Process evaluation of a lifestyle physical activity counseling intervention for in-patients with major depressive disorders

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List of abbreviations

MDD	Major Depressive Disorder
COVID-19	Coronavirus Disease 2019
CI	Confidence interval
DALY	Disability adjusted life years
YLD	Years lived with disability
US	United States
HPA	Hypothalamic-pituitary-adrenal
BDNF	Brain-derived neurotrophic factor
SSRI	Serotonin reuptake inhibitors
SSNRI	Serotonin and noradrenaline reuptake inhibitors
g	Hedge's g
EPA	European Psychiatric Association
CRF	Cardio-respiratory fitness
VEGF	Vascular endothelial growth factor
WHO	World Health Organization
MET	Metabolic equivalent task
RPE	Rating of perceived exertion
HRR	Heart rate reserve
ACSM	American College for Sports Medicine
HIIT	High intensity interval training
MVPA	Moderate-to-vigorous physical activity
d	Cohen's d
SMD	Standard mean difference

GDP	Gross domestic product
OR	Odds ratio
MoVo	Motivation-Volition
BCW	Behavior Change Wheel
BMI	Body mass index
BCT	Behavior Change Techniques
PACINPAT	Physical activity counseling in in-patients with Major Depressive Disorders
RCT	Randomized controlled trial
SIMPAQ	Simple physical activity questionnaire
CAS	Certificate of Advanced Studies

Summary

Background: Major Depressive Disorder is a wide-spread and often chronic psychiatric disease affecting physical and psychosocial health. The global lifetime prevalence is 15-18% and approximately 12% of afflicted people are admitted to in-patient treatment at least once during their lifetime. Insufficient physical activity is prevalent among afflicted individuals, despite its potential antidepressant and protective effects. Theory-based interventions targeting psychosocial determinants of and implicit attitudes towards physical activity behavior can be effective in increasing physical activity levels. In particular, physical activity counseling has proven positive effects in healthy people as well as in out-patients. It remains unknown how a physical activity counseling intervention can be implemented and work during and after in-patient treatment, which contextual factors may be influential and how physical activity levels may be affected.

Aim: The aim of this PhD thesis was to conduct a process evaluation of a theory-based, tailored lifestyle physical activity counseling intervention for in-patients with Major Depressive Disorder within the PACINPAT (physical activity counseling for in-patients with Major Depressive Disorders) study. This was conducted according to the Medical Research Council Framework and entailed quantitatively and qualitatively evaluating contextual factors, intervention implementation, mechanisms of impact as well as behavioral outcomes (objectively measured and self-reported physical activity levels).

Methods: The PACINPAT study is a multi-center randomized controlled trial set in four Swiss psychiatric clinics. Adults who were insufficiently physically active upon admission to in-patient treatment were recruited (N = 244) and randomized into an intervention group (n = 123) who received tailored lifestyle physical activity counseling sessions (two in-person sessions and 26 sessions via telephone) for 12 months or a control group (n = 121) who received two in-person non-tailored counseling sessions during in-patient treatment. Quantitative data were collected at baseline (approximately 2 weeks after admission to in-patient treatment), post (approximately 6 weeks after discharge from in-patient treatment) and follow-up (12 months after discharge from in-patient treatment). Qualitative data were collected upon completion of the intervention and study participation. Data pertaining to psychosocial health (perceived

stress, health status and insomnia symptoms) as well as psychosocial determinants of physical activity were measured with validated and reliable questionnaires. Data pertaining to implicit attitudes towards physical activity were assessed with a computer-based Single Target Implicit Associations Test. Self-reported physical activity was assessed via structured interviews based on the Simple Physical Activity Questionnaire. Additionally, physical activity was measured with a hip worn accelerometer. Major Depressive Disorder symptoms were measured both by self-report with the Beck Depression Inventory as well as via structured interview based on the Hamilton Depression Scale. Data pertaining to the implementation of the intervention were collected from the implementers' documentation and participant satisfaction data were collected via questionnaire. Qualitative data were gathered via semi-structured interviews conducted in-person and online.

Results: The evaluation of contextual factors revealed that, the unforeseen contextual circumstance of a global pandemic caused by the Coronavirus Disease 2019 and ensuing state-mandated lockdown seems not have elicited differences in psychosocial health, psychosocial determinants of and implicit attitudes towards physical activity as well as self-reported physical activity levels among individuals who were in in-patient treatment at that time. Depression severity did, however, seem to negatively impact certain psychosocial determinants of physical activity. The evaluation of the intervention implementation showed that the intervention dose varied between early dropouts and completers with high and low participation rates. The in-person intervention fidelity was partly achieved and so adapted, whereas the remote intervention fidelity was well achieved. Additionally, the participants reported satisfaction with the intervention and implementers. Upon deeper investigation of the mechanism of impact, i.e., how the intervention was experienced, four experience patterns were recognizable (expansive, adoptive, stagnant and confirmatory), which influenced both physical activity behavior and well-being during and after the intervention. The evaluation of the short-term intervention outcomes (6 weeks after discharge from in-patient treatment) revealed that moderate-to-vigorous physical activity as well as step count decreased in both the intervention and control group, however less so in the intervention group, indicating that physical activity counseling may be a valuable asset to explore further. Additionally, psychosocial determinants of and implicit attitudes towards physical activity seemed to remain unchanged between the groups, but positive changes (decreases in negative outcome expectancies and increases in action and coping planning) were seen over time in both groups.

Conclusion: The theory-based, tailored lifestyle physical activity counseling intervention was implemented successfully during and after in-patient treatment. The process evaluation of the contextual factors, intervention implementation, mechanism of impact and short-term outcomes revealed valuable insights into future intervention refinement. This may entail adapting physical activity counseling to illness severity and how the individual is managing their illness. Especially with potentially declining physical activity behavior during the transition out of in-patient treatment, offering support during this vulnerable phase is particularly important. Further research is required, to ascertain the long-term effects of physical activity counseling in in-patients with Major Depressive Disorder. Followed by the adaptation and broader dissemination of physical activity promotion programs to reach those most in need.

Zusammenfassung

Hintergrund: Major Depressive Disorder ist eine weit verbreitete und oft chronische psychiatrische Erkrankung, die die körperliche und psychosoziale Gesundheit beeinträchtigt. Die globale Lebenszeitprävalenz liegt bei 15-18 % und ca. 12 % der Betroffenen werden mindestens einmal im Leben stationär behandelt. Betroffene sind oft unzureichend körperlich aktiv, trotz der möglichen sowohl antidepressiven als auch präventiven Wirkung der körperlichen Aktivität. Theoriebasierte Interventionen, die auf psychosoziale Determinanten der körperlichen Aktivität sowie auf automatische Bewertungsprozesse, die das Bewegungsverhalten steuern, abzielen, können eine Steigerung der körperlichen Aktivität bewirken. Insbesondere Bewegungscoaching zeigte positive Effekte bei Gesunden sowie bei ambulanten Patient*innen. Bis anhin wurde noch nicht untersucht, wie ein Bewegungscoaching während und nach einem stationären Klinikaufenthalt umgesetzt werden kann, wie die Intervention wirkt, welche kontextuellen Faktoren die Intervention beeinflussen und wie die Intervention sich auf die körperliche Aktivität auswirkt.

Ziel: Das Ziel dieser Doktorarbeit war es, eine Prozessevaluation einer theoriebasierten, individualisierten Lebensstilintervention mittels Bewegungscoachings für stationäre Patient*innen mit Major Depressive Disorders im Rahmen der PACINPAT (*physical acitvity counseling for in-patients with Major Depressive Disorder*) Studie durchzuführen. Dies wurde unter Einhaltung der Richtlinien des Medical Research Councils durchgeführt und beinhaltete eine quantitative und qualitative Bewertung der Kontextfaktoren, der Interventionsimplementierung, der Wirkmechanismen sowie der Ergebnisse des Verhaltens (objektiv gemessene sowie selbstberichtete körperliche Aktivität).

Methode: Die PACINPAT-Studie ist eine multizentrische, randomisierte, kontrollierte Studie, die in vier Schweizer Psychiatriekliniken durchgeführt wurde. Es wurden erwachsene Personen rekrutiert (N = 244), die bei Eintritt in die stationäre Behandlung nicht ausreichend körperlich aktiv waren, und in eine Interventions- oder Kontrollgruppe randomisiert. Die Proband*innen der Interventionsgruppe (n = 123) erhielten während 12 Monaten ein individualisiertes Coaching in zwei persönlichen und 26 telefonischen Sitzungen. Die Proband*innen der Kontrollgruppe (n = 121) erhielten während der stationären Behandlung zwei persönliche, nicht

individualisierte Coachinggespräche. Quantitative Daten wurden zu Studienbeginn (ca. 2 Wochen nach stationärem Eintritt), Post (ca. 6 Wochen nach stationärem Austritt) und Follow-up (12 Monate nach stationärem Austritt) erhoben. Qualitative Daten wurden nach Abschluss der Intervention und Studienteilnahme erhoben. Daten zur psychosozialen Gesundheit (wahrgenommener Stress, Gesundheitszustand und Symptome der Insomnie) sowie psychosoziale Determinanten der körperlichen Aktivität wurden mit validierten und reliablen Fragebögen erhoben. Daten zu automatischen Bewertungsprozessen wurden mittels einem computergestützten Single Target Implicit Associations Test erhoben. Die selbstberichtete körperliche Aktivität wurde durch ein strukturiertes Interview auf Grundlage des Simple Physical Activity Questionnaire erfasst. Zusätzlich wurde die körperliche Aktivität mit einem an der Hüfte getragenen Akzelerometers gemessen. Depressionssymptome wurden mit dem Beck Depression Inventory selbstberichtet erhoben sowie durch strukturierte Interviews auf Grundlage der Hamilton Depression Scale gemessen. Daten zur Interventionsimplementierung wurden aus der Dokumentation der Coaches entnommen und Daten zur Teilnahmezufriedenheit wurden via Fragebogen ermittelt. Qualitative Daten wurden über halbstrukturierte Interviews gesammelt, sowohl persönlich als auch online durchgeführt wurden.

Resultate: Die Evaluation der Kontextfaktoren ergab, dass die unvorhergesehenen Umstände der globalen Pandemie, verursacht durch das Coronavirus 2019 und dem daraus resultierenden staatlich verordneten Lockdown, keine Unterschiede in der psychosozialen Gesundheit, den psychosozialen Determinanten der körperlichen Aktivität, den automatischen Bewertungsprozessen und der selbstberichteten körperlichen Aktivität bei stationären Patient*innen ergab. Die Schwere der Depressionssymptome hatte jedoch negativen Einfluss auf bestimmte psychosoziale Determinanten der körperlichen Aktivität. Die Evaluation der Interventionsimplementierung zeigte, dass die Interventionsdosis zwischen Personen, welche früh aus der Intervention ausstiegen und Personen, welche die Intervention mit hohen und niedrigen Teilnahmequoten absolvierten, variierte. Die Interventionstreue bezüglich der persönlichen Coachinggespräche wurde teilweise erreicht und entsprechend angepasst, während die Interventionstreue bezüglich der telefonischen Coachinggespräche gut eingehalten wurde. Darüber hinaus gaben die Proband*innen an, mit der Intervention und den Coaches zufrieden gewesen zu sein. Bei vertiefter Untersuchung der Wirkmechanismen, also des Erlebens der Intervention, konnten vier Erfahrungsmuster (expansiv, adaptiv, stagnierend und bestätigend) festgestellt werden, welche sowohl das Bewegungsverhalten als auch das

Wohlbefinden während und nach der Intervention beeinflussten. Die Auswertung der kurzfristigen Interventionsergebnisse (6 Wochen nach stationärem Austritt) zeigte, dass sowohl in der Interventions- als auch in der Kontrollgruppe die moderate bis intensive körperliche Aktivität sowie die Schrittzahl abnahmen, jedoch weniger in der Interventionsgruppe. Dies weist darauf hin, dass das Coaching wertvoll sein kann, weshalb es den Coachingprozess weiter zu erforschen gilt. Darüber hinaus waren die psychosozialen Determinanten der körperlichen Aktivität und automatischen Bewertungsprozesse zwischen den Gruppen unverändert. Im Zeitverlauf wurden positive Veränderungen in Form einer Abnahme der negativen Ergebniserwartungen und einer Zunahme der Handlungs- und Bewältigungsplanung beobachtet.

Fazit: Die theoriebasierte, individualisierte Lebensstilintervention mittels Bewegungscoaching wurde erfolgreich während der stationären Behandlung und nach Klinikaustritt umgesetzt. Die Prozessevaluation der Kontextfaktoren, der Interventionimplementierung, der Wirkungsmechanismen und der kurzfristigen Ergebnisse der Verhaltensänderung ermöglicht wertvolle Schlussfolgerungen für die zukünftige Weiterentwicklung dieser und vergleichbarer Interventionen. Dies kann durch eine Anpassung des Coachings an die Schwere der Krankheit, oder durch die Mitberücksichtigung des individuellen Umgangs der Person mit ihrer Krankheit geschehen. Gerade bei möglicherweise nachlassendem Bewegungsverhalten beim Austritt aus der stationären Behandlung ist es umso wichtiger, in dieser vulnerablen Phase Unterstützung anzubieten. Weitere Forschung ist erforderlich, um die langfristigen Auswirkungen des Coachings bei stationären Patienten mit Major Depressive Disorders zu ermitteln. Daraufhin sollte die Anpassung und Verbreitung von Programmen zur Bewegungsförderung folgen, um die Personen zu erreichen, welche es am meisten benötigen.

Chapter 1 Introduction

This thesis is about the process evaluation of a lifestyle physical activity counseling intervention for in-patients with Major Depressive Disorder (MDD). In the following chapters information regarding the nature of MDD and the meaning of physical activity in general as well as specifically for individuals with MDD will be presented to gain a better understanding of the targeted population and behavior. This is followed by evidence and strategies for the design of a behavior change intervention. The study upon which this thesis is based began in 2018 and is ongoing until 2023. Accordingly, the Coronavirus Disease (COVID-19) which commenced in 2019 impacted the conduct of the study and relevant information is provided correspondingly.

1. Major Depressive Disorder

1.1. Diagnosis and course

The term “depression” originates from the word “depress”. It is used in the field of economy to indicate a “reduction in activity, amount, quality or force” associated with rising levels of unemployment. It is used in the field of biology to indicate “lowering of physical or mental vitality or of functional activity”. It can also be used to describe a place that is lower than the surrounding area or the action of pressing something down (Merriam-Webster Dictionary). Despite its wide use, the meaning remains similar: to be pressed down or lowered. Its application in the field of psychology is said to come from observations of behaviors being pressed down by life and circumstance (Ramnerö et al., 2016). The psychiatric diagnosis “Major Depressive Disorder” (MDD) used today is, in short, a mood disorder - its cardinal symptom: depressed or low mood (American Psychiatric Association, 2013).

Diagnosis

Diagnosis occurs based on the presence of five or more of the following symptoms: depressed mood; anhedonia (the inability to feel pleasure); feelings of worthlessness or guilt; suicidal ideation, plan or attempt; fatigue or loss of energy; disturbances in sleep; disturbances in weight and appetite; reduced ability to think or concentrate or indecisiveness; psycho-motoric retardation or agitation. The symptoms must occur almost daily over two weeks and at least one of the symptoms must be a fundamental one (depressed mood, anhedonia). Symptoms are often accompanied by functional impairments, which are more likely with increasing number and severity of symptoms. MDD is further specified in terms of illness pattern (single episode, recurrent episode, rapid cycling, seasonal), clinical features (anxious, atypical, melancholic,

catatonic, psychotic), severity (mild, moderate, severe), onset (early, late, post-partum) and remission status (partial, full; American Psychiatric Association, 2013).

Course

The onset of MDD may be gradual or sudden and episodes are variable in number, duration and pattern. Hence, the course of MDD is considered to be inherently unpredictable. Recovery from an episode is defined as the lack of symptoms and regained functioning. With treatment, episodes last approximately 3 to 6 months. The risk of recurrence increases with every episode and it is estimated that about 80% of people who experienced an episode will experience at least one more in their lifetime. When regarding one episode, approximately 50% of the affected individuals recover within 6 months, 75% within 12 months, however, 30% may not recover and develop chronic MDD. Long-term recovery rates are approximately 60% at 2 years, 40% at 4 years and 30% at 6 years (Malhi & Mann, 2018).

1.2. Prevalence and implications

Global prevalence

According to the World Mental Health Survey, global lifetime risk of MDD is 15-18%, which means that almost one in five people experience one episode in their lifetime. In high income countries estimations of the average lifetime and 12-month prevalence of MDD are 14.6% and 5.5% correspondingly. In all included countries the female to male ratio is approximately 2 to 1 on average for having a major depressive episode (Bromet et al., 2011). There is known seasonal variation in the prevalence of MDD, with highest proportions being reported in December, January and February and lowest in June, July and August. The prevalence in January may be up to 70% higher than in August (Patten et al., 2017). This is according to survey data collected in Canada and can therefore only be generalized for geographic areas with similar seasonal environmental variations. More recently, increased prevalence of MDD has been associated with daily COVID-19 infections ($\beta = 18.1$, 95% Confidence Interval (*CI*) = 7.9 to 28.3, $p < 0.01$) and pandemic-induced reduced mobility ($\beta = 0.9$, 95% *CI* = 0.1 to 1.8, $p = 0.029$). Females are affected more than males and younger age groups more than older age groups. A COVID-19-induced increase of 27.6% (53.2 million cases) was estimated globally, resulting in a prevalence of 3’153 cases per 100’000 people and 49 million disability adjusted life years (DALYs) worldwide (Santomauro et al., 2021).

Regional prevalence

According to the Federal Office for Statistics in Switzerland, MDD is the most commonly occurring psychiatric disorder with 9% of the population afflicted in 2017. The prevalence in women (9%) and young people (13%) is higher than in men (8%) and people over 65 (4%) (Bundesamt für Statistik, 2017). According to the Swiss Health Observatory report (Obsan Bericht) low educational status, migration background, unemployment or invalidity, restrictions caused by physical health problems and loneliness are risk factors for MDD in the Swiss population (Schuler et al., 2020). In line with global data relating to the effects of the COVID-19 pandemic, according to a study conducted in the south of Switzerland, prevalence of moderate to severe MDD increased from 7.5% in August 2020 to 12.5% in May 2021. People with chronic diseases were particularly at risk (odds ratio (*OR*) = 1.82, 95% *CI* = 1.12 to 2.96) for MDD when compared with individuals without chronic disease (Piumatti et al., 2022).

Individual implications

According to a systematic analysis for the Global Burden of Disease Study 2017, depressive disorders were found globally to be one of the leading causes of years lived with disability (YLD) for both women and men. Along with lower back pain and headache disorders, depressive disorders have remained a leading cause for non-fatal health loss globally for the past three decades leading to an accumulation of 162 million YLDs in 2017, representing almost one in five YLD globally (James et al., 2018). According to the Global Burden of Disease Study 2019 mental disorders are still one of the top ten foremost causes of burden globally (Global Burden of Disease 2019 Mental Disorder Collaborators, 2022). Besides the inherent burden of MDD, it is also associated with heart disease (Charlson et al., 2013; Correll et al., 2017; Gerber et al., 2021), hypertension (Meng et al., 2012), stroke (Dong et al., 2012), diabetes (Vancampfort et al., 2015a), Alzheimer's disease (Sáiz-Vázquez et al., 2021), obesity (Luppino et al., 2010) and cancer (Wang et al., 2020). Overall mortality caused by MDD is estimated at a pooled relative risk of 1.52 (95% *CI* = 1.45 to 1.59; Cuijpers et al., 2014). MDD is a known risk factor for suicide (Brådvik, 2018) and is the leading cause of death by suicide globally (Ferrari et al., 2013). It is estimated that 1.4% of premature deaths are suicides and that half the completed suicides are related to mood disorders (Bachmann, 2018). Overall, MDD and especially severe and comorbid MDD negatively affect quality of life, which is lower than that of the general population (IsHak et al., 2011; Sivertsen et al., 2015). Individuals with MDD report experiencing misery, despair and tears; anger and violence towards self and others; a bleak view of everything; and isolation and cutting off from the world (Midgley et al., 2015). In addition, MDD affects workplace productivity, with increased absenteeism, lower income

and higher rates of unemployment (Lépine & Briley, 2011). MDD severity has been negatively associated with level of work performance ($p < 0.001$, $R^2 = 0.20$) irrespective of age, sex, industry and work position. Lastly, depression symptoms (impaired concentration, anhedonia, depressed mood and self-criticism) may explain presenteeism, i.e., being physically present at the workplace, yet not working at full capacity (Johnston et al., 2019).

Societal implications

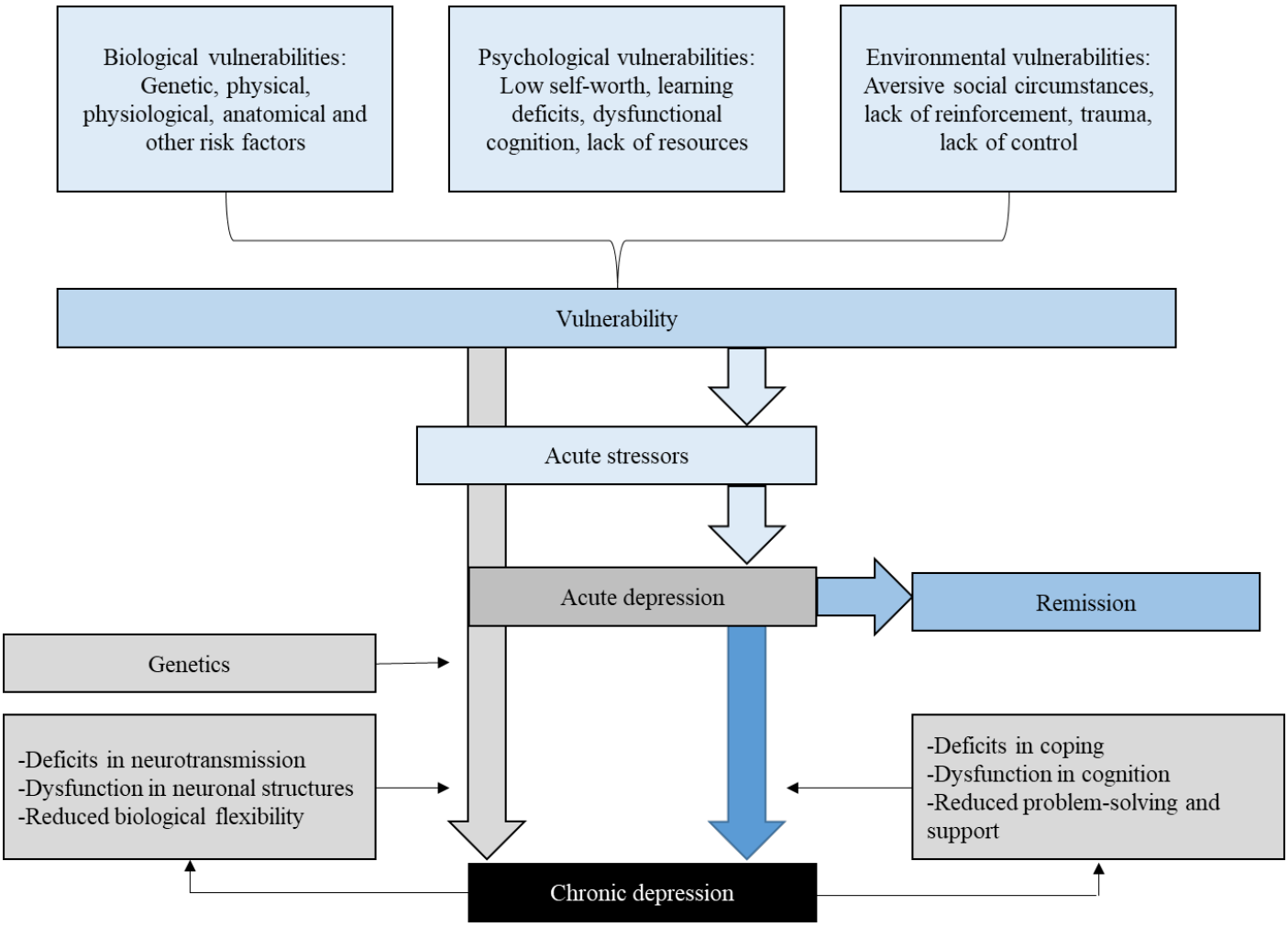
Productivity losses along with increased health care costs have a societal impact (Abdin et al., 2021). Meta-analytic data suggest higher direct costs (ratio of means = 2.58, 95% *CI* = 2.01 to 3.31) and indirect costs (ratio of means = 2.28, 95% *CI* = 1.75 to 2.98) for individuals with MDD compared with without MDD (König et al., 2019). In the United States (US) total health care costs were estimated to be double for people with moderate to severe MDD (9'010 U.S. dollars) compared with those with few or no MDD symptoms (4'654 U.S. dollars; Schousboe et al., 2019). In Switzerland psychiatric care costs 2 billion Swiss Francs, which constituted 6% of the overall compulsory health insurance costs in 2018 (Schuler et al., 2020).

1.3. Etiology and treatment

Etiology

The etiology of MDD is complex and not understood fully. In an attempt to capture holistically the many levels explaining the origins of MDD, the biopsychosocial-vulnerability-stress model was developed. According to this model certain biological, psychological and social circumstances lead to vulnerability, which, when combined with acute life stressors may lead to acute depression (or an episode of MDD). The experienced episode may go into remission or become chronic. Treatment options are typically linked to etiological assumptions with pharmaceutical medication addressing biological aspects and psychotherapy addressing psychosocial and environmental factors (Brakemeier et al., 2008).

Figure 1. The etiology of MDD according to Brakemeier et al. (2008)



Biological vulnerabilities include the genetic heritability hypothesis (Sullivan et al., 2000; Kendler et al., 2001; McGuffin et al., 2007; Menke et al., 2012; Shadrina et al., 2018); the monoamine hypothesis stating that low synaptic concentrations of serotonin, noradrenaline and dopamine lead to MDD (Hirschfeld, 2000; Andrews et al., 2015; Muma & Mi, 2015), which has been questioned in a recent meta-analysis (Moncrieff et al., 2022); the hypothalamic-pituitary-adrenal (HPA) axis hypothesis stating that elevated levels of cortisol and a blunted cortisol-suppression response lead to MDD (Varghese & Brown, 2001; Carroll et al., 2007; Penninx et al., 2013; Nandam et al., 2019; Bertollo et al., 2020); the cytokine hypothesis stating that heightened immune responses lead to MDD (Schiepers et al., 2005; Slavich & Irwin, 2014; Cassano et al., 2017; Zou et al., 2018; Roohi et al., 2021; Yui et al., 2022); and the neurogenic hypothesis stating that reduced brain-derived neurotrophic factor (BDNF) leading to reduced neurogenesis and hippocampal volume lead to MDD (Duman et al., 1997; Malberg et al., 2000; Lucassen et al., 2009; Kishi et al., 2018; Ferrer et al., 2019; Emon et al., 2020).

Psychological vulnerabilities include a fragile sense of self-worth (Freud, 1917; Park & Yang, 2017; Nguyen et al., 2019; Harrison et al., 2022); learning deficits including lack of availability and responsiveness to positive reinforcement and reward (Lewinsohn, 1975; Pizzagalli et al., 2008; Dichter et al., 2009; Huston et al., 2013; Pizzagalli & Roberts, 2022) as well as uncontrollable, aversive events eliciting defeatist behaviors (Miller & Seligman, 1975); and dysfunctional cognition characterized by negative thoughts, attitudes and beliefs towards the self, the world and the future (Siegle et al., 2002; Goeleven et al., 2006; Joormann & Gotlib, 2008; Gotlib & Joormann, 2010; Gärtner et al., 2018).

Environmental vulnerabilities include deprivation; low socio-economic status (Baum et al., 1999; Lee et al., 2021); (childhood) trauma (Kessler, 1997; Negele et al., 2015) in particular emotional abuse (LeMoult et al., 2020) offering an explanation for excessive stress followed by dysregulation in the HPA axis (Kuzminskaite et al., 2021) and leading to emotional problems in adulthood mediated by unemployment and poor relational functioning (Golm et al., 2020).

Additionally, from a behavioral perspective time spent being sedentary (relative risk = 1.10 95% *CI* = 1.03 to 1.19; Huang et al., 2020) as well as insufficient physical activity (adjusted *OR* = 0.83, 95% CI = 0.79 to 0.88, when comparing low with high levels of physical activity; Schuch et al., 2018) have been positively associated with increased risk of MDD.

Treatment

According to Swiss treatment recommendations, there are four basic treatment elements for MDD depending on symptom severity: watchful waiting in the case of mild MDD, pharmaceutical antidepressants, psychotherapy and the combination thereof for moderate to severe MDD. Some of the most common pharmaceutical antidepressants are selective serotonin reuptake inhibitors (SSRI), selective serotonin and noradrenaline reuptake inhibitors (SSNRI) and tricyclic antidepressants. There are three recognized evidence-based approaches to psychotherapy in Switzerland: psychoanalysis, cognitive behavioral therapy and systemic therapy (Holsboer-Trachsler et al., 2016). MDD is treated in out-patient, in-patient and partial in-patient settings. Out-patient treatment generally takes place in practices and is provided typically by general practitioners and psychologists or psychiatrists trained in psychotherapy. In-patient and partial in-patient treatment generally take place in psychiatric clinics. General practitioners and psychotherapists may refer a patient to in-patient treatment in the presence of severe depression symptoms, co-morbidity, lacking improvement with psychotherapy or antidepressants or if the patient is a danger to themselves (acute suicidality) or others. Additional indications for in-patient treatment may be when out-patient services cannot provide

the necessary close supervision or when precarious life situations (e.g., family conflict, domestic violence, threat of loss of employment or living space) prevail (Bundesärztekammer, 2022).

In 30% - 50% of cases a lack of response to antidepressants is observed, in which case either an alternative antidepressant, or a combination or augmentation with another antidepressant can be chosen or the psychotherapeutic approach may be re-evaluated (Holsboer-Trachsler et al., 2016; Rafeyan et al., 2020). Lack of response may be characterized as less than 25% improvement in depression symptoms, partial response as more than 25% but less than 50% (Jackson et al., 2020). However, given the additional issues of medication induced side effects including restlessness, sexual dysfunction as well as negative neurological and gastrointestinal impacts, non-adherence to medication and limitations within psychotherapy, additional augmentation therapies have been sought. These include herbal remedies for mild MDD, electroconvulsive therapy for severe MDD, light therapy for seasonal affective disorder and therapeutic sleep deprivation (Holsboer-Trachsler et al., 2016). Especially because of the negative side effects of the standard treatments, the multifaceted etiology and prevalent chronicity of MDD, more emphasis on additional therapies is warranted. A "Lifestyle Medicine" approach, including physical activity, dietary modification, adequate relaxation and sleep, social interaction, mindfulness-based meditation and the reduction of recreational substances (e.g., nicotine, drugs, alcohol) has been suggested. Along with standard treatments these therapeutic options may address the complexity of human illness and wellbeing in a much needed integrative manner (Sarris et al., 2014). Physical activity in particular is known to promote psychological as well as physical health in people with a wide range of mental health disorders (Schuch & Vancampfort, 2021) and has been deemed an acceptable and effective treatment by afflicted patients (Searle et al., 2011).

Physical activity as a treatment option

Since the early 2000s, physical activity has been found to decrease depressive symptoms compared with no treatment (Lawlor & Hopker, 2001; Rethorst et al., 2009). Furthermore, physical activity can be as effective in reducing depressive symptoms as antidepressant medication (Blumenthal et al., 1999; Dimeo et al., 2001; Singh et al., 2001; Mather et al., 2002; Blumenthal et al., 2007; Cooney et al., 2013; Schuch et al., 2015). In difficult to treat cases such as treatment-resistant MDD, increases in remission rates were found in groups performing aerobic, structured exercise, albeit non-significant compared with groups receiving antidepressants only (Mota-Pereira et al., 2011). Not only short-term effects of physical activity have been observed, lower relapse rates (Babyak et al., 2000) and higher remission rates have

been associated with physical activity (Hoffman et al., 2011) at 10 and 12 month follow-ups, respectively. Overall, evidence points towards physical activity having a moderate-to-large effect in the short-term (Hedge's g *(g)* = -0.68) and a small effect in the long-term (*g* = -0.22; Kvam et al., 2016). Not only is exercise a viable treatment option, it also has the potential to prevent (Mammen & Faulkner, 2013) and predict (Hoffman et al., 2011) future depressive episodes. Now, almost 20 years later, the European Psychiatric Association (EPA) has released guidance on physical activity as treatment for mental illness based on a meta-review. It states that physical activity can reduce depressive symptoms in people with MDD compared with control conditions and is comparable with antidepressant and psychotherapy effects (Stubbs et al., 2018).

Working mechanisms of physical activity as a treatment option

Physical activity positively impacts cardio-respiratory fitness (CRF), which improves cardiovascular health (Kodama et al., 2009; Stubbs et al., 2016) and is associated with lower levels of burnout, depressive symptoms as well as an enhanced capacity to cope with stress (Gerber et al., 2013). There is evidence of increased levels of serotonin (Patrick & Ames, 2015) and dopamine (Heyman et al., 2012) after exercising. Further exercise-induced mood enhancement results from an activation of the endocannabinoid system when exercising at vigorous intensities (Dietrich & McDaniel, 2004; Heyman et al., 2012). Physical activity activates the HPA axis to elevate blood sugar for energy, however with increased fitness, stress-induced cortisol responses are lowered (Hötting et al., 2016). Similarly, inflammatory factors increase with exercise, however, in this circumstance they do not trigger inflammation but anti-inflammatory antagonists, ultimately inhibiting inflammatory markers (Lancaster & Febbraio, 2014). When exercise is performed in such a way that the HPA axis is not overstimulated, neurogenesis may result through exercise-induced releases of beta-endorphins, vascular endothelial growth factor (VEGF), BDNF and serotonin (Ernst et al., 2006; Lou et al., 2008). Consequently, in the time after exercising, executive function may improve (Kubesch et al., 2003; Kramer & Colcombe, 2018).

Physical exercise offers the opportunity to enhance self-efficacy through personal mastery (Rodgers et al., 2014). It may also elicit improvements in self-perception and body-image leading to improvements in self-esteem, quality of life and affect (Zamani Sani et al., 2016). Improvements in quality of life are further associated with physical activity-induced improvements in sleep, pain, energy and body satisfaction (Carta et al., 2008). Positive affect can be achieved with even a single bout of exercise (Brand et al., 2018). Based on these and other similar research findings, increasing emphasis on the immediate effects of exercise on

quality of life over the long term health benefits has been encouraged (Stevens & Bryan, 2012). Additionally, physical activity has the potential to distract from negative thoughts and endow a sense of purpose (Dietrich, 2003; Dietrich & Sparling, 2004; Searle et al., 2011). Furthermore, according to meta-analytic data and a systematic review, improved social interaction is consistently and positively associated with physical activity in adolescents and adults (Eime et al., 2013; Mendonça et al., 2014; Scarapicchia et al., 2017).

2. Physical activity and its absence

The above presented evidence shows that MDD is burdensome, wide-spread and standard treatment options have some limitations. A lifestyle measure such as physical activity has the potential to reduce MDD symptoms by addressing a plethora of processes which may be involved in the etiology of MDD and is increasingly recommended as a treatment option. In the present chapter, more information will be provided on the definition, dose and measurement of physical activity. Importantly, the issue of insufficient physical activity, which is prevalent among people with MDD, will be addressed and underlying mechanisms of physical activity will be highlighted, giving first insights into how changing physical activity behavior may be approached.

2.1. Definition, dose and measurement

Definition

According to the World Health Organization (WHO) physical activity is defined as "any bodily movement produced by skeletal muscles that requires energy expenditure" and can be performed in leisure time, as transportation or at work (Caspersen et al., 1985). Physical activity intensity refers to the rate of metabolic energy required for the movement and can be categorized as light, moderate or vigorous. Moderate and vigorous intensities are separated by ventilatory or lactate thresholds, best measured in incremental tests. Moderate intensity corresponds to about 3 to < 6 metabolic equivalent of task (METs, where 1 MET is about the energy expenditure while at rest), or 5-6 on a rating of perceived exertion (RPE) 10-point scale, or between 40 and 59% of heart rate reserve (HRR, maximum heart rate minus resting heart rate). In more practical terms, moderate intensity may be achieved by brisk walking, dancing or raking a yard. Vigorous intensity corresponds to > 6 METs, or 7-8 on a RPE, or 60 to 84% of HRR. Practical examples include jogging, fast swimming or shoveling snow (MacIntosh et al., 2021). Typically, the general public may not be aware of the measures MET, RPE and HRR. Therefore, intensity can be estimated by the talking test: below the ventilatory or lactate

threshold (when the ventilatory requirement for movement is not yet so strong), one can talk comfortably (i.e., moderate intensity), while at or above said threshold (when ventilatory requirements are all used up for movement), one cannot talk comfortably anymore (i.e., vigorous intensity; Reed & Pipe, 2014). According to the American College of Sports Medicine (ACSM), aerobic exercise is any movement including the large muscle groups, which can be done continuously and is powered by the supply and use of oxygen. Anaerobic exercise, on the other hand, is movement of very short duration at high intensity, fueled by energy from within the contracting muscle. Examples for this are sprinting and high intensity interval training (HIIT; Patel et al., 2017). More recently, a broader definition of physical activity has been suggested with the aim of moving away from the solely biomedical values ("bodily movement", "skeletal muscles" and "energy expenditure") to a more holistic view to adequately capture the complexity of physical activity behavior. The suggested definition is as follows:

> "Physical activity involves people moving, acting and performing within culturally specific spaces and contexts, and influenced by a unique array of interests, emotions, ideas, instructions and relationships." (Piggin, 2020, page 5).

With this definition the author aims to include the cerebral, social, situated, and political aspects of physical activity. Although the WHO definition is vital for the epidemiology of physical activity, this definition adds new ways of thinking about physical activity which may be particularly important when teaching, researching, and devising policy for physical activity. It offers the opportunity to consider interdisciplinary cooperation, which may be considered to be underplayed in the field of physical activity promotion so far (Piggin, 2020).

Dose

To reap the health benefits of physical activity, the recently updated WHO recommendations state at least 75 to 150 minutes of moderate-to-vigorous physical activity (MVPA) per week for adults aged 18 to 64 years. Additionally, muscle strengthening exercises involving all major muscle groups are recommended twice a week or more frequently. Furthermore, it is recommended to limit time spent being sedentary and replace this with being physically active (Bull et al., 2020). These recommendations may be carried out during the week or on a single weekend (the so called "weekend warriors") and may reduce all-cause mortality with a hazard ratio of 0.85 (95% *CI* = 0.83 to 0.88) and 0.92 (95% *CI* = 0.83 to 1.02) respectively, compared with physically inactive individuals. These analyses are based on self-reported physical activity data (Dos Santos et al., 2022). A threshold for reduced mortality has been found at 3 to 5 times

the recommended dose and no harmful effects at up to 10 times the recommended dose, according to self-reported physical activity (Arem et al., 2015).

Generally, the WHO recommendations are also valid in the treatment of MDD, as exemplified in a study comparing the "public health dose" (equivalent to WHO recommendations) with a "low dose". Results showed that the energy expenditure of the "public health dose", irrespective of frequency, yielded significant decreases in depression severity (47% from baseline) after 12 weeks (Dunn et al., 2005). According to more recent meta-analytic data, 45 minutes of aerobic exercise at moderate intensity performed 3 times per week for 9 weeks may result in a large antidepressant effect (g = -0.79, 95% *CI* = -1.01 to -0.57; Morres et al., 2019). Especially, in some cases such as non-remitted MDD or in people requiring increased physiological improvements, evidence suggests higher intensities to be more beneficial (Trivedi et al., 2011; Krogh et al., 2012). However, there is also evidence to suggest that there is no significant difference between physical activity intensities in relation to MDD outcomes. In one study, significant decreases in MDD scores were detected for light (-4.05, 95% *CI* = -5.94 to -2.17), moderate (-2.08, 95% *CI* = -3.98 to -0.18) and vigorous (-3.13, 95% *CI* = -5.07 to – 1.19) intensities compared with treatment as usual and no significant differences were found among groups (Helgadottir et al., 2016). This phenomenon may be explained by the affective response induced by physical activity. It is noteworthy, that exercise may not only elicit pleasant but also unpleasant affective responses, which may influence participation (Ekkekakis et al., 2020). Exercise below the blood lactate accumulation threshold results almost homogeneously in pleasant affective responses whereas, physical activity performed above this threshold but below critical power is subject to inter-individual variability regarding quality of affective response. And any activity performed between critical power and maximal oxygen uptake results almost homogeneously in negative affective responses (Ekkekakis, 2009). Along these lines, exercising at preferred intensities compared with prescribed intensities has been shown to be more effective (Cohen's d (*d)* = 0.86) at alleviating depressive symptoms (Callaghan et al., 2011). When considering modality, sprint interval training and continuous aerobic exercise in in-patients with MDD have elicited similar outcomes with regard to motivation, positive affect, cardiorespiratory fitness, perceived fitness, depression symptoms and self-reported physical activity levels, indicating that both exercise modalities are effective in these areas (Gerber et al., 2018b). It may be inferred that various modalities seem to be effective in eliciting physiological and psychological benefits, however, a sufficient total volume may be recommended (Hoffman et al., 2011). This is confirmed in more recent meta-analytic evidence

stating that moderate-to-vigorous aerobic physical activity has a large and significant effect on reducing symptoms of MDD (Schuch et al., 2016; Stubbs et al., 2018).

Measurement

Physical activity is typically measured objectively with wearable devices such as pedometers or accelerometers (Aadland & Ylvisåker, 2015) or via self-report with questionnaires and surveys (Haskell, 2012). Objective measures are considered more accurate and particularly recommended for people with mental illness (Soundy et al., 2014). Self-reports are easily obtained, however they are subject to recall and social desirability bias as well as the varying perception of intensities (Haskell, 2012; Gorzelitz et al., 2018). Generally, there is consensus that more standardized, quantitative methods of gathering physical activity data are needed (Guthold et al., 2018; Silfee et al., 2018).

2.2. Prevalence and implications of insufficient physical activity

Global prevalence

According to a pooled analysis of almost 2 million people, the world-wide age-standardized prevalence for self-reported insufficient physical activity was 27.5% (95% *CI* = 25.0 to 32.2) in 2016. Evidence pointed towards women (31.7%, 95% *CI* = 28.6 to 39.0) having higher rates of insufficient physical activity compared with men (23.4%, 95% *CI* = 21.1 to 30.7). The levels of insufficient physical activity increased in western high-income countries from 31.6% (95% *CI* = 27.1 to 37.2) in 2001 to 42.3% (95% *CI* = 39.1 to 45.4) in 2016 (Guthold et al., 2018). According to meta-analytic data from adults the average objectively measured sedentary time may range from 8.5 to 10.5 hours per day and MVPA from 8 to 35 minutes per day (Ekelund et al., 2020). The COVID-19 pandemic has had varying effects on physical activity levels. A review including objectively measured and self-reported physical activity, suggests that the COVID-19 pandemic and ensuing lockdown led to increases in walking and moderate physical activity but also in sedentary time (Stockwell et al., 2021). There is also some evidence that there was an increased use of parks and trails and therefore increased recreational physical activity (Park et al., 2022). According to a large online survey, however, the COVID-19 induced lockdown had a negative effect on all intensities of physical activity while self-reported sedentary time increased from 5 to 8 hours per day (Ammar et al., 2020).

Global prevalence in individuals with MDD

People with MDD are at particular risk of insufficient physical activity. According to meta-analytic data including both objectively measured and self-reported physical activity, when comparing individuals with and without MDD, the former spent less time being physically active (standard mean difference (*SMD*) = -0.25, 95% *CI* = -0.03 to 0.15) and spent more time being sedentary (*SMD* = 0.09, 95% *CI* = 0.01 to 0.18). Additionally, the rate of people with MDD not adhering to physical activity recommendations was estimated to be 85.7% in objective measures (Schuch et al., 2017). The relationship between MDD and physical activity is bi-directional: individuals with high levels of physical activity have low odds of developing MDD (adjusted *OR* = 0.83, 95% CI = 0.79 to 0.88; Schuch et al., 2018). Further evidence suggests that those individuals adhering to at least half the WHO recommendations, may have 18% (95% *CI* = 13 to 23) lower risk of developing MDD (Pearce et al., 2022).

Regional prevalence

In Switzerland, according to a national survey, physical inactivity has decreased from 38% in 2002 to 24% in 2017 (Bundesamt für Statistik, 2018). In a small Swiss study of 76 office workers, it was found that according to self-report 17% of the participants became less active during the COVID-19-induced lockdown and 29% became more physically active. Whereby 75% of the participants adhered to the WHO recommendations both before and during the lockdown (Aegerter et al., 2021). Further self-reported physical activity data from Switzerland reveal that the lockdown led to more time spent in walking and moderate physical activity (approximately 10 minutes per day) as well as sedentary behavior (approximately 75 minutes per day; Cheval et al., 2020), which is in line with the afore-mentioned global reports.

Implications

It is estimated that globally, 7.2% of all-cause mortality and 7.6% of mortality caused by cardiovascular disease is attributable to physical inactivity. As for non-communicable diseases, 1.6% of hypertension cases and 8.1% of dementia cases are estimated to be attributable to physical inactivity (Katzmarzyk et al., 2022). Further, it is estimated that 6% of coronary heart disease cases, 7% of type II diabetes cases, 10% of breast cancer cases and 10% of colon cancer cases may be attributable to physical inactivity. It is not only physical inactivity that is problematic, mortality risk also increases with increasing sedentary time. Hazard ratios for all-cause mortality in relation to sedentary time above 10 hours per day have been estimated to be 1.65 (95% *CI* = 1.24 to 2.21; Chau et al., 2015). It is estimated that about 30 to 40 minutes of MVPA per day may attenuate the association between sedentary time and mortality risk (Ekelund et al., 2020). Additionally, if people were to adhere to the WHO physical activity

recommendations, it is estimated that the global gross domestic product (GDP) would increase between 0.15 and 0.24% annually by 2050 corresponding to about 314 to 446 billion US dollars per year. These estimates are based on the analysis of work place productivity and mortality risk (Hafner et al., 2020). Additionally, physical inactivity in patients with COVID-19, has been known to lead to increased risk of hospitalization (*OR* = 2.26, 95% *CI* = 1.81 to 2.83), admission to intensive care units (*OR* = 1.73, 95% *CI* = 1.18 to 2.55) and death (*OR* = 2.49, 95% *CI* = 1.33 to 4.67) when compared with patients meeting the WHO recommendations (Sallis et al., 2021).

2.3. Underlying mechanisms of physical activity behavior

The above presented evidence shows that insufficient physical activity is prevalent, particularly among people with MDD and has far-reaching negative implications. Prevalent insufficient physical activity among people with MDD is particularly troublesome because, as stated in Chapter 1, physical activity can be an effective treatment for MDD. Therefore, it seems worthwhile to address physical activity behavior in this population. Along these lines it is of importance to better understand and consider internal and external behavioral influences on physical activity. For this purpose the use of theoretical frameworks was introduced to the field of exercise psychology (Rhodes et al., 2019). Benefits of a theory-based approach are the definition of determinants, their structure and how they are expected to operate, hypothesis testing as well as replication and generalization of studies (Rhodes & Nigg, 2011; Hagger et al., 2020). In the present chapter, some of the most important theoretical constructs are introduced and the one used in the design of the intervention which was evaluated in this thesis is highlighted.

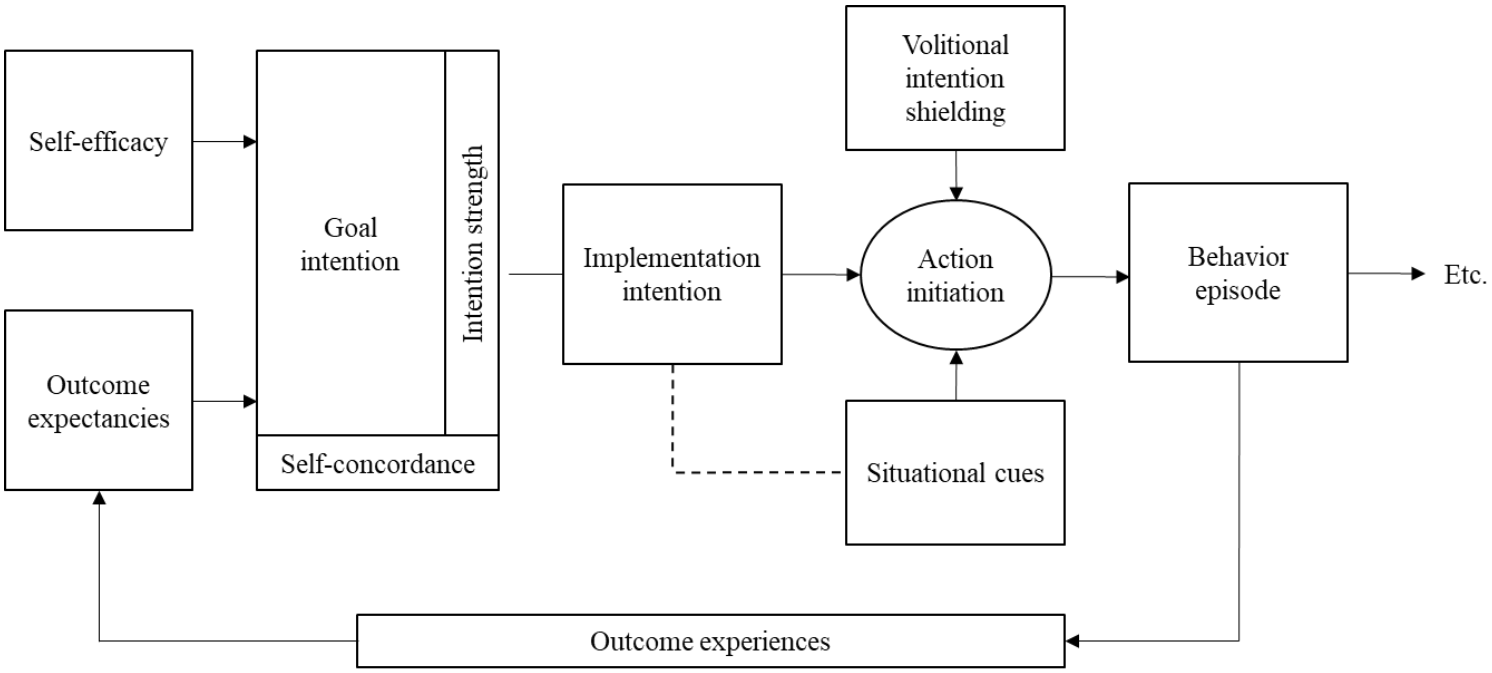
With the expansion beyond behavioral explanations of physical activity, cognition-based explanations were sought in social cognitive frameworks (Spear, 2007). The premise was that individuals acted based on expectations, toward the behavioral outcome (e.g., risks and benefits) as well as toward the capability to perform the behavior (e.g. self-efficacy and competency; Ajzen, 1991; Bandura, 2000). This is to say, individuals intend to be physically active if they believe physical activity to be beneficial and that they are capable of being physically active. Since influencing peoples' behavior via their expectations has not changed behavior to the desired degree (according to meta-analytic data: effect size *d* = -0.02; Conn et al., 2011), a humanistic framework was introduced based on assumptions that humans are not only motivated by what is believed to be good for them but also by the innate drive to realize their potential (Maslow, 1943). The most prominent theory born from this movement was the theory of self-determination (Ryan & Deci, 2000). Two of the most frequently applied sub-

theories are those of the three psychological needs: relatedness, autonomy and competence as well as the motivation continuum ranging from amotivation (lack of motivation) to extrinsic motivation (derived from external sources) to intrinsic motivation (performing an activity for its own sake; Ryan et al., 2009). According to a systematic review, intrinsic motivation is consistently associated with long-term physical activity behavior and competence is a consistent positive predictor for physical activity (Teixeira et al., 2012).

One theory, derived from both the social cognitive as well as the humanistic framework is the Motivation-Volition (MoVo) process model (Figure 2), which was used in the design of the intervention which was evaluated in this thesis. According to this model, high self-efficacy and positive outcome expectancies lead to a self-concordant and strong goal intention, this in turn leads to an implementation intention including action planning and shielding the intention from situational cues in the form of coping planning. In combination this leads to an episode of the desired behavior. With positive outcome experiences, positive outcome expectations are boosted and the behavior is repeated (Fuchs et al., 2007). Goal intention is the main motivational construct which, in line with social cognitivism, results from weighing benefits and costs of the behavior (outcome expectancies) and the appraisal of one's own abilities (self-efficacy). The goal intention does not only need to be strong but also self-concordant, which refers to the extent to which the goal is in line with personal interests and values (Sheldon & Elliot, 1999). Highly self-concordant goals have been linked with an increased likelihood of achieving them (Sheldon & Houser-Marko, 2001). This is in line with the motivation continuum of the self-determination theory whereby amotivation and external motivation correspond with no or low self-concordance and intrinsic motivation corresponds with high self-concordance (Ryan & Deci, 2000). Volition, said to be the bridge between motivation and behavior, is represented by implementation intentions constituting plans of when, where and how the intended behavior will be carried out (Fuchs et al., 2007). This was derived from evidence pointing towards planning increasing the likelihood of executing behaviors (Milne et al., 2002), which has since been confirmed in multiple studies (Krämer et al., 2014b; Pfeffer & Strobach, 2020; Wee & Dillon, 2022). During implementation, self-regulation plays an important part in initiating and maintaining the intended behavior (Sniehotta et al., 2005), because despite sufficient planning, both internal (e.g., low energy) and external (e.g., workload) barriers may interfere with executing plans (Fuchs et al., 2007; Schwarzer, 2008). Intention shielding may constitute mood management, cognitive restructuring, and stimulus as well as attention control (Schwarzer, 2008). Lastly, outcome experiences which influence outcome expectancies, are of particular importance for behavioral maintenance (Rothman, 2000). Outcome expectancies, or

mindset towards a behavior, may not only determine whether the behavior is performed or not, it may even influence its effects (Crum & Langer, 2007). Furthermore, it has been found that the fulfillment of emotional outcome expectancies is particularly important for the long-term adaptation of physical activity behavior (Klusmann et al., 2015).

