomatic rehabilitation between measurement points T1 and T2. For the recruitment process and data collection process, see Figure 5. Time to complete the survey at measurement point T1 took, on average, 29.28 minutes (SD = 33.10) and at measurement point T2 took, on average, 30.16 minutes (SD = 52.37). Ethical approval for the online survey concerning psychosomatic

rehabilitation patients was given by the Ethics Committee at Jacobs University Bremen on June 25, 2000.





Digital Intervention Only for the Second Sample of Psychosomatic Rehabilitation Patients

Digital trainings were provided via the internet before patients' rehabilitation stay to optimally prepare them for their medical rehabilitation treatment and to make good use of the treatment components, including psychoeducation, physical training, psychotherapy, and the training of skills, particularly concerning working ability in the clinic. Such trainings could address rehabilitation goals.

The digital training on rehabilitation goals was offered to the patients in a digital PowerPoint (Microsoft) presentation training without face-to-face elements. Participants were able to participate in the digital training before their rehabilitation stay with a computer, laptop, tablet, or smartphone. The training included exercises on formulating precise plans for the rehabilitation stay. After the training, the patients were encouraged to make use of a digital

exercise booklet containing exercises on formulating plans as well as writing journal entries. Participation was voluntary. In addition, participants from two out of four psychosomatic rehabilitation clinics with a diagnosis of depression took part in group therapy for depression in the form of a flipped classroom as part of the rehabilitation treatment program (i.e., digital group training for depression).

The digital group training for depression was a combination of digital and face-to-face components. The training was divided into six sessions, each consisting of a 5-minute digital training followed by a 45-minute analog group session. The digital training, including input from a therapist with flip chart accompaniment, was either viewed independently or was watched as a group at the beginning of the analog group session. Participation for patients with a diagnosed depressive disorder was mandatory. The digital group training for depression was based on cognitive behavioral therapy (CBT) and contained evidence-based components of eCBT and internet-delivered CBT interventions, based on the current state of the art (Karyotaki et al., 2018; Luo et al., 2020; Sasseville et al., 2021). Contents of the group sessions included, for example, an explanation of depression symptoms and how to cope with them in the form of psychoeducation, underlying models, and different available treatments (i.e., drug therapy and psychotherapy).

Instruments

Table 12 provides an overview of all questionnaires and scales used for the two subsamples as part of this study.

Instruments Used for the General Population and the Psychosomatic Rehabilitation
Patients

Worries Related to the COVID-19 Pandemic. Items assessing worries related to the COVID-19 pandemic were derived from a study that measured frequently reported burdens and worries due to the COVID-19 pandemic (Varga et al., 2021). Consequently, an item pool of 77 elements was developed, of which 17 items were of interest for further analysis, as they

described common worries related to the COVID-19 pandemic. All items were refined by psychologists and a medical professional with expertise in the field of health psychology and psychosomatic rehabilitation.

Depressive Symptoms and Symptoms of Anxiety. For both subsamples, symptoms of depression and anxiety were measured with the 4-item Patient Health Questionnaire (PHQ-4), which is the composite measure of the 2-item Patient Health Questionnaire (PHQ-2; Kroenke et al., 2003) and the 2-item Generalized Anxiety Disorder scale (GAD-2; Kroenke et al., 2007), which measure symptoms of depression and anxiety, respectively (Löwe et al., 2010). The PHQ-4 consists of four items rated on a 4-point Likert scale from 0 (not at all) to 3 (nearly every day). Summed scores of 3 or higher for both the PHQ-2 (Spearman ρ = .75) and the GAD-2 (Spearman ρ = .74) indicated a probable case of depression and anxiety (Kroenke et al., 2007; Löwe et al., 2005). The PHQ-2 and the GAD-2 were not used as diagnostic tools in this study but, rather, were used to highlight symptoms associated with depression and anxiety.

Perceived Stress. *The Perceived Stress Scale* (*PSS*; Cohen et al., 1983) is a globally used self-report scale that measures perceived stress; the PSS was presented to the general population and psychosomatic rehabilitation patients. The scale assesses "the degree to which situations in one's life are appraised as stressful" (Cohen et al., 1983, p. 387), situations that are, therefore, perceived as unpredictable, uncontrollable, and overloaded during the past month. For this study, perceived stress was assessed using the short version of this scale, the 4-item PSS (PSS-4; Cohen & Williamson, 1988). It assesses perceived stress by rating four items on a 5-point Likert scale from 0 (never) to 4 (very often), with a Cronbach α of .79.

Loneliness. Loneliness was assessed with two items: "How often do you feel lonely?" stemming from the Center for Epidemiologic Studies–Depression scale (Radloff, 1977), and "How often do you feel unhappy to be alone?" from the UCLA (University of California, Los Angeles) Loneliness Scale (Russell, 1996; Spearman $\rho = .85$). The items were rated on a 4-

point Likert scale from 1 (not at all) to 4 (almost every day). Both items were presented to the general population and the psychosomatic rehabilitation patients.

Intention to Use Apps or Digital Trainings During the COVID-19 Pandemic. Intention to use apps or digital trainings as supportive means during the COVID-19 pandemic was assessed by rating three items on a 5-point Likert scale from 1 (no, I do not intend to) to 5 (yes, and it is very easy for me). These items were adapted based on the stages of change as part of the HAPA, which suggests that individuals typically progress through stages of behavior change independently of any time frame (Lippke et al., 2009, 2010).

Instruments Used Only for Psychosomatic Rehabilitation Patients: Perceived Usefulness of Digital Trainings. Based on the different digital trainings that psychosomatic rehabilitation patients took part in, the perceived usefulness of the offered digital trainings was measured by rating two items on a 5-point Likert scale from 1 (not at all useful) to 5 (completely useful): one item for the digital training on rehabilitation goals and one item for the digital, flipped classroom, group therapy for depression. Both items were adopted and modified based on the Technology Acceptance Model, which was originally designed to evaluate patients' responses to health information technology (Davis, 1989).

Sociodemographic and Additional Information. Additional data on sociodemographic information included participants' age, sex, and educational status. Age was categorized into five groups: ≤ 29 years, 30-39 years, 40-49 years, 50-59 years, and ≥60 years. Sex was categorized into three groups: male, female, and diverse. The highest obtained educational status was categorized into four groups: 10 or 11 years of schooling, 12 or more years of schooling, vocational training, and university degree. All variables were measured as categorical variables.

Table 12. Overview of Questionnaires and Scales Used for the General Population and the Psychosomatic Rehabilitation Patients.

Questionnaire or scales,	General population	Psychosomatic		
means $(SD)^a$		Rehabilitation Patients		
	n = 1812	n = 1719		
Overall worries related to the	48.10 (9.07)	51.47 (7.51)		
COVID-19 pandemic ^b				
Depression (PHQ-2°)	2.21 (1.89)	3.47 (1.65)		
Anxiety (GAD-2 ^d)	1.95 (1.85)	3.61 (1.69)		
Perceived stress (PSS-4 ^e)	7.40 (3.56)	9.44 (2.56)		
Loneliness (CES-D ^g ; UCLA ^h	4.14 (2.12)	4.49 (1.77)		
Loneliness Scale)	, ,	. ,		
Intention to use apps/ digital	5.43 (3.24)	6.51 (3.08)		
trainings (HAPA ⁱ)				
Perceived usefulness of	N/K^K	5.22 (1.90)		
digital trainings (TAM ^j)				
	n (%)	n (%)		
Age				
≤ 29 years	407 (22.5%)	70 (4.1%)		
30 to 39 years	416 (23.0%)	216 (12.6%)		
40 to 49 years	352 (19.4%)	390 (22.7%)		
50 to 50 years	385 (21.2%)	803 (46.8%)		
≥ 60 years	252 (13.9%)	236 (13.8%)		
Sex				
Male	529 (29.5%)	602 (35.3%)		
Female	1267 (70.5%)	1104 (64.7%)		
Education				
Secondary diploma	193 (10.7%)	398 (23.5%)		
High School Diploma	421 (23.2%)	241 (14.2%)		
Vocational Training	507 (28.0%)	791 (46.6%)		
University Diploma	690 (38.1%)	266 (15.7%)		

Note.

^cPHQ-2: 2-item Patient Health Questionnaire; items were rated on a 4-point Likert scale from 0 (not at all) to 3 (nearly every day), with summed scores from 0 to 6.

^dGAD-2: 2-item Generalized Anxiety Disorder scale; items were rated on a 4-point Likert scale from 0 (not at all) to 3 (nearly every day), with summed scores from 0 to 6.

^aMean (SD) and frequency values before propensity score matching.

^bOverall worries were measured by 17 items on a self-constructed questionnaire.

^ePSS-4: 4-item Perceived Stress Scale; items were rated on a 5-point Likert scale from 0 (never)

to 4 (very often), with summed scores from 0 to 16.

^fLoneliness items were rated on a 4-point Likert scale from 1 (not at all) to 4 (almost every day),

with summed scores from 0 to 8.

^gCES-D: Center for Epidemiologic Studies–Depression scale.

^hUCLA: University of California, Los Angeles.

ⁱHAPA: Health Action Process Approach; items were rated on a 5-point Likert scale from 1

(no, I do not intend to) to 5 (yes, and it is very easy for me), with summed scores from 3 to 15.

^jTAM: Technology Acceptance Model; items were rated on a 5-point Likert scale from 1 (not

at all useful) to 5 (completely useful), with summed scores from 2 to 10.

^kN/A: not applicable; this item was not relevant to the general population.

Data Analysis for Both Subsamples

Literature has shown that propensity score matching (PSM) has been able to effectively

reduce biases of treatment selection in nonrandomized studies (D'Agostino, 1998). Through

PSM, covariates can be balanced between groups (Loux, 2015). Hence, in this study, a PSM

analysis was used to minimize the effect of confounding variables as well as the uneven

distribution of covariates in the two groups before comparing them. The matching algorithm

was based on logistic regression. Participants were matched based on sex, age, and educational

status; the match tolerance was .01 without any failures to match.

After PSM, 2054 participants were included for further analyses, and data from the

general population and the psychosomatic clinics were examined for differences. To assess

whether individuals recruited from the general population and individuals from the

psychosomatic clinics differed in their expression concerning psychological symptoms of

depression, anxiety, loneliness, and perceived stress, a multivariate analysis of covariance was

performed, controlling for gender, age, and educational level. Afterward, an exploratory factor

analysis (EFA) was carried out to determine factors within the worries related to the COVID-19 pandemic based on items' factor loadings. Regarding the EFA, meaningful factors to retain for further analysis were based on the scree plot as well as the percentage of common variance explained by a given factor with an eigenvalue above 1. Meaningful factors were retained for varimax rotation. Items with a factor loading above .40 were used for interpretation purposes. Hence, out of 17 items primarily used to analyze worries related to the COVID-19 pandemic, one item was eliminated due to a low item loading. After EFA, significant differences between the data from the general population and the psychosomatic clinics, regarding the defined factors measuring worries related to the COVID-19 pandemic, were examined by a multivariate analysis of covariance controlling for gender, age, educational status, perceived stress, loneliness, depressive symptoms, and symptoms of anxiety.

In addition, a repeated-measures analysis of covariance was performed, controlling for gender and age on 738 psychosomatic rehabilitation patients to examine whether individuals from the psychosomatic clinics showed a change in psychological symptoms on the variables of depression, anxiety, loneliness, and perceived stress before and after their rehabilitation stay. To evaluate whether taking part in digital trainings (i.e., rehabilitation goals and group therapy for depression) was associated with a significant change in symptom intensity concerning depression, anxiety, loneliness, and perceived stress, a repeated-measures analysis of covariance was performed, controlling for age and gender.

To examine the intention to use common digital apps and trainings with a focus on health that were not offered during the rehabilitation stay concerning the general population and patients from the psychosomatic rehabilitation clinics, an analysis of covariance was performed controlling for age, gender, and educational status. Finally, to evaluate the perceived usefulness of internet trainings offered during the rehabilitation stay and the association with patients' mental health status after their rehabilitation stay, a hierarchical regression analysis was performed. All data analyses were carried out using SPSS, version 27 (IBM Corp).

Missing Data. The amount of missing data was below 5% for all items and 1.3% on average. Participants with missing data on the social-cognitive variables were included for further analysis if they had at least one non-missing data point under the assumption of missing completely at random. However, no missing data points were imputed due to the overall low percentage of missing data points.

Results

Participants before Propensity Score Matching: General Population

Overall, 3531 participants completed the online questionnaire. Concerning the general population, 1812 participants participated in the data collection. Out of these participants, 1267 (69.9%) were female and 16 (0.9%) did not respond. Age ranged from 18 to over 60 years. Out of 1812 participants, 193 (10.7%) had 10 or 11 years of schooling, 421 (23.2%) had 12 or more years of schooling, 507 (28.0%) had completed vocational training, and 690 (38.1%) had a university degree; there was 1 (0.1%) missing data point.

Participants before Propensity Score Matching: Psychosomatic Rehabilitation Patients

Concerning participants from the psychosomatic rehabilitation clinics, 1719 participants participated in the survey before their rehabilitation stay. Of these participants, 1104 (64.2%) were female and there were 13 (0.8%) missing data points. Age ranged from 18 to over 60 years. Out of 1719 participants, 398 (23.2%) had 10 or 11 years of schooling, 241 (14.0%) had 12 or more years of schooling, 791 (46.0%) had completed vocational training, and 266 (15.5%) had a university degree; there were 23 (1.3%) missing data points. After the rehabilitation stay, 738 participants participated in the survey.

Participants after Propensity Score Matching – General Population

Concerning the general population of 1027 participants, 684 (66.6%) were female, their age ranged from 18 to over 60 years, 163 (15.9%) had 10 or 11 years of schooling, 173 (16.8%)

had 12 or more years of schooling, 409 (39.8%) had completed vocational training, and 282 (27.5%) had a university degree.

Participants after Propensity Score Matching – Psychosomatic Rehabilitation Patients

With regard to the 1027 participants from the psychosomatic rehabilitation clinics, 659 (64.2%) were female, their age ranged from 18 to over 60 years, 167 (16.3%) had 10 or 11 years of schooling, 194 (18.9%) had 12 or more years of schooling, 404 (39.3%) had completed vocational training, and 262 (25.5%) had a university degree.

Difference in Psychological Symptoms

The multivariate analysis of covariance revealed significant differences in mental health between the general population and individuals from the psychosomatic clinics (F(4,2028) = 183.74, p < .001, $\eta_p^2 = .27$), with age, gender, and education being significant covariates. Individuals from the psychosomatic clinics displayed significantly higher scores on all four psychological variables compared to individuals recruited from the general population: depression (F(1,2036) = 460.51, p < .001, $\eta_p^2 = .19$), anxiety (F(1,2036) = 682.11, p < .001, $\eta_p^2 = .25$), loneliness (F(1,2036) = 90.31, p < .001, $\eta_p^2 = .05$), and perceived stress (F(1,2036) = 424.65, p < .001, $\eta_p^2 = .17$; see Table 13).

Table 13. Descriptive Statistics and Mean Differences^a between the General Population and the Sample from the Psychosomatic Clinics (i.e., Medical Sample) across the Test Variables of Depression, Anxiety, Loneliness, and Perceived Stress.

Test variables	General populati on Mean (SD)	Medical sample Mean (SD)	Mean _{diff}	95% CI	P-Value	Cohen's d^b
Depression (PHQ-2 ^c)	1.85	3.43	-1.58		<.001	.57
	(1.70)	(1.64)		2.71		
Anxiety (GAD-2 ^d)	1.65	3.58	-1.93	2.54 –	<.001	.69
	(1.67)	(1.68)		2.68		
Loneliness ^e CES-D ^f ;	3.70	4.47	-0.77	4.01 -	<.001	.23
UCLAg Loneliness	(1.92)	(1.75)		4.17		
Scale						
Perceived stress (PSS-	6.75	9.46	-2.71	7.98 –	<.001	.30
4 ^h)	(3.42)	(2.56)		8.23		

Note.

^cPHQ-2: 2-item Patient Health Questionnaire; items were rated on a 4-point Likert scale from 0 (not at all) to 3 (nearly every day), with summed scores from 0 to 6.

^dGAD-2: 2-item Generalized Anxiety Disorder scale; items were rated on a 4-point Likert scale from 0 (not at all) to 3 (nearly every day), with summed scores from 0 to 6.

^eLoneliness items were rated on a 4-point Likert scale from 1 (not at all) to 4 (almost every day), with summed scores from 0 to 8.

^fCES-D: Center for Epidemiologic Studies–Depression scale.

^gUCLA: University of California, Los Angeles.

^hPSS-4: 4-item Perceived Stress Scale; items were rated on a 5-point Likert scale from 0 (never) to 4 (very often), with summed scores from 0 to 16.

^aDescriptive statistics and mean differences after propensity score matching.

^bCohen d: 0.20=small effect, 0.50=medium effect, and 0.80=large effect.

Analysis of Worries Related to the COVID-19 Pandemic

After varimax rotation, 16 items were retained in the analysis with factor loadings of \geq 0.40 with the respective factor (Table 14). Four factors were able to explain 67.14% of the total variance. Factors identified included satisfaction with communication (six items measured on a 6-point Likert scale from 1 (completely disagree) to 6 (completely agree); reliability indicator Cronbach α = .90), health-related worries (six items measured on a 5-point Likert scale from 1 (never) to 5 (always); reliability indicator Cronbach α = .82), financial worries (two items measured on a 5-point Likert scale from 1 (no, completely disagree) to 5 (yes, completely agree); reliability indicator Spearman ρ = 0.65), and household-related worries (two items; reliability indicator Spearman ρ = 0.28). With regard to household measures, one item was assessed on a 4-point Likert scale from 1 (not at all) to 4 (completely). The second item was assessed on a 6-point Likert scale from 1 (never or less than once per month) to 6 (daily or several times per day). Hence, the Likert scale of the second item was transformed to a 4-point Likert scale. For all factors, composite mean scores were computed.

Table 14. Exploratory Factor Analysis: Factor Loadings with all Study Participants from the General Population and the Medical Sample (N = 2054).

Scale and	Label	Faktor Loadings					
Item		1	2	3	4		
Scale 1	= Satisfaction with communication (SC)						
SC1	Clear explanation	.92	_b	-	-		
SC2	Early communication	.91	-	-	-		
SC3	Sufficient information	.89	-	-	-		
SC4	Taken seriously during communication	.87	-	-	-		
SC5	Made sure that everything was understood	.85	-	-	-		
SC6	Including accompanying persons and respecting situation	.61	-	-	-		
Scale 2	= Health-related worries (HW)						
HW1	Concerned about getting infected	-	.86	-	-		
HW2	Concerned about becoming ill	-	.84	-	-		
HW3	Concerned about visiting a doctor	-	.71	-	-		
HW4	Concerned about infecting others	-	.70	-	-		
HW5	Concerned about visiting the hospital	-	.66	-	-		
HW6	Anxious when hearing the news	-	.62	-	-		
Scale 3	= Financial worries (FW)						
FW1	Worries about one's job	-	-	.87	-		
FW2	Afraid of financial difficulties	-	-	.87	-		
Scale 4	= Household-related worries (HO)						
HO1	Conflicts in household	-	-	-	.80		
HO2	Grown as a household	-	-	-	.75		

Note.

The same factor structure was found in both samples. A total of 70.32% of the variance could be explained in the general population and 64.33% of the variance could be explained in the sample of psychosomatic rehabilitation patients.

Summarizing the results from the factor analysis, the factor structure of the evaluated worries associated with the current COVID-19 pandemic was equal across samples. Hence, the overall EFA across samples revealed four factors associated with the COVID-19 pandemic:

^aExploratory factor analysis and factor loadings after propensity score matching.

^bFactor loadings were reported for their corresponding scales.

satisfaction with communication, health-related worries, financial worries, and household-related worries.

Differences in Worries Related to the COVID-19 Pandemic Between Groups

Results from the multivariate analysis of covariance indicated significant differences between the two groups (F(4,835) = 17.17, p < .001, $\eta_p^2 = .08$) concerning worries related to the COVID-19 pandemic (see Table 4): satisfaction with communication (F(1,838) = 31.66, p < .001, $\eta_p^2 = .04$), for household-related worries (F(1,838) = 5.34, p = .02, $\eta_p^2 = .01$), as well as for financial worries (F(1,837) = 38.87, p < .001, $\eta_p^2 = .04$). Age, gender, perceived stress, loneliness, depressive symptoms, and symptoms of anxiety were significant covariates. Hence, patients recruited from the psychosomatic clinics perceived significantly greater satisfaction with communication, and increased household-related worries, but significantly lower financial worries before their rehabilitation stay (see Table 15).

Patients reported being unemployed more frequently prior to their rehabilitation stay (n = 253; 24.6%) compared to the general population (n = 123; 12.0%; Tab. 3). Furthermore, the patient sample reported more *health-related worries* (Table 14). However, the difference between the groups was revealed to be non-significant (F(1,837) = 0.13, p = .72, $\eta_p^2 = .01$).

Table 15. Descriptive Statistics and Mean Differences^a between the General Population and the Sample from the Psychosomatic Clinics (i.e., Medical Sample) across COVID-19-Related Worries.

Test variable ^b	General population Mean (SD)	Medical sample Mean (SD)	Mean _{diff}	95% CI	P-Value	Cohen's d^c
Satisfaction with	24.45	26.53	-2.08	25.06 -	<.001	.05
communication ^d	(7.45)	(5.69)		25.94		
Health-related	14.56	15.69	-1.13	14.77 –	.02	.04
worries ^e	(5.60)	(4.88)		15.46		
Financial worries ^f	4.48	4.31	0.17	4.24 -	<.001	.03
	(2.52)	(2.21)		4.55		
Household-related	6.06	5.93	0.13	5.90 –	.72	.08
worries ^g	(1.32)	(1.28)		6.08		

Note.

^dSatisfaction with communication: 6 items were rated on a 6-point Likert scale from 1 (completely disagree) to 6 (completely agree), with summed scores from 6 to 36.

eHealth-related worries: 6 items were rated on a 5-point Likert scale from 1 (never) to 5 (always), with summed scores from 5 to 25.

^fFinancial worries: 2 items were rated on a 5-point Likert scale from 1 (no, completely disagree) to 5 (yes, completely agree), with summed scores from 2 to 10.

gHousehold-related worries: the first item was rated on a 4-point Likert scale from 1 (not at all) to 4 (completely) and the second item was measured on a 6-point Likert scale from 1 (never of less than once per month) to 6 (daily or several times per day). After transformation to a 4-point Likert scale, summed scores ranged from 2 to 8.

^aDescriptive statistics and mean differences after propensity score matching.

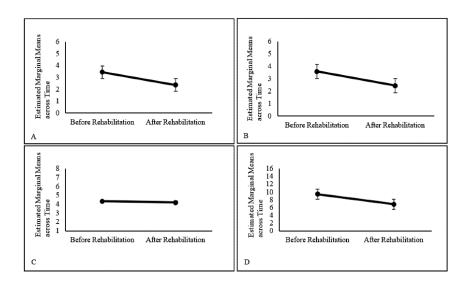
^bScales were aggregated from items reported in Table 2.

^cCohen d: 0.20 = small effect, 0.50 = medium effect, and 0.80 = large effect.

Changes in Psychological Symptoms Before and After the Rehabilitation

Results of the repeated-measures analysis revealed overall significant differences across time (F(1,712) = 23.21, p < .001, $\eta_p^2 = .04$). Taking a closer look at individual test variables, results revealed a significant reduction in depression (F(1,723) = 0.98, p < .001, $\eta_p^2 = .02$), anxiety (F(1,723) = 0.99, p < .001, $\eta_p^2 = .01$), perceived stress (F(1,720) = 19.69, p < .001, $\eta_p^2 = .03$) and loneliness (F(1,722) = 0.99, p < .05, $\eta_p^2 = .005$) in psychosomatic patients after their rehabilitation (see Figure 6).

Figure 6. Estimated Marginal Means after Propensity Score Matching for Symptoms of Depression (A), Symptoms of Anxiety (B), Perceived Loneliness (C), and Perceived Stress (D). Error bars Represent Standard Errors of the Mean.



Intention to Use Common Digital Trainings and Apps

Results of the multivariate analysis of variance revealed an overall significant difference between individuals from the general population and individuals from the medical, and psychosomatic rehabilitation clinics (F(3,2021) = 51.41, p < .001, $\eta_p^2 = .07$). Patients appeared more inclined to use common apps and digital trainings offered outside of their rehabilitation

stay supporting them in their communication with health care professionals (F(1,2027) = 6.66, p = .01, $\eta_p^2 = .01$) as well as COVID-19–related health care apps (F(1,2027) = 144.51, p < .001, $\eta_p^2 = .07$).

Association Between Taking Part in Digital Trainings and Changes in Psychological Symptom Intensity

We examined whether taking part in digital training on rehabilitation goals (i.e., only digital training) and digital group therapy for depression (i.e., a combination of digital and face-to-face components) were associated with a decrease in symptom intensity after the rehabilitation stay compared to before. The results highlighted the following significant differences: taking part in the digital group therapy for depression was associated with a significant decrease in symptom intensity after the rehabilitation stay with regard to depression $(F(1,725) = 4.82, p = .03, \eta_p^2 = .01)$ and anxiety $(F(1,725) = 6.22, p = .01, \eta_p^2 = .01)$.

Perceived Usefulness of Digital Trainings and the Association with the Mental Health Status

Table 16 shows the association between the perceived usefulness of the digital trainings (i.e., digital training on rehabilitation goals and digital group therapy for depression) evaluated by participants after their rehabilitation stay and their mental health status after their rehabilitation stay. Overall, increased perceived usefulness of digital training on rehabilitation goals was significantly associated with a higher reduction in perceived depression, anxiety, loneliness, and stress post-rehabilitation

Chapter

Table 16. Association Between Perceived Usefulness of Digital Trainings and Mental Health Status of Psychosomatic Rehabilitation Patients after their Rehabilitation Stay.

Predictor	Dependent Variable								
	Depression β (95% CI)	p Value	Anxiety β (95% CI)	p Value	Loneliness β (95% CI)	p Value	Perceived stress β (95% CI)	p Value	
Participation in digital depression group therapy	.08 (01 to .25)	.08	.08 (02 to .24)	.11	.09 (02 to .25)	.08	.05 (12 to .39)	.30	
Participation in digital training on rehabilitation goals	14 (37 to - .07)	<.001	13 (36 to - .05)	<.001	19 (46 to - .16)	<.001	19 (90 to - .31)	<.001	

Note.

^aEach column represents a separate analysis after propensity score matching. Analyses controlled for age, gender, and education, with gender being significant at p < .05 for anxiety and perceived stress, age being significant for loneliness and stress, and education being significant for education.

Data Availability

The data that support the findings of this study are available from the corresponding author (SL) upon reasonable request.

Discussion

In this study, differences between a sample of 684 individuals from the general population and 659 patients from medical, psychosomatic rehabilitation clinics in depression, anxiety, loneliness, and perceived stress during the COVID-19 pandemic were examined using the internet after PSM. The expression of symptoms and worries related to the COVID-19 pandemic were psychometrically assessed and tested for differences between the two samples (research questions 1 and 2). As a third research question, a potential decrease in symptom intensity on the test variables was examined for psychosomatic rehabilitation patients before starting and after their rehabilitation stay. Moreover, this paper evaluated the differences in intention to use digital apps and trainings during the COVID-19 pandemic between individuals from the general population and individuals from the psychosomatic rehabilitation clinics (research question 4). With regard to the potential decrease in symptoms, research question 5 evaluated the association between participation in digital trainings addressing rehabilitation goals and digital depression group therapy. Furthermore, the perceived usefulness of digital trainings before (i.e., digital training on rehabilitation goals) and during (i.e., digital group therapy for depression) the rehabilitation stay was evaluated concerning the symptom intensity of depression, anxiety, loneliness, and perceived stress after the rehabilitation stay.