Figure 2. The Motivation-Volition Process model according to Fuchs et al. (2007)



Limitations in cognitivist and humanistic frameworks and particularly the observed persisting lack of maintenance of physical activity behavior (Richards et al., 2013; Murray et al., 2017) led to the introduction of dual process frameworks of physical activity. These posit that information is processed in two separate yet linked ways: consciously (reflectively) and non-consciously (automatically; Strack & Deutsch, 2004; Deutsch & Strack, 2006; Hagger, 2016). The conscious, reflective processes are based on the afore-mentioned social-cognitive and self-determination determinants of physical activity (beliefs, expectations, self-efficacy, intention, motivational regulation), whereas the non-conscious processes relate to less tested determinants such as habit and automatic valuations (Rebar et al., 2016). A habit can be understood as a behavior resulting from reinforcement-based learned associations which are provoked in response to a certain stimulus (Hull, 1943; Smith & Graybiel, 2016; Wood & Rünger, 2016). According to a study examining habit formation, it may take between 18 and 254 days until behavior becomes automatic, i.e., a habit. The variation depends on personal factors as well as the complexity of the behavior being performed. Additionally, repetition of the behavior in early stages is more important for increased automaticity than at a later stage (Lally et al., 2010).

In a cross-sectional study, intention was statistically significantly associated with behavior (β= 0.15, p = 0.04) in groups with average or above average habit strength compared with those with below average habit strength (β = -0.03, p = 0.75; Jung et al., 2021). Automatic valuations are expressions of learned associations between a stimulus and affective experiences (Conroy & Berry, 2017). Consequentially the impulse to engage in a behavior or not can be traced back to approach (upon positive valuation) and avoidance (upon negative valuation) tendencies (Rebar, 2017). This mechanism is also referred to as implicit attitudes or bias (Berry et al., 2011; Rebar, 2017). Positive associations with physical activity have been associated with greater physical activity participation (Antoniewicz & Brand, 2016a; Rebar et al., 2016; Brand & Ekkekakis, 2018; Chevance et al., 2018; Chevance et al., 2019). Differences in associations have been said to explain exercise behavior, with individuals exhibiting initially negative associations changing to more positive associations performing more physical activity ($F_{(2, 38)}$ = 7.84, $p < 0.001$, η_p^2 = 0.29) than those with unchanged, positive associations. This provides evidence that it is both possible and beneficial to change physical activity associations (Hyde et al., 2012; Antoniewicz & Brand, 2016b). Non-conscious processes have also been put into context with hedonic motivational patterns (Brand & Ekkekakis, 2018), with affect during exercise being predictive of future exercise behavior (Ekkekakis et al., 2020).

Finally, socioecological frameworks for physical activity may be considered. Here the premise is that physical activity behavior is influenced not only by personal factors but also interpersonal, organizational, community and policy factors (Bronfenbrenner, 1977; McLeroy et al., 1988). In addition to the cognitive and psychological personal aspect already discussed, lack of time is one of the most frequently cited reasons for physical inactivity in adults. Among unemployed people, additionally, cost is a frequently reported barrier (Borodulin et al., 2016). Furthermore, health status, personal physical activity history, age and sex have been reported as relevant correlates of physical activity in adults (Bauman et al., 2012). Interpersonal factors, such as social support provided by family, friends, and colleagues, may vary depending on individual preferences (Bauman et al., 2012; Stapleton et al., 2015; Fennell et al., 2016; Smith et al., 2017; Steltenpohl et al., 2019; Van Luchene & Delens, 2021). Researchers who have examined these frameworks to date, do suggest that personal and interpersonal factors are the dominant determinants, however, also that the built environment plays an important role in providing opportunities for physical activity (Giles-Corti & Donovan, 2002; McNeill et al., 2006). A systematic review found that intention-behavior relations were greater when access to recreational spaces was closer as opposed to further away and those who did not enjoy being

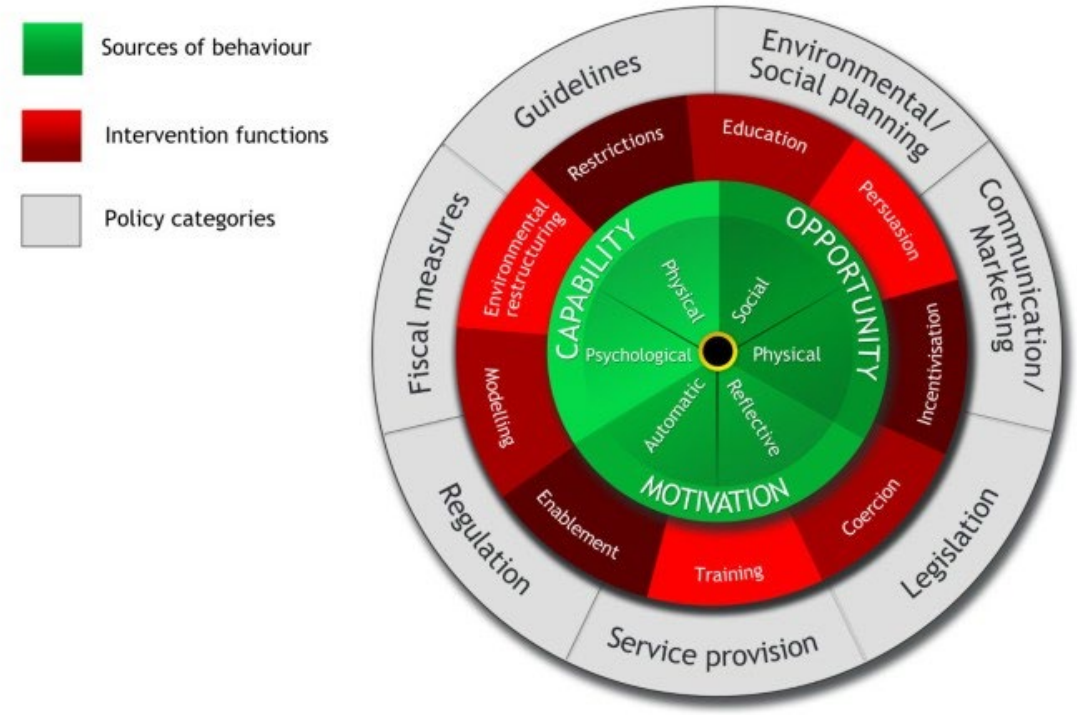
physically active were more likely to be physically active in environments with better aesthetics compared with those who did enjoy being physically active anyway (Rhodes et al., 2018).

In conclusion it can be stated that changing health behavior, especially physical activity, is considered to be complex, given the extent and interplay of determinants (Bauman et al., 2012). And it takes more than a sole recommendation from health professionals to make a real difference (Aittasalo et al., 2016). Therefore, it is of great importance to develop and implement behavior change interventions that are equal to the challenge.

3. Behavior change intervention design

There are many strategies to design a behavior change intervention. A strategy which is particularly broad and thus allows for the consideration of the multiple determinants of behavior described above is derived from the Behavior Change Wheel (BCW, Figure 3), which was used in the design of the intervention which was evaluated in this thesis. The BCW is a framework encompassing various health behavior theory concepts. It consists of a center where the sources of behavior are explained, followed by intervention functions and policy categories (Michie et al., 2011). In the following chapters the design of the intervention which was evaluated in this thesis will be described according to the BCW.

Figure 3. The Behavior Change Wheel according to Michie et al. (2011)



3.1. Sources of behavior

According to the technique by Michie et al. (2011) developing a behavior change intervention starts by understanding the population and the intended behavior (Michie et al., 2011). For the design of the intervention which was evaluated in this thesis, the population consisted of in-patients with MDD and the intended behavior was lifestyle physical activity. When addressing the sources of physical activity behavior (center of the wheel) in people with MDD considerations are required.

Physical and psychological capacity

In a review of relevant literature, factors negatively influencing the physical activity behavior of people with MDD are high body mass index (BMI) and physical co-morbidities (Vancampfort et al., 2015b). With regard to high BMI and obesity, becoming physically active feels different with different body compositions, hence physical activity may elicit negative affect if the dose is too high or not self-selected (Ekkekakis & Lind, 2006). This experience may reinforce negative outcome expectancies and thus lead to behaviors not being repeated (Fuchs et al., 2011). Further depressive symptoms such as fatigue and low energy may be barriers to physical activity (Bláfoss et al., 2019; Frikkel et al., 2020). Increased psychosocial stress has been associated with reduced physical activity (Stults-Kolehmainen & Sinha, 2014). More specifically, along with low mood, stress was reported as one of the main reasons preventing people with severe mental illness from being physically active (Firth et al., 2016). Additionally, qualitative findings state that a lack of knowledge or being unsure of what to do were reported as barriers for people with MDD. Furthermore, not identifying as a “sporty” person, feeling self-conscious and not prioritizing physical activity were reported as barriers (Glowacki et al., 2017).

Social and physical opportunity

Meta-analytic data show that lack of support (reported by 50% of participants) is one of the main barriers to physical activity in people with severe mental illness (Firth et al., 2016). This is corroborated with data from a review stating lack of encouragement and support from others as barriers to physical activity. Additionally, lack of environmental access and lack of equipment (e.g., clothes) were reported as barriers (Glowacki et al., 2017). Along these lines, living in urbanized areas has been associated with both risk of MDD and physical inactivity (Rhodes et al., 2018; Hoare et al., 2019).

Reflective and automatic motivation

In a review of relevant literature, factors negatively influencing the physical activity behavior of people with MDD are high levels of depressive symptoms as well as low self-efficacy (Vancampfort et al., 2015b). The dysfunctional cognition characterized by negative thoughts towards the self and the future (Gotlib & Joormann, 2010) and learned helplessness (Miller & Seligman, 1975) may result in low exercise-related self-efficacy and predominantly negative outcome expectancies towards physical activity (Krämer et al., 2014a; Krämer et al., 2014b). According to social-cognitive theory, this in turn may result in reduced intention to be physically active (Ajzen, 1991; Bandura, 2000). Impaired executive functions may make it difficult to plan, follow through and shield intended behavior (Krämer et al., 2014a; Krämer et al., 2014b). Additionally, people with MDD have exhibited increased levels of habitual sitting, making the move to physical activity more difficult (Vancampfort et al., 2017). Evidence suggests that when self-regulatory resources (i.e., drivers of the reflective system such as beliefs and intention) are depleted, the impulse derived from automatic valuations are stronger than reflected plans (Vohs, 2006). If people with MDD have a habit of being more sedentary than physically active and self-regulatory resources are depleted (e.g., used for behaviors other than physical activity) the impulse to remain physically insufficiently active may be strong. Furthermore, the reduction in responsiveness to positive reinforcement (Pizzagalli & Roberts, 2022) may hamper the formation of positive attitudes towards physical activity and so act as a barrier to movement (Rebar, 2017). There are no data to support the relationship between implicit attitudes and physical activity, as it is seen in healthy individuals, in patients with psychiatric disorders and generally evidence in this area is scarce (Gerber et al., 2018a).

These considerations facilitate a better understanding of why people with MDD may be physically inactive and areas upon which to focus potentially when aiming to change physical activity behavior in this population.

3.2. Intervention functions

According to Michie et al. (2011) there are nine possible intervention functions, which affect at least one of the sources of behavior: education, persuasion, incentivization, coercion, training, enablement, modeling, environmental restructuring and restrictions. Ninety-three Behavior Change Techniques (BCTs), which are considered the smallest observable and replicable active ingredients of a behavior change intervention, are assigned to these functions (Michie et al., 2011). Behavior Change Techniques have been hierarchically structured into a taxonomy for ease of use and to create a common language (Michie et al., 2013). This allows

for an intervention to target multiple different behavioral determinants. Additionally, a consistent reporting format of intervention content is particularly beneficial for the implementation as well as the evaluation of interventions (Michie et al., 2015). The challenge, however, is to identify which BCTs work in which context for which people targeting which behavior (Michie et al., 2018). According to meta-analytic data the most effective BCTs to promote physical activity self-efficacy with small effect (overall d = 0.23, 95% CI = 0.16 to 0.29) are "action planning", "time management", "prompting self-monitoring of behavioral outcome" and "planning social support / social change" (Olander et al., 2013). Further meta-analytic data have concluded that for physical activity motivation the following BCTs are to be considered for an effective intervention with effect sizes ranging from d = 0.12 to d = 0.46: "behavioral goal setting", "self-monitoring of the behavior", and "behavioral practice / rehearsal" (Knittle et al., 2018). To promote physical activity directly in the short term "teaching to use prompts/cues", "prompt practice" and "prompt rewards contingent on effort or progress towards behavior" (overall d = 0.50, 95% CI = 0.38 to 0.63; Olander et al., 2013), "goal setting", "self-monitoring of behavior" (overall d = 0.37, 95% CI = 0.26 to 0.48; Samdal et al., 2017), "biofeedback," "demonstration of the behavior," "behavior practice/rehearsal," and "graded tasks" (overall d = 0.32, 95% CI = 0.16 to 0.48; Howlett et al., 2019) have been deemed particularly effective. And to promote physical activity directly in the long term "goal setting of outcome", "feedback on outcome of behavior", "implementing graded tasks", "adding objects to the environment" (overall d = 0.24, 95% CI = 0.15 to 0.33; Samdal et al., 2017), "action planning," "instruction on how to perform the behavior," "prompts/ cues," "behavior practice/rehearsal" and "self-reward" (overall d = 0.21, 95% CI = 0.12 to 0.30; Howlett et al., 2019) seem to yield greatest intervention efficacy. The number of BCTs used has been said to affect outcomes (β = 0.033, 95% CI = 0.008 to 0.059) and evidence points to more favorable outcomes when more BCTs are used compared with fewer (Webb et al., 2010; Samdal et al., 2017; Sharp et al., 2020).

3.3. Policy categories

According to Michie et al. (2011) there are seven policy categories to support at least one of the intervention functions: legislation, communication / marketing, environmental / social planning, guidelines, fiscal measures, regulation and service provision. Although the name suggests that they are intended primarily for national policy they are used to support the organization of any behavior change intervention (Michie et al., 2011). Examples of policy categories for physical activity promotion are guidelines provided by organizations like the

WHO comprising recommendations for physical activity dose (WHO, 2010) or environmental / social planning involving the creation of safe footpaths to facilitate walking in urban areas (Devarajan et al., 2020). For the intervention evaluated in this thesis, the policy category "service provision" was used as the supporting category for behavior change. There are many components of a behavior change intervention, which contribute to its efficacy such as the above mentioned active ingredients as well as intervention type, dose, adaptation and delivery. These will be presented in the present chapter.

Efficacy of physical activity interventions

Meta-analytic evidence suggests that physical activity interventions in general have an overall small yet significant effect (mean effect size $d = 0.19$, equating to 496 steps per day) in healthy adults (Conn et al., 2011). According to meta-analytic data, physical activity interventions compared with control conditions had larger effects on behavior maintenance 6 to 9 months after the intervention (*SMD* = 0.28, 95% *CI* = 0.20 to 0.35) compared with 9 to 15 months (*SMD* = 0.20, 95% *CI* = 0.13 to 0.26; Murray et al., 2017). Results from a more recent meta-analysis point towards a larger effect of physical activity interventions for behavior change ($d = 0.32$, 95% *CI* = 0.16 to 0.48) and similar results for behavior change maintenance ($d = 0.21$, 95% *CI* = 0.12 to 0.30; Howlett et al., 2019). In a meta-analysis on the efficacy of physical activity interventions for men, the overall mean effect was even higher ($d = 0.35$, 95% *CI* = 0.26 to 0.45), corresponding approximately to 97 minutes per week or 980 steps per day (Sharp et al., 2020). In sedentary adults an overall small to moderate effect ($d = 0.31$) has been established (Hillsdon et al., 2005). Whereas for adults with chronic illness, a moderate effect ($d = 0.45$, equating to 48 minutes of physical activity per week) was found (Conn et al., 2008). In a review of qualitative literature, it was found that people with mental illness taking part in a physical activity program particularly appreciated social interaction and support; the sense of meaning, purpose and achievement; the feeling of safety (physically and psychologically); improved symptoms; and rebuilding a sense of self or identity (Mason & Holt, 2012).

Efficacy of physical activity counseling interventions

Lifestyle or behavioral physical activity interventions in particular are recommended for physical activity promotion (Conn et al., 2008; Conn et al., 2011; Heath et al., 2012; Stonerock & Blumenthal, 2017). For example, physical activity counseling, which is considered an educational, professional, client-centered and goal-oriented approach in which there is a cooperative relationship between the client and the coach providing the counseling sessions. The aim is to support the client in problem-solving / coping skills and to foster independent initiative. Such counseling sessions may take place spontaneously in a single contact or planned

in repeated contacts of varying durations (Nupponen, 1998). Importantly, there is a distinction between an expert approach, in which the service provider uses their skills to identify a client's problem and solve it and a coach approach, in which the service provider uses their skills to empower the client to tackle a problem in a cooperative way with the goal of lasting behavior change. The coach approach may be considered as curious, open, appreciative, compassionate and honest (Phillips et al., 2020).

A physical activity counseling intervention was developed based on the above presented MoVo process model, which includes goal setting, action planning, barrier management and self-monitoring as the active ingredients delivered in two group and one individual counseling session (Fuchs et al., 2011). This counseling approach has been effective in orthopedic rehabilitation patients resulting in a self-reported weekly increase of 28 minutes ($p = 0.05$) of physical activity in the intervention group compared with the control group at 12 months follow-up (Fuchs et al., 2011). A mediation analysis showed that the underlying MoVo process model had a substantial total effect on physical activity behavior ($\beta = 0.33$, $p < 0.01$; Fuchs et al., 2012). Similar effects have been evidenced in different populations. In adults with obesity, an increase of 26 minutes of exercise per week was reported 12 months after completion of the MoVo intervention (exercise at baseline: 82 minutes/week, 12 months after baseline: 108 minutes/week; Gerber et al., 2010). In insufficiently physically active cardiac patients, those who received the MoVo counseling intervention reported 175 minutes more physical activity per week directly after the intervention and 94 minutes more physical activity at 12 months follow-up compared with the control group. This constitutes a large ($d = 1.03$) short-term and medium ($d = 0.57$) long-term intervention effect (Wurst et al., 2019).

In a further physical activity counseling intervention using BCTs evidenced to promote physical activity as active ingredients delivered via telephone during 6 months to healthy insufficiently active adults resulted in an initial increase of 32 minutes of accelerometer-based physical activity per week (95% *CI* = 0.1 to 63) the intervention compared with the control group (Fischer et al., 2019). Physical activity levels decreased back to baseline levels at 12 months follow-up, however still remained significantly improved compared to the control group whose physical activity levels fell below baseline (Fischer et al., 2019). Physical activity maintenance beyond the intervention period has however been achieved in a different physical activity counseling intervention in healthy adults, in which objectively measured physical activity increased in the intervention group and persisted 1 year after completion of the intervention compared with the control group (Tripette et al., 2021).

Physical activity counseling has been implemented in individuals with MDD in an ambulatory setting. Results showed that participants in the intervention group reported increased physical activity (adjusted *OR* = 2.27, 95% *CI* = 1.32 to 3.89) during the follow-up period (Chalder et al., 2012). The intervention was based on motivational interviewing, a person-centered approach encouraging individuals to explore and resolve ambivalence towards health behaviors (Miller & Moyers, 2017), which is a frequently used technique in physical activity counseling (Haase et al., 2010; Rasinaho et al., 2012; Stonerock & Blumenthal, 2017; Hoekstra et al., 2021) and evidence points towards associations with increased adherence to, motivation for and levels of physical activity (Sevick et al., 2007; Hardcastle et al., 2008; O'Halloran et al., 2014; Soderlund, 2018). In another study applying motivational interviewing, physical activity counseling for MDD was delivered to people with multiple sclerosis. The main outcome was MDD score, however, results also showed significant increases in physical activity levels in the intervention group (Bombardier et al., 2013).

Intervention dose

To date there is no known optimum number of contacts and length of intervention to promote physical activity successfully (Kettle et al., 2022). There is some evidence that physical activity counseling over the course of 12 months may be preferable compared with a brief counseling session for adults in general (Fortier et al., 2007). Whereas physical activity counseling equal to or less than 12 weeks with 1 or more contact per week is reported to be preferred by the people targeted by the intervention, in particular by men (Sharp et al., 2020). Typically, the MoVo intervention is delivered in three sessions (Fuchs et al., 2011). Other physical activity counseling intervention durations range from 12 weeks with 9 sessions for people with multiple sclerosis (Bombardier et al., 2013), 6 months with 12 sessions for healthy adults (Fischer et al., 2019), 8 months with 13 sessions for out-patients with MDD (Chalder et al., 2012), 1 year with 5 sessions for healthy adults (Tripette et al., 2021), 1 year with 9 sessions for cardiac patients (Reid et al., 2012) and 2 years with 6 sessions for elderly individuals (Rasinaho et al., 2012) . All these doses have achieved increases in subjective and / or objective physical activity at post and follow-up. In addition to potential dose-effect relationships, constraints in terms of resources for intervention development and the amount of counseling to which participants can be exposed may be considered (Crutzen et al., 2017).

Intervention adaptation

To adapt the content to the population optimally, tailored interventions may be implemented. Tailoring may be considered as collecting and assessing information pertaining to the person

(characteristics, needs, preferences and context) and their behavior so as to create content which is particularly relevant to the receiver. Hence, not a "one size fits all" approach, but an individualized approach (Kreuter & Wray, 2003). This seems particularly salient in physical activity promotion because of the many types of underlying mechanisms which are affected differently according to the individual. Generally, three strategies can be applied when tailoring: Firstly, personalization. For example, calling the person by name and tailoring the message to their demographic context. Secondly, feedback. This can be given descriptively, e.g., acknowledging information, comparatively, e.g., creating social comparison or in an evaluative way, e.g., reminding the receiver of their beliefs and attitudes. Thirdly, content matching. This entails matching the content to the receiver's status on a key theoretical determinant (e.g., identifying deficits in intention, skill, ability, and environmental facilitators). These strategies are often combined (Hawkins et al., 2008). Evidence of the efficacy of tailoring to date is inconsistent. A meta-analysis and reviews suggest that tailored interventions are effective (Kroeze et al., 2006; Noar et al., 2007; Krebs et al., 2010; Richards et al., 2013) and may be superior to control conditions (Richards et al., 2007). Studies in which BCTs were explicitly used generally also support the efficacy of tailoring (Michie et al., 2009; Michie et al., 2013; Olander et al., 2013). Conversely, according to meta-analytic data, generic interventions (d = 0.2) were more effective than tailored ones (d = 0.04; Conn et al., 2011). Furthermore, tailored interventions have been shown to have small effects (g = 0.21, 95% CI = 0.07 to 0.27; Webb et al., 2010). However, there is evidence suggesting that tailored interventions may be particularly useful in promoting physical activity in people with chronic disease and disability (Allen et al., 2018; Li et al., 2018; Ma et al., 2019). This indicates it may also be worthwhile for individuals with MDD. Some evidence suggests that interventions for people with MDD may best be tailored to motivational and volitional aspects of behavior change with a focus on pessimistic beliefs and planning deficits (Krämer et al., 2014b).

Intervention delivery

Physical activity counseling entails a person-centered style of supporting the individual's autonomy, which is considered to be particularly important in behavior change (Samdal et al., 2017). In so doing the implementer of the intervention prioritizes patient-determined goals, incorporates self-discovery, facilitates active learning processes, and encourages accountability for behaviors. Typically, an implementer is trained in behavior change theories and techniques as well as in communication. Importantly, physical activity counseling takes place within a consistent relationship, which may positively contribute to outcomes (Wolever et al., 2013).

Particularly for individuals with MDD, an emphasis is put on professional support to identify and achieve physical activity goals (Firth et al., 2016).

Individual-based physical activity interventions have traditionally been performed face-to-face, however new technologies, such as mobile phones and the internet, are increasingly used as delivery methods (Foster et al., 2013). The benefits of so-called remote delivery methods are that interventions are time and location independent and can be delivered broadly, to many individuals in a cost-effective way (Vandelanotte et al., 2007; Brouwer et al., 2010; Rochester, 2022).

Both face-to-face and telephone-based physical activity counseling have led to increases in self-reported physical activity, self-efficacy, and social support as well as decreases in self-reported sedentary time and trait anxiety (Opdenacker & Boen, 2008). In addition to telephone counseling, mobile applications may be implemented. So, for example, physical activity counseling delivered by mobile technology resulted in more perceived improvement in physical activity behavior compared with without (Verwey et al., 2016). Interventions using mobile technology only may even evoke moderate effect size increases (d = 0.47) in planned exercise and leisure time physical activity compared with paper-based interventions (Plow & Golding, 2017). According to meta-analytic data, interventions based on mobile phones may elicit an average increase of 10.49 minutes (95% CI = 3.37 to 17.60) of physical activity as well as 735.17 steps (95% CI = 227.72 to 1242.61) per day over time (Feter et al., 2019). However, most recent meta-analytic data point towards increased efficacy of application-based interventions, when personal components (e.g., in-person session, phone call or personalized text message) are included (Laranjo et al., 2021).

Furthermore, internet delivered interventions may also be considered. Meta-analytic data suggest an overall small yet significant mean effect (d =0.14) of internet-delivered interventions to promote physical activity (Davies et al., 2012). Moreover , interventions supplemented by communication, like short message service, proved to be even more effective (Webb et al., 2010). Despite this, high dropout rates have been reported in digital interventions and concerns have been raised about usability, security and privacy (Davies et al., 2012; Ossebaard et al., 2013; Paganini et al., 2021).

To benefit from both the personal contact in in-person and telephone counseling as well as time and cost effectiveness in digital interventions, so called blended care interventions, including personal and digital components have been introduced with small effect sizes in the field of physical activity promotion (Kloek et al., 2017; Hohberg et al., 2022a). Examples of successful blended care interventions to promote physical activity in healthy adults (Fischer et al., 2019)

and out-patients with MDD (Chalder et al., 2012) as well as to reduce MDD symptoms in people with multiple sclerosis (Bombardier et al., 2013) have been described above.

Overall, it can be said that physical activity interventions in general and counseling interventions in particular, which are tailored to individual needs, delivered both in-person and remotely with support from technology can be effective in increasing physical activity levels in various populations including those with psychiatric disorders.

4. Call to action

Following persistently low levels of physical activity globally, the WHO has called for measures to be put in place to reduce the prevalence of insufficient physical activity by 15% by 2030 with an emphasis on the need to contextualize physical activity in, among others, individuals with chronic disease (Hämäläinen et al., 2020). It has been said that physical activity recommendations alone are insufficient to elicit the required change in physical activity behavior and there is a need for personnel in public health, sport science and sports and exercise medicine to provide physical activity programs (Lambert et al., 2020).

When considering one chronic disease in particular, namely MDD, evidence shows that it is a prevalent and burdensome disease (Malhi & Mann, 2018) with particularly high rates of insufficient physical activity (Schuch et al., 2017) despite potential therapeutic effects (see for example Stubbs et al., 2018). According to health behavior theories, a plethora of physical activity determinants have been identified (see for example Rhodes et al., 2019), which may be impacted negatively by MDD (see for example Krämer et al., 2014a). Physical activity counseling allows for targeting cognitive, psychological, affective and environmental determinants of physical activity through the application of the appropriate BCTs (Michie et al., 2008), a tailored approach (Olander et al., 2013), a personal relationship (Wolever et al., 2013), and the in-person as well as remote delivery options with the potential for digital supplementation (Hohberg et al., 2022a). Physical activity counseling has been effective in increasing levels of physical activity in various populations (Gerber et al., 2010; Fuchs et al., 2011; Fischer et al., 2019; Wurst et al., 2019) including chronically ill adults (Conn et al., 2008), out-patients with MDD (Chalder et al., 2012) as well as patients with depression symptoms albeit according to self-report (Bombardier et al., 2013).

To date it is unknown how physical activity counseling affects determinants and objective levels of physical activity in in-patients with MDD. This is of particular interest because it is estimated that approximately 12% of people with MDD will be admitted to in-patient treatment

at least once during their lifetime (Chakravarthy et al., 2014). The main reasons are severity of illness, inadequate social support and lacking response to out-patient treatment (American Psychiatric Association, 2013). Additionally, one of the risks after discharge from psychiatric in-patient treatment is re-hospitalization (Donisi et al., 2016). According to meta-analytic data, implementing a physical activity promotion intervention during in-patient treatment in general may have a small yet significant effect. The authors conclude that providing an intervention both during and after in-patient treatment, using a theoretical model, multiple BCTs and coaching by a professional are favorable strategies for physical activity outcomes (de Leeuwerk et al., 2022).

5. The PACINPAT study

The "physical activity counseling in in-patients with major depressive disorders" (PACINPAT) randomized controlled trial (RCT) addresses this gap. It was designed as a multi-center RCT taking place in four Swiss psychiatric clinics in cooperation with the Department of Sport, Exercise and Health of the University of Basel.

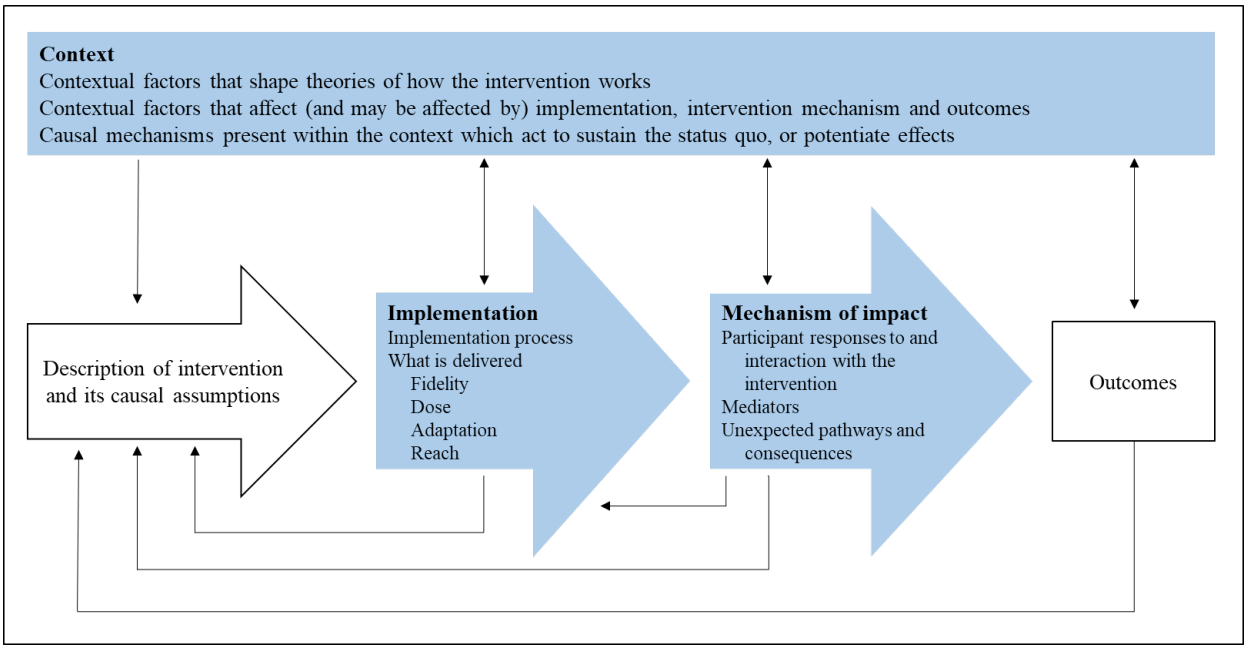
In-patients with MDD were recruited and assessed at the four study sites. The aim was to increase lifestyle physical activity in initially insufficiently physically active in-patients with MDD receiving a 12-month theory-based and tailored physical activity counseling intervention delivered by trained physical activity coaches. The intervention consisted of two theoretical bases as well as two delivery modes. The initial phase of the intervention was designed based on the MoVo process model and corresponding intervention to target cognitive and psychological determinants of physical activity. It consisted of three counseling sessions (two in-person during in-patient treatment, and one via telephone after in-patient treatment). The second part of the intervention was designed based on the BCW including 30 core BCTs proven to influence physical activity behavior positively, additionally targeting affective and environmental determinants of physical activity (26 bi-weekly telephone calls as continuation after in-patient treatment). In addition, a mobile application was implemented for self-monitoring of the behavior and outcome and weekly personalized text messages were sent to the study participants by the coaches. Outcomes of individuals receiving this intervention were compared with equally insufficiently physically active in-patients with MDD, who were allocated to a control group. The control group received two in-person counseling sessions in which the general health benefits of physical activity were discussed.

The primary outcome of the PACINPAT study was physical activity levels measured by hip-worn accelerometers. Secondary outcomes included: self-reported physical activity, cardiorespiratory fitness, autonomic function, perceived fitness, psychosocial determinants of exercise (motivation, volition, and social support), depression severity, perceived stress, perceived health status, insomnia symptoms, cognitive function, blood pressure, anthropometrics, blood lipids and glucose, MDD blood markers including BDNF, tumor necrosis factor alpha and insulin-like growth factor 1. Additionally, the study design included a qualitative nested study with the aim of eliciting an understanding of the intervention from the participants' point of view. Quantitative data were collected at baseline (approximately 2 weeks after admission to in-patient treatment) and 6 weeks (post) and 12 months (follow-up) after discharge from in-patient treatment. Qualitative data were gathered from a sub-sample upon completion of the intervention and trial participation.

Chapter 2 Aims of the PhD thesis

The aim of this PhD thesis was to evaluate the process of the PACINPAT intervention quantitatively and qualitatively according to the Medical Research Council (MRC) guidance for the process evaluation of complex interventions (Moore et al., 2015). Interventions are considered complex based on the number of components, range of behavioral outcomes, required expertise and skill, number of groups, setting and permitted level of flexibility (Skivington et al., 2021). The above described PACINPAT trial consists of multiple components, i.e., the MoVo intervention, BCTs, in-person counseling sessions embedded in individual in-patient programs, telephone counseling sessions, the use of a mobile application and the receipt of text messages. There was one behavioral outcome, however, based on the evidence provided in the Introduction, because physical activity behavior may be considered as inherently complex. Additionally, the intervention was implemented in four psychiatric clinics (two private, two public) in different regions of Switzerland with diverse personnel and clinical structures as well as procedures. This resulted in complex processes regarding both participant recruitment and the coordination of data collection. Lastly, even though the intervention was theory-based, and the coaches were monitored regularly, there was flexibility in the intervention content (coaches' choice of appropriate BCT during telephone counseling sessions) and there were multiple coaches delivering the intervention to all participants. As seen in Figure 4, the framework consists of a description of the intervention and its causal assumptions and evaluations of the contextual factors, implementation, mechanism of impact, and outcomes (Moore et al., 2015).

Figure 4. Key functions of process evaluation according to Moore et al. (2015)



Aims

Aim 1: Description of the PACINPAT study

The first aim was to design and describe the multi-center randomized controlled trial including the intervention and its causal assumptions.

Aim 2: Evaluation of contextual factors

The second aim was two-fold. Firstly, to ascertain whether the state-mandated COVID-19 lockdown elicited differences in psychosocial health (perceived stress, insomnia symptoms, and health related quality of life), psychosocial determinants (motivation, volition, and social support) of and implicit attitudes towards physical activity as well as self-reported physical activity in in-patients with MDD. Secondly, to examine whether psychosocial physical activity determinants (motivation, volition, and social support) of and implicit attitudes towards physical activity differed according to MDD severity.

Aim 3: Evaluation of the implementation

The third aim was three-fold. Firstly, to evaluate the intervention according to its reach, dose, fidelity and adaptation. Secondly, to analyze whether the duration and content of the counseling sessions differed according to subgroups of varying intervention attendance. Thirdly, to present participants' satisfaction with the intervention.

Aim 4: Evaluation of the mechanism of impact

The fourth aim was to investigate how the participants randomized to the intervention group and who completed the intervention to varying degrees experienced the intervention.

Aim 5: Evaluation of short-term outcomes

The fifth aim was to evaluate the short-term outcomes of the intervention with regard to psychosocial determinants of (motivation, volition, and social support) and implicit attitudes towards physical activity and accelerometer as well as self-reported physical activity levels.

Outline and hypotheses

Step 1

In accordance with Aim 1, we published the study protocol, which can be considered as the first step of the process evaluation as we described the intervention and its causal assumptions. Furthermore, we provided a rationale for the study, described the design including the setting, participants and recruitment, explained all procedures including data collection and assessment as well as measurement instruments and presented a schedule with milestones (see Publication 1).

Step 2

In accordance with Aim 2, we evaluated arising contextual factors. That is to say, a year after the study was launched, the COVID-19 pandemic broke out and various restrictions followed including a state-mandated lockdown. All non-essential research activities in the clinics and at the University of Basel were temporarily discontinued. Thus, recruitment and data collection had to be interrupted. The COVID-19 pandemic was an unforeseen contextual factor, which was hypothesized to impact potentially the conduct of the trial and the targeted health behavior. Hence, we conducted a cross-sectional analysis of the data collected at baseline before and during/after the state-mandated lockdown pertaining to potential differences in psychosocial health, physical activity determinants and physical activity levels (see Publication 2).

Step 3

In accordance with Aim 3, we evaluated the implementation of the intervention. This included evaluating whether the intervention reached the target audience, the dose of the intervention was adhered to, the content was delivered according to how it was designed, i.e., intervention fidelity, and whether adaptations were made to the intervention. Furthermore, we analyzed whether the intervention duration and content differed according to intervention dose by

creating subgroups according to intervention attendance. Lastly, we presented the participants' reported satisfaction with the intervention (see Publication 3).

Step 4

In accordance with aim 4, we wanted to gain deeper insight into the mechanism of impact of the intervention from the perspective of the recipients. Hence, we conducted a nested qualitative study with participants who had completed their study participation to gain a better understanding of the responses to and interaction with the intervention (see Publication 4).

Step 5

In further accordance with Aim 2, we wanted to explore the contextual factors shaping the underlying theory of the intervention. Inherent deficits in physical activity determinants are known, so it was hypothesized that increased MDD severity may negatively impact physical activity determinants. Hence, we evaluated the association between psychosocial determinants of and implicit attitudes towards physical activity and MDD severity of the entire sample at baseline (see Publication 5).

Step 6

In accordance with Aim 5, we evaluated the short-term outcomes of the intervention by analyzing differences within and between the intervention and control group from baseline to post, after delivery of the MoVo intervention. We hypothesized that the intervention group would exhibit increased physical activity levels (according to accelerometer and self-reporting) and more favorable psychosocial determinants of and implicit attitudes towards physical activity compared with the control group over time (see Publication 6).

Chapter 3 Publication 1

The impact of lifestyle Physical Activity Counselling in IN-PATients with major depressive disorders on physical activity, cardiorespiratory fitness, depression, and cardiovascular health risk markers: study protocol for a randomized controlled trial

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Trials

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The impact of lifestyle Physical Activity Counselling in IN-PATients with major depressive disorders on physical activity, cardiorespiratory fitness, depression, and cardiovascular health risk markers: study protocol for a randomized controlled trial

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Abstract

Background: Major depressive disorder (MDD) is a widespread and burdensome psychiatric issue. Physical activity counselling may increase lifestyle physical activity and cardiorespiratory fitness in this specific and particularly vulnerable population, which often suffers from both mental and physical health problems. Therefore, this study will examine the impact of a lifestyle physical activity counselling intervention on physical activity, cardiorespiratory fitness, depression, and cardiovascular health risk markers among in-patients diagnosed with MDD compared to controls. Secondary purposes are to examine the acceptability and perceived usefulness of the intervention among these patients, to find out whether the effectiveness of the intervention is moderated by genetic factors, and to compare baseline values with an age- and gender-matched group of healthy controls.

Methods: The study is designed as a multi-centric two-arm randomized clinical trial including an intervention group and a placebo control group, allocation concealment, single-blinding, and intention-to-treat analysis. Participants ($N = 334$) will be continuously recruited from four clinics specialized in the treatment of MDD. The intervention builds on a standardized, theory-based, low-cost lifestyle physical activity counselling programme, which was specifically designed for an in-patient rehabilitation setting. The placebo control condition consists of general instructions about health-enhancing physical activity. Data assessments will take place 2–3 weeks after admission to in-patient treatment (baseline), and 6 weeks (post) and 12 months (follow-up) after discharge from in-patient treatment. The primary outcome is objectively assessed physical activity at follow-up.

(Continued on next page)

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Discussion: Because regular physical activity has proven to be an important predictor of long-term response and remission in patients with major depression, we believe that our planned study may lay important groundwork by showing how individually tailored lifestyle physical activity counselling can be integrated into given clinical structures. Improving physical activity may have important implications for tackling metabolic and cardiovascular disease and increasing mood and cognitive functioning in this at-risk population, hence limiting the future burden of multiple chronic conditions. Increased physical activity may also reduce the likelihood of future depressive episodes. By moving towards the primary prevention of chronic physical conditions, much can be done to enhance the quality and quantity of life of people with MDD.

Trial registration: ISRCTN, ISRCTN10469580. Registered on 3 September 2018.

Keywords: Acceptability, Biomarkers, Cardiorespiratory fitness, Cardiovascular risk markers, Counselling, Depression, Exercise, In-patients, Physical activity, Psychiatry, Serotonin transporter polymorphic promoter region

Background

Major depressive disorder (MDD) is a psychiatric issue characterized by the loss of interests and pleasure in activities that were otherwise interesting and pleasant for the individual. Further, individuals with MDD report impaired sleep, suicidal behaviour, cognitive impairments, social withdrawal, diffuse and complex pain syndromes and issues, along with loss of sexual interests. As shown by the World Health Organization [1], MDD is widespread and its course is often chronic. Estimates of lifetime prevalence for MDD range between 10 and 20%, and the 1-year prevalence varies between 5 and 10%, affecting people of all ages, genders, and socio-economic status [2, 3]. Depression is often recurrent, and the risk of relapse is also high. Significant associations have been reported between MDD, morbidity, disability, mortality, and suffering for patients and their families [4]. The WHO Global Burden of Disease study suggests that mild to moderate depressive disorder is associated with the second greatest number of life years lost due to premature death or disability (DALY) [5] and will most likely be the leading cause in 2030 [6]. Moreover, MDD is the leading cause of years of life lived with disability (YLD) in men and women [7].

Close links have been found between MDD and poor quality of life, high medical expenditure, and increased use of healthcare services [8]. Moreover, a high comorbidity with other chronic medical conditions has been found in patients with MDD, all of which put a considerable burden on the healthcare system. For instance, people with depression are more than twice as likely to develop metabolic conditions (e.g. diabetes and metabolic syndrome) and cardiovascular diseases [9–13]. MDD is also linked with impaired cognitive functioning, leading to declines in information processing and reduced memory functioning [14].

As a possible moderator for both disease vulnerability and treatment response on the one hand, and occurrence of (somatic) comorbidities on the other, a dysfunction of serotonergic homeostasis has been proposed to play a crucial role [15–17]. Moreover, a polymorphic region in the promotor of the serotonin transporter (5-HTT) gene (5-HTTLPR), which is characterized by two alleles, a long (l) and a short (s) allele [18], has been suggested to be associated with the incidence of depression after exposure to stressful life events [17]. However, this association remains inconclusive, since some studies failed to replicate these findings [19, 20]. The inconsistencies might be due to unidentified environmental factors. In this regard, Rethorst et al. [21] recently found a significant interaction between the 5-HTTLPR genotype, physical activity, and depressive symptoms. Individuals with at least one s allele had significant higher levels of depressive symptoms at low-level physical activity compared to individuals with the ll genotype.

Further, people with both MDD and subthreshold depressive symptoms have an increased risk of premature mortality compared to the general population [22, 23]. There is a life expectancy gap of 10–15 years between psychiatric patients (including MDD) and people without psychiatric diagnosis. Importantly, around 80% of all preventable deaths are due to physical conditions, whereas suicide is only responsible for 14% [24]. Although these disparities have been recognized since the mid-1980s, this life expectancy gap has widened during the last 30 years [25]. Lawrence et al. [24] therefore concluded that "public efforts should be directed towards improving physical health to reduce mortality in people with mental illness, in addition to on-going efforts to prevent suicide" (p. 1).

Standard treatment, remission rates, and complementary treatment options

Treatment options for MDD consist of pharmacological and non-pharmacological interventions [26], including psychotherapy, neuromodulation [27], physical activity [28], and nutritional supplements such as adjuvant omega-3-polyunsaturated fatty acids [29], or the combination of both pharmacological and non-pharmacological

treatments [30–32]. However, the effectiveness of standard pharmacological treatment is limited [33], and the use of antidepressant medication is associated with side effects [34] and poor adherence [35]. It has been estimated that only about 30–50% of all patients show a response to a first antidepressant trial with single-action or dual-action antidepressant monotherapy [36, 37]. Remission is found in an even smaller portion of participants (15–40%) [37, 38]. In other words, more than 50% of all patients do not respond after first-line treatment. Current clinical practice employs switch, combination, and/or augmentation strategies after failure of first-line treatment. These augmentations include co-administration of antidepressants with alternative pharmacology, atypical neuroleptics, or mood stabilizers [8]. However, even these additional treatments often do not result in remission [39].

In light of the massive burden associated with MDD, the low rate of full recovery is problematic [37]. Researchers have therefore claimed that a greater variety of cost-effective, accessible, and alternative/complementary treatments are needed [40, 41]. A further justification for this claim comes from the studies which found relatively low compliance with antidepressant medication, indicating that 20–60% of primary care patients stop taking their medication within the first 3 weeks after drug prescription [42]. One important reason is that the use of psycho-pharmaceuticals may have negative side effects, such as clinically significant weight gain and, above all, SSRI-related sexual dysfunction [43, 44]. Specifically, weight gain is of particular relevance, as it is associated with reduced quality of life, social stigma, greater morbidity (e.g. cardiovascular disease, diabetes mellitus, osteoarthritis), and mortality [45].

As a consequence, non-pharmacological and complementary strategies have been envisaged to improve the prognosis of MDD [26], including exercise therapy [28]. The use of alternative and complementary treatments is popular and widespread in western societies. For instance, in a US-based sample of severely depressed participants, more than half indicated having used such options during the past year [46], most likely because these alternatives are consistent with their own values, beliefs, and philosophical orientations towards health and life [47]. Part of such orientation is physical activity, and therefore, according to Dunn et al. [48], exercise seems a viable treatment option because it "can be recommended for most individuals, and does not carry a negative social stigma" (p. 1).

Exercise as an alternative or complementary therapy in the treatment of MDD

In several countries, health foundations have encouraged general practitioners to prescribe exercise as a front-line strategy in the treatment of MDD [40, 49, 50]. Research also shows that regular exercise and physical activity have the potential to reduce the risk of developing depression [51, 52]. Meanwhile, several meta-analyses have examined the effects of exercise on depressive symptoms in randomized controlled trials (RCTs) among adult populations. The first meta-analysis was published in 2005 by Lawlor and Hopker [49]. Based on 14 studies, their findings showed that exercise treatment was associated with an effect size of $d = -1.10$, pointing towards a significant reduction in depressive symptoms compared to no treatment. However, a higher effect size was found in studies with shorter follow-up periods. Using a more extensive search procedure, Rethorst et al. [40] identified 58 RCTs and found an overall effect size of $d = -0.80$, highlighting that exercise treatment results in significantly decreased depression scores compared to controls.

In a recent Cochrane review, Cooney et al. [53] found similar effects ($d = -0.62$) when comparing exercise to standard treatment, no treatment, or placebo control. However, after excluding trials which did not fulfil the adequate quality standards (such as allocation concealment, blinded outcome assessment, intention-to-treat analysis), the effect size was no longer significant ($d = -0.18$). Nevertheless, those eight studies which presented long-term follow-up data resulted in a moderate effect ($d = -0.33$) in favour of exercise treatment. Moreover, Schuch et al. [54] pointed out that publication bias may lead to an underestimation of the standardized mean difference reported in RCTs, and that programmes are particularly effective if they promote moderate intensity physical activity, if they have an emphasis on aerobic exercise activities, and if the interventions are provided and supervised by exercise professionals. Kvam et al. [55] summarized in their meta-analysis that physical activity interventions showed large effects sizes when compared to no interventions ($g = 1.24$), and moderate effect sizes when compared to control conditions ($g = 0.68$) and to usual care ($g = 0.48$) . However, when compared to psychological interventions ($g = 0.22$) or antidepressant medication ($g = 0.08$), effect sizes were small. However, again when combined with antidepressant medication, effect sizes were moderate ($g = 0.50$). Further, and most importantly, Kvam et al. [55] showed that the effect of physical activity had a moderate to large significant effect on depression compared to control conditions ($g = -0.68$), but that the effect was small and not significant at follow-up ($g = -0.22$). The latter result clearly indicates the need for and necessity to build up a well-designed intervention to thoroughly monitor the transition from guided and supervised interventions during stays in hospital and the patients' conditions and settings after discharge, when they should monitor the physical activity themselves. Evidence also supports that individual tailoring is recommendable, as both aerobic

and anaerobic exercise activities have a similar potential to reduce depression [56, 57] and to foster exercise motivation [58].

Blumenthal et al. [4, 31] compared whether 4-month aerobic exercise programmes are more effective than pharmacotherapy in two separate studies with 156 older patients and 202 adults with MDD. Taken together, these studies reveal that exercise and antidepressant medication lead to similar reductions in depressive symptoms, and that both treatments are associated with higher remission rates compared to a placebo control condition [4]. Beyond these short-term outcomes, Hoffman et al. [59] examined the long-term effects of the different treatments. While neither group assignment (exercise vs pharmacotherapy) nor antidepressant medication usage during the follow-up period were related to response or remission at 12-month follow-up, regular exercise during the follow-up period proved to be the only significant predictor. In other words, patients who regularly engaged in exercise activities after the initial treatment were less likely to have MDD at follow-up. These results corroborate previous research with older adults, showing that regular post-treatment exercise leads to a considerably lower relapse rate 6 months after the end of the treatment [60].

While these results suggest that exercise therapy can be equally effective in reducing depressive symptoms as antidepressants in the short run and that prolonged regular exercise might prevent relapses after the end of treatment, it is evident that the positive effects of exercise therapy may dissipate if the intervention is discontinued and if patients are not able to maintain a physically active lifestyle.

Effects of exercise training on cardiorespiratory fitness and cardiovascular health

A physically active lifestyle is associated with increased cardiorespiratory fitness (CRF), and high levels of CRF are associated with a reduced risk of cardiovascular morbidity and other chronic conditions such as obesity, diabetes, cognitive decline, or specific forms of cancer [61]. Moreover, high CRF is associated with reduced risks of premature mortality, even after controlling for the influence of hereditary factors [62, 63].

Nevertheless, several studies show that people with depression have lower physical activity [64, 65] and CRF levels [66, 67]. Thus, it has been hypothesized that low physical activity and CRF constitute a possible link between depression and comorbid somatic disorders [68, 69]. Importantly, a meta-analytic study revealed that exercise interventions significantly contribute to increased CRF in patients with MDD [70]. Based on seven RCTs, an overall effect size of 0.64 was found, which corresponds to a mean increase of 3.05 ml/kg/min of oxygen uptake. As shown in population studies, improvements of 3.5 ml/kg/min in VO_2max are associated with a 13 and 15% decrease in cardiovascular disease and all-cause mortality [63].

Summary of main findings and special challenges in patients with major depressive disorder

Strong empirical evidence exists showing that exercise plays a beneficial role in the treatment of MDD. Exercise, antidepressants, and psychotherapy have comparable effects among patients with MDD [71], although, above all, the combination of both physical activity and standard medication treatment appears to be particularly promising [55]. Further, exercise might even be successful in reducing treatment-resistant depression [28]. Given these observations, it seems recommendable to use exercise more systematically as an add-on to standard care during inpatient treatment [50, 55, 72]. Moreover, promoting lifestyle physical activity seems to have the potential to prevent relapses after the end of hospitalization [59, 73].

Initiating and maintaining regular exercise among patients with MDD is a major challenge, especially because depressive symptoms interfere with their capacity to self-regulate health-related behaviours [33, 68]. MDD is often cyclical, including recurrent depressive episodes, which might lead to an interruption of exercise regimes. Moreover, depression can be linked with motivational and volitional deficits in all areas of daily life due to hopelessness, pessimism, loss of interest and enjoyment in ordinary things, persistent low mood, low self-efficacy, limited capacity to plan due to impaired executive function, and a tendency to postpone tasks [33, 68]. In line with this, studies show that depression is associated with limited exercise self-efficacy, stronger negative outcome expectations, reduced intentions to exercise, poor maintenance self-efficacy, and increased perception of situational barriers [68, 74]. At the same time, higher body mass index (BMI), and the presence of somatic comorbidities are particularly important barriers for people with depression to engage in regular physical activity [75]. In other words, engagement with and adherence to recommended physical activity levels remain a major challenge. Providing MDD patients with professional support to identify and achieve their physical activity and exercise goals may enable them to overcome psychological barriers, and maintain motivation towards regular physical activity. Thus, Gerber et al. [76, 77] suggested that looking into lifestyle physical activity counselling should become a top priority to improve patients' behavioural skills such as action planning, coping with exercise-related barriers, and social support. Such behavioural skills are key to maintaining a more physically active lifestyle and to achieve long-term positive outcomes in mental health.

Physical activity counselling and behavioural skill training to foster regular exercise participation

Several theories have been developed to facilitate change in health behaviour [78]. Two recent models are the Health Action Process Approach model [79] and the Motivation and Volition-process model [80]. The common ground of these models is that they focus on both motivational (how people form an intention) and post-intentional (volitional) processes, including action planning, identification of personal and environmental barriers, coping planning, and relapse management. Both models have resulted in theory-based intervention programmes that provide support for long-term behaviour change in overweight people and patients suffering from somatic conditions [81–84]. As an example, Fuchs et al. [81] showed that amongst 220 inactive in-patients of an orthopaedic rehabilitation clinic, motivational and volitional counselling resulted in a moderate-to-large short-term increase ($d = 0.72$) in physical activity in the intervention group compared to the control group. Although the group difference diminished until 12-month follow-up, the intervention group still reported increased physical activity levels. Nevertheless, while these findings are promising, research about the potential of such programmes in patients with MDD is scarce.

A recent study showed that lifestyle counselling (including diet, exercise, sunlight exposure, and sleep) can be an effective add-on to antidepressant treatment. While remission reached 60% in the combined treatment group, this rate was considerably lower in the control group (10%) [85]. So far, only one RCT exists in which the effects of individually tailored physical activity counselling through professionally trained physical activity facilitators have been tested in patients with MDD [86–88]. While the findings showed that the intervention group had significantly increased physical activity levels at follow-up, this study was carried out in an out-patient setting, did not focus on patients with low physical activity levels, and did not assess physical activity objectively.

Purpose of the study

Given this background, the main purpose of this study is to implement and evaluate a randomized controlled trial to examine the effectiveness of an individually tailored lifestyle physical activity counselling intervention on objectively assessed physical activity among in-patients diagnosed with MDD compared to (placebo) controls. Patients will receive exercise prescriptions tailored towards their current physical activity level, activity type, and intensity preferences in order to change their exercise and physical activity habits beyond their stay at the clinic. To ensure a high adherence among patients assigned to the intervention group across the entire study period, new technologies such as an app-based coaching platform and remote physical activity counselling (telephone coaching and message prompts) will be used [89].

Secondary purposes are as follows:

a) to examine how the intervention impacts on the secondary outcomes (self-reported physical activity, cardiorespiratory fitness, autonomic function, cognitive and social determinants of exercise, depression severity, self-perceived physical and psychological health, insomnia symptoms, cognitive function, cardiovascular risk profile, and biomarkers of MDD);
b) to find out whether the serotonin transporter (5-HTT) polymorphic promoter region (5-HTTLPR) as a genetic factor moderates the effects of the intervention;
c) to gain insights into the acceptability and perceived usefulness of the intervention among patients; and
d) to compare baseline values with an age- and gender-matched group of healthy controls.

Methods/design

Study design

The study is designed as a multi-centric, two-arm RCT including an intervention group (IG) and a placebo control group (PCG), allocation concealment, single-blinding, and intention-to-treat analysis. The study is a cooperation between four Swiss psychiatric clinics (two public, two private) and the Department of Sport, Exercise and Health of the University of Basel. Figure 1 provides an overview of the planned study design. The 25-item CONSORT checklist was used when designing the study. Figure 2 represents the SPIRIT figure, providing an overview of foreseen time points, interventions, and assessments. The description of the study protocol contains all elements listed in the SPIRIT checklist (see Additional file 1).

Patients will be assigned randomly (stratified by age, gender, and clinic) to an extended personalized physical activity and exercise counselling programme (IG) or to general instructions about health-enhancing physical activity (PCG). To ensure allocation concealment, allocation to groups will be done by a computer-generated code after the baseline assessment has taken place. A researcher (OF) will generate an allocation sequence and assign participants to either the intervention or placebo control group. Further researchers engaged in field work (RC and SR) will recruit and enrol participants. Clinicians, researchers, and physical activity facilitators will not be blinded to treatment allocation because of the nature of the study.

To minimize subjective bias, patients do not know whether they have been allocated to the intervention or placebo control group. Before providing informed consent, patients will be informed that the goal of the study

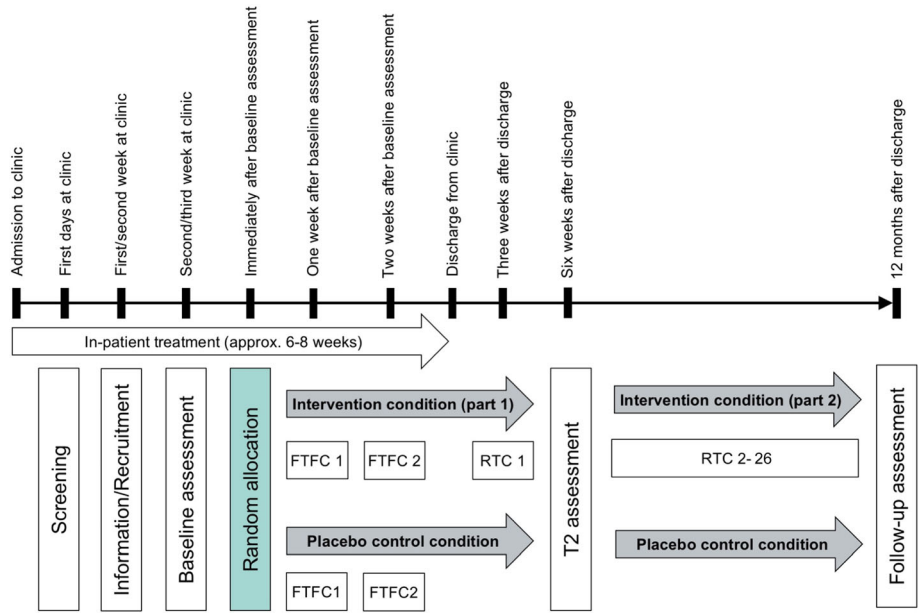

Fig. 1 Overview of the planned randomized controlled trial study design. FTFC face-to-face counselling with coach (behaviour skill training for intervention group; written information and video clip about health-enhancing physical activity for placebo control group), RTC remote telephone counselling, T2 6 weeks after discharge

is to test different methods to promote a more physically active lifestyle among patients with MDD who do not meet levels of physical activity recommended by the American College of Sports Medicine [90, 91]. Outcomes will be assessed by researchers who do not know whether a patient belongs to the IG or the PCG.

Participants

Recruitment and power calculations

Clinical in-patients aged 18–65 years with a current diagnosis of major depression (ICD-10) will be continuously recruited from the Psychiatric Services Solothurn, Psychiatric Clinics of the University of Basel, Psychiatric Clinic Wyss, Münchenbuchsee, and the Psychiatric Clinic Sonnenhalde, Riehen. In previous studies with non-depressed individuals, individually tailored physical activity promotion was associated with a moderate effect ($d = 0.50$) on the primary outcome (physical activity) [80, 81]. So far, only one study exists examining physical activity counselling among outpatients with depression, yielding an adjusted odds ratios of 2.27 across the 4-month, 8-month, and 12-month follow-up (corresponding $d = 0.45$). Conversely, a relatively small effect size ($d = 0.28$) was observed in a Cochrane review of intervention studies promoting physical activity among generally healthy people [92]. Similarly, remote interventions such as telephone-based, app-based, and Internet-based coaching versus a control group were associated with rather small effect sizes for change in physical activity ($d = 0.20$) [93]. Given these observations, we assume a small-to-moderate effect of our intervention on the primary outcome ($d = 0.30$). Accordingly, the optimal sample size to detect a significant effect at follow-up is 278 participants (two independent groups, one-tailed, α-error probability = 0.05, power = 0.80). With 20% expected dropouts from baseline to follow-up [94], the targeted sample size is $N = 334$ (IG, $n = 167$: PCG, $n = 167$). This means that every centre will recruit approximately 40 participants per year ($n = 20$ in the IG, $n = 20$ in the PCG). Dependent on the size of the clinics, this corresponds to a recruitment rate of 20–25% of the patients. Enrolment will be systematically monitored by the sponsor-investigator in order to recruit a sufficient number of participants within the planned timeframe.

Screening

A structured clinical interview will be conducted by a psychiatrist to ensure that all participants fulfil the ICD-10 diagnosis for a single episode (F32), recurrent MDD (F33), or bipolar disorder type II (F31-II). The screening also includes assessment of the duration of the current depressive episode, the number of previous depressive episodes, psychiatric and somatic comorbidities, and family history of psychiatric and somatic conditions. To assess symptom severity, a trained staff member will apply the 17-item Hamilton Depression Rating Scale (HAMD17) [95] as part of a clinical interview [96], while patients' self-ratings are based on the 21-item Beck Depression Inventory (BDI) [97, 98], along with the short version of the International Physical Activity Questionnaire (IPAQ) [99] to assess self-

	Study period				
	Enrolment	Allocation	Follow-up		
Timepoints	**-t1**	**0**	**T1**	**T2**	**T3**
Enrolment					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Interventions					
Intervention group			2 weeks after admission	6 weeks after discharge	12 months after discharge
Placebo control group			2 weeks after admission	6 weeks after discharge	12 months after discharge
Healthy control group			Only assessed once		
Assessment					
Physical activity					
Objective physical activity			X	X	X
Self-reported physical activity			X	X	X
Cardiorespiratory fitness			X	X	X
Autonomic function			X	X	X
Biomarkers					
Blood pressure			X	X	X
Body composition			X	X	X
Blood lipids and glucose			X	X	X
BDNF, TNF- α, IGF-1[a]			X	X	X
5-HTTLPR[b]			X		
Psychological dimensions					
Perceived fitness			X	X	X
Exercise-related self-efficacy			X	X	X
Exercise intention			X	X	X
Exercise-related self-concordance			X	X	X
Action planning			X	X	X
Perceived exercise barriers			X	X	X
Coping planning			X	X	X
Exercise-related social support			X	X	X
Depression severity			X	X	X
Self-perceived stress			X	X	X
Self-perceived health			X	X	X
Insomnia symptoms					
Cognitive function			X	X	X

Fig. 2 SPIRIT figure providing an overview of time points, interventions, and assessments of the PACINPAT randomised controlled trial. BDNF brain-derived neurotrophic factor, 5-HTTLPR serotonin transporter polymorphic promoter region, IGF-1 insulin-like growth factor 1, PACINPAT Physical Activity Counselling in IN-PATients, SPIRIT Standard Protocol Items: Recommendations for Interventional Trials, TNF-α tumor necrosis factor alpha

reported physical activity (referring to the last week before entering the clinic).

Criteria for inclusion/exclusion

Inclusion criteria are: women and men; 18–65 years of age; presence of MDD according to ICD-10 diagnostic criteria (F31 type II, F32, F33); BDI ≥ 17 (at least borderline clinical depression); currently not meeting the ACSM physical activity recommendations (IPAQ < 150 min/week of moderate-to-vigorous physical activity); written informed consent; and ability to speak and read German.

Exclusion criteria are: presence of history of bipolar disorder type I (F31 type I), history of schizophrenia, or schizoaffective disorder; current active alcohol or drug abuse or dependence; any significant medical condition that contraindicates safe participation in physical activity; active suicidal intent; evidence of significant cardiovascular, neuromuscular, or endocrine disorders limiting regular physical activity as per ACSM absolute contraindications to exercise (including a recent significant change in the resting ECG suggesting significant ischaemia, recent myocardial infarction or other acute cardiac event, unstable angina, uncontrolled cardiac dysrhythmias causing symptoms or haemodynamic compromise, symptomatic severe aortic stenosis, uncontrolled symptomatic heart failure, acute pulmonary embolus or pulmonary infarction, acute myocarditis or pericarditis, and suspected or known dissecting aneurysms) or medical contraindications to physical activity indicated by the Physical Activity Readiness Questionnaire (PAR-Q) [100]; and inability to speak and read German.

Healthy controls

To compare baseline differences in the primary and secondary outcome(s) between patients and healthy controls, an age- and gender-matched sample of 167 participants will be recruited through advertisements in newspapers and through word-of-mouth recommendation. Inclusion criteria for healthy controls are: women and men; 18–65 years of age; HAMD17 ≤ 7; BDI ≤ 13; currently not meeting the ACSM physical activity recommendations (IPAQ < 150 min/week of moderate-to-vigorous physical activity); written informed consent; and ability to speak and read German.

Procedures

Data assessment

Screening will take place in the first week after admission to in-patient treatment. Identical data assessment will take place 2–3 weeks after admission to in-patient treatment (baseline), and 6 weeks (post) and 12 months (follow-up) after discharge from in-patient treatment. The primary outcome is objectively assessed physical activity (Actigraph wGT3x-BT monitor, 7 days). Secondary outcomes are self-reported physical activity, cardiorespiratory fitness, autonomic function cognitive and social determinants of exercise, depression severity, self-perceived physical and psychological health, insomnia symptoms, cognitive function, cardiovascular health risk markers, and biomarkers of MDD. Moreover, the serotonin transporter (5-HTT) polymorphic promoter region (5-HTTLPR) is assessed as a potential moderator of intervention effects [21]. More information regarding the various instruments is presented in the following.

Intervention and placebo control condition

Patients assigned to the IG or the PCG receive treatment as usual from their psychiatrists according to the Swiss treatment guidelines for major depression [101]. Moreover, patients from both groups continue the therapy provided by their practitioner and therapist for their depression (i.e. psychotherapy, use of antidepressants).

Intervention programme: individually tailored physical activity promotion

Patients assigned to the IG will receive an individually tailored physical activity counselling to provide support and encouragement to increase physical activity. Two face-to-face meetings will take place during the clinical treatment which lasts between 6 and 8 weeks on average. The meetings will take place approximately in weeks 4 and 6 of in-patient treatment. The same physical activity facilitator will develop a physical activity plan with the participant, tailored to the individual's current activity levels, activity type, and intensity preferences, and will promote behavioural change techniques which have been proven effective in previous studies [102–107]. Additionally, starting 1 week after discharge from in-patient treatment, patients of the IG will receive bi-weekly telephone counselling and SMS prompts until 12 months after discharge. Telephone counselling and push notifications will help to ensure adherence of patients to their physical activity and exercise plans/prescription, or facilitate the adaptation of these plans. Furthermore, a smartphone app will be developed which can be used to support patients in their planning and self-monitoring of physical activity and exercise behaviour.

Exercise prescriptions follow the standards of the American College of Sports Medicine [90, 91], stating that individuals should engage in at least 30 min of moderate-intensity physical activity on 5 days per week, or 20 min of vigorous-intensity aerobic exercise on 3 days each week. A variety of activities such as aerobic exercise, resistance exercise, multi-modal group-based exercise, daily physical activity (e.g. walk or take bike for grocery shopping), and so forth, will be advised.

The intervention builds on a standardized, theory-based, short, low-cost lifestyle physical activity counselling programme, which was specifically designed for an in-patient rehabilitation setting (MoVo-Lisa = Motivation, Volition and Lifestyle-integrated Sport Activity). It consists of two individual (face-to-face) counselling sessions and an extended counselling session via telephone after discharge from the clinic. The first session (60–75 min) will take place 1 week after the baseline data assessment. The second session (45–60 min) will take place 1 week before the end of in-patient treatment. The third session (75–90 min) will take place 1–2 weeks after discharge from in-patient treatment via telephone to give patients the possibility to test their physical activity plans in their familiar environment, and to allow the identification of real-life physical activity obstacles.

All sessions aim at promoting motivational and volitional strategies to foster long-term behavioural change. Following Michie et al.'s [102] behaviour change taxonomy, motivational strategies include: clarification of personal health objectives (*goal setting [outcome]*, V1: 1.3); contemplation of different actions to achieve the health objectives (*goal setting [behaviour]*, V1: 1.1); reflection of pros and cons associated with the new behaviour (*pros and cons*, V1: 9.2); checking self-concordance of these goals (*review behaviour/outcome goals*, V1: 1.5/1.7); and reflection of outcome experiences (*monitoring of emotional consequences*, V1: 5.4). Volitional strategies include: generation of implementation intentions (*action planning*, V1:1.4); anticipating personal barriers (*problem-solving*, V1:1.2); developing counter strategies (*restructuring of the physical/social environment*, V1:12.1/12.2); contracting (*behavioural contract*, V1:1.8);

mobilization of social support (*social support*, V1:3); and self-monitoring the new behaviour (*self-monitoring of the behaviour and outcomes of the behaviour*, V1:2.3/2.4) . The intervention will be designed to match the specific stage of depression. Facilitators will focus on pessimistic beliefs such as negative outcome expectations and self-efficacy, as well as planning deficits linked with depression [108]. Recently, reviewers identified losing weight (83% of patients), improving mood (81%), and reducing stress (78%) as the most relevant motives for exercise in patients with severe mental illnesses, whereas low mood and stress (61%) and lack of social support (50%) turned out to be the most relevant exercise barriers [69]. Physical activity facilitators will place a special emphasis on these motives and barriers when developing physical activity promotion strategies.

Administration of experimental intervention

The aim is to have at least two face-to-face individual counselling sessions, have 26 follow-up telephone contacts (on a bi-weekly basis), and send 52 message prompts by the 12-month time point. Telephone contacts will be used to discuss problem-solving around barriers, reinforce progress towards behaviour change, and adapt initial goals and plans. Moreover, follow-up contacts serve to strengthen relapse strategies so that patients understand that relapses are common during behaviour change, and that dysfunctional cognitions, emotion, and behaviours can jeopardize maintenance of a physically active lifestyle [33].

Smartphone application

A smartphone app will support patients in their planning and self-monitoring of physical activity and exercise behaviour. This newly developed app designed for online coaching will serve as a tool for communication, exchange of weekly activity plans, and documentation of physical activity. Via the app, the physical activity facilitator can assist the participant in developing physical activity plans and can access the self-monitoring data. Both participants and physical activity facilitators can access and modify the physical activity plans online.

Adherence to the intervention protocol will be monitored by the physical activity facilitators. A thorough documentation of the physical activity facilitator's work with the participant will ensure that the adherence to the protocol will be visible. Bi-weekly meetings with the physical activity facilitators and the study team will allow for continued training and minimize differences in the delivery of the intervention between facilitators and within facilitators over time.

Placebo control condition

One week after the baseline assessment, in addition to treatment as usual, patients assigned to the PCG will receive written information about health-enhancing physical activity based on the "Core document for Switzerland" published by the Federal Office of Sport (BASPO) in collaboration with other institutions. This document summarizes the current knowledge in relation to health-enhancing physical activity. The patients will obtain information about the following topics: why is physical activity healthy; what are the minimal physical activity recommendations; how physically active are people in Switzerland; and what are the costs of physical inactivity?

One week before the end of the in-patient treatment, patients will meet the physical activity facilitator. The facilitator will summarize the key contents of the "core document" by showing a short animation film (https://www.youtube.com/watch?v=zNZenOnGI0U) and discuss questions with the patient. The control condition is not intended as a bona fide intervention [109, 110] and an active therapy, but to control for placebo effects of the intervention condition.

Selection, education, and training of the physical activity facilitator

Physical activity counselling will be done by personnel with a background in exercise science and/or psychology, because a majority of patients want professional support when trying to engage in more physical activity [69]. Physical activity facilitators will be trained in behavioural change techniques and coaching through the supervisors. The facilitators will be regularly supervised by the investigators. Knowledge and coaching style of each facilitator will be tested prior to the first coaching session.

Participation in physical activity and exercise programmes during in-patient treatment

The physical activity facilitator will inform all participants about the existing exercise activities offered at the clinic. Both groups (IG and PCG) have the possibility to voluntarily participate in these activities.

Ethical considerations

The proposed research will be carried out in accordance with the ethical principles laid down in the Declaration of Helsinki (1964). Central ethical approval has been confirmed from the "Ethikkommission Nordwest- und Zentralschweiz" (ref. approval no. 2018-00976). Moreover, local ethical approval has been obtained for all study sites. Thus, local ethical approval has been obtained from the "Ethikkommission Nordwest- und Zentralschweiz" for the clinics located in Basel, Riehen,

and Solothurn, and from the "Ethikkommission Bern" for the clinic located in Münchenbuchsee. The intervention study was registered in the WHO trial register (trial number ISRCTN10469580). All participants will be informed about the general goals of the study. Informed written consent is required before study entry. Participants are informed that participation in the study is voluntary and that they can withdraw or discontinue at any time without further obligation or potential disadvantages. The participants and outcome assessors are blinded. Medication intake will be recorded as a part of the baseline, post intervention, and follow-up assessments.

After completion of the data assessment, all personal data of the patients will be encoded (each patient will receive a project ID number), so that it will no longer be possible to identify the patients. Data will be entered into an SPSS file. The collected data will be saved digitally. Backup files will be stored regularly on the external cloud *Switchdrive@Universität Basel*. The coding list will be stored in a safe place. Data will only be used for scientific purposes, and will be discarded after completion of the laboratory analyses. Paper records of the study will only be accessible to the main investigators, and will be kept in locked cupboards. After 10 years, all records will be destroyed.

Measures

The primary outcome, secondary outcomes, moderators, and covariates will be assessed identically at baseline, post intervention, and follow-up by the same examiner at the clinic. As an incentive, healthy controls will receive 50 CHF for their participation in the study. Patients will receive 20 CHF if they participate in the post-intervention and follow-up assessments (as a compensation for their travel expenses). After each data assessment, healthy controls and patients will receive a health profile with information regarding their physical activity and fitness level, blood pressure, blood glucose, blood lipid profile, and body composition. Participants will be instructed to abstain from food and liquids (including coffee and tea) from 22:00 the night before the evaluation for the accurate measurement of blood glucose, blood lipids, and autonomic function. Assessments will last approximately 2 h. The following procedures will be applied by well-trained staff adhering to standardized, quality-controlled protocols.

Primary outcome

Objective physical activity

Objective physical activity will be assessed with an accelerometer (wGT3x-BT; Actigraph, Shalimar, FL, USA) worn around the hip. The devices will be worn during daytime for 7 consecutive days to assess a full weekly period. The sampling epoch will be set at 10 s [111]. Time per day spent in moderate physical activity (MPA; 1952–5723 counts per minute, > 3 MET) and vigorous physical activity (VPA; > 5274 counts per minute, > 6 MET) is determined based on the raw accelerometer counts and the ActiLife® computer software, with cut-off values derived from Freedson et al. [112]. Participants will fill in a non-wear time sheet (e.g. to assess physical activities during which it was not possible to wear the monitor, such as swimming). Physical activities listed on the non-wear time sheet will be included as moderate-to-vigorous physical activities, based on the intensity levels defined in the Physical Activity Compendium [113, 114]. To be included in the data analyses, participants will need at least 5 valid days, including ≥4 valid weekdays and ≥ 1 valid weekend day [115]. Following Herrmann et al. [116], only days with at least 10 h of wear time are considered a valid measure of daily physical activity. The validity of the Actigraph accelerometer device has been documented previously [117]. To the best of our knowledge, no minimal clinically important change (MCID) scores are currently available for physical activity in patients with MDD. The ACSM recommends that individuals should accumulate at least 150 min of moderate-to-vigorous physical activity per week [91]. This is in line with a study by Hoffman et al. [59] showing that in patients with MDD there is a linear increase associated with self-reported exercise regarding the probability of at least partial remission until 150 min of exercise per week, whereas the response curve flattens off beyond this threshold.

Secondary outcomes

Self-reported physical activity

Self-reported physical activity will be assessed with a newly developed questionnaire (Simple Physical Activity Questionnaire (SIMPAQ)) specifically developed for the use with psychiatric patients [118]. Validation of this instrument with psychiatric patients is currently underway (see www.simpaq.org). Data for healthy people show that the instrument is reasonably associated with objectively assessed physical activity [119]. The SIMPAQ uses an interview format (5–10 min in duration) to assess time in bed, structured exercise participation, and incidental or non-structured physical activity. Data from our research group assessed in university students show that moderate-to-vigorous physical activity estimated with the SIMPAQ correlates moderately to highly with accelerometer data (r = 0.30–0.70) [119]. The same public health recommendations apply as for objectively measured physical activity [91].

Cardiorespiratory fitness

The Åstrand and Rodahl indirect test of maximal oxygen uptake (VO_2max) will be used to assess cardiorespiratory fitness [120]. The test will be performed on a bicycle ergometer (Bike Forma; Technogym) at the same time of the day (starting between 08:00 and 10:00). This test has been validated for the purposes of measuring submaximal fitness [120]. The pedalling frequency during the Åstrand test will be set at 50 rpm, and the workload adjusted so that the heart rate is kept between 130 and 160 beats per minute (bpm) in participants younger than 40 years old and between 120 and 150 bpm in participants older than 40 years old. To ensure that participants maintain their exercise intensity level at 13 or 14 (slightly strenuous), we will employ the Borg Rating of Perceived Exertion scale [121]. When the heart rate remains stable after 5 or 6 min, a steady state is reached. Peak oxygen uptake (l/min) will be estimated based on mean steady state, sex, and power output, using a nomogram [120], and including a correction factor for age. After correction of body weight, oxygen uptake will be expressed as peak VO_2max (ml/kg/min). Gender and age-adjusted cut-off values will be used to categorize participants into groups with low, moderate, and high CRF [66]. The reliability and validity of the Åstrand nomogram and linear extrapolation for deriving VO_2max has been documented in a previous study [122].

Autonomic function

Using heart rate monitors (V800; Polar Electro, Finland), following a 5-min period of rest, R–R intervals will be recorded over 5 min; based on their variation, the heart rate variability (HRV) is calculated. This non-invasive method allows for the accurate evaluation of autonomic nervous system activity [123]. Recorded R–R intervals will be processed and analysed with Kubios HRV [124]. Evidence for the validity of the Polar V800 monitor for the assessment of HRV at rest has been documented in a prior study [125]. In the time domain, the standard deviation of normal-to-normal intervals (SDNN) and the root mean square of standard deviation (RMSSD) will be examined. Additionally, low-frequency power (LF nu; bandwidth 0.04–0.15 Hz) and high-frequency power (HF nu; bandwidth 0.15–0.4 Hz), expressed as normalized units, as well as the LF nu/HF nu ratio will be examined as frequency-based HRV parameters. To the best of our knowledge, no MCID scores are currently available for HRV [126].

Perceived fitness

A one-item proxy measure is used to assess subjectively perceived physical fitness [127]. The following item will be used: "Overall, how would you rate your physical fitness?" Answering options range from 1 (very poor fitness) to 10 (excellent fitness). The validity of this item as an indicator of perceived fitness has been established previously. High correlations were found with the 12-item Perceived Physical Fitness scale [128]. Moreover, this measure proved to be reasonably associated with objective physical fitness, perceived well-being, and sleep [128, 129]. No MCID scores exist for this measure.

Exercise-related self-efficacy

Three items referring to beginning, maintaining, and restarting exercise after a relapse are used to assess exercise-related self-efficacy beliefs (e.g. "I feel confident to start with a new exercise activity") [130]. This scale proved to be a psychometrically sound measure in a previous study [130] and has been used in previous intervention studies [80–82, 131]. The scale ranges from 0 (not at all confident) to 5 (100% confident in myself). The three items are added to obtain a single score. No MCID scores exist for this measure.

Exercise-related outcome expectancies

Nine positive ('pros'; e.g. "I can improve my physical appearance if I regularly exercise") and seven negative formulated items ('cons'; e.g. "If I exercise, I end up in situations where I feel embarrassed") are used to assess outcome expectancies [132]. The items are anchored on a 4-point Likert-type scale from 1 (not true) to 4 (completely true). Satisfactory psychometric properties of these items have been demonstrated [132]. Items are combined into two composite scores (positive and negative) by the arithmetic mean of each. No MCID scores exist for this measure.

Exercise intention

One item is used to assess exercise-related goal intentions [130]. More specifically, participants are asked about the strength of their intention to exercise regularly during the next few weeks and months (0 = no intention to 5 = very strong intention). This measure proved to have acceptable reliability and validity in previous studies [133, 134]. No MCID scores exist for this measure.

Exercise-related self-concordance

Exercise-related self-concordance is assessed with the 12-item SSK scale [133], which is consistent with the self-concordance model by Sheldon and Elliot [135]. The SSK scale consists of four subscales that assess the intrinsic (e.g. "I (would) exercise because it's just fun for me"), identified (e.g. "I (would) exercise because I have good reasons to be physically active"), introjected (e.g. "I (would) exercise because otherwise I would have a guilty conscience") and extrinsic (e.g. "I (would) exercise because others tell me to become physically active")

reasons for exercising. All items are answered on a 6-point Likert scale from 1 (not at all true) to 6 (completely true). An overall index is built by summing the identified and intrinsic mean scores and subtracting the introjected and extrinsic mean scores. The reliability and validity of this instrument have been established previously [133]. No MCID scores exist for this measure.

Action planning

Five items with established reliability and validity are administered to collect information about participants' level of action planning [134, 136]. These items assess the degree to which individuals have pre-planned their exercise participation. Thus, participants are asked whether they normally make plans when, where, how, how often, and with whom they exercise. Answers range from 1 (not at all true) to 4 (completely true). The item scores are summed to obtain an overall index. No MCID scores exist for this measure.

Perceived exercise barriers

A 19-item scale that lists various obstacles to regular exercise participation is used to measure perceived exercise barriers [137]. Satisfactory psychometric properties of this instrument were reported previously [68, 137, 138]. Participants indicate on a 4-point Likert scale from 1 (almost never) to 4 (almost always) how often they perceive these barriers (e.g. "I have too much work to do"). The mean is computed to obtain a single score. No MCID scores exist for this measure.

Coping planning

A 5-item index is used to gain insight into coping planning [136]. Participants are asked to what degree they use self-regulation strategies to overcome potential exercise barriers (e.g. "I have made a detailed plan regarding what to do in difficult situations in order to act in according to my intentions"). Answers range from 1 (not at all true) to 4 (completely true). The item scores are summed up to obtain a composite index. The reliability and validity of this scale have been established previously [134, 136]. No MCID scores exist for this measure.

Exercise-related social support

A seven-item index is used to assess social support from relevant others (e.g. "Close family or friends help me plan my exercise") [132]. Answers are given on a 4-point Likert scale with values from 1 (almost never) to 4 (almost always). This scale proved to be a psychometrically sound measure in previous studies [131, 132]. No MCID scores exist for this measure.

Depression severity

The HAMD17 total score [95] and the Beck Depression Inventory (BDI) [97, 98] are used to assess depression severity. The BDI is a 21-item tool frequently used to assess symptoms of unipolar depression such as affective, behavioural, cognitive, and somatic symptoms (e.g. "I am so unhappy/sad that I can't stand it"). Four response options exist, which reflect increasing levels of depressive symptomatology. The HAMD17 and BDI total scores range from 0 to 52 and from 0 to 63, respectively, with higher scores reflecting stronger depressive symptoms. The reliability and validity of the HAMD17 [139, 140] and the BDI [141] are well documented in the scientific literature. Response and remission are defined based on the HAMD17 scores. Response is defined as ≥ 50% decrease of symptoms from baseline to the endpoint, partial response as 25–49% reduction, and non-response as < 25% reduction, whereas remission is accomplished if the HAMD17 total score is ≤ 7 [142]. With regard to the BDI, scores between 0 and 9 indicate that a person is not depressed, scores between 10 and 18 reflect mild–moderate depression, scores between 19 and 29 indicate moderate-to-severe depression, and scores ≥ 30 indicate severe depression [97]. Button et al. [143] further suggested for the BDI that the MCID is best measured on a ratio scale, with a reduction of 17.5% of the initial scale representing a clinically meaningful change in depressive symptoms.

Self-perceived stress

Perceived stress will be assessed with the Perceived Stress Scale (PSS) [144, 145]. The 10-item PSS is a well-established self-report measure of stress and is based on the cognitive-transactional stress theory. Answers are given on a 5-point Likert scale ranging from 1 (never) to 5 (very often). Evidence for the validity and reliability of the PSS has been reported previously [146]. No MCID scores exist for this measure.

Self-perceived health

The Medical Outcomes Study 12-Item Short Form Health Survey (SF-12) is used to assess participants' self-perceived health [147]. This instrument is among the most widely used measures within general population research [148], and the reliability and validity of the SF-12 are well documented [149, 150]. The composite scores of both subscales (physical and psychological health) are calculated by weighting each item as described in the SF-12 manual. Higher scores reflect increased health functioning. A study with low back pain patients suggests that improvements of > 3.77 in the psychological subscale and of > 3.29 in the physical subscale can be regarded as suitable MCID scores [151].

Insomnia symptoms

Sleep complaints are assessed with the seven-item Insomnia Severity Index (ISI) [152]. Answers are given on a 5-point rating scale, ranging from 0 (not at all) to 4 (very much). Evidence for the reliability and validity of this instrument has been documented previously [153, 154]. These items are in line with DSM-IV criteria for insomnia and include symptoms such as difficulties falling asleep, difficulties maintaining sleep, early morning awakening, increased daytime sleepiness, low daytime performance, low satisfaction with sleep, and worrying about sleep. Higher scores reflect a higher level of sleep complaints. Scores of 0–7 indicate absence of insomnia, scores of 8–14 indicate subthreshold insomnia, scores of 15–21 indicate moderate insomnia, and scores of 22–28 indicate severe insomnia [153].

Cognitive function

Today, there is no gold standard regarding the assessment of cognitive and executive function [155]. With regard to cognitive function, we decided to apply an odd-ball paradigm, the two-back test, and the Flanker task to assess sustained attention, working memory, and inhibition, respectively. The odd-ball paradigm [156] requires participants to press a button to deviants, which appear with a lower frequency (25%) than standard stimuli (75%). In the two-back task [157], participants are instructed to identify whether or not the presented letter matches the one presented two trials before by pressing a button corresponding to yes or no. Lastly, the Flanker task [158] requires participants to respond to the direction of a centrally presented arrow and to ignore the flanking arrows, which either point in the same or the opposite direction. These computer-based cognitive tests are well recognized neuropsychological tests for assessing attention [159] and executive function [160], and have been found to be reliable tools in previous research [161–163]. In the present study, the cognitive tasks will be administered with E-Prime 3.0 (PST, USA). Separately for each test, the reaction time (on response-correct trials) and accuracy will be extracted for statistical analyses. No established MCID scores exist for this measure.

Blood pressure

Systolic (SBP) and diastolic (DBP) blood pressure will be measured after the participant has rested for 5 min while seated. Blood pressure is taken twice within 5 min with the Omron® digital blood pressure monitor. A cuff size appropriate to the arm circumference of the participants will be chosen. Evidence for the validity of Omron® oscillometric blood pressure measurement devices has been reported previously [164]. Reductions in SBP and DBP of 2 mmHg are considered meaningful MCID scores [165]. Participants will be considered hypertensive if they have SBP scores of ≥ 140 mmHg and DBP scores of ≥ 90 mmHg [166].

Body mass index, percentage of body fat, and waist circumference

Body weight will be measured with a digital weighing scale (BC-545; Tanita, USA) without shoes (to the nearest 0.1 kg, in light clothes). To measure height, each participant will stand against a stadiometer without shoes. Body height will be taken (to the nearest 0.5 cm). BMI will be calculated with the following formula: weight (kg) / (standing height (m))^2. Based on WHO standards [167], participants will be classified as overweight if their BMI is ≥ 25.0 kg/m^2, and as obese with a BMI of ≥ 30.0 kg/m^2. Following an expert consensus [168], 5% weight loss is considered the MCID among people classified as overweight or obese. The BC-545 weighing scale can also be used for bioelectrical impedance analysis to assess percentage body fat. With regard to healthy body fat, the WHO [167] recommends maximum levels of ≥ 32% for women and ≥ 25% for men. In the present study, a reduction of 2% is defined as the MCID for percentage body fat [169]. A flexible tape at the natural waist (halfway between the ribcage and the iliac crest) is used to determine waist circumference. The expert panel of the National Cholesterol Education Program [170] defines a waist circumference of ≥ 80 cm (women) and ≥ 94 cm (men) as a risk factor for metabolic syndrome.

Cholesterol, triglycerides, and HbA1c

To perform blood tests, venous blood is drawn between 07:00 and 08:30 after fasting since 22:00 the day before by a trained nurse. For the assessment of blood lipid profiles (total cholesterol (TC), low-density-lipoprotein cholesterol (LDL-C), high-density-lipoprotein cholesterol (HDL-C), and triglycerides (TG)) and HbA1c, blood samples will be analysed via the Afinion test (Alere Technologies; Abbott, Wädenswil, Switzerland). One drop of blood will be taken up by the test strip and read by the machine. Good correspondence exists between the Alere point-of-care (PAC) analyser results and reference laboratory tests for HbA1c and lipid levels [171, 172]. Following Rodondi et al. [173], the following clinically relevant cut-off values should be considered for total cholesterol (≥ 5.6 mmol/l), HDL-C (≤ 1.41 mmol/l), and LDL-C (≥ 3.40 mmol/l). To our knowledge, no officially established MCID score exists for cholesterol levels, although some authors suggested considering a 10% increase in HDL-C and a 10% decrease in LDL-C as a meaningful score [174]. Following the American Diabetes Association [175] and the WHO [176], HbA1c scores of 5.7–6.4% point towards pre-diabetes, whereas scores of ≥ 6.5% can be used as diagnostic cut-off point

for diabetes, and reductions of ≥ 0.5% are generally considered the MCID for type 2 diabetes [177].

Brain-derived neurotrophic factor

Serum BDNF levels [178] will be determined in duplicate with an enzyme-linked immunosorbent assay (BDNF Emax Immunoassay System; Promega, USA). This method showed intra- and inter-assay variation coefficients of 6.0 and 8.5%, respectively [179]. No MCID scores exist for this measure.

Tumour necrosis factor alpha

The solid-phase Enzyme Amplified Sensitivity Immunoassay TNF-α ELISA from DRG (Switzerland) will be used to assess TNF-α [178]. The assay uses monoclonal antibodies (mAbs) directed against distinct epitopes of TNF-α. The amount of substrate turnover is determined colourimetrically by measuring the absorbance, which is proportional to the TNF-α concentration. No MCID scores exist for this measure.

Insulin-like growth factor 1

The DRG IGF-I 600 ELISA Kit (DRG), a solid phase enzyme-linked immunosorbent assay (ELISA), based on the principle of competitive binding, will be used to assess IGF-1 [180]. Patient samples, standards, and controls are acidified and neutralized prior to the assay procedure. No MCID scores exist for this measure.

Moderator

Serotonin transporter gene (5-HTTLPR)

To assess the 5-HTTLPR genotype [181] at baseline, 9 ml EDTA blood is collected from each participant (patients and controls). Within 2 h the blood sample is centrifuged without a break at 2500 × *g* for 10 min at room temperature to separate the cellular components. White blood cells are enriched in the resulting intermediate layer, which is carefully transferred to a reaction tube and stored at − 20 °C for no longer than 4 weeks prior to further processing. The next steps involve DNA extraction according to the manufacturer's instructions using the QUIAamp DNA blood mini kit (Quiagen, Switzerland), 5-HTTLPR-specific DNA amplification using GoTaq Polymerase and the Promega PCR Master Mix (Promega), and the following 5-HTTLPR primers: forward, GGC GTT GCC GCT CTG AAT GC (annealing temperature 66 °C); and reverse, GAG GGA CTG AGC TGG ACA ACC AC (annealing temperature 74 °C). After completion of the PCR, the products are electrophoretically evaluated.

The four afore-mentioned biochemical and genetic analyses for BDNF, TNF-α, IGF-1, and 5-HTTLPR will be performed at the Neurobiological Laboratory of the Psychiatric University Clinics Basel (Prof. Anne Eckert).

Covariates

The following variables will be assessed as potential covariates. Based on participants' self-reports, we will assess their gender, age, language, nationality, marital status, level of education, employment (rate) prior to hospitalization, years of job experience, smoking status, and the number of children living at home. In addition, based on a clinical interview with the treating psychiatrist, we will assess information regarding duration of the current depressive episode, number of prior depressive episodes, age of onset of depression, and current medication.

Qualitative data assessment

A nested qualitative study will be carried out using semi-structured interviews to assess the experience and acceptability of the intervention for the patients. All interviews will be tape-recorded, transcribed, and analysed with qualitative content analysis [182]. Moreover, the physical activity facilitator will register the number of hours needed for the counselling of each patient. As a result, we will be able to calculate the costs that need to be covered by a clinic if a trained professional is employed to facilitate physical activity adoption and maintenance. To assess cost-effectiveness of a physical activity intervention, Baxter et al. [87] and Chalder et al. [88] used a similar procedure in a previous study.

Data collection and statistical analysis

Types of data to be collected include: quantitative data on social and demographic background, anthropometric measurements, physical activity, cardiorespiratory fitness, exercise-related variables (cognitive and social determinants), indicators of psychological functioning, cardiovascular risk factors, and biomarkers of MDD; and qualitative data, based on semi-structured interviews, on the acceptability and perceived usefulness of the intervention among the patients. The collected data will be entered and merged into a single datafile. Statistical analysis will be performed using SPSS.

Treatment group, age, gender, baseline HAMD17 score, and the amount of previous depressive episodes will be selected as covariables. Changes in outcome variables over the three time points will be analysed using repeated-measures analyses of covariance (rANCOVAs), with a between-subject factor group (IG vs PCG) and a within-subject factor time (baseline, post intervention, follow-up). If significant group or time interactions are present, Bonferroni-adjusted post-hoc tests will be performed to identify individual differences. The statistical significance level will be defined at $\alpha = 0.05$. Effect sizes will be calculated according to the recommendations of Cohen [183], with $0.49 \geq d \geq 0.20$ indicating small effect (e.g. negligible practical importance), $0.79 \geq d \geq 0.50$

indicating medium effect (moderate practical importance), and $d \geq 0.80$ indicating large effect (crucial practical importance).

In the case of missing values (e.g. when patients drop out before follow-up), all analyses will be performed with and without intention to treat [184]. After a thorough dropout analysis, a decision will be reached regarding the method best suited to analyse intention-to-treat effects (e.g. last observation carried forward, imputation of missing values) [185].

Data monitoring and publishing of data

The sponsor-investigator will have monitoring visits at each site prior to the start and during the course of the intervention, to assure standardization across all four centres. Any observed discrepancies will be documented and further procedure discussed.

Furthermore, we will provide every fourth month a report to an external person (Prof. Uwe Pühse, Head Division Sport and Health Pedagogy, DSBG, University of Basel) regarding the recruitment quote, number of performed counselling sessions, state of the post-intervention and follow-up data assessments, and the dropout quote. In case of insufficient progress of the study, an agreement regarding potential countermeasures will be sought within the data monitoring committee (consisting of the external monitor (UP), the sponsor-investigator, and the responsible researchers of the four clinics (JB, MH, CI, UL)). The data monitoring committee will also coordinate the interim analysis and the international dissemination of the study results through presentations at national and international conferences and publications in peer-reviewed literature (primarily open access). The data monitoring committee will further decide which researchers (beyond those listed as co-authors in the present publication) will have access to the final trial dataset. In agreement with the other members of the data monitoring committee, the sponsor-investigator has the right to terminate the study prematurely according to certain circumstances, including ethical concerns, insufficient participant recruitment, when the safety of the participants is doubtful or at risk, respectively, alterations in accepted clinical practice that make the continuation of the trial unwise, and early evidence of benefit or harm of the experimental intervention.

At the end of the study, the results will be communicated to relevant healthcare professionals, the public, and other relevant institutions/groups.

Safety

All serious adverse reactions (SAEs) and adverse events (AEs) that occur during the study will be immediately reported to the sponsor-investigator. More specifically, during the entire duration of the study, all AEs and all SAEs will be collected, fully investigated, and documented in source documents and case report forms. The study duration encompasses the time from when the participant signs the informed consent until the last protocol-specific procedure has been completed, including a safety follow-up period. The sponsor-investigator will ensure obtaining required insurance coverage for the trial under applicable laws.

Schedule and milestones

Recruitment of patients started in January 2019. Each study centre treats approximately 150 patients per year. Assuming a recruitment rate of approximately 25%, inclusion will stop in January 2021, with follow-up assessments ending in January 2022. Recruitment of healthy controls started in January 2019 and will last until January 2020. An approximate schedule is presented in Table 1.

Discussion

People with mental illnesses are especially vulnerable to cardiovascular and metabolic diseases primarily caused by a sedentary lifestyle. Individually tailored physical

Table 1 Planned schedule and milestones

	2019				2020				2021				2022			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Recruitment of patients	X	X	X	X	X	X	X	X	X							
Screening	X	X	X	X	X	X	X	X	X							
Baseline tests	X	X	X	X	X	X	X	X	X							
Implementation of intervention programme	X	X	X	X	X	X	X	X	X							
Post assessments		X	X	X	X	X	X	X	X	X						
Follow-up assessments					X	X	X	X	X	X	X	X	X			
Assessment of healthy controls	X	X	X	X	X											
Qualitative interviews		X	X	X	X	X	X	X	X							
Data analyses, writing-up results									X	X	X	X	X	X		

activity counselling may increase lifestyle physical activity and cardiorespiratory fitness in a particularly vulnerable population which often suffers from a mix of mental and physical health problems. Improving physical activity and cardiorespiratory fitness may have important implications for tackling metabolic and cardiovascular disease and increasing cognitive functioning in this at-risk population, hence reducing the future burden of multiple chronic conditions. Increased physical activity and cardiorespiratory fitness may also reduce the likelihood of future depressive episodes. By moving towards the primary prevention of chronic physical conditions, much can be done to enhance the quality and quantity of life of people with MDD.

These findings may strengthen the evidence for "exercise as medicine" as a holistic care option in routine clinical practice for people with MDD, by helping patients to adopt and maintain physically active lifestyles after the end of their hospital stay. The study can show feasible ways to achieve long-term behaviour change by integrating physical activity and exercise counselling in given clinical structures. Moreover, the study will show whether such an approach is acceptable for in-patients treated for MDD, and how much financial resources are needed to systematically implement lifestyle physical activity counselling.

Trial status

The study protocol corresponds to the second protocol version, as submitted to the EKNZ and EKB on 28 September 2018. Recruitment started on 1 January 2019. Follow-up data assessment will be complete at the latest in January 2022. Ethical approval has been obtained from the relevant review boards in Switzerland.

Additional file

Additional file 1: SPIRIT 2013 Checklist (DOC 123 kb)

Abbreviations

5-HTTLPR: Serotonin transporter polymorphic promoter region; ACSM: American College of Sports Medicine; AE: Adverse event; BASPO: Swiss Federal Office of Sport; BDI: Beck Depression Inventory; BDNF: Brain-derived neurotrophic factor; BMI: Body mass index; CRF: Cardiorespiratory fitness; DALY: Disease-adjusted life years; DBP: Diastolic blood pressure; DSM-IV: *Diagnostic and Statistical Manual of Mental Disorders* (4th edition); ECG: Electrocardiogram; EKB: Ethikkommission Bern (Ethical Review Board of the Canton Bern); EKNZ: Ethikkommission Nordwest- und Zentralschweiz (Ethical Review Board of Northwestern and Central Switzerland); ELISA: Enzyme-linked immunosorbent assay; HAMD17: 17-item Hamilton Depression Rating Scale; HDL-C: High-density-lipoprotein cholesterol; HF nu: High-frequency normalized units; HRV: Heart rate variability; ICD-10: International Classification of Diseases (10th edition); IG: Intervention group; IGF-1: Insulin-like growth factor 1; IPAQ: International Physical Activity Questionnaire; ISI: Insomnia Severity Index; LDL-C: Low-density-lipoprotein cholesterol; LF nu: Low-frequency normalized units; mAb: Monoclonal antibody; MDD: Major depressive disorder; MET: Metabolic equivalents of task; MoVo-Lisa: Motivation, Volition and Lifestyle-integrated Sport Activity; MPA: Moderate physical activity; PAR-Q: Physical Activity Readiness Questionnaire; PCG: Placebo control group; PSS: Perceived Stress Scale; rANCOVA: Repeated-measures analysis of covariance; RCT: Randomized controlled trial; R–R interval: Inter-beat interval for peak of the QRS complex of the ECG wave; SAE: Serious adverse event; SBP: Systolic blood pressure; SDNN: Standard deviation of normal-to-normal intervals; SF-12 : 12-item Short Form Health Survey; SIMPAQ: Simple Physical Activity Questionnaire; SNSF: Swiss National Science Foundation; SPSS: Statistical Package for the Social Sciences; SSK: Exercise-related self-concordance; TC: Total cholesterol; TG: Triglycerides; TNF-α: Tumour necrosis factor alpha; VO_2max: Maximal oxygen uptake; VPA: Vigorous physical activity; WHO: World Health Organization; YLD: Years of life lived with disability

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Authors' contributions

MG, JB, SB, RC, LD, AE, OF, XF, MH, EH-T, CI, UL, SM, TM, AO, UP, SR, A-KS, NS, US, and LZ were involved in the design of the study. MG wrote the manuscript draft. JB, SB, RC, LD, AE, OF, XF, MH, EH-T, CI, UL, SM, TM, AO, UP, SR, AKS, NS, US, and LZ authors read and critically commented on the draft. All authors read and approved the final manuscript.

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Availability of data and materials

Data will be made publicly available as supplementary online material and stored in digital archives that correspond with FAIR Data Principals after publication of the data (in form of an SPSS file). Variables are clearly labelled in the SPSS file and described in the SPSS variable view. For each publication, a separate SPSS file will be created with the data used for the specific data analyses.

Ethics approval and consent to participate

Central ethical approval has been confirmed from the "Ethikkommission Nordwest- und Zentralschweiz" (ref. approval no. 2018-00976), and local ethical approval has been obtained for all study sites. Thus, local ethical approval has been obtained from the "Ethikkommission Nordwest- und Zentralschweiz" for the clinics located in Basel, Riehen, and Solothurn, and from the "Ethikkommission Bern" for the clinic located in Münchenbuchsee. The intervention study was registered in the WHO trial register (trial number ISRCTN10469580). All participants will be informed about the general goals of the study. Informed written consent is required before study entry. The study will be carried out in accordance with the ethical principles laid down in the Declaration of Helsinki (1964). Important protocol modifications will be communicated to participants and trial registries.

Consent for publication

After completion of the data assessment, all personal data of the patients will be encoded (each patient will receive a project ID number), so that it will no longer be possible to identify the patients. No publication of case reports is planned where the manuscript could contain individual person's data.

Competing interests

The authors declare that they have no competing interests.

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Chapter 4 Publication 2

Psychosocial Health and Physical Activity in People With Major Depression in the Context of COVID-19

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Introduction: Major depression is a psychiatric disease associated with physical inactivity, which in turn affects mental and physical health. A randomized controlled trial is being implemented to facilitate physical activity in people with major depression. In March 2020, Swiss state authorities temporarily legislated a lockdown to contain the Coronavirus disease-19 (COVID-19), which influenced health, behavior and research. The aim of this study was to find out whether data gathered before and during/after the lockdown among in-patients with major depression differ with regard to psychosocial health, physical activity and related attitudes and to establish whether baseline data have been affected by the lockdown.

Methods: This is a cross-sectional analysis within a randomized controlled trial. Physically inactive, adult in-patients diagnosed with major depression were recruited from four Swiss psychiatric clinics between January 2019 and December 2020. Psychosocial health was measured with questionnaires pertaining to stress, sleep and health-related quality of life. Physical activity was measured with the Simple Physical Activity Questionnaire. Explicit attitudes were measured with seven questionnaires pertaining to physical activity-related motivation and volition. Implicit attitudes toward physical activity were captured with a single target implicit association test.

Results: The sample consisted of 165 participants (n = 119 before lockdown, n = 46 during/after lockdown). No statistically significant differences were found between in-patients with major depression assessed before and during/after the COVID-19 lockdown with regard to psychosocial health (stress, $p = 0.51$; sleep, $p = 0.70$; physical component of health-related quality of life, $p = 0.55$; mental component of health-related quality of life, $p = 0.64$), self-reported physical activity ($p = 0.16$) and explicit as well as implicit attitudes toward physical activity ($p = 0.94$). Hence, the COVID-19-induced lockdown seems not to have led to group differences.

Conclusion: Baseline data gathered in in-patients suffering from major depression who are physically inactive upon admission to in-patient treatment in Switzerland seem to be unaffected by the COVID-19-induced lockdown. To assess changes in said population regarding psychosocial health and physical activity patterns over time, longitudinal data are needed.