The findings from this study confirm that individuals felt affected by the COVID-19 pandemic in terms of their mental health and well-being. For individuals in psychosomatic medical rehabilitation, symptoms of depression, anxiety, loneliness, and perceived stress were elevated compared to the general population. Thus, we can answer research question 1 by showing that individuals assigned to medical, and psychosomatic rehabilitation clinics perceive and express more mental health symptoms, which is in line with our hypothesis. In prior research, individuals with a pre-existing mental health disorder reported poorer access to support services since the beginning of the pandemic, had earlier discharges from psychiatric units, or had discontinuation of psychotherapy treatments (Chevance et al., 2020; Hao et al., 2020; Yao et al., 2020). The loss of such support systems due to the COVID-19 pandemic may have led to negative consequences, such as an increase in symptom intensity, increased social isolation, and perhaps even suicidal behavior (Chevance et al., 2020). Therefore, digital interventions and trainings that target positive thinking, active stress coping, and social support to reduce depression, anxiety, loneliness, and perceived stress need to be implemented for individuals with a pre-existing mental health disorder, irrespective of taking part in rehabilitation; these may also work as primary preventative measures for the general population (Budimir et al., 2021). Accordingly, research questions arise in the context of digital prevention as well as digital support interventions, which should be investigated further.

Surprisingly, psychosomatic patients perceived significantly greater satisfaction in communication with health care professionals and had significantly lower financial worries but higher household-related worries, even after statistically controlling for confounding variables. However, no significant difference between the groups was found with regard to health-related

worries, which is contrary to the hypothesis that they would experience more worries (research question 2). The fact that psychosomatic rehabilitation patients perceived greater satisfaction with communication before their rehabilitation stay may be due to previous information obtained digitally (i.e., through the digital training on rehabilitation goals) from the clinic as well as participating in surveys and tasks before their stay. Furthermore, contact with the rehabilitation clinics might have been perceived as an emerging support system by the rehabilitation patients, offering the hope that their situation would soon improve and that they would receive help during the pandemic. Literature has shown that effective communication with patients may prove empowering for patients (Tsamakis et al., 2020).

The results concerning financial worries are partly in line with van Rheenen et al. (2020). Their study indicated that individuals with a mood disorder expressed lower concerns with personal finances, as they were more commonly unemployed or unable to work (Topper et al., 2010). As with the results of this study, psychosomatic rehabilitation patients increasingly indicated that they were either unemployed or unable to work before the rehabilitation stay. Due to pre-existing unemployment or lack of participation in the workforce, there was already a lower financial status and greater job insecurity as well as financial uncertainty (Lippke et al., 2020). Additionally, the inability to work due to disabilities is, in part, financially subsidized by the German social system (Brenke & Ziemendorff, 2008). Besides, pre-existing mental health disorders are associated with greater incapacity to work and may lead to an earlier disability pension (Zielke, 2014). Hence, these patients may not be aware of, nor concerned with, job uncertainty as a result of the COVID-19 pandemic due to their medical treatment, which was partially digitally supported.

Psychosomatic rehabilitation patients indicated greater worries associated with their household, which includes conflicts within the family or dissatisfaction with household dynamics before their rehabilitation stay, as compared with individuals from the general population. As the COVID-19 pandemic is characterized by strict travel restrictions, an increase in working from home and homeschooling, short-term employment, or unemployment, people tend to either spend more time with immediate family at home, leading to an increase in family conflicts, or experience isolation while quarantining. The results by Guo et al. support the results of this study. They highlight that a risk factor associated with reduced mental health status during the COVID-19 pandemic is living alone (Guo et al., 2020). Nevertheless, family conflicts as a correlate of the COVID-19 pandemic may, conversely, also be a stressor contributing to diminishing mental health. Digital solutions offer the option to bridge the gap to mobile rehabilitation, especially if family constraints prevent patients from attending rehabilitation treatment on-site. According to the research, questions arise and should be investigated further.

Moreover, individuals with and without mood disorders reported a similar frequency of worries related to health, such as worries about loved ones falling sick with COVID-19 as well as implications for one's health and well-being. This is in line with results by van Rheenen et al. highlighting equal concerns about the health and well-being of the social environment for individuals with mood disorders (i.e., depression and anxiety) and those without a mental health disorder. Furthermore, individuals with and without a mental health disorder indicated almost equal concerns regarding own health and well-being during the COVID-19 pandemic (Van Rheenen et al., 2020). This shows that health concerns about others and oneself during the

coronavirus pandemic are estimated as equally important, irrespective of the mental health status of individuals.

In addition, results indicated that for psychosomatic patients, symptoms of depression and anxiety, as well as perceived stress and loneliness, decreased significantly between preand post-rehabilitation, thus answering in favor of the third research question. This underlines
the importance and necessity of medical rehabilitation treatment for patients with chronic
mental disorders (Haaf, 2005): in particular, the group therapy for depression in the form of a
flipped classroom design shows support for the decrease in symptom intensity concerning
depression and anxiety post-rehabilitation compared to before the rehabilitation stay. Past
evidence has shown that the combination of digital therapeutic elements and regular face-toface therapy was able to improve the mental health outcomes of patients significantly (Davies
et al., 2014; Davies et al., 2020; Huckvale et al., 2020), which is in line with the results of this
study.

Interestingly, compared to individuals from the general population, psychosomatic rehabilitation patients reported a greater intention to use common apps and digital trainings focusing on health that are not offered during rehabilitation. This offers important insights into research question 4. First of all, patients who have applied for a rehabilitation stay may already be more open to medical and lifestyle interventions. Hence, pre-existing motivation to change may foster intentions to pursue a change. Furthermore, patients with an affective disorder may be more prone to excessive reassurance-seeking, which may be defined as the repeated need for safety-related information (Joiner et al., 1999; Parrish & Radomsky, 2010). Therefore, one may postulate that by reassurance-seeking through the use of health care-related apps, patients with

an affective disorder may fulfill their desires for safety behaviors. However, upon the increased intention to use those apps, patients need to learn effective coping strategies and skills to perform and maintain the actual behavior without using excessive reassurance-seeking and relying on safety behaviors. Shafran et al. highlighted the importance of daily self-monitoring through, for example, digital trainings in supporting patients with reduced mental health status in translating intentions into actual behavior (Shafran et al., 2018).

Next to the increased intentions of psychosomatic rehabilitation patients to use digital trainings, those who evaluated the perceived usefulness of the digital training on rehabilitation goals as increasingly useful and helpful post-rehabilitation stay also displayed lower symptoms regarding depression, anxiety, loneliness, and perceived stress compared to the general population. This finding supports a positive association that was examined in the final research question. One might postulate that useful and helpful preparation for the rehabilitation stay provides the basis for effective digital training, such as digital group therapy for depression. Feeling well prepared, informed, and being offered additional material before the rehabilitation stay may motivate the patients to be active agents and engage effectively in the subsequent digital treatment programs. Moreover, the result can be explained by the assumptions of the HAPA (Schwarzer, 2008). During the voluntary participation in the digital rehabilitation goals training, an intention to achieve a better mental health status post-rehabilitation may be created. Based on this intention and in combination with the supplementary support provided during the digital training on rehabilitation goals, participants may develop adequate planning strategies to reach the desired health outcome.

With the support of the digital group therapy addressing depression, the desired behavior of achieving a better mental health status may be facilitated by means of developing coping strategies, learning new skills, and activating resources. Initial approaches in offering psychosomatic rehabilitation patients digital therapy tools for aftercare have been made by Schmädeke et al. and have proven to be effective (Schmädeke et al., 2019). Hence, for future studies, digital trainings focusing on the preparation for a medical rehabilitation stay, the support of face-to-face therapy, and empowering patients for the time after rehabilitation should be developed and evaluated based on the HAPA model, as our results are promising. In addition, such digital training should be assessed further concerning its effectiveness in the form of a randomized controlled trial with a waiting control group.

Overall, psychosomatic rehabilitation is an effective treatment, especially during the pandemic, and should be offered to all people who either suffer from a pre-existing chronic mental disorder or who developed mental disorders due to the pandemic and its restrictions. In addition, digital trainings should be integrated with the rehabilitation process for patients with an affective mood disorder. As the COVID-19 pandemic poses several barriers to the uptake of a psychosomatic treatment (Chevance et al., 2020), it must, therefore, be ensured that people with pre-existing or newly developed mental disorders have simple, straightforward access to psychosomatic rehabilitation and additional internet-delivered supplements. Hence, possible access opportunities for psychosomatic patients may also be provided in the form of low-threshold digital trainings to offer support before a rehabilitation stay.

This study highlights the need to offer individuals support to maintain sufficient mental health, especially in times of a pandemic and its aftermath. This can be achieved in multiple,

low-threshold ways that meet different needs and preferences. It may include offering individuals—not only limited to individuals with a prior mental health diagnosis to ensure prevention—facilitated access to video and telephone consultation hours, digital preventive programs, or psychosomatic rehabilitation stays. Facing a substantial lack of medical doctors, therapists, and other health care workers and the need to reduce physical contact, it is necessary to develop and establish internet-based programs and trainings as one component of therapy as well as digital support systems and platforms.

Internet-delivered treatment components offer different advantages that need to be planned more systematically. For instance, physicians or general practitioners should briefly screen all patients perceived to be at risk for stress, anxiety, or depression due to the pandemic (i.e., using the GAD-2 and the PHQ-2) and then recommend further online services (Rogers et al., 2017; Sin et al., 2020; Torous et al., 2020) or hybrid options to those with elevated symptoms. Moreover, individualized recommendations on how to deal with mental health difficulties for the general population, as well as for individuals with a pre-existing mental health disorder, should be created. Suggestions on how to deal with barriers, such as finding specialist care and waiting times during the pandemic, should be a key component of these recommendations (Dong et al., 2020), especially if individuals are confronted with hygiene regulations that might conflict with the need to connect socially with others or to seek professional

Limitations and Suggestions for Future Research

Several limitations need to be considered while interpreting the findings of this study.

First of all, the data evaluated from the general population are cross-sectional. Also, any

changes due to the COVID-19 pandemic (i.e., situation, perception, behavior, well-being, or mental health) could not have been controlled for significant events such as lockdown measures in Germany.

Furthermore, the items assessing worries related to the COVID-19 pandemic were non-validated items based on research found in the literature so far. Hence, for future studies, the analyzed items should be examined for validity, while this study provides the first results regarding reliability. Another critical point to highlight is that mental health, in the form of symptoms of depression, anxiety, loneliness, and stress, was self-reported. In addition, the questionnaires that were used (i.e., the PHQ-2 and the GAD-2) only indicated the symptom intensity but were not used as diagnostic tools.

Furthermore, we had no indication of symptoms or clinical mental health diagnoses before the start of the COVID-19 pandemic. Hence, we cannot be certain that the levels of psychological symptoms reported by participants were subject to the COVID-19 pandemic. However, it has been suggested that symptoms of anxiety and depression increased as a result of the COVID-19 pandemic compared to historical normative data (Nelson et al., 2020).

In addition, the digital training on rehabilitation goals and group therapy for depression was not tested concerning their effectiveness beforehand. Furthermore, with regard to the data collected with the psychosomatic clinics, it remains to be evaluated in future research whether somatic aspects, including a potential COVID-19 infection, are a confounding factor for the expression of symptoms of depression, anxiety, loneliness, and perceived stress.

Conclusion

This study provides insights into the mental health status and perceived well-being of psychosomatic rehabilitation patients compared to the general population during the COVID-19 pandemic. In addition, this study was able to evaluate COVID-19-related worries between the general population and psychosomatic rehabilitation patients. Further, the usefulness of internet-delivered trainings and their association with the mental health status of psychosomatic rehabilitation patients in Germany was assessed. The results suggest that psychosomatic rehabilitation patients perceived greater symptoms of depression, anxiety, loneliness, and stress compared to the general population before their rehabilitation stay, which validates their status as assigned to rehabilitation. Future studies should replicate these findings in other countries and with individuals from different cultural backgrounds. In particular, the question remains as to whether different health care systems and rehabilitation treatments (e.g., delivered at a higher proportion in a mobile, internet-delivered mode) would result in the same outcomes. It is also imperative to disentangle which components of the internet-delivered interventions were especially effective in which patients.

The general population perceived greater financial worries, whereas patients before their rehabilitation stay perceived greater worries associated with their health and household. In addition, our results underline that in comparison to before their medical rehabilitation stay, patients' symptoms of depression, anxiety, and perceived stress were significantly lower after their rehabilitation stay. This stresses the value and necessity of psychosomatic rehabilitation treatments, concerning the psychotherapy of chronic mood disorders, and their relevance during the COVID-19 pandemic, especially among individuals with elevated symptoms and needs.

Internet-delivered medical rehabilitation components integrated into face-to-face therapy have the option to accelerate mental health improvements due to rehabilitation, which is especially important in times of limited treatment capacities and the need to reduce the transmission of viruses (i.e., physical contact between treatment providers and patients). Internet-delivered medical treatment can bridge the gap and can also help patients to cope with a potential aftermath of the COVID-19 pandemic in terms of more patients in need of care than available resources at the patients' residence.

Acknowledgments

We would like to thank the Dr. Becker clinics Möhnesee, Norddeich, Juliana, and Burg for their assistance in data collection. Furthermore, we would like to thank Jing Liu and Nerma Pasic for proofreading the final version of this manuscript. This work was supported by the German Innovation Fund (Project No. 01VSF18023) of The Federal Joint Committee (G-BA) as part of the research project "TeamBaby – Safe, digitally supported communication in obstetrics and gynecology" (grant 01VSF18023). The open access fee was provided by the Konfuzius Institute Bremen/Hanban. The Konfuzius Institute Bremen/Hanban had no role in the study design, study implementation, data collection, data analysis, manuscript preparation, or publication decision. The work is the responsibility of the authors.

Authors' Contributions

FMK conceived the research questions, designed the study, and set up the data collection survey tool. FMK, AD, and SL conducted the statistical analysis and drafted the manuscript. FMK, AD, CD, LK, and SL finalized the manuscript. All authors assisted in the questionnaire design, supported the data collection and interpretation and gave comments concerning the

interpretation of the findings of the manuscript. FMK, AD, CD, LK, and SL had full access to all data from the study and were responsible for the integrity of the data. FMK was responsible for the accuracy of the data analysis. SL acquired funding for TeamBaby and AD acquired funding for Anhand-COVID19.

Conflicts of Interest

None declared.

Abbreviations

CBT: cognitive behavioral therapy

eCBT: electronically delivered cognitive behavioral therapy

EFA: exploratory factor analysis

GAD-2: 2-item Generalized Anxiety Disorder scale

HAPA: Health Action Process Approach

mHealth: mobile health

PHQ-2: 2-item Patient Health Questionnaire

PHQ-4: 4-item Patient Health Questionnaire

PSM: propensity score matching

PSS: Perceived Stress Scale

PSS-4: 4-item Perceived Stress Scale

SARS: severe acute respiratory syndrome

T1: first time point (6 weeks before the start until the first day of rehabilitation)

T2: second time point (after rehabilitation)

UCLA: University of California, Los Angeles

WHO: World Health Organization

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Chapter 6: Distress, Loneliness, and Mental Health during the COVID-19 Pandemic: Test of the Extension of the Evolutionary Theory of Loneliness

Keller, F. M., Derksen, C., Kötting, L., Dahmen, A., & Lippke, S. (2022). Distress, loneliness, and mental health during the COVID-19 pandemic: Test of the extension of the Evolutionary Theory of Loneliness. *Applied Psychology: Health and Well-Being*, 1–25. https://doi.org/10.1111/aphw.12352

Distress, Loneliness, and Mental Health during the COVID-19 Pandemic: Test of the

Extension of the Evolutionary Theory of Loneliness

Abstract

COVID-19 restrictions such as lockdowns or quarantines may increase the risk of social isolation and perceived loneliness. The mechanisms can be modeled by Cacioppo's Evolutionary Theory of Loneliness (ETL), which predicts that a lack of perceived social connectedness may lead, in the long term, to mental and physical health consequences. However, the association between COVID-19 pandemic distress, mental health, and loneliness is not sufficiently understood. The present longitudinal study examined the relationship between distress and depression, and the mediating effects of anxiety and loneliness in a German rehabilitation sample (N=403) at two timepoints (≤ 6 weeks pre-rehabilitation; \geq 12 weeks post-rehabilitation; mean time between T1 and T2 was 52 days). Change scores between T1 and T2 were examined for the variables COVID-19 Peritraumatic Distress Index (CPDI), anxiety, loneliness, and depression. The results of the serial mediation analysis indicated that anxiety and loneliness were able to explain the relationship between distress and depression with 42% of the variance in depression accounted for. Findings extend research on the relationship between COVID-19 and mental health by considering anxiety and loneliness as sustaining factors of depressive symptoms, thus, successfully applying the ETL. Results stress the necessity to consider anxiety and loneliness in the treatment or prevention of depression.

Keywords: Serial Mediation, Anxiety, Depressive Symptoms, Psychosomatic

Rehabilitation Patients

Introduction

The effects of the coronavirus disease 2019 (COVID-19), which has been termed a pandemic by the World Health Organization on March 11, 2020, have led to long-lasting and profound changes in human interaction, human health behavior, and mental well-being. As part of the containment measures proposed by governments such as the one in Germany, individuals were, on the one hand, encouraged to reduce physical contact as much as possible but, on the other hand, also decided to reduce their contacts to take responsibility for their own health and the health of others. Despite these regulations being effective, changes in social interaction have led to increased distress and perceived loneliness as a consequence of physical isolation as well as a deterioration in mental health displayed by higher reported symptoms of depression and anxiety (Balkhi et al., 2020). Therefore, studies examining consequences of previous virus outbreaks have concluded that distress associated with a possible infection, loneliness, boredom, symptoms of anxiety, depression, or even suicidal thoughts may be the results of pandemic contexts and can lead to negative long-term psychological effects or a deterioration of a pre-existing poor mental health status (Asmundson et al., 2020; Hao et al., 2020).

This has been especially pronounced for individuals with a prior mental health diagnosis such as individuals from psychosomatic rehabilitation clinics. Evidence has highlighted that patients with pre-existing mental health disorders have shown to be more vulnerable to stress-related events (Phillips et al., 2009). As those individuals need to invest more resources to cope with the original mental health disorder, they are less likely, compared to healthy individuals or the general population, to engage in active problem-solving strategies in the face of stressful

and distressing life events (Phillips et al., 2009). Several studies have evaluated the impact of the COVID-19 pandemic as a distressing and traumatic event on the mental health status of individuals with a pre-existing mental health disorder and of the general population. Individuals with a pre-existing mental health condition reported increased distress, anxiety, loneliness, and depression (Groarke et al., 2020; Hao et al., 2020). As people with a pre-existing mental health disorder are frequently neglected (Hao et al., 2020), we aim to gain a better understanding of the role of symptoms of anxiety and loneliness in the relationship between COVID-19 Peritraumatic Distress Index (CPDI) and general symptoms of depression by using the Evolutionary Theory of Loneliness (ETL) as a theoretical basis and by investigating changes in the proposed variables over time.

Evolutionary Theory of Loneliness

The ETL by Cacioppo provides a theoretical explanation for the perception of loneliness (Cacioppo & Cacioppo, 2018). The theory assumes that feelings of loneliness emerge, and are maintained, over time and that loneliness can affect physiological and mental health. According to the ETL, social isolation or loneliness has been termed as a signaling function that is similar to physical pain. Cacioppo's ETL states that people have an innate desire to connect to others to obtain and provide protection against a possible threat. If that need for social connection cannot be fulfilled, individuals may consequently report feeling lonely (Cacioppo & Hawkley, 2009).

If individuals become socially isolated, they are deprived of social connectedness, especially in a pandemic context. This is the case even when individuals willingly reduce their social contacts such as in the event of the COVID-19 pandemic. Nevertheless, seeing others as

a potential threat of infection and the need to further isolate oneself can lead to maladaptive strategies such as increased avoidance behavior. As a result, lonely individuals perceive social interactions more negatively, which is reinforced by pandemic containment measures. In addition, daily routines have changed to reduce physical contact by working from home and home schooling where necessary. This might have a long-term impact in Germany and other industrialized countries, creating a more flexible work life. Nevertheless, this flexibility and uncertainty are likely to challenge individuals especially if resources, such as stable work and good mental and physical health, are lacking. Thus, ways need to be found to reduce loneliness and fear of social interaction without endangering the containment of COVID-19. Otherwise, this process may lead to a self-defeating social behavior and ultimately to a vicious circle, which has the potential to cause a decreased mental and physical health status.

Mushtaq et al. (2014) have shown that increased loneliness has been associated with a decreased mental health status. The relationship between anxiety and loneliness, as well as between loneliness and depression, has been well studied concerning the general population. However, adequate research is lacking for psychosomatic rehabilitation patients with a pre-existing mental health diagnosis. Therefore, with respect to the current study, experienced peritraumatic distress may possess the function of signaling potential danger that may lead to feelings of distress. These feelings, in turn, have the potential to increase anxiety-related symptoms leading to a voluntary withdrawal from social situations and connections as a safety measure. If the social withdrawal is maintained for a longer period of time, it likely results in feelings of loneliness. This may, in turn, result in increased depressive symptoms.

Depression is characterized by a lack of interest, general withdrawal, feelings of worthlessness, loneliness, or reduced interest and pleasure in activities. Hence, concerning the ETL, it may be assumed that specifically during the COVID-19 pandemic the interplay between peritraumatic distress, anxiety, loneliness, and depression may depict a vicious circle as one part of the ETL which will be examined further in the present study.

CPDI in Association with Symptoms of Depression

Peritraumatic distress, as conceptualized by Brunet et al. (2001), describes emotional and physical responses either at the time or immediately after, a traumatic event. It has been termed as a state condition with decreasing or, even diminishing, perceived severity over time. The COVID-19 pandemic represents a traumatic series of events over a prolonged time that may lead to peritraumatic distress accompanied by psychiatric outcomes such as depression, anxiety, acute stress disorder, sleep disturbances, traumatic grief disorders, or psychological distress (Megalakaki et al., 2021). Liu et al. (2021) have shown that the psychological distress due to the COVID-19 pandemic has significantly increased from 24% to 66% between April 2020 and May to September 2020 in Germany. To measure peritraumatic distress, Brunet et al. (2001) originally developed the peritraumatic distress inventory that was used as the basis for the development of the COVID-19 CPDI. The CPDI assesses several aspects related to the psychological and physiological impact of the COVID-19 pandemic (Qiu et al., 2020). In addition, several studies have examined the association between general peritraumatic distress and depression or post-disaster depression (Bell et al., 2017). However, Megalakaki et al. (2021) were the first to examine the association between CPDI and mental health conditions in the context of the COVID-19 pandemic. Their results underline the assumption that an

increased CPDI index is associated with increased symptoms related to depression and are in line with previous research on general peritraumatic distress and depression, respectively.

CPDI and the Association with Anxiety and Loneliness

The definition of an anxiety syndrome is attributed to an increase in pandemic-related psychological distress, fear, and generalized stress (Bäuerle et al., 2020) in connection with the COVID-19 pandemic. The anxiety syndrome according to Nikčević and Spada (2020) has been characterized by increased avoidance, checking, worrying, and threat monitoring, which have all been noticed during the COVID-19 pandemic. Results from the beginning of the COVID-19 pandemic have reported increased stress-related and anxiety-related symptoms as a response to the pandemic (Wang et al., 2020). Literature has also highlighted the association between pandemic-related psychological distress and anxiety as those suffering from increased psychological distress also reported higher levels of anxiety (Wheaton et al., 2012). Specifically, with regard to COVID-19 peritraumatic distress, a higher CPDI has been able to predict symptoms of anxiety (Megalakaki et al., 2021). However, the role of loneliness in this context has, so far, not been researched.

Loneliness has been defined as "a distressing feeling that accompanies the perception that one's social needs are not being met by the quantity or especially the quality of one's social relationships" (Hawkley & Cacioppo, 2010, page 1). Concerning the association between CPDI and loneliness, literature revealed that increased peritraumatic distress corresponds with living alone and the subjective perception of being avoided by others or the social environment (Liu & Heinz, 2020). These results are in line with research by Liu and Heinz (2020) suggesting that increased psychological distress, such as the distress experienced during the COVID-19

pandemic, has consequently been associated with an increase in loneliness. However, due to virus containment measures individuals are not aiming to become lonely but only aim for social isolation to comply with legal requirements and to prevent the spread of the SARS-CoV-2 virus. Hence, loneliness and social isolation need to be treated as distinct concepts.

Results have highlighted that individuals with an increased generalized anxiety score reported increased symptoms of loneliness. Alasmawi et al. (2020) have shown that perceived loneliness or the severity of reported loneliness differs depending on the mental health diagnosis. Hence, individuals with a common mental health disorder (i.e., anxiety) and people with a personality disorder reported higher rates of loneliness compared to individuals diagnosed with a psychotic disorder.

Anxiety and Loneliness in Association with Symptoms of Depression

Symptoms of anxiety and loneliness are related to symptoms of depression in psychosomatic rehabilitation patients. Protective measures such as lockdowns or quarantining have been known to have a deteriorating effect on mental health (Brooks et al., 2020). In ambiguous and uncertain situations (such as a pandemic) insecurity, fear, and distress among the population may increase (Liu et al., 2020; Liu et al., 2021; Mamun et al., 2021). Consequently, increased intensity of fear and distress may lead to increased worrying about becoming infected (Lin, 2020). These negative emotions associated with worrying and fear can have detrimental effects on well-being and have the potential to evolve into or intensify severe psychological illnesses such as depression, anxiety, and in extreme situations, even suicidal thoughts (Mamun et al., 2021). Therefore, fears associated with an infection may lead to chronic

vigilance for COVID-19-related stressors that may contribute to a development of or an increase in the symptomatology of anxiety (Harding et al., 2008).

Previous research has highlighted the strong association between loneliness and anxiety and has shown that increased loneliness was associated with a higher score in affective symptoms related to an affective disorder such as depression (Wang et al., 2020). Individuals with a lower perceived social support or social connectedness, as during the COVID-19 pandemic, display increased levels of loneliness. This can, in turn, lead to negative cognitive biases which consequently reinforce and foster feelings and associated behaviors related to depression (West et al., 1986). Additionally, results by McPherson et al. (2021) revealed that loneliness experienced at the beginning of a lockdown provided a risk factor for developing clinically significant depression. Gallagher et al. (2021) have examined whether feelings of loneliness have the potential to increase or exacerbate the risk of depression in individuals with a pre-existing cancer diagnosis during COVID-19. Results highlighted that loneliness experienced during the pandemic was predictive of an increased risk of depression.

While fleeting perceptions of loneliness can lead to adaptive responses such as an active search for connectedness, chronic loneliness can lead to maladaptive strategies such as negative cognitions and hence further social withdrawal (Hawkley & Cacioppo, 2010). The COVID-19 pandemic has the potential to enhance this negative "feedback loop" since it reinforces withdrawal and distancing. This is especially true for individuals with limited health since they might lack strategies or opportunities for compensation (Greig et al., 2021). The ETL (Cacioppo & Cacioppo, 2018) can further explain the mechanisms. Nevertheless, it has rarely been applied to individuals with mental or physical health impairments.