Keywords: psychosocial health, COVID-19, depression, physical activity, attitudes, lockdown

INTRODUCTION

Major depressive disorder (MDD) is a psychiatric disease that affects 10–15% of people worldwide at least once in their lifetime (Lépine and Briley, 2011). Twenty to thirty percent of cases are chronic, lasting 2 years or longer (Riso et al., 2002) engendering suffering for the afflicted person and their social network from a psychological, medical, economical as well as social point of view (Pincus and Pettit, 2001). Population studies have found that depression symptoms as well as major depression are associated with double the risk of premature mortality (SMR = 1.9 in men; SMR = 2.1 in women); significantly higher risk of all-cause mortality (HR = 1.05; 95% CI = 1.02–1.10); and double the risk of cardiovascular, specifically stroke, mortality (OR = 2.24; 95% CI = 1.37–3.60) compared to general populations (Lépine and Briley, 2011). The relationship between MDD and physical activity seems to be bi-directional (De Moor et al., 2006; Lindwall et al., 2014). Longitudinal data show that people suffering from MDD tend more toward sedentary behavior (Firth et al., 2016; Stubbs et al., 2018). Thus, physical activity recommendations according to the World Health Organization stating a minimum of 150 min of moderate-to-vigorous physical activity per week (WHO, 2010) may not be adhered to. According to a meta-analytic analysis including data from North America, Europe and Australia, people with MDD spend 126 min (95% CI = 91.90–160.10) and 8.5 hours (95% CI = 7.51–9.62) per day engaging in all types of physical activity and sedentary behavior, respectively. Compared to healthy people, they spend a mean difference of −11.6 min (95% CI = −25.70–2.60) less being physically active and a mean difference of −0.2 h (95% CI = −19.7–0.8) more in sedentary behavior. These differences are deemed statistically significant ($p < 0.05$; Schuch et al., 2017). On the other hand, low levels of physical activity may perpetuate symptoms and even increase the risk for MDD (Mammen and Faulkner, 2013). This is also supported by meta-analytic data, which states that compared to people engaging in low levels of physical activity, those engaging in high levels have lower odds to develop MDD (OR = 0.83; 95% CI = 0.79–0.88), and that physical activity can have a protective effect across ages and geographic regions (Schuch et al., 2018). Inactivity leads to negative outcomes such as obesity, diabetes, more severe negative mental health symptoms and poor socio-occupational functioning (Firth et al., 2016).

Reasons for inactivity among people suffering from psychiatric illnesses can be physical co-morbidities such as obesity and diabetes as well as demographic influences such as sex (female), age (inverse) and lower educational level (Gerber et al., 2016a; Schuch et al., 2017). Additionally, psychological determinants correlated with engaging in health behaviors such as motivation, self-efficacy and volition may be impacted in people with MDD (Bauman et al., 2012; Vancampfort et al., 2015; Cortis et al., 2017). In recent years, increasing evidence points toward behavior being a result of two different information processing systems; one deliberate system requiring reflection, the other automatic requiring minimal cognitive resources (Chaiken and Trope, 1999; Kahneman and Frederick, 2002; Strack and Deutsch, 2004). Hence, behavior can be considered deliberative and rational decision-making enhanced by automatic, subconscious processes (Calitri et al., 2009; Conroy et al., 2010; Hyde et al., 2010). Decision-making is a slow process running on self-regulatory resources such as planning and goal setting. These are explicit motivational processes regulating intentional physical activity (Deutsch and Strack, 2006; Vohs, 2006). Additionally, intrinsic motivation may increase positive attitudes toward physical activity, thus leading to greater participation in and adherence to a physically active lifestyle (Haase et al., 2010). Attitudes are not only regulated by explicit motivational processes but also by automatic evaluative processes (Strack and Deutsch, 2004). Implicit attitudes have been shown to explain behavior beyond explicit attitudes (Greenwald and Banaji, 1995; Calitri et al., 2009; Rebar et al., 2016). They can be described as mental associations between a concept (e.g., physical activity) and its positive or negative evaluation (Chen and Bargh, 1999; Calitri et al., 2009). Automatic evaluative processes may influence immediate decisions regarding the target behavior (Brand and Schweizer, 2015); however, changes within the system are slow and gradual (Deutsch and Strack, 2006). Non-conscious processes explain the repetitious nature of physical activity, aspects unaccounted for in intention and maintenance when self-control resources are depleted (Aarts et al., 1997; Dimmock and Banting, 2009; Friese et al., 2011; Marteau et al., 2012; Rebar et al., 2016). Thus, pre-existing positive automatic evaluation of exercise may act as a buffer for potentially negative experiences (Antoniewicz and Brand, 2016a). Furthermore, implicit attitudes have been shown to be associated with previous self-reported physical activity, attentional biases to physical activity cues (Calitri et al., 2009), and may predict automatic / unplanned physical activity (e.g., taking the stairs instead of the lift) as well as objectively measured physical activity (Conroy et al., 2010).

In December 2019, first cases of Coronavirus disease-19 (COVID-19) were reported in China (WHO, 2021). By February 2020, the first cases were confirmed in Switzerland and a state legislated lockdown commenced in March until the end of April 2020. During the months between April and October, many

restrictions were lifted; shops and restaurants re-opened, school recommenced as usual and sport facilities were accessible again. However, with increasing number of cases, protective measures were implemented again in October 2020. This included wearing masks in all public areas, restrictions of gatherings and recommendations for working from home (BAG, 2020). This ongoing pandemic is impacting lives as well as research in a multitude of ways. People may be experiencing mental health issues and decreases in well-being and mood, which in turn may be associated with negative impacts on lifestyle behaviors (Ammar et al., 2020). In an Australian nation-wide online survey, Stanton et al. (2020) found that people reporting negative changes in physical activity behavior had higher depression, anxiety and stress symptoms [see also Lindwall et al. (2014), Gerber et al. (2020), Meyer et al. (2020)]. These negative changes may have occurred because of the inaccessibility of gyms and outdoor spaces. When comparing online questionnaires before and during lockdown completed by healthy individuals in France and Switzerland, an increase of moderate physical activity and walking of about 10 min per day was found, whereas a decrease in vigorous physical activity became evident. Additionally, an increase in sedentary behavior of about 75 min per day was observed. Increased physical activity showed positive effects on physical health, whereas increased sedentary behavior had a negative influence on physical and mental health (Cheval et al., 2020). In line with findings from Stanton et al. (2020), changes in health behaviors are attributed to practical reasons, such as fewer opportunities to be physically active (Cheval et al., 2020). In addition, affective factors such as anxiety and stress are highlighted since they negatively influence mood and interest in activity (Cheval et al., 2020). Bi-directional effects of decreased mental health and physical activity have also been observed. According to an online survey conducted in the United Kingdom, a lockdown-induced reduction in physical activity may lead to increased symptoms of loneliness and depression, hence negatively impacting mental health (Creese et al., 2020). Not only do decreased physical activity levels influence mental health, self-isolation measures as experienced during quarantine may evoke feelings of anxiety and depression. These have been linked to long quarantine durations, fear of infection, frustration, boredom, inadequate supplies and information, financial loss and stigma (Brooks et al., 2020). For ongoing clinical trials, the COVID-19 pandemic has led to trials being stopped or paused. Issues such as missing data, incomplete follow-up, reduced on-site data monitoring with implications for data quality and integrity, missed treatments, changes in usual care and heterogeneity of patients included in trials are becoming prevalent in trial work (Kunz et al., 2020; Sathian et al., 2020). An analysis of data gathered before the pandemic can be helpful for deciding how to proceed (Kunz et al., 2020). Potential confounding caused by COVID-19 may also be detected by examining outcome rates before and during the pandemic (Tuttle, 2020). Trials, which have continued have been subject to decreased recruitment rates because of the need to reduce face-to-face interactions, and alternatives such as video conferences to obtain informed consent as well as collect data are being explored. Communication with clinic staff and sponsors has increased to develop individual solutions regarding COVID-19 implications for access to patients and funding matters. Additionally, some interventions have been interrupted or adapted to adhere to social and physical distancing standards (Mitchell et al., 2020). This gap can be filled with tools developed in recent years such as telehealth and home-based testing or monitoring technologies. There have also been cases in which recruitment rates have recovered, where attention must be payed to the potential effect COVID-19 may have on the study outcomes. For example, pre-existing conditions may have changed and lifestyle changes may have been made to adhere to safety guidelines (Tuttle, 2020).

Given the fact that changes in physical activity, as well as psychosocial health, have been detected in COVID-19 associated research so far, a closer look at data collected during this time is warranted. Hence, the aim of this study was to assess any potential differences in psychosocial health (stress, sleep, health related quality of life), self-reported physical activity and explicit as well as implicit attitudes toward physical activity in in-patients suffering from MDD recruited and assessed before COVID-19 in Switzerland and those recruited and assessed during/after the COVID-19-induced lockdown. It is of interest to see if trends that have been recognized in the afore-mentioned cohort studies are also visible in this sample. Additionally, it is of importance for the conduct of this trial to assess whether the COVID-19-induced lockdown in March and April 2020 has impacted the integrity of the baseline data in light of the planned longitudinal analyses.

MATERIALS AND METHODS

Study Design

This is a cross-sectional analysis conducted within the PACINPAT randomized controlled trial (Physical Activity Counseling in In-Patients with Major Depression) taking place in four centers in three Swiss cantons (Basel, Solothurn, and Bern) (Gerber et al., 2019). Recruitment started in January 2019, paused from March to April 2020 because of a COVID-19-induced lockdown and was taken up again in May 2020 at half the rate (January 2019–February 2020, $N = 143$, $M = 10$ participants per month vs. March 2020–December 2020, $N = 52$, $M = 5$ participants per month). Participants were screened by clinic personnel and included in the trial upon providing written informed consent to a member of the study team. An individual, in person baseline assessment was completed during the first weeks of in-patient treatment conducted by a member of the study team. This consisted of a 90 min session in which demographic data, information regarding past and current depressive episodes, medication, secondary diagnoses, self-reported physical activity, and self-perceived fitness were collected via interview. Additionally, self-perceived fitness was assessed with a 1-item question: "Overall, how would you rate your physical fitness?" This question was answered on a scale ranging from 1 (very poor fitness) to 10 (excellent fitness). Psychosocial health (psychosocial stress, sleep and health-related quality of life) and explicit attitudes (physical activity-related intention, self-concordance, self-efficacy, action and planning coping, outcome expectancies, perceived barriers, and social support) toward physical activity were assessed with

corresponding questionnaires (see below for more details). Implicit attitudes toward physical activity were assessed with a computer-based single target implicit association test. At this time, the participants did not receive any instructions regarding physical activity from the study team.

Participants and Procedures

The current study sample consists of in-patients who were being treated for unipolar major depressive disorder at the time of recruitment and data collection. The inclusion criteria were as follows: women and men between 18 and 65 years, ICD-10 diagnosed depressive episode (single episode or recurrent), Beck Depression Inventory score (BDI) of at least 17 representing clinical depression, physical inactivity as defined by <150 min of moderate-to-vigorous physical activity per week prior to in-patient treatment, and adequate German language skills. The eligible patients, who provided written informed consent were included in the study. The patients were recruited at varying durations of clinic stay, and were receiving various pharmacological and complementary treatments. Physical activity 1 week prior to admission to in-patient treatment was measured with the International Physical Activity Questionnaire (IPAQ) in which days per week and minutes per day spent in physical activity are used to calculate a total amount of minutes per week spent in moderate-to-vigorous physical activity. According to a validation and reliability study, this measure is sufficiently representative of physical activity behavior (Craig et al., 2003). Depression severity was measured with the BDI, a 21-item self-report instrument used to assess the symptoms and attitudes referring to depression. Items are rated from 0 to 3 in terms of intensity, individual item scores are added to reach a total score. Scores bellow 10 indicate no or minimal depression, scores between 10 and 18 mild-to-moderate depression, scores between 19 and 29 moderate-to-severe depression and scores between 30 and 63 severe depression (Beck et al., 1988). According to meta-analytic analysis, the BDI has high internal consistency, content validity, sensitivity to change, and validity in differentiating between subjects. Thus, its psychometric properties are acceptable and recognized world-wide (Richter et al., 1998). Six patients were recruited despite a BDI score < 17 based on the lead physician's estimation of sufficient depression severity. In addition, depression severity was assessed using the Hamilton Depression (HAMD) scale, which is a structured clinical interview. Scores range from 0 to 52 with higher scores representing more severe depression symptoms. This is a valid instrument with high discriminatory sensitivity (Fava et al., 1982). In addition, comparative reliability and validity have been established (Endicott et al., 1981).

All procedures received ethical approval from the "Ethikkommission Nordwest- und Zentralschweiz" and the "Ethikkommission Bern" (approval number: 2018-00976). Additionally the PACINPAT trial is registered in the ISRCTN registry (ISRCTN10469580) and the study protocol is published for more details (Gerber et al., 2019). All procedures are in line with the guidelines for Good Clinical Practice (ICH GCP) and with the ethical standards defined in the Declaration of Helsinki.

Measures

Internal consistency of the questionnaires for the current study was measured by calculating the Cronbach's alpha (including 95% CIs) for each questionnaire individually. Values of ≥ 0.70 were deemed as satisfactory (Bland and Altman, 1997).

Psychosocial Health

Psychological Stress

The Perceived Stress Scale (PSS) was used to assess the degree to which, in the past month, life was appraised as unpredictable, uncontrollable and overloaded (Cohen et al., 1983). The ten questions were answered on a scale from 1 (never) to 5 (very often) (e.g., "In the last month, how often have you been upset because of something that happened unexpectedly?"). To obtain the score, positive items (questions 4, 5, 7, and 8) were reversed, then the total sum over all items was calculated, hence the score ranges from 0 to 40, with higher scores reflecting higher perceived stress levels. A review on the psychometric properties revealed Cronbach's alpha ranging from 0.78 to 0.91 across cultures (Lee, 2012). A German translation of the tool was validated in a representative German sample with satisfactory internal consistency and construct validity (Klein et al., 2016). The internal consistency in the present sample was satisfactory (Cronbach's alpha: $\alpha = 0.80$, 95% CI = 0.74–0.84). The mean score across both groups was M = 37.14 (95% CI = 36.28 to 37.99).

Sleep

To measure symptoms and consequences of insomnia, which can be a common complaint in MDD (WHO, 2004), the seven-item Insomnia Severity Index (ISI) covering sleep complaints over the last 10 weeks was used. Three items relate to onset and maintenance (during the night and in the morning) of sleep on a scale from 0 (no difficulties) to 4 (very difficult). One item addresses satisfaction with sleep pattern, also ranging from 0 (very satisfied) to 4 (very dissatisfied). The next item refers to the extent to which the sleep problem interferes with daily functioning ranging from 0 (not at all) to 4 (very much). A further item relates to the perceived noticeability of others regarding the link between sleep problems and impaired quality of life of the person in question also ranging from 0 (not at all) to 4 (very much). The last item captures the degree to which the sleep problem causes distress on a scale from 0 (not at all) to 4 (very much). The final score is computed by the sum of all items which ranges from 0 to 28 with higher scores indicating higher levels of insomnia (0–7 = no clinical insomnia, 8–14 = subthreshold insomnia, 15–21 = moderate clinical insomnia, 22–28 = severe clinical insomnia). This is a self-reported measure which can be completed in 5 min (Bastien et al., 2001). Reliability as well as concurrent and content validity were deemed satisfactory for the original English questionnaire (Bastien et al., 2001) as well as the German translation (Gerber et al., 2016b) used in this study. The internal consistency in the present sample was satisfactory ($\alpha = 0.77$, 95% CI = 0.71–0.82). The mean score across both groups was M = 12.11 (95% CI = 11.24–12.98).

Health-Related Quality of Life

The Medical Outcomes Study Short Form 12 (SF-12) was used to assess health-related quality of life. This questionnaire originated in a longer form, SF-36 including eight domains: general health, physical functioning, social functioning, role limitations caused by physical problems, role limitations caused by emotional problems, mental health, vitality and bodily pain. The reliability of this questionnaire has been tested in both general and psychiatric populations, and has been proven to be internally consistent and valid in people with depression (McHorney et al., 1994; Leidy et al., 1998). It was found that two factors, the Physical Component Summary (PCS) and Mental Component Summary (MCS) account for >80% of the variance of individual scales with reliability estimates usually exceeding 0.90 (Ware et al., 1994). Additionally, these factors require fewer items and are easy to interpret. In the shorter form (SF-12) the PCS and MCS have been found to correlate highly with those of the SF-36 (Ware et al., 1996). Sound psychometric properties of the SF-12 in people with severe mental illness have been proven (Salyers et al., 2000). Both PCS and MCS scores range from 0 to 100 with higher scores indicating higher health-related quality of life correspondingly. In the present sample, the internal consistency was satisfactory for both the PCS and MCS ($\alpha = 0.76$, 95% CI = 0.70–0.82 and 0.70, 95% CI = 0.62–0.77, respectively). The mean scores across both groups were M = 49.21 (95% CI = 47.83–50.60) for the Physical Component Summary and M = 26.60 (95% CI = 25.61 to 28.19) for the Mental Component Summary.

Self-Reported Physical Activity

The Simple Physical Activity Questionnaire (SIMPAQ), a questionnaire conducted as a personal interview consisting of five categories (time spent in bed, in sedentary behavior, walking, in structured exercise and in incidental physical activity), was used (SIMPAQ, 2020). It was developed for populations at high risk of increased levels of sedentary behavior, such as people suffering from psychiatric illness. The sum of all categories should equal 24 h, representing an average day in the previous week. There is no minimum time requirement set in any category. Intensities are not included except in the category of structured exercise, in which the number of sessions per week and time as well as intensity spent in each session is recorded. The intensity is elicited via a visual analog scale ranging from zero to ten. A large-scale validation study is being conducted to compare SIMPAQ results with accelerometer-based data (Rosenbaum and Ward, 2016). However, an exploratory study in a sample of healthy young adults was conducted. Significant correlations ($p < 0.001$) were found for moderate-to-vigorous physical activity between self-reported and accelerometer-based data (rho = 0.49). This study also includes the validation of the German language translation (Schilling et al., 2018).

Explicit Attitudes Toward Physical Activity

Physical Activity-Related Intention

The following one item was used to assess participants' intention to engage in physical activity: "How strong is your intention to be physically active in the next weeks and months?" Answer options range from 0 (no intention) to 5 (very strong intention). This measure is reliable and valid according to previous studies (Seelig and Fuchs, 2006; Gerber et al., 2011).

Physical Activity-Related Self-Concordance

Four subscales of motivation: intrinsic ("I would exercise because it is just fun"), identified ("I would exercise because I have good reasons to be physically active"), introjected ("I would exercise because otherwise I would have a guilty conscience") and extrinsic ("I would exercise because others tell me to") were assessed with the 12-item self-concordance scale (Seelig and Fuchs, 2006). All items are answered on a 6-point Likert scale ranging from 1 (not at all true) to 6 (completely true). The scores of the three questions pertaining to intrinsic motivation were added, and the mean derived to obtain a score for intrinsic motivation. The same was done for all subscales. This instrument has proven to be psychometrically sound (Seelig and Fuchs, 2006; Fuchs et al., 2012). In the present sample, the internal consistencies for all subscales was as follows: intrinsic: $\alpha = 0.71$ (95% CI = 0.62–0.78), identified: $\alpha = 0.54$ (95% CI = 0.40–0.65), introjected: $\alpha = 0.69$ (95% CI = 0.60–0.77) and extrinsic: $\alpha = 0.72$ (95% CI = 0.63–0.79). Cronbach's alpha for the overall scale was $\alpha = 0.69$ (95% CI = 0.62–0.76). Despite the Cronbach's alpha for the subscale of identified motivation being below the acceptable threshold, this was accepted given the sample size and the acceptability of the overall scale value of Cronbach's alpha. The mean score across both groups was M = 3.59 (95% CI = 3.51–3.67).

Physical Activity-Related Self-Efficacy

Physical activity related self-efficacy was assessed with a 3-item score, with answers ranging from 0 (not at all confident) to 5 (100% confident in myself). The contents include self-efficacy beliefs regarding the initiation, maintenance and resumption of physical activity (e.g., "I feel confident to start with a new exercise activity"). The mean score is calculated from the three items, with higher scores representing higher self-efficacy levels. This questionnaire has been validated in a previous study (Fuchs, 2008). The internal consistency in the present sample was satisfactory ($\alpha = 0.82$, 95% CI = 0.77–0.87). The mean score across both groups was M = 3.61 (95% CI = 3.45 to 3.76).

Physical Activity-Related Action Planning

A 5-item questionnaire was used to measure action planning (Sniehotta et al., 2005). Questions pertain to when, where, how, how often and with whom participants are usually physically active. Answers range from 1 (not at all true) to 4 (completely true). The mean represents the final score with higher values indicating higher levels of pre-planned physical activity. Reliability and validity have been established in previous studies (Sniehotta et al., 2005; Gerber et al., 2011). The internal consistency in the present sample was satisfactory ($\alpha = 0.81$, 95% CI = 0.77–0.86). The mean score across both groups was M = 2.64 (95% CI = 2.54–2.75).

Physical Activity-Related Coping Planning

A 5-item questionnaire was used to evaluate coping planning (Sniehotta et al., 2005). On a 4-point Likert scale, participants

give information pertaining to the extent to which they implement self-regulatory strategies to overcome barriers. One such question is "I have made a detailed plan regarding what to do in difficult situations in order to act in accordance to my intentions." Answers range from 1 (not at all true) to 4 (completely true). The final score consists of the mean of all items. Psychometric properties have been evaluated resulting in acceptable reliability and validity of the scale (Sniehotta et al., 2005; Gerber et al., 2011). The internal consistency in the present sample was satisfactory ($\alpha = 0.84$, 95% CI = 0.79–0.88). The mean score across both groups was M = 2.11 (95% CI = 1.99–2.22).

Physical Activity-Related Outcome Expectancies

Nine positive (e.g., "If I exercise or am physically active, I become more flexible") and seven negative formulations (e.g., "If I exercise or am physically active, I could injure myself") are provided to assess outcome expectancies (Fuchs, 1997). Answers range from 1 (not true) to 4 (completely true). The mean is calculated for positive as well as negative outcome expectancies, with higher scores indicative of higher positive or negative outcome expectancies correspondingly. This instrument has been proven to be reliable and valid (Fuchs, 1997; Fuchs et al., 2012). The internal consistency in the present sample was satisfactory for both positive ($\alpha = 0.77$, 95% CI = 0.71–0.82) and negative outcome expectancies ($\alpha = 0.74$, 95% CI = 0.67–0.80). The mean scores across both groups were M = 3.23 (95% CI = 3.16–3.30) for positive outcome expectancies and M = 2.00 (95% CI = 1.92–2.09) for negative outcome expectancies.

Physical Activity-Related Perceived Barriers

A 19-item tool was used to assess perceived barriers to physical activity (Krämer and Fuchs, 2010). Items take on the following nature: "I have too much work to do." Answers range from 1 (almost never) to 4 (almost always). The mean is computed representing the overall score. Satisfactory psychometric properties have been proven in previous studies (Krämer and Fuchs, 2010; Kramer et al., 2014). The internal consistency in the present sample was satisfactory ($\alpha = 0.84$, 95% CI = 0.80–0.88). The mean score across both groups was M = 2.13 (95% CI = 2.06–2.21).

Physical Activity-Related Social Support

A 7-item index, which has proven reliability and validity, was used to measure social support (Gerber et al., 2010). Questions addressed the extent to which the participant experiences support from their social network (e.g., "Close family or friends help me plan my exercise"). Answers range from 1 (almost never) to 4 (almost always). The overall score is represented by the mean with higher values indicating more social support compared to low values. The internal consistency in the present sample was satisfactory ($\alpha = 0.88$, 95% CI = 0.84–0.90). The mean score across both groups was M = 2.43 (95% CI = 2.32–2.54).

Implicit Attitudes Toward Physical Activity

The computer-based Single Target-Implicit Association Test (ST-IAT) was used to assess implicit attitudes toward physical activity (Greenwald et al., 1998). It is a response-time based test using a target concept, in this case physical activity, and target categories, in this case good and bad. The visual stimuli were people exercising displaying no obvious affect as well as emoticons (smileys and frownies) (Greenwald et al., 2003). First, the participants were instructed to accurately categorize the stimuli by pressing a button corresponding to the respective target category. The test was initiated with a practice block containing 16 trials, in which only the emoticons had to be categorized as good (smileys) or bad (frownies). Following a fixation period of 250 ms, stimuli were presented until a response was collected. After the initial block, participants were instructed to assign emoticons and target images to one of the response categories, which presented sport either along with the good or bad category. The order of the categorization was counterbalanced across participants. Participants completed two blocks with 32 trials each, which were preceded by 16 practice trials to reduce learning effects. Upon incorrect response, a repetition took place at the end of the block. For statistical analysis, the D-score was calculated by dividing the ST-IAT raw scores (reaction time difference between the two block types) by the within-subject standard deviation of reaction times. The D-score can take on values between −2 and +2 and the interpretation goes as follows: 0.15 = slight, 0.35 = moderate, 0.64 = strong preference/aversion (Blanton et al., 2015). This version has been developed specifically for inactive in-patients suffering from depression using E-prime 2.0 (PST, USA) software and images obtained from Adobe Stock and has been pilot tested. General reliability and discriminant validity of the ST-IAT has been well-established (Greenwald et al., 2003; Bluemke and Friese, 2008; Blanton et al., 2015; Antoniewicz and Brand, 2016b).

Given that sustained attention may affect ST-IAT scores (Wright and Meade, 2012) this cognitive domain was assessed using a computerized Oddball Paradigm (Calitri et al., 2009) administered with E-Prime 2.0 (PST, USA). Task instructions were presented on the screen. Speed and accuracy were equally emphasized across both tests. The Oddball Paradigm required participants to press one button to frequent stimuli (75%) and another button to infrequent stimuli (25%). Visual stimuli were the letters "X" and "O" and the stimulus-response mapping was counterbalanced across participants. Following an inter-stimulus interval varying randomly between 800 and 1,500 ms, visual stimuli were presented over 250 ms and responses were allowed within 1,000 ms. The task encompassed a practice block of 10 trials and two test blocks with 40 trials each. Reaction time (on response-correct trials) accuracy were extracted for analyses. Reliability for the oddball paradigm has been proven in a previous study (Williams et al., 2005).

Statistical Analyses

Descriptive statistics (M, SD, *n*, and %) were calculated for the total sample ($N = 165$) as well as both groups: pre-lockdown ($N = 119$) and post-lockdown ($N = 46$). Kolmogorov-Smirnov and Shapiro Wilk tests revealed that the assumptions of normality of the populations and homogeneity of population variance were violated in part. Hence, differences in potential confounders were measured with Brown Forsythe (BF) one-way Analyses of Variance (ANOVAs) to additionally adjust for unequal sample

TABLE 1 | Descriptive statistics and differences in potential confounders.

	Total sample ($N = 165$) M (SD)	Pre-lockdown ($N = 119$) M (SD)	Post-lockdown ($N = 46$) M (SD)	Brown Forsythe		ANOVA		
				F	*p*	*F*	*p*	η^2
Metric variables								
Age (years)	41.88 (12.48)	41.94 (12.29)	41.74 (13.09)	0.01	0.93	0.01	0.93	<0.001
Education (years)	14.10 (3.41)	14.02 (3.58)	14.29 (2.94)	0.24	0.62	0.20	0.65	<0.001
BDI score at screening	28.72 (8.78)	28.14 (9.08)	30.32 (7.73)	2.01	0.16	1.72	0.19	0.01
BDI score at baseline	21.36 (9.83)	21.71 (9.95)	20.55 (9.62)	0.45	0.51	0.43	0.51	<0.001
HAMD at baseline	13.44 (5.25)	14.03 (5.09)	11.89 (5.39)	5.39	0.02	5.67	0.02	0.03
Prior episodes (number of)	2.90 (6.13)	3.24 (7.16)	2.13 (2.51)	1.95	0.16	1.05	0.31	0.01
Age (years) at 1st episode	32.03 (14.20)	31.77 (14.11)	32.62 (14.55)	0.11	0.74	0.11	0.74	<0.001
Pre-clinic PA (min/week)	33.29 (49.33)	28.85 (47.04)	41.55 (52.90)	1.70	0.20	1.82	0.18	0.01
Perceived fitness (1–10)	3.77 (1.56)	3.82 (1.56)	3.65 (1.56)	0.39	0.53	0.39	0.53	<0.001
	n (%)	*n* (%)	*n* (%)	χ^2	phi			
Categorical variables								
Sex				0.70	−0.06			
Women	84 (51)	63 (53)	21 (46)					
Men	81 (49)	56 (47)	25 (54)					
Primary diagnosis				2.96	0.13			
F32.1	39 (24)	30 (25)	9 (19)					
F32.2	22 (13)	18 (15)	4 (9)					
F32.3	2 (1)	1 (1)	1 (2)					
F33.1	71 (43)	50 (42)	21 (46)					
F33.2	31 (19)	20 (17)	11 (24)					
Civil status				2.82	−0.13			
Single	113 (68)	77 (65)	36 (78)					
Married	52 (32)	42 (35)	10 (22)					
Employment (pre-clinic)				0.03	−0.01			
Yes	124 (75)	89 (75)	35 (76)					
No	41 (25)	30 (25)	11 (24)					
Yearly income				1.18	0.09			
<50,000 CHF	55 (42)	38 (43)	17 (39)					
50,000–100,000 CHF	51 (38)	35 (40)	16 (36)					
>100,000 CHF	26 (20)	15 (17)	11 (25)					

BDI, Beck Depression Inventory; HAMD, Hamilton Depression Score; PA, physical activity; Perceived fitness scale ranging from 1 = not fit to 10 = very fit. F32.1, major depressive disorder, single episode, moderate; F32.2, major depressive disorder, single episode, severe; F32.3, major depressive disorder, single episode, severe, with psychotic features; F33.1, major depressive disorder, recurrent, moderate; F33.2, major depressive disorder, recurrent, severe; CHF, Swiss Francs.

sizes. Differences in categorical variables were measured with χ^2-tests. The BF procedure is robust, thus known to control Type 1 errors given heterogeneity of variance (Lix et al., 1996). To further analyze group differences in psychosocial health, physical activity and explicit as well as implicit attitudes toward physical activity, Analyses of Covariance (ANCOVAs) using age, sex and number of previous episodes as covariates as defined in the study protocol were conducted. Additionally, for implicit attitudes, sustained attention was controlled for by including reaction time on infrequent targets as a covariate. To test whether sex had a moderating effect, a two-factorial ANCOVA was carried out with the factors group (pre- vs. post), sex (female vs. male) and group by sex interactions. Effect sizes and partial eta-squared (η^2) were computed to determine the relative degree of variance associated with each of the main effects. Statistical significance was set at $p < 0.05$ across all analyses. All analyses were conducted in SPSS software for Windows (version 26, IBM Corp., Armonk, NY, USA).

RESULTS

Descriptive Statistics

As shown in **Table 1**, the sample consisted of approximately equal amounts of women and men who were on average middle-aged, single, employed before in-patient treatment and most of whom, were diagnosed with moderate recurrent depression. As reflected in BDI-scores at screening compared to baseline, depression scores reduced in line with being in in-patient treatment. HAMD

TABLE 2 | Between-group differences in psychosocial health.

	Pre-lockdown		Post-lockdown		Brown Forsythe		ANCOVA		
	M	SD	M	SD	*F*	*p*	*F*	*p*	η^2
Psychosocial health									
Stress	36.88	5.84	37.55	4.57	0.43	0.51	3.76	0.05	0.03
Sleep	12.23	5.17	11.82	6.31	0.15	0.70	0.26	0.61	<0.001
PCS	48.95	8.75	49.87	8.45	0.36	0.55	0.01	0.91	<0.001
MCS	26.71	8.22	27.36	7.69	0.21	0.64	0.41	0.52	<0.001

PCS, physical component scale of the SF-12; MCS, mental component scale of the SF-12. Brown Forsythe without co-variates.

scores differed statistically significantly between pre-lockdown (M = 14.03, SD = 5.10) and post-lockdown [M = 11.89, SD = 5.40, Brown Forsythe: $F_{(1, 77.8)} = 5.39$, $p = 0.02$, ANOVA: $F_{(1, 163)} = 5.67$, $p = 0.02$, $\eta^2 = 0.03$], and were thus taken into account as co-variates in further analyses. Furthermore, the sample did not reach the weekly recommended 150 min of moderate-to-vigorous physical activity and perceived their fitness below average. Information about medication, specific antidepressants and secondary diagnoses is provided as supplementary material (see **Supplementary Tables 1–3**).

Between-Group Differences in Psychosocial Health and Stress

Table 2 shows that there were no statistically significant between-group differences with regard to psychosocial health (stress, sleep, physical and mental quality of life). Perceived stress scores in both groups were high (scores ranging from 0 to 40). The sample exhibited subthreshold insomnia (scores between 8 and 14). Both groups revealed relatively low scores in perceived physical and mental health with perceived mental health rated lower than physical health in both groups. Participants with a secondary diagnosis relating to physical health had lower scores for physical health (M = 46.93, SD = 8.58) than in the participants with no secondary diagnosis relating to physical health (M = 51.11, SD = 8.28).

Between-Group Differences in Self-Reported Physical Activity and Explicit and Implicit Attitudes Toward Physical Activity

Table 3 shows that there were no statistically significant differences in self-reported physical activity levels. However, the post-lockdown group did achieve the recommended 150 min of moderate-to-vigorous physical activity per week (M = 170.10, SD = 149.74 min/week) whereas the pre-lockdown group did not (M = 137.42, SD = 144.70 min/week). Additionally, there were no statistically significant differences in explicit (intention, motivation, self-efficacy, planning, coping, positive and negative expectancies barrier and social support) or implicit attitudes toward physical activity. Results show that the sample had the intent to be physically active and they were most driven by intrinsic and identified motivation. Scores for planning physical activity, coping with physical activity related barriers, perceived barriers and social support were low in both groups (scores ranging from 1 to 6). Yet negative outcome expectancies were low and positive ones were high, indicating that the participants may have had more positive attitudes toward the expected outcomes they may gain from physical activity. These results, which may be interpreted as a leaning toward positive explicit attitudes, seem in accordance with the ST-IAT scores, which indicated slight implicit preference for physical activity in both groups.

Table 4 shows a small yet statistically significant difference between women and men [$F_{(1, 131)} = 4.88$, $p = 0.03$, $\eta^2 = 0.04$), regarding positive outcome expectancies of physical activity with women reporting higher rates of positive outcome expectancies compared to men.

DISCUSSION

The main finding from this analysis is that there are no statistically significant differences between in-patients with MDD recruited and assessed before and during/after the COVID-19-induced lockdown with regard to psychosocial health (stress, sleep, health-related quality of life), self-reported physical activity and explicit as well as implicit attitudes toward physical activity.

Hence, the COVID-19-induced lockdown is not likely to have impacted the baseline data collected during this ongoing trial. This is an important finding because the COVID-19 pandemic has had a negative impact on the conduct of clinical trials especially in vulnerable samples (van Dorn, 2020). The successful reuptake of recruitment and data collection in this trial was largely because the systems in place were linked to care as usual. Additionally, these activities took place on site with a maximum of two individuals in a room, wearing masks and practicing physical distancing. The continuation of quality research is needed especially in this time to overcome existing as well as COVID-19 related conditions. For example, research on physical activity behavior may be particularly important as it may have protective effects. It is known that regular moderate exercise contributes to a well-functioning immune system through reductions in inflammation, alterations in the composition of immune cells and relief of psychological stress (Simpson et al., 2015). The effects of physical activity on the immune system can be particularly meaningful with regard to viral diseases, hence, it is suggested that physical activity could

TABLE 3 | Between-group differences in self-reported physical activity and explicit and implicit attitudes toward physical activity.

	Pre-lockdown		Post-lockdown		Brown forsythe		ANCOVA		
	M	SD	M	SD	*F*	*p*	*F*	*p*	η^2
Self-reported physical activity									
Minutes per week	137.42	144.70	170.10	149.74	2.05	0.16	0.82	0.37	0.01
Explicit attitudes toward physical activity									
Intention	3.82	1.05	3.88	1.03	0.34	0.56	0.09	0.76	<0.001
Intrinsic motivation	3.88	1.06	3.88	0.96	0.09	0.77	0.02	0.89	<0.001
Identified motivation	4.85	0.71	4.84	0.64	0.02	0.89	0.01	0.91	<0.001
Introjected motivation	3.57	1.05	3.53	0.92	<0.001	0.98	<0.001	1.00	<0.001
Extrinsic motivation	2.19	1.03	2.18	0.93	0.01	0.92	0.03	0.86	<0.001
Self-efficacy	3.62	0.99	3.52	1.01	0.53	0.47	1.67	0.20	0.01
Planning	2.62	0.68	2.74	0.61	1.51	0.22	0.32	0.57	<0.001
Coping	2.12	0.68	2.14	0.61	0.18	0.67	<0.001	0.95	<0.001
Positive expectancies	3.23	0.38	3.19	0.52	0.45	0.50	0.18	0.67	<0.001
Negative expectancies	2.06	0.57	1.86	0.46	5.62	0.02	2.69	0.10	0.02
Barriers	2.17	0.49	2.05	0.38	2.34	0.13	0.50	0.48	<0.001
Social support	2.33	0.71	2.58	0.72	2.88	0.09	2.96	0.09	0.02
Implicit attitudes toward physical activity									
D-Score	0.16	0.44	0.19	0.44	<0.001	0.94	0.42	0.52	<0.001

Brown Forsythe without co-variates.

TABLE 4 | Between-group differences in psychosocial health, self-reported physical activity and explicit/implicit attitudes toward physical activity, with group by sex interactions.

	Group 1: Pre-lockdown (*N* = 119)		Group 2: Post-lockdown (*N* = 46)		Group		Sex		Group × sex	
	Women	Men	Women	Men						
	M (SD)	M (SD)	M (SD)	M (SD)	*F*	η^2	*F*	η^2	*F*	η^2
Psychosocial health										
Stress	37.89 (6.17)	35.87 (5.38)	37.35 (4.50)	37.71 (4.72)	3.47	0.03	0.06	<0.001	1.79	0.01
Sleep	12.90 (5.09)	11.48 (5.38)	11.65 (7.00)	11.96 (5.83)	0.22	<0.001	0.03	<0.001	0.48	<0.001
PCS	47.53 (9.56)	50.46 (7.23)	50.89 (8.08)	48.93 (8.85)	0.02	<0.001	0.16	<0.001	2.03	0.02
MCS	26.30 (8.94)	27.61 (7.81)	27.08 (7.40)	27.62 (8.10)	0.40	<0.001	0.12	<0.001	0.02	<0.001
Self-reported physical activity										
Minutes per week	130.63 (138.64)	144.16 (151.64)	161.20 (137.08)	177.58 (162.03)	0.80	0.01	0.21	<0.001	0.01	<0.001
Explicit attitudes										
Intention	3.84 (1.07)	3.80 (1.04)	3.63 (1.01)	4.08 (1.02)	0.16	<0.001	0.91	0.01	0.15	0.01
Intrinsic motivation	3.94 (1.05)	3.83 (1.08)	3.89 (0.97)	3.89 (0.97)	0.02	<0.001	0.30	<0.001	0.09	<0.001
Identified motivation	4.89 (0.74)	4.81 (0.70)	4.81 (0.81)	4.87 (0.46)	0.02	<0.001	0.03	<0.001	0.39	<0.001
Introjected motivation	3.49 (1.10)	3.66 (1.00)	3.62 (0.90)	3.46 (0.95)	<0.001	<0.001	<0.001	<0.001	1.08	0.01
Extrinsic motivation	2.14 (1.16)	2.24 (0.88)	1.94 (0.85)	2.38 (0.96)	0.02	<0.001	2.49	0.02	0.76	0.01
Self-efficacy	3.64 (0.96)	3.60 (1.03)	3.43 (1.02)	3.60 (1.01)	1.74	0.01	0.01	<0.001	0.45	<0.001
Implementation	2.72 (0.61)	2.52 (0.75)	2.74 (0.55)	2.75 (0.67)	0.26	<0.001	1.31	0.01	1.11	0.01
Coping	2.23 (0.65)	2.00 (0.70)	2.04 (0.70)	2.23 (0.52)	0.02	<0.001	0.38	<0.001	3.73	0.03
Positive expectancies	3.31 (0.37)	3.16 (0.37)	3.29 (0.61)	3.10 (0.42)	0.17	<0.001	4.88*	0.04	0.08	<0.001
Negative expectancies	2.00 (0.56)	2.12 (0.58)	1.77 (0.49)	1.93 (0.44)	2.72	0.02	3.87	0.03	0.10	<0.001
Barriers	2.16 (0.46)	2.18 (0.53)	2.08 (0.35)	2.03 (0.41)	0.47	<0.001	0.19	<0.001	0.14	<0.001
Social support	2.28 (0.72)	2.38 (0.70)	2.56 (0.68)	2.61 (0.77)	2.93	0.02	0.39	<0.001	0.02	<0.001
Implicit attitudes										
D-Score	0.13 (0.46)	0.19 (0.43)	0.20 (0.50)	0.15 (0.40)	0.24	<0.001	0.04	<0.001	0.92	0.01

$p < 0.05$. PCS, physical component scale of the SF-12; MCS, mental component scale of the SF-12.

be an important complement to preparing the immune system to fight COVID-19 infections (da Silveira et al., 2020). Additionally, being physically active has been shown to be associated with a lower prevalence of COVID-19 related hospitalizations (de Souza et al., 2020). When regarding the effect of physical activity on mortality caused by respiratory diseases in general, such as influenza, a study found that those adults performing low, moderate or frequent exercise were less at risk of mortality compared to those never or rarely engaging in exercise (Wong et al., 2008). Furthermore, a study conducted in elderly men examining different training patterns in relation to vaccine response found that both moderate and intense training patterns are associated with high antibody responses, which also last longer (de Araújo et al., 2015). In addition, regular physical activity during the pandemic may lead to fewer self-reported symptoms of depression and anxiety. This is especially true when comparing physical activity to no physical activity, or activity performed with lower volume and frequency. According to a rapid systematic review, there is no consensus regarding the exact volume and frequency of physical activity, however, in the included studies vigorous physical activity done regularly as opposed to irregularly was significantly associated with fewer depression symptoms (Wolf et al., 2020). This is of particular relevance for this sample population, which shows low levels of self-reported physical activity and may be at risk of decreased immune response.

One characteristic of the current pandemic contributing to psychological stress is social isolation, which has resulted from protective measures put in place (Clemente-Suárez et al., 2020). Isolation and the accompanying loneliness are associated with depression (Matthews et al., 2016) while depression is also associated with a small social network (Domènech-Abella et al., 2017). In combination this delineates the distinction between emotional and social loneliness and that both are present in symptoms of depression (Domènech-Abella et al., 2017). Hence, a hypothesis could be that people already suffering from depression may not notice the decline in social contact brought on by COVID-19 as much compared to healthy populations. Additionally, in the current sample, the participants were not in their everyday environment, but in in-patient treatment where social interactions are provided and encouraged (Holsboer-Trachsler et al., 2016). Another noteworthy point regarding psychosocial stress levels is that the current population had high levels of perceived stress in both groups. Hence, it could be hypothesized that the stress levels in the current sample of in-patients with MDD were at a level at which the addition of the pandemic may not have had a further impact. With regard to the lack of difference in sleep patterns, complaints may have been addressed by the structured nature of in-patient treatment and medication regimes. On the topic of health-related quality of life, it is known that people reporting increased symptoms of depression also generally report poorer health-related quality of life (lower scores in the chosen measuring instrument) involving physical, psychological and social domains which in turn may negatively affect functioning. The implications thereof are that dysfunctions can be targeted in tailored therapy settings (Daly et al., 2010). The association between poor health-related quality of life and increased depression symptoms has also been confirmed in people with major depression (Sivertsen et al., 2015). A lack of difference in psychosocial health may be explained by the population at hand. Previous evidence shows that there are negative influences of COVID-19 on psychosocial health, however particularly in children, older people and their care-givers. When considering people with psychiatric conditions it is especially those suffering from obsessive-compulsive disorder (OCD) and those at risk of relapse or discontinuation of therapy who are at risk (Dubey et al., 2020). In this population all participants were in in-patient care and receiving therapy, thus the possibility of relapse was very low. When looking at other research being done in the area of psychosocial distress in the context of COVID-19, studies can be found on university students (Villani et al., 2021), health care workers (Shayganfard et al., 2021) and the general population (Wang et al., 2020). Further indicating that a change in people already diagnosed with major depression has not been investigated and may, for the afore-mentioned reasons, not be particularly likely.

A lack of difference in physical activity in the context of COVID-19 has also been found in Swiss office workers. According to IPAQ assessments, 75% of the participants reached physical activity recommendations and there was no significant evidence of decreased physical activity comparing measures in January to April 2020. Seventeen per cent reported less activity, while 29% even reported more activity (Aegerter et al., 2021). Similar results are found in Iranian adults engaging in team sports. Here physical activity intensity did decrease, however, frequency increased and physical activity patterns were unrelated to mood (Aghababa et al., 2021). Increases in physical activity from screening to baseline in this study may be attributable to different patterns of behavior when living at home vs. being in in-patient treatment. The large standard deviations may be explained by the range of physical activity (0–150 min per week) permitted according to the inclusion criteria. Corresponding to the level of physical activity, the related explicit attitudes elicited from the questionnaires indicate a positive inclination. This can be explained by the fact that they all enrolled in a trial to facilitate a more physically active lifestyle. Hence, a certain interest in becoming more active could be expected as can also be confirmed when taking into consideration that intrinsic motivation levels were high, indicating that physical activity goals were concordant with other interests and values and less induced by external forces (Fuchs, 2008). Arguably, these results could be influenced by social desirability, which is a weakness of the assessment of explicit attitudes (Axt, 2017) and a selection bias occurring during the recruitment process. However, there is a positive tendency in explicit as well as implicit attitudes. Concordant explicit and implicit attitudes, especially with regard to physical activity, have proven to be advantageous for performing the behavior in future (Muschalik et al., 2019). Attitudes generally do not change quickly, building motivational self-regulation takes time, and deep seated automatic evaluations change slowly (Deutsch and Strack, 2006). Hence, no group differences in attitudes is in line with the current state of knowledge. It could be hypothesized that if attitudes toward physical activity

actually would differ, they might differ both in a positive and negative direction. The COVID-19-induced lockdown has led to more leisure time and thus people may spend more of it being physically active (Cheval et al., 2020). Additionally, the protective benefits of physical activity may become even more tangible. On the other hand, anxiety regarding safe locations and types of physical activity during COVID-19 may contribute to more negative attitudes.

The relevance of the present study for research is that the ongoing trial can be continued with the assumption that baseline data may not have been contaminated. In addition, it may provide trials with similar designs, contents and population the basis for checking data quality and integrity and supporting findings. Furthermore, it is of clinical relevance to note the levels of self-reported physical activity. Thus, in-patient treatment may have the potential to be the platform from which to influence health behaviors such as physical activity. Along these lines, in-patients may be given the possibility to engage in physical activity and receive encouraged and positive feedback in continuing and increasing physical activity during in-patient care irrespective of when they were admitted.

The strengths of the current analysis are that potential COVID-19-induced interference with baseline data in this study have been monitored, thus contributing to data integrity. Meaningful co-variables for the variables of interest were collected and included in the analyses, hence, allowing for an optimized explanation of variance. The appropriate instruments were used for the measures, especially noteworthy is the population-specific ST-IAT. To investigate the accuracy of measures of depression severity, the HAMD score was checked for the influence of different researchers who performed the interviews and no differences were found. Additionally, the HAMD and BDI scores correlated positively, thus the assumption may be safe that the measuring method was accurate. The decrease in BDI score from screening to baseline is most likely because of the onset of treatment upon clinic admission.

Despite these strengths, there are limitations to be considered. This is a small sample of Swiss in-patients who were assessed at varying duration of stay and receiving a variety of treatments. Hence, the results cannot be generalized to all people with depression or indeed any other population. Given the cross-sectional nature of the data, the effect of the COVID-19-induced lockdown on psychosocial health and physical activity in people with major depression remains unknown and no causation can be inferred. There is a potential for selection bias, which may be visible in the group differences in HAMD scores. With this in mind, the possibility of systemic differences between the two groups does exist. Furthermore, the lack of difference between the two groups may also be explained by the smaller sample recruited and measured after the COVID-19-induced lockdown, which may have lead to decreased statistical power. Additionally, to investigate whether psychosocial stress, physical activity and attitudes toward physical activity in people suffering from MDD change over time in relation to the COVID-19 pandemic, longitudinal data are needed.

CONCLUSION

In the present study, it can be said that the COVID-19-induced lockdown did not lead to differences in the current groups recruited and assessed before and during/after the lockdown. However, to assess changes in people with MDD with regard to psychosocial health, physical activity and attitudes toward physical activity longitudinal data are needed. For the ongoing trial, this means that baseline data gathered in in-patients suffering from depression who are physically inactive upon admission to in-patient treatment seem not to be impacted by the COVID-19-induced lockdown in March 2020 in Switzerland. For the future, an analysis of longitudinal data would be of importance in light of changes in psychosocial health and physical activity behavior brought on by COVID-19 discovered in healthy populations given that these aspects are also of particular importance for people with MDD. For other clinical trials continuing during this pandemic, it will be necessary to assess potential effects of COVID-19 on data and intervention delivery.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Ethikkommission Nordwest- und Zentralschweiz and Ethikkommission Bern. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

MG, JB, LD, AE, CI, MH, EH-T, UL, SL, TM, AO, NS, LZ, and OF have contributed to the design of the study. MG serves as principal investigator of the study. UL and NS (Basel), JB, AO, and AR (Riehen), CI and SM (Münchenbuchsee), and MH and TM (Solothurn) are responsible for the coordination and the recruitment of patients of the study in the four partner clinics. SL is responsible for the selection, programming and processing of data of the computer-based tests. EH-T, LZ, OF, and SB served as project advisors. RC and J-NK implement the recruitment and data assessment at the four partner clinics and were also responsible for the data entry, cleaning, and processing. RC and MG are responsible for the data analysis strategy applied in this paper. RC performed all statistical analyses and wrote the first draft of the manuscript. All authors contributed to manuscript revision, read, and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fspor.2021.685117/full#supplementary-material

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Chapter 5 Publication 3

An implementation evaluation of the physical activity counseling in in-patients with major depressive disorders (PACINPAT) randomized controlled trial

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Abstract

Background: The physical activity counseling for in-patients with major depression (PACINPAT) randomized controlled trial was launched to tackle physical inactivity in in-patients with major depressive disorder. Evidence shows that despite potential treatment effects, physical inactivity is prevalent in this population. To contribute to the assessment of the impact of this in-person and remote, theory-based, individually tailored intervention, the aim of this study is to evaluate its implementation.

Methods: This implementation evaluation was conducted within a multi-center randomized controlled trial according to the Process Evaluation Framework by the Medical Research Council including the analysis of reach, dose, fidelity and adaptation. Data were collected from the implementers and the participants randomized to the intervention group of the trial.

Results: The study sample comprised 95 physically inactive in-patients (mean age: 42 years, 53% women) with diagnosed major depressive disorder. The intervention reached the intended population. The intervention dose varied between early dropouts and study completers with both low and high participation rates. Differences in the attendance groups were recognizable in the first two counseling sessions. Fidelity of the in-person counseling content was partly achieved and adapted, whereas that of the remote counseling content was well achieved. Participants reported satisfaction with the intervention and the implementers. Adaptations were made to content, delivery mode and dose.

Conclusion: The PACINPAT trial was implemented in the intended population, in varying doses and with adaptations made to in-person counseling content and remote counseling dose. These findings are key to understanding outcome analyses, further developing interventions and contributing to implementation research.

Trial registration: ISRCTN, ISRCTN10469580, registered on 3rd September 2018, https://www.isrctn.com/ISRCTN10469580

Keywords: intervention implementation**,** process evaluation, physical activity counseling, depression

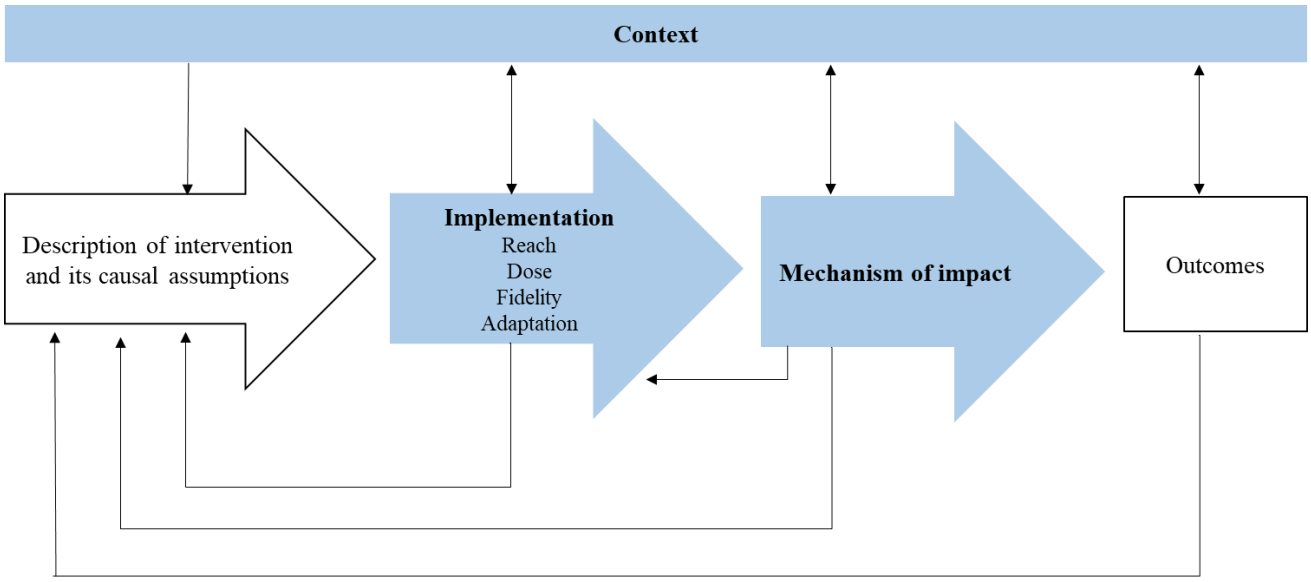
1 Background

Worldwide, 27.5% of adults are not sufficiently physically active (1). It is estimated that physical inactivity causes 9% (range 5.1-12.5) of premature mortality, 6% (range 3.2-7.8) of the burden of coronary heart disease, 7% (range 3.9-9.6) of type 2 diabetes, 10% (range 5.6-14.1) of breast cancer and 10% (range 5.7-13.8) of colon cancer globally (2). Additionally, it has been shown that people with higher levels of physical activity have lower odds of developing depression (adjusted odds ratio = 0.83, 95% CI 0.79 to 0.88) (3). In turn, according to meta-analytic data, people with depression tend to be less physically active than peers without depression (standard mean difference = -0.25, 95% CI -0.03 to 0.15) and over half (67%) do not meet physical activity recommendations (4). It would appear to be worthwhile to promote physical activity among people with major depressive disorders because evidence shows that physical exercise can have moderate to large effects on depression when comparing to control conditions (Hedges' g = -0.68). When comparing to no treatment as well as usual care, the effects have been large (g = -1.24) and moderate (g = -0.48) respectively (5). Thus underlining the need of interventions to facilitate a more physically active lifestyle among people with major depressive disorders.

Physical activity counseling has been effective in changing physical activity behavior in physically inactive adults (increases of 32 min/week, 95% CI 0.1 to 63, at intervention follow up) (6). Similarly, in people with depression, facilitated physical activity counseling has led to increased physical activity levels (adjusted odds ratio 2.27, 95% CI 1.32 to 3.89) in out-patients (7). To investigate the efficacy of an in-person and remote, theory-based, individually tailored physical activity counseling intervention in in-patients with depression, the physical activity counseling for in-patients with major depression (PACINPAT) multi-center randomized controlled trial (RCT) was launched. The trial protocol has been published previously (8).

The impact of such a physical activity counseling intervention depends not only on its efficacy, as assessed within the RCT, but also its reach, adoption, implementation and maintenance (9). Hence, additional assessments are required to adequately evaluate a complex intervention (10). Along these lines, the Medical Research Council (MRC) provided a framework for the process evaluation of complex interventions as depicted in Figure 1 (11). The framework describes three components to be considered, namely implementation (what is implemented and how?), mechanism of impact (how does the delivered intervention produce change?) and context (how does context affect implementation and outcomes?). The evaluation of intervention implementation in turn consists of four components; reach (target audience), dose (of delivery and receipt), fidelity (delivered as intended) and adaptations (modifications for contextual fit).

Figure 1. Process evaluation according to Moore et al. (2015)



In the case of the PACINPAT trial, the intervention and its causal assumptions have been described in the study protocol (8). The mechanism of impact was assessed in a nested qualitative study on the participants' experience of the intervention (12). Upon completion of the trial, outcomes with respect to physical activity levels and secondary outcomes as defined in the study protocol will be published. The context shaping assumptions, implementation, mechanisms and outcomes is considered in each step of the evaluation process.

Hence, the aim of the present study is threefold: First, to evaluate the implementation of the intervention by addressing the following questions: (i) did the intervention reach the targeted audience? (ii) how many of the planned counseling sessions took place and how long was their duration (dose)? (iii) was the content delivered as planned? and (iv) what, if any, adaptations were made to the intervention? Second, to analyze whether the duration and content of the counseling sessions differed according to the intervention dose. And third, to present the recipients' satisfaction with the intervention.

By establishing the actual dose of the intervention potential future implementation in practice in terms of remuneration of implementers can be informed, as the entire counseling duration (including preparation and debriefing time) will become visible.

This study will therefore complete the process evaluation of the PACINPAT trial and allow a deeper understanding of what may account for future observed effects of this physical activity intervention for people with major depression.

2 Methods

2.1. Study aim and design

The aim of the study is to evaluate the implementation of the intervention within the PACINPAT multi-center randomized controlled trial. Hence, this study follows the Process Evaluation Framework provided by the MRC (11). It is based on quantitative data provided by the implementers and participants of the PACINPAT trial.

2.2. Setting and participants

The PACINPAT trial is being conducted in four Swiss psychiatric clinics (study cites in Basel, Riehen, Solothurn and Münchenbuchsee). The participants were screened by clinicians according to the following inclusion criteria: adult (18-65 years) women and men with episodic or recurrent moderate to severe depression according to the International Classification of Disease, 10th Edition (ICD-10), who were physically insufficiently active upon admission to in-patient treatment (<150 minutes of moderate-to-vigorous physical activity per week). Once clinically screened, the clinicians referred the patient to a member of the study team who explained the study procedures, emphasizing the voluntary basis of participation and anonymity of data. Patients who decided to take part signed a written informed consent form and were randomized into an intervention and control group. Data used in this publication pertain only to the participants randomized into the intervention group.

2.3. Development of the intervention

The intervention consisted of physical activity counseling which took place in-person and remotely including text messages and the use of a mobile phone application during one year. The delivery mode, timing, content and underpinning theory are shown in Table 1.

Table 1. Intervention design

	Session	Delivery	Timing	Content	Theory
Phase 1: in-person	1	In-person (2h)	During in-patient treatment	- Introduction and organizational aspects of the intervention - Health goal - Physical activity ideas	Mo-Vo
	2	In-person (1.5h)	During in-patient treatment	- Physical activity plan (what, when, where and with whom) including check for suitability, practicability, precision and effectiveness - Instruction for self-monitoring of physical activity including introduction to mobile app as self-monitoring tool - Introduction to remote sessions - Appointment for next session (first telephone session)	Mo-Vo
Phase 2: remote	3	Telephone (1h)	2 weeks after discharge from in-patient treatment	- Physical activity barriers (internal and external) - Strategies (e.g., prioritizing physical activity, making an appointment with a friend, preparing required equipment) - Instruction to implement physical activity plan, self-monitoring and strategies - Introduction to text messages - Appointment for next session	Mo-Vo
	4-28	Telephone (0.5h)	Bi-weekly (26 in 12 months)	- Check implementation of physical activity plan, self-monitoring and strategies - Appropriate BCTs selected from the Anchor List (see supplement) - Intermittent goal setting and reviewing in sessions 4, 9, 14, 19, 24 and 28 (every 2 months) - Appointment for next session	BCW
		Text messages	Weekly (52 in 12 months)	- Feedback - Reminder - Information	BCW
		Mobile App		- Physical activity diary including setting of time, place, with whom, duration and intensity, including the option to confirm the activity took place - Profile to save anthropological and physical activity data - Notepad to summarize goals, ideas, barriers and strategies	

Notes: h = hours, App = mobile application, BCT = Behavior Change Technique, Mo-Vo = Motivation Volition Model, BCW = Behavior Change Wheel

The intervention was theory-based. The first three sessions were based on the Motivation-Volition (Mo-Vo) Model developed by Fuchs and colleagues (13). The model assumes that strengthening both motivational (self-efficacy and goal intention) and volitional (action planning and barrier management) constructs, behavior can be initiated and maintained through positive outcome experiences (13). There is a corresponding intervention designed as a short physical activity counseling intervention to be delivered to in-patients (14), according to which the initial stages of the present intervention were designed. In the following stages, the intervention was based on the Behavior Change Wheel (BCW), which is a framework containing concepts from health behavior theories (15). At the core of the wheel, behavior is explained by capability (physical and psychological), opportunity (environmental and social) and motivation (reflective and automatic). There are 93 Behavior Change Techniques (BCTs), defined according to a taxonomy (version 1), which can be implemented to target these determinants of behavior (16). A BCT "Anchor List" was developed in a previous study (6), containing thirty BCTs. Ten of which, were effective for physical activity promotion according to evidence and were thus classified as main BCTs. The remaining twenty BCTs were explicitly or implicitly used in physical activity counseling according to evidence and were thus classified as secondary BCTs. This "Anchor List" was used for the present intervention (see Table 2).

Table 2. Behavior Change Techniques Anchor List for physical activity

Taxonomy Version 1
1.1. Goal setting (behavior)
1.3. Goal setting (outcome)
1.2. Problem solving
1.4. Action planning
8.7. Graded tasks
1.5. Review behavior goal(s)
1.7. Review outcome goal(s)
1.6. Discrepancy between current behavior and goal
1.8. Behavioral contract
2.2. Feedback on behavior
2.7. Feedback on outcomes of behavior
2.3. Self-monitoring of behavior
2.4. Self-monitoring of outcomes of behavior
3.1. Social support (unspecified)
4.1. Instruction on how to perform the behavior
5.1. Information about health consequences
5.2. Salience of consequences
6.1. Demonstration of the behavior
6.2. Social comparison
7.1. Prompts/cues
8.1. Behavioral practice/rehearsal
8.3. Habit formation
9.2. Pros and cons
10.3. Non-specific reward
12.1. Restructuring the physical environment
12.2. Restructuring the social environment
12.3. Avoidance/reducing exposure to cues for the behavior
13.2. Framing/reframing
15.2 Mental rehearsal of successful performance
15.3. Focus on past success

Notes: italic = main BCT, BCTs are numbered according to Taxonomy V1.

In addition to the theoretical underpinning of the intervention, the aim was also to allow for individual tailoring of the intervention content. The implementers of the intervention, i.e. coaches, were provided with questionnaire data from the participants before the first session, in which they gained motivational and volitional information. Tailoring continued throughout all sessions, in which the coaches were instructed to select and apply BCTs from the "Anchor List", which fitted the assessed needs.

The coaches were sport science and psychology graduates. They were recruited in stages and trained by the study team. The training (duration of 8 weeks with 2 hourly sessions weekly) contained insight into the trial procedures including background on depression and behavior change in this population, underpinning theory and tailoring of the intervention, structure of the

intervention including delivery mode, and the role of a coach including conversational conduct and relationship building. Additionally, the training included weekly exercises, listening to and analyzing audio recordings and a know-how-check, in which the coaches role-played a scenario with a member of the study team. The coaches received a manual containing the training content as well as a detailed guide of every session, including checklists and instructions for debriefing. The coaches were instructed on how to document the implementation of the intervention including number, duration and content of each session. For the remote phase of the intervention, a protocol was developed specifying the procedures in case of missed appointments, participants who were difficult to reach and defining the expected availability of the coaches. The implementation was monitored continuously by the study team during monthly team meetings with the coaches. Information regarding the intervention development can also be found in the study protocol (8).

2.4. Data collection

Data representing the reach of the intervention were demographic and clinical data, collected during in-patient treatment at screening. The clinician referring the participant to the study team communicated age, sex, physical activity level and depression diagnosis as well as depression severity to the study team confidentially. Depression diagnoses were stated according to ICD-10. Depression severity was assessed with the Beck Depression Inventory (BDI), containing 21 questions pertaining to depression symptoms resulting in a sum score ranging from 0 to 63 points (17). Physical activity was assessed using the International Physical Activity Questionnaire (IPAQ), containing seven questions to elicit the amount of moderate and vigorous physical activity performed in the preceding seven days (18).

Date representing the dose and content of the intervention were collected by the coaches using a predefined tool, containing the date of contact with the participant, duration of preparation, counseling and debriefing and the content (Mo-Vo as well as BCTs) of each counseling session. Additionally, the dates of all text messages sent were documented and for each counseling session there was the opportunity for free text comments. The coaches entered these data regularly after every counseling session and were monitored by the study team.

Adaptations to the intervention were documented during the regular team meetings and the counseling materials were adjusted accordingly.

Satisfaction data were collected from the participants via questionnaire at two time points during their study participation. The first time was 6 weeks (post) and the second 12 months (follow-up) after discharge from in-patient treatment. The questionnaire contained questions

regarding expectations, understandability of the content, satisfaction with the coach, helpfulness of the text messages, user friendliness and helpfulness of the mobile application, achieving (intermittent) goals, motivation to continue and recommendation of the intervention, suitability for health promotion, general satisfaction, perceived effort in relation to success. These questions were all answered on a 4-point Likert scale ranging from no, mostly no, mostly yes to yes. The scale for the last question ranged from too high, mostly too high, appropriate to low. Additionally, there was a question pertaining to the perception of intervals between sessions, which was answered on a scale ranging from too long, just right to too short. Lastly, the question was asked whether a different fitness application was being used. This question was answered with yes or no.

2.5. Data Analysis

To analyze whether the duration and content of the counseling sessions differed according to the intervention dose, subgroups were defined according to intervention attendance. "Early dropouts" dropped out of the intervention after leaving in-patient treatment, "low dose" was defined as less than 75% of the remote intervention and "high dose" was defined as 75% or more of the intended remote intervention. This cut off is supported by meta-analytic data on the adherence to physical activity interventions in other chronic conditions (cancer, cardiovascular disease and diabetes), which show that the average adherence rate is 77% (95% CI 0.68 to 0.84) of the intended dose (19). Additionally, number and duration of counseling sessions were separately analyzed for in-person and telephone counselling.

Metric data were reported in means (*M*) and standard deviations (*SD*). Group differences for metric data were analyzed with Analyses of Variance (ANOVA) tests and reported with *F*-statistics and eta-squared (η^2). For comparisons of more than two groups Bonferroni post hoc tests were conducted. Group differences for categorical data were analyzed with chi-squared tests (χ^2) and reported with corresponding chi-squared values and Cramer's *V*, appropriate for contingency tables larger than 2x2. The significance level for analyses was set at $p < 0.05$ across all analyses. Analyses were performed in STATA (StataCorp. 2017. *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC.).

3 Results

3.1. Reach

The intervention did reach the targeted audience and no significant differences were found between the groups of intervention attendance with regard to age, sex, depression severity and

diagnoses, or study site. A total of 127 participants were recruited and randomized to the intervention group. By January 2022, 101 participants (80%) completed their participation in the PACINPAT trial, which comprises the current sample size. For the current analyses, three people were excluded because their primary diagnosis did not fit the defined inclusion criteria. Additionally, those who were randomized to the intervention group but did not participate in the intervention at all (n = 3) were excluded. This resulted in a total sample of N = 95 participants, whose characteristics are described in Table 3.

Table 3. Participant characteristics

	Total (N = 95)	Early Dropout (ed) (n = 18)	Low Dose (ld) (n = 37)	High Dose (hd) (n = 40)	ANOVA F	η^2	
Age in years, mean (*SD*)	42 (13)	42 (13)	42 (14)	43 (12)	0.18	0.00	
Depression severity according to BDI, mean (*SD*)	21 (12)	24 (12)	21 (11)	18 (12)	1.58	0.03	
					χ^2	V	p
Sex, *n* (%)							
Women	50 (53)	11 (61)	20 (54)	19 (47)	0.97	0.10	0.615
Men	45 (47)	7 (39)	17 (46)	21 (52)			
Depression diagnosis according to ICD-10, *n* (%)							
Moderate episode (F32.1)	24 (25)	6 (33)	10 (27)	8 (20)	2.58	0.12	0.859
Severe episode (F32.2)	14 (15)	2 (11)	4 (11)	8 (20)			
Recurrent depression, current moderate episode (F33.1)	35 (37)	6 (33)	15 (40)	14 (35)			
Recurrent depression, current severe episode (F33.2)	22 (23)	4 (22)	8 (22)	10 (25)			
Study site, *n* (%)							
Basel	20 (21)	4 (22)	12 (32)	4 (10)	6.27	0.18	0.393
Riehen	22 (23)	4 (22)	8 (22)	10 (25)			
Solothurn	18 (19)	4 (22)	6 (16)	8 (20)			
Münchenbuchsee	35 (37)	6 (33)	11 (30)	18 (45)			

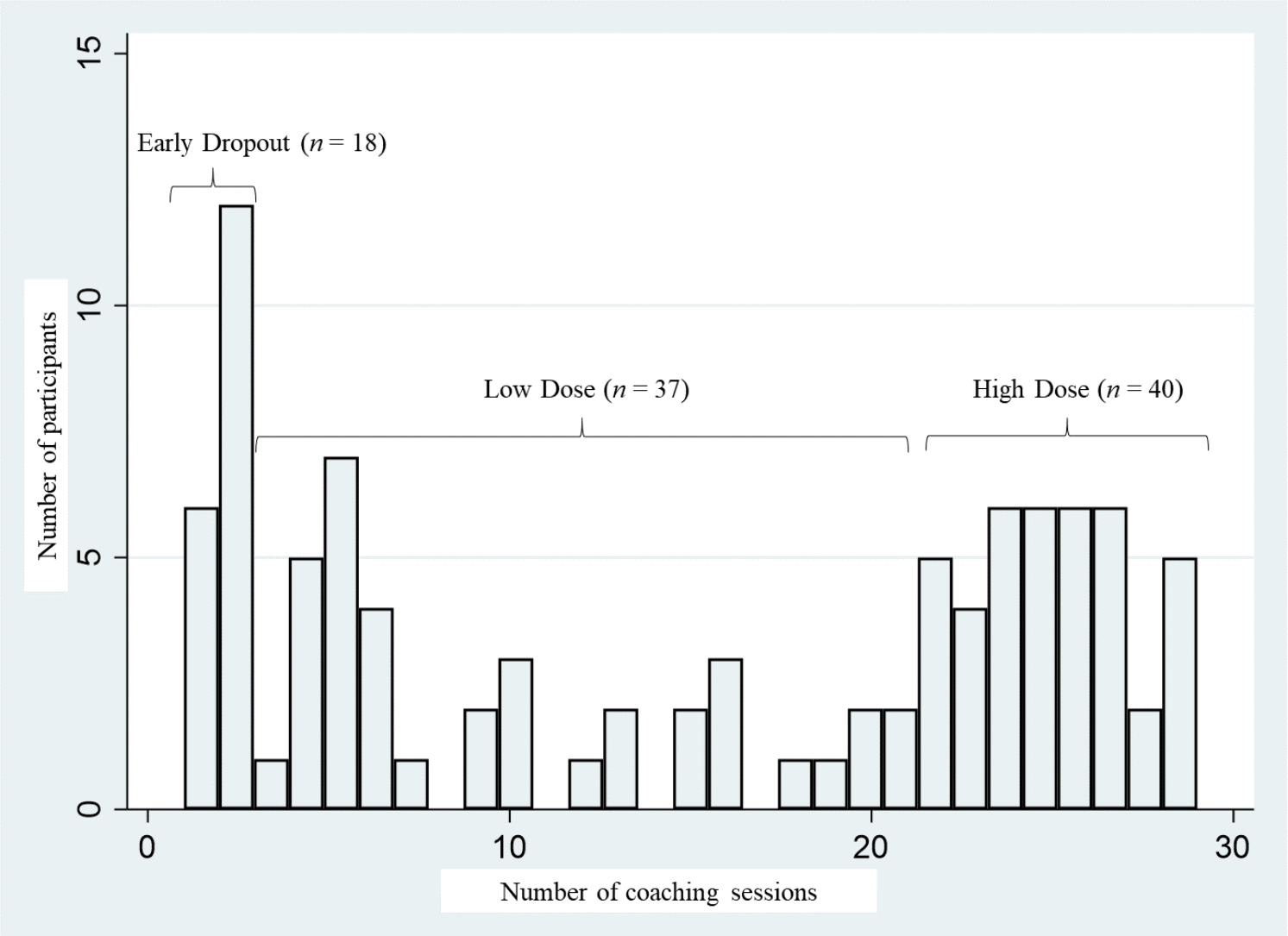
Notes: BDI = Beck Depression Inventory, ICD-10 = International Classification of Disease, 10th Edition

3.2. Dose

The planned number of counseling sessions was two in-person sessions during in-patient treatment and 26 telephone sessions with an interval of 14 days during 12 months.

Not all participants achieved the planned number of counseling sessions. Hence the subgroups according to intervention attendance, which can be seen in Figure 2.

Figure 2. Intervention attendance



The actual number of counseling sessions and their durations, in total as well as in the two intervention phases (in-person and telephone), are shown in Table 4. ANOVA tests revealed significant differences in all parameters referring to the number of sessions, thus confirming the three different groups of attendance. According to Bonferroni post hoc testing, only the number of in-person counseling sessions were not significantly different between the low and high dose groups.

When considering the duration of the in-person counseling sessions, it is noteworthy that the "early dropout" group had significantly shorter sessions compared to both other groups. Correspondingly, the debriefing time for in-person counseling session was less. When considering the duration of the telephone counseling sessions, the "high dose" group had significantly longer preparation, counseling and debriefing time compared to the "low dose" group. With regard to intervals and duration of the remote intervention, the groups differed

significantly. Intervals between the telephone counseling sessions differed significantly between the "high dose" (M = 17 days, SD = 2 days) and "low dose" (M = 25 days, SD = 10 days) groups ($F = 99.75_{(2,92)}$, $\eta^2 = 0.68$, $p < 0.001$). The overall duration of the remote intervention also differed significantly between the "high dose" (M = 13 months, SD = 1 month) and "low dose" (M = 6 months, SD = 5 months) groups ($F = 107.27_{(2,92)}$, $\eta^2 = 0.70$, $p < 0.001$).

Table 4. Intervention dose

	Total (N = 95) ***M (SD)***	Early Dropout (ed) (n = 18) ***M (SD)***	Low Dose (ld) (n = 37) ***M (SD)***	High Dose (hd) (n = 40) ***M (SD)***	ANOVA ***F***	***η²***	Significant group differences[a]
Number of							
Total coaching sessions	14.91 (10.24)	1.67 (0.48)	10.05 (5.88)	25.37 (2.20)	268.79	0.85*	ld vs hd hd vs ed hd vs ld
In-person	1.67 (0.48)	1.83 (0.38)	2 (0)	2 (0)	18.64	0.29*	ld vs ed hd vs ed
Telephone	12.98 (10.15)	0 (0)	8.05 (5.88)	23.37 (2.20)	264.50	0.85*	ld vs ed hd vs ed hd vs ld
Messages	26.04 (20.81)	0 (0)	16.65 (14.43)	46.45 (5.22)	172.62	0.79*	ld vs hd hd vs ed hd vs ld
Duration of preparation							
In-person (min)	9.00 (9.46)	6.50 (5.21)	9.38 (8.41)	9.77 (11.61)	1.25	0.03	
Telephone (min)	2.63 (2.31)	---	1.69 (1.55)	4.69 (1.49)	86.55	0.65*	
Duration of coaching							
In-person (min)	57.37 (17.05)	45.39 (20.38)	60.57 (15.45)	59.80 (14.74)	6.10	0.11*	ld vs ed hd vs ed
Telephone (min)	9.27 (8.34)	---	5.44 (3.37)	16.99 (6.53)	99.23	0.68*	
Duration of debriefing							
In-person (min)	9.09 (6.76)	5.55 (3.73)	9.36 (6.98)	10.44 (7.16)	3.46	0.07*	hd vs ed
Telephone (min)	3.77 (3.40)	---	2.24 (1.79)	6.89 (2.50)	93.73	0.67*	

Notes: min = minutes, d = days, [a]Significant group differences according to Bonferroni post hoc tests, *$p < 0.05$.

3.3.Fidelity

Fidelity, i.e. whether the content of the intervention was delivered as intended, was assessed by considering the content delivery as reported by the coaches and satisfaction as reported by the participants.

In Table 5 the content according to the Mo-Vo Model is exemplified. Group differences already appeared in the second counseling session, in which plans were made less often in the "early dropout" group compared to both other groups. Additionally, the mobile application was introduced less frequently in the "low dose "group. Over half of the "early dropout" group discussed barriers (72%) and strategies (55%) even though this was intended in the third session (first telephone session).

Table 5. Content based on the Motivation-Volition Model

	Total sample (N = 95)	Early Dropout (ed) (n = 18)	Low Dose (ld) (n = 37)	High Dose (hd) (n = 40)			
	n (%)	***n (%)***	***n (%)***	***n (%)***	χ^2	***V***	***p***
Idea set (C1)	92 (97)	17 (94)	36 (97)	39 (97)	0.42	0.07	0.811
Goal set (C1)	91 (96)	17 (94)	36 (97)	38 (95)	0.35	0.06	0.839
Plan made (C2)	71 (75)	6 (33)	30 (81)	35 (87)	20.58	0.46*	< 0.001
App explained (C2)	70 (74)	7 (39)	30 (81)	33 (82)	13.89	0.38*	< 0.001
Barriers identified (C3)	61 (64)	13 (72)	20 (54)	28 (70)	2.75	0.17	0.253
Strategies identified (C3)	56 (59)	10 (55)	20 (54)	26 (65)	1.06	0.10	0.589
Intermittent goals	65 (68)	0	27 (73)	38 (95)	52.43	0.74*	< 0.001
Overall goal reached (C28)	15 (16)	0	2 (5)	13 (32)	14.78	0.39*	< 0.001

In Table 6 the content based on BCTs used during the telephone counseling is shown. Additionally, BCTs used in order of frequency can be seen in Figure 3. According to ANOVA analyses, eleven of the BCTs were used significantly more frequently in the “low dose” group compared to the “high dose” group, three of which were main BCTs (self-monitoring of behavior (2.3.), social support (3.1.), information about health consequences (5.1.)).

Table 6. Content based on Behavior Change Techniques

	BCT used at least once (n = 77)	Frequency of use relative to number of coaching sessions for at least one use (n = 77)			ANOVA		
	***N* (%)**	**Total (%)**	**Low Dose (%)**	**High Dose (%)**	***F***	**η^2**	***p***
1.1. Goal setting (behavior)	71 (92)	52	58	48	2.50	0.03	0.12
1.3. Goal setting (outcome)	36 (47)	12	20	9	9.63	0.22*	< 0.01
1.2. Problem solving	73 (95)	41	45	38	2.02	0.03	0.16
1.4. Action planning	74 (96)	51	51	51	0.01	< 0.01	0.93
8.7. Graded tasks	60 (78)	30	37	25	8.50	0.13*	< 0.01
1.5. Review of behavior goals	68 (88)	60	62	58	0.41	< 0.01	0.52
1.7. Review of outcome goals	50 (65)	10	18	8	30.56	0.39*	< 0.01
1.6. Discrepancy between current behavior and goal	35 (45)	54	50	57	0.26	< 0.01	0.61
1.8. Behavioral contract	7 (9)	6	8	5	0.39	< 0.01	0.56
2.2. Feedback on behavior	71 (92)	71	70	72	0.14	< 0.01	0.71
2.7. Feedback on outcomes of behavior	39 (51)	10	15	8	5.66	0.13*	0.02
2.3. Self-monitoring of behavior	60 (78)	30	40	24	7.12	0.11*	< 0.01
2.4. Self-monitoring of outcomes of behavior	11 (14)	14	24	10	5.03	0.36	0.05
3.1. Social support (unspecified)	44 (57)	17	27	12	11.75	0.22*	< 0.01
4.1. Instruction on how to perform the behavior	48 (62)	17	26	13	11.45	0.20*	< 0.01
5.1. Information about health consequences	62 (80)	23	33	16	15.63	0.21*	< 0.01
5.2. Salience of consequences	39 (51)	14	16	13	1.56	0.04	0.22
6.1. Demonstration of the behavior	12 (15)	7	8	6	0.26	0.02	0.62
6.2. Social comparison	8 (10)	5	5	5	0.18	0.03	0.69
7.1. Prompts/cues	23 (30)	10	21	6	8.55	0.29*	< 0.01
8.1. Behavioral practice/rehearsal	59 (77)	22	27	19	3.50	0.06	0.07
8.3. Habit formation	60 (78)	24	28	21	2.18	0.04	0.14
9.2. Pros and cons	11 (14)	6	5	6	0.02	< 0.01	0.90
10.3. Non-specific reward	30 (39)	14	19	11	3.71	0.12	0.06
12.1. Restructuring the physical environment	19 (25)	8	9	7	0.21	0.01	0.65
12.2. Restructuring the social environment	5 (6)	8	12	6	3.82	0.56	0.14
12.3. Avoidance/reducing exposure to cues for the behavior	18 (23)	8	15	6	7.65	0.32*	0.01
13.2. Framing/reframing	22 (28)	11	13	10	0.76	0.04	0.39
15.2. Mental rehearsal of successful performance	27 (35)	11	16	10	4.12	0.14	0.05
15.3. Focus on past success	37 (48)	11	16	8	7.43	0.17*	0.01

Notes: BCT = Behavior Change Technique, BCTs are numbered according to Taxonomy V1, italic = main BCT, *p < 0.05.

When comparing the ten most frequently used BCTs to the ten main BCTs on the "Anchor List", discrepancy between current behavior and goal (1.6.) (54%) and graded tasks (8.7.) (30%) were among the top ten, however they were not among the main BCTs on the "Anchor List". While the BCTs social support (3.1.) (17%) and instruction on how to perform behavior (4.1.)

(17%) were among the main BCTs on the "Anchor List", they were not among the ten most frequently used BCTs.

Results from the satisfaction questionnaire can be seen in Table 7. When considering the elements from the implementation evaluation dose and content, at post assessment, 74% of the participants rated the intervals between the counseling sessions (intended interval: 2 weeks), as too short, while at follow up assessment only 12% reported the intervals to be too short and 80% experienced them as just right. When considering intervention content, 76% (post assessment) and 80% (follow up assessment) reported the content to be appropriate and understandable. When considering other elements of the remote intervention, the text messages were reported to be helpful by approximately 70% of the participants at both assessment time points. The only area where lower rates of satisfaction were reported was pertaining to the mobile application (helping to stay motivated, to implement plans and reach goals). Approximately 30% of the participants rated these questions with "no" and a further 30% with "mostly no". Overall, the participants reported that they were satisfied with their coach (89% post assessment, 86% follow up assessment).

Adaptation

Adaptations to the original Mo-Vo intervention by Fuchs and colleagues (13) were made a priori to fit the PACINPAT context as stated in the study protocol (8). The original design consists of three in-person sessions, the first and last as individual sessions and the second a group session. Given the in-patient structure at the study sites, group sessions were replaced by individual sessions. The third counseling session was conducted during a telephone counseling session as it could be expected that engagement would be greater in a remote setting versus an in-person setting once the participant had left in-patient treatment.

During the first weeks of the intervention it was decided that the timing of the Mo-Vo content could be adapted by the coach if it became evident that the participant was not ready yet to discuss health goals, physical activity ideas and plans. In such cases, the initial counseling sessions were primarily used to build a working relationship. Additionally, during the remote intervention phase, the intervals between telephone sessions was adapted to the preference of the participant, however, a minimum of 2 weeks was maintained. These adaptations were carried out with all participants.

4 Discussion

4.1. Main Results

This study gives a differentiated insight in to the implementation of the planned complex intervention. The PACINPAT intervention was reached by all but three participants in the intervention group. The subgroup analysis showed that not only the number of coaching sessions differed according to dose, but also the duration of the preparation, counseling and debriefing as well as the content. The "high dose" group received the dose in approximately the intervals (bi-weekly) and duration (12 months) as planned, whereas the "low dose" group and "early dropouts" did not. The early dropout group was already recognizable during the in-person counseling sessions, which were significantly shorter and physical activity plans were made less frequently and the mobile application was introduced less frequently. BCTs used in over 50% of the remote counseling sessions were action planning (1.4.), goal setting (behavior) (1.1.), discrepancy between current behavior and goal (1.6.), review of behavior goals (1.5.) and feedback on behavior (2.2.). All but two of the BCTs on the "Anchor List" for physical activity were frequently used. Participants reported overall satisfaction with the intervention at post as well as follow up assessments. The Mo-Vo intervention was adapted in delivery mode and timing of content. The interval between telephone counseling sessions was adapted to the participants.

It is known that participants with major depression may drop out of physical activity interventions within RCTs as presented in meta-analytic data, a dropout rate of 17.2% (95% CI 13.5 to 21.7) is to be expected (20). With this in mind, 19% of the current sample dropping out of the intervention early is in keeping with expectations in this population receiving a physical activity intervention. Additionally, in a physical activity counseling intervention for out-patients with depression, it was reported that adherence to the intervention was generally good with 71% of the participants receiving an adequate dose of the intervention by the end of their participation in the trial, however how the adequate dose was specified remains unclear (7). Lower adherence rates to physical activity interventions have been reported in adults (42.6%, 95% CI 39.5 to 45.6), with depression significantly predicting less adherence (21). When considering adherence to the Mo-Vo intervention specifically, in a study on the efficacy of the Mo-Vo intervention in orthopedic patients, 90.1% of the intervention group received the intervention as intended. Keeping in mind that the intervention duration consisted of three counseling sessions. Hence, this is comparable to the intervention dose, that even the "early dropouts" in the current study achieved. Additionally, approximately 35% of the orthopedic patients dropped out of the study, i.e. did not complete all assessments (22). In a more recent

study in which cardiac patients received the Mo-Vo intervention, the implementation rate was not reported, however similarly a dropout rate from trial participation of approximately 37% was reported (23). Recognizing such participatory patterns can be useful, as exemplified in a study differentiating physical activity maintainers, fluctuators, late dropouts and early dropouts, which increased the success of predicting behavior according to selected psychological variables (24). Attendance in exercise programs may be linked with associations to exercising, as shown by Antoniewicz and Brand (25). In a dropout analysis of a 3-month exercise program, they discovered that automatic positive associations towards exercising was a strong discriminating factor when investigating adherence patterns (25). Links between implicit associations and physical activity behavior have been shown (26), however this has yet to be established in people with psychiatric disorders (27). Further correlates have been identified for people with depression and their engagement in physical activity, for example depressive symptoms, higher body mass index and the presence of co-morbidities (28). Correlations between severe depression as primary diagnosis and early dropout were not present in this analysis, however early dropouts did tend to make plans less frequently in the initial counseling sessions compared to the low and high dose groups, even though no group differences were expected at that point. There is evidence suggesting that more severe depressive symptoms are associated with impaired volitional capacities resulting in reduced planning, and maintenance self-efficacy as well as higher susceptibility to distraction (29). This may be a way of explaining the shorter counseling sessions as well as the differences in intervention fidelity. Nevertheless, with the present data, it is not possible to recognize whether the participants were less interested in participation or the coaches engaged them less in the intervention, resulting in the shorter duration.

The frequently used BCTs in the intervention are in line with a recent remote intervention to promote physical activity in people with depression (30). Noticeably, the BCTs used in this study pertain more strongly to the behavior than to the outcome, i.e. goal setting (behavior) (1.1.) is more frequently used than goal setting (outcome) (1.3.), review of behavior goals (1.5.) more frequently than review of outcome goals (1.7.), self-monitoring of behavior (2.3.) more frequently than self-monitoring of outcomes of behavior (2.4.) and feedback on behavior (2.2.) more frequently than feedback on outcome of behavior (2.7.). On the one hand this reiterates that the content was implemented as designed, because these BCTs were defined as main BCTs (as can be seen in Table 2). Additionally, It could be hypothesized that, given the cyclical nature of depression (31), it may be more attractive for people with depression to focus on behavior, which is a more immediate concept, than on outcomes, which may be too far in the

future and less within the sense of behavioral control (32). Correspondingly, the third most frequently used BCT, not among the main BCTs on the "Anchor List", discrepancy between current behavior and goal (1.6.), may bridge the gap between behavior and outcome that is needed. Further evidence suggests that the behavior focused BCTs behavioral goal setting (1.1.), self-monitoring (2.3.) and behavioral practice (8.1.), are associated with physical activity motivation (33). The second BCT that was not one of the main BCTs on the "Anchor List", yet frequently used, was graded tasks (8.7.). The reason was perhaps because the concept of intermittent goals setting was integrated into the intervention design. The coaches were instructed to encourage the participant to set an intermittent goal every two months, in an attempt to increase the participants' belief in their capabilities over the duration of the intervention (16). Main BCTs on the "Anchor List", which were not frequently used were social support (3.1.) and instruction on how to perform behavior (4.1.). It is known that people with depression may have smaller social circles (34) and that social support may be an important factor in improving depressive symptoms (35). Additionally, according to a systematic review social support contributes positively to physical activity behavior, especially so in leisure time physical activity (36). Social support (3.1.) includes the encouragement of engaging a "buddy", housemate or partner in events or raising awareness for group activities. From the current analysis it is not possible to gauge whether the coaches did not use this BCT frequently because sufficient social support was provided or because the opposite was true. In which case, in a remote setting, it was not possible for the coach to offer any further means of social support. Instruction on how to perform behavior (4.1.) includes skill training and is related to behavioral practice and demonstration of the behavior. Despite the fact that remote interventions are an attractive option from the point of view of low cost and wide reach (37), they may not be the ideal platform to deliver BCTs of this nature. Alternatively, the chosen physical activity behaviors may not have been particularly complex and thus not requiring much instruction.

The remote counseling further included text messages and the use of mobile application. Evaluations of applications for mental health have found that most frequent persuasive techniques used are self-monitoring, personalization and reminder (38), which are in line with the concept of the PACINPAT remote intervention. According to the satisfaction data, the text messages were overall considered helpful. This was also the case in the preceding study of physical activity counseling in health physically inactive adults, however outcome analyses suggested that the text messages did not have an additional impact on actual physical activity behavior (6).

The adaptations made to the Mo-Vo intervention mean it was not fully implemented as intended in this population. Even though goals and ideas were set by most participants in the first session, planning, barriers and strategies were not discussed as frequently as expected. The Mo-Vo model, as designed by Fuchs and colleagues (13), was intended for orthopedic patients. It has been implemented in people with obesity (39) with increased physical activity outcomes, however there is no information whether the intervention was implemented as intended. Currently, studies implementing the interventions based on the Mo-Vo model in psychiatric (40) and oncology (41) populations are ongoing. It could be hypothesized that the Mo-Vo content is suitable for people with major depression, however there may need to be initial counseling sessions devoted to trust and relationship building before the behavior change content is addressed. This hypothesis is supported by qualitative findings, iterating the importance of the source of physical activity support in people with severe mental illness (42). Finally, the intervals of the telephone counseling sessions were adapted to the preferences of the participants. It proved challenging for the coaches to reach some of the participants in the intended interval of two weeks. It could be hypothesized that, as with physical activity itself, the intervention may best be provided in the dose that suits the participant. It has been discovered that affect is impacted differently by physical activity depending on whether the intensity is self-selected or imposed, whereby a self-selected dose is associated with more positive affect (43). In turn, positive affect is associated with more motivation and engagement (44). However, increased intervals between counseling sessions also result in longer breaks and in this case a shorter overall intervention duration. This in turn, assuming the counseling has an effect on behavior, has the potential of disturbing the repetition of the behavior in recurring contexts, leading to habit formation (45). The implications of variability in intervals may become clearer in future outcome analyses.

4.2. Strengths and Limitations

This study was conducted according to the MRC guidelines of evaluating complex interventions and thus answers their call for a more holistic approach to trial evaluations (10). In so doing, it also addresses recommendations from a recent systematic review stating that theory-based complementary process evaluations are needed to enhance the generalizability of quantitative trials (46). Evaluating the implementation of an intervention of this length, i.e. delivered during 12 months, may be particularly poignant, because the potential for variation in dose, content and adaptation may arguably be greater. In particular, this part of the process evaluation of the PACINPAT trial will help to interpret the outcome analyses and lends

important insight into the mechanisms of a physical activity intervention in an in-patient psychiatric setting and beyond. More generally, it may encourage the movement towards increasingly conducting more extensive evaluations in similar settings. This implementation evaluation entails multiple data sources, covering aspects from the intervention designers, implementers and recipients. Data provided by the implementers are particularly valuable because they were captured directly after each counseling session, thus they are less prone to recall bias. Additionally, they provide information on the content of an individually tailored counselling session for each participant. The presented participant satisfaction data can also be seen as a strength, despite the early dropouts not being represented, because they did not take part in the post and follow up assessments. Overall, these quantitative data allow an objective and reliable evaluation of the reach, dose and fidelity of the intervention.

Despite these strengths, there are limitations to be considered. There is a potential for recruitment bias, because only people who were interested in becoming more physically active took part in the trial, thus leaving it unknown how the intervention would have been implemented with a less motivated sample. The variability of the intervention dose does not allow general conclusions regarding the content and adaptation of the intervention. However, examining only selected participants would not correspond to practice. Therefore, the subgroup analysis was deemed a suitable solution to evaluate the intervention implementation concisely while preserving variability. The attendance cut off rate of 75% used to make the subgroups was supported by meta-analytic data, however to date there seems to be little consensus regarding the definition and measure of adherence in physical activity interventions (47). Some researchers do suggest that it is common to compare high and low adherence to exercise programs, whereby the former refers to ≥70% adherence and the latter <70% adherence, as measured, for example, with accelerometry (48). However, this pertains to adherence to physical activity and not to physical activity counseling interventions. Adherence guidelines, as they exist for medication (49), may be required for behavioral counseling interventions. Additionally, there are some limitations with regard to the nature of the presented data. For example, it cannot be gauged why the early dropouts had shorter in-person counseling sessions, why some people preferred longer intervals during the remote counseling sessions or why coaches used some BCTs more frequently than others. To explore these aspects, collecting and adding qualitative data resulting in a mixed method approach would be necessary. For an even more comprehensive analysis of the implementation, the use of the mobile application and timing of the receipt as well as reading of the text messages would have been of interest. However, these data were not available in the current study.

5 Conclusion

The PACINPAT intervention reached the intended participants and was attended by early dropouts and participants engaging in low or high doses. The high dose comprised 75% of the intended number of counseling sessions in approximately the intended interval between sessions. Group differences were already recognizable in the first two sessions according to session length and fidelity of content. This may represent a vulnerable stage of the intervention. Further research is needed to validate this and investigate potential improvement strategies. Frequently used behavior-focused (as opposed to outcome-focused) BCTs and adaptations made in dose (longer intervals) and content (Mo-Vo) provide interesting insight into the potential needs of the population receiving this intervention for the first time. Overall, the intervention was rated positively by the participants. These findings are important for designing and implementing physical activity interventions in psychiatric care and for the future interpretation of the PACINPAT outcome evaluations.

6 List of abbreviations

PACINPAT	Physical activity counseling in in-patients with major depression
CI	Confidence interval
Min	Minutes
RCT	Randomized controlled trial
MRC	Medical research council
ICD-10	International classification of disease, 10^{th} edition
BDI	Beck depression inventory
Mo-Vo	Motivation volition
BCW	Behavior change wheel
BCT	Behavior change technique
IPAQ	International physical activity questionnaire
M	Mean
SD	Standard deviation

ANOVA Analysis of variance

7 Declarations

7.1. Ethics approval and consent to participate

The PACINPAT trial was approved by the "Ethikkommission Nordwest- und Zentralschweiz" (EKNZ, project number 2018-00976). The PACINPAT trial has also been registered in the ISRCTN registry (ISRCTN10469580). Before participation in the trial participants were informed about the goals, their right to withdraw from the study at any time without negative consequences and signed an informed consent form.

7.2. Consent for publication

The consent for publication was given when participants signed the informed consent form for participation.

7.3. Availability of data and materials

The data and materials will be made available by the corresponding author (Robyn Cody) upon request, without undue reservation.

7.4. Competing interests

The authors declare that they have no competing interests.

7.5. Funding

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7.6. Author's contributions

RC, RM, JNK and XF co-designed the intervention and intervention materials. JB, MH, CI, UEL, SM, TM, AO and NS supported the patient screening and recruitment processes on the four study sites. RC and JNK recruited the participants. RC, RM, JNK and XF trained the coaches. RM, LW, LSR and NK coached the participants and contributed to adaptations made during the intervention. SB offered thematic support. RC and LW prepared the data for

analyses. RC, JNK, OF and MG were responsible for conceptualizing the manuscript and the statistical analyses. RC wrote the first draft of the manuscript. All listed co-authors read, contributed to and approved the final manuscript.

7.7. Acknowledgments

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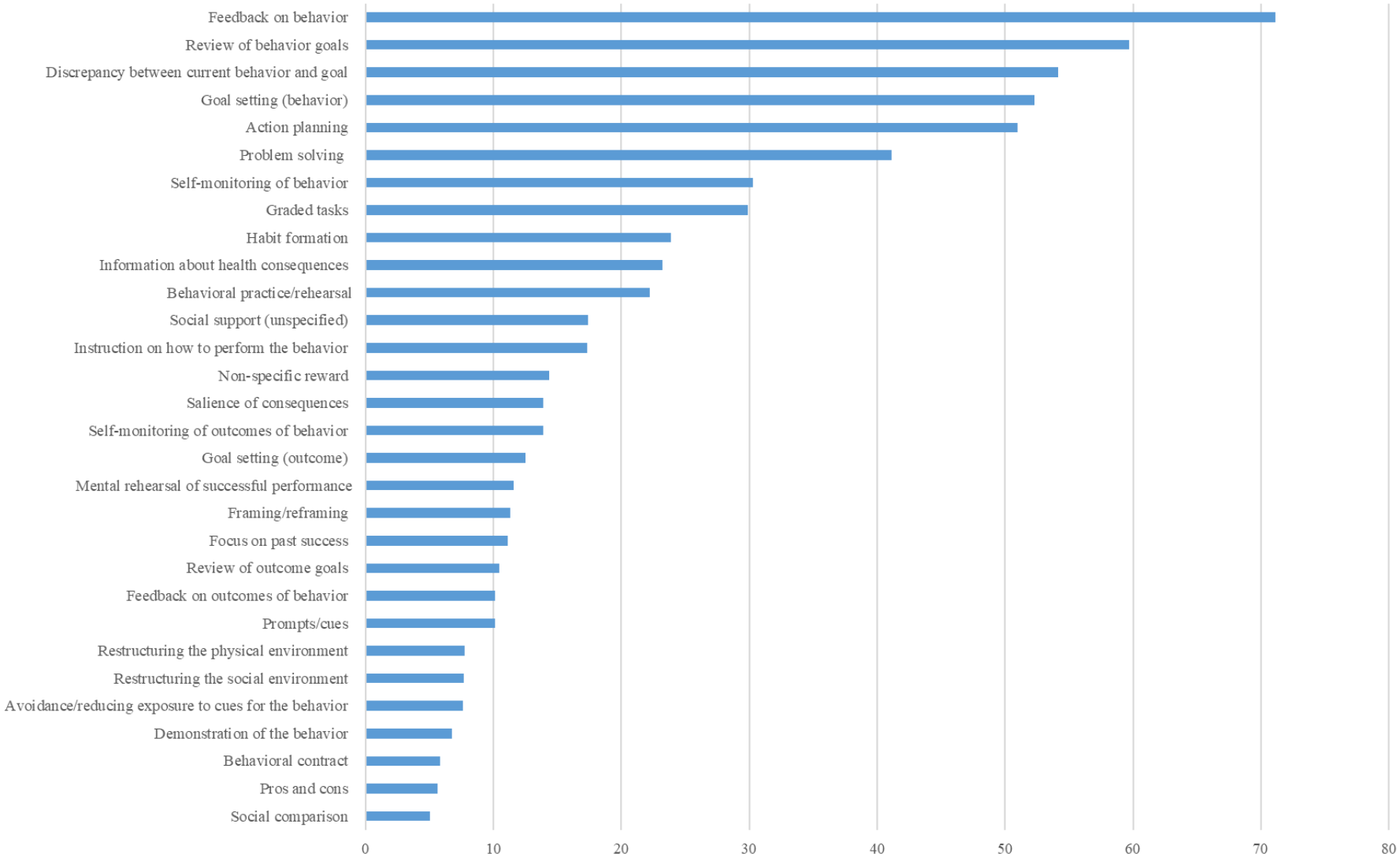
Table 7. Participant satisfaction

	Post in-patient treatment (n = 63)				Post intervention (N = 50)			
	n (%) **No**	*n* (%) **Mostly no**	*n* (%) **Mostly yes**	*n* (%) **Yes**	*n* (%) **No**	*n* (%) **Mostly No**	*n* (%) **Mostly yes**	*n* (%) **Yes**
Have your expectations been met?	3 (5)	7 (11)	22 (35)	31 (49)	4 (8)	6 (12)	10 (20)	30 (60)
Is the content appropriate and understandable?	0 (0)	0 (0)	15 (24)	48 (76)	0 (0)	0 (0)	10 (20)	40 (80)
Are you satisfied with your coach?	1 (2)	0 (0)	6 (9)	56 (89)	0 (0)	1 (2)	6 (12)	43 (86)
Would you prefer a different coach?	61 (97)	2 (3)	0 (0)	0 (0)	47 (94)	3 (6)	0 (0)	0 (0)
Are the weekly messages helpful to stay motivated?	6 (10)[a]	10 (16)[a]	21 (34)[a]	25 (40)[a]	3 (6)	5 (10)	20 (40)	22 (44)
Are the weekly messages helpful to implement your plans?	7 (11)	11 (18)	24 (38)	21 (33)	4 (8)[b]	7 (14)[b]	21 (43)[b]	17 (35)[b]
Are the weekly messages helpful to reach your goals?	8 (13)[a]	10 (16)[a]	23 (37)[a]	21 (34)[a]	3 (6)[b]	8 (16)[b]	22 (45)[b]	16 (33)[b]
Is the app user-friendly/understandable?					6 (12)[c]	8 (17)[c]	21 (44)[c]	13 (27)[c]
Is the App helpful to stay motivated?					15 (31)[b]	13 (26)[b]	16 (33)[b]	5 (10)[b]
Is the App helpful to implement your plans?					15 (31)[b]	12 (24)[b]	19 (39)[b]	3 (6)[b]
Is the App helpful to reach your goals?					16 (33)[b]	14 (28)[b]	14 (28)[b]	5 (10)[b]
Have you achieved intermittent goals that you set during the program?					3 (6)[b]	6 (12)[b]	27 (55)[b]	13 (27)[b]
Do you move more (increased duration or frequency)?	2 (3)	9 (14)	32 (51)	20 (32)	5 (10)	8 (16)	20 (40)	17 (34)
Are you motivated to continue your participation in the program?	1 (2)	3 (5)	24 (38)	35 (55)				
Would you recommend the program?	2 (3)	18 (28)	1 (2)	42 (67)	1 (2)[b]	3 (6)[b]	14 (29)[b]	31 (63)[b]
Do you think the program is a suitable health promotion measure?	1 (2)	0 (0)	19 (30)	43 (68)	0 (0)	0 (0)	21 (42)	29 (58)
Generally, are you satisfied with the program?	1 (2)	0 (0)	15 (24)	47 (74)	0 (0)	3 (6)	15 (30)	32 (64)
	Too high	**Mostly too high**	**Appro-priate**	**Low**	**Too high**	**Mostly too high**	**Appro-priate**	**Low**
How do you perceive the effort you put into participating in the program in relation to your success?	2 (3)	4 (6)	52 (83)	5 (8)	1 (2)	4 (8)	41 (82)	4 (8)
	Too long	**Just right**	**Too short**		**Too long**	**Just right**	**Too short**	
How do you perceive the intervals between the coaching sessions?	1 (2)	15 (24)	47 (74)		4 (8)	40 (80)	6 (12)	
	No		**Yes**		**No**		**Yes**	
Do you use a different Fitness App or activity tracker (e.g. Fitbit, Garmin, Huawei Band, Moov, Samsung, Amazfit)	48 (77)[a]		14 (23)[a]		36 (72)		14 (28)	

Notes: [a]Sample size of 62. [b]Sample size of 49.[c]Sample size of 48.

Figure 3. Frequency of Behavior Change Techniques



Chapter 6 Publication 4

The experience of a physical activity counseling intervention among people with major depression within the PACINPAT trial – A reflexive thematic analysis

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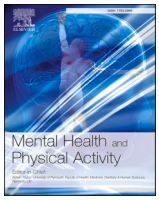

The experience of a physical activity counseling intervention among people with major depression within the PACINPAT trial – A reflexive thematic analysis

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ABSTRACT

Introduction: Physical activity can be an effective complementary treatment for major depression, yet among afflicted people, physical inactivity is prevalent. The aim of the "Physical Activity Counseling in In-Patients with Major Depression" (PACINPAT) trial was to promote a more physically active lifestyle by implementing a theory-based in-person and remote counseling intervention. It is not only important to establish whether this approach works, but also how, when and why it works. Hence, the aim of this study was to explore how participants receiving a theory-based physical activity counseling intervention experienced the intervention.

Methods: Semi-structured interviews were conducted with 12 participants who were recruited purposively after completing the intervention and data assessments within the PACINPAT randomized controlled trial being conducted in four Swiss psychiatric clinics. The interviews were analyzed according to the six steps of reflexive thematic analysis.

Findings: Twelve initially physically inactive adults described managing life with depression as "balancing pressures" which strongly influenced their well-being and physical activity behaviors. This became visible in the varying experiences to the intervention: (1) Expansive: increasing well-being with maintained physical activity; (2) Adoptive: fragile well-being with relationship-dependent physical activity; (3) Stagnant: declining well-being with shift away from physical activity; and (4) Confirmatory: unchanged well-being with unaffected physical activity.

Conclusion: Participants with major depression who took part in the same physical activity counseling intervention experienced it in four distinguishable ways, which were noticeably linked with their level of self-management. Identifying these experience patterns is promising, because it could lead to refining the intervention to improve effectiveness for individuals. Further investigation is required to validate these suggested experience patterns.

Trial registration: SRCTN, ISRCTN10469580, registered on 3rd September 2018.