The Current Study

The aim of the current study is to investigate and examine symptoms of anxiety and loneliness as serial mediators in the positive relationship between CPDI and symptoms of depression in a sample of psychosomatic rehabilitation patients. This study answers the research question: How are anxiety and loneliness associated with the relationship between peritraumatic stress and symptoms of depression? Consequently, we hypothesize that higher CPDI predicts higher symptoms of depression through a serial mediation pathway from higher symptoms of anxiety and loneliness in a longitudinal manner.

Methods

The present study was funded as part of the research project "TeamBaby – Communication and patient safety in gynecology and obstetrics" (ClinicalTrials.gov Identifier: NCT03855735), which is funded by the Innovation Fund of the Federal Joint Committee (Project No. 01VSF18023). In addition, this study was funded by the research project "ASAP – Assisted Immediate Augmented Post-/Long-COVID Plan" (ClinicalTrials.gov Identifier: NCT05238415), which is supported by the Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit (Project No. AZ-2490-PC-2021-V7-D56613/2021). The current study and data collection were conducted as part of the project "Anhand-COVID19-Offer to achieve treatment and rehabilitation goals in compliance with hygiene and social-distancing rules" (ClinicalTrials.gov Identifier: NCT04453475), which is supported by the Dr. Becker clinic group.

Recruitment of the Psychosomatic Rehabilitation Patients

Participants were recruited through four participating medical rehabilitation clinics from the Dr. Becker clinic group. Patients were admitted to the clinics due to psychosomatic diagnoses and were invited to take part in the online survey through their clinic before starting their treatment. Before participation, patients were informed about the study by writing on the rehabilitation clinic group's online portal. The survey was administered via the survey platform Unipark.

All data collected as part of this study were pseudonymized. No form of compensation was offered to participants. The survey was administered between April 2021 and September 2021. Patients were asked to fill out the online questionnaire from 6 weeks before until the first day of rehabilitation (T1) as well as after their rehabilitation stay (T2), which was possible up to 12 weeks post rehabilitation. At baseline, N = 676 participants participated in the study. After rehabilitation, a total of 273 participants dropped out, leaving 403 participants who completed the survey at both measurement timepoints.

Due to the pandemic situation, contact restrictions were introduced (i.e., no visitors allowed or only one or two visitors at a fixed time, reduced group sizes for therapy sessions, and the avoidance of physical contact) to reduce the potential of a COVID-19 infection. These contact restrictions persisted during the entire data collection phase and were applicable to all

patients.³ Ethical approval for the online survey concerning psychosomatic rehabilitation patients was given by the Ethics Committee at Jacobs University Bremen (protocol code 2020_09) on June 25, 2020.

Participants from the Psychosomatic Rehabilitation Clinics

Of the 403 patients participating at both measurement timepoints, 264 (65.8%) patients were female. Participants' age ranged from 18 to above 60 years. Forty-nine (12.2%) were 39 years or younger, 84 (20.9%) patients between 40 and 49, 205 (51.0%) between 50 and 59 years of age, and 64 patients (15.9%) were 60 years or older. Educational level was categorized into four groups: 67 (16.9%) patients indicated to have received 10 or 11 years of schooling, 77 (19.4%) answered to have received 12 or more years of schooling, 185 (46.7%) indicated to have obtained vocational training, and 67 (16.9%) indicated to have obtained a university degree.

Age, gender, and educational levels were measured as categorical variables. The 232 (61.2%) patients were diagnosed upon discharge with a mood (affective) disorder, 135 (35.6%) were diagnosed with a neurotic, stress-related, and somatoform disorder, and 12 (3.2%) patients were given a diagnosis pertaining to other diagnoses. The 84 participants answered to the current status of their living situation. Eighteen (21.4%) indicted to be living alone, and 66

³ Analyses examining differences in time-periods (periods April to Mai 2021, June to July 2021, and August to September 2021) revealed no significant difference with regard to the variables at interest.

(78.6%) answered to be living with at least one other person in a shared household.⁴ Patients spend on average 52 days (SD = 12 days) in the clinics. The minimum and maximum of days spend at the rehabilitation clinics were 2 days and 97 days, respectively. On average 67 days passed between taking part in the survey at T1 and T2 (SD = 24 days) with a minimum of 26 and a maximum of 209 days.

Instruments

COVID-19 Peritraumatic Distress Index (CPDI) Questionnaire

The COVID-19 CPDI was assessed by 24 items at T1 and T2 (Qiu et al., 2020). All items were measured on a 5-point Likert scale from 0 (not at all) to 4 (extremely). The sum of all items results in a raw score. The displayed score can be obtained by adding 4 to the raw score. The total score of the CPDI ranges from 0 to 100. All items were aggregated in terms of a sum score with good internal reliability with Cronbach's alpha of .87 at T1 and Cronbach's alpha of .90 at T2.

Mental Health - Symptoms of Depression and Anxiety

Mental Health was measured by symptoms of depression and anxiety via the 2-item Patient Health Questionnaire (PHQ-2; Kroenke et al., 2003), and the 2-item Generalized Anxiety Disorder scale (GAD-2; Kroenke et al., 2007). The PHQ-2 (Kroenke et al., 2003), assesses symptoms related to depression, and the GAD-2 (Kroenke et al., 2007) measures symptoms of anxiety. Symptoms of depression were measured by the following: "Over the last

⁴ No significant differences with regard to loneliness were found between individuals with different living arrangements.

2 weeks, how often have you been bothered by any of the following problems? Little interest or pleasure in doing things" and "Feeling down, depressed or hopeless". Anxiety-related symptoms were measured by the two items: "Over the last 2 weeks, how often have you been bothered by any of the following problems? Feeling nervous, anxious or on edge" and "Not being able to stop or control worrying". All four items were rated on a 4-point Likert scale from 0 (not at all) to 4 (nearly every day). Summed scores of 3 or higher indicated a probable case of depression or an anxiety diagnosis. Concerning the current study, the PHQ-2 (internal reliability with Spearman's $\rho = .71$ at T1 and with Spearman's $\rho = .75$ at T2) and the GAD-2 (internal reliability with Spearman's $\rho = .71$ at T1 with Spearman's $\rho = .76$ at T2) were not used as a diagnostic tool but rather were used as an indicator of symptom intensity.

Loneliness

Perceived loneliness was assessed by the item: 'How often do you feel unhappy to be alone?' from the UCLA Loneliness Scale (Russell, 1996). In addition, the item "How often do you feel lonely?" stemming from the Center for Epidemiologic Studies-Depression Scale (CESD; Radloff, 1977) was used. Both items were measured on a 4-point Likert scale from 1 (not at all) to 4 (almost every day). The items were aggregated in terms of a sum score which revealed good internal reliability with Spearman's ρ of .81 at T1 and Spearman's ρ of .85 at T2.

Socio-Demographic Characteristics

Data on socio-demographic characteristics considered gender, age, educational level, and ICD-10 diagnosis upon rehabilitation discharge. Gender was categorized into two subgroups: female and male. For this study, age in years was assessed in the following four categories: < 39, 40–49, 50–59, and > 60. Age needed to be assessed in categories at the clinics

to ensure confidentiality concerning the patient data used as part of this study. In addition, educational level was categorized into four groups, and information on the ICD-10 diagnosis was categorized into three groups.

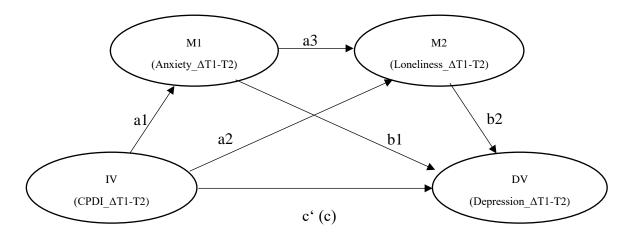
Statistical Analyses

For all analyses, SPSS Version 28 was used (IBM Corp., Armonk, NY, USA). For all analyses, a change score between T1 and T2 for all variables at interest was calculated to analyze the longitudinal association between the variables. Therefore, scores reported at T1 were subtracted by scores reported at T2. First, the correlations of the study variables at interest (CPDI, depression, anxiety, and loneliness) were analyzed by Pearson's correlation. Afterward, a multiple step mediation analysis was conducted to test the hypothesis. As part of this analysis, the dependent variable, that is, symptoms of depression was regressed on the independent variable, that is, CPDI via a chain of two serial mediators (M1 and M2; i.e., anxiety and loneliness). Therefore, the independent variable was hypothesized to predict M1 in the first step. M1 was further modeled to predict M2 in the second step and finally, M2 was hypothesized to predict the dependent variable in the third and last step.

The serial mediation model was analyzed using the PROCESS macro Model 6 for SPSS (Hayes, 2013). The bias-corrected 95% confidence interval (CI) was calculated with 5000 bootstrapping re-samples. If the value zero was not included in the 95% CI, it was indicated that the mediating effect was significant. A statistical significance was defined as a two-tailed value of p < .05. The analysis of the serial mediation was controlled for the covariates age, gender, educational level, and ICD-10 diagnosis upon discharge. We assessed multicollinearity by using the variance inflation factor (VIF) test. The VIF as well as the tolerance values

indicated no problems with multicollinearity as all values for VIF were < 10 (Hair et al., 2014). The theoretical model is depicted in Figure 7.

Figure 7. Theoretical Model of the Serial Mediation Model.



Note. The serial mediation model contains six path coefficients (a1, a2, a3, b1, b2, c') and the total effect (c). Note. IV = independent Variable, DV = dependent variable, M1 = Mediator 1, M2 = Mediator 2.

Data availability

The data presented in this study are available on request from the corresponding author.

The data are not publicly available due to confidential patient information being used.

Results

Attrition Analysis

As part of the attrition analysis, we examined differences between those who retained versus those who dropped out after measurement point T1 concerning the four variables at interest. Hence, the results highlight no differences between the patients who dropped out after

measurement timepoint T1 and those who retained (see Appendix 5). To validate the findings of the present study, a validation study was performed with all n = 676 patients. Missing data of patients who dropped out from the study after T1 was imputed by means of the expectation—maximization-algorithm (see Appendix 6). Results between the original study and the validated study with imputed data did not differ concerning the serial mediation model.

Bivariate Correlations among all Variables

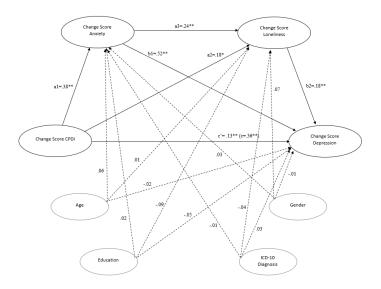
Table 39 in Appendix 7 provides an overview of means (M), standard deviations (SD), and bivariate Pearson's correlations (r) among all examined study variables at both measurement timepoints T1 and T2. The results of the correlation analysis were consistent with our hypothesis as all variables measuring the change from pre- to post-rehabilitation were significantly associated with one another at the level of p < .01 (two-tailed). In addition, intercorrelations between all variables at T1, T2, and change scores are represented in Table 39 (see Appendix 7)

Longitudinal Serial Mediation Analysis

The results of the longitudinal serial mediation analysis for CPDI (IV) on anxiety (M1) and loneliness (M2) on symptoms of depression (DV) controlling for age, gender, educational level, and ICD-10 diagnosis are shown in Figure 8 and Table 17. The change score of the CPDI was significantly positively associated with the change score of symptoms of generalized anxiety. The change score of symptoms of generalized anxiety was in turn positively associated with the change score of loneliness. Further, a significant association was found between the change score of the CPDI index and the change score of loneliness. Finally, the change score of loneliness significantly predicted the change score of symptoms of depression. The total

effect of the independent variable CPDI on the dependent variable symptoms of depression was significant and also remained significant upon the inclusion of the mediator variables in the model.

Figure 8. Longitudinal Serial Mediation Model for CPDI, Symptoms of Anxiety, Loneliness, and Symptoms of Depression in N = 342 Rehabilitation Patients.



Note. The model is controlled for age, gender, education, and ICD-10 diagnosis. Reported coefficients are standardized betas coefficients, in brackets is the total effect; * p < .05; ** p < .01 (see Figure 12 in the Appendix 6 for the full sample).

Concerning the present serial mediation path model, three possible indirect effects were examined. The total indirect path from CPDI to symptoms of depression through the mediator variables: symptoms of anxiety and loneliness, was significant. In addition, the specific indirect path through symptoms of anxiety was also significant ($\beta = .173, 95\%$ CI [0.106, 0.243]) as well as the specific indirect path through loneliness ($\beta = .176, 95\%$ CI [0.118, 0.241]).

Table 17. Hypothesized Longitudinal Serial Mediation Model of Symptoms of Anxiety and Loneliness between CPDI and Symptoms of Depression in N = 342 rehabilitation patients.

Pathway	Effect	SE	BootLLCI	BootULCI
Total effect (c)	.364	.008	0.041	0.072
Direct effect (c')	.134	.007	0.007	0.035
a1	.381	.009	0.043	0.076
a2	.111	.009	0.002	0.036
a3	.241	.062	0.116	0.358
b1	.507	.051	0.408	0.606
b2	.184	.045	0.099	0.274
Indirect effects				
Total indirect effects	.230	.035	0.163	0.299
Indirect 1	.193	.032	0.134	0.257
Indirect 2	.021	.013	0.002	0.048
Indirect 3	.017	.008	0.006	0.031

Abbreviation: Indirect 1, CPDI → symptoms of anxiety → symptoms of depression; Indirect 2, CPDI→ loneliness → symptoms of depression; Indirect 3, CPDI→ symptoms of anxiety → loneliness → symptoms of loneliness. BootLLCI, bootstrapping lower limit confidence interval; BootULCI, bootstrapping upper limit confidence interval; SE, standard error; Effect, standardized regression coefficient (see Table 38 in Appendix 6 for the full sample).

Symptoms of anxiety, as well as loneliness, served as independent mediators of the relationship between CPDI and symptoms of depression. All covariates (gender, age, educational level, and ICD-10 diagnosis) were not significantly associated with either variable in the serial mediation model. Overall, 42.11% of the variance in symptoms of depression was accounted for.

Discussion

The present study examined the mechanisms between distress, anxiety, loneliness, and depression based on the ETL, a potentially vicious circle. Hence, this study tested whether COVID-19 peritraumatic distress predicted higher depressive symptoms through a serial mediation pathway of increased anxiety and increased reported loneliness. The present findings support our hypothesis that symptoms of anxiety and loneliness are serial mediators in the positive association between COVID-19 peritraumatic distress and symptoms of depression in a sample of psychosomatic rehabilitation patients. The serial mediation was conducted longitudinally by examining change scores (before rehabilitation – after rehabilitation) for all variables. In line with the proposed hypothesis, a higher CPDI predicted symptoms of depression through a serial mediation pathway of symptoms of anxiety and loneliness. The results concerning the direct effect suggested that peritraumatic distress is positively correlated with symptoms of depression in medical, psychosomatic rehabilitation patients, as other studies have shown before (Megalakaki et al., 2021).

Additionally, to the overall mediation effect, the mediators, symptoms of anxiety and loneliness, also served as individual mediators between peritraumatic distress (CPDI) and symptoms of depression. Hence, as no previous study has examined this specific mediation effect, the present research adds new empirical evidence to provide a greater understanding of how the relationships between peritraumatic distress and depression are connected in the pandemic context.

Further, our results are in line with a study by Megalakaki et al. (2021) revealing a positive association between an increase in COVID-19 peritraumatic distress and increased

generalized anxiety. Our data also integrates well with previous research. Individuals with a pre-existing mental health diagnosis during the COVID-19 pandemic displayed a positive link between peritraumatic distress and an increased anxiety score (Megalakaki et al., 2021; Wheaton et al., 2012). Individuals with higher reported distress have also been shown to display higher signs of worry and fear related to an anxiety disorder (Liu et al., 2020).

The present findings reflect previous research indicating that higher peritraumatic distress is positively associated with feelings of loneliness due to the mitigation strategies of physically distancing oneself due to the COVID-19 pandemic. Earlier studies found that individuals with increased peritraumatic distress reported increased loneliness, a lower frequency of social networks, and more fear of being alone in the future compared to individuals with a lower CPDI (Liu & Heinz, 2020). This was especially pronounced for individuals with a pre-existing mental health disorder.

Our results confirm a positive association between peritraumatic distress and loneliness. This association is also in line with previous studies showing that individuals with increased distress reported a lower number of social contacts and a lower frequency of weekly contact with others (Benke et al., 2020). Therefore, traumatic distress due to the COVID-19 pandemic seems to be positively associated with generalized anxiety and loneliness as well.

The significant association between anxiety and loneliness demonstrates that symptoms of anxiety are associated with loneliness in the domain of symptoms of depression. The present results can be well integrated into the existing literature. Previous studies found that loneliness has been significantly associated with an increase in depressive symptoms (Gallagher et al., 2021; McPherson et al., 2021). Further, it has been shown that increased anxiety can increase

levels of experienced loneliness (Ebesutani et al., 2015). In addition, reported loneliness appears to precede and lead to increased reported symptoms of depression (Gallagher et al., 2021; McPherson et al., 2021). So far, only one study by Ebesutani et al. (2015) has examined the role of loneliness as a mediator in the relationship between anxiety and depression in youth. Therefore, the present findings extend the understanding of this association.

In addition to the multiple step mediation effect, present results revelated that both anxiety and loneliness fully mediated the relationship between peritraumatic distress and depression. This underlines the importance of recognizing symptoms of anxiety and loneliness as sustaining factors for depression. While, according to cognitive models of anxiety and depression, the core difference between depression and anxiety is the emotional pattern (Dobson, 1985). In other words, anxiety is future-oriented and predictive of a potential threat. On the contrary, depression is associated with either imminent or past events which bear a potential threat to self-esteem. Literature has postulated that anxiety and depression often co-occur (Borsboom, 2017). However, rather than viewing anxiety and depression as separate or categorical entities, literature has termed an alternative view called the network approach to psychopathology (Borsboom, 2017).

The network approach of psychopathology postulates that symptoms of both anxiety and depression actively reinforce one another leading to comorbidity (Borsboom, 2017). For example, an individual perceiving a pandemic fear as threatening may experience physical and cognitive symptoms of anxiety. The individual may also be tenser when confronted with a threatening situation or anticipating possible consequences of a threatening situation, potentially developing the tendency to avoid situations in which a threat may be predominant.

The consequent loss of social interactions and the associated perceived loneliness related to avoidance may lead to the development of symptoms related to a depressive episode (i.e., lower self-esteem and lower self-worth).

Overall, our analyses and findings were based on the ETL which suggests that individuals who feel lonelier tend to engage in self-defeating and pessimistic cognitions. This may, in turn, increase the risk for depressive symptoms (Cacioppo & Cacioppo, 2018; Cacioppo & Hawkley, 2009). The ETL theory seems applicable to the new background of the COVID-19 pandemic. Our results thus provide an extension to the ETL theory in that they suggest that distress associated with a traumatic or uncertain situation (such as the COVID-19 pandemic) and a consequent increase in anxiety. This could play a role in the development and maintenance of loneliness. The ETL has been discussed concerning disability, which could be a crucial barrier against adaptive strategies, hence facilitating the development of maladaptive strategies. Nevertheless, only very few previous approaches have been made in applying it to people suffering from psychological and physical health conditions. Hence, our study extends the applicability to psychosomatic rehabilitation patients.

Implications

Our results indicate that reducing anxiety as well as loneliness is useful and necessary for patients with a pre-existing psychological disorder to reduce or stabilize reported symptoms of depression. Therefore, it is important to provide patients with adequate information about the COVID-19 pandemic and its SARS-COV2 virus in the media to reduce COVID-related distress and anxiety, respectively. As recommended, a common coping strategy during the pandemic has been to limit exposure to news reports. This has been of importance especially

for individuals with a pre-existing mental health condition, as those individuals may be more sensitive to distressing information which may in turn spark an anxious and depressive reaction (Asmundson et al., 2020). This reaction may be further complicated and strained by the loss of face-to-face social support networks due to the requirement to physically isolate from others (Asmundson et al., 2020).

Research suggests that the loss of social networks in the face of the pandemic may consequently lead to an increase in mood-related disorders (Grey et al., 2020). As individuals with a pre-existing mental health condition are often overwhelmed with applying adequate and effective coping strategies, support strategies need to be put into place. Therefore, individuals with a pre-existing reduced mental health status should receive interventions that promote resources and protective factors, such as character strength to increase individual well-being (Umucu et al., 2021). In addition, low threshold digital or face-to-face support networks should be offered to individuals to reduce perceived anxiety by providing adequate and adaptive coping strategies that can help overcome loneliness according to the ELT (Cacioppo & Cacioppo, 2018). Furthermore, individuals should be encouraged to engage in more social contact either face-to-face with necessary protective measures or in a digital mode to alleviate feelings of loneliness. By forming new contacts, or reactivating existing social contacts, patients may be able to reduce reported symptoms of depression. Therefore, to break through the vicious circle of fear that leads to depression, the mediating and, therefore, maintaining factors of anxiety and loneliness need to be acknowledged and treated. Since the pandemic is likely to become endemic and it is questionable whether there will be an "end of COVID-19", it is necessary to face the possibility of a "new normal" including different strategies to contain the virus in daily life: To support this process of acceptance and integration, activities should be taken up that satisfy basic psychological needs to enhance satisfaction, coping, and self-regulatory skills (Behzadnia & FatahModares, 2020), thereby decreasing the potential psychological burden on mental health. In this way, individuals with limited mental and overall health can be supported in finding their "new normal," that is, by using digital methods of communication and work, especially for rehabilitation patients who might be challenged in adapting to a new normal.

Furthermore, the present findings suggest the necessity for tailoring COVID-19-related mental health interventions to support patients with a pre-existing mental health condition to facilitate them in coping with fearful and uncertain situations effectively. In addition, our results have highlighted a significant relationship between anxiety and depression, indicated by individuals with higher symptoms of anxiety who also reported higher symptoms of depression.

Limitations and Suggestions for Further Research

Several study limitations need to be recognized. First, the study measured depressive and anxiety symptoms by means of two two-item scales. To examine the extent of the symptoms of depression and anxiety, a broader assessment may be necessary. In addition, as there are currently no comparable longitudinal studies available that assess depression and anxiety at similar time points within the pandemic in the general population in Germany, the generalizability of our findings may be limited. Therefore, future studies should also focus on comparing symptoms between psychosomatic rehabilitation patients and the general population and similar points within the COVID-19 pandemic. Further, we observed a rather high dropout rate during the follow-up period of about 40.4%. Even though the high drop-out rate might limit the generalizability of the current results, several other studies have encountered similar

drop-out rates in studies performed with psychosomatic rehabilitation patients (e.g., Lippke et al., 2021). Further, the results obtained by the validation study, which assesses the serial mediation model with imputed data for measurement time point two, mimic the results of the present study.

Moreover, future studies should evaluate the specific mechanisms, that is, whether the different variables interrelate or whether there are real causal effects. Accordingly, experimental designs are needed to investigate this. Also, examining and analyzing longitudinal trends in symptom changes to conclude long-lasting symptom changes in psychosomatic rehabilitation patients is necessary. Moreover, as this study only examined anxiety, loneliness, and depression only within a small time frame (i.e., before and after rehabilitation), future research should also measure the constructs at additional time points after rehabilitation. Furthermore, no causal conclusion can be drawn as part of our study, as we did not adopt an experimental research design. Translating our findings into interventions integrated into the rehabilitation process is needed. Such interventions should be tested in a randomized controlled trial with a waiting control group.

Conclusion

Our study suggests that an increase in COVID-19 peritraumatic distress, as well as intensified symptoms of anxiety and loneliness, may lead to elevated symptoms of depression or are, at least, maintaining factors for depression among psychosomatic rehabilitation patients.

A theory that can be used in psychosomatic rehabilitation is the ETL. Therefore, this paper stresses the necessity to not only treat ICD-10 diagnoses such as anxiety and depression but

also to acknowledge loneliness and stress associated with the COVID-19 pandemic as a sustaining factor.

Acknowledgments

We would like to thank the Becker clinics Möhnesee, Norddeich, Juliana, and Burg for their assistance in data collection. Furthermore, we would like to thank Katharina Schiffer and Grace Wire for proofreading the final version of this manuscript.

Funding

Funding for the study stems from the research project "TeamBaby – Communication and patient safety in gynecology and obstetrics" (ClinicalTrials.gov Identifier: NCT03855735), which is funded by the Innovation Fund of the Federal Joint Committee (Project No. 01VSF18023) and by the research project "ASAP - Assisted Immediate Augmented Post-/Long-COVID Plan" (ClinicalTrials.gov Identifier: NCT05238415), which is funded by the Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit (Project No. AZ-2490-PC-2021-V7- D56613/2021). Furthermore, the current study was conducted as part of the project "Anhand-COVID19-Offer to achieve treatment and rehabilitation goals in compliance with hygiene and social-distancing rules" (ClinicalTrials.gov Identifier: NCT04453475), which is supported by the Dr. Becker clinic group.

Conflict of Interest

The authors declare no conflict of interest.

Ethical Approval

Ethical approval for the study was given by the Ethics Committee at Jacobs University Bremen (protocol code 2020_09 and date of approval: 25 June 2020).

Clinical Trial Registration

ClinicalTrials.gov Identifier: NCT04453475

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Chapter 7: Implementing Digital Trainings within Medical Rehabilitations: Improvement of Mental Health and Synergetic Outcomes with Healthcare Service

Keller, F. M., Dahmen, A., Derksen, C., Kötting, L., & Lippke, S. (2021a). Implementing Digital Trainings within Medical Rehabilitations: Improvement of Mental Health and Synergetic Outcomes with Healthcare Service. *International Journal of Environmental Research and Public Health*, *18*(17), 8936. https://doi.org/10.3390/ijerph18178936

Implemented New Technologies within the Complexity of Medical Rehabilitations:

Improvement of Mental Health and Synergetic Outcomes with Healthcare Service

Effects

Abstract

The need for new technologies in health care services has been stressed. However, little is known about the effectiveness of digital interventions integrated into psychosomatic rehabilitation processes. Data from 724 patients from psychosomatic rehabilitation clinics were analyzed with regard to the effectiveness of digital trainings indicated by a change in symptoms related to depression, anxiety, stress, and loneliness from pre- to post-rehabilitation. Rehabilitation satisfaction was examined in association with reaching rehabilitation goals and satisfaction with communication. A mixed repeated measures analysis of covariance, analyses of covariance, and hierarchical stepwise regression analyses were performed. Results indicated a superior effectiveness for the intervention group receiving all offered digital treatments in addition to the regular face-to-face rehabilitation program with regard to symptoms of depression, F(2,674) = 3.93, p < .05, $\eta_p^2 = .01$), anxiety, F(2,678) = 3.68, p < .05, $\eta_p^2 = .01$), post-rehabilitation, with large effect sizes for both depression (d = 1.28) and anxiety (d = 1.08). In addition, rehabilitation satisfaction was positively associated with reaching rehabilitation goals and perceived communication with health care workers. Digital interventions appeared effective in supporting the mental health of psychosomatic rehabilitation patients postrehabilitation. These findings support the inclusion of multidisciplinary and interdisciplinary digital and face-to-face treatment programs and call for more implementations of new technologies in a context of complexity to improve health and health care services.

Keywords: Mental Health; Psychosomatic Rehabilitation; Internet-Delivered Digital Trainings; Multidisciplinary and Interdisciplinary Interventions

Introduction

Mental Health and the COVID-19 Pandemic

The effects of the coronavirus disease 2019 (COVID-19) on individuals' health, especially on mental health and perceived well-being, are likely to be profound and long-lasting (Holmes et al., 2020). Not only has the COVID-19 pandemic led to rapid changes in human interaction, hygiene behavior, communication behavior, and self-care, but it has also led to increased feelings of uncertainty, distress, and social isolation resulting in stress reactions, symptoms of depression, and anxiety, and general fear of the virus (Balkhi et al., 2020). Several studies have pointed out that elevated rates of depression, anxiety, and stress, as well as post-traumatic stress, were associated with the COVID-19 pandemic (Rogers et al., 2020). Therefore, in case of a prolongation of restriction measures, individuals, especially those who are already susceptible to a mental health disorder, may develop serious mental health issues (Fiorillo & Gorwood, 2020; Van Rheenen et al., 2020).

For individuals with a pre-existing mental health disorder, the lockdown measures have shown to be major stress factors and are associated with a deterioration of their mental health status due to changes in daily routine and social rhythms (Van Rheenen et al., 2020), reduced access to support services, earlier discharge from psychiatric units or discontinuation of psychotherapy treatments (Chevance et al., 2020; Hao et al., 2020; Yao et al., 2020).

To partially compensate for reduced access to support systems and discontinuation of psychotherapy, therapists have been more prone to offer digital psychotherapy sessions in addition to face-to-face sessions to guarantee the continuation of treatment as well as to protect and support the mental health of patients. The idea of blended psychotherapy as a combination of an online treatment with face-to-face psychotherapy is rather a new research field and has received more attention during the COVID-19 pandemic (Baumeister et al., 2018; Erbe et al., 2017; Kemmeren et al., 2019; Kleiboer et al., 2016). Blended psychotherapy has shown to provide many advantages over face-to-face psychotherapy as it supports bridging distances

between residence and treatment placement, flexibility, as well as increased patient empowerment (Schuster et al., 2018; Titzler et al., 2018).

However, even though a few studies have examined the effectiveness of blended psychotherapy in outpatient settings (Friedl et al., 2020), the effectiveness of integrating digital interventions in form of a blended psychotherapy concept into medical, psychosomatic rehabilitation treatment programs has yet to be evaluated.

Therapy for Medical, Psychosomatic Rehabilitation Patients

The overarching aim of the rehabilitation system in Germany is to reintegrate and support social participation of patients but not to curate disorders. Patients admitted to rehabilitation clinics in Germany are generally treated based on the biopsychosocial model (World Health Organization, 2001). This is in contrast to patients with severe mental health disorders who are typically seen by a psychiatrist and are potentially being admitted to a psychiatric hospital and treated by an interdisciplinary and multidisciplinary team according to the German national regulations and guidelines. Hence, rehabilitation is usually an in-patient program providing psychoeducation, psychotherapy in form of individual and group therapy, physical therapy, and occupational therapy, as well as trainings in skills relevant for the reintegration and return to work (RTW; Scheidt, 2017). One of the skills necessary for reintegration and social participation is effective communication. Therefore, during psychotherapy sessions, patients are informed about, encouraged, and supported to improve their communication skills to obtain and maintain a healthy mental well-being.

Research has shown that blended therapy can be well integrated into the preparatory process before a rehabilitation stay (Becker et al., 2016), during the rehabilitation process at the rehabilitation clinics itself (Zwerenz et al., 2015), and for aftercare and stabilization (Zwerenz et al., 2013). First attempts to provide patients with digital support after rehabilitation have already been made by the Curriculum Hannover Online (Dahmen et al., 2021) and the internetand mobile-based intervention (IMI) DE-RENA (Schmädeke et al., 2019). Although digital

trainings are usually accepted as suitable in the context of health care and rehabilitation (particularly to buffer negative consequences of the COVID-19 pandemic and ensure treatment options), methods and techniques need to be carefully planned and implemented. A non-suitable training might affect rehabilitants' health and well-being negatively since no immediate support is available in a digital setting if trainings pose a strain on individuals with mental health symptoms. Additionally, digital interventions might negatively affect rehabilitants' treatment motivation if the contents and mode of delivery are not suitable, thus inhibiting effective inpatient rehabilitation. However, so far, no study has attempted to evaluate digital trainings offered before or during medical, or psychosomatic rehabilitation.

Importance of Communication in Medical, Psychosomatic Rehabilitation Treatment

Programs

Communication is the central element of psychotherapy and thus a central element of the psychosomatic rehabilitation process. Based on a patient's verbal and nonverbal communication, psychotherapists can foster a diagnostic-therapeutic alliance with the patient (Moscara & Bergonzini, 2021; Yeomans et al., 2015; Zerbo et al., 2013). Further, patients are encouraged by trainings, such as elements of social competence training, to learn and apply effective communication strategies. Additionally, the therapist is encouraged to promote effective communication strategies tailored to the individual patient to understand maladaptive behaviors and to support the patient with treatment options and coping skills It has been shown that effective communication skills with patients throughout the therapeutic process (i.e., through transparency, goal-value clarification, or through an empathic approach) foster and encourage therapy motivation as well as motivation to change. One strategy that has been proven effective in the treatment of depression and anxiety is communication-focused therapy (CFT; Haverkampf, 2017b, 2017a). CFT assumes that changes as part of the therapeutic process (i.e., changes in learning processes, as well as acceptance and behavioral adaptions) are determined by the results of effective communication processes between a patient and a

therapist. Therefore, to encourage a therapeutic alliance to provoke therapeutic changes, therapists are encouraged to improve own communication skills relevant to the health care context.

An example of communication skills required in the health care context has been proposed by Rider & Keefer (2006). In the study, the authors highlighted the importance to communicate effectively with patients by focusing on interpersonal relations. Hence, health care professionals are encouraged to communicate clearly and accurately and to provide the patient with sufficient information by also acknowledging the patient's situation. However, concerning the setting of medical, psychosomatic rehabilitation treatment, the exact association between perceived effectiveness of communication from the patients' perspective and rehabilitation effectiveness as well as satisfaction has so far not been evaluated.

Compensatory Carry-Over Action Model

One theoretical model that describes the relationship between mental well-being and factors associated with well-being is the Compensatory Carry-Over Action Model (CCAM; Lippke et al., 2021). The CCAM describes how health outcomes, such as a decrease in symptoms of depression and anxiety or perceived loneliness and stress, resulting from different health-related behaviors such as participation in digital trainings, adaptions of communication behavior, and how they change also as a result of one another. In addition, the CCAM assumes that relevant, higher-order goals such as workability and participation may be achieved by implementing goals for individual health-related behaviors through the use of action plans. Important for the transfer between the individual behaviors (i.e., participation in digital trainings or improved communication competencies and reduced mental health symptoms) are personal psychological resources (Lippke et al., 2021).

The psychiatrist or therapist fosters an early diagnostic-therapeutic alliance with the patient. S/he integrates information obtained through both the patient's verbal and nonverbal communication and his or her own countertransference (Yeomans et al., 2015; Zerbo et al.,

2013). Therefore, the CCAM provides the theoretical basis to explain how adaptions to the rehabilitation process (i.e., by offering digital trainings, supporting goal attainment, or improving communication competencies of therapists) are associated with a change in symptoms of depression, anxiety, perceived loneliness, and stress from pre- to post-rehabilitation.

Goal of the Study

The goal of the current study was to test the effectiveness of digital trainings provided to rehabilitation patients before and during their medical rehabilitation stay. In addition, as communication is a central element of (psycho)therapy, the present study aimed to evaluate the interrelation of communication with rehabilitation satisfaction and consequently with perceived rehabilitation success.

With these research aims in mind and on basis of the theoretical background of the CCAM and previous findings, the following hypotheses were formulated. (1) Symptoms of depression, anxiety, perceived stress, and loneliness will decrease from pre- to post-rehabilitation. Additionally, we expected that (2) the intervention group who received all digital trainings will have a more substantial decrease in symptoms concerning depression, anxiety, perceived stress, and loneliness. Further, we assumed that (3) the patients from the intervention group receiving all digital trainings will indicate a higher perceived rehabilitation success. We also predicted that (4) patients who perceived greater satisfaction with communication will be more satisfied with their rehabilitation process and will more likely indicate that they have achieved their rehabilitation goals.

Materials and Methods

Study Design

The present study was conducted at four psychosomatic rehabilitation clinics from the Dr. Becker clinic group in a longitudinal manner. Participants recruited to this study received regular treatment programs concerning psychological and physical interventions. Those treatment programs included among others individual and group psychotherapy, physiotherapy, and occupational therapy.

Recruitment and Data Collection

Participants were recruited through the four participating clinics from the Dr. Becker clinic group. Before participation, patients were informed about the study in writing on the rehabilitation clinic group's online portal. Thereby, it was guaranteed that only patients who had access to the digital portal with an individualized participant code could participate. Patients were invited to take part in a survey administered via the survey platform Unipark. Before participating in the survey, patients were asked to read the participation information and were asked to give informed consent. All data collected as part of this study were pseudonymized. Participants were not offered any form of compensation for participating in the study. The survey at the four psychosomatic clinics was administered between July 2020 and June 2021. Data collection was longitudinal with two measurement time points. Patients were invited to participate from six weeks before until the first day of rehabilitation (T1) as well as after their rehabilitation stay (T2). Participation after rehabilitation was possible for a maximum of 12 weeks post-rehabilitation. Reminders were sent out to the participants for the T2 survey after 1, 4, and 11 weeks post-rehabilitation. Ethical approval for the online survey concerning

psychosomatic rehabilitation patients was given by the Ethics Committee at Jacobs University Bremen (protocol code 2020_09 and date of approval: 25 June 2020). The current study was conducted as part of the project "Anhand-COVID19-Offer to achieve treatment and rehabilitation goals in compliance with hygiene and social-distancing rules" (ClinicalTrials.gov Identifier: NCT04453475), which is supported by the Dr. Becker clinic group.

Participants

In total, N = 1279 patients participated in the online survey at time point 1 (before rehabilitation stay). A total of 555 patients dropped out after the baseline assessment, leaving 724 participants who completed the survey at measurement timepoint 1 pre—rehabilitation as well as the survey at measurement timepoint 2 post-rehabilitation.

The most common three diagnoses that patients received, according to the International Classification of Disease-10 (ICD–10) manual, were as follows: a major depressive disorder, recurrent, moderate (F33.1) with n = 193 (26.7%); an adjustment disorder (F43.2) with n = 159 (22.0%); and a major depressive disorder, single episode, moderate (F32.1) with n = 93 (12.8%). Patients' ages ranged from 18 to above 60 years. Within the sample, 466 (64.4%) patients were female. Additionally, 155 (21.7%) patients had a secondary school diploma, 106 (14.8%) patients had a high school diploma, 319 (44.6%) patients had completed vocational training, and 135 (18.9%) patients indicated having a university degree.

Interventions

As part of the incoming process and before the beginning of the treatment stay, participants were asked to participate in a digital training on rehabilitation goals presented to patients in a digital PowerPoint presentation without face-to-face elements. Participation was voluntarily. The digital training on rehabilitation goals could be accessed from home with a computer, laptop, tablet, or smartphone. This training was designed as a combination between psychoeducation and practical elements. Patients were educated on the importance of

formulating goals and plans as well as on how to formulate those. After the educative element, participants were instructed to formulate their own plans for their rehabilitation treatment process. Further interactive tools such as digital exercise booklets supporting goal and plan formulation were provided to patients online. Patients were encouraged to make use of the supporting material after the training.

As part of the rehabilitation process, participants diagnosed with a major depression were required to take part in the digital group training for depression. The digital group training was based on cognitive behavioral therapy (CBT) guidelines with evidence-based components of computerized cognitive behavioral therapy (eCBT) and internet-delivered cognitive behavior therapy (iCBT) interventions (Karyotaki et al., 2018; Luo et al., 2020; Sasseville et al., 2021). The group therapy for depression was conducted in a flipped classroom manner with a combination of digital and face-to-face components. The digital group therapy for depression was divided into six therapy sessions. Each session lasted for about 50 min. The 50 min sessions were divided into a 5 min digital training followed by a 45 min analog group session. Contents discussed during the group sessions included psychoeducation on the symptoms of and coping mechanisms for depression, underlying models, as well as different available treatments such as drug therapy and ambulatory or stationary psychotherapy.

The informative digital training on legal rights for (severely) disabled was offered to all patients once during their rehabilitation stay in the form of a group session. Participation was mandatory irrespective of the ICD-10 diagnosis. The training consisted of a 20 min informative video and a subsequent 25 min face-to-face group session in which in-depth questions were discussed following the flipped classroom manner. Contents of the video and the group discussion included aspects of the law on severe disabilities, requirements for obtaining a degree of disability, and its consequences on everyday life.

Hence, the study design was set up as follows: participants allocated to the control group received the care-as-usual rehabilitation program. Patients allocated to intervention group 1

(IG1) took part in the digital training on rehabilitation goals prior to the rehabilitation stay in addition to the care-as-usual rehabilitation program. As part of intervention group 2 (IG2), patients took part in the digital training on rehabilitation goals before the rehabilitation stay, the digital group therapy on depression, and the digital training on legal rights for (severely) disabled in addition to the regular care-as-usual rehabilitation treatment.

Instruments

Depressive Symptoms and Symptoms of Anxiety

To measure symptoms of depression and anxiety, the Patient Health Questionnaire-4 (PHQ-4) was used. The questionnaire was not used as a diagnostic tool as part of this study but rather used as a measure of symptom intensity. The PHQ-4 is a composite measure with four items of the PHQ-2 (Kroenke et al., 2003) and the GAD-2 (Löwe et al., 2010). All four items are measured on a four-point Likert scale from 0 ('not at all') to 3 ('nearly every day'). A scale sum score of \geq 3 for both the PHQ-2 (T1 Spearman's rho=.70; T2 Spearman's rho = .71) and the GAD-2 (T1 Spearman's rho = .64; T2 Spearman's rho = .67) depicts the cut-off value between the normal range and a probable case of depression and anxiety (Kroenke et al., 2007; Löwe et al., 2005).

Perceived Stress

As a measure of stress, the Perceived Stress Scale (PSS; Cohen et al., 1983)) was used. The PSS is a globally used self-report scale measuring perceived stress. With regard to the current study, perceived stress was measured by the short four-item version of the PSS scale (PSS-4; Cohen & Williamson, 1988). The PSS-4 assesses perceived stress on a 5-point Likert scale from 0 ('never') to 4 ('very often') with a Cronbach's alpha at T1 of .71 and T2 of .85.

Loneliness

Perceived loneliness was assessed through two items: 'How often do you feel lonely?' stemming from the Center for Epidemiologic Studies-Depression (CES-D) Scale (Radloff, 1977) and 'How often do you feel unhappy to be alone?' from the UCLA Loneliness Scale

(Russell, 1996) (T1 Spearman's rho = .81, T2 Spearman's rho = .81). Both items were measured on a four-point Likert scale from 1 ('not at all') to 4 ('almost every day').

Rehabilitation Goals

Before and after rehabilitation, patients were asked to indicate whether they aimed to achieve eight possible rehabilitation goals on a scale from 1 ('not at all') to 4 ('completely') with a Cronbach's alpha at T1 of .65 and at T2 of .89. Examples of possible rehabilitation goals included the reduction of mental health symptoms, an improvement of stress coping capabilities, improvement of cognitive abilities, ability to relax and rest, or the improvement of/return to past earning capacities. The items assessing rehabilitation goals were developed based on the provided content and the outcome aims of the digital trainings provided before and during the rehabilitation treatment.

Perceived Communication

Perceived communication between rehabilitation patients and health care professionals (i.e., psychotherapists, occupational therapists, doctors, nurses, or other health care staff) was examined from the perspective of rehabilitation patients through six items developed based on Rider and Keefer's interpersonal communication competencies with a Cronbach's alpha of .88 (Rider & Keefer, 2006).

Satisfaction with Rehabilitation

Post rehabilitation, patients were asked to indicate their satisfaction with medical rehabilitation with one item on a 6-point Likert scale from 1 ('very dissatisfied') to 6 ('very satisfied').

Statistical Analyses

For all analyses, SPSS Version 27 was used (IBM Corp., Armonk, NY, USA). The data were analyzed using 724 patients who were either allocated to the control group or the intervention groups (IG1 to IG2). A randomization check was performed to confirm successful allocation to groups. Hence, the different groups (control group and two intervention groups)

were compared for age, gender, educational status, symptoms of depression and anxiety, perceived stress, and perceived loneliness before rehabilitation. Therefore, a one-way ANOVA was used for continuous variables. Chi-squared tests were used for nominal variables. According to Tabachnick and Fidell (2019), it has been suggested that, in case of a significant difference, correlations between the significant variable and the dependent variable should be computed to assess whether the significant variable should be included as a covariate in our analyses.

As the amount of missing data was below 5% for all items, no imputation of missing data was performed. Patients with missing data on the social-cognitive variables (i.e., age or gender) were included for further analyses if they had at least one non-missing data point under the assumption of missing data (completely) at random.

To evaluate significant changes in the symptom intensity concerning depression, anxiety, stress, and loneliness, a 2×3 linear mixed-model repeated measures analysis of covariances (MMRM ANCOVA) was performed. To explain a significant time x intervention group interaction effect, the mean difference scores for the two time points were computed (before rehabilitation to after rehabilitation). Based on the mean difference scores, a series of analyses of covariances were performed to identify differences between the interventions.

To determine the effect sizes of all measurements, partial eta squared and Cohen's *d* values were computed. Based on the recommendation by Field (2009), partial eta squared values of 0.01, 0.06, and 0.14 represent weak, moderate, and strong effects (Cohen, 1988; Kirk, 1996). Cohen's *d* values of 0.20, 0.50, and 0.80 represent small, medium, and large effect sizes (Cohen, 1988).

Further, we performed several multivariate analyses of covariance (MANCOVA) to evaluate which treatment group was more likely to reach the proposed rehabilitation goals. Additionally, we investigated the association between the estimation of achieving rehabilitation

goals and overall satisfaction with rehabilitation treatment by employing a stepwise hierarchical linear regression.

Results

Randomization Check

With regard to the current study, n = 55 (7.6%) patients did not participate in any of the three digital trainings and were thus defined as the control group. 570 (78.7%) patients participated in the digital trainings on rehabilitation goals (intervention group 1 – IG1), and 80 (11.0%) patients participated in all three digital trainings (intervention group 2 – IG2). 19 patients (2.6%) were excluded from the analyses.

There were no significant differences for gender, $X^2(2, n = 701) = 1.60$, p = .45, for age $X^2(8, n = 703) = 11.84$, p = .16, and for educational level $X^2(6, n = 696) = 2.80$, p = .83. In addition, there were no significant differences for symptoms of depression F(2,695) = 0.78, p = .46, $\eta_p^2 = .01$, for symptoms of anxiety F(2,698) = 1.15, p = .32, $\eta_p^2 = .01$, as well as for perceived stress F(2,695) = 1.61, p = .20, $\eta_p^2 = .01$, and perceived loneliness F(2,686) = 1.22, p = .30, $\eta_p^2 = .01$.

MMRM ANCOVA from before Rehabilitation Treatment to after Rehabilitation

Treatment

Results indicated a significant main effect across time, controlling for age and gender for symptoms of depression, F(1,674) = 13.34, p < .01, $\eta_p^2 = .02$, symptoms of anxiety F(1,678) = 6.80, p < .01, $\eta_p^2 = .01$, and perceived stress F(1,672) = 17.63, p < .01, $\eta_p^2 = .03$ as well as for perceived loneliness F(1,662) = 4.00, p < .05, $\eta_p^2 = .01$).

Significant interaction between time x intervention controlling for age and gender and intervention group emerged for symptoms of depression F(2,674) = 3.93, p < .05, $\eta_p^2 = .01$) and symptoms of anxiety F(2,678) = 3.68, p < .05, $\eta_p^2 = .01$). However, no significant interaction

effect was found for perceived stress F(2,672) = 1.80, p = .17, $\eta_p^2 = .01$) as well as for perceived loneliness F(2,662) = 2.69, p = .07, $\eta_p^2 = .01$).

No significant main effect for intervention, controlling for age and gender was found for all four outcome domains: Depression F(2,774) = 0.58, p = .56, $\eta_p^2 = .01$, anxiety F(2,678) = 0.42, p = .66, $\eta_p^2 = .01$, perceived stress F(2,672) = 0.832, p = .44, $\eta_p^2 = .01$, and loneliness F(2,662) = 1.43, p = .24, $\eta_p^2 = .01$. Reported effect sizes for the main effects of time and intervention as well as for the interaction effect of *time x intervention* were small for all outcome domains.

Changes in Mental Health Symptoms with regard to Intervention Group from before

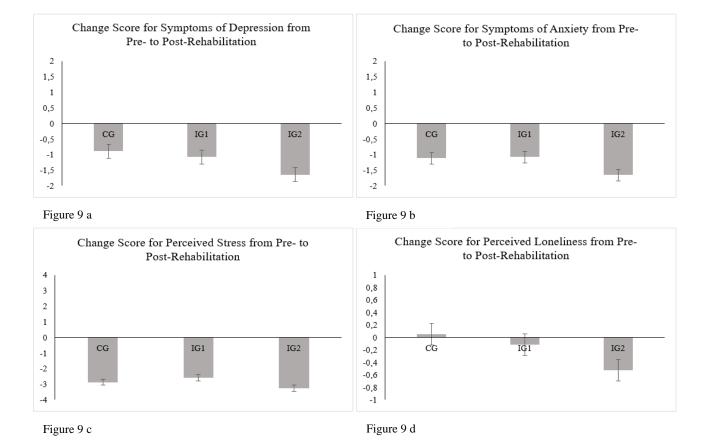
Rehabilitation Treatment to after Rehabilitation Treatment

Overall, the average scores showed an improvement from pre–rehabilitation treatment to post-rehabilitation treatment concerning symptoms of depression, symptoms of anxiety, and perceived stress across the control group and intervention groups (see Figure 9 a–d). For perceived loneliness, however, a reduction in perception was found for intervention groups 1 and 2, but not for the control group.

Figure 9 (a-d). Estimated Marginal Means for Symptoms of Depression (Figure 9 a),

Symptoms of Anxiety (Figure 9 b), Perceived Stress (Figure 9 c), and Perceived Loneliness

(Figure 9 d).



Note. Error bars are represented by standard errors of the mean. Higher negative scores represent a greater reported symptom change from pre- to post-rehabilitation and thus, a better mental health status post-rehabilitation.

The results of the ANCOVA showed significant between group differences with regard to the decrease in symptoms in the outcome domains from pre-rehabilitation to post-rehabilitation. Hence, significant differences were found for symptoms of depression F(2,638) = 4.50, p < .05, $\eta_p^2 = .02$ and symptoms of anxiety F(2,638) = 4.19, p < .05, $\eta_p^2 = .02$, however,

not for perceived stress F(2,638) = 2.38, p = .09, $\eta_p^2 = .01$ and perceived loneliness F(2,638) = 2.39, p = .09, $\eta_p^2 = .01$.

Bonferroni's post-hoc test indicated a significant difference the KG and IG2 (M_{diff} = -.74, p = .40) and a significant difference between IG 1 and IG2 (M_{diff} = -.55, p = .02) for symptoms of depression. With regard to symptoms of anxiety, Bonferroni's post-hoc test indicated a significant difference between IG1 and IG2 (M_{diff} = -.58, p = .02).

Looking at the mean scores in Table 18, this effect is highlighted by the results for depression and anxiety of the IG2 group reporting a significantly decreased symptoms intensity post-rehabilitation. In addition, the average symptoms of perceived stress and perceived loneliness post-rehabilitation were lowest in intervention group two. These results suggest an improved mental health, especially for intervention group three.

Table 18. Descriptive Statistics (Estimated Marginal Means [M], and Standard Deviations [SD]) for Treatment Outcomes for all Treatment Groups from Pre-Rehabilitation to Post-Rehabilitation (N = 705).

Measure	Group	Pre-treatment	Post-treatment
		M(SD)	M(SD)
Symptoms of	Depression		
	CG	3.48 (1.87)	2.59 (1.70)
	IG1	3.43 (1.63)	2.33 (1.68)
	IG2	3.67 (1.51)	2.01 (1.08)
Symptoms of	Anxiety		
	CG	3.73 (1.74)	2.61 (1.69)
	IG1	3.56 (1.63)	2.47 (1.66)
	IG2	3.83 (1.56)	2.24 (1.36)
Perceived Str	ress		
	CG	9.84 (2.83)	7.00 (3.35)
	IG1	9.35 (2.31)	6.78 (3.27)
	IG2	9.68 (2.04)	6.45 (2.96)
Perceived Lo	neliness		
	CG	4.51 (1.74)	4.54 (1.66)
	IG1	4.29 (1.63)	4.17 (1.66)
	IG2	4.56 (2.00)	4.13 (1.64)

Note. CG = control group (n = 55; no digital intervention except regular rehabilitation treatment), IG1=intervention group 1 (n = 570, in addition to regular rehabilitation treatment participation in digital rehabilitation goals), IG2=intervention group 2 (n = 80, in addition to regular rehabilitation treatment participation in digital rehabilitation goals, digital group therapy on depression, and on legal rights for (severely) disabled).

Effect Sizes

Effect sizes were estimated for the outcome domains of symptoms of depression, anxiety, and perceived stress between the measurement time points (pre- and post-rehabilitation) and for group comparison purposes post-rehabilitation. From pre- to post-rehabilitation, Cohen's d values indicated a medium effect for overall symptoms of depression (0.69) and symptoms of anxiety (0.69). From pre- to post-rehabilitation, the effect size of Cohen's d values, considering the intervention and control group, for depression was significantly larger in the IG2 group (1.27) compared to the IG1 group (0.66) and in the control group (0.31). For symptoms of anxiety, Cohen's d values were significantly larger in the IG2 group (1.08) than in the IG1 group (0.66).

Association between reaching Rehabilitation Goals Post-Rehabilitation and Satisfaction with Rehabilitation Post-Rehabilitation

To evaluate the association between reaching rehabilitation goals post-rehabilitation and satisfaction with rehabilitation treatment, a stepwise hierarchical regression analysis was performed controlling for age, gender, and intervention group with rehabilitation goals as predictors. Results underlined that patients who indicated to have achieved the following rehabilitation goals also were more satisfied with the overall rehabilitation treatment process: reduction of psychological symptoms (b = .20, p < .01), improvement of physiological status (b = .14, p < .01), relaxation and resting (b=.14, p < 01), improvement of coping with stress and management of stress (b = .12, p < .05), and improvement of one's own confidence (b = .11, p < .05; see Table 19). However, results showed a non-significant difference between treatment groups associated with the estimation of reaching rehabilitation goals post-rehabilitation, F(16,1314) = 1.524, p = .08, $\eta_p^2 = .02$. In addition, no significant differences regarding

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Table 19. Step-Wise Hierarchical Regression Results: Satisfaction with Rehabilitation Post-Rehabilitation as a Predictor in N = 663 Rehabilitation Patients.