1. Introduction

Major depressive disorder (MDD) is a mood disorder, characterized by symptoms such as persistent sadness, loss of interest and decreased energy (American Psychiatric Association, 2013). The onset of MDD is gradual and the course is episodic and unpredictable (Malhi & Mann, 2018). It is estimated that the average lifetime prevalence of major depressive episodes is 14.6% in high-income countries with age of onset at 25.7 years and 11.1% in low-to middle-income countries with age of onset at 24 years and the female to male ratio is about 2 to 1 (Aquino et al., 2018; Bromet et al., 2011). Depressive disorders are one of the leading causes of years lived with disability (James et al., 2018), associated with somatic co-morbidities and overall mortality (Penninx et al., 2013), cognitive deficits impacting psychosocial functioning and quality of life (Rock et al., 2014), as well as economic burden (König et al., 2019). The etiology of depression may be best explained with a

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biopsychosocial-vulnerability-stress model, stipulating that certain biological (e.g., genetics), psychological (e.g., dysfunctional cognition) and social circumstances (e.g., trauma) lead to vulnerabilities, which combined with acute life stressors (e.g., unemployment, relocation, divorce) may lead to depression (Brakemeier et al., 2008). Depending on depression severity standard treatment comprises watchful waiting, psychotherapy (e.g., psychoanalysis, cognitive behavioral therapy and systemic therapy), pharmaceutical antidepressants (e.g., tricyclic antidepressants, 2nd and 3rd generation antidepressants), or a combination (Holsboer-Trachsler et al., 2016).

Physical activity has gained increased attention as a complementary treatment, because it tackles both physical and psychological symptoms (Gerber et al., 2016). Evidence shows that improvements in physical fitness (maximal aerobic capacity) after a 12-week physical activity intervention were associated with a reduction in depressive symptomology, enhanced well-being and improved sleep (Gerber, Minghetti, et al., 2019). Even acute bouts of moderate intense exercise have been shown to improve mood, reduce rumination and have a positive effect on social interactions (Brand et al., 2018). Further evidence also suggests that strength training (Nebiker et al., 2018) and high-intensity interval training (Gerber et al., 2018; Minghetti et al., 2018) are effective options. Despite these benefits people with depression spend less time being moderately-to-vigorously physically active (standard mean deviation (SMD) $= -0.30$, 95%$CI = -0.40$ to 0.21) compared to people without depression (Schuch et al., 2017). The interference between depressive symptoms and the capacity to self-regulate health behaviors, through motivational and volitional deficits, is a particular challenge (Gerber et al., 2016; Krämer et al., 2014; Pomp et al., 2012). Low or depleted self-regulatory resources may mean affect-driven impulses lead to or perpetuate physical inactivity (Brand & Ekkekakis, 2018). Qualitative findings show that low motivation, lack of confidence (Searle et al., 2011), medication, mental illness itself (Hodgson et al., 2011) including symptoms of anxiety (e.g., worry and avoidance) (Mason et al., 2019) are known barriers to physical activity in this population.

Physical activity interventions have shown positive effects in changing physical activity behavior in inactive adults (Howlett et al., 2019). To date such interventions are typically grounded in theory to better understand mechanisms of the intervention (Hagger, Cameron, et al., 2020; Hagger, Moyers, et al., 2020; Michie et al., 2008). One such theory is the Motivation-Volition (MoVo) model, in which it is assumed that a strong and self-concordant intention has the potential to lead to implementation intentions (i.e. planning), that shielding these intentions from inner (e.g. low mood) and outer barriers (e.g. bad weather) will lead to initiating physical activity and that positive outcome experiences thereof will secure maintenance of the behavior (Fuchs, 2008). The corresponding intervention is a short, low cost, lifestyle physical activity counseling intervention, which has been implemented, among others, in orthopedic patients leading to increased physical activity levels (intervention group: 156 min/week versus treatment as usual control group: 83.5 min/week; $F(1, 218) = 27.3$; $p < .001$; $\eta^2 = 0.11$) (Fuchs et al., 2011). Physical activity counseling based on self-determination theory has also been successful in promoting physical activity in out-patients with depression (Chalder et al., 2012). The Behavior Change Wheel, a framework which explains behavior through Capability (psychological and physical), Opportunity (social and physical) and Motivation (reflective and automatic), referred to as COM-B, can also be used (Michie et al., 2011). It is assumed that implementing Behavior Change Techniques (BCTs) within nine intervention types (e.g., training, education, persuasion) behavior can be changed and interventions can be scaled up through seven policy options (e.g., guidelines, regulation, service provision) (Michie et al., 2011). BCTs associated with effective physical activity promotion are: biofeedback, demonstration of behavior, behavior practice/rehearsal, graded tasks, action planning, instruction on how to perform the behavior, prompts/cues and self-reward (Howlett et al., 2019).

Participants taking part in physical activity interventions have experienced them as acceptable treatment options (Searle et al., 2011). Qualitative analyses show that participants experienced physical activity as helpful through biomechanical pathways, distraction from negative thoughts, providing a sense of purpose (Searle et al., 2011) as well as improved mood, feelings of enjoyment and achievement (Carter et al., 2016; Pickett et al., 2017). In a recent meta-ethnographic systematic review the experience of initiating physical activity for people with serious mental illness was described as a complex journey including thought processes, expectations, barriers and support needs (Quirk et al., 2020).

According to the newest update of Medical Research Council (MRC) guidance for developing and evaluating complex (behavioral) interventions, research in this area goes beyond whether an intervention works in terms of end point outcomes and addresses six core elements: the context, underpinning theory, economic value, key uncertainties, and refinement of the intervention as well as the inclusion of stakeholder perspectives, which are to be considered continually throughout the research process and can be addressed with qualitative methods (Skivington et al., 2021). Additionally, qualitative research can contribute to optimizing intervention and trial conduct, facilitate the interpretation of outcomes, and identify interventions most likely to be effective (Cathain et al., 2013). Despite this, only 0.24% of clinical trials registered in three registries use qualitative methods (Clement et al., 2018).

A RCT named PACINPAT (Physical Activity Counseling in INPATients with major depressive disorders) was conducted in four Swiss psychiatric clinics and aimed to increase physical activity levels in people with MDD by implementing a theory-based physical activity counseling intervention (Gerber, Minghetti, et al., 2019). Efficacy outcomes (e.g., physical activity levels) will be published separately.

To date, little is known about how physical activity counseling interventions themselves are experienced by people with MDD. Additionally, in line with MRC guidelines, gaining contextual understanding of the PACINPAT intervention is necessary to contribute to the possibility of its future refinement. Hence, the aim of this study was to explore how participants receiving a theory-based physical activity counseling intervention experienced the intervention.

2. Methodology and methods

This is a qualitative study within the PACINPAT randomized controlled trial, hence it is an embedded design (Creswell & Planto Clark, 2006). As seen in Fig. 1, during the ongoing PACINPAT randomized controlled trial, qualitative data were collected and analyzed from individuals who had completed the intervention and outcome data assessments. In this study, interpretations of the qualitative results with a focus on intervention refinement are presented.

For the embedded qualitative study steps of reflexive thematic analysis according to Braun, Clarke, Hayfield, and Terry (2019) were followed with a constructivist orientation. The underlying assumption is that humans engage in meaning-making through cultural and social discourses resulting in emergent and developed explanations of reality, described as knowledge. Therefore, knowledge is constructed through

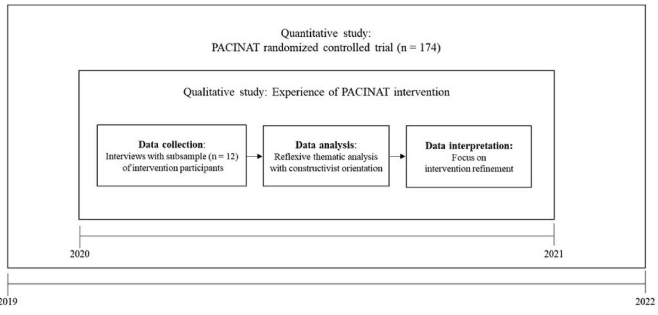

Fig. 1. Embedded design adapted from Creswell and Planto Clark (2006)

an active process of interactions between what is already known (existing personal models of the world) and discrepant new experiences and insights which are added when in contact with one's surroundings. Along these lines meaning is non-transferable (as a teacher may attempt to transfer meaning to a learner), but individually created based on contextually meaningful experiences in which patterns are sought out, questions asked, ideas modelled, interpreted and defended (Fosnot, 2013).

2.1. Setting and sampling

The PACINPAT trial took place in four Swiss psychiatric clinics. The inclusion criteria of the trial, which can also be viewed in the study protocol (Gerber, Beck, et al., 2019), were: adults aged 18–65 years, with moderate to severe depression according to the International Classification of Disease, 10th edition (ICD-10) including diagnoses for depressive episodes (F32) and recurrent depression (F33), who were physically inactive prior to in-patient treatment (i.e. performed less than 150 min of moderate-to-vigorous physical activity weekly). Depression severity was measured using the Beck Depression Inventory with scores $\geq$17 indicating at least moderate depression (Beck et al., 1988). Physical activity was measured using the International Physical Activity Questionnaire (Craig et al., 2003).

In-patients in the psychiatric clinics were screened according to these criteria and a member of the study team was contacted for potential candidates. This member of the study team provided an in-person meeting with the candidate to clarify the aim and procedures of the study and to ensure the candidate understood participation was voluntary, all data would be anonymized and only used for research purposes. Thereafter, candidates who decided to partake provided written informed consent.

Sampling for the qualitative study took place in Mid-December 2020. By that time, 174 participants were included in the trial, 87 of which were randomized to the intervention group, 44 of which had finished their trial participation. From this sample, we purposefully sampled participants with maximum variation regarding sex, age, center of care, depression status, comorbidities and dose of intervention (partially or totally completed). Twelve out of seventeen participants who were contacted provided written informed consent and were included. The aim was not to reach data saturation but information power, which is recommended in exploratory analyses to present information relevant to the study aim (Malterud et al., 2016).

2.2. The PACINPAT intervention

The intervention consisted of two parts. The first part comprised two in-person counseling sessions (lasting 60–90 min) based on the Motivation Volition (MoVo) process model to which there is a corresponding Motivation Volition intervention (Fuchs et al., 2007; Gerber et al., 2014). During these sessions, motivational (intention and planning) and volitional (barrier and expectation management) processes were targeted. The second part comprised bi-weekly telephone counseling sessions ($n = 26$, lasting 15–20 min), weekly text messages ($n = 52$) and the use of a mobile application for self-monitoring during one year. The implementation of eHealth (web-based, web and mobile application and e-mail based) interventions has been associated with increased physical activity levels as well as improved mental health profiles of people with a mental health condition (Moran et al., 2018). This part was based on the design of a previous intervention study facilitating physical activity in a healthy population, using appropriate BCTs such as: goal setting, action planning, problem solving, feedback on behavior and self-monitoring of behavior (Fischer et al., 2019). These were used by the coaches as needed. Text messages were based on the following BCTS: delivering reminders, providing information on the benefits of physical activity and feedback on behavior. The physical activity coaches were sport science and psychology graduates who were trained and supervised continually. More information can be found in the study protocol (Gerber, Beck, et al., 2019).

2.3. Data collection

Data was collected in semi-structured interviews using an interview guide (see Supplement 1 and 2). The guide was developed by the research team based on literature (Kallio et al., 2016) and practice knowledge about the intervention. The first draft was used with a pilot participant. Based on this experience, the interview guide was reduced to one main open-ended guiding question ("Tell me about the physical activity counseling program you took part in during the past year. What remained in your memory in particular?") and a series of follow-up questions to deepen the topics raised by the participants (e.g. How did you feel, how did you change, can you give an example?). Both interviewers (RC and MC) were trained in conducting qualitative interviews.

Given restrictions because of the COVID-19 pandemic, six interviews were performed digitally using the applications Zoom© or Skype©. The other six were conducted as planned in-person in the clinic, in which the participant had originally been treated.

Interviews lasted an average of 34.97 min (range = 22.19 min–49.44 min), were audio recorded and transcribed verbatim according to transcription rules by the interviewers. Identifiers were removed to ensure anonymization of the data. Hand written field notes were taken during and after the interview to facilitate the interview and analysis.

2.4. Data analysis

Qualitative data were analyzed using the six steps of reflexive thematic analysis according to Braun et al. (2019) using the software MAXQDA Plus 2018 (version 18.2.0). Reflexive thematic analysis was deemed an appropriate method given the assumption that humans engage in meaning-making and their realities are constructed contextually. Participants in this study talked about the experience of the intervention given their particular context. Similarly, meaning across and between all experiences and contexts was derived through the interactions of the researchers with the data. By following the six phases shown in Table 1, thematic patterns were identified and similarities as

Table 1
Phases of thematic analysis.

Phase	Description of the process
1 Familiarization	RC and MC listened to the recordings and read textual data, making notes on first impressions, possible connections and passages to be looked at more closely. Initial impressions and tricky passages were discussed with DN to share perspectives, adding depth and nuance to each transcript.
2 Generating codes	RC and MC inductively organized text passages with similar meaning and denoted them with labels, i.e. preliminary codes. These labels were discussed and refined with DN resulting in diversified codes.
3 Constructing themes	RC and MC identified preliminary themes by using the codes as building blocks. Collaborative discussions with DN lead to the further identification of umbrella themes and possible titles as well as definitions.
4 Revising themes	RC and MC revised the themes by continually checking consistency with the data leading to renaming or let go of conceptually weak or overlapping themes. The remaining themes were discussed with DN to consolidate their meaning.
5 Defining themes	RC and MC defined each theme delineating boundaries and central organizing concept to clarify scope and essence of each theme. RC and MC created thematic maps, which were discussed and reflected upon with DN.
6 Producing the report	RC revisited the research question, field notes, codes and themes checking for consistency with the data. The structure of the report was discussed between RC and DN. RC produced a first draft in close collaboration with DN. The final report was discussed and approved by MC, JNK, OF, MG and DN.

well as differences were reflected upon in an iterative manner, resulting in relevant knowledge regarding the experienced intervention. Non-exhaustive examples of the analysis process are shown in Supplement 3.

2.5. Reflexivity

The researchers had an active role in generating the knowledge in this study. Researchers recruiting the participants, conducting the interviews and analyzing the data approached this research with a sport science background and had been involved in the PACINTAT trial. The researcher further involved in the analysis approached it with a nursing science background and was not involved in the PACINAT trial at all. After each interview, a debriefing session consisting of written and verbal reflections took place. Additionally, each step of data analysis was reflected within the research team and documented. Trustworthiness is given in qualitative research, when consensus within a study can be found through triangulation in which the effect of individual researcher bias can be reduced (Sandelowski, 1993). This was achieved, as described in Table 1, during the analysis with discussions among the involved researchers. Additionally, the quality and methodological rigor of this analysis is given considering the adherence to a 15-point checklist of criteria for good thematic analysis (Braun & Clarke, 2006) (Supplement 4).

3. Findings

3.1. Participant characteristics

Twelve participants shared their experience of the physical activity counseling intervention. Before the physical activity counseling intervention, ten participants took antidepressants. Seven participants continued taking the same medications and doses throughout the intervention time, while two participants reduced their intake and one increased. The remaining two participants started and ended the intervention without antidepressant medication, yet periodically took antidepressants during the intervention year. Eleven participants completed the intervention with an average of 25 counseling sessions (range: 4 to 29) during 12 months and took part in all three quantitative data collection time points. One participant dropped out of the intervention after four counseling sessions, however, took part in all quantitative data collection time points. Participant characteristics are shown in Table 2.

Table 2
Participant characteristics.

	M (*SD*)
Age (years)	49.75 (12.46)
Physical activity before admission (min/week)	32.50 (44.02)
Beck Depression Inventory Score at admission	27.27 (8.26)
	***N* (%)**
Sex	
Women	7 (58)
Men	5 (42)
Primary diagnosis	
Moderate depressive episode	2 (17)
Severe depressive episode	4 (33)
Recurrent depression, currently moderate episode	6 (50)
Secondary diagnosis	
Somatic	7 (58)
Mental and behavioral disorders	2 (17)
Nonpsychotic mental disorders	4 (33)
Disorders of adult personality and behavior	2 (17)
Pervasive and specific developmental disorders	1 (8)
Problems related to health care	1 (8)
Civil status	
Single	9 (75)
Married	3 (25)
Employment before admission	
Yes	11 (92)
No	1 (8)

Notes: Min = Minutes.

3.2. Lived experience of depression: balancing pressure

It became clear during the interviews that the experience of the intervention was linked in every case with the experience of depression, despite the interview guide containing no such questions. The participants described all life events in the context of their diagnoses and what it meant for their lives. This lead to a recurrent theme throughout all stories, which precedes the experience of the intervention as it gives important contextual information, which allows a more in-depth understanding of how the intervention was experienced. Participants portrayed living with depression as a balance between being under pressure and striving for well-being, which required allocating their sparse resources accordingly. Pressure was talked about in terms of living and financial situations ranging from struggles with keeping living spaces clean and unemployment to deciding whether to relocate and self-employment. Pressure was also referred to with continuity of care. Participants explained that a lot of time was invested in finding ambulatory care, corresponding with authorities and care providers. Additionally, pressure was said to stem from the challenge of not falling back into daily routines and "bad habits", which were described as being "stuck in a rut". For example, participants described prioritizing other people's needs before their own, socially isolating themselves and getting caught in the "rat race" at work again. They reported that their well-being was curbed by wave-like recurrence of low mood, characterized by feeling overwhelmed with life and wanting to withdraw. Participants expressed, that this too, required great amounts of energy to overcome and "just do the necessary": getting out of bed, eating and in some cases working.

Consequentially, it was said that balancing these pressures of life and managing symptoms of depression negatively influenced health behaviors, in particular physical activity. In this situation, participants described the offered intervention either as a source of support, hope or at least a chance they did not want to miss out on to move toward improved wellbeing and increased physical activity. Their experiences of the intervention appeared to vary, depending on their mindset towards physical activity in general and the momentary burden of managing their illnesses. These influences were particularly salient upon entering the intervention and became the main topic of conversation in the interviews. Accordingly, the intervention including the coach were said to take on different meanings. Thus, leading to different states of well-being and physical activity behavior, described by four different experience patterns as follows and depicted in Fig. 2: (1) Expansive: increasing well-being with maintained physical activity; (2) Adoptive: fragile well-being with relationship-dependent physical activity; (3) Stagnant: declining well-being with shift away from physical activity; and (4) Confirmatory: unchanged well-being with unaffected physical activity. These four experience patterns will be described in more detail in the following sections.

Additional characteristics of the participants are displayed in Table 3, including information regarding the dose of the intervention, depression severity and diagnoses.

3.3. Experience patterns

3.3.1. Expansive: increasing well-being with maintained physical activity

These participants explained that at some point, following deep reflection on living with depression with many ups and downs, they realized that there was no quick fix. For them, this realization formed the fundament from which to start a process of continuous and well-balanced change toward improved well-being. As one participant described: "I told myself you can't go on like you have done the past 20 years." (P9, 50–60 years).

In this context, they were offered to participate in the intervention.

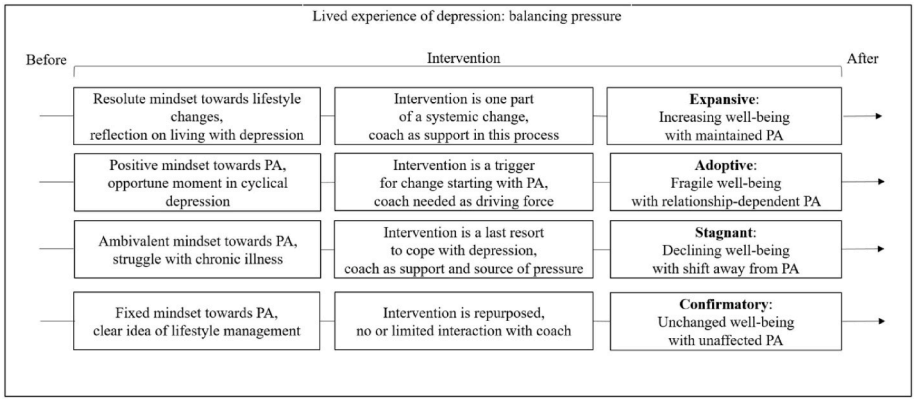

Fig. 2. Overview of experience patterns identified in qualitative interviews.

Table 3
Participant characteristics according to differing experiences of the intervention.

	Expansive	Adoptive	Stagnant	Confirmatory
	M (SD)	M (SD)	M (SD)	M (SD)
Number of participants	4	4	2	2
Age (years)	54.75 (4.11)	41.50 (8.58)	58.00 (9.90)	42.00 (26.87)
Number of coaching sessions	25.25 (3.77)	24.50 (0.58)	27.00 (0)	12.5 (10.61)
Intervals between telephone sessions (days)	18.28 (4.35)	16.60 (1.17)	15.94 (0.03)	15.75 (11.90)
Intervention duration (months)	13.59 (0.86)	12.27 (0.79)	13.10 (0.02)	7.51 (9.60)
Beck Depression Inventory Score at admission	25 (6.88)	26 (10.39)	36 (0)	30 (9.90)
	n (%)	**n (%)**	**n (%)**	**n (%)**
Primary diagnosis				
Moderate depressive episode	0	1 (25)	0	1 (50)
Severe depressive episode	2 (50)	0	1 (50)	1 (50)
Recurrent depression, currently moderate episode	2 (50)	3 (75)	1 (50)	0
Secondary diagnosis				
Somatic	3 (75)	2 (50)	1 (50)	1 (50)
Mental and behavioral disorders	0	0	1 (50)	1 (50)
Nonpsychotic mental disorders	1 (25)	2 (50)	1 (50)	0
Disorders of adult personality and behavior	1 (25)	1 (25)	0	0
Pervasive and specific developmental disorders	0	0	1 (50)	0
Problems related to health care	1 (25)	0	0	0

They emphasized that they perceived this offer as a welcome part of a systemic change they were going through during in-patient treatment. This became evident as they explained changes were taking place in their relationships, employment status and health in general which may have included but was not limited to physical activity.

For these participants, the coach served as a support during this process. Once the intervention started, they explained that physical activity goals, which were related to a specific performance, e.g., walking up the hill in 20 min, were perceived as too much pressure. In addition, these goals did not contribute to increased well-being. In order to reduce pressure, they said that they preferred setting more holistic well-being goals. For example, walking up the hill at a pace, which felt good, so as when they reached the top they would not only have done some exercise but they would feel fulfilled and would have enjoyed the experience. It was explained that realizing performance is not the measure for success but enjoyment and regular activity, was a pivotal moment for them. As one participant described: "It [the intervention] really is a form of working on one's self." (P3, 54 years). In a broader sense, they said this also included (re)gaining the ability to stand up for one's self and one's beliefs as well as noticing and communicating boundaries.

> "I became more aware that I can be more decisive, I do not have to ask for permission. […]. When something annoys me now and I see that the behavior of a work colleague is unacceptable to me, I get up and say it like it is. That never happened before." (P6, 50–60 years)

Participants described a heightened sense of self-awareness regarding how, when and where they wanted to be physically active and communicated this clearly with their coaches and in their social environment. This could mean attending weekly classes, riding a bike and taking public transport instead of driving a car or setting up an exercise room at home.

At the end of the intervention, these participants reported an increase in their overall well-being through achieving individual goals, regaining a sense of self and body awareness, avoiding pressurizing situations and (re)building social and work environments. With regard to physical activity, participants said that they were happy with what they had achieved and that they were not going to let the absence of the coach influence their routines. In some cases, they expressed not being at their physical limit and the wish or possibility to be even more physically active, which they may address in future. One participant described the coaching as a process, in which the coach is a type of crutch and with time, one learns to continue on one's own. Another stated:

> "[…] It [physical activity] is part of me […]. I can motivate myself, I get dressed and I go out into the woods. It does not have to be jogging or anything but just getting some air, just for myself […]. And now that is internalized, so in that regard it [the intervention] has helped." (P12, 50–60 years)

3.3.2. Adoptive: fragile well-being with relationship-dependent physical activity

These participants expressed having positive previous experience

with physical activity, always having liked being physically active and seeing the importance therein, however, being hampered by their depressive mood. They explained that when they felt well and had their life under control, they enjoyed exercising and committed to do so alone or in groups in the past. They described the occurrence of low mood in combination with a struggle in every-day life and with that, the perceived opportunity and motivation for physical activity decreasing.

According to these participants, they were offered to participate in the intervention at an opportune moment. One participant described the in-patient treatment as a "recovery break" and "the exact right moment to get to grips with physical activity" (P11, 50–60 years). Another stated that the intervention was one of the best programs to take part in during in-patient treatment. As such, the intervention was said to be a trigger for change, starting with physical activity. Having been previously physically active, these participants said they were looking for ways to prioritize physical activity again in life and tools for committing even during depressive episodes. In this context, the coach was said to be a necessary driving force, a constant companion and someone who kept an eye on progress. The participants explained that they enjoyed and were motivated by setting physical activity specific goals and making plans to achieve them. These participants also said that reflecting on why they wanted to be physically active was a novel undertaking in which they realized that physical activity can be fun; done according to one's own preferences; and benefit both physical and mental strength. A major part of the coaching, they said, was dealing with the loss of motivation or a failed plan. Strategies such as having a bag packed with sports clothes to reduce the effort to go to the gym after work, or making appointments with themselves or with friends were reported to have helped. Participants repeatedly mentioned that coming up with backup plans was particularly important because of the cyclical nature of depression. "Physical activity habits need to be built and re-built" (P5, 37 years) as one participant explained. This also required the ability to be patient and forgiving with one's self. One participant explained:

> "I allow myself not to exercise some days even if I had planned to. I do not see it as a failure but accept that today was just not the day for it. I trust that I will catch up on my activities another day." (P4, 30–40 years)

Participants also emphasized the importance of acknowledging their achievements. They explained how, with help from the coach, they felt proud of themselves and their bodies again and realized their capabilities leading to positive feelings. They did, however, also mention the struggle with expectations towards themselves, which were too high and in some cases were said to have been perpetuated by friends and family resulting in pressure to be physically active (enough). Participants explained that with help of the coach, their expectations were lowered and put in relation to the momentary state of other daily pressures, such as recurrent depressive episode, financial difficulties, or living situations, hence, finding a balance:

> "It is useful to stay committed and at the same time not want too much. It is not about [increasing performance], other things are more important such as continuity. So, I was always correcting my perspective so to say." (P7, 40–50 years)

At the same time, others said that some pressure exerted by the coach or social support system was positive and even necessary for success. For example, the coach checking in on progress and having to explain why a plan was not implemented or goal was not reached was said to be helpful when reflecting and re-adjusting behaviors. According to another participant, this kind of positive pressure or obligation was also present in group settings or classes, which helped overcome some initial lack of motivation.

At the end of the intervention, participants described their well-being as more or less fragile and very influenced by the struggles with recurrent depressive symptoms and getting to grips with life. They explained how this lead to multiple attempts to initiate physical activity while relying heavily on their coach. As one participant explained: "My physical activity behavior reduces when my coach is on holiday. The absence of the coach will leave a gap in my life." (P5, 30–40 years) and confirmed by another: "I'm sad that the coaching is over, it gave me so much motivation to get going" (P11, 50–60 years).

3.3.3. Stagnant: declining well-being with shift away from physical activity

These participants initially expressed ambivalence towards physical activity and the intervention itself as described by one participant: "I was wondering would I be able for this? Asking myself what have I let myself in for?" (P1, 60–70 years). Additionally, these participants reported struggles with further complex and chronic issues such as addiction, other psychiatric disorders/syndromes and physical illnesses, which impacted their ability to be physically active. At the same time, physical activity was reported to seem like a possible way of improving their physical issues such as being overweight.

These participants said that they decided to take part in the intervention without particular expectations and more or less as a last resort to cope with their various ailments: "I had no idea what it [the intervention] was actually about but I just tried it." (P8, 50–60 years). There were initial positive influences of the intervention as one participant described feeling encouraged by the regular counseling sessions. Another stated:

> "I started getting into it [the flow] slowly, it did increasingly motivate me and I noticed being gripped by ambition […] to sit down at the end of the day and think about all my activities and write them down." (P1, 60–70 years)

Participants described an increase in physical activity such as taking the long way home to increase daily steps, going for a cycle and strength exercises. However, they reported that they soon lost momentum mainly because of what they perceived to be failure or lack of improvement. The perceived failure was more closely described as the body giving in and becoming injured, which made being physically active difficult, and in turn perpetuated feelings of fear and self-doubt. In this case, it seemed that physical activity was actually facilitating and not countering some depressive symptoms.

> "I could not do many things I wanted to […]. I was in so much pain that I just had to stop. […] It really put the brakes on […] and I started to develop anxiety." (P1, 60–70 years)

Lack of improvement was more closely described as not reaching weight loss goals, for example, despite doing the recommended exercises. Additionally, not receiving the desired ambulatory care as well as ongoing appointments with medical specialists and bureaucrats left them feeling hopeless and discouraged to further engaging in physical activity. As described by one participant, the amount of energy required for everyday life "leaves one paralyzed, unable to do anything" (P8, 51 years). Despite this, the coach was often perceived as supportive. Participants said that with the help of their coach they were more aware of physical activity in their daily lives and still tried to do what was possible. For example, leaving the house earlier to walk to an appointment instead of taking public transport. At the same time, participants reported being partly relieved by the end of the intervention because it is "one less appointment to keep and worry about" (P8, 50–60 years).

At the end of the intervention, participants relayed that their well-being declined during the time of the intervention and thereafter. This was characterized by worsening negative spirals including both physical and mental health deteriorations, which they did not ascribe to the coach or intervention specifically, but to their situations in general. They reported struggles with physical health and disappointment in the system they were expected to act within (organization of ambulatory care, disability insurance, etc.). Therefore, they also reported a shift away from prioritizing physical activity to address their mental health in different ways.

3.3.4. Confirmatory: unchanged well-being with unaffected physical activity

These participants said that they already had physical activity routines with which they were satisfied, at least some of the time. They explained that they had helped themselves with regard to their mindset and lifestyle the most and that external advice was not the way in which they experienced motivation. Despite this, some people had decided to take part in the intervention even though they may not have fully identified with it:

> "I did not bring anything into it [the intervention] and also had no interest, that's why I thought this might be good for other people. I felt well again very soon, so maybe it [the intervention] would be good for people who are sicker." (P2, 20–30 years)

On this basis, the intervention was either reported to be used to check up on own interests such as body weight and percentage of body fat or was discontinued. In the case of repurposing the intervention, participants said that they often missed, postponed or forgot the telephone contact with the coach and that they perceived the conversations as annoying and repetitive. In some cases, the phone calls were skipped completely because participants said "counseling is just not for me. My motivation does not work like that". According to these participants, the coach was remembered as a pleasant person with, at times, good suggestions yet ultimately not necessary for progress. Instead, they talked about being self-motivated for physical activity, in some cases this included meticulous plans, whereas in some no plans at all because physical activity goals are achieved at work. An additional weariness of support from professionals was mentioned, for example, input from some clinic personnel, physiotherapists or fitness instructors was not welcomed and a wish expressed to be left alone.

> "In the clinic […] I talk to the chef and make sure I get the right food and I have my own exercise program. […] I have a very clear idea of what I need. […] I don't need that [instructions]." (P10, 60–70 years)

All participants said that the appointments for the data collection were particularly interesting and thus prioritized because this was an opportunity to confirm whether they were on track.

> "Getting the results [from the quantitative data] was good. […] That is what always interested me, to see whether things got better or worse." (P2, 20–30 years)

At the end of the intervention, participants expressed a neutral stance towards the intervention, it was neither good nor bad. They maintain that their well-being remained unchanged, either with recurrent depressive episodes accompanied by physical inactivity followed by depression-free episodes with plenty of physical activity or a steady state of mental as well as physical well-being. Participants explained that they recognized these patterns and could confirm them through conversations they had during the study participation. Consequently, they reported that their physical activity behavior too, remained unaffected.

4. Discussion

Twelve participants provided insight into living with depression and receiving a physical activity counseling intervention. They revealed that managing life with depression, described as "balancing pressures", before and during the intervention was central and influenced well-being and physical activity behaviors. This became visible and can be summarized in the varying experiences of the intervention: (1) Expansive: increasing well-being with maintained physical activity; (2) Adoptive: fragile well-being with relationship-dependent physical activity; (3) Stagnant: declining well-being with shift away from physical activity; and (4) Confirmatory: unchanged well-being with unaffected physical activity.

Participants' different ways of managing depression, which influenced their experiences of the intervention, all had the aspect of "balancing pressure" in common. This is reminiscent of the concept of self-management during illness, a process of medically and emotionally managing symptoms, treatment, consequences and lifestyle changes inherent in chronic illness (Barlow et al., 2002). The term self-management originates from the recognition that patients take an active role in the treatment of chronic illness and it is considered necessary for both health behaviors as well as living with chronic illness (Lorig & Holman, 2003). Also in more recent times it has been emphasized as a promising strategy in the treatment of chronic conditions (Grady & Gough, 2014). More specifically, in depression, learning to cope with cyclical distressing emotional states and reducing their interference with daily life independently, i.e. self-management, is reported to be one of the main desired treatment outcomes (Krause et al., 2021).

Our results show participants experiencing the intervention *expansively* (increased wellbeing with maintained PA) seem to have achieved a level of self-management at which physical activity was maintained and less subject to outside influences. They explained that they achieved this through reducing external and internal pressure and finding ways to enjoy physical activity, thus building intrinsic motivation. These experiences are well reflected in existing literature. People with mental illness have described "struggling with inner and outer limitations" including negative feelings resulting from fear of overwhelming demands, having to perform, inner stress and sadness when not achieving what is expected of them when approaching lifestyle changes (Lundström et al., 2017). Along these lines, outcome priorities for youths with depression include "relieving stress and experiencing a happier emotional state" as outcome priorities (Krause et al., 2021). The enjoyment of physical activity has previously been described as the key experience by people with depression to engage in physical activity and transitioning from external to internal motivation (Pickett et al., 2017). This is supported by quantitative evidence which shows that a positive attitude towards and positive experiences during physical activity are predictors for future physical activity behavior (Ekkekakis et al., 2011). It can be said that people experiencing the PACINPAT intervention expansively received it the way it was intended. These participants were or became ready to identify physical activity goals and ideas, make plans and implement these with increasing independence, seemingly responding well to the BCTs applied by the coaches. Thus the intervention fit and worked well for these people.

In contrast other participants, responding in *adoptive* (fragile well-being with relationship-dependent PA) and *stagnant* (declining well-being with shift away from PA) ways, perhaps achieved lower levels of self-management. Consequentially, they reported less stable well-being and physical activity behavior. These participants required more support. In some cases, the coach could provide this as exemplified by participants with an *adoptive* experience. They reported positive outcomes of the counseling sessions, which ceased without contact with the coach. The importance of social support for encouraging movement is well-documented. A dancing intervention for people with depression showed that non-judgmental professional support can lead to increased confidence and self-acceptance. While group involvement can elicit feelings of social acceptance and connection contributing to maintained participation. Both effects were reported to dissipate without professional or group support (Murrock & Graor, 2016). These findings are consistent with quantitative meta-analytic data, showing that physical activity supervised by professionals predicts fewer dropouts of an exercise program among people with depression compared to non-supervised classes (Stubbs et al., 2016). It can be said that people experiencing the PACINPAT intervention adoptively may have exhibited volitional difficulties, which were not adequately addressed. Thus the intervention could be refined in such a way that the coach would deliver or encourage supervised physical activity sessions and focus more on volitional aspects, such as plan implementation and intention shielding, during the coaching sessions.

In cases where the coach could not provide sufficient support, as exemplified by participants with a *stagnant* experience. These participants talked about the inhibiting burden of additional physical and psychiatric diagnoses. According previous research treating pain and other comorbidities may be a way to help people with depression become more active (Vancampfort et al., 2015). To underpin this, the fear-avoidance model stipulates that pain may lead to fear, which in turn may lead to avoidance behavior. Thus, pain in these participants may have led to a learned fear response, which then perpetuated physical inactivity and depression symptoms (Marshall et al., 2017; Vlaeyen et al., 2016). Additionally, depression-specific factors need to be understood and addressed in any attempt to increase physical activity (Machaczek et al., 2018), especially as the experience of disease can inherently serve as a barrier (Rezaie et al., 2017). Beliefs regarding the cause of depression have been linked to beliefs regarding what type of physical activity which may be helpful (Searle et al., 2011). It can be said that the PACINPAT intervention could be adjusted for people with a *stagnant* experience. Intervention refinement may include a highly integrative intervention, in which health providers work collaboratively to increase quality, user satisfaction and efficiency of care (Gröne & Garcia-Barbero, 2001). Such a collaborative care model approach was taken in a study for adolescents with depression involving psychiatrists and pediatricians (Kodish et al., 2019). For the PACINPAT intervention this could mean the physical activity coaches working in collaboration with psychiatrists and psychologists. Furthermore, the underpinning theory of the intervention may be refined to include affective considerations (Brand & Ekkekakis, 2018). It can be hypothesized, that when depressive symptoms are present, which are mainly affective in nature, negative affective responses may act as barriers which cannot be overcome by merely addressing motivational and volitional aspects of physical activity. This too could be addressed in a more collaborative intervention approach.

Participants experiencing the intervention in a *confirmatory* way (unchanged well-being with unaffected PA), indicated that they may not have been primarily motivated to engage in behavior change but were driven by body image and control issues. Evidence shows that depression is associated with a larger perceived body size and higher body image dissatisfaction, independent of body mass index. Particularly body image dissatisfaction is worrisome because it has been observed to lead to disorders such as anorexia and bulimia as well as a generally unhealthy lifestyles (Paans et al., 2018). In these cases, again, understanding how the person in question is experiencing their particular illness may be of primary importance to deliver a fitting intervention (Bromley et al., 2016). It can be said that the PACINPAT intervention could also profit from being adjusted for people with a *confirmatory* experience. Although the underpinning theory consists of motivational aspects, it assumes a fundamental interest in changing behavior. People with this experience pattern may be better understood with the Transtheoretical Model, in which it could be assumed that they are in the pre-contemplation stage at which people are first encouraged to even consider behavior change (Prochaska et al., 1992). The intervention could hence be refined in a way to address this more adequately. This could take the shape of a short intervention based on motivational interviewing (O'Halloran et al., 2014).

4.1. Implications

Based on the four experience patterns reported in this study, there are important implications for intervention refinement. The type of refinement potentially required seems to be linked to the level of individual self-management. In practice, this means that assessments would have to take place prior to the intervention to gain insight into self-management and the illness experience besides the quantitatively derived motivational physical activity determinants.

For people with more advanced self-management, the PACINPAT intervention as described seems suitable. For people with less developed self-management skills, an addition of supervised physical activity and emphasis on volitional competencies during counseling may be required. For people with low levels of self-management, who experience their illness as one of the primary barriers to physical activity, an integrative and collaborative approach with mental health care professionals and a focus on affective responses to physical activity may be advisable. For people who may not actually be interested in changing their physical activity behavior, a short intervention based on motivational interviewing may be ideal to prompt behavior change contemplation. Thus, it can be said, that tailoring according to determinants of the target behavior is important yet limited. Adding experiential evidence to tailoring behavioral interventions may contribute to their success.

Future research could be dedicated to validating these experience patterns of a physical activity counseling intervention in people with MDD and their distribution within this population. Before refinement takes place these findings would need to be validated. Furthermore, research could address similarities in demographic and illness characteristics of people experiencing physical activity counseling interventions in a similar way. Additionally, an economic analysis of the resources required for a more in-depth assessment before initiation of physical activity intervention could be conducted.

4.2. Limitations

The PACINPAT trial represents one approach, i.e. physical activity counseling, to increase physical activity in people with MDD. Assumptions regarding its efficacy are evidence-based, however, it is noteworthy, that other approaches should also be taken into consideration.

The strong focus on physical activity in both the design and implementation of the intervention may be because it was mainly approached from a sport science background. The process potentially could have benefitted from an additional psychological and/or psychiatric approach.

The pre-existing relationship between interviewer and participant had the advantage of established trust and rapport. The disadvantage was that participants may have held back negative statements and criticism. The advantage of some of the interviews being conducted digitally, especially in people with or recovering from depression, was ease of accessibility for participants who felt more comfortable at home. The disadvantage is that some non-verbal cues may get lost or sounds can be misheard or misinterpreted (Edwards & Holland, 2020).

The methodology applied in the embedded qualitative study allows an insight in to the dynamic experience patterns of the interviewed participants. There may be additional and more varying experiences to be discovered upon investigating experiences of other people receiving the intervention. Thus, the presented evidence applies to those who participated in this study at this time and is not quantifiable or generalizable.

No inference can be made from the quantitative data presented based on the sample size and design of this qualitative study. However, it can be hypothesized that depression severity and somatic diagnoses may explain some of the difference in experiences this population. This could be investigated in further research.

5. Conclusion

This study shows that participants with MDD who took part in the same physical activity counseling intervention experienced it in four distinguishable ways, which were noticeably linked with their level of self-management. Identifying these experience patterns is promising, because it could lead to refining the intervention to improve effectiveness for individuals. The refinement could involve assessing and tailoring to self-management and illness experience as well as adjusting the underpinning theory and delivery mode of the intervention. This in turn may require systematic changes to establish more integrative

models of care. Further investigation is required to validate these suggested experience patterns. However, these findings do contribute towards increased equity for people with psychiatric illness receiving adequate and suitable health-enhancing physical activity promotion.

Ethics

The PACINPAT trial including this qualitative study have been approved by the "Ethikkommission Nordwest-und Zentralschweiz" (EKNZ, project number 2018-00976). The PACINPAT trial has also been registered in the ISRCTN registry (ISRCTN10469580). Before participation in the trial as well as the nested study, participants were informed about the respective goals, about their right to withdraw from the study at any time without negative consequences and signed an informed consent form.

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Author's contributions

MG and OF contributed to the design of the RCT. MG serves as principal investigator of the RCT. DN and RC designed the qualitative study. RC and JNK recruited participants for the RTC. RC and MC recruited participants and collected data for the qualitative study. RC and MC transcribed the interviews. RC, MC and DN analyzed the data. RC wrote the first draft and all authors contributed to manuscript revision, read and approved the submitted version.

Consent for publication

The consent for publication was given when participants signed the informed consent form for participation.

Availability of data and materials

Dataset can be made available upon request.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.mhpa.2022.100464.

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Chapter 7 Publication 5

Depression severity and psychosocial determinants of physical activity behavior in in-patients with major depressive disorders

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Depression severity and psychosocial determinants of physical activity behavior in in-patients with major depressive disorders

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ABSTRACT

Background: Physical inactivity is a world-wide health issue. In people with major depressive disorders approximately 68% do not reach the recommended physical activity levels. Psychosocial determinants of and implicit attitudes towards physical activity serve to explain physical activity behavior and may form the basis of interventions to promote physical activity. The aim of this study was to examine, whether psychosocial determinants and implicit attitudes towards physical activity vary according to depression severity.

Methods: Physically inactive, adult in-patients diagnosed with major depressive disorder (according to ICD-10) were recruited from four Swiss psychiatric clinics. Psychosocial determinants of physical activity were assessed with seven questionnaires pertaining to motivational and volitional aspects of physical activity. Implicit attitudes towards physical activity were measured with a computer-based Single Target Implicit Association Test.

Results: In-patients ($N = 215$, $M_{age} = 41 \pm 13$ years, 53% female) with major depressive disorder reporting more severe ($n = 52$) depression symptomology exhibited less favorable psychosocial determinants for physical activity behavior (self-efficacy, negative outcome expectancies, intention, intrinsic motivation, introjected motivation, external motivation, action planning, perceived barriers, coping planning) compared to those with mild ($n = 89$) and moderate ($n = 74$) depression symptomology. Positive outcome expectancies, identified, social support and implicit attitudes towards physical activity did not vary according to depression severity.

Conclusions: Psychosocial determinants of physical activity do vary according to depression severity. Attempts to promote physical activity among people with major depressive disorder should take depression severity into account when developing and delivering interventions.

Trial registration: ISRCTN registry, ISRCTN10469580, registered on 3rd September 2018, https://www.isrctn.com/ISRCTN10469580.

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1. Background

Physical inactivity is a world-wide issue with approximately one third of the adult population not meeting physical activity guidelines (Guthold, Stevens, Riley, & Bull, 2018) and so at increased risk of non-communicable diseases (Lee et al., 2012). People with major depressive disorders (MDD) in particular, tend to be less physically active compared to people without such a diagnosis. According to meta-analytic data, people with MDD spend less time being physically active in total (standard mean difference [*SMD*] = −0.25, 95% confidence interval [*CI*] = −0.03 to 0.15), at moderate to vigorous intensities (*SMD* = −0.30, 95% *CI* = −0.40 to 0.21) and spend more time being sedentary (*SMD* = 0.09, 95% *CI* = 0.01 to 0.18) (Schuch et al., 2017). This is supported by further meta-analytic data, confirming that people with severe mental illness, including MDD, spend significantly more time being sedentary compared to age- and gender-matched healthy controls (*SMD* = 0.1, 95% *CI* = 0.0 to 0.2) (Vancampfort et al., 2017). The relationship between MDD and physical activity seems to be bidirectional as low levels of physical activity are associated with higher odds of developing depressive disorder (adjusted odds ratio = 0.83, 95% *CI* = 0.79 to 0.88) compared to high levels of physical activity (Schuch et al., 2018). Furthermore, low and moderate levels of physical activity are associated with more severe depression (negative correlation between moderate-to-vigorous physical activity and depression score: $r = -0.47$, $p < 0.01$) (Görgülü et al., 2021).

Beyond health status, other individual factors such as age, sex, self-efficacy and motivation have shown to be associated with physical activity behavior and may thus provide more insight into reasons why some people are physically active and others are not (Bauman et al., 2012). Motivational theories in exercise psychology suggest that self-efficacy, intrinsic motivation, intentions, planning and outcome expectancies are positively associated with physical activity behavior at varying degrees of psychological processing (Biddle & Fuchs, 2009; Rhodes, McEwan, & Rebar, 2019). One such theory is the Motivation-Volition Process Model which states that the motivational aspects of high self-efficacy and positive outcome expectancies lead to a strong and self-concordant goal intention with regard to the desired behavior (Fuchs, Goehner, & Seelig, 2011). In this model, self-concordant goals are to be understood in terms of the level of self-determination and thus the regulation of motivation on the continuum ranging from non-self-determined amotivation to external motivation to self-determined intrinsic motivation (Ryan & Deci, 2000; Sheldon & Houser-Marko, 2001). In addition to these motivational aspects, volitional skills are said to bridge the gap between motivation and behavior. That is to say, the goal intention may lead to an implementation intention and action initiation requiring action planning, which must be shielded from internal and external situational cues in form of coping planning. These processes then are said to lead to a behavioral episode. If the outcome thereof is experienced as positive, this will strengthen positive outcome expectancies and lead to the repetition of the behavioral episode, eventually leading to behavioral maintenance (Fuchs, Goehner, & Seelig, 2011).

More recently, motivational theories relying on explicit cognitive appraisals have been questioned as the sole source of explaining behavior and dual process models have been introduced (Ekkekakis & Zenko, 2016; Rhodes et al., 2019). So, for example the affective-reflective theory (ART) of physical inactivity states that a physical activity stimulus is processed according to a cognitive appraisal, including motivational considerations, as well as an affective response, including an automatic valuation of the situation. Both processes together decide the outcome. If they are congruent in favor of a behavior, the behavior is likely to be enacted. If, however they are incongruent and self-regulatory resources are low, it is assumed that automatic responses may prevail (Brand & Ekkekakis, 2018). Along these lines, research on explicit and implicit motivation (comparable to reflective and affective responses) for physical activity has shown that increases in both areas were associated with increased physical activity behavior (Chevance, Héraud, Varray, & Boiché, 2017; Rebar et al., 2015).

Further determinants of physical activity are social and physical environments (Bauman et al., 2012). According to a systematic review, positive associations were found between physical activity-related social support and physical activity behavior, especially when provided by family members in older adults (Lindsay Smith, Banting, Eime, O'Sullivan, & van Uffelen, 2017). A further systematic review suggests that social influence was among the most important motivators for physical activity for older and middle-aged adults (Spiteri et al., 2019).

To date, little is known about the influence of depression severity on these determinants of physical activity in in-patients with MDD. This is of importance because the time during in-patient treatment lends itself to addressing physical activity behavior change, which may reduce symptoms of depression and enhance well-being. To address insufficient physical activity adequately, knowledge with regard to physical activity determinants which may form the basis of a physical activity intervention are necessary. Therefore, the purpose of this study was to examine whether psychosocial determinants of physical activity (self-efficacy, outcome expectations, intention, motivation, action and coping planning, perceived barriers and social support) and implicit attitudes towards physical activity differ between in-patients with mild, moderate and severe symptom severity.

The hypothesis was that in-patients with severe symptom severity would score significantly lower on motivational aspects of physical activity, i.e. lower self-efficacy, higher negative outcome expectancies with regard to physical activity, weaker intention to engage in more physical activity in the forthcoming weeks, less favorable motivational regulation (lower intrinsic motivation and higher extrinsic motivation). This is derived from evidence suggesting that psychological processing may be disturbed in MDD (Hagiwara, Iwatsuki, Isogai, Van Raalte, & Brewer, 2017) and that with increasing symptom severity, these disturbances become more severe (American Psychiatric Association, 2013). So, for example, dysfunctional cognitions in MDD lead to negative thoughts, attitudes and beliefs towards the self, the world and the future (Gotlib & Joormann, 2010). Based on this enhanced negativity, it may be hypothesized that self-efficacy and outcome expectancies may be affected. Furthermore, learned helplessness, which is one of the hypothesized etiological determinants of MDD, posits that people with MDD do not expect their actions to improve the outcome (Miller & Seligman, 1975; Song & Vilares, 2021), which may further reinforce negative outcome expectations. According to the Motivation-Volition Process Model, deficits in these areas may lead to reduced intention (Fuchs, Goehner, & Seelig, 2011). Furthermore, it is known that lack of motivation is one of the most cited reasons that people with mental illness do not engage in physical activity (Firth et al., 2016).

A further hypothesis was that in-patients with severe symptom severity would score significantly lower on volitional aspects of physical activity, i.e. lower levels of physical activity action and coping planning and more perceived barriers to physical activity. This is based on evidence suggesting that people with MDD exhibit deficits in executive functions (Rock, Roiser, Riedel, & Blackwell, 2014), which also increase according to depression severity (American Psychiatric Association, 2013). This in turn may lead to reduced self-regulation including lack of planning and barrier management with regard to physical activity behavior (Krämer, Helmes, & Bengel, 2014).

In contrast, no differences in positive outcome expectancies with regard to physical activity and social support were expected in in-patients with severe symptoms. This is based on evidence that positive outcome expectancies have not differed in previous research when comparing the physical activity behavior of people with MDD to those without (Krämer, Helmes, Seelig, Fuchs, & Bengel, 2014). Furthermore, neurobiological research has shown that responsiveness to positive reinforcement is significantly reduced in people with compared to without MDD (Pizzagalli, Iosifescu, Hallett, Ratner, & Fava, 2008).

Hence, it can be hypothesized that irrespective of MDD severity, positive outcome expectancies may remain unchanged. Evidence does suggest that MDD is associated with loneliness, social isolation (Matthews et al., 2016) and small social networks (Domènech-Abella et al., 2017), which may be an additional explanation for reduced physical activity behavior in this population (Babiss & Gangwisch, 2009). Furthermore, lack of social support has been known as a predictor of depression symptoms, yet there seems to be little known about the correlation between physical activity-related social support and MDD severity (Miller et al., 2019). Additionally, during and after in-patient treatment a certain level of social support is provided for in terms of psychotherapy and home visits (Gowda, Gajera, Srinivasa, & Ameen, 2019; Holsboer-Trachsler, Beck, Brand, Hemmeter, & Keck, 2016). Hence, it could be hypothesized that in this setting, social support may not vary.

Lastly, given the scarce evidence in psychiatric populations (Gerber et al., 2018), no clear hypothesis was made regarding the relationship between implicit attitudes towards physical activity and depression severity.

2. Methods

2.1. Study design

In the present article, we present baseline data from "Physical Activity Counseling in In-Patients with Major Depressive Disorders" (PACINPAT) trial. In this multi-centric two-arm randomized trial, participants are assigned to an intervention group (receiving individually tailored physical activity counseling every second week for 12 months) or a placebo control group (receiving general information about the health-related benefits of physical activity during in-patient treatment). More detailed information about the PACINPAT trial has been published previously (Gerber et al., 2019). The PACINPAT intervention trial is currently ongoing (recruitment finalized in October 2021; last data assessment planned for November 2022), and findings on the effects of the intervention on physical activity determinants, physical activity, physical fitness, depressive symptom severity and cardiovascular health risk markers will be presented in future publications.

2.2. Participants and procedures

Patients were recruited from four Swiss psychiatric clinics (two public, two private) in the Northwestern, German-speaking part of Switzerland. Clinical in-patients were recruited continuously between January 2019 and October 2021. Based on an a-priori power calculation, the targeted sample size for the randomized controlled trial was 334 in-patients. Because of COVID-19-related challenges, the study was delayed and recruitment had to be finalized after recruiting 244 patients. For the purpose of the present study, data from 215 patients who presented with valid data for depression severity (assessed with the Beck Depression Inventory-II) were used. A post-hoc power analysis showed that the achieved sample size is sufficient to detect weak-to-moderate effects ($f = 0.21$) in univariate analyses of variance (α-error: 0.05, power: 0.80, three groups, one covariate).

All in-patients underwent a clinical interview with a psychiatrist to confirm the following inclusion criteria: men and women; 18–65 years of age; presence of MDD based on the 10th version of the International Classification of Disease (ICD-10) diagnosis for a single episode (F32), recurrent MDD (F33) or bipolar disorder type II (F31-II); currently not meeting the American College of Sports Medicine's (ACSM) physical activity recommendation, assessed with the International Physical Activity Questionnaire (IPAQ <150 min/week of moderate-to-vigorous physical activity); written informed consent; and the ability to speak and read German. In-patients were excluded if they had a history of bipolar disorder type I (F31 type 1); history of schizophrenia or schizoaffective disorder; current active alcohol or drug abuse/dependence; any significant medical condition that contra-indicated safe participation in physical activity; active suicidal intent; evidence of significant cardiovascular, neuromuscular, or endocrine disorders limiting regular physical activity as per ACSM absolute contra-indications to exercise or medical contra-indications to physical activity by the Physical Activity Readiness Questionnaire (PAR-Q) (Thomas, Reading, & Shephard, 1992); and inability to speak and read German.