	Model		Model		Model		Model		Model		Model	
	1		2		3		4		5		6	
	ß	p	ß	p	ß	p	ß	p	ß	p	ß	p
Age	.07	.09	.05	.12	.05	.17	.04	.25	.03	.37	.02	.46
Gender	.05	.23	.06	.06	.07	.05	.07	.03	.07	.03	.07	.03
Intervention Group	01	.84	03	.32	02	.55	02	.51	02	.61	03	.45
Reduction of psychological symptoms	-	-	.50	< .01	.38	< .01	.27	< .01	.23	< .01	.20	< .01
Improvement of physiological status	-	-	-	-	.22	< .01	.18	< .01	.15	< .01	.14	< .01
Improvement of coping with stress and management of stress	-	-	-	-	-	-	.19	< .01	.16	< .01	.12	.01
Relaxation and resting	-	-	-	-	-	-	-	-	.15	< .01	.14	< .01
Improvement of one's own confidence	-	-	-	-	-	-	-	-	-	-	.11	.01
R^2		.01		.26		.29		.31		.32		.33

Note. β-values are represented as standardized coefficients. Age was categorized into below 29 years of age, 30-39 years of age, 40-49 years of age,

50-59 years of age, and above 60 years of age. Gender was categorized into male and female.

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Association between Perceived Communication and Satisfaction with Rehabilitation

Post-Rehabilitation

To evaluate the association between perceived effectiveness of communication and satisfaction with rehabilitation treatment post-rehabilitation, a hierarchical stepwise regression was performed controlling for age, gender and the intervention groups. Results showed that rehabilitation patients who indicated higher effectiveness of communication were also more satisfied with their rehabilitation treatment on the following communication dimensions: early enough discussion on treatment steps and plans (b = .22, p < .01), taking worries and fears seriously (b = .25, p < .01), and provision of sufficient information (b = .12, p < .05). The covariates intervention group (b = .01, p = .91), age (b = .01, p = .98), and gender (b = .02, p = .47) were not significantly associated with the relationship between perceived communication and satisfaction with treatment (see Table 20)

Table 20. Step-Wise Hierarchical Regression Results: Satisfaction with Rehabilitation Post-Rehabilitation as a Predictor in N = 641 Rehabilitation Patients.

	Model 1		Model 2		Model 3		Model 4	
	ß	p	ß	p	β	p	ß	p
Age	.05	.24	.02	.50	.01	.78	.01	.98
Gender	.04	.29	.01	.76	.02	.55	.02	.47
Intervention Group	01	.89	.01	.89	.01	.78	.01	.91
Taking worries and fear seriously	-	-	.48	< .01	.29	< .01	.25	< .01
Early enough discussion on treatment steps and plans	-	-	-	-	.28	< .01	.22	< .01
Sufficient provision of information	-	-	-	-	-	-	.12	.03
R^2		.01		.24		.28		.29

Note. β-values are represented as standardized coefficients. Age was categorized into below 29 years of age, 30-39 years of age, 40-49 years of age, 50-59 years of age, and above 60 years of age. Gender was categorized into male and female.

Discussion

The present study assessed the decrease in symptoms of depression, anxiety, perceived stress, and loneliness from pre- to post-rehabilitation by also evaluating the effectiveness of different digital trainings offered to medical, and psychosomatic rehabilitation patients concerning symptom reduction in the aforementioned mental health outcome domains. The digital trainings were implemented for medical, and psychosomatic rehabilitants in preparation for their rehabilitation stay. Thus, they were implemented under the conditions of the German rehabilitation system, which is characterized by interdisciplinary care in sectoral organization, and applications by insured persons (Mittag & Welti, 2017).

Furthermore, this study also assessed the association between perceived effectiveness with communication and satisfaction with the rehabilitation process as well as with having achieved rehabilitation goals. In general, the digital trainings seemed to be a suitable part of the rehabilitation if participants achieved their rehabilitation goals.

Reduction in Mental Health related Symptoms and the Effectiveness of different Digital trainings

Previous research has already indicated that the rehabilitation process can support symptom reduction in patients from a medical, psychosomatic clinic (Keller et al., 2021; Liebherz & Rabung, 2014; Steffanowski et al., 2001). This is in line with our results, highlighting that symptoms of depression, anxiety, stress, and perceived loneliness decreased significantly from pre- to post-rehabilitation, irrespective of the intervention or control group. These findings provide insight that offering psychotherapy in addition to regular interventions, such as occupational therapy, relaxation, and physiotherapy, supports the symptom reduction of not only ICD-10 diagnoses, such as depression and anxiety but also of symptoms associated with ICD-10 diagnoses, such as perceived stress and loneliness. The results were significant irrespective of patients' age or gender.

However, when examining the interaction effect between symptom change over time and the intervention group, significant differences were only found concerning symptoms of depression and anxiety. It may be postulated that reducing symptoms of stress and loneliness is not the central goal of the German medical, psychosomatic rehabilitation system and treatment process, as stress and loneliness are not considered ICD-10 diagnoses. The overall treatment process is formulated based on the theoretical biopsychosocial model of the International Classification of Functioning, Disability, and Health (ICF) and with consideration of the ICD-10 diagnosis. Hence, complaints are, thus, translated by diagnostic tests into diagnoses, which are necessary and a prerequisite for the treatment process (Aboussouan et al., 2020; Stuckl et al., 2002). Consequently, symptoms of stress and loneliness may not be specifically targeted by the different digital interventions offered in addition to the regular treatment process. It may be suggested, that because loneliness and stress are central sustaining factors for depression and anxiety, digital interventions should be adapted to also reduce these symptoms respectively.

Concerning the effectiveness of different digital trainings offered during rehabilitation, results have highlighted that, for patients receiving different combinations of digital trainings (i.e., training on rehabilitation goals and training on legal rights for (severely) disabled), an average symptom reduction was found for depression, anxiety, and perceived stress. We found the same for participants who were part of the control group as well. However, perceived loneliness did not decrease for patients as part of the control group. Hence, the present results would suggest a beneficial effect of the rehabilitation setting, especially concerning depression, anxiety, and perceived stress. These findings are consistent with previous findings (Keller et al., 2021; Liebherz & Rabung, 2014; Steffanowski et al., 2001).

This was especially pronounced when comparing the patients allocated to the control group with patients from intervention group 1 (digital rehabilitation goals) as well as patients from intervention group 1 with participants from intervention group 2 (digital rehabilitation goals, group therapy on depression, and digital training on legal rights for (severely) disabled)

concerning symptom reduction in depression. With regard to symptom reduction in anxiety, this effect was significant when comparing intervention group 1 with intervention group 2. Hence, intervention group 2 was shown to be significantly superior concerning symptom reduction concerning depression and anxiety. Considering symptom reduction of perceived stress and perceived loneliness, intervention group 2 was shown to be on average superior to either intervention group 1 or the control group. These findings indicate that the interdisciplinary and multidisciplinary medical, psychosomatic rehabilitation program as a whole had a positive impact on mental health status, a finding that adds to previous research (Aboussouan et al., 2020; Brakemeier et al., 2015). However, the long-lasting effects of the interdisciplinary rehabilitation program were not analyzed as part of this study and will need to be considered when assessing stabilization of mental health, return to work (RTW), and social participation after rehabilitation. Hence, further research is necessary to evaluate the mentioned research questions and to validate the results of the present study.

Despite the promising results highlighted by the present study, it needs to be stressed that digital trainings as part of the psychosomatic rehabilitation process need to constantly be tailored, evaluated, adapted, and modified to the needs of the patients, to current treatment guidelines, as well as to the newest scientific developments to ensure an effective care and treatment program as well as overall patient safety.

Interpretation of Effect Sizes

So far, effect size benchmarks have only been postulated for regular face-to-face treatment but not for digital trainings as part of a medical, psychosomatic treatment process. Previous literature has defined effect size benchmarks for psychologically-based treatment programs from pre- to post-treatment stay (Fenton & Morley, 2013; Liebherz & Rabung, 2014). As part of the study, the authors suggested average effect sizes across different measurement domains, among others for depression to be at 0.35, which has been recommended to be used for the assessment of treatment programs. In the present study, the pre- to post-treatment effect

sizes (Cohen's *d*) for outcome variables (i.e., symptoms of depression (0.69) and symptoms of anxiety (0.69) were revealed to be of medium effect size. Effect sizes across all symptom outcome domains were largest in the IG2 group, i.e., Cohen's *d* for depression was 1.27 and 1.08 for anxiety. Therefore, our results are in line with the proposed effect size benchmarks by Fenton and Morley (2013) and Liebherz & Rabung (2014). Hence, future research should focus on recommending effect size benchmarks for digital trainings in a medical, psychosomatic rehabilitation setting.

Rehabilitation Goals

Results stressed that patients who perceived greater satisfaction with rehabilitation goals (i.e., reduction of psychological symptoms, improvement of physiological status, relaxation and resting, improved stress coping capabilities, and improvements in own confidence and self-esteem) also displayed greater satisfaction with the overall rehabilitation treatment process. Additionally, patients who were more satisfied with their treatment also perceived greater satisfaction with communication (i.e., early discussions on treatment steps and plans, taking patients' worries and fears seriously, and providing sufficient information). However, no significant difference was found concerning the intervention groups. These results are in line with previous literature on the potential of telemedicine generally and especially in times of crisis like the COVID-19 pandemic (Chevance et al., 2020).

Limitations and Suggestions for Future Research

One of the main limitations of the current study is that we had no indication of the mental health status of psychosomatic rehabilitation patients before the outbreak of the COVID-19 pandemic. Hence, we cannot be certain whether the COVID-19 pandemic was associated with an aggravated symptom increase for symptoms of depression, anxiety, stress, and loneliness, as shown by previous literature (Keller et al., 2021; Nelson et al., 2020). A further limitation that needs to be discussed is that participation in the digital training on rehabilitation goals and legal rights for (severely) disabled was on a voluntary basis. Hence, it may have occurred that patients

who were especially motivated to work on their symptoms and benefited from the treatment procedures offered during the rehabilitation stay, also participated in more digital interventions. Therefore, future studies should also consider motivational factors.

In addition, this study did not consider possible confounding correlations of physiological symptoms (i.e., disabilities, chronic pain, cancer-related illness, or a potential COVID-19 infection) with mental health. Another limitation that needs to be considered is that the digital trainings offered before and during the rehabilitation stay so far have not been validated or standardized, but rather align with the German regulations for rehabilitation treatments and were developed based on experiences by the rehabilitation clinics. Hence, concerning future research, a standardized manual, such as the Curriculum Hannover for aftercare (Kobelt & Grosch, 2005), should be developed to effectively integrate standardized and evaluated digital trainings into the rehabilitation treatment process. In Germany, a cultural particularity of rehabilitation is that rehabilitation is mostly done in in-patient settings and has to be applied for with pension insurance funds by insured persons. The main goal is social and work participation. In other cultural contexts, the digital trainings may not be applicable without adaptation due to the rather unique nature of the German rehabilitation system that aims to bring the UN Disability Rights Convention into practice. Due to the historical development, the rehabilitation system in Germany is a complex system to ensure social security against diseases, unemployment, age, and disability.

In addition, Cronbach's alpha value of rehabilitation goals before the rehabilitation stay is relatively low at .65 (Streiner, 2003) compare to post-rehabilitation (α =.89). It may be postulated that the items presented to the patients may be, on the one hand, heterogeneous in their nature, since individual rehabilitation goals differ; on the other hand, they may not be as relevant to the sample population pre-rehabilitation compared to post-rehabilitation. Patients may have been unsure of what to expect and how to work on their undertaken goals. Hence, this may also be an indicator of the need to provide more effective communication prior to the

rehabilitation stay to patients about expectations and goals as well as how to set and work on rehabilitation goals.

As countries are becoming more culturally diverse, further research should also be considered to replicate and validate the current findings in countries with different rehabilitation systems and with patients from different cultural backgrounds. Concerning the different cultural expression of emotions and acknowledgments of psychological disorders, as well as acceptance of psychotherapy as a form of treatment, the question remains whether different health care systems and psychosomatic rehabilitation treatments (i.e., delivered at a higher proportion in a digital mode or even solely digital) would result in a similar outcome arises.

Conclusions

The findings of this study suggest that medical, psychosomatic rehabilitation is effective in reducing symptoms related to mental health disorders. By providing new technologies, i.e., digital elements as part of the health care services and the treatment process, symptoms of depression, anxiety, perceived stress, and perceived loneliness could be reduced post-rehabilitation. This was especially the case with the multidisciplinary and interdisciplinary rehabilitation treatment program, i.e., a treatment program including digital rehabilitation goals, digital group therapy for depression, and digital training on legal rights for the (severely) disabled. They were shown to be especially effective concerning symptom reduction of depression and anxiety, which are the central goals of the medical, and psychosomatic rehabilitation process. Furthermore, greater satisfaction with the rehabilitation process was associated with the perception of rehabilitation goals as well as with greater satisfaction with communication between patients and health care professionals.

Author Contributions

Conceptualization, A.D., S.L., and F.M.K..; Methodology, F.M.K.; Software, F.M.K, S.L. A.D; Validation, A.D., S.L. and C.D.; Formal Analysis, F.M.K..; Investigation, S.L, A.D., F.M.K.; Resources, A.D. and S.L.; Data Curation, F.M.K.; Writing – Original Draft **283** | P a g e

Chapter 7

Preparation, F.M.K.; Writing – Review & Editing, S.L, A.D., C.D., L.K..; Visualization, F.M.K, S.L.; Supervision, S.L.; Project Administration, A.D.; Funding Acquisition, A.D. All authors have read and agreed to the published version of the manuscript.

Funding

This research was funded by the Innovation Fund of The Federal Joint Committee, grant number 01VSF18023.

Institutional Review Board Statement

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee of Jacobs University Bremen (protocol code 2020_09 and date of approval: 25.06.2020).

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

The data presented in this study are available on request from the corresponding author.

The data are not publicly available due to confidential patient data being used.

Acknowledgments

We would like to thank the Dr. Becker clinics Möhnesee, Norddeich, Juliana, and Burg for their assistance in data collection. Furthermore, we would like to thank Nerma Pasic for proofreading the final version of this manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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Chapter 8: General Discussion

The COVID-19 pandemic as a crisis has brought about many changes and challenges to patient safety, mental health care, and well-being, as well as to daily living. First of all, to ensure safety for patients, regardless of whether they are inpatients or outpatients, hygiene standards had to be raised in primary health care settings. However, mitigation strategies or containment strategies and the associated strain of the COVID-19 pandemic on mental health and well-being have shown to aggravate or worsen symptoms related to anxiety, depression, loneliness, distress, and general stress for both the general population as well as individuals with a pre-existing limited mental health status. As the group of individuals with a pre-existing limited mental health status is at increased risk for a worsening or chronic development of psychological symptoms according to the present research, continuing treatment possibilities buffering the negative effect of the COVID-19 pandemic are necessary. These may be provided in form of digital supplements in addition to the regular face-to-face treatment option, which have shown to be effective in the psychosomatic rehabilitation setting.

The following section of this dissertation serves to provide an overview of the findings of the five papers by synthesizing the results. In an overview, the different methodologies used in the five papers will be summarized. In a second step, this thesis will answer the proposed research gaps by demonstrating the essential results of the presented papers. Results will be discussed within the wider context of present evidence in literature from the following fields of research: health psychology, rehabilitation psychology, and clinical psychology. Further, the limitations and strengths of this PhD thesis will be discussed. Lastly, this thesis will provide an outlook on implications for theory (advancements), and practical implications and will consider possible limitations of the present thesis.

8.1. Summary of the Methodologies Used in the Different Studies

Several different methodological approaches have been used in the presented five studies focusing on psychological aspects relating to coping behavior, emotional distress, worries, and concerns as well as coping responses, loneliness, and ultimately behavior change related to preventative behaviors, mental health, and well-being. Data were either analyzed in a cross-sectional (study 1 and partially studies 2 and 3) or in a longitudinal fashion (partially studies 2 and 3, study 4, study 5). Table 21 provides an overview of all methodological approaches used for the respective studies.

Table 21. Overview of the Study Design and Methodological Approaches of the Studies.

Study	Design of the	e studies	Methodological Approach		
	Cross- Sectional	Longitudinal			
Study 1	Х		 Exploratory factor analysis Item-scale concurrent and divergent validity Reliability analysis 		
Study 2	X	X	 Structural equation modeling Analysis of latent means Binary logistic regression analyses 		
Study 3	X	X	 Propensity score matching Multivariate analysis of covariance Repeated-measures analysis of covariance 		
Study 4		X	 Serial mediation analysis with change scores 		
Study 5		X	 Linear mixed-model repeated measures analysis of covariances Analysis of effectiveness (i.e., partial eta squared values and Cohen's d values) Stepwise hierarchical regression analysis 		

A more thorough overview of the methodological approaches will be outlined in the following. Chapter 3 (study 1) aimed to develop and evaluate the psychometric properties of a questionnaire constructed based on literature. The questionnaire assessed possible triggers of preventable adverse events from the perspective of patients. Data were collected from individuals from the general population between November 2019 and April 2020 who had previously been admitted to a hospital as either an in or outpatient. The data collection was performed via an online survey that lasted on average 10 minutes. N= 210 participants took part in the survey. To perform an exploratory factor analysis, missing data were imputed via the Output Management System (OMS procedure) in SPSS Version 25. It has been acknowledged that summated rating scores for each subscale, defined by the following exploratory factor analysis (EFA), could not be estimated with the same degree of confidence while using missing data. After the EFA, a multi-trait scaling analysis was performed to evaluate the internal consistency and reliability of the proposed scales. A confirmatory factor analysis (CFA) could not be conducted, as no second comparable data set was available to confirm results from the EFA. Item-scale concurrent and item-scale discriminant validity were analyzed. An item-scale analysis to evaluate concurrent and discriminant validity was chosen as no comparable questionnaire could be correlated with the developed questionnaire to examine validity estimates. To examine the robustness of the questionnaire by examining whether patients with and without symptoms of depression and anxiety perceived triggers of preventable adverse events differently, multivariate analyses of covariance were performed. Data were evaluated in a cross-sectional manner.

Chapter 4 (study 2) examined whether hand hygiene behavior as a health behavior can be described based on the HAPA. In addition, study 2 evaluated whether mental health or the social-cognitive variables may be responsible for explaining changes in as well as maintenance of hand hygiene behavior. Furthermore, it was examined whether compliance or non-compliance with hand hygiene behavior and the transition from compliance and non-

compliance was associated with the mental health status of participants. In a two-study design, data were firstly collected from N = 279 participants through an online survey in a crosssectional manner. Data collection occurred between November 2019 and June 2020 in Germany. Data were collected in three waves: n = 97 before the SARS-CoV-2 pandemic, n = 9785 during the first lockdown in Germany, and n = 97 after the lockdown measures were reduced. Bivariate correlations between all HAPA variables were examined. Afterward, a structural equation modeling via AMOS was performed to test whether the data fitted the proposed HAPA model. The advantages of structural equation modeling (SEM) have been emphasized in previous literature as it is a statistical technique that combines factor analysis and multiple regression analysis. Hence, by employing SEM it is possible to examine theoretical complex model structures, modeling effects over time as well as multigroup invariances with several independent variables, mediator variables as well as dependent variables (Burkholder & Harlow, 2003; Byrne, 2004). The model indices were evaluated based on recommendations by Hu & Bentler (1999). To examine potential differences in the social-cognitive variables of the HAPA and hand hygiene behavior concerning the mental health status, latent means were analyzed for individuals below and above the symptom threshold for depression and anxiety. Missing data were imputed via the Full Information Maximum Likelihood method (FIML) in AMOS. In the second study of paper 2, N = 1073 psychosomatic rehabilitation patients were examined. Data were collected in a longitudinal fashion (pre- and post-rehabilitation) from four psychosomatic rehabilitation clinics between July 2020 and June 2021. Progression or regression from compliance to non-compliance and vice versa were evaluated through binary logistic regression analyses. Wald statistic was used to provide an indication of the significance of the regression coefficients. Data were either analyzed with SPSS Version 26 or AMOS Version 26.

Chapter 5 (Study 3) aimed to examine the psychological burden of the COVID-19 pandemic on the general population and psychosomatic rehabilitation patients (i.e., individuals

with a pre-diagnosed mental health condition). Levels of reported symptoms of depression, anxiety, stress, and loneliness were evaluated. In addition, COVID-19-related worries and concerns were assessed by examining whether individuals from the general population compared to psychosomatic rehabilitation patients perceived different themes of worries and different intensities in the reported worries. Further, the intention to use digital apps as well as their usefulness to prevent a deterioration of the mental health status or worsening of already existing symptoms was examined between the general population and psychosomatic rehabilitation patients. Lastly, it was examined whether participating in digital interventions before the rehabilitation stay and perceiving digital interventions as useful, would result in a decrease in pre-to-post rehabilitation symptom expression.

N = 1812 participants from the general population took part in an online survey between May 2020 and April 2021. With regard to the psychosomatic patient sample, data were collected at two timepoints -N = 1719 before the rehabilitation stay and N = 738 after the rehabilitation stay. Data collection took place between July 2020 and April 2021. Missing data were not imputed for both samples, as the average amount of missing data was 1.3%. To effectively compare individuals from the general population and psychosomatic rehabilitation patients, propensity score matching was applied to reduce the bias of treatment selection in nonrandomized studies. Propensity score matching (PSM) analysis has been termed to have several advantages over traditional regression analysis. Firstly, PSM uses data to create groups for treated and non-treated or control individuals with similar covariate values so that comparisons between the two matched groups are not confounded by differences in the distributions of covariates (Austin et al., 2018). Despite the limitations in experimental design in (mental) health care research, PSM offers the possibility to conduct quasi-experimental designs as with the current study. Following PSM, n = 2054 participants from both groups of individuals were included for further analyses. A multivariate analysis of covariance was performed to evaluate differences in reported psychological symptoms. To define potential worries associated with the COVID-19 pandemic, an exploratory factor analysis was carried out. Significant differences in the proposed factors between the general population and the psychosomatic rehabilitation sample were examined by a multivariate analysis of covariance. To examine whether psychosomatic rehabilitation patients displayed a change in symptom intensity from pre- to post-rehabilitation, a repeated-measures analysis of covariance was performed. In addition, to evaluate whether participation in digital training was associated with a significant change in perceived symptom intensity, a further repeated-measures analysis of covariance was performed. The intention to use common digital interventions and trainings for the general population and psychosomatic rehabilitation patients was examined through an analysis of covariance. As the last point, to evaluate the perceived usefulness of internet-delivered trainings during the rehabilitation stay and the association with mental health status after their rehabilitation, a hierarchical regression analysis was conducted. For all analyses, SPSS Version 27 was used.

Chapter 6 (study four) examined the relationship between the following psychological variables: distress, anxiety, loneliness, and depression. It was assumed that anxiety and loneliness were serial mediators of the relationship between distress and depression. Data were collected from N = 676 psychosomatic rehabilitation patients before the rehabilitation stay. N = 403 participants participated in the follow-up survey post-rehabilitation which was conducted online. The timeframe during which data were collected extended from April 2021 to September 2021. An attrition analysis was performed to determine possible variables associated with drop-out. To evaluate the association between all variables longitudinally, a serial mediation model, informed by literature, with change scores (two measurement timepoints; preto post-rehabilitation) was performed. Therefore, the PROCESS macro Model 6 for SPSS Version 28 was used with a bias correction of a 95% confidence interval with 5000 bootstrap re-samples. As the study was faced with a rather high drop-out between pre- to post-

rehabilitation, a validation study was conducted in line with the same methodology by imputing missing data via the expectation-maximization algorithm (EM imputation).

Chapter 7 (study five) aimed to evaluate the effectiveness of digital intervention programs or trainings in addition to the regular face-to-face rehabilitation treatment program in five rehabilitation clinics. In addition, the interrelation between communication and rehabilitation satisfaction as well as rehabilitation success was evaluated. Therefore, data from N = 724 psychosomatic rehabilitation patients, who answered an online survey at two timepoints (pre- and post-rehabilitation) were analyzed. Data were collected between July 2020 and June 2021. Of those 724 patients, who participated in the study, n = 55 were allocated to the control group (i.e., not participating in additional digital trainings), n = 570 patients were allocated to the intervention group one (i.e., patients who participated in the digital intervention before the rehabilitation stay), and n = 80 participants were allocated to intervention group two (i.e., patients who participated in all digital trainings either before or during the rehabilitation stay). Randomization checks concerning the socio-demographic variables as well as baseline mental health symptoms were performed through a one-way analysis of variance for continuous variables and a chi-squared test for nominal variables. Missing data were not imputed due to the average low percentage of missings. To evaluate symptom changes (i.e., depression, anxiety, stress, and loneliness) from pre- to post-rehabilitation, a 2 x 3 linear mixed-model repeated measures analysis of covariances was conducted. The effectiveness of the treatments was evaluated by means of partial eta squared values and Cohen's d values. Finally, multivariate analyses of covariances were performed to evaluate which treatment group (control group, intervention group one, intervention group two) was more likely to reach envisioned rehabilitation goals. The association between the perception of achieving rehabilitation goals and overall satisfaction with the rehabilitation stay was evaluated by a stepwise hierarchical linear regression analysis. SPSS Version 27 was used for all analyses.

8.2. Summary of the Main Findings

Table 22 provides an overview of the proposed research questions, hypotheses, results, and conclusions for each study.

 Table 22. Overview of the Proposed Research Questions, Hypotheses, Results, and Conclusions for each Evaluated and Discussed Study.

Chapter	Aims and hypotheses	Findings	Conclusions
3	 What are potential triggers that may lead to preventable adverse events posing a danger to patient safety? Is mental health associated with different perceptions of preventable adverse events? 	 Five factors associated with patient safety: (1) Information and communication with patients, (2) time constraints, (3) diagnosis and treatment, (4) hygiene and communication among health care professionals, and (5) knowledge and operational procedures. Good psychometric properties and robustness against changes in mental health, hence, confirming the proposed hypotheses. 	 Valuable questionnaire to measure preventable adverse events from the perspective of patients. Further research: Evaluation of the applicability in different health care settings and with larger sample sizes.
4	 Can hand hygiene as a health behavior be explained by health behavior change models such as the HAPA model? Is mental health predictive of changes in hand hygiene behavior and hand hygiene compliance? 	 able to explain hand hygiene behavior. Planning bridged the intention-behavior gap. Invariances concerning the social-cognitive variables irrespective of mental health. 	 for the development and implementation of interventions in primary health care settings. Social-cognitive variables instead of the mental health status may be able to
5	 How do the two groups compare concerning: (a) psychological symptoms, (b) experienced worries and concerns (c) and the intention to use digital supplements to prevent a deterioration of the mental health status? The symptom changes of psychosomatic rehabilitation patients from pre- to post-rehabilitation. 	 of concern. Patients: reported household-related worries, lower concerns with finances, and higher satisfaction with communication. 	 being for both samples; more pronounced for patients. Offering low-threshold intervention to prevent the decline of chronic development of symptoms.

Chapter	Aims and hypotheses	Findings	Conclusions
6	How do frequently experienced symptoms during the COVID-19 pandemic, such as perceived distress, anxiety, loneliness and depression interrelate?	perceived loneliness served as serial mediators in	 Distress as well as symptoms of anxiety and perceived loneliness were associated with increased depression. Mediators may be termed as sustaining and maintaining factors of depression (i.e., in form of a vicious and self-sustaining circle).
7	Does taking part in digital interventions lead to a reduction in psychological symptoms? Differences in effectiveness of partaking in none, some, and all digital interventions concerning symptom reduction.	 stress was reported in all three examined groups. Partaking in all digital offers revealed the highest symptom change from pre- to post-rehabilitation. 	 Providing patients the opportunity to enrich their rehabilitation process (before and during) with online interventions has shown to be effective in symptom reduction. Digital interventions allow to follow containment strategies, and compensate for a possible shortage of personnel while also allowing patients to practice transfer from face-to-face therapies to independent participation in digital interventions.

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8.2.1. Common and Distinct Findings

Findings from all studies contribute to an understanding of the reactions and consequences of a crisis, in this case, the COVID-19 pandemic, on an individual as well as on a symptom level. On the one hand, on the individual level, study 3 was able to show cognitive reactions (i.e., worries and fears) associated with the crisis (COVID-19 pandemic). Further, study 4 was able to show an increase in perceived distress as a form of an emotional reaction on the individual level. Studies 2 and 5 highlighted the behavioral reaction (i.e., hand hygiene behavior and distancing) due to the corona virus pandemic on the individual level. Concerning the consequences on an individual level resulting from the reactions, studies 3, 4, and 5 have shown a reported increase in depression, anxiety, and loneliness, which have been assumed to develop based on the described reactional level.

Concerning the system level, reactions due to the crisis (COVID-19 pandemic) have been associated with changes to the health care system, such as changes in therapy settings or discontinuation of therapies, changes in health care provision such as rescheduling or canceling preventative appointments, or the prioritization of high-risk individuals or a different understanding of constitutes of patient safety. All these reactions had the consequence that more digital interventions were introduced to compensate for closures and discontinuations. In addition, changes in patient care towards the maxim "Stop the Spread" (Desai & Patel, 2020) were introduced that, however, on the downside, posed a general threat to patient safety as introduced in Chapter 1.

To conclude, these findings all contribute to an understanding of the reactions and consequences of the corona virus pandemic according to the adapted version of the SORKC model. However, the findings differentiate to that effect as they are all focused on either the reactions or consequences while focusing on the individual or the system level. However, what needs to be stressed is the inter-connectedness between the reactions and consequences as well

as between the individual and the system level. Results from the above-described studies will first be discussed within the wider context of pre-existing literature and will, secondly, be aggregated and interpreted within the context of the adapted SORKC model in the following.

8.3. General Discussion

8.3.1. Conceptualization of Patient Safety and Potential Triggers

Over the last decade research in health care has experienced a shift from evaluating patient safety from the perspective of health care professionals towards an integrated understanding of involving the patient as an active agent in care processes, thereby focusing on patient-centered care. However, focusing on patients as the central factor in patient safety has been relatively understudied. Vincent and Coulter have argued that "Patients who know what to expect in relation to quality standards can check on appropriate performances of clinical tasks" (Vincent & Coulter, 2002; p. 77), thereby underlining the importance of patient involvement. Therefore, patient-centered care may be divided into two areas: First, informing patients about safety and risk factors, and second, involving the patients as active agents in their care processes (Jorm et al., 2009). Factors identified by Chapter 3 (i.e., information and communication with patients, time constraints, diagnosis and treatment, hygiene and communication among health care professionals, and knowledge and operational processes) have been considered of importance in previous reviews and qualitative analyses (Elder & Dovey, 2002; Makeham et al., 2008). It has been known that patients can reflect on care processes, identify, and report experiences of errors (Gallagher & Mazor, 2015; Gurley et al., 2016). Despite patients not being able to judge the accuracy of diagnosis and treatment, they can identify communication issues (i.e., such as the negative attitude of health care professionals) as well as inconsistencies in medication that could potentially lead to (preventable) adverse care processes (Riskin et al., 2015). Further, experiences of patients with diagnostic procedures and treatment procedures have shown to lead to a comprehensive understanding of why potential errors in care processes have occurred. In addition, patient reports may help to develop strategies for mitigation (Giardina et al., 2018). Therefore, the questionnaire designed to assess triggers of potential threats to patient safety in Chapter 3, provides a generic, timely, and necessary evaluation tool that can be implemented within the primary health care context.

All these proposed areas defined by the questionnaire ground in patient-centered care, patient involvement, and patient empowerment. To support patients in raising concerns concerning own patient care, patients need to be empowered to voice their own opinion. Patient empowerment has been predominantly associated with developing own skills and capacities of patients to perform informed decisions (McAllister et al., 2012). This form of empowerment in providing control has been shown to follow along three stages: (1) Motivation: patients need to possess motivation and self-efficacy beliefs to be active agents in their treatment processes as well as being motivated concerning seeking meaning in life in form of positive outcome expectancies and a reduced loss of hope; (2) Mastery over the illness: patients need to be encouraged to develop an own understanding about their illness or treatment processes to deal with those factors individually as well as together with family members and health care professionals; (3) Transformational thoughts: patients need to be encouraged to change the way they think about their illness, the treatment, and their life in general, away from stances towards a form of acceptance and integration (Mok, 2001). Accordingly, lack of options being provided by a health care professional or not being consulted and involved during the planning of own treatments, specifically on a superficial level, were typically regarded as disempowering. Patient engagement and patient control according to Mok do not depend too much on decisional control but rather on enabling the patient to decide their degree of willingness to participate in decision-making, thereby, handing over the control to the patient. However, this ability and willingness are often dependent on how the patient perceived the time and effort as well as the information obtained by the health care professional, underlying the necessity for sufficient, accurate, contextualized, concise, and interpersonal communication (Agner & Braun, 2018; Mok, 2001). Despite this approach being helpful in supporting the patient in becoming an active agent in their own treatment processes, critical voices have been raised concerning the following two assumptions: On the one hand, health care professionals have raised concerns about whether patients have the ability to engage in an appropriate and informed health behavior process and be internally rather than externally motivated. On the other hand, the assumption of patient empowerment tends to overlook the psychological connection between patients and their care programs (i.e., integrating the treatment into their own daily life and perceiving that it belongs to them). Therefore, psychological ownership needs to be considered in the context of patient safety as individuals raise their voices, adhere to behaviors, and maintain behaviors more if they experience that the treatment process is tailored towards their own needs (Karnilowicz, 2011; Mifsud et al., 2019).

To sum up, providing the patient a sense of control by actively involving the patient in care processes through effective communication, provides the patient a sense of control. As a consequence, psychological ownership may be increased to effectively follow through with the treatment process but also raise concerns when threats to individual treatment and well-being become apparent.

8.3.2. To what Extent can Hand Hygiene be Explained by a Model Invariant to the Mental Health Status?

Hand hygiene has been an important determinant in reducing health care-associated infection in primary health care settings. Results by Rabie and Curtis (2006) suggested that hand washing reduces respiratory infections by about 16%. However, global hand hygiene is poorly practiced, as only 31% of men and 65% of women on average wash their hands after visiting public restrooms (Lhakhang et al., 2015; Reyes Fernández et al., 2016). The most comprehensive initiative to promote hand hygiene is the World Health Organization's (WHO)

"SAVE LIVES: Clean Your Hands" campaign which aims to prevent up to 150.000 infections per year (Reichardt et al., 2009; World Health Organization, 2009). The multimodal approach includes the provision of alcohol-based hand rubs and education of health care professionals and patients in form of reminders or trainings to practice effective hand hygiene in primary health care settings. However, previous studies were mainly concerned with hand hygiene among health care workers with only a few considering the population of patients (Sands & Aunger, 2020). Only some studies have examined the role of patient involvement in hand hygiene by using posters, patient videos, or brochures to foster patient empowerment (Sande-Meijide et al., 2019). The "Commission for Hospital Hygiene and Infection Prevention" suggests the following indications for hand disinfection of patients and visitors: (1) when entering the patient's room, (2) when leaving the patient's room, (3) before eating, (4) after using the bathroom, (5) before and after contacts with wounds, mucous membranes, and (6) before entering risk areas (Niknam, 2017). Many individuals are, however, not yet sufficiently aware that they, in the role of a patient, can also actively participate in hand hygiene and, thus, protect themselves and others from infections. This has also been confirmed by the following results (Barker et al., 2014). In order to perform effective hand hygiene behavior, certain socialcognitive strategies are necessary, such as those of the HAPA model. However, previous studies have limited their evaluation of hand hygiene behavior only to some aspects of the HAPA model and have refrained from examining the entire structural framework (Lhakhang et al., 2015). As symptoms of depression and anxiety are associated with a decrease in motivation as well as a decrease in hygiene behavior, results of the present study have also examined the role of mental health in relation to changes in hand hygiene behavior along the lines of the HAPA model as well as to evaluate changes in compliance. The results of study 2 (Chapter 4) have shown that data on hand hygiene behavior fitted well to a trimmed structure of the HAPA model. However, mental health does not seem to play a relevant role with regard to changes or compliance rates in hand hygiene behavior. The results are in line with previous studies stating that hand hygiene may be explained by the HAPA framework in health care settings, both for health care professionals and for patients as well as visitors (Gaube et al., 2021; von Lengerke et al., 2019). As shown in other fields, planning was able to close the intention-behavior gap leading to improved maintenance (Rhodes et al., 2022). Research concerning the health care context has shown that even though health care workers often have positive intentions to follow and comply with hand hygiene guidelines on wards, this may not necessarily translate into an intention. The same may hold true for patients and visitors. Therefore, it has been suggested that planning may need to be trained to lead to greater hand hygiene compliance rates (Gaube et al., 2021; Gollwitzer & Sheeran, 2006). This assumption has been stressed by results concerning study 2. These findings were the first to show that planning was able to bridge the intention-behavior gap concerning the hand hygiene behavior of patients. Further, the results of study 2 have underlined that mental health does not seem to play a predictive role in either explaining potential changes in hand hygiene behavior, social-cognitive variables, or compliance rates. These results can be explained in line with findings suggesting no differences in motivational mechanisms between individuals with and without a pre-existing limited mental health status (Farholm & Sørensen, 2016). In addition, results from literature examining the association between fear, hand hygiene, and mental health have shown that irrespective of the mental health status when individuals perceive greater fear of infection or greater anxiety, they tend to engage in good and effective hand hygiene behavior (Lippke et al., 2022). Therefore, it may be concluded, that hand hygiene behavior itself can be well explained by the socialcognitive mechanism of the dual-phase HAPA model, irrespective of the mental health status of individuals.

Chapter 4 has confirmed the predictive validity of the HAPA model with regard to hand hygiene behavior. A meta-analysis by Zhang and colleagues has recently confirmed the important role of self-efficacy, outcome expectancies, intention, and planning in predicting

health behaviors (Zhang et al., 2019). However, what needs to be discussed further, is the interplay between mitigation, self-regulation abilities, and protective action adherence to health behaviors. The social ecological model provides an explanation of the role of societal-level determinants of individual actions such as health policies promoting, fostering or hindering health behaviors such as hand hygiene behavior, and physical and social distancing (Kaushal et al., 2020). Based on previous evidence it is assumed that policies shape individual actions directly through changing individual perceptions and beliefs. Therefore, several ways concerning the containment and mitigation measures and proposed health policies may interrelate with individual actions. On the first note, the proposed governmental policies disrupted and changed everyday routines and consequently rendered the focal actions such as hand hygiene behavior or physical and social distancing more salient. As a consequence, it may be assumed that adherence to the proposed measures may be strengthened. Secondly, literature has reported that strict policies, however, not adapted to the needs of individuals may be regarded as infringements of own liberty rights. When individuals perceive an infringement of their own liberty rights, they may be more likely to generate opposition and thus report a lower motivation to follow guidelines and policies. However, imposing less strict policies concerning containment measures increases the probability of infection. Therefore, individuals needed to engage in more self-regulatory strategies and efforts to reduce the likelihood of an infection. Nevertheless, on a positive note, less strict policies have been shown to promote and foster individual-level responsibility, increase motivation to protect oneself and others, and have provided individuals with more control concerning their own well-being and health (Laurin et al., 2013; Luszczynska et al., 2021; Turoldo, 2009).

However, not only do social-cognitive variables need to be considered when examining the motivation and volition to perform hand hygiene behavior, but also further factors of the individual- as well as the environmental or system level. According to the *social cognitive*

theory by Bandura (1986) and the theory of planned behavior by Ajzen (1988), it has been assumed that to enhance knowledge of hand hygiene behavior and to develop skills necessary for performing effective hand hygiene behavior, behavioral capacities, perceived susceptibility, perceived risk and seriousness of the threat, attitude, and subjective norms need to be activated. It has been shown that social support through normative beliefs, subjective norms, and attitudes will be strengthened. On an environmental or system level, providing options to practice hand hygiene or hand washing (i.e., through washing stations) has shown to foster, together with the individual level factors, the intention to adopt and maintain a safe hand hygiene practice which is assumed to translate into actual hand hygiene behavior (Ajzen, 1988; Appiah-Brempong et al., 2018; Bandura, 1986). However, even though social-cognitive variables have been shown to foster hand hygiene behavior, the predictors of those variables have been rather neglected in existing models such as the HAPA, the theory of planned behavior, or the social cognitive theory. Therefore, it remains to be examined what predicts self-efficacy, outcome expectancies, and risk perceptions and how these factors or variables can be strengthened with regard to hand hygiene behavior. Hence, further studies are needed to develop a more coherent picture of initial predictors of self-efficacy, outcome expectancies, and perceptions of risks.

8.3.3. Reactions and Consequences of the Pandemic: A Group Comparison

Results of study 3 (*Chapter 5*) underline the assumption that the COVID-19 pandemic has increased the mental and psychological burden on individuals with and without a prediagnosed mental health condition. These results are in line with previous research indicating a decrease in mental health and well-being for both groups. On the one hand, concerning the general population, susceptibility characteristics have been defined such as being female, being of younger age, and having negative self-perceptions (Losada-Baltar et al., 2021). Another study has shown that negative emotions during the COVID-19 pandemic for example anxiety,

depression, and indignation have increased whereas positive emotions and life satisfaction decreased at the beginning of the COVID-19 pandemic (Li et al., 2020).

For individuals, however, with a limited pre-existing mental health status, such as psychosomatic rehabilitation patients, results have shown on average higher symptoms with regard to depression, anxiety, stress, and loneliness, which is consistent with previous studies (Asmundson et al., 2020; Hao et al., 2020). It has been assumed that individuals with a pre-existing psychological disorder may experience more distress due to a possible higher vulnerability to worrying and experiencing concerns to the news. In addition, whereas individuals without a pre-existing limited mental health status tend to engage in problem-focused coping, individuals with a pre-existing limited mental health status rather engage in emotion-focused coping and generally tend to engage with less effective coping strategies (Cheng et al., 2021).

The results have shown different areas of worrying and concern for individuals with and without a pre-existing limited mental health status. On the one hand, psychosomatic rehabilitation patients perceived greater satisfaction in communication and reported higher household-related worries. On the other hand, individuals from the general population reported higher financial worries. Results concerning the findings for psychosomatic rehabilitation patients may be explained concerning greater perceived communication, as patients were involved in communications processes with the clinic and during the data collection phase. Hence, it may be postulated that increased satisfaction in communication with health care professionals may be associated with the perception of emerging support and hope for improvement. According to a study, communicating effectively with patients may in turn empower patients in their treatment process (Tsamakis et al., 2020). Furthermore, it has been shown that relying on effective communication strategies will help in coping with mental health issues during stressful times such as during the COVID-19 pandemic (Roy et al., 2021). Results with regard to financial worries are in line with research by van Rheenen et al. (2020). It may

be suggested that due to the financial circumstances and the work ability of the psychosomatic rehabilitation patient (i.e., either being unemployed or on sick leave), changes in work circumstances (i.e., loss of a job or the introduction of short-term work) due to the COVID-19 pandemic may have been perceived as less threatening. Besides, in Germany, being on sick leave for a long time, being unemployed, or even receiving an early disability pension, are in parts subsidized by the German social system (Lippke et al., 2020; Zielke, 2014). To sum up, those individuals may be less concerned with their financial status, as it was known to those individuals that regardless of the COVID-19 pandemic their financial status would not be impacted.

Findings, that individuals with a pre-existing mental health diagnosis are more likely to report increased worries associated with household conflicts are in line with present research. It has been suggested that individuals with a pre-existing mental health condition experienced increased conflict and abuse within their own family environment (i.e., including domestic violence; Sheridan Rains et al., 2021). Hence, support systems should be made available throughout the COVID-19 pandemic to alleviate stressors and worries associated with the individual household.

Psychosomatic rehabilitation patients reported a greater intention to use digital apps and digital trainings focusing on health. These findings may be explained by two assumptions: As within the psychotherapeutic context, if clinical distress is perceived as significant and challenging, individuals with a pre-existing mental health status may be more prone to look for changes and support, hence, turning to digital intervention in the lack of availability of therapy placement options. However, according to evidence in the literature, higher distress has been associated with an increased difficulty to decide on whether therapy may be helpful (Elliott et al., 2015). Hence, digital interventions and trainings may provide a low-threshold intervention to aid individuals in the uptake of taking advantage of therapy services. The other assumption may concern excessive reassurance-seeking of individuals with a pre-existing mental health

condition. Through the use of digital trainings or e-Mental health options, patients may be able to fulfill their desire for safety-related behaviors (Joiner et al., 2009; Parrish & Radomsky, 2010).

In addition, the rehabilitation stay (i.e., inclusive of all offered treatment programs) has shown to be successful in reducing symptoms related to anxiety, depression, loneliness, and perceived stress, which aligns with previous evidence examining the effectiveness of German psychosomatic rehabilitation treatment programs (Baron & Linden, 2009). Results could have shown that those who evaluated initial digital treatments as useful, displayed lower symptoms related to the examined mental health variables post-rehabilitation. As the initial digital training focused on goal setting before the therapy sessions, it may be postulated that individuals taking part in this training, may perceive certain usefulness and relevance to their rehabilitation stay. Moreover, it may be assumed that while training to formulate effective goals and plans, individuals may be more focused on fulfilling those goals, which in consequence may lead to more effective therapy. Therefore, these results underline the importance of sharpening goals before the rehabilitation stay for an effective treatment process and outcome to occur.

Psychological understanding and according to theories propose several explanations for the presented findings such as the following: The phenomenological variant of the *ecological systems theory* by Spencer, assumes that the risk characterized by net vulnerability and net stress engagement interacts with coping strategies, such as reactive coping processes, emergent identities, and stable coping responses, to inform possible outcomes and consequences for mental health and well-being (Spencer, 2006). Specifically, the net stress engagement concerning a crisis (i.e., the current COVID-19 pandemic) refers to the acute perceived and experienced risk that requires a response in form of a reactive coping process to engage in problem-solving strategies to reduce the negative impact of risks of outcomes. Two proposed net stress factors part of a crisis, such as the COVID-19 pandemic, that may potentially inform mental health outcomes are disruptions in daily life and a protective as well as a reactive coping

response. Disruptions to daily life have been characterized by job loss, unstable housing options, multimodal insecurities, reductions in social connectedness, and changes in the health care profession. All these factors have commonly been associated with a reduced mental health status among adults (Grasso et al., 2021). Nevertheless, reactive coping processes may help to reduce the impact of a crisis and include the provision of ongoing treatment, engaging in a healthy lifestyle (i.e., healthy eating and physical exercise), and turning to social support (Spencer, 2006). Therefore, individuals, specifically those, with a pre-existing limited mental health condition, need to be supported in reactive coping processes to counteract or prevent deteriorations in mental health and well-being according to the phenomenological variant of the *ecological systems theory*.

Several pieces of evidence have highlighted different social and psychological risk factors for a poor mental health status that might exacerbate during the coronavirus pandemic. These risk factors range from genetic and biomedical to psychological and sociocultural risk factors. Social support and social isolation or physical isolation have been shown to be interrelated concepts of loneliness. The number, function of social relations, and type have been deemed important predictors of mental health and well-being (Leigh-Hunt et al., 2017). Another psychological risk factor for a poorer mental health status during a crisis such as the COVID-19 pandemic is perceived threat. The *protection motivation theory* may be able to explain the aforementioned relationship. Hence, how individuals perceive a threat appraisal, depends on how strongly they perceive the threat and how vulnerable they perceive themselves to be concerning the threatful situation. Accordingly, individuals with a pre-existing limited health status have shown to be more susceptible to perceiving a threat as dangerous and have perceived themselves as more vulnerable to uncontrollable changes (Hubbard et al., 2021; Milne et al., 2000). Based on the evidence, it has been suggested that threat, experienced with regard to the severity and vulnerability, may be directly associated with anxiety and depression. Hence,

threat appraisal may increase anxiety. In turn, however, a pre-disposed anxiety may also amplify perceptions of threats, thus, leading to a vicious circle (Hubbard et al., 2021).

8.3.4. Interrelation Between Perceived Distress, Anxiety, Loneliness, and Depression

Results of study 4 (Chapter 6) examined the relationship between distress, anxiety, loneliness, and depression via a serial mediation model along the lines of the Evolutionary Theory of Loneliness (ETL; Cacioppo & Cacioppo, 2018). Findings highlighted that, in addition to the overall mediation effect, anxiety and loneliness both served as separate mediators in the positive association between distress and depression. The results confirm previous assumptions about individual relationships between the variables (Ebesutani et al., 2015; Gallagher et al., 2021; Liu et al., 2020; McPherson et al., 2021; Megalakaki et al., 2021). However, study four was the first to examine the relationship between the variables along with the ETL as well as to provide an extension of the theory. According to the ETL, individuals who perceive greater loneliness may tend to engage more frequently in self-defeating and pessimistic thinking, which in turn may pose as a relevant factor for an increase in depressive symptoms (Cacioppo & Cacioppo, 2018; Cacioppo & Hawkley, 2009). As this study provides an extension to the ETL, the results underline the assumption that increased distress experienced during worrisome, stressful, or even traumatic situations, or crisis as the COVID-19 pandemic, may increase perceptions of anxiety, thus, leading to a withdrawal from daily life to protect oneself as well as others from an emerging threat. The increased withdrawal, if maintained over a longer period of time, may subsequently produce increased feelings of loneliness, which in turn may elicit feelings of depression. Hence, the results of study 4 underline the necessity to consider anxiety and loneliness as sustaining factors of depression. Consequently, results call for validation of the present results and a possible adaption of treatment protocols for depression.

Several theoretical accounts have been able to explain the relationship between perceived distress, anxiety, loneliness, and depression besides the ETL. The *vulnerability stress*

model for example suggests that extrinsic psychosocial stressors such as the COVID-19 pandemic and the associated mitigation strategies and posed changes and challenges are associated with psychological distress. According to evidence, it has been shown that mental illnesses manifest themselves when the stress threshold of an individual is exceeded and additional stress can no longer be tolerated. Hence, it may be proposed that based on the *vulnerability stress model*, intensified containment measures and mitigation strategies could lead to a reported increase in feelings of anxiety, sadness, or depression (Esterwood & Saeed, 2020; Goh & Agius, 2010).

According to previous evidence, it has been shown that in the context of crises such as the COVID-19 pandemic, concerns, worries, and feelings of distress are associated with increased perception of anxiety and distress (Barzilay et al., 2020). The *stress-buffering hypothesis* assumes that human contact is needed to compensate for feelings of distress, feelings of anxiety, loneliness, and consequently depression. Based on previous findings, however, it has been shown that specifically distress and worries have been known to increase anxiety whereas loneliness also increases feelings of depression and potentially suicide. Hence, the *stress-buffering hypothesis* suggests concerning crises, that social support plays a protective role against negative effects of worries and perceptions of distress that could consequently increase anxiety, further withdrawal (i.e., loneliness), and depression (Baumeister, 2012; Cassel, 1976). Therefore, support measures should be implemented for individuals to counteract the detrimental effects on mental health and well-being due to disruptions in daily life, mitigation, and containment strategies.

8.3.5. Added Value of Digital Interventions in the Rehabilitation Process

The overarching goal of study 5 (*Chapter 7*) focused on the evaluation of the effectiveness of digital trainings in addition to the regular face-to-face interventions offered during a psychosomatic rehabilitation stay measured by a symptom change in depression,

anxiety, loneliness, and stress from before to after the rehabilitation stay. Results from the study confirm results from study 3 (Chapter 5), in that symptoms concerning depression, anxiety, stress, and loneliness significantly decreased for all individuals, hence, underlining the importance of rehabilitation clinics (Liebherz & Rabung, 2014). Extending on those findings, it was evaluated whether making use of digital intervention in addition to the face-to-face therapy treatment options would result in a symptom change in the aforementioned symptoms. Results indicated significant changes with regard to depression, anxiety, and perceived stress. These results are consistent with previous research (Liebherz & Rabung, 2014). However, the exact mechanisms on why loneliness did not reduce in the face of adding digital elements to treatment processes, remain to be evaluated in future studies. It may be postulated, however, that digital offers do not increase feelings of belonging, as patients were not instructed to engage in bi-directional contact with another person or an avatar (i.e., such as with chatbots) during the use of the provided digital interventions (Rojas et al., 2019). However, as literature is relatively scarce concerning the theoretical and practical examination of the sense of belonging in e-Mental health settings, more research is necessary to provide optimal care processes and interventions. Nevertheless, patients taking advantage of all three digital interventions offered during the rehabilitation stay revealed a significantly higher symptom reduction postrehabilitation compared to the other intervention and control group. The findings underline the valuable multidisciplinary and interdisciplinary approach part of blended rehabilitation interventions and add to previous literature (Aboussouan et al., 2021; Brakemeier et al., 2015).

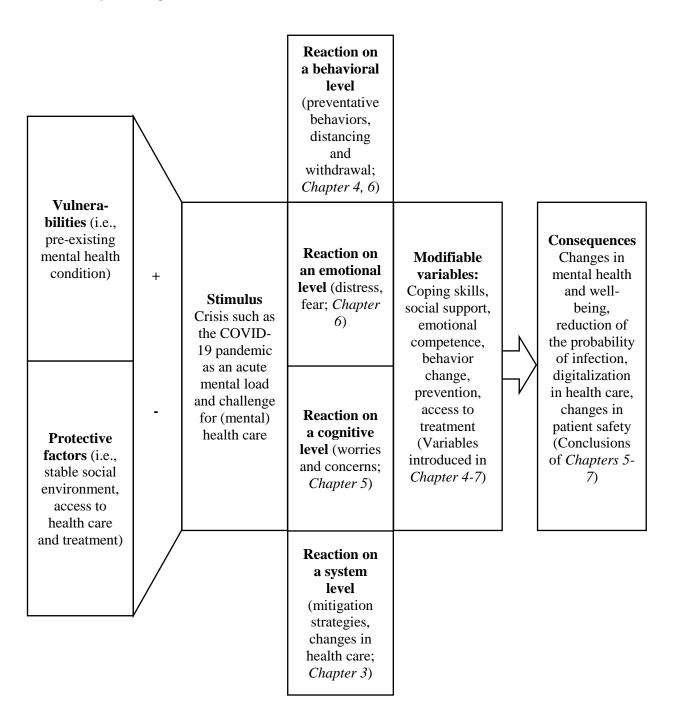
Despite the positive findings of *Chapter 7*, the pre-requisites for a successful implementation of digital interventions into therapeutical processes need to be further explored. The *self-determination theory*, therefore, provides a solid psychological perspective on how motivation needs to be developed to effectively partake in digital interventions and to obtain the proposed benefits of those interventions. The theory assumes autonomy, competence, and

relatedness as three inherent psychological needs of individuals. Accordingly, satisfaction with the fulfillment of the psychological needs has been associated with an increased likelihood of engaging in the desired behavior, increased maintenance or persistence, and increased overall well-being. On the contrary, lack of satisfaction or a non-fulfillment of psychological needs may result in a reduced motivation to engage and consequently a reduced psychological well-being. Therefore, the *self-determination theory* provides an opportunity to consider barriers and benefits of the uptake of the implementation and integration of digital interventions into pre-existing face-to-face therapeutical structures (Deci & Ryan, 2000; Keenan et al., 2021).