Screening was performed in the first week after admission to in-patient treatment. Baseline data-assessment was carried out 2–3 weeks after admission to in-patient treatment. After baseline data assessment, in-patients were then assigned to either the intervention or placebo control group. All procedures were in accordance with the ethical principles described in the Declaration of Helsinki. Ethical approval was obtained from the Ethikkommission Nordwest-und Zentralschweiz (EKNZ; ref. approval no. 2018–00976) and from local ethical research boards from all study sites. The intervention trial was registered in the ISRCTN registry (trial number ISRCTN10469580). Informed consent was collected from all participants before study entry. Participants were informed that the general goal of the project was to compare two different methods to increase lifestyle physical activity among psychiatric in-patients. They were also informed that participation in the study was voluntary and withdrawing or discontinuing was possible at any time without further obligation or potential disadvantages.

2.3. Measures

2.3.1. Major depressive disorder; self-rating

Depression severity was assessed with the Beck Depression Inventory-II (BDI-II) (Beck, Sheer, & Brown, 1996). The BDI-II consists of 21-items and is a frequently used instrument (Beck, Steer, & Carbin, 1988) to assess symptoms of unipolar depression such as affective, behavioral, cognitive, and somatic symptoms (e.g. "I am so unhappy/sad that I can't stand it"). There are four response options for each item (from 0 to 3) reflecting increasing levels of depressive symptomatology. The BDI-II total score ranges from 0 to 63, with higher scores reflecting stronger depressive symptoms. The reliability and validity of the BDI-II have been established previously (Richter, Werner, Heerlein, Kraus, & Sauer, 1998). In the present study, three groups of patients with mild depression (BDI-II = 0–19), moderate depression (BDI-II = 20–28) and severe depression (BDI-II = 29–63) were compared, representing recognized depression severity categories (Beck et al., 1996).

2.3.2. Psychosocial determinants of physical activity

An overview of the applied instruments is given in Table 1. All measures have been used in prior research, and evidence for the validity and reliability of these measures have been published previously as can be ascertained in the published study protocol (Gerber et al., 2019).

For all instruments, an increase in the score indicates an increase in the corresponding concept, e.g., an individual reporting a self-efficacy score of 1 (close to feeling not at all confident) considers themselves to be less self-efficacious than if they reported a score of 5 (feeling 100% confident). It may be said that there is no precise interpretation of single scores but the differences between respondents is of interest (Fuchs & Schwarzer, 1994). To date there are no known minimally important clinical differences (MCID) for the applied questionnaires (Gerber et al., 2019).

2.3.3. Implicit attitude towards physical activity

Implicit attitudes to physical activity were assessed with a computer-based Single Target-Implicit Association Test (ST-IAT), which is a response-time test including a target concept (physical activity), target categories (good and bad) and visual stimuli (people exercising and both smiling and frowning emoticons) (Greenwald, McGhee, & Schwartz, 1998; Greenwald, Nosek, & Banaji, 2003). Participants were asked to assign the visual stimuli to one of the target categories. This was repeated in two blocks with 32 trials, both preceded by 16 practice trials. The order of the categories was counterbalanced among the

Table 1
Measures.

Measure	Initial description	Examination of psychometric properties	Exemplary item	Scaling
Exercise-related self-efficacy	Fuchs (2008)	(Fuchs, Göhner, & Seelig, 2011; Fuchs, Göhner, & Seelig, 2011)	I feel confident to start with a new exercise activity.	0 (not at all confident) to 5 (100% confident)
Exercise-related outcome expectancies				
Positive outcome expectancies	Fuchs (1997)	(Fuchs, 1997; Gerber, Fuchs, & Pühse, 2010)	I can improve my physical appearance if I exercise regularly.	1 (not true) to 4 (completely true)
Negative outcome expectancies	Fuchs (1997)	(Fuchs, 1997; Gerber et al., 2010)	If I exercise, I end up in situations where I feel embarrassed.	1 (not true) to 4 (completely true)
Exercise intention in forthcoming weeks	Fuchs (2008)	(Gerber, Mallett, & Pühse, 2011; Seelig & Fuchs, 2006)	Strength of my intention to exercise regularly during the next few weeks and months.	0 (no intention) to 5 (very strong intention)
Exercise-related self-concordance				
Intrinsic motivation regulation	Seelig and Fuchs (2006)	(Coimbra, Cody, Kreppke, & Gerber, 2021; Schnider, Schilling, Cody, Kreppke, & Gerber, 2021)	I (would) exercise because it is just fun for me.	1 (not at all true) to 6 (completely true)
Identified motivation regulation	Seelig and Fuchs (2006)	(Coimbra et al., 2021; Schnider et al., 2021)	I (would) exercise because I have good reasons to be physically active.	1 (not at all true) to 6 (completely true)
Introjected motivation regulation	Seelig and Fuchs (2006)	(Coimbra et al., 2021; Schnider et al., 2021)	I (would) exercise because otherwise I would have a guilty conscience.	1 (not at all true) to 6 (completely true)
External motivation regulation	Seelig and Fuchs (2006)	(Coimbra et al., 2021; Schnider et al., 2021)	I (would) exercise because others tell me to become physically active.	1 (not at all true) to 6 (completely true)
Exercise-related action planning	Sniehotta, Schwarzer, Scholz, and Schüz (2005)	(Coimbra et al., 2021; Fischer, Donath, Zahner, Faude, & Gerber, 2020)	I know already when I will do this particular exercise activity.	1 (not at all true) to 4 (completely true)
Perceived exercise barriers	Krämer and Fuchs (2010)	Krämer, Helmes, Seelig, et al. (2014)	I have too much work to do.	1 (almost never) to 4 (almost always)
Exercise-related coping planning	Sniehotta et al. (2005)	(Coimbra et al., 2021; Fischer et al., 2020)	I have made a detailed plan regarding what to do in difficult situation in order to act according to my intentions.	1 (not at all true) to 4 (completely true)
Exercise-related social support	Fuchs (1997)	Gerber et al. (2010)	Close family or friends help me plan my exercise.	1 (almost never) to 4 (almost always)

participants. A D-score was calculated by dividing the ST-IAT raw scores (reaction time difference between the two categories) by the within-subject standard deviation of reaction times. This score can be interpreted as follows: 0.15 = slight, 0.35 = moderate, 0.64 = strong preference (for positive values) or aversion (for negative values) (Blanton, Jaccard, & Burrows, 2015). E-prime 3.0 (PST, USA) software and images obtained from Adobe Stock were used. Reliability and discriminant validity of the ST-IAT have been established (Antoniewicz & Brand, 2016; Blanton et al., 2015; Bluemke & Friese, 2008; Greenwald et al., 2003).

2.4. Statistical analyses

Data screening was carried out, including checks for implausible answers as well as univariate outliers (defined as scores of 3.5 standard deviations [*SD*] below/above mean [*M*]) (Tabachnick & Fidell, 2013). Descriptive statistics are presented as *M*, *SD*, *n* and %. Differences between groups with mild, moderate and severe depression severity were analysed via χ^2-tests, and one-way (uni- and multivariate) analyses of variance ([M]ANOVAs). Bonferroni post-hoc tests were used to examine which of the three groups differed from each other. All analyses were carried out with SPSS version 27 (IBM Corp., Armonk NY, USA). The level of statistical significance was set at $p < 0.05$ across all analyses. Eta-square (η^2) values were considered to interpret the strength of the differences. Following Cohen (1988), the following cut-offs were used: Small (0.010 to < 0.060), medium (0.060–0.139), large (≥0.140).

3. Results

3.1. Sample description

In total, 215 patients presented with valid data for depression severity. The mean age of the sample was 40.87 ± 12.66 years, with 52.6% being female ($n = 113$). The mean BDI-II score upon entry to inpatient treatment was 29.45 ± 8.84 (range: 17–56), whereas at baseline it was 22.20 ± 10.27 (range 2–50). With regard to depression severity, 41.4% ($n = 89$) were classified as having mild depression, 34.4% ($n = 74$) presented with moderate depression, and 24.2% ($n = 52$) fell into the category of severe depression. Further details about the sample characteristics are provided in Table 2. Table S1 and S2 (supplementary online material) show additional information with regard to the primary diagnoses of the participants, other diagnosed mental disorders, presence of somatic disorders, antidepressant medication and other medication. As shown in Supplement 1, most of the participants were diagnosed with either recurrent depression with a current moderate episode (F33.1) (40.9%, $n = 88$), recurrent depression with current severe episode (F33.2) (21.9%, $n = 47$), a moderate depressive episode (F32.1) (21.4%, $n = 46$), or a severe depressive episode (F32.2) (13.5%, $n = 29$). As shown in Supplement 2, the most frequently used antidepressant medication was Trazadone (24%, $n = 52$), followed by Escitalopram (19%, $n = 41$), and Vortioxetine (17%, $n = 36$). Table S2 also shows that a considerable percentage of the participants took antipsychotic medication (27%, $n = 58$). Furthermore, bivariate correlations between psychosocial determinants of physical activity and implicit attitudes towards physical activity can be seen in Supplement 3.

3.2. Descriptive findings

Table 3 displays the descriptive findings of the main study variables. None of the variables showed severe violations of normality (defined as skewness >2 and/or kurtosis >7) (West, Finch, & Curran, 1995). With regard to internal consistency, with two exceptions (identified and introjected motivation regulation), all scales had acceptable Cronbach's alpha scores of ≥0.70 (Nunnally & Bernstein, 1994).

3.3. Between-group differences

Patients with mild, moderate and severe depression did not significantly differ in any of the social and demographic background variables.

With regard to psychosocial determinants of physical activity (Table 4), the MANOVA pointed towards a significant main effect of depression severity, Wilks-Lambda: $F(24,402) = 2.51$, $p < 0.001$, $\eta^2 = 0.125$. Univariate ANOVAs followed by Bonferroni post-hoc tests showed that compared to patients with mild depression, those with

Table 2
Sample characteristics and group differences.

	Total sample			Mild (n = 89)		Moderate (n = 74)		Severe (n = 52)			
	N	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*F*	η^2
Age (years)	215	40.87	12.66	42.70	13.01	39.92	13.03	39.08	11.28	1.67	.015
Height (cm)	215	171.48	9.61	171.70	9.84	172.18	9.04	170.11	10.03	0.75	.007
Weight (kg)	215	80.33	21.24	79.42	18.68	79.56	20.10	82.99	26.51	0.54	.005
Body Mass Index (BMI; kg/m^2)[a]	214	27.07	6.12	26.87	5.81	26.73	6.21	27.90	6.53	0.63	.006
Years of education[b]	213	14.39	3.34	14.75	3.65	13.93	2.98	14.45	3.25	1.21	.011
Years of professional experience	215	18.10	12.52	19.86	12.67	17.51	13.51	15.93	10.45	1.75	.016
Number of previous depressive episodes[c]	199	3.07	5.97	2.90	6.29	3.17	6.39	3.11	4.84	0.06	.001
Age (years) at first depressive episode[d]	200	29.71	14.18	31.60	14.37	28.57	14.62	28.08	13.15	1.29	.013
Number of antidepressants at baseline	215	1.31	0.75	1.28	0.75	1.24	0.74	1.44	0.78	1.16	.011
Depression severity (BDI-II) at baseline	215	22.20	10.27	12.64^{A,B}	4.47	23.89^{A,C}	2.51	36.15^{B,C}	6.06	478.87[f]	.819
				Mild (n = 89)		Moderate (n = 74)		Severe (n = 52)			
	N	*%*		*n*	*%*	*n*	*%*	*n*	*%*	χ^2	Φ
Sex											
Female	113	52.6		42	37.2	40	35.4	31	27.4	2.13	.099
Male	102	47.4		47	46.1	34	33.3	21	20.6		
Nationality											
Swiss	178	82.8		77	43.3	61	34.3	40	22.5	2.13	.099
Foreign	37	17.2		12	32.4	13	35.1	12	32.4		
Language											
German	188	87.4		82	43.6	64	34.0	42	22.3	3.96	.134
Foreign	27	12.6		7	25.9	10	37.0	10	37.0		
Civil status											
Single	155	72.1		64	41.3	51	32.9	40	25.8	0.98	.067
Married/in a relationship	60	27.9		25	41.7	23	38.3	12	20.0		
Children living at home											
Yes	52	24.2		25	48.1	16	30.8	11	21.2	1.27	.077
No	163	75.8		64	39.3	58	35.6	41	25.2		
Employment											
Yes	63	29.3		21	33.3	24	38.1	18	28.6	2.46	.106
No	152	70.7		68	44.7	50	32.9	34	22.4		
Income[e]											
<50′000 CHF/year	82	44.6		29	35.4	32	39.0	21	25.6	4.86	.160
50′000 to 100′000 CHF/year	62	33.7		30	48.4	21	33.9	11	17.7		
>100′000 CHF/year	40	21.7		21	52.5	10	25.0	9	22.5		
Smoking status											
Smoking	86	40.0		41	47.7	24	27.9	21	24.4	3.16	.120
Non-smoking	129	60.0		48	37.2	50	38.8	31	24.0		

Capital superscript letters above the mean (M) indicate which of the three groups differed from each other based on Bonferroni post-hoc tests. Means (M) with the same letters are significantly different at $p < 0.05$.
Notes:
[a] 1 participant with missing values
[b] 2 participants with missing values
[c] 16 participants with missing values
[d] 15 participants with missing values
[e] 31 participants with missing values.
[f] $p < 0.001$.

severe depression had significantly lower scores for physical activity-related self-efficacy, intention, intrinsic motivation, action planning, and coping planning. In turn, they reported higher negative outcome expectancies and had higher scores for introjected and external motivation. They also perceived more barriers for regular physical activity. No statistically significant differences were observed for positive outcome expectancies, identified motivation regulation and social support. A univariate ANOVA further revealed that no between-group differences occurred for implicit attitudes towards physical activity.

4. Discussion

4.1. Key findings

The results of this study showed that in-patients with MDD taking part in a randomized controlled trial to increase physical activity, reporting more severe depression symptomology, exhibited less favorable psychosocial determinants for physical activity behavior, except in the areas of positive outcome expectancies, identified motivation and social support. Implicit attitudes towards physical activity did not vary according to depression severity and were overall slightly positive in this population.

The present findings are important for the forthcoming analyses of the intervention effects, as we identify depression severity as a potential moderator.

The hypotheses that in-patients with severe symptom severity would report significantly lower physical activity-related self-efficacy, higher negative outcome expectancies with regard to physical activity, weaker intention to engage in more physical activity in the forthcoming weeks, less favorable motivation in terms of external regulation, lower levels of physical activity action and coping planning and more perceived barriers to physical activity, compared to those with mild and moderate symptom severity could be confirmed. These findings may be likely to have occurred because of the inherent difficulties in MDD. With increasing symptom severity, emotional symptoms such as depressed mood, negativity and feelings of worthlessness as well as neurocognitive symptoms such as the ability to think or concentrate and make decisions become more severe and result in a cumulative functional impairment

Table 3
Descriptive statistics and psychometric properties of the main study variables.

Psychosocial determinants of physical activity	*N*	*M*	*SD*	Range	Skew/ Kurt	α (items)
Self-efficacy	215	3.53	1.00	0.00–5.00	−0.55/ 0.14	.80 (3)
Outcome expectancies						
Positive outcome expectancies	215	3.18	0.43	1.33–4.00	−0.35/ 0.77	.79 (9)
Negative outcome expectancies	215	2.01	0.50	1.00–3.57	0.33/-0.13	.70 (7)
Intention[a]	214	3.75	1.05	0.00–5.00	−0.88/ 0.69	— (1)
Self-concordance						
Intrinsic motivation regulation[a]	214	3.77	1.04	1.00–6.00	−0.32/-0.32	.71 (3)
Identified motivation regulation[a]	214	4.80	0.71	3.00–6.00	−0.44/-0.29	.54 (3)
Introjected motivation regulation[a]	214	3.52	1.02	1.00–6.00	−0.09/-0.18	.68 (3)
External motivation regulation[a]	214	2.16	0.97	1.00–5.33	0.72/-0.06	.74 (3)
Action planning	215	2.62	0.69	1.00–4.00	−0.47/-0.03	.84 (5)
Perceived barriers	215	2.14	0.45	1.00–3.68	0.35/-0.18	.83 (19)
Coping planning	215	2.15	0.66	1.00–3.60	0.03/-0.63	.85 (5)
Social support	215	2.45	0.70	1.00–4.00	0.24/-0.39	.87 (7)
Implicit attitudes towards physical activity						
D-score[b]	210	0.18	0.43	−1.28–1.39	0.04/ 0.31	–

Notes:
[a] 1 participant with missing values
[b] 5 participants with missing values.

(American Psychiatric Association, 2013). The negativity in general and towards the self in particular may explain both the low self-efficacy, negative outcome expectancies and higher levels of perceived barriers. The decreased ability to think and concentrate may contribute to lower levels of planning. Additionally, it is well-established according to social-cognitive theory, that reduced self-efficacy and negative outcome expectancies lead to reduced intention (Ajzen, 2002; Bandura, 2000), which is also in line with the Motivation Volition Process Model (Fuchs, Goehner, & Seelig, 2011).

Furthermore, the hypotheses that no significant differences would be found in positive outcome expectancies with regard to physical activity and social support according to depression severity were also confirmed. It can be said that the hypothesis pertaining to social support may be accurate because of the setting. All social support scores were an average of two out of four, which may be consistent with what is expected in in-patient treatment where support is provided from professionals and peers (Cody et al., 2022).

Unexpectedly, not all motivational regulation forms differed according to depression severity. Less favorable motivational regulation was indeed found among those with more severe symptoms (less intrinsic regulation, more introjected and external regulation), however interestingly, no differences were found in identified motivation. According to the self-determination continuum, motivation and the regulation thereof ranges from amotivation without any regulation, through extrinsic motivation regulated by external, introjected and identified forces, to intrinsic motivation regulated by intrinsic forces. Along this continuum the level of self-determination increases (Ryan & Deci, 2002). External regulation is characterized by solely external impulses, introjected by the avoidance of negative outcomes, identified by beliefs and personal values, intrinsic by the goal/activity itself (Seelig & Fuchs, 2006). It has been established that higher levels of depression are associated with avoidant motivations (part of extrinsic motivation) and lower levels of goal self-concordance (Vorontsova & Ellett, 2017) in general as well as external and introjected motivation in particular (Scarapicchia et al., 2014). In this sample, it could be assumed that the participants, irrespective of depression severity, held physical activity as a value and believed they all had good reasons to become more physically active. Hence, their willingness to take part in a physical activity promotion program.

While participants with more severe depression symptoms reported higher negative outcome expectancies, positive outcome expectancies did not differ, as hypothesized. However, a trend towards less positive outcome expectancies in people with severe symptomology was recognized. Outcome expectancies are particularly powerful, not only as determinants for behavior, but also in therapeutic effects, as exemplified by evidence suggesting higher expectancies of a positive therapeutic effect is associated with greater improvement in psychiatric symptoms (Rutherford, Wager, & Roose, 2010). It is known that depressive symptoms and negative mood are associated with reduced ability to process positive information or learn from positive experiences (Kube & Glombiewski, 2021). This lack of positive outcome expectancies in turn may be predictive of future depression (Horwitz, Berona, Czyz, Yeguez, & King, 2017). Hence, it may be assumed that with less severe depressive symptoms increased positive expectations may be possible, in keeping with the trend recognized in this study. Along these lines, influencing outcome expectancies is a therapeutic method for MDD (Kube, Rief, & Glombiewski, 2017; Seligman, 2006). For example, future-directed therapy (FDT), during which a focus is laid on creating positive expectancies about the future, achieved significantly improved depression symptoms compared to cognitive-based therapy (Vilhauer et al., 2012).

No clear hypothesis was stated regarding the implicit attitudes towards physical activity based on scant evidence to date. In this study, implicit attitudes towards physical activity did not seem to vary according to depressive symptom severity. All groups (mild, moderate and severe depression) showed slightly positive attitudes towards physical activity. This too could be explained by the characteristics of the sample. It can be assumed that all participants entering the trial had a fundamental interest and preference for physical activity. This, however, is not reflected in all areas of explicit attitudes, as described above. The opposite was found in a study comparing implicit and explicit attitudes towards physical activity in healthy participants, in which relatively negative automatic valuations of physical activity and more positive reflective evaluations explained the discrepancy in ideal frequency of physical activity versus actual frequency of physical activity (Brand & Antoniewicz, 2016). According to evidence on the discrepancy between implicit and explicit attitudes towards physical activity in healthy populations, such a mismatch may have a negative effect on actual physical activity behavior (Muschalik, Elfeddali, Candel, Crutzen, & de Vries, 2019). Hence, in the PACINPAT population, there may be a need to address explicit attitudes so as to align them with the more positive implicit ones. However, even with regard to the implicit attitudes, they could also conceivably increase. In a behavioral intervention to increase physical activity for people in pulmonary rehabilitation, results showed that implicit attitudes toward physical activity became more positive and were associated with increases in actual physical activity (Chevance et al., 2017). Hence, it will be interesting to see in the PACINPAT trial if the behavioral intervention can achieve such results.

4.2. Strengths and limitations

The strength of this study is that it delivers information on both

Table 4
Group differences in main study variables.

Psychosocial determinants of physical activity	Mild (n = 89)		Moderate (n = 74)		Severe (n = 52)			
	M	*SD*	*M*	*SD*	*M*	*SD*	*F*	η^2
Self-efficacy	3.82^{A}	0.90	3.55^{B}	0.95	$3.03^{A,B}$	1.03	11.27[c]	.096
Outcome expectancies								
Positive outcome expectancies	3.19	0.41	3.20	0.45	3.15	0.46	0.31	.002
Negative outcome expectancies	1.87^{A}	.048	2.05	0.44	2.18^{A}	0.54	7.39[c]	.065
Intention[a]	3.99^{A}	0.94	3.64	1.09	3.48^{A}	1.11	4.54[c]	.041
Self-concordance								
Intrinsic motivation regulation[a]	3.99^{A}	1.07	3.65	0.97	3.56^{A}	1.05	3.50[d]	.032
Identified motivation regulation[a]	4.91	0.67	4.74	0.74	4.70	0.71	1.93	.018
Introjected motivation regulation[a]	$3.27^{A,B}$	1.04	3.67^{A}	0.94	3.72^{B}	1.04	4.61[d]	.042
External motivation regulation[a]	$1.88^{A,B}$	0.84	2.27^{A}	1.03	2.49^{B}	0.96	7.77[c]	.069
Action planning	2.75^{A}	0.70	2.61	0.61	2.44^{A}	0.76	3.47[d]	.032
Perceived barriers	2.00^{A}	0.47	2.14^{B}	0.39	$2.38^{A,B}$	0.37	13.70[c]	.114
Coping planning	2.22^{A}	0.67	2.19	0.59	1.95^{A}	0.70	3.05[d]	.028
Social support	2.49	0.67	2.39	0.67	2.46	0.79	0.41	.004
Implicit attitudes towards physical activity								
D-score[b]	0.17	0.41	0.15	0.46	0.22	0.44	0.37	.004

Capital superscript letters above the mean (M) indicate which of the three groups differed from each other based on Bonferroni post-hoc tests. Means (M) with same letters are significantly different at $p < 0.05$.
**$p < 0.01$
Notes:
[a] 1 participant with missing values
[b] 5 participants with missing values.
[c] $p < 0.001$
[d] $p < 0.05$.

explicit and implicit determinants of physical activity behavior in relation to depression severity. Explicit determinants were ascertained with reliable and validated questionnaires and implicit attitudes with a ST-IAT, specifically designed for this population (Gerber et al., 2019). One limitation of this study is that at the time of data collection, the participants had been in the clinic for varying durations and received varying treatments. Therefore, people in the mild depression severity group may have received more effective treatment or treatment over a longer period of time, which in turn may have influenced their psychosocial determinants. Additionally, this study is based on cross-sectional data and so the direction of the associations between depression severity and physical activity determinants cannot definitively be determined. Finally, this population may be positively biased towards physical activity because they decided to take part in a physical activity promotion program. Consequently, the ST-IAT scores may not be representative of other clinical or out-patient populations.

4.3. Practical implications

This study suggests that people with more severe depression symptoms exhibit less favorable psychosocial determinants for physical activity compared to those reporting mild and moderate symptoms. Accordingly, it may be assumed that people reporting more severe symptoms may benefit from an intervention targeting self-efficacy; negative outcome expectancies; intention; intrinsic, introjected and external motivational regulation; action and coping planning; as well as perceived barriers differently to those with less severe symptoms.

In the following, aspects derived from theory, which could be considered are presented. To address intention and intrinsic motivation to become more physically active, increasing pleasure during physical activity, has been found to be effective (Ekkekakis, Parfitt, & Petruzzello, 2011) and may be especially pertinent for those with severe depressive symptoms. In turn, increased intention may favorably influence self-efficacy, which has been shown to be correlated in people with MDD (Krämer, Helmes, Seelig, et al., 2014). In terms of outcome expectancies, it is noteworthy that people with MDD are at risk of maintaining negative outcome expectancies despite experiencing positive outcomes, a phenomenon referred to as immunization (Kube et al., 2017). To counteract this, particular emphasis may be put on positive outcomes and conditions may be explored under which the participant will not disregard the experience as a mere coincidence or question its validity (Rief & Joormann, 2019). Along these lines, the concept of graded physical activity may be highlighted, i.e. making small, gradual and consistent steps towards a more physically active lifestyle (Gerber, Jonsdottir, Arvidson, Lindwall, & Lindegård, 2015). This is particularly important to avoid the risk of perceived failure, which in turn could lead to decreases in self-efficacy, increases in negative expectancies, perceived barriers and ultimately to people returning to less physically active lifestyles, thus perpetuating the cycle of learned helplessness (Gerber, Holsboer-Trachsler, Puhse, & Brand, 2016).

In terms of action and coping planning, it is noteworthy to keep in mind that people with MDD may have impairments in executive functioning, which may negatively affect planning skills (Carelli et al., 2018). Hence, more time and individual support may be considered when creating physical activity plans. Potentially with decreasing depressive symptoms, more detailed planning including coping planning may become possible.

In terms of implicit attitudes, it is worthwhile to know that a certain population may already be positively inclined towards physical activity which can be regarded as a strength, to potentially enhance the improvement of explicit attitudes towards physical activity.

5. Conclusions

Psychosocial determinants of physical activity do vary according to depression severity, with people reporting more severe depression symptoms also reporting less favorable psychosocial determinants of physical activity, yet no differences in implicit attitudes towards physical activity, compared with people reporting less severe symptoms. Hence, taking depression severity into account seems particularly meaningful when tailoring behavioral interventions to explicit psychosocial determinants of physical activity. Whereas when targeting

implicit attitudes towards physical activity, depression severity may not need to be taken into account. This could result in the design of interventions with varying parts pertaining to motivational and volitional skills according to reported depression severity and consistent parts to further encourage positive implicit attitudes towards physical activity.

6. Ethical approval and consent to participate

The PACINPAT trial was approved by the "Ethikkommission Nordwest-und Zentralschweiz" (EKNZ, project number 2018–00976). The PACINPAT trial has also been registered in the ISRCTN registry (ISRCTN10469580). Before participation in the trial participants were informed about the goals, their right to withdraw from the study at any time without negative consequences and signed an informed consent form.

7. Consent for publication

Consent for the publication of the collected data was provided in the informed consent signed by the participants.

8. Availability of data and materials

The data and materials will be made available by the authors upon request, without undue reservation.

Author's contributions

JB, MH, CI, UEL, SM, TM, AO and NS supported the patient screening and recruitment processes on the four study sites. RC and JNK recruited the participants and collected the data. SB, LD, AE, OF, EHT, UP and LZ offered thematic support. RC and MG were responsible for conceptualizing the manuscript. MG conducted the statistical analyses. RC wrote the first draft of the manuscript. All listed co-authors read, contributed to and approved the final manuscript.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.psychsport.2022.102294.

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Chapter 8 Publication 6

Short-term outcomes of physical activity counseling in in-patients with Major Depressive Disorder: Results from the PACINPAT randomized controlled trial

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Short-term outcomes of physical activity counseling in in-patients with Major Depressive Disorder: Results from the PACINPAT randomized controlled trial

Robyn Cody[1]*, Johannes Beck[2], Serge Brand[1,3,4,5,6], Lars Donath[7], Oliver Faude[1], Martin Hatzinger[8], Christian Imboden[9], Jan-Niklas Kreppke[1], Undine E. Lang[3], Sebastian Ludyga[1], Sarah Mans[9], Thorsten Mikoteit[8], Anja Oswald[2], Nina Schweinfurth[3], Lukas Zahner[1] and Markus Gerber[1]

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Introduction: A physical activity counseling intervention based on a motivation-volition model was developed and delivered to in-patients with Major Depressive Disorders with the aim of increasing lifestyle physical activity. The aim of this study is to evaluate the short-term outcomes of this intervention.

Methods: A multi-center randomized controlled trial was conducted in four Swiss psychiatric clinics. Adults who were initially insufficiently physically active and were diagnosed with Major Depressive Disorder according to ICD-10 were recruited. The sample consisted of 113 participants in the intervention group (M_{age} = 42 years, 56% women) and 107 in the control group (M_{age} = 40 years, 49% women). Motivation and volition determinants of physical activity were assessed with questionnaires. Implicit attitudes were assessed with an Implicit Association Test. Physical activity was self-reported and measured with hip-worn accelerometers over 7 consecutive days starting on the day following the data collection.

Results: According to accelerometer measures, step count decreased on average 1,323 steps less per day (95% *CI* = −2,215 to −431, $p < 0.01$) over time in the intervention group compared to the control group. A trend was recognized indicating that moderate-to-vigorous physical activity decreased on average 8.37 min less per day (95% *CI* = −16.98 to 0.23, $p < 0.06$) over time in the intervention group compared to the control group. The initial phase of the intervention does not seem to have affected motivational and volitional determinants of and implicit attitudes toward physical activity.

Conclusion: Physical activity counseling may be considered an important factor in the transition from in-patient treatment. Methods to optimize the intervention during this period could be further explored to fulfill the potential of this opportunity.

Clinical trial registration: https://www.isrctn.com/ISRCTN10469580, identifier ISRCTN10469580.

KEYWORDS

physical activity counseling, determinants, attitudes, physical activity, Major Depressive Disorder

1. Introduction

Individuals with Major Depressive Disorder (MDD) tend to be less physically active compared to their counterparts without MDD (1). Major Depressive Disorder is a psychiatric disorder with a global lifetime risk of 15–18%, which affects mood, psychosocial functioning and quality of life (2). According to meta-analytic data, in studies informed by objective measures of physical activity, 86% of people with MDD do not meet the recommended 150 min of moderate-to-vigorous physical activity (MVPA) per week (1). This is problematic because physical activity is known to be a promising treatment for depression (3) seeing as it influences biological and psychological processes associated with MDD such as neuroplasticity, oxidative stress, self-esteem, self-efficacy, and social support (4). Despite the complex processes involved in both the physiology of MDD and physical activity leading to unclear precise working mechanisms, clinical evidence to date clearly points toward the benefits of physical activity in relation to MDD (5). Furthermore, physical activity has a protective effect against non-communicable diseases and cardiovascular mortality, which people with MDD may be more prone to (6). According to the European Psychiatric Association, MVPA is particularly recommended for people with MDD (3). However, evidence also points toward positive effects of increasing step count to the recommended 10,000 a day on mental health parameters including symptoms of depression, anxiety, stress, and wellbeing (7, 8). Furthermore, increasing daily steps is associated with lower risk of all-cause mortality (9). Thus, tackling the issue of physical inactivity in this population seems worthwhile.

Physical activity determinants can go a long way in explaining why people are more or less active (10). Motivational determinants, such as intention, self-efficacy, and outcome expectancies influence physical activity behavior (11–13). Motivational determinants may be affected negatively in people with MDD, as inherent negative self-perception and view of the world and the future may lead to reduced self-efficacy and increased negative outcome expectancies, which in turn may lead to reduced intention to be physically active (14, 15). In addition, volitional aspects, such as action planning and barrier management, are said to bridge the gap between motivation for physical activity and actual physical activity behavior (16, 17). Volitional determinants may be affected negatively in people with MDD given impaired executive function leading to reduced capacity for planning and intention shielding (15). Furthermore, less tangible, implicit attitudes may explain behavior (18). Along these lines, deeply ingrained memories and experiences elicit an immediate affective valuation when deciding whether to be physically active (upon positive valuation) or not (upon negative valuation) (19). In MDD, little is known regarding implicit attitudes toward physical activity (20), however, previous experiences with physical activity may be crucial for the successful uptake of a more physically active lifestyle (21). That is to say, the more positive associations and experiences are linked to a behavior, the more likely the behavior is to be performed in the future (22). Knowing the facilitators of physical activity behavior lends a basis upon which to change behavior (23).

As such, theory-based physical activity interventions often target determinants of physical activity with the premise that accessing underlying mechanism will lead to behavioral changes (24, 25). Physical activity counseling offers the potential to address these determinants (26, 27). Such interventions have traditionally been delivered in-person (28), yet are increasingly offered remotely to address cost and accessibility (29). Telephone counseling interventions are particularly attractive because they allow for a personal relationship and regular contact to promote behavior change (30, 31). Additionally, digital interventions including the use of websites, text messages, games, emails, and social media may result in significant behavior change in the areas of diet and physical activity (32). These remote delivery modes have become particularly meaningful during the COVID-19 pandemic (33). In a theory-based physical activity counseling intervention for healthy insufficiently physically active adults delivered *via* telephone, the intervention group reported higher levels of intention and self-efficacy as well as more positive outcome expectancies after 6 months and increases in action planning and barrier management after 12 months compared to the control group (34). Additionally, according to objective measure, physical activity increased by 32 min per week (95%*CI* = 0.1 to 63) in the intervention group (35). Tailored physical activity counseling has also been implemented in out-patients with MDD. Data pertaining to depression symptoms and self-reported physical activity levels were measured at three time points: four, eight and 12 months after randomization. According to the 12-month follow-up analysis the intervention group reported increases in physical activity compared to the control group (adjusted odds ratio = 2.27, 95% *CI* = 1.32 to 3.89) (36). The corresponding intervention lasted 6 to 8 months and was based on motivational interviewing techniques and behavioral strategies and was delivered in-person as well as *via* telephone (37). Physical activity counseling may also include determining optimal step count and increment of increase taking physical and psychological factors into account (38). This may include the recommendation of monitoring step count with a device or mobile application, as this has proven to aid increases in step

count inherently (39). To date there is scant evidence regarding the effect of physical activity counseling on implicit attitudes toward physical activity. However, generally, the aim of influencing implicit attitudes toward physical activity, i.e., increasing positive attitudes, is to increase positive affect and future engagement in the target behavior (40). When considering physical activity behavior, the type and intensity of physical activity may elicit a variety of affective responses. Evidence shows that self-selected type and intensity of physical activity is likely to evoke positive affect (41). Physical activity counseling inherently emphasizes the recipients' choice and autonomy (27), which in turn may ensure that participants chose their own intensity at which they are most likely to experience positive affect and perform physical activity again in the future (42).

In the "Physical activity counseling in in-patients with Major Depressive Disorders" (PACINPAT) trial, such a theory-based, individually tailored in-person and remote physical activity counseling intervention was delivered with the aim of increasing lifestyle physical activity among people with MDD (43). Thus, the aim of this study was to assess whether the initial phase of the PACINPAT intervention elicited changes in the targeted motivational and volitional determinants of and implicit attitudes toward physical activity as well as the behavioral outcome of MVPA levels and step count.

People receiving the intervention were hypothesized to report increases in intention, motivational regulation (intrinsic, identified, introjected, external), self-efficacy, positive outcome expectancies, action and coping planning, and positive attitudes toward physical activity as well as decreases in negative outcome expectancies and perceived barriers based on the providers of the intervention offering support (external motivation); information on the multiple health-benefits of physical activity (intention, identified and introjected motivation, outcome expectancies, attitudes); and guided planning of preferred physical activity (planning, intrinsic motivation, self-efficacy) as well as intention shielding (planning, intention, barriers). Following the hypothesized favorable changes in physical activity determinants and attitudes, increases in MVPA and step count in the intervention group were hypothesized.

2. Materials and methods

2.1. Study design

The PACINPAT study is a multi-center, two-arm randomized controlled trial conducted in Switzerland as a cooperation between four psychiatric clinics and the University of Basel.

Participants were randomized into either an intervention or control group. The allocation ratio of the randomization was 1 to 1. The method used to generate the random allocation was a permuted block randomization with the strata age, sex, and clinic. To ensure allocation concealment, allocation to groups was done after the baseline assessment took place. The random allocation sequence was computer-based and generated by OF. RC and J-NK enrolled the participants and assigned participants to the groups according to the allocation provided by OF who was not otherwise involved in the intervention. The participants were blinded to their group allocation, however, given the nature of the trial it was not possible to blind the study team or intervention providers.

The reported results are according to CONSORT guidelines and concern the efficacy of the initial phase of intervention based on one of the two underlying theoretical constructs.

The study protocol has been published previously (43).

2.2. Setting and participants

Participants were recruited continuously from four German-speaking Swiss psychiatric clinics between January 2019 and October 2021. Eligibility criteria for participation in the trial were the following: adult in-inpatients (18–65 years) with a diagnosed MDD according to the International Classification of Disease, 10th edition (ICD-10) and a minimum Beck Depression Inventory (BDI) (44) score of 17 upon admission to in-patient treatment who were insufficiently physically active prior to in-patient treatment (<150 min of MVPA per week) and who had sufficient spoken and written German skills. Diagnosis of MDD was performed by senior clinicians at the four study sites. Patients were included if they met diagnostic criteria of moderate-to-severe unipolar depressive episode (first or recurrent) according to ICD-10. People were considered insufficiently physically active (performing less than 150 min of MVPA per week) because this is the equivalent of not meeting the recommendations issued by the American College for Sports Medicine (ACSM) for sufficient physical activity (45). Exclusion criteria included bipolar disorder type 1, history of schizophrenia or schizoaffective disorder, current and active alcohol or drug abuse or dependence (not including current abstinence), active suicidal intent and any medical contraindication for physical activity.

Clinicians screened potential participants upon entering in-patient treatment by checking the patient's date of birth, performing the diagnosis, asking the patient to fill in a BDI and checking that the score was above or equal to 17, performing the short-form of the International Physical Activity Questionnaire (IPAQ-SF) (46) to elicit number of minutes spent in MVPA in the week prior to admission to in-patient treatment, and ascertained that there was no active suicidal intent. If these inclusion criteria were fulfilled, the patient was referred to the study team. A member of the study team conducted an in-person meeting to confirm the inclusion criteria including German language skills. In addition, the Physical Activity Readiness Questionnaire (PARQ) was filled in to ensure the patient did not fulfill any of the contraindications for physical activity (47). Thereafter, the member of the study team informed the patient of all study procedures and ensured that the patient was fully informed and wanted to participate by their free will before signing an informed consent form.

2.3. Procedures

2.3.1. The intervention group

The intervention group received a theory-based and individually tailored physical activity counseling intervention delivered by trained physical activity coaches in-person and remotely with the supplement of a mobile application and text messages. The entire intervention, lasting 12 months, consisted of an initial phase (in-person and remote) based on a health behavior change theory and a fully remote

phase based on the Behavior Change Wheel framework (48). For the present analyses, only the initial phase of the intervention is relevant and described in the following.

The initial phase of the intervention was delivered in two in-person sessions during in-patient treatment and during one remote session after discharge from in-patient treatment. It was developed based on the Motivation Volition (MoVo) model and corresponding short, low-cost physical activity counseling intervention, originally developed to increase lifestyle physical activity in orthopedic in-patients (49, 50). As can be seen in **Figure 1**, the underlying MoVo model assumes that self-efficacy and positive outcome expectancies lead to a self-concordant and strong goal intention. This in turn leads to implementation intention including action initiation and intention shielding from situational cues, resulting in an episode of the desired behavior. Subsequent outcome experiences may then influence future behavior and ultimately behavior maintenance (50).

The corresponding MoVo intervention entails identifying a health goal, gathering physical activity ideas (e.g., walking) to reach said goal (e.g., achieving a 7 km walk) and an introduction to making a suitable, precise, practicable, and effective plan (e.g., when, with whom and for how long shall the walk take place) in a first session. In a second session, the created plan is discussed and adjusted if needed. Furthermore, potential barriers (e.g., rain) and corresponding strategies (e.g., purchase of suitable protective clothing) are developed and methods of self-monitoring are discussed (11). In the PACINPAT trial, a mobile application account was provided for the participants for the purpose of self-monitoring of behavior and giving the coach insight into activities between counseling sessions. Features included a physical activity diary, a personal profile with data pertaining to body weight, body mass index and time spent in physical activity, as well as a notes section in which the coach as well as the participant could create notes pertaining to the content of the counseling sessions. If the participant did not have access to a smart phone or computer or did not wish to use the mobile application, a hand-written diary to document behavior was encouraged. The second and fully remote phase of the intervention was then built upon the goals, ideas, plans, and strategies derived from this initial phase.

The physical activity coaches were sport science and psychology graduates, who were specifically trained and monitored by the study team. More information is provided in the published study protocol (43).

2.3.2. The control group

The control group received two in-person counseling sessions with a physical activity coach. However, these were not individually tailored, but contained general information on the health-enhancing benefits of regular physical activity. These sessions were informed by the "Core document for Switzerland" covering physical activity recommendations, physical activity levels of the Swiss population, benefits of physical activity and costs of physical inactivity. The document was published by the Swiss Federal Office of Sport in collaboration with other institutes.[1] The participants received this document in writing, watched a corresponding short animation and had the opportunity to discuss the content and related questions with the physical activity coach. All participants in both groups received treatment as usual provided in the context of their in-patient treatment regime.

2.4. Data collection

Data, informing the efficacy of the initial phase of the intervention, were collected at two time points in the clinic: after recruitment, approximately 2 weeks after entry to in-patient treatment (baseline) as well as 6 weeks after discharge from in-patient treatment and completion of the initial phase of the intervention (post). Data collection took place in the clinic in which the participant was or had been an in-patient and was conducted face-to-face by a member of the study team.

2.4.1. Motivational and volitional determinants of physical activity

In accordance with the MoVo model, a series of determinants were assessed with six psychometrically sound German questionnaires. Intention was assessed with a single item ("How strong is your intention to exercise regularly during the next few weeks and months?") with the answer ranging from 0 (no intention) to 5 (very strong intention) (51–53). The four regulation modi of motivation: intrinsic [e.g., "I (would) exercise because it is just fun for me."], identified [e.g., "I (would) exercise because I have good reasons to be physically active."], introjected [e.g., "I (would) exercise because otherwise I would have a guilty conscience."], and external [e.g., " I (would) exercise because others tell me to become physically active."] were assessed with 12 items, 3 items each, with answers ranging from 1 (not at all true) to 6 (completely true) (53–55). Self-efficacy was assessed with three items pertaining to the confidence in initiating ("I am confident to start a new exercise activity."), maintaining ("I am confident to continue an exercise activity over a couple of months."), and re-initiating physical activity ("I am confident that I can start an exercise activity again after a longer break."). Answers ranged from 0 (not at all confident) to 5 (100% confident) (50, 51). Outcome expectancies were assessed with 16 items in terms of positive (e.g., "I can improve my physical appearance if I regularly exercise.") and negative (e.g., "If I exercise, I end up in situations where I feel embarrassed.") expectancies. Answers ranged from 1 (not true) to 4 (completely true) (56, 57). Action and coping planning were assessed with 10 items (e.g., "I already know when I will do a particular exercise activity." and "I have made a detailed plan regarding what to do in a difficult situation in order to act in accordance with my intentions."). Answers also ranged from 1 (not at all true) to 4 (completely true) (16, 54). Lastly, perceived barriers were assessed with 19 items (e.g., "I have too much work to do."), which were rated on a scale from 1 (almost never) to 4 (almost always) (15, 58).

2.4.2. Implicit attitudes toward physical activity

Implicit attitudes were assessed with a computer-based single target implicit association test (ST-IAT) (59, 60). During the test, participants were provided with visual stimuli of physical activity (target concept) as well as smileys and frownies and were asked to allocated them to target categories (good and bad). Smiles were always to be allocated to the good category and frownies to the bad category. The physical activity stimuli were to be allocated to

1 https://www.hepa.ch/de/bewegungsempfehlungen.html

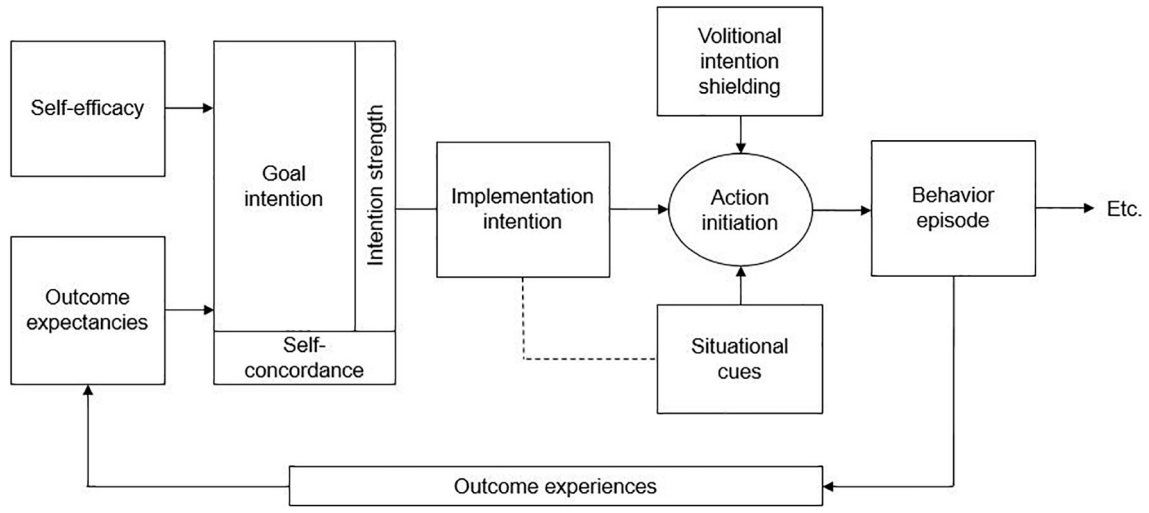

FIGURE 1
Motivation volition (MoVo) model according to Fuchs et al. (50).

good and bad in counterbalanced blocks with 32 trials preceded by 16 practice trials. The reaction time difference between the two categories (ST-IAT raw score) was divided by the within-subject standard deviation of reaction times to create a D-score, which can be interpreted as follows: 0.15 = slight, 0.35 = moderate, 0.64 = strong preference (for positive values) or aversion (for negative values) (61). The images were obtained from Adobe Stock. The software used was e-prime 3.0 (PST, USA). Discriminant validity and reliability of the ST-IAT have been established in previous research (60–62).

2.4.3. MVPA and step count

Moderate-to-vigorous physical activity (MVPA) was measured objectively with a wGT3x-BT accelerometer device (Actigraph, Shalimar, FL, USA). The device was worn around the hip for seven consecutive days. The sampling frequency was 60 Hz and epoch length was set at 60 s (63). Raw accelerometer counts and the ActiLife computer software were used to establish time per day spent in moderate physical activity (2,691–6,166 counts per minute, >3 MET) and vigorous physical activity (>6,167 counts per minute, >6 MET) (64), which were then added to elicit MVPA levels. Additionally, steps per day were captured with the accelerometer. A non-wear time sheet was completed to assess physical activities during which the device could not be worn. The device had to be worn for at least four valid days (including ≥ 3 valid weekdays and ≥1 valid weekend day) (65, 66). Only days with at least 8 h of wear time were considered to be valid (66, 67). Validity of the accelerometer device has been published previously (64).

Moderate-to-vigorous physical activity (MVPA) was also measured subjectively *via* self-report using an interview based on the Simple Physical Activity Questionnaire (SIMPAQ) specifically developed for psychiatric patient populations (68). The average hours per day (24 h) spent sleeping, sitting, walking, engaging in sports and other activities of moderate intensity in the preceding 7 days are captured. Time spent in MVPA is calculated by adding time spent walking and engaging in sport (69). This questionnaire has been tested for reliability and validity in 23 countries (69).

2.4.4. Depression severity

Depression severity was assessed by a member of the study team in a structured interview with the participant using the 17-item Hamilton Depression Rating Scale (HAMD17) (70). The questions pertain to symptoms of MDD during the previous 7 days and were developed for an in-patient population. Answers range from zero to two or four. Scores for two of the items (retardation and agitation) are made by the assessor based on the observation of slowness of thought and speech, impaired ability to concentrate or decreased motor activity (retardation) and fidgetiness, playing with hands or excessive moving about (agitation). A sum score is achieved by adding the highest score from each question and ranges from zero to 52. The higher the score the more severe the depression symptoms.

Additionally, depression severity was measured *via* self-report in form the Beck Depression Inventory (BDI) (44). This is a reliable and validated instrument (71) containing 21 questions to asses affective, behavioral, and somatic symptoms of unipolar depression (e.g., "I am so unhappy/sad that I can't stand it"). Answers range from zero to three. To reach a sum score, the highest score from each question is added with a final sum score ranging from zero to 63. A higher score indicates more severe depression symptoms.

2.5. Data analysis

Descriptive statistics are reported in means (*M*), standard deviation (*SD*), counts and percentages (%). A dropout analysis to elicit baseline differences between post and lost to post was conducted using unpaired *t*-tests. To assess group differences (intervention versus control group) over time (baseline to post) in the main study variables (intention, motivation, self-efficacy, positive and negative outcome expectancies, action and coping planning, perceived barriers, implicit attitudes, accelerometer-based and self-reported MVPA and step count) linear mixed models were used. Linear mixed models are known to be robust with regard to missing values (72). Main study variables were used as dependent variables. Group, time, and the interaction between groups and time were set as fixed effects while participants were set as random effects to account

for between—subject heterogeneity. All models were adjusted for age, sex and depression severity (BDI score at baseline). Residual plots were used to check the model assumptions. Results are presented as estimated differences in mean scores (β) within subjects, within groups and between the groups over time. Negative differences in means indicate lower scores in the control group. Corresponding *p*-values and 95% confidence intervals (*CI*) are reported.

According to the original power calculation as stated in the study protocol (43), the optimal sample size was 278 participants (power = 0.80). Considering a possible dropout rate of 20%, a sample size of 334 participants was calculated. This was based on the assumption of a small-to-moderate effect (d = 0.30) of the intervention on accelerometer-based physical activity. In previous research individually tailored physical activity promotion has yielded a moderate effect (d = 0.50) on physical activity in healthy individuals (50). While a small effect size (d = 0.28) was detected in a Cochrane review (73) and remote interventions have also resulted in a small effect size (d = 0.20) in relation to physical activity outcomes in previous studies (29). In out-patients receiving in-person and remote physical activity counseling, a moderate effect size (d = 0.45) was detected on self-reported physical activity (36).

Disruptions and reduced recruitment caused by the COVID-19 pandemic, led to the finalization of recruitment when 244 participants were enrolled in the trial, 166 of which provided valid data at post assessment. Statistical significance was set for *p*-values less than or equal to 0.05. All statistical analyses were performed in Stata 15 (StataCorp, College Station, TX, USA).

2.6. Ethical considerations

The PACINPAT study received ethical approval from the Ethikkommission Nordwest- und Zentralschweiz (EKNZ; approval number 2018-00976) and from the local ethical boards of the participating study sites. All procedures were conducted according to the ethical principles of the Declaration of Helsinki. Written informed consent was given by all study participants upon being informed of the study's aims, the voluntary nature of their participation, their right to withdraw at any time without negative consequences as well as the anonymization and publication of their data.

3. Results

3.1. Participant characteristics

Participants assessed for eligibility, randomized, and analyzed are displayed in the provided Flow Diagram (**Figure 2**).

In total, 1,207 in-patients were assessed for eligibility, thereof 963 were excluded. Reasons are given in the Flow Diagram (**Figure 2**). In-patients not meeting the inclusion criteria (n = 249) consisted of those with an age above 65 years (n = 11), BDI below 17 (n = 41), bipolar disorder type 1 (n = 9), schizoaffective disorder (n = 1), current and active alcohol or drug abuse or dependence (n = 17), a primary diagnosis other than MDD (n = 52), medical contraindication for physical activity (n = 7), more than 150 min of physical activity per week (n = 74), active suicidal intent (n = 9), and a lack of German skills (n = 28). After randomization, 24 participants (10%) withdrew their consent (intervention group: n = 10 control group: n = 14) and so did not take part in any data assessments or intervention. Hence, the sample at baseline consisted of 220 participants (M_{age} = 41 years, 52% women) with 113 in the intervention group and 107 in the control group. In the intervention group (n = 113), 92 participants (81%) took part in all three MoVo counseling sessions, 18 participants (16%) took part in the MoVo intervention partially [two counseling sessions: n = 12 (11%) and one counseling session: n = 6 (5%)] and 3 participants (3%) declined to take part in the MoVo intervention entirely.