8.4. Aggregation of Results within the Context of (Mental) Health Care

Based on the different psychological theories being able to explain the reactions and consequences on an individual level as well as on a system level, it may be concluded that there is so far not one framework or theory that can explain the change in mental health or mental health care. Nevertheless, based on the proposed adaption of the SORKC model (see Chapter 1) on an aggregational level and considering the results obtained from all five discussed studies, an integrative cross-level, multifactorial-probabilistic, and bio-psycho-social vulnerability stress model can be drawn up to summarize and explain the findings from Chapters 3 to 7. This proposed model assumes an extension of the adapted SORKC model introduced in Chapter 1 of this dissertation. The model integrates the individual and system level and adds the role of vulnerabilities as well as protective factors. In addition, the proposed final model relies on modifiable variables that determine the magnitude of experienced and reported consequences (see Figure 10).

Figure 10. Aggregated Model based on an Integrative Cross-Level and Multifactorial-Probabilistic Approach as well as on the Bio-Psycho-Social Vulnerability Stress Model as an Extension of the Adapted SORKC Model.



According to studies 3, 4, and 5, individuals with a pre-existing limited mental health status are more vulnerable to a worsening or chronic development of their symptoms if they do not receive the necessary support and treatment. The worsening or chronic development of the mental health status of individuals, irrespective of a pre-existing condition, has been assumed to occur during crises, such as during the COVID-19 pandemic (Rajkumar, 2020; Tso & Park, 2020; Wang et al., 2020). This notion has been supported by results from study 3, indicating that both groups of individuals (i.e., those with a pre-existing mental health diagnosis and those without) reported a perceived decrease in mental health, with individuals from the psychosomatic rehabilitation clinics reporting a stronger burden concerning their mental health. If crises become overwhelming and exceed individual or system coping responses, reactions on different levels, such as on the behavioral, the emotional, the cognitive as well as the system level may occur. Therefore, studies 2 and 4 could show that during crises, such as during the COVID-19 pandemic, individuals engage in more preventative behavior such as hand hygiene behavior or physical and social distancing. If, however, necessary coping skills or social support are not available or access to preventative strategies is not obtainable, it may result in overwhelming feelings that consequently lead to a decrease in mental health, a chronic development, or in the worst case to suicidal attempts or suicide (Cheng et al., 2021; Söllner et al., 2007).

Next to the reactions on a behavioral level, study 4 highlighted distress as a response to a crisis such as the COVID-19 pandemic on the *emotional level*. According to previous evidence and based on the results of study 4, distress was significantly intercorrelated with an increase in loneliness, anxiety, and depression, thus, suggesting that an increased perception of distress may be associated with a decrease in mental health and well-being. Hence, without necessary coping strategies, termed modifiable variables, variables such as distress, anxiety,

loneliness, and depression may be sustained by developing into a vicious and interrelated circle leading to a worsening or chronic development of mental health symptoms (study 4).

Further, *reactions* based on the COVID-19 pandemic as a crisis have been reported on the *cognitive level*. Study 3 was able to show worries and concerns associated with the COVID-19 pandemic. Results highlighted that individuals with a pre-existing mental health diagnosis (i.e., psychosomatic rehabilitation patients) reported greater worries associated with household-related topics but lower financial worries and overall greater satisfaction in communication with health care professionals compared to individuals without a pre-existing mental health diagnosis (i.e., the general population). As previously discussed, these findings are in line with Van Rheenen et al. (2020). Providing support for the different groups of individuals by enhancing coping skills and offering support networks, will provide a buffer for a decrease in or chronic development of mental health-related symptoms.

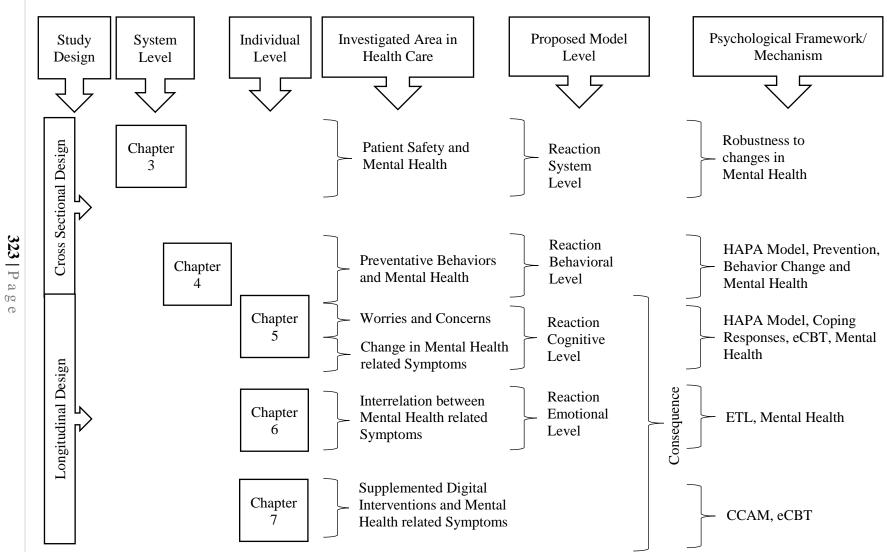
Not only has the COVID-19 pandemic as a crisis led to reactions on an individual level. At the beginning of the pandemic, hospitals and mental health services were restricted in their offering of treatment and therapy because of the necessary containment strategies imposed by governmental regulations. This, however, has put, as introduced before, an additional strain on employees and the health care system as a whole, leading to lasting changes in the health care profession and patient safety. Besides the negative aspects, however, this offered also opportunities for the introduction of digital components into the treatment process, such as blended psychotherapy. This opens access to more treatment options, thus, providing an option to compensate for and cope with mental health symptoms resulting from an increased burden associated with crises.

What all results point towards is the improvement and support with regard to the modifiable variables to reduce the consequences for the individual as well as for the health care system. This assumption has been strengthened by results from studies 3 and 5 highlighting the

beneficial role and necessity to offer rehabilitation treatment options during the pandemic for individuals with a pre-existing mental health condition to avoid chronic development concerning the symptoms. Furthermore, the beneficial role of offering digital interventions in addition to the care-as-usual or traditional face-to-face rehabilitation while also complying with the proposed mitigation strategies has been shown to be beneficial with regard to symptom reduction (study 5). Accordingly, a necessary and sufficient number of treatment options need to be made available, which can be supplemented by digital components, to foster and increase (1) effective coping strategies, (2) to increase preventative opportunities, (3) to avoid a chronic development of symptoms, (4) to facilitate behavior change, and (5) to reduce the overall perceived burden of challenging situations or crisis.

To sum up, the results on an aggregational level by considering the research design, the proposed analyzed and evaluated level (i.e., either individual or system level), the investigated area of health care, the proposed model level, as well as the psychological framework or mechanism, Figure 11 provided a holistic and all-encompassing overview.

Figure 11. Aggregated Structure of the Dissertation Papers.



8.5. Implications for Theory (Advancements) and Practice

8.5.1. Patient Safety: Theoretical Advancement and the Need for Patient Safety Reporting Systems for Patients

The reported results concerning improving patient safety and patient care call for the incorporation of more insights on preventable adverse events from the perspective of patients through qualitative and observational studies. To recommend improvements in patient safety, theoretical models are necessary to provide a basis or common vocabulary while describing key aspects of targeted behaviors, context, constraints, and interventions. Such theoretical bases, consequently, have the ability to examine factors potentially influencing or at least intercorrelating with the effectiveness of interventions and allow for an overall and holistic understanding of what aspects of interventions work and how they work (i.e., an explanation of the psychological mechanisms). Hence, it may be postulated that generalization through theoretical frameworks or models allows for overall greater generalization compared to simple replication of studies within different health care settings (Improved Clinical Effectiveness through Behavioural Research Group (ICEBeRG), 2006). Translating this view to patient safety and possible triggers of patient safety, the UK Medical Research Council was able to highlight the importance of integrating theoretical assumptions into the development and evaluation of interventions at different stages. Accordingly, theory can be applied to different stages of a framework to evaluate clinical and organizational behavior and to inform the selection of frequently occurring triggers of preventable adverse events as well as to understand their effects and intercorrelates. Hence, the development of general knowledge with regard to triggers of patient safety and constitutes of patient safety may be necessary (Skivington et al., 2021). However, having a theoretical understanding of triggers related to patient safety is considered insufficient in defining the most relevant ones in primary health care from the perspective of the patient. Therefore, quantitative research in form of rigorous quasi-experimental studies as well as qualitative research in form of evaluation of interviews, focus groups, and workshops is necessary. In addition, to increase the transparency of patient safety-related incidences, primary health care settings should think about the adoption of anonymous critical incident reporting systems for patients.

8.5.2. Hand Hygiene: Extending the Scope of Theoretical Models and Effective Strategies to Promote Effective Hand Hygiene

The HAPA has been able to effectively explain health behavior changes such as changes in hand hygiene by relying upon social-cognitive variables. However, evidence and theoretical information are necessary to get a better understanding of what constitutes effective hand hygiene behavior. So far, when examining hand hygiene behavior and the constitutes of hand hygiene behavior, theories such as the TPB or the HAPA have been used to predict changes by evaluating determinants (i.e., social-cognitive predictors) of hand hygiene behavior. For both theories, however, an individual's conscious intentions are strongly associated with hand hygiene behavior, hence, rather neglecting less conscious, more impulsive, or automatic determinants including habits and emotions. Specifically, studies have shown that emotions commonly associated with hand hygiene have been named as feeling disgusted, dirty, or containment in the health care context. It has been reported that those experienced emotions are the motivational driving force to engage in hand hygiene behavior (Chatfield et al., 2017; Whitby et al., 2006). With regard to habits, evidence in the literature has shown that effective and reliable hand hygiene behavior may be performed in habitual contexts (Dyson et al., 2011; Smiddy et al., 2015), such as in health care settings in which automated behaviors are more likely to be performed. One behavioral theory that recognized those determinants and variables is the theory of interpersonal behavior, which acknowledges automatic determinants (i.e., habits) and specific barriers. Therefore, future research should consider extending the HAPA framework by recognizing the importance of emotions and habits as less conscious processes in explaining behavior change. However, what needs to be recognized is that adherence to hand hygiene behavior and associated containment measures over a long period of time may take its toll on individuals. Negative consequences (i.e., lack of freedom) may, in turn, stimulate individuals from deviating from hygiene measures. Therefore, what should be addressed in future psychological and interdisciplinary research are the following: When do individuals deviate from performing effective hand hygiene behavior, why do they deviate, and how? This notion ties in with the proposed model (Figure 10) highlighting the necessary role of offering preventive measures and encouraging behavior change to cope with stressors and consequently reduced the burden of experienced crises. Future research should be concerned with factors promoting effective prevention strategies that elicit a wanted behavior change in individuals taking psychological factors and mechanisms (i.e., focusing on modifiable psychological variables that support behavior change) more into account.

According to the World Health Organization, performing hand hygiene during the right situations is the most effective way to prevent health care-associated infections in primary health care settings (World Health Organization & WHO Patient Safety, 2009b). The WHO has recommended the implementation of monitoring and feedback strategies for hand hygiene to achieve best practices and to ensure patient safety (World Health Organization & WHO Patient Safety, 2009a). Hence, to follow those recommendations, health care facilities have increasingly turned to monitoring devices such as wearable devices in ensuring adequate hand hygiene. One of those tools, that has been shown to be a reliable device in promoting hand hygiene actions in various conditions is Smartrub® (Guitart et al., 2021). Smartrub® is one of the first tools providing direct feedback to users on hand hygiene performance. As this monitoring device seems promising in improving hand hygiene behavior among health care professionals, similar tools should also be developed for patients, as they are also known for a reduced adherence to hand hygiene behavior in health care settings.

8.5.3. Contents of Behavioral Digital Interventions Grounded in Theory

The development of digital interventions could benefit from the greater use and application of health behavior (change) theories (Riley et al., 2011). The HAPA as a wellknown health behavior change theory has been shown to provide the theoretical basis for digital interventions (Degroote et al., 2021; Yeager et al., 2018). However, research centering around health behavior change has mainly focused on the HAPA and turned less to other theoretical frameworks such as the CCAM, that could explain compensatory carry-over actions between two desired outcomes as well as integrating higher-level goals, such as improvements in mental health, into its model structure. Next to the consideration of health behavior change theories, adherence to and drop-out from digital interventions need to be promoted. Research has shown that individuals with a pre-existing limited mental health status have a higher tendency to dropout from digital interventions due to motivational deficits (Lippke et al., 2021). Therefore, adherence and prevention of drop-out should be targeted by theoretically based interventions already in the initial stages of the development of digital trainings. These include for example the Integrate, Design, Assess, and Share (IDEAS) method (Mummah et al., 2016), the behavioral wheel method (Michie et al., 2011), the Information-Motivation-Behavioral skills (IMB) method (Meunier et al., 2016) or even gamification (Wattanasoontorn et al., 2013). All of these are effective in improving adherence and preventing drop-out from digital interventions. Therefore, future development of digital interventions should consider involving other health behavior change theories outside the scope of the HAPA model and consider preventing drop-out and increasing adherence.

8.5.4. Need for Low-Threshold Interventions during Crisis Situations such as during COVID-19.

The COVID-19 pandemic, as a crisis, has affected individuals regardless of their mental health status. Several studies have raised the need for low-threshold interventions in promoting help-seeking and reducing the burden on mental health due to factors associated with a crisis

or other stressful or distressing situations (Calvano et al., 2021; Kohls et al., 2021). These interventions should target mainly the activation of intra- and inter-personal resources. Further, these low-threshold interventions should be developed based on theoretical models such as the CCAM or other aforementioned theories or methods (i.e., considering drop-out and adherence). Several challenges for the development and evaluation of digital low-threshold interventions, however, should be considered: pace and efficiency, engagement, theory, evaluation of effectiveness, as well as the evaluation of cost-effectiveness and consideration of regulations, ethics, and information governance (Michie et al., 2017). One of the first and only digital lowthreshold interventions developed based on a theoretical behavior change model, the HAPA model, is 'MyDayPlan'. This intervention focuses on increasing physical activity and has shown good effectiveness concerning behavior change. However, a limitation of the digital intervention that needs to be stressed is that no carry-over effect (i.e., when individuals stop using the app) was found. As a possible suggestion, the CCAM should be considered in ensuring carry-over effects to other behaviors and should be used to provide a long-term carryover effect. Nevertheless, these research attempts provide building blocks for future developmental efforts of digital low-threshold interventions in the sector of mental health and well-being (Degroote et al., 2021).

Low-threshold digital interventions should also focus on the sense of belonging or inclusion. Concerning crises (i.e., the COVID-19 pandemic) and the associated containment or mitigation strategies, individuals were either encouraged to physically or socially distance themselves from others or chose to do so, to protect their own as well as the health of others. This prolonged distancing may, however, heighten feelings of social isolation which has been defined as "a state in which the individual lacks a sense of belonging socially, lacks engagement with others, has a minimum number of social contacts and they are deficient in fulfilling and quality relationships" (Nicholson, 2009; p. 1346). Social isolation, further, has been associated with a decrease in mental health and well-being (Coyle & Dugan, 2012; Loades et al., 2020;

Pancani et al., 2021). Therefore, when offering low-threshold digital interventions for individuals to compensate for the deterioration of mental health and well-being, incorporating elements that increased perceptions of belonging or inclusion are of importance (i.e., use of avatars, use of chat rooms, chatbots, or use of digital group activities).

8.5.5. Fixed and Flexible Digital Trainings for Rehabilitation Settings – Before, During, and After Rehabilitation

Studies, such as surveys and qualitative evaluations, among psychotherapists have revealed that blended therapeutical approaches are considered acceptable and beneficial concerning the overall treatment outcome while considering the advantages over conventional or traditional face-to-face psychotherapy (i.e., bringing distances between the therapist and the patient, flexibility with regard to time and place, patient empowerment, and support for the psychotherapist by providing standardized materials; Baumeister et al., 2020; Renn et al., 2019; Titzler et al., 2018). First attempts in offering digitalized and standardized treatment programs have been made with the German Digitalen Versorgungsgesetz (DVG; digital supply act). Within the DVG, digital health applications (Digitale Gesundheitsanwendungen (DiGA)) have been added to a catalog for regular and standard care opportunities of the German health insurances. DiGAs can be prescribed by psychotherapies or physicians to enhance standard or traditional face-to-face treatment options with digital elements. Studies have highlighted the beneficial effect of the use of adjunct web-based therapy tools in comparison to only face-toface psychotherapy concerning symptom reduction in for example depression (Berger et al., 2018). However, so far evidence of digital or web-based therapy tools adjunct to the psychosomatic rehabilitation treatment process is missing. Therefore, the results of the present dissertation call for the development of digital toolbox materials that may be used in the rehabilitation setting to foster the introspective abilities of patients, as well as provide psychoeducation and exercises to improve and restructure cognitive, behavioral, and emotional expressions. It is recommended that based on the experiences with DiGAs, digital content needs to be tailored to the specific diagnosis of the patients, hence, allowing for individualization of the treatment of mental health problems.

8.5.6. What Happens After Rehabilitation?

Return to work has been defined as the ideal outcome of medical, psychosomatic rehabilitation treatment. However, for return to work to be successful, several aspects need to be considered. The CCAM provides a theoretical basis for explaining how multiple healthrelated behaviors and social-cognitive determinants necessary for a return to work are interconnected and interact with one another. For a successful return to work to occur, individuals need to develop an acceptance of their limitations, disease, or illness. To achieve such an acceptance, individuals need to progress through three stages according to Mok: (1) the motivational stage, (2) the stage where individuals perceived mastery over their illness, and (3) the need to experience transformational thoughts (Mok, 2001). After acceptance of the current state of health, individuals need to identify barriers and facilitators that encourage or hinder the return to work. According to several psychological models such as the HAPA or the CCAM, facilitators may be social support systems. Even though it may be argued that the rehabilitation setting itself poses a support system, this may, however, only be of short-time effectiveness. Therefore, future research should focus on providing (digital) support systems for all medical and psychosomatic rehabilitation patients to develop and strengthen self-efficacy beliefs and outcome expectancies that may translate into intentions that could in the long run translate into actual behavior. However, not only are these support systems important for an initial uptake and intention formation of return to work, but also for the process of maintenance (Schwarzer, 2008; Schwarzer et al., 2011). Next to the increase in motivational aspects, individuals need to perceive mastery experiences (i.e., being able to reach their own goals). Thereby they need to perceive an emotional relevance to reach higher-order goals. These factors are key in initiating and maintaining the desired behavior (i.e., return to work). As the return to work is conceptualized as several individual health behaviors (i.e., physical well-being, psychological well-being, reduction of pain, stable financial environment), the CCAM assumes that various psychological mechanisms, so-called carry-over mechanisms, act between health behaviors and can be transferred from one to another (Fleig et al., 2011). Therefore, according to the model, resources that individuals perceive may be transferred from one domain to another and compensatory cognitions can stimulate or inhibit the formation of an intention as well as the realization of the other behavior. However, even though the CCAM or the HAPA has successfully been applied to various health behaviors (i.e., healthy eating, physical activity, smoking cessation), these frameworks have rarely been analyzed within the medical psychosomatic rehabilitation context (Tan et al., 2018). Future research is necessary to understand the constitutes and interrelations of psychological mechanisms behind a successful return to work. In a second step, (digital) interventional programs should be developed based on those theoretical frameworks to guide the process of returning to work after rehabilitation.

8.5.7. Encouraging and Promoting the Use of Digital Interventions

Several challenges to the implementation of digital interventions into pre-existing face-to-face therapy structures need to be considered when encouraging and promoting the use of digital interventions. One major concern is privacy and protection of user data, as psychotherapy involves the sharing of personal and sensitive information by the patient as well as by the therapist (Lambert & Barley, 2001). Even though the European data regulations provide rigorous guidelines concerning data collection, data storage, and data deletion, new technological data security strategies should be integrated into data collection and communication processes. One example of such a new technological advancement is homomorphic encryption, which allows for the processing of user responses over encrypted data (Yi et al., 2014).

Several other practical aspects, however, need to be acknowledged and considered in future research attempts such as potential contraindications for online treatments or digital interventions such as the following: low self-management skills, low technical skills, or a low

computer affinity or factors inherent with the disease of the individual (i.e., psychotic episodes or experiences, severe depressive disorders or multiple comorbidities). As these factors were not considered in the development and implementation of the evaluated digital interventions, future research agendas call for the refinement and adaption of the previously evaluated interventions to ensure adherence, satisfaction, and long-term transfer as well as symptom stabilization.

Next to the rather practical implications that should be considered for future research, person-based approaches (i.e., how to motivate the individuals to engage in behavior change interventions) on a theoretical level should also be acknowledged. According to the person-based approach, understanding and addressing the individual needs of the users are vital in developing a health behavior intervention that has a long-lasting effect on the desired outcome (i.e., improvements in mental health). This idea is critical with regard to overcoming low rates of uptake and adherence as well as a drop-out. Thereby, supporting the user's autonomy, and competencies, as well as fostering positive experiences and relatedness, are essential in empowering users to become their own health and well-being coaches (Yardley et al., 2015). Overall, future research agendas call for digital interventions to be designed within the psychological framework of a person-centered approach.

8.5.8. What Skills Make Therapists (More) Successful?

Not only do patients need skills and competencies to partake in digital interventions and to benefit from those, but also are skills of relevant digital treatment options required from therapists. Literature has shown three main themes that can be considered as promoting or hindering factors: (1) the needs of the therapists concerning the uptake of digital interventions, (2) the role of the therapists in motivating patients, and (3) previous experiences with the use of digital interventions.

Concerning the needs of the therapists, training is required to learn and familiarize oneself with the technical aspects of digital tools. Thereby, it has been shown that ongoing

support is of key importance to providers. In addition, the motivation of therapists should be encouraged and promoted to create a readiness for an uptake of digital interventions. Concerning digital interventions, one role of the therapists is to motivate the patients to partake and maintain adherence to participate in digital interventions. Therefore, patients need to be informed, their eligibility and progress need to be monitored, and patient resistance needs to be recognized and addressed by the therapist. To build upon previous experiences with the use of digital interventions, positive effects need to be stressed concerning the treatment format, the therapeutic relationship, and direct online feedback possibilities (Mol et al., 2019). Therefore, manuals and trainings should be offered to therapists to make them feel more comfortable with the use of digital interventions. Hence, these training materials for therapists should focus on common psychological models that explain behavior changes such as the HAPA or the CCAM to foster the intention to use digital intervention as well as the maintenance.

8.6. Limitations of this PhD Thesis and Suggestions for Future Research

This dissertation has, up to this point, presented the results and contributions of the discussed studies to health psychology, rehabilitation psychology, and clinical psychology. However, these results and contributions need to be discussed and interpreted with several limitations accompanying this PhD thesis.

First of all, all studies part of this PhD thesis relied on exploratory analyses rather than including confirmatory factor analyses. Together with the lack of power calculations performed for the analyzed outcomes, the generalizability of our findings needs to be interpreted with caution. As most data were collected within the setting of health care and health service research, data robustness, sample sizes, robustness to biases, the clinical relevance of effect sizes as well as drop-out between pre- and post-measurements need to be considered concerning the limitation of generalizability of the results.

In addition, triggers of preventable adverse events were only assessed within the framework of health care settings (i.e., hospitals). Hence, the transfer to different health care settings such as general practitioners, rehabilitation settings or psychiatry may be limited, as those settings may be faced with different potential threats to patient safety. In addition, the constructed questionnaire that aims to assess and measure triggers of preventable adverse events was developed based on a literature review and refinement of health care professionals. However, despite aiming to mirror and consider the perspective of patients, patients were not involved in the developmental process, for example in form of needs assessments. Hence, qualitative data should have been collected from patients in form of interviews, focus groups, or workshops to provide a more holistic assessment of triggers of preventable adverse events from the perspective of patients. Further, despite study 1 demonstrating good psychometric properties of the developed questionnaire, the questionnaire was not compared to previous tools assessing patient safety. Hence, interpretations of concurrent validity need to be treated with caution.

Hand hygiene behavior as the main health behavioral outcome was only assessed by retrospective and qualitative analysis (i.e., questionnaire data). As the bias of social desirability needs to be acknowledged while examining hand hygiene behavior, evaluations of the frequency and the effectiveness of hand hygiene should include the use of observational data and data from technological devices to collect information on effective hand hygiene behavior.

Most of the interpretations and the conclusions drawn from the presented results are based on data that was collected during the COVID-19 pandemic which has been shown to be a stressful time for individuals. However, the question remains whether the conclusion drawn will also be applicable in terms of the generalizability to post-COVID times or to other potential epidemics or pandemics, or crises in the future.

Another methodological point that needs to be considered is the use of either crosssection data or data with only one follow-up measurement time point. Concerning the crosssection data used in study 1, and partially in studies 2 and 3, no longitudinal conclusion could have been drawn. However, as with the longitudinal data, no trends could have been shown or discussed as the post-measurement was conducted between one- and 12-weeks post-rehabilitation. For trends in symptom changes and lasting effects to be concluded, further measurement points should have been introduced (i.e., after six months or one year). In addition, data collected on a longitudinal basis revealed rather high drop-out rates of about 40%. Several reasons may need to be considered: On the one hand, post-rehabilitation data were collected up to 12 weeks after rehabilitation. Hence, at the point of data evaluation, patients may have not taken part in the post-rehabilitation examination as they were just released from rehabilitation. On the other hand, motivational deficits need to be considered with regard to partaking in the follow-up survey which may in part be due to the limited psychological health status of patients. Therefore, future research should also evaluate motivation as a predictor of drop-out or retention.

Digital trainings offered to the patients during the rehabilitation setting were developed based on elements of CBT. However, as with study 1, patients were not included in the development of the digital trainings in form of needs-based assessments. Hence, qualitative data is missing in form of interviews, focus groups, or workshops to mirror the needs during the therapy of patients. Furthermore, digital literacy or literacy in general as well as demographic data, as well as the primary ICD-10 diagnosis should be considered in the design of digital trainings to provide individualized e-Mental health treatment options. In addition, the digital trainings offered during the rehabilitation do not depict the current state of the art (i.e., such as DiGAs). Therefore, the digital interventions should be transferred to the current state of the art and should be reanalyzed and reevaluated.

The effectiveness of different digital treatment options was evaluated by two intervention groups and one control group. However, instead of relying on standardized allocation or even randomization to an intervention group or a control group, the patients were

allocated to the groups based on their participation in the offered digital interventions. This was in part because randomization to a control or intervention group would have been ethically incorrect, as some patients would have been withheld from necessary treatment. However, it needs to be acknowledged that participation in digital treatment programs may have been dependent on the motivational status of patients. As, however, motivation or rather a lack of motivation has often been associated with mental health-related issues, these factors should have been considered while forming intervention and control groups. Therefore, to compensate for these limitations future research should employ a two-group pre-test post-test design or consider the use of a wait list control group.

Overall, due to the correlational nature of the study designs of all five studies, no causal conclusion can be drawn as part of this dissertation. Hence, as aforementioned, different study designs are necessary such as a two-group pre-test post-test design or a wait list randomized controlled trial is warranted to draw causal conclusions based on the obtained results.

8.7. Conclusion

Continuous psycho-social support for individuals, irrespective of their mental health status, has been deemed more important than ever during crises such as the current coronavirus pandemic. Therefore, the reactions, consequences, as well as the modifiable variables to counteract potential negative consequences, need to be understood on several levels. First of all, evidence and studies discussed during this dissertation have shown reactions of the individual on a behavioral (i.e., changes in individual containment strategies), emotional (i.e., perceived distress and fear), and cognitive level (i.e., worries and concerns). Secondly, the system level (i.e., patient and (mental) health care provision), should also be considered concerning reactions evoked by crises. Hence, these reactions lead to consequences on both the individual (i.e., symptoms of depression, anxiety, and loneliness) as well as the system level (i.e., changes in (mental) health care provision and changes in the perception of patient safety).

Previous theoretical frameworks related to clinical psychology, such as the SORKC model, the vulnerability-stress model or the bio-psycho-social model, as well as frameworks related to health psychology, such as the HAPA, the CCAM or the TPB, have all been attempting to explain the psychological mechanisms associated with crises, such as the COVID-19 pandemic. Therefore, the studies presented in this dissertation have relied on those models and frameworks. Nevertheless, what all these psychological frameworks are missing is an integrative cross-level, multifactorial-probabilistic, and bio-psycho-social vulnerability stress model that accounts for behavior change and prevention. Results from the studies discussed contribute to an integrated view of the psychological mechanisms associated with the COVID-19 pandemic (i.e., a crisis) as a stimulus for reactions and consequences on multiple dimensions. The proposed model further adds information on modifiable variables, such as prevention, behavior change, digital interventions concerning treatment options, or an increase in access to treatment, that have the function to modify or buffer the relationship between reactions and consequences. Results from this dissertation underline the necessity to strengthen and support those modifiable variables through theory-based interventions tailored to the needs of the individuals to offer the best possible support (i.e., by employing needs assessment tailoring).

Therefore, this dissertation also recommends stepping away from the traditional ICD-10 diagnostic criteria toward a more all-encompassing understanding of what factors and symptoms or even comorbidities lead to, maintain, and should be considered while treating psychological disorders.

Hence, this dissertation addresses different groups of individuals, professions, areas of work, as well as political stakeholders. On the one hand, the results of this thesis aim to encourage individuals, irrespective of their mental health status, to turn to support networks or therapies if they perceive that the perceived burden or stress exceeds their coping capabilities. It is, therefore, necessary, also from a political perspective, to introduce strategies to reduce the stigma surrounding mental health. Further, more treatment options, both digital and face-to-

face treatments, should be made available to reduce waiting times, thereby, providing quicker access to care. This notion also calls for more research in the development and validation of digital treatment options that may be made available as DiGAs. Therefore, more understanding of needs and psychological processes concerning digital interventions is a central topic that should be investigated in further research projects. Results also inform psychotherapists and clinics of the possibility and the beneficial aspects to integrate digital interventions into more traditional face-to-face therapies to support desired treatment outcomes. Therefore, therapists and clinics need to be trained in using digital therapy formats but also need to be financially compensated for their additional efforts which call for changes in compensation possibilities by health care insurance.

To sum up, this dissertation offers an extended and new theoretical framework for understanding patients and mental health and its respective care during crises, such as the COVID-19 pandemic, through an integrative and holistic psychological lens. Several needs, resources as well as implications for different groups of individuals, areas of work, and stakeholders were identified. These include the need to support modifiable psychological variables such as coping skills, social support, emotional competence, behavior change, prevention, and access to treatment. The fostering and support of these modifiable psychological variables have shown to be of importance, as they provide a buffer for a possible worsening or deterioration of the mental health status in situations or circumstances of crisis such as during the COVID-19 pandemic.

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Appendix

 Table 23. Final Questionnaire Assessing Preventable Adverse Events (pAEs) in German.

Während meines letzten Aufenthalts oder Besuchs im Krankenhaus habe ich mindestens einmal beobachten oder erfahren können, dass	Trifft überhaupt nicht zu	Trifft eher nicht zu	Trifft eher zu	Trifft voll und ganz zu
die Mitarbeiter des Krankenhauses sich die Hände nicht gut genug gewaschen oder desinfiziert haben.	0	0	0	0
es Konflikte unter den Mitarbeitern des Krankenhauses gab.	0	0	0	0
die Mitarbeiter des Krankenhauses nicht ausreichend informiert waren.	0	0	0	0
ich nicht ausreichend aufgeklärt wurde.	\circ	0	0	0
ich nicht ausreichend über den Ablauf von Untersuchungen im Vorhinein informiert wurde.	0	0	0	0
Diagnosen bei mir zu voreilig gestellt wurden.	0	0	0	0
Diagnosen falsch gestellt wurden.	\circ	0	0	\circ
Diagnosen erst zu spät gestellt wurden.	0	0	0	0
die von Mitarbeitern des Krankenhauses vorgeschlagene Behandlung nicht ausreichend war.	0	0	0	0
ich nicht ausreichend über Behandlungsmaßnahmen aufgeklärt wurde.	0	0	0	0
ich nicht ausreichend oder verständlich genug über Medikamente und ihre Nebenwirkungen aufgeklärt wurde.	0	0	0	0
die Mitarbeiter des Krankenhauses sich nicht genug	\circ	0	0	0
Zeit für mich genommen haben ich oft lange warten musste zu wenig Personal da war.	0	0	0	0

Während meines letzten Aufenthalts oder Besuchs im Krankenhaus habe ich mindestens einmal beobachten oder erfahren können, dass	Trifft überhaupt nicht zu	Trifft eher nicht zu	Trifft eher zu	Trifft voll und ganz zu
die Mitarbeiter des		\circ	\circ	\cap
Krankenhauses emotional belastet erschienen.	O	O	O	O
es viele Verzögerungen gab. die Mitarbeiter des	0	0	0	0
Krankenhauses sich nicht gut mit technischen Geräten auskannten.	0	0	0	\circ
das Krankenhaus nicht nach dem neuesten Stand gearbeitet hat.	0	0	0	0
Gerätschaften in den Untersuchungsräumen fehlten.	0	0	0	\circ
die Mitarbeiter des Krankenhauses unsicher gewirkt haben.	0	0	0	0

Table 24. Final Questionnaire Assessing Preventable Adverse Events (pAEs) Translated to English (tested in German).

During my last stay or visit to the hospital, I have observed or experienced at least once that	Completely disagree	Somewhat disagree	Somewhat agree	Completely agree
hospital staff did not wash or disinfect their hands well enough.	0	0	0	0
there were conflicts among the hospital staff.	0	\circ	0	0
the hospital staff was not sufficiently informed.	0	0	0	0
I was not sufficiently informed overall.	0	0	0	0
I was not informed of the progress of any examination in advance.	0	0	0	0
diagnoses were made too hasty for me.	0	\circ	0	\circ
diagnoses made were incorrect diagnoses were made too late.	\circ	0	0	0
the treatment proposed by hospital staff was not sufficient.	0	0	0	0
I have not been adequately informed about treatment procedures.	0	0	0	0

During my last stay or visit to the hospital, I have observed or experienced at least once that	Completely disagree	Somewhat disagree	Somewhat agree	Completely agree
I was not sufficiently or understandably informed about medications and their side effects.	0	0	0	0
the health care professionals did not make enough time for me.	0	0	0	0
I often had to wait for a long time.	0	0	\circ	0
there was a shortage of staff.	\circ	\circ	\circ	0
the health care professionals seemed emotionally burdened.	0	\circ	\circ	0
there were many delays.	0	\circ	\circ	0
the health care professionals were not well versed with technical equipment.	0	0	0	0
the hospital has not been operating at the most up-to-date level.	0	0	0	0
equipment was missing from the examination rooms.	0	\circ	0	0
the health care professionals seemed uncertain.	0	0	0	0

Table 25. Risk Perception – Cross-Sectional.

	Significantly below average	Below average	Rather below average	Average	Rather above average	Above average	Signifi- cantly above average
Compared to an average person of my gender and age, my risk of getting an infection from poor hand hygiene is	a way						

 Table 26. Action Self-Efficacy – Cross-Sectional.

I am sure that I can regularly wash and disinfect my hands, even if	Completely not applicable	Not applicable	Rather not applicable	Rather applicable	Applicable	Com- pletely applicable
I have to						
force myself to						
do it.						
it is time-						
consuming.						
others do						
not wash their						
hands.						
even if my						
hands get dry.						

Table 27. Outcome Expectancies – Cross-Sectional.

If I regularly	Com-	Not	Rather not	Rather	Applica-	Com-
disinfect or	pletely	applicable	applicable	applicable	ble	pletely
wash my	not					applicable
hands, then	applicable					
I will stay						
healthy.						
others will						
see that I am a						
clean person.						

If I regularly disinfect or	Com- pletely	Not applicable	Rather not applicable	Rather applicable	Applica- ble	Com- pletely
wash my	not					applicable
hands, then	applicable					
I will feel						
good with						
clean hands'						
I will not						
infect others.						
I will						
successfully						
contribute to						
general						
hygiene.						

Table 28. *Intention – Cross-Sectional.*

I intend to wash or disinfect my hands properly	Completely not applicable	Not applicable	Rather not applicable	Applic- able	Com- pletely applicable
•••					
if I have					
come into					
contact with					
germs or dirt.					
when I am					
sick.					

Table 29. Action Planning – Cross-Sectional.

I have already planned concretely	Completely not applicable	Not applicable	Rather not applicable	Applic- able	Com- pletely applicable
when to wash or					
disinfect my					
hands where to					
wash or					
disinfect my					
hands.					

Table 30. Coping Planning - Cross-Sectional.

To continue washing or disinfecting my hands in difficult situations, I have a concrete plan of what I do when	Completely not applicable	Not applicable	Rather not applicable	Rather applicable	Applic- able	Completely applicable
being in a hurry.						
no						
disinfection						
possibility or						
soap is						
available.						

 $\textbf{Table 31.} \ \textit{Maintenance Self-Efficacy} - \textit{Cross-Sectional}.$

I am sure that I can disinfect or wash my hands regularly, even	pletely not	Not applicable	Rather not applicable	Rather applicable	Applic- able	Completely applicable
<u>if</u>						_
I am						
stressed.						
I do not feel						
well.						
I do not						
have support						
from others.						

Table 32. *Hand Hygiene Behavior – Cross-Sectional.*

Now please answer the	Never	Rarely	Sometimes	Often	Always
following questions					
about what you do in					
your daily life.					
I wash my hands daily					
with soap and water.					
When my hands are					
visibly dirty, I wash them					
with soap and water.					
After going to the toilet, I					
wash my hands with soap					
and water.					

Now please answer the	Never	Rarely	Sometimes	Often	Always
following questions					
about what you do in					
your daily life.					
Before eating, I wash my					
hands with soap and					
water.					
I wash my hands with					
soap and water before					
preparing meals.					
If I have touched raw					
meat, eggs, or					
vegetables, I wash my					
hands with soap and					
water.					
If I am a patient in the					
hospital, I disinfect my					
hands when I enter.					
When I am a visitor to					
the hospital, I disinfect					
my hands when I enter.					
If I am a patient in the					
hospital, I disinfect my					
hands when I leave.					
If I am a visitor to the					
hospital, I disinfect my					
hands when I leave.					
After touching a door					
handle in the hospital, I					
disinfect my hands.					
After using a telephone					
in the patient room, I					
disinfect my hands.					

 $\textbf{Table 33.} \ \textit{PHQ-9} \ (\textit{Depression}) - \textit{Cross-Sectional}.$

Over the last 2 weeks, how often	Not at all	Several	More than	Nearly
have you been bothered by any of		days	half the	every day
the following problems?			days	
Little interest or pleasure in doing				
things				
Feeling down, depressed, or				
hopeless				
Trouble falling or staying asleep,				
or sleeping too much				
Feeling tired or having little				
energy				
Poor appetite or overeating				

Feeling bad about yourself or that
you are a failure or have let
yourself or your family down
0 1 1 0 1 1 0

<i>j o a all o a lalland o l lia (o lo l</i>				
yourself or your family down				
Over the last 2 weeks, how often	Not at all	Several	More than	Nearly
have you been bothered by any of		days	half the	every day
the following problems?		-	days	
Trouble concentrating on things,				
such as reading the newspaper or				
watching television				
Moving or speaking so slowly				
that other people could have				
noticed. Or the opposite being so				
fidgety or restless that you have				
been moving around a lot more				
than usual				
Thoughts that you would be better				
off dead, or hurting yourself				

Table 34. *GAD-7* (*Anxiety*) – *Cross-Sectional*.

Over the last 2 weeks, how often	Not at all	Several	More than	Nearly
have you been bothered by any of		days	half the	every day
the following problems?			days	
Feeling nervous, anxious, or on				
edge				
Not being able to stop or control				
worrying				
Worrying too much about				
different things				
Trouble relaxing				
Being so restless that it is hard to				
sit still				
Becoming easily annoyed or				
irritable				
Feeling afraid as if something				
awful might happen				

Table 35. Hand Hygiene Behavior Stage Item – Longitudinal.

	No, I don't intend to	No, but I've thought about it	No, but I've decided to do it	Yes, but it's hard for me	Yes, and it's easy for me
Do you wash or disinfect your hands before and after every purchase, touch door handles outside your own home, take public transport, etc.?					

 $\textbf{Table 36.} \ PHQ\text{--}4 \ (Depression \ and \ Anxiety) - Longitudinal.$

Over the last 2 weeks, how often	Not at all	Several	More than	Nearly
have you been bothered by any of the		days	half the	every day
following problems?			days	
Feeling nervous, anxious, or on edge				
Not being able to stop or control				
worrying				
Feeling down, depressed or hopeless				
Little interest or pleasure in doing				
things				

Difference between participants from the three measurement waves

To examine differences in participants across the three measurement waves, chi-square analyses and analyses of variance were performed. The results showed no significant differences with respect to symptoms of depression $\chi^2(2, n = 248) = 0.08$ and for symptoms of generalized anxiety controlling for age and gender. In addition, no significant differences between the three waves were found with regard to the HAPA variables: outcome expectancies $F(2, 266) = 1.07, p = .34, \eta_p^2 = .02$, risk perception $F(2, 266) = 1.75, p = .18, \eta_p^2 = .01$, action self-efficacy F(2, 266) = 2.76, p = .06, $\eta_p^2 = .02$, intention F(2, 278) = 2.49, p = .07, $\eta_p^2 = .02$, maintenance self-efficacy F(2, 266) = 1.79, p = .17, $\eta_p^2 = .03$, and planning F(2, 278) = 3.00, p = .03= .51, η_p^2 = .02 controlling for age and gender. In addition, no significant differences were found with regard to hand hygiene behavior between the three measurement waves F(2, 266) = 0.45, p = .64, $\eta_p^2 = .01$. However, results revealed to be significant with regard to resources F(2, 266)= 15.08, p < .01, $\eta_p^2 = .10$ and support F(2, 266) = 13.67, p < .01, $\eta_p^2 = .10$ while controlling for the covariates age and gender. Therefore, participants perceived greater resources and support while lockdown measures were released compared to before COVID-19 and during the first lockdown. However, examining the whether the mental health status was different between the three measurement waves, results did reveal to be insignificant (p < .05)

Appendix 4

Differences in variables concerning time of hospital visit.

In order to control for time differences with regard to hospital visit as either an inpatient or an outpatient, variables related to the HAPA model as well as hand hygiene behavior and mental health related symptoms were examined for significant differences. No significant differences were revealed for the following variables: hand hygiene behavior, F(2, 266) = 2.67, p = .07, $\eta_p^2 = .02$, action self-efficacy, F(2, 266) = 2.37, p = .10, $\eta_p^2 = .02$, risk perception F(2, 266) = 1.13, p = .32, $\eta_p^2 = .01$, outcome expectancies, F(2, 266) = 0.29, p = .75, $\eta_p^2 = .01$, intention F(2, 266) = 0.06, p = .94, $\eta_p^2 = .01$, maintenance self-efficacy, F(2, 266) = 0.30, p = .74, $\eta_p^2 = .01$, planning, F(2, 266) = 0.51, p = .60, $\eta_p^2 = .01$, resources, F(2, 266) = 3.04, p = .54, $\eta_p^2 = .02$, and support F(2, 266) = .73, p = .48, $\eta_p^2 = .01$, symptoms of depression, F(2, 237) = 0.49, p = .61, $\eta_p^2 = .01$, and symptoms of generalized anxiety, F(2, 246) = 2.50, p = .08, $\eta_p^2 = .02$ controlling for age and gender.

Appendix 5

Attrition Analysis

CPDI, symptoms of depression, symptoms of anxiety and symptoms of loneliness. The attrition analysis revealed no significant differences with regard CPDI ($M_{\text{Drop-out after T1}} = 32.13$; $M_{\text{longitudinal sample}} = 31.24$; t(998) = 1.42; p = .156) for symptoms of depression ($M_{\text{Drop-out after T1}} = 3.42$; $M_{\text{longitudinal sample}} = 3.36$; t(998) = 0.93; p = .350), symptoms of anxiety ($M_{\text{Drop-out after T1}} = 3.43$; $M_{\text{longitudinal sample}} = 3.41$; t(998) = 0.263; p = .793) and symptoms of loneliness ($M_{\text{Drop-out after T1}} = 4.59$; $M_{\text{longitudinal sample}} = 4.51$; t(998) = 0.870; p = .384).

Validation of results

Aim

To validate the findings of the study examining the longitudinal relationship between symptoms of anxiety and loneliness as serial mediators in the relationship between CPDI and symptoms of depression, data from the entire sample, including drop-out participants, were evaluated. To impute missing data at measurement timepoint 2 (post-rehabilitation), the expectation-maximization-algorithm (EM imputation) was chosen.

Participants from the psychosomatic rehabilitation clinics

Of the 676 recruited psychosomatic rehabilitation patients participating at both measurement time-points, 455 (67.3%) patients were female. Participants' age ranged from 18 to above 60 years. 117 (17.3%) were 39 years or younger, 154 (22.8%) patients between 40-49, 304 (45.0%) between 50-59 years of age, and 100 patients (14.8%) were 60 years or older. Educational level was categorized into 4 groups: 106 (15.9%) patients indicated to have received 10 or 11 years of schooling, 130 (19.5%) answered to have received 12 or more years of schooling, 301 (45.1%) indicated to have obtained vocational training, and 130 (19.2%) indicated to have obtained a university degree. 124 participants answered about the current status of their living situation. 36 (29.0%) were indicated to be living alone and 88 (71.0%) answered to be living with at least one other person in a shared household.⁵ Age, gender, and educational level were measured as categorical variables. 412 (60.9%) patients were diagnosed upon discharge with a mood (affective) disorder, 239 (35.4%) were diagnosed with a neurotic, stress-related, and somatoform disorder, and 25 (3.7%) patients were given a diagnosis of other diagnoses.

⁵ No significant differences with regard to loneliness were found between individuals with different living arrangements.

Instruments

The same instruments as in the original study were used for the validation study.

Statistical Analyses

For the validation study, SPSS Version 28 was used (IBM Corp., Armonk, NY, USA). Change scores between T1 and T2 were calculated for all variables of interest (T1 scores – T2 scores). Correlations between all variables (CPDI, anxiety, loneliness, and depression) were analyzed by Pearson correlation. A multiple step mediation analysis was conducted to validate the results of the original study. Depression, as the dependent variable, is regressed on CPDI (the independent variable) via a chain of mediators: anxiety and loneliness.

Bivariate correlations among all variables

An overview of means (M) and standard deviations (SD), as well as of the Pearson correlations (r) between all study variables, are provided in Table 37. Comparable to the original study, all variables were significantly and positively associated with one another at the level of p < .01 (two-tailed).

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Table 37. Bivariate correlations among T1, T2, and change scores related to CPDI infection, symptoms of anxiety, loneliness, and symptoms of depression (N = 671).

	M±SD	Range	1	2	3	4	5	6	7	8	9	10	11	12
1 COVID-19	35.38 ±	0-100	-											
Peritraumatic	14.12													
Distress														
Index (CPDI)														
T1														
2 Anxiety	3.50 ±	0-6	.562**	-										
(GAD) T1	1.65													
(GAD) T1 3 Loneliness T1	4.70 ±	2-8	.358**	.350**	-									
T1	1.77													
4 Depression	3.45 ±	0-6	.513**	.709**	.412**	-								
(PHQ) T1	1.64													
5 COVID-19	31.02 ±	0-100	.816**	.564**	.291**	.532**	-							
Peritraumatic	12.78													
Distress														
Index (CPDI)														
T2														
6 Anxiety	2.65 ±	0-6	.514**	.637**	.228**	.621**	.698**	-						
(GAD) T2	1.40													
7 Loneliness	$4.50 \pm$	2-8	.395**	.254**	.720**	.345**	.417**	.294**	-					
T2	1.51													
8 Depression	2.44 ±	0-6	.498**	.533**	.356**	.695**	.673**	.778**	.473**	-				
(PHQ) T2	1.39													

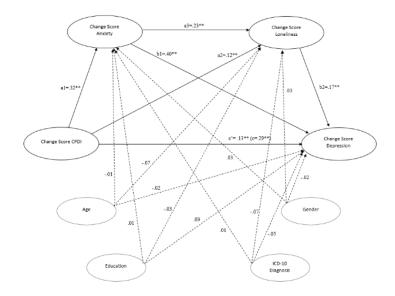
Ī		M±SD	Range	1	2	3	4	5	6	7	8	9	10	11	12
	9 Change	4.35 ±	-100 –	.448**	.089*	.163**	.054	151**	204**	.031	188**	-			
	score	8.25	100												
	COVID-19														
	Peritraumatic														
	Distress														
	Index														
	10 Change	0.85 ±	- 6 – 6	.165*	.479**	.197**	.229**	028	260**	.008	152**	.324**	-		
	Score	1.32													
	Anxiety														
	(GAD)														
	11 Change	0.20 ±	-8 – 8	.029	.189**	.545**	.166**	093*	033	190**	068	.193**	.267**	-	
37	Score	1.25													
371	Loneliness														
Рa	12 Change	1.02 ±	- 6 – 6	.123**	.349**	.154**	.558**	056	058	073	210**	.297**	.491**	.306**	-
9	Score	1.21													
	Depression														
	(PHQ)														

Note. * p < .05; ** p < .01 (two-tailed).

Longitudinal serial mediation analysis

The results of the validated longitudinal serial mediation analysis for CPDI (IV) on anxiety (M1), loneliness (M2), and symptoms of depression (DV) controlling for age, gender, educational level, and ICD-10 diagnosis are shown in Figure 12 and Table 38. Compared to the original study, the results of the present study show that CPDI was not significantly associated with the change score of symptoms of generalized anxiety. However, as in the original study, the change score of symptoms of generalized anxiety was significantly and positively associated with the change score of loneliness. Further, a significant association was found between the change score of the CPDI and the change score of loneliness. Finally, the change score of loneliness significantly predicted the change score of symptoms of depression. The total effect of the independent variable CPDI on the dependent variable symptoms of depression was significant and also remained significant upon the inclusion of the mediator variables in the model.

Figure 12. Validating the Longitudinal Serial Mediation Model CPDI, Symptoms of Anxiety, Loneliness, and Symptoms of Depression with N = 651 Rehabilitation Patients (Retaining Dropouts by means of Missing Imputation).



Note. The model is controlled for age, gender, education, and ICD-10 diagnosis. Reported coefficients are standardized betas coefficients, in brackets is the total effect; ** p < .01.

Concerning the present serial mediation path model, three possible indirect effects were examined: (1) the total indirect path from CPDI to symptoms of depression through symptoms of anxiety and loneliness which was significant; (2) the specific indirect path through symptoms of anxiety which was not significant ($\beta = .107, 95\%$ CI [0.063, 0.154]; (3) and the specific indirect path through loneliness ($\beta = .115, 95\%$ CI [0.077, 0.156] which was also significant.

Table 38. Hypothesized Longitudinal Serial Mediation Model of Symptoms of Anxiety and Loneliness between CPDI and Symptoms of Depression in N = 632 Rehabilitation Patients (Full Sample).

Pathway	Effect	SE	BootLLCI	BootULCI
Total effect (c)	.289	.006	0.029	0.054
Direct effect (c')	.131	.006	0.008	0.030
a1	.315	.007	0.036	0.065
a2	.118	.007	0.005	0.031
a3	.226	.043	0.132	0.300
b1	.402	.034	0.293	0.429
b2	.169	.035	0.090	0.227
Indirect effects				
Total indirect effects	.159	.024	0.112	0.208
Indirect 1	.127	.021	0.086	0.171
Indirect 2	.020	.009	0.005	0.039
Indirect 3	.012	.004	0.005	0.022

Abbreviation: Indirect 1, CPDI → symptoms of anxiety → symptoms of depression; Indirect

2, CPDI→ loneliness → symptoms of depression; Indirect 3, CPDI→ symptoms of anxiety → loneliness → symptoms of loneliness. BootLLCI, bootstrapping lower limit confidence interval; BootULCI, bootstrapping upper limit confidence interval; SE, standard error; Effect, standardized regression coefficient.

Symptoms of anxiety, as well as loneliness, served as independent mediators of the relationship between CPDI and symptoms of depression in the validated analyses. All covariates (gender, age, educational level, ICD-10 diagnosis) were not significantly associated with either variable in the serial mediation model. Overall, 28.75% of the variance in symptoms of depression was accounted for.

Conclusion

To validate the findings from the original study investigating a serial mediation model only in patients who took part in the survey at both measurement timepoint (pre- and post-rehabilitation), a validation study was performed by assessing the serial mediation model with



Table 39. Bivariate Correlations among T1, T2, and Change Scores related to CPDI, Symptoms of Anxiety, Loneliness, Symptoms of Depression (N = 403).

	M ± SD	Range	1	2	3	4	5	6	7	8	9	10	11	12
1 COVID-19	32.48 ±	0-100	-											
Peritraumatic	13.18													
Distress														
Index (CPDI)														
T1														
2 Anxiety	3.48 ±	0-6	.580**	-										
(GAD) T1	1.68													
3 Loneliness	4.57 ±	2-8	.368**	.381**	-									
T1	1.76													
4 Depression	3.42 ±	0-6	.508**	.732**	.450**	-								
(PHQ) T1	1.66													
5 COVID-19	30.42 ±	0-100	.700**	.476**	.315**	.449**	-							
Peritraumatic	13.99													
Distress														
Index (CPDI)														
T2														
6 Anxiety	2.63 ±	0-6	.485**	.550**	.303**	.510**	.693**	-						
(GAD)	1.66													
_T2														
7 Loneliness	4.30 ±	2-8	.312**	.243**	.607**	.286**	.386**	.379**	-					
T2	1.70													

		$M\pm SD$	Range	1	2	3	4	5	6	7	8	9	10	11	12
8 Depre	ession	2.43 ±	0-6	.478**	.468**	.372**	.581**	.667**	.787**	.491**	-				
(PHQ)	T2	1.70													
9 Chang	ge	2.06 ±	-100 —	.321**	.091	.041	.039	452**	312**	123*	288**	-			
score		10.55	100												
COVID) -19														
Peritrau	ımatic														
Distress	S														
Index															
10 Chai	nge	0.85 ±	- 6 – 6	.108*	.481**	.089	.240**	220**	467**	136**	330**	.422**	-		
Score		1.58													
Anxiety	y														
(GAD)															
11 Chai	nge	0.25 ±	-8 – 8	.076*	.163**	.474**	.185**	076	098	411**	136	.199**	.278**	-	
Score		1.53													
Lonelin	ess														
12 Chai	nge	0.99 ±	- 6 – 6	.032	.276**	.080	.442**	244**	314**	228**	473**	.362**	.623**	.344**	-
Score		1.54													
Depress	sion														
(PHQ)															

Note. * p < .05 (two-tailed); ** p < .01 (two-tailed)