On average, post data assessments took place 9 weeks (SD = 4 weeks, range 3–26 weeks) after discharge from in-patient treatment. Thirty participants (26%) from the intervention group and 24 (22%) from the control group were lost to post. Of those who did attend (total: n = 166, intervention group: n = 83, control group: n = 83), 12 participants (7%) had re-entered psychiatric in-patient treatment, 23 participants (14%) were in partial in-patient treatment, and 102 participants (60%) were in outpatient treatment. According to the dropout analysis, participants lost to post showed significantly higher BDI (attenders: M = 20, SD = 1, lost to post: M = 25, SD = 1; 95% CI = 0.11 to 0.73) and Hamilton scores (attenders: M = 13, SD = 0.5; lost to post: M = 15, SD = 1; 95% CI = 0.10 to 0.72) as well as fewer years in education (attenders: M = 15, SD = 0.2; lost to post: M = 13, SD = 0.4; 95% CI = −0.72 to −0.10). More information regarding characteristics and demographic background can be found in **Table 1**. Inferential statistics showed no statistically significant differences between the groups at baseline in sociodemographic background variables. More information regarding primary and secondary diagnosis are available in **Supplementary material 1** and information regarding medication in **Supplementary material 2**.

3.2. MVPA and step count

The accelerometer-based measure showed that step count decreased significantly in both groups over time (β = −835, 95% CI = −1,485 to −184), yet significantly more so in the control group (β = −1,323, 95% CI = −2,215 to −431). According to a *post-hoc* test, the contrast of marginal means at post was not significantly different between groups (estimated difference = 841 steps, 95% CI = −1,778 to 97). Furthermore, a trend was recognizable with regard to accelerometer-based MVPA. Similarly, there were significant decreases in both groups over time (β = −9.76, 95% CI = −16.04 to −3.49), however, with a tendency toward a greater decrease in the control group (β = −8.37, 95% CI = −16.98 to 0.23). Conversely, self-reported MVPA increased significantly in both groups over time (β = 1.07, 95% CI = 0.45 to 1.68), with no significant differences between the groups (**Table 2**).

3.3. Motivational and volitional determinants of physical activity

Overall, no statistically significant differences were found between the intervention and control group over time (**Tables 2**, **3**). However, across the entire sample over time, negative outcome expectancies significantly decreased (β = −0.6, 95% CI = −0.72 to −0.44), while action planning (β = 0.3, 95% CI = 0.17 to 0.46) and coping planning (β = 0.4, 95% CI = 0.24 to 0.54) significantly

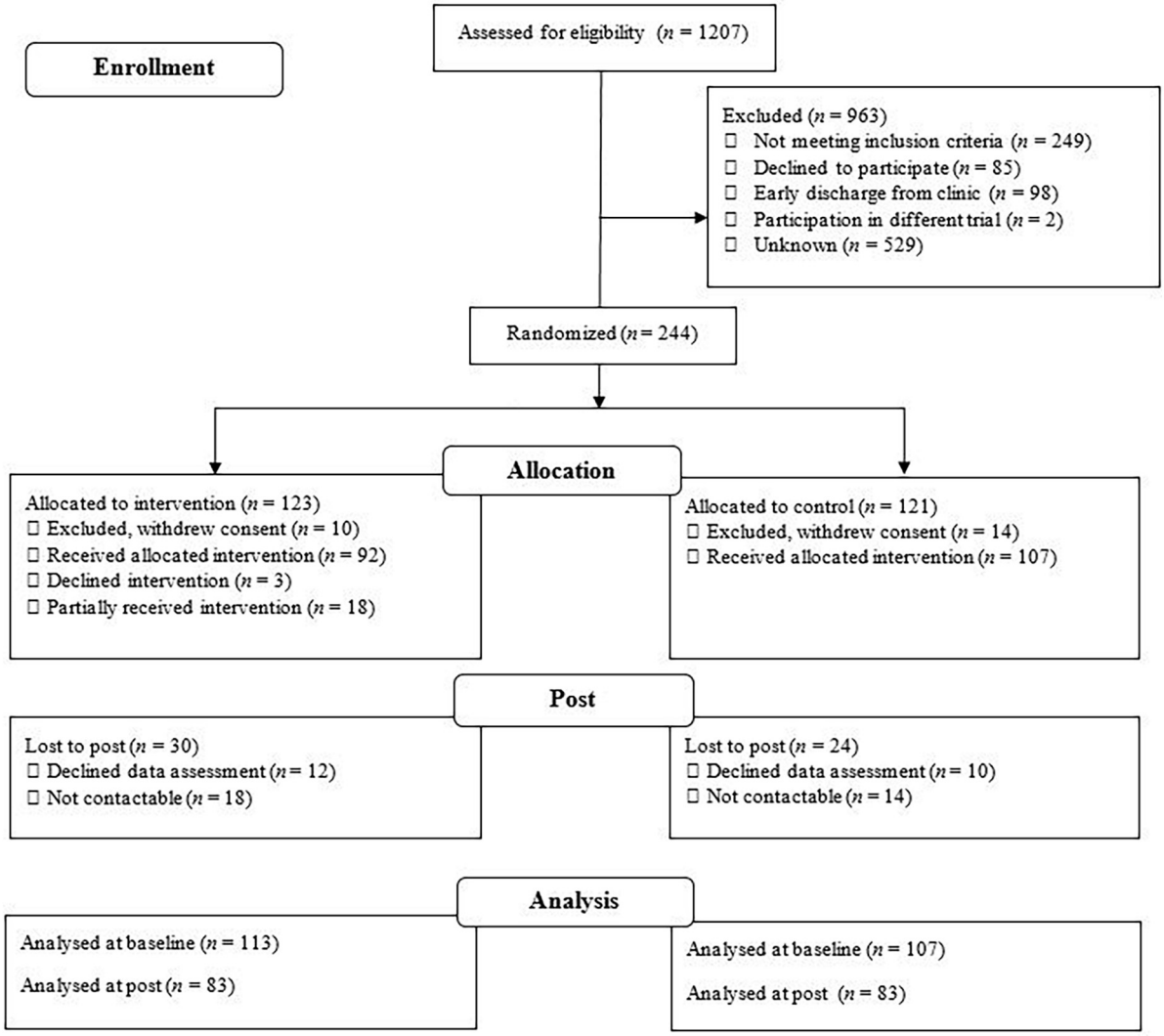

FIGURE 2
Flow diagram according to CONSORT (2010).

increased. According to Cronbach's alpha, internal consistency of the questionnaires was acceptable for all at baseline ($\alpha \geq 0.7$) and for all except identified motivation ($\alpha = 0.63$) at post.

3.4. Implicit attitudes toward physical activity

No statistically significant group differences over time were detected (Tables 2, 3). However, there may be less positive implicit attitudes in the control group over time ($\beta = -0.07$, 95%$CI = -0.24$ to 0.10).

3.5. Depression severity

Both self-reported (BDI score; $\beta = -4.59$, 95% $CI = -6.70$ to -2.47) and objective (Hamilton score; $\beta = -3.97$, 95% $CI = -5.18$ to -2.75) measures of depression severity decreased in both groups over time without significant between groups differences.

4. Discussion

The aim of this study was to assess whether the initial phase of the PACINPAT intervention elicited changes in the targeted motivational and volitional determinants of and implicit attitudes toward physical activity as well as the behavioral outcome of MVPA levels and step count.

The main results of this study show that the initial phase of the intervention seems to have led to a less severe decrease in step count compared to the control condition. Additionally, a trend was observed with regard to accelerometer-based MVPA, which also may have decreased less severely in the intervention compared to the control condition. In contrast, the initial phase of the intervention does not seem to have affected motivational and volitional determinants of and implicit attitudes toward physical activity. However, favorable changes in negative outcome expectancies and action and coping planning overall were observed.

These results contribute to the current literature by providing a first insight into the physical activity patterns of individuals with MDD during as well as after psychiatric in-patient treatment.

TABLE 1 Participant characteristics.

	Total (N = 220)	Intervention group (n = 113)	Control group (n = 107)
	M (SD)	*M (SD)*	*M (SD)*
Age in years	40.89 (12.59)	41.78 (12.94)	39.95 (12.20)
Height (in cm)	171.39 (9.58)	171.68 (10.09)	171.09 (9.04)
Weight (in kg)	80.16 (21.04)	79.69 (22.56)	80.66 (19.39)
BMI (in kg/m^2)	27.04 (6.06)	26.82 (6.36)	27.27 (5.75)
Beck Depression Inventory Score at admission[a]	29.47 (8.89)	30.56 (9.22)	28.27 (8.40)
Beck Depression Inventory Score at baseline	21.69 (10.68)	22.57 (11.88)	20.77 (9.21)
Hamilton Score at baseline	13.37 (5.31)	14.19 (5.28)	12.50 (5.24)
Education in years[b]	14.33 (3.33)	14.16 (3.49)	14.51 (3.16)
Employment in years	18.08 (12.42)	19.13 (12.98)	16.98 (11.76)
	M (SD, Min−Max)		
Physical activity 1 week prior to admission (min/week)	33.06 (48.56, 0–150)	26.74 (43.99, 0–150)	39.46 (52.25, 0–150)
	N (%)	*n* (%)	*n* (%)
Sex			
Women	115 (52)	63 (56)	52 (49)
Men	105 (48)	50 (44)	55 (51)
Language			
German	178 (81)	93 (82)	85 (79)
German and second language	13 (6)	7 (6)	6 (6)
Other	29 (13)	13 (11)	16 (15)
Nationality			
Swiss	162 (74)	85 (75)	77 (72)
Swiss dual citizenship	20 (9)	10 (9)	10 (9)
German	22 (10)	12 (11)	10 (9)
Other	16 (7)	6 (5)	10 (9)
Civil status			
Single	157 (71)	85 (75)	72 (67)
Married	63 (29)	28 (25)	35 (33)
Yearly net income[c]			
<50,000 CHF	84 (45)	43 (45)	41 (44)
50,000–100,000 CHF	65 (34)	31 (32)	34 (37)
>100,000	40 (21)	22 (23)	18 (19)

Of 244 participants who were randomized, 24 withdrew consent, hence the sample at baseline consisted of 220 participants.
[a]24 participants missing, [b]2 participants missing, [c]31 participants missing.

4.1. MVPA and step count

Following the hypothesized favorable changes in physical activity determinants and attitudes, increases in MVPA and step count in the intervention group were hypothesized compared to the control group. This hypothesis could not be confirmed, as MVPA and step count decreased, yet more so in the control condition compared to the intervention condition.

Decreases in MVPA and step count can be explained by the transition from in-patient treatment to every-day life. During in-patient treatment participants were in a structured environment and had the opportunity to participate in a broad range of therapeutic sessions including physical activity, while after discharge physical activity had to be planned individually. It is known that after psychiatric hospitalization, medication non-compliance may occur (74). In a broader sense, taking medication adherence may be seen as a health behavior, which has been identified as a common behavioral goal in physical activity interventions (75).

It is also known that distinct life events and transitions, such as a change in living situation, can impact physical activity behavior negatively. Discharge from in-patient psychiatric treatment may be seen in a similar light, as the living space, structure of daily life and illness management change (76), and thus may contribute to a decrease in physical activity behavior. Similarly, a change in physical activity behavior can be seen in the increase in MVPA from 1 week prior to admission to in-patient treatment to the baseline data

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TABLE 2 Descriptive statistics of main variables at baseline and post assessment.

	Intervention group				Control group			
		Baseline		Post		Baseline		Post
	n	*M (SD)*	*n*	*M (SD)*	*n*	*M (SD)*	*n*	*M (SD)*
Intention (0–5)	110	3.72 (1.00)	80	3.86 (0.91)	105	3.77 (1.10)	83	3.70 (1.14)
Motivation (1–6)								
Intrinsic	110	3.79 (1.03)	79	3.91 (1.05)	105	3.76 (1.08)	83	4.05 (1.00)
Identified	110	4.84 (0.76)	79	4.93 (0.64)	105	4.77 (0.65)	83	4.84 (0.79)
Introjected	110	3.52 (1.11)	79	3.58 (1.06)	105	3.52 (0.92)	83	3.54 (0.96)
External	110	2.19 (1.00)	79	2.27 (1.01)	105	2.13 (0.93)	83	2.05 (0.94)
Self-efficacy (0–5)	109	3.43 (1.04)	80	3.59 (0.98)	106	3.64 (0.94)	83	3.71 (0.89)
Positive outcome expectancies (1–4)	110	3.20 (0.45)	81	3.17 (0.42)	105	3.17 (0.42)	82	3.24 (0.43)
Negative outcome expectancies (1–4)	113	2.57 (0.89)	81	2.00 (0.55)	107	2.55 (0.69)	83	1.86 (0.42)
Action planning (1–4)	109	2.64 (0.75)	81	3.03 (0.53)	106	2.61 (0.63)	83	2.90 (0.54)
Coping planning (1–4)	109	2.17 (0.72)	81	2.63 (0.61)	106	2.10 (0.59)	83	2.51 (0.62)
Perceived barriers (1–4)	113	2.09 (0.59)	81	1.95 (0.48)	107	2.10 (0.45)	83	1.83 (0.40)
D-Score (−2 to +2)	111	0.18 (0.44)	78	0.21 (0.50)	103	0.17 (0.42)	79	0.14 (0.36)
MVPA								
Accelerometer-based (min/day)	95	55.83 (27.82)	62	47.51 (30.22)	89	60.04 (26.91)	66	47.60 (24.83)
Self-report (hours/week)	112	2.92 (1.99)	83	4.20 (2.89)	107	3.22 (2.19)	83	4.15 (2.58)
Steps per day	95	7,900 (2,838)	62	7,341 (3,445)	89	8,453 (2,864)	66	7,052 (2,880)
Depression								
BDI	113	22.57 (11.88)	81	17.42 (11.59)	107	20.77 (9.21)	83	14.61 (10.39)
Hamilton	113	14.19 (5.28)	82	10.01 (5.83)	107	12.50 (5.24)	83	8.30 (5.00)

MVPA, moderate-to-vigorous physical activity; min, minutes; BDI, Beck Depression Inventory. Unequal samples are because of missing values in specific outcomes.

collection time point. It can be hypothesized that physical activity patterns change because of a change in environment. Typically, in-patient treatment offers a more structured every-day life, which may also include forms of therapy in which movement is integrated (77). This may explain an initial increase in physical activity during the first weeks of in-patient treatment. This is in line with previous research stating that people in psychiatric in-patient care are likely to meet physical activity recommendations when engaging in exercise and sport programs (78).

The difference of approximately 10 min of physical activity per day between the intervention and control group can be considered clinically meaningful: According to accelerometer data from 4,840 participants (53% women) in the United States (U.S.), 10 min of physical activity per day is associated with approximately 7% decrease in the number of deaths per year, i.e., adding 10 min of physical activity per day is estimated to lead to ca. 111,000 (95% *CI* = 79,594 to 142,754) preventable deaths yearly in the U.S. (79). In this sample MVPA levels were high. This could be explained by the sample being particularly interested in physical activity as a consequence of their trial participation. A further explanation could be that the participants presenting valid accelerometer data (85% at baseline and 75% at post) were more physically active than non-compliers, resulting in high average levels of MVPA. However, in this case, even if the control group did not exercise at all, the intervention group would profit, by achieving almost half the recommended daily dose of physical activity (assuming approximately 10 min of physical activity per day) and sufficient steps per day (±7,000) for health benefits (80).

The observed discrepancy in accelerometer and self-reported MVPA has been reported previously, with subjective measures being both lower and higher than objective measures (81). Influencing factors are demographic characteristics like education (82) and differences in perceptions of MVPA (83). Evidence also suggests that, even though wearing a physical activity measurement device does not increase objective measure of physical activity, self-reports may increase (84). According to a meta-analytic review on physical activity behavior in people with MDD, time in physical activity, especially light physical activity was underreported, while vigorous physical activity was over-reported. The authors conclude that self-reported MVPA in people with depression may be inaccurate (1). All participants in this trial, reported increases in MVPA over time. This is in line with self-reported MVPA in previous physical activity counseling in healthy adults (35) and out-patients with MDD (36). However, given that self-reported MVPA is known to be over-reported in this population and that generally objectively measured physical activity is more trustworthy than self-reported (85), it must be assumed that the objectively observed decreases in MVPA are more accurate in this study population.

4.2. Determinants of and implicit attitudes toward physical activity

People receiving the intervention were hypothesized to report increases in intention, motivational regulation (intrinsic, identified,

TABLE 3 Group differences over time in main variables.

	Baseline differences between groups	Baseline to post difference within groups	Interaction effects between-groups from baseline to post
	β (95% *CI*)	β (95% *CI*)	β (95% *CI*)
Intention	0.00 (−0.27 to 0.27)	0.04 (−0.23 to 0.30)	−0.26 (−0.62 to 0.11)
Motivation			
Intrinsic	−0.06 (−0.32 to 0.21)	−0.01 (−0.17 to 0.15)	0.17 (−0.05 to 0.39)
Identified	−0.07 (−0.26 to 0.11)	0.04 (−0.11 to 0.21)	−0.04 (−0.26 to 0.18)
Introjected	0.06 (−0.20 to 0.32)	0.20 (−0.01 to 0.42)	−0.08 (−0.38 to 0.21)
External	−0.01 (−0.25 to 0.23)	0.17 (−0.01 to 0.36)	−0.10 (−0.35 to 0.15)
Self-efficacy	0.11 (−0.13 to 0.35)	−0.08 (−0.27 to 0.10)	−0.04 (−0.29 to 0.21)
Positive outcome expectancies	−0.03 (−0.15 to 0.08)	−0.02 (−0.09 to 0.06)	0.05 (−0.06 to 0.18)
Negative outcome expectancies	0.00 (−0.17 to 0.17)	−0.58 (−0.72 to −0.044)	−0.06 (−0.25 to 0.14)
Action planning	−0.04 (−0.02 to 0.11)	0.31 (0.17 to 0.46)	−0.12 (−0.32 to 0.07)
Coping planning	−0.07 (−0.23 to 0.09)	0.39 (0.24 to 0.54)	−0.08 (−0.29 to 0.12)
Perceived barriers	0.04 (−0.07 to 0.16)	−0.04 (−0.13 to 0.06)	−0.08 (−0.22 to 0.05)
D-Score	−0.00 (−0.12 to 0.11)	0.05 (−0.07 to 0.17)	−0.07 (−0.24 to 0.10)
MVPA			
Accelerometer-based (min/day)	3.23 (−4.48 to 10.95)	−9.76 (−16.04 to −3.49)	−8.37 (−16.98 to 0.23)
Subjective (hours/week)	0.21 (−0.40 to 0.83)	1.07 (0.45 to 1.68)	−0.44 (−1.30 to 0.41)
Steps per day	482 (−336 to 1,300)	−835 (−1,485 to −184)	−1,323 (−2,215 to −431)
Depression			
BDI	−1.90 (−4.74 to 0.94)	−4.59 (−6.70 to −2.47)	−0.99 (−3.97 to 1.99)
Hamilton	−1.72 (−3.13 to −0.31)	−3.97 (−5.18 to −2.75)	0.01 (−1.70 to 1.73)

Results from linear mixed models. MVPA, moderate-to-vigorous physical activity; min, minutes; β, regression coefficient representing estimated group mean difference; BDI, Beck Depression Inventory.

introjected, external), self-efficacy, positive outcome expectancies, action and coping planning, and positive attitudes toward physical activity as well as decreases in negative outcome expectancies and perceived barriers. Unexpectedly, these favorable changes in relation with the intervention could not be confirmed.

Measurable changes in intention, action planning, and barrier management have been reported 12 months after completion of the MoVo intervention (50, 86). In the current analysis, intervention effects were measured on average 9 weeks after discharge from in-patient treatment, which was on average 6.5 weeks after administering the initial phase (MoVo phase) of the intervention. Hence, it may be argued that changes in motivational and volitional determinants may only be seen over more time. Additionally, compared to the original efficacy analysis of the MoVo intervention, the control group received no intervention at all (50), in this study the control group received two in-person counseling sessions. Hence, group differences may not be expected yet.

According to meta-analytic data physical activity interventions have the potential to elicit small yet significant changes in self-efficacy, especially those including feedback on past behavior (87). Providing feedback was part of the PACINPAT intervention, however, only at a later stage during the remote intervention, once physical activity plans had been carried out and feedback on past behavior became possible. Another coaching intervention for patients with type 2 diabetes suggests that changes in illness-related self-efficacy were visible 3 months after the intervention and no longer 9 months after the intervention (88), further implying that the time of assessment influences whether changes will be seen or not. With regard to health behavior in general, changes in self-efficacy are known to be associated with changes in intention (89). Therefore, intention may also be exposed to the same temporal dependency. Similarly, in a meta-analysis on effective physical activity interventions for motivation, behavioral experience and self-regulation seemed to be intervention characteristics particularly associated with change in motivation (90). Both behavioral experience and self-regulation were part of the PACINPAT intervention, introduced in the initial phase yet presumably enacted later. Even though behaviors explained by implicit attitudes tend to be impulsive indicating the required information is quickly accessible, changes in attitudes occur slowly because they are based on previously learned associations (91). Hence, new associations need to be learned and embedded and changes may not be measurable at this early stage.

Across the entire sample decreases in negative outcome expectancies and increases in action as well as coping planning were observed over time. This may be associated with the observed decrease in depression severity in both groups over time. Major Depressive Disorders have been characterized by learned helplessness (92) and a lack of response-contingent positive reinforcement (93). Both resulting in increased negative outcome expectancies, in turn leading to reduced intention and planning in individuals with MDD (14). On a neurological level, evidence shows that deficits in executive

function, memory, and attention are associated with MDD (94). More specifically, task-related hypoactivity in the left dorsolateral prefrontal cortex, as observed in people with MDD (95), is associated with negative emotional judgment (96) and reduced planning and action control (14, 97). These malfunctions seem to be caused by structural changes, hence may be reversible with improvement in illness trajectory (97, 98). Further evidence corroborating this can be found in the effects of psychotherapy, which participants received as standard treatment in the clinics and, has proven effective in reducing feelings of hopelessness (99), which may lead to less negative outcome expectancies.

The group difference in step count despite there being no group differences in physical activity determinants could be explained by the bi-directional relationship between determinants and actual behavior. It is known, for example, that a sense of purpose in life (a concept closely related to intention, self-efficacy, and planning) is positively associated with physical activity and the reverse is also true, that physical activity is positively associated with a sense of purpose (100). Also, the concept of self-efficacy has been shown to be both a determinant as well as consequence of physical activity (101). Such bi-directional relationships have also been found in the area of executive function (102). Hence, the measured determinants in this study may not necessarily precede physical activity behavior. Additionally, the effect of measuring physical activity may be taken into account. According to a systematic review and meta-analysis, step-count monitoring using a pedometer increases step-count both in the short and long-term (39). This is corroborated by evidence from a RCT in which participants' monitoring of their step-count with pedometers increased their average step-count per day by 2,256 steps (95% *CI* = 978 to 3,537) more than participants in the control condition (103). This hypothesis is in line with the Hawthorne effect, which stipulates that merely the feeling of being observed may influence participants' behavior (104).

4.3. Strengths and limitations

The strength of this study is that the variables of interest were measured from multiple sources. MVPA was measured both objectively and subjectively. Determinants of physical activity were assessed explicitly and implicitly. The questionnaires are psychometrically sound and have been used in previous studies examining the efficacy of physical activity counseling interventions, thus making results comparable to existing research. The ST-IAT was developed specifically for this population of individuals with MDD. Furthermore, the intervention is theory-based hence standardized, yet also individually tailored. All physical activity coaches were recruited and trained specifically for the implementation of this intervention, which was monitored continuously. Additionally, it is one of the first randomized controlled trials evaluating the MoVo intervention in in-patients with MDD, hence providing insight regarding how this intervention works in a different population to which it was original developed.

The limitations are: First, the required sample size to evidence a small-to-medium effect size with regard to accelerometer-based MVPA was not achieved. This reduction in statistical power may have led to a lack of a statistically significant group difference in the MVPA measure. Second, there is a selection bias. It can be assumed that participants were interested *per se* in physical activity and thus may have exhibited increased motivation. According to the drop out analysis, people with more severe depression symptoms dropped out of the trial. Hence, these results are not generalizable across all in-patients with MDD. Third, the timing of the post data assessment was conducted sooner in relation to the intervention completion than in other comparable studies. Additionally, the post data assessment took place during a potentially vulnerable time for in-patients transitioning back to every-day life. Hence the results may not be representative of usual activities of daily life. Fourth, all participants had different standard medical and psychotherapeutic treatments provided by the clinics and varying durations of in-patient treatment. However, these effects should not have a bearing on the results because of the randomized study design. Fifth, the self-reported instruments used to assess motivational and volitional determinants as well as MVPA are subject to recall and social desirability bias. Lastly, the accelerometer data analysis method described in the study protocol was adjusted. However, there is evidence showing that 4 days is representative of 1 week (65) and that there are no meaningful differences between 8, 10, and 12 h of wear time (67). In doing so, more data could be considered without compromising reliability and validity of the measure (66).

5. Conclusion

In conclusion, the intervention led to a less severe decrease in step count and a trend toward a less severe decrease in MVPA compared to the control condition, yet no intervention effects were visible in motivational and volitional determinants of or implicit attitudes toward physical activity. Decreases in MVPA and step count may be explained by the transition out of in-patient treatment, which represents a time in which health behaviors may suffer. Unaffected determinants and attitudes may be explained by the time required for changes to become evident. However, promisingly with decreases in depression symptoms, there also seem to be favorable changes in outcome expectancies and planning. The protective effect of the initial phase of the PACINPAT intervention indicates that physical activity counseling may be an important factor in the transition from in-patient treatment. Methods to optimize the intervention during this period could be further explored to fulfill the potential of this opportunity.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Ethikkommission Nordwest- und Zentralschweiz. The patients/participants provided their written informed consent to participate in this study.

Author contributions

MG was the principle investigator of the PACINPAT trial. RC and J-NK co-designed the intervention and intervention materials,

recruited the participants, and monitored the intervention. JB, MH, CI, UL, SM, TM, AO, and NS supported the patient screening and recruitment processes on the four study sites. OF was responsible for randomization of the participants. SB, LD, SL, and LZ offered thematic support. RC and MG were responsible for conceptualizing the manuscript. RC performed the statistical analyses and wrote the first draft of the manuscript. All authors read, contributed to the article, and approved the final manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2022.1045158/full#supplementary-material

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Chapter 9 Synthesis & Discussion

1. Synthesis

The aim of this PhD thesis was to evaluate the process of the PACINPAT intervention quantitatively and qualitatively according to the MRC guidelines.

Aim 1: Description of the PACINPAT study

To begin with, the PACINPAT study protocol was published (Gerber et al., 2019) and the trial was registered in the ISRCTN registry (number: ISRCTN10469580) on 3rd September, 2018 (https://www.isrctn.com/ISRCTN10469580). The first patient was recruited in January 2019. Because of an intermittent cessation of recruiting new participants caused by the COVID-19 lockdown in 2020 there was a consequent reduced recruitment rate (Cody et al., 2021), in total 244 out of the initially intended 334 participants were recruited and randomized to the intervention or control group by October 2021. Ten per cent of the recruited participants dropped out before baseline data collection, resulting in a baseline sample size of 220 participants. Six weeks after discharge from in-patient treatment a further 25% dropped out of trial participation, resulting in a sample size of 166 participants at post data collection (Cody et al., 2023).

Aim 2: Evaluation of contextual factors

Despite the global severity of the COVID-19 pandemic, psychosocial health (perceived stress, health status and insomnia symptoms), psychosocial determinants of physical activity (self-efficacy, outcome expectancies, intention, action and coping planning, perceived barriers and social support), implicit attitudes towards physical activity and self-reported physical activity in in-patients with MDD (N = 165, M_{age} = 42±12 years, 51% female) recruited between January 2019 and December 2020, did not differ before (n = 119) and during/after (n = 46) the state-mandated lockdown at baseline data assessment (Cody et al., 2021).

The inherent difficulties of living with MDD may, however, affect physical activity determinants. This in turn may shape how the underlying theory, targeting said determinants, makes the intervention work. Specifically, according to an analysis of in-patients with MDD (N = 215, M_{age} = 41±13 years, 53% female) at baseline, people with severe MDD symptoms (n = 52) exhibit lower levels of self-efficacy, intention, intrinsic motivation and action and coping planning as well as higher levels of introjected and external motivation, negative outcome expectancies and perceived barriers compared with those with mild (n = 89) and moderate (n =

74) MDD symptoms. Implicit attitudes towards physical activity did not differ according to MDD severity (Cody et al., 2022a).

Aim 3: Evaluation of the implementation

According to data from 95 (M_{age} = 42±13 years, 53% female) in-patients with MDD who were randomized to the intervention group and who completed their trial participation, the intervention dose varied between early dropouts (2±0.5 sessions), low (10±6 sessions) and high (25±2 sessions) attenders. The content fidelity was achieved partly and adapted during in-person counseling and well achieved in the remote sessions. According to a satisfaction questionnaire, 80% of the participants reported that the content was understandable and appropriate and 86% reported being satisfied with their coach. Differences in intervention attendance groups were recognized already in the first two in-person counseling sessions. The early dropouts (n = 18) had significantly shorter counseling sessions (early dropouts: 45±20 minutes, low and high dose: 60±15 minutes, $F_{(2,92)} = 6.10$, $\eta^2 = 0.11$, $p < 0.05$) compared with those with low (n = 37) and high (n = 40) attendance doses, plans were made less frequently (early dropout: 33%, low dose: 81%, high dose: 87%) and the mobile application was introduced less frequently (early dropout: 39%, low dose: 81%, high dose: 82%) (Publication 3).

Aim 4: Evaluation of the mechanism of impact

Twelve purposively recruited participants (M_{age} = 50±12 years, 58% female) took part in semi-structured interviews after completing the intervention and / or follow-up data assessment. The participants reported the lived experience of depression as balancing pressure serving as the context in which the intervention was being delivered and which influenced well-being and physical activity *per se*. Before initiation of the intervention mindsets towards physical activity varied (resolute, positive, ambivalent, and fixed) as did stage of illness (reflection on living with MDD, opportune moment in cyclical MDD, struggle with MDD and limited reflection on living with MDD). This influenced the experienced intervention which ranged from it being part of a systemic change, a trigger for change, a last resort or repurposed to serve other interests. The coach was correspondingly experienced as supportive, a required driving force, a source of pressure or was avoided. This resulted in different trajectories after the intervention. In summary, those who experienced the intervention expansively reported increased well-being and maintained physical activity. Those with an adoptive experience reported fragile well-being and relationship-dependent physical activity. Those with stagnant experiences reported declining well-being and a shift away from physical activity. Those with a confirmatory

experience reported unchanged well-being and physical activity. It was concluded that physical activity behavior may be linked with self-management of chronic illness, with those reporting increased self-management experiencing the intervention expansively and seemingly reaping the greatest benefits (Cody et al., 2022b).

Aim 5: Evaluation of short-term outcomes

In the final sample of 220 in-patients with MDD (M_{age} = 41±13 years, 52% women), 113 participants were randomized to the intervention group and 107 to the control group. According to accelerometer-derived data, MVPA and step count decreased in both the control group and the intervention group from baseline to post. However, in the intervention group MVPA decreased on average 8.37 minutes less per day (95% *CI* = -16.98 to 0.23, $p = 0.057$) and on average 1'323 steps less per day (95% *CI* = -2'215 to -431, $p < 0.010$) than in the control group. According to the self-reported measure, MVPA increased in both groups on average by 1 hour per week (95% *CI* = 0.45 to 1.68, $p < 0.01$) from baseline to post. The initial phase of the intervention, i.e., the part based on the MoVo process model, does not seem to have affected psychosocial determinants of and implicit attitudes towards physical activity at this time. However, some positive changes were seen in both groups from baseline to post, with decreases in negative outcome expectancies (β = -0.58, 95% *CI* = -0.72 to -.044, $p < 0.01$) and increases in action planning (β = 0.31, 95% CI = 0.17 to 0.46, $p < 0.01$) and coping planning (β = 0.39, 95% CI = 0.24 to 0.54, $p < 0.01$; Cody et al., 2023).

2. Discussion

2.1. Explicit and implicit determinants of physical activity

A better understanding of the underlying mechanisms of physical activity behavior in in-patients with MDD was gained in this thesis, giving increased insight into contextual factors that shape the theory of how the intervention works (Cody et al., 2022a). However, in terms of intervention effects, it remains unclear, whether and when changes may occur and become measurable in psychosocial determinants of and implicit attitudes towards physical activity (Cody et al., 2023).

A bidirectional relationship between physical activity determinants and physical activity behavior may be considered. In a longitudinal study, it was found that an increased sense of purpose in life was associated with higher levels of self-reported physical activity and physical activity in turn was associated with future levels of sense of purpose in life. The authors further posit that the concept of "sense of purpose in life" is related to the underlying mechanisms of

physical activity such as intentions, self-efficacy and planning (Yemiscigil & Vlaev, 2021). This is corroborated by further quantitative evidence (Pfund et al., 2022). Additionally, according to qualitative evidence, it is said that one of the reasons for being physically active is to have an increased sense of purpose in life and physical activity in turn provides feelings of mastery, self-belief and satisfaction (Morgan et al., 2019). The concept of self-efficacy itself has been shown not only as a determinant of physical activity but also as a consequence thereof (Mudrak et al., 2015). With regard to outcome expectancies, it is known that mastery, reportedly a possible consequence of physical activity (Morgan et al., 2019), contributes to positive outcome expectancies (Sheu et al., 2018). Hence, the formation of expectancies may also occur as a result of physical activity experiences, as posited in the MoVo process model (Fuchs et al., 2007). Furthermore, a bidirectional relationship between executive function and physical activity has been found according to longitudinal survey data of over 4'000 adults. Although the magnitude of change in the association between high levels of executive function and increases in physical activity levels over time ($\beta = 0.05$, standard error = 0.01, t = 6.54, $p < 0.001$) was 50% greater than in the association between physical activity and increases in executive function over time ($\beta = 0.03$, standard error = 0.01, t = 5.09, $p < 0.001$), this shows, that changes in these domains are not necessarily consecutive (Daly et al., 2015). The domain of executive function is interesting insofar that volitional skills such as physical activity intention shielding and planning require sufficient executive functioning (Allan et al., 2016). Finally, there is also a bidirectional relationship between affect and physical activity. Negative affect is associated with reduction in physical activity, while physical activity is associated with less negative and more positive affect (Cushing et al., 2017; Schultchen et al., 2019). In summary, based on this evidence, it may be considered that changes in psychosocial determinants of and implicit attitudes towards physical activity may not necessarily precede measurable changes in physical activity behavior.

Additionally, a point of interest in the examined determinants is their interaction. In the PACINPAT population a potential discrepancy between some psychosocial determinants of and implicit attitudes towards physical activity was observed. Namely, people with more severe MDD symptoms reported significantly lower levels of self-efficacy, intention, intrinsic motivation, action and coping planning and higher levels of introjected and external motivation, negative outcome expectancies and perceived barriers, compared with those with mild and moderate symptoms, yet implicit positive attitudes did not differ significantly according to MDD severity (Cody et al., 2022a). If the explicit and implicit measures were aligned, corresponding differences could be expected (Muschalik et al., 2018). Evidence suggests that a

discrepancy between explicit and implicit attitudes towards physical activity may be detrimental for physical activity behavior (Muschalik et al., 2019). Furthermore, it has been evidenced that implicit attitudes may moderate the relationship between self-efficacy and physical activity as well as intention and physical activity. Negative implicit attitudes may also strengthen the negative relationship between perceived barriers and intention, while positive implicit attitudes may strengthen the positive relationship between self-efficacy and intention (Muschalik et al., 2018). Associations between implicit associations and physical activity in psychiatric in-patients were not found in one of the few studies examining this phenomenon. However, the issue with an in-patient population, is that (physical activity) behavior may be less self-regulated and more externally regulated given the nature of in-patient treatment (Gerber et al., 2018a; Cody et al., 2021). The same may be stated of the sample in the PACINPAT study. Both samples exhibited overall relatively high levels of physical activity and slightly positive implicit attitudes towards physical activity, potentially because in-patient treatment plans included physical activity options, which were strongly recommended by clinicians (Gerber et al., 2018a). Gerber et al. (2018) recommended repeat measures of implicit attitudes and physical activity behavior, ideally with one data collection time point after discharge from in-patient treatment. This was performed in the PACINPAT study, and it was discovered that the transition out of in-patient treatment may also not be representative of natural living conditions because of the adjustments associated with this phase (Cody et al., 2023). The follow-up data assessment in the PACINPAT study will therefore be of great value to examine further the potential changes and interactions between explicitly measured psychosocial determinants and implicit attitudes towards physical activity in this sample. In addition to perhaps being more representative of everyday life, more time will have elapsed. This may be relevant because significant associations between explicit and implicit attitudes towards physical activity and actual physical activity behavior have been found over longer periods of time, as exemplified in a recent study in people with obesity, in which associations were found in a longitudinal design over 4 months (Chevance et al., 2018) and 6 months in a pulmonary rehabilitation setting (Chevance et al., 2017).

2.2. Objective and self-reported physical activity

A better understanding of physical activity behavior and the perception thereof in in-patients with MDD was gained. That is to say, maintaining physical activity levels during the transition out of in-patient treatment is challenging (Cody et al., 2023). A decrease in physical activity after a physical activity counseling intervention based on the MoVo process model was not observed previously. However, physical activity levels in preceding literature were measured

after a longer duration following no contact with participants (Gerber et al., 2010; Fuchs et al., 2011; Fischer et al., 2019; Wurst et al., 2019). Decreasing physical activity levels after in-patient treatment have not been reported previously. However, it is in line with observed decreases in other health behavior such as medication adherence (Loch, 2014). Knowledge regarding this behavioral pattern is valuable because it indicates a vulnerable stage during which a lifestyle intervention may be particularly important to counteract reductions in health behaviors (de Leeuwerk et al., 2022). This is exemplified in evidence from this thesis, showing that physical activity counseling may prevent a more severe decrease in physical activity levels compared with receiving only recommendations on the health enhancing benefits of physical activity as assessed via accelerometer (Cody et al., 2023). The reduced decrease in physical activity over time of 10 minutes of MVPA per day elicited by the intervention may be considered clinically meaningful. That is to say, 10 minutes of physical activity per day (measured by accelerometer) is associated with a 7% decrease in yearly mortality rates according to data from the US (Saint-Maurice et al., 2022). Furthermore, evidence points towards the psychological benefits of a single bout of exercise. Albeit transient, it has the potential to enhance mood and increase psychological functioning in people with mental disorders (Meyer et al., 2016; Brand et al., 2018). Besides the reduced mortality risk and immediate psychological relevance, even small amounts of physical activity, particularly when frequently repeated in a context-specific manner, may contribute to habit formation (Bouton, 2000; Lally et al., 2010) and behavioral maintenance (Kwasnicka et al., 2016).

Interestingly, these objectively measured physical activity levels were not in line with self-reported physical activity levels in in-patients with MDD (Cody et al., 2023). According to a narrative synthesis of evidence concerning the selection, use and psychometric properties of physical activity assessment tools for people with severe mental illness, the conclusion was that objective measures may be best suited to accurately capture physical activity in this population (Soundy et al., 2014). Light physical activity is known to be underreported in people with MDD, while vigorous physical activity tends to be over-reported (Schuch et al., 2017). Despite this, in the following years, the Simple Physical Activity Questionnaire (SIMPAQ) was developed specifically for people with mental illness (Rosenbaum & Ward, 2016). According to a 23-country reliability and validity study, the SIMPAQ had good test-retest reliability and validity was assessed against accelerometer data (Rosenbaum et al., 2020). This also holds true for samples without mental illness, as exemplified in university students where accelerometer-based MVPA correlated significantly with self-reported MVPA (rho = 0.49, $p < 0.001$) measured with the SIMPAQ (Schilling et al., 2018). In the PACINPAT study, this could not be

confirmed, because accelerometer-derived physical activity levels decreased, yet according to self-report physical activity levels increased (Cody et al., 2023). These results are, however, in line with previous results from physical activity counseling in out-patients with MDD also reporting increases in self-reported physical activity after the intervention (Chalder et al., 2012). Possible reasons for higher self-reported physical activity levels compared with objectively measured levels are social desirability, the epoch length (i.e., the minimum amount of time the participant is expected to recall) and variability in the energy expenditure required for the same activity (Olds et al., 2019). With this in mind, levels of physical activity reported in the publication regarding psychosocial health and physical activity in people with MDD in the context of COVID-19 may need to be considered with caution as only self-reported physical activity is reported (Cody et al., 2021). On the other side, correlations between self-reported physical activity and health-related quality of life, physical and psychological well-being as well as social support have been found, albeit in adolescents without any known mental illness (Wunsch et al., 2021). Hence, self-reported increases of physical activity may be indicative of critical changes in relevant domains of physical, psychological and social health, even if they are incongruent with accelerometer data. To further understand the physical activity behavior patterns in the PACINPAT study, a mixed methods approach could be taken, putting self-reported and accelerometer physical activity data in relation to the four experience patterns found in the qualitative study (Cody et al., 2022b).

2.3. Physical activity counseling

Insight was gained regarding how suitable physical activity counseling is for individuals with MDD delivered during and after in-patient treatment. High satisfaction was reported with the coach and the majority (63%) of the participants who filled in the survey at follow-up would recommend physical activity counseling (Publication 3). This is corroborated by evidence from the qualitative analysis, in which participants experiencing the intervention in an expansive and adoptive way, described the support of the coach as a beneficial factor in the intervention experience. Furthermore, the counseling was reported to support systemic change and help initiate physical activity leading to, in some cases, reported increases in well-being and physical activity levels (Cody et al., 2022b). The importance of a supportive coach is in line with a further qualitative study investigating the experiences of community-based physical activity interventions (Quirk et al., 2020). Additionally, according to the implementation evaluation an acceptable rate of participants (19%) dropped out of the intervention early, i.e., after the first two in-person counseling sessions (Publication 3). However, the duration and content of

counseling sessions did already differ between those who dropped out early and those who received low and high doses of the intervention when no differences were to be expected. This may potentially indicate that these participants did not respond as well as others to this type of intervention at that point (Publication 3). This is supported by qualitative findings, suggesting that participants experiencing the intervention in a stagnant and confirmatory way, may not have fully benefitted from the physical activity counseling the way it is designed currently. One of the participants experiencing the intervention in a confirmatory way did in fact drop out of the intervention early (Cody et al., 2022b). These findings may indicate a potential for refining the intervention so that more individuals may reap the benefits of physical activity counseling.

Adapting the type and dose

One such adjustment could be an increased emphasis on implicit attitudes towards physical activity, which interestingly remained unchanged throughout the investigations carried out in this thesis (Cody et al., 2021; Cody et al., 2022a; Cody et al., 2023). One of the main symptoms of MDD is anhedonia, i.e. diminished feelings of pleasure (American Psychiatric Association, 2013) and pleasant affective responses to physical activity are linked to positive implicit attitudes (Brand & Ekkekakis, 2018). Additionally, according to the qualitative study, finding and pursuing pleasurable physical activity was mentioned as a key factor for engaging in physical activity (Cody et al., 2022b). Hence, perhaps addressing physical activity related affect in the intervention design for people with an affective disorder may be worthwhile.

To do this, physical activity counseling could be supplemented with an element of an in-person structured physical activity session. Physical activity is an experiential behavior during which immediate effects can be felt in the body, which contribute to implicit attitudes towards physical activity and ideally elicit pleasurable affect (Ekkekakis & Brand, 2021). As described in the qualitative study, people with MDD may have issues with self and body awareness (Cody et al., 2022b), potentially hampering the full impact of said experiential effects. Especially for those with more severe MDD, it could be hypothesized, that talking about performing physical activity during a counseling session may not suffice to perform the discussed activity. Hence, the unique experiential aspect of physical activity could be taken advantage of by providing such an experience first-hand. Particularly people experiencing the PACINPAT intervention in an adoptive way, reported that an in-person physical activity session would have been helpful to overcome an initial lack of motivation (Cody et al., 2022b). Such an in-person structured physical activity session could also be offered in a group, which would enhance social support, not only provided by the coach but also by peers (Murrock & Graor, 2016). As for example, in a study for out-patients with depressive, anxiety, sleep and attention-deficit/hyperactivity

disorders who received a 12-week group intervention consisting of supervised and unsupervised aerobic moderate intensity exercise as well as telephone counseling during which appropriate BCTs were delivered. Results showed increases in self-reported physical activity levels in the intervention compared with the control group (d = 1.45, p < 0.001) one to two weeks after the intervention. Additionally, self-reported depression symptoms reduced (d = 0.63, p = .031) and sleep quality increased (d = 0.61, p = .035) significantly in the intervention compared with the control group (Zeibig et al., 2021). Additionally, group-based physical activity has been reported to be preferred mode of structured physical activity for people with MDD (Machaczek et al., 2018). Group interventions have been known to improve volitional deficits (Oeland et al., 2010) and evoke a sense of obligation and not wanting to let others down, which may be beneficial for attendance (Grant et al., 2017). However, the issue of dependence needs to be addressed, as observed in the PACINPAT participants experiencing the intervention in an adoptive way, reporting that physical activity tended to cease without contact with the coach (Cody et al., 2022b). It is suggested that this could be counteracted by specifically strengthening self-efficacy during counseling sessions (Machaczek et al., 2018). Additionally, the social aspect of physical activity varies individually with some preferences for solitary physical activity (Machaczek et al., 2018; Cody et al., 2022b), which also must be taken into account.

Types of physical activity, which could be offered in an in-person physical activity session are walking, swimming, or a gym session, which have been reported as preferred activities for people with MDD (Machaczek et al., 2018). Further types of physical activity particularly fostering a mind-body connection and flow state, considered important for enjoyment of and thus engagement in physical activity (Chockalingam & Anand, 2021) may be considered especially for people with MDD (Burnett-Zeigler et al., 2016). For example, dancing is evidenced to be particularly effective in decreasing MDD symptoms through embodiment, the relationship between body and mind and the creative experience (Murrock & Graor, 2016; Hyvönen et al., 2020). Additionally, yoga is said to promote physical and mental well-being through uniting body and mind and according to a systematic review has been effective in MDD treatment (Bridges & Sharma, 2017). Lastly, when considering supplementing physical activity counseling with an in-person structured physical activity session, nature-based outdoor activities could be considered. According to meta-analytic data, being physically active outdoors may improve depressive mood (d = -0.64, 95% CI = 1.05 to -0.23) and increases positive affect (d = 0.95, 95% CI = 0.59 to 1.31; Coventry et al., 2021). One suggested working mechanism for the beneficial effects of nature on affect is the reduction in rumination with increased nature contact (Bratman et al., 2021). Further evidence suggests that green exercise,

i.e., exercise performed in nature, may have a positive effect on self-esteem (d = 0.46, 95% CI = 0.34 to 0.59) and mood (d = 0.54, 95% CI = 0.38 to 0.69; Barton & Pretty, 2010). When comparing outdoor and indoor physical activity, according to a systematic review, the former may increase levels of enjoyment (Lahart et al., 2019). Furthermore, outdoor activities in a natural environment may even be more beneficial than outdoor activities in urbanized areas (Wicks et al., 2022).

The dose of physical activity counseling may also be considered. It is known from open-ended psychotherapy that people with more severe psychopathology have longer treatment duration and exhibit slower rates of change compared with people with less severe cases. However, people with longer treatment duration also exhibited greater overall benefits (Nordmo et al., 2021). This would suggest that the required dose of physical activity counseling may also vary according to MDD severity and / or difficulty in initiating or maintaining physical activity. This is in line with findings that some motivational and volitional determinants of physical activity are negatively associated with more severe MDD symptoms (Cody et al., 2022a). An additional consideration could be to decrease the frequency of physical activity counseling gradually over time as was done in the physical activity counseling for out-patients with MDD study (Haase et al., 2010). This may also reduce the potential negative effect of dependency on the coach.

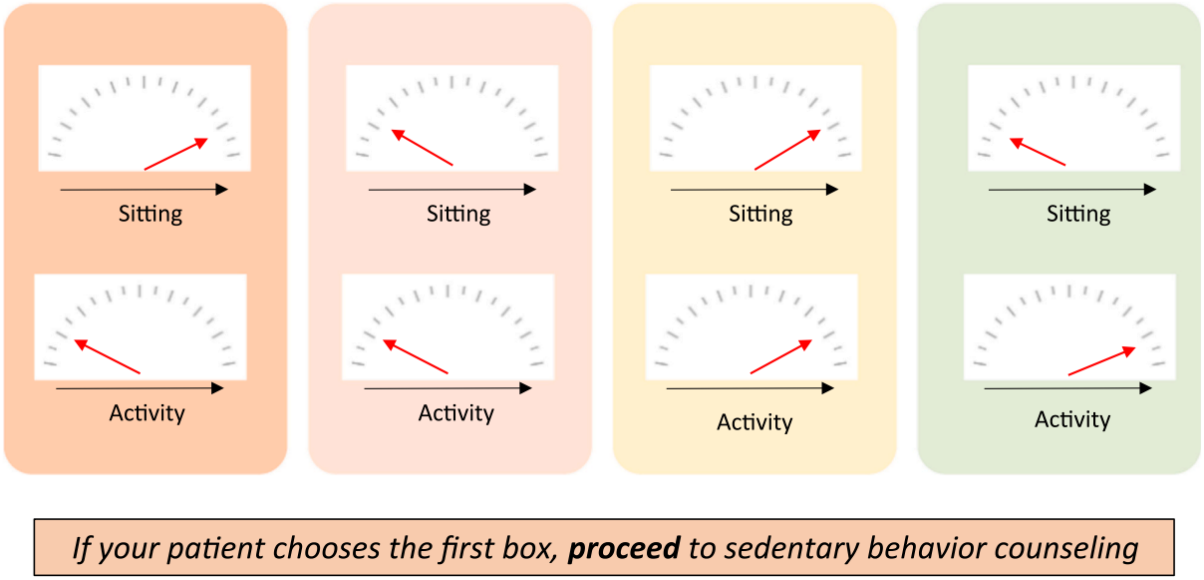
Adapting the content

Increasingly MDD is being viewed as an inherently co-morbid psychiatric diagnosis including anxiety and personality disorders, to mention only a few (Ribeiro et al., 2018). In line with this, there is a movement towards a trans-diagnostic understanding of mental health problems regarding to their onset, maintenance and treatment. As such, mental health symptoms may not align with established diagnostic boundaries used to date (e.g., the "simple" presence or absence of depression symptoms) but are more likely to be influenced by lifelong experiences (Dalgleish et al., 2020). With a broader definition of MDD, perhaps physical activity counseling could target more behaviors and include stress management and healthy eating. According to a meta-analysis of RCTs, interventions targeting multiple health behaviors in groups of youths with increased risk of MDD, had a favorable effect on depression symptoms compared with control groups (g = -0.28, 95% CI = -0.52 to 0.05; Bourke et al., 2022).

Tackling physical activity behavior in insufficiently active individuals may also be approached, not by starting with physical activity but first addressing sedentary behavior in a "sedentary behavior counseling approach". The premise being, aiding individuals in interrupting sedentary time may lead to bouts of physical activity in a step-wise approach (Dogra et al., 2022). It has been evidenced that the excessive time spent being consecutively sedentary requires even

higher volumes of MVPA (>400 minutes per week) to counteract detrimental health effects (Ekelund et al., 2016). Hence the message “sit less, move more” could be an appropriate initiation of the physical activity promotion process (Ekelund et al., 2019). Replacing sedentary time incrementally in 30-to-60 minute intervals has shown to reduce all-cause mortality and cardiovascular mortality (Del Pozo-Cruz et al., 2018). According to a narrative review, sedentary behavior counseling may be particularly valuable for people with high levels of sedentary behavior, chronic illness, and physical impairments, because achieving MVPA levels may simply not be attainable. It is proposed that initiating change in sedentary behavior may be a strategy to evade the perceived downsides of physical activity as a barrier to behavior change. Furthermore, a screening tool is proposed to identify whether an individual would profit more from sedentary behavior or physical activity counseling as seen in Figure 5. The box on the left represents predominantly sedentary behavior with low levels of physical activity, indicating the need for a “sedentary behavior counseling” approach to interrupt sedentary time. The next box represents low levels of sedentary as well as physical activity behavior, indicating the need for the promotion of light physical activity. Hence, only when levels of sedentary time have been reduced sufficiently, does it make sense to progress to promoting light levels of physical activity. The next box represents high levels of both sedentary and physical activity behavior, indicating the need for the promotion of MVPA. Lastly, the box on the right, represents low levels of sedentary behavior and high levels of physical activity, from this stage a focus may be placed on increasing fitness (Dogra et al., 2022).

Figure 5. Screening tool according to Dogra et al. (2022)



Adapting the tailoring and delivery

The intervention was tailored to physical activity related determinants (motivation and volition, and social support) of and preferences for physical activity (Gerber et al., 2019). This has proven important in physical activity counseling previously (Fischer et al., 2019). According to the results of this thesis, some psychosocial determinants are associated with MDD severity (Cody et al., 2022a). Additionally, according to the qualitative analysis, self-management during illness, i.e., coping with distressing states and reducing interference in activities of daily life, seems to be an important factor when attempting to initiate and maintain physical activity levels (Cody et al., 2022b). Self-management is known to be essential, not only for living with chronic illness but also for behavior (Lorig & Holman, 2003). So, for example, it is reported that physical activity interventions are likely not to fulfill their maximum potential if they are delivered during a "low point" (depressive episode) of cyclically recurrent MDD (Machaczek et al., 2018). Hence, it may be valuable to tailor, not only to physical activity determinants but also MDD-specific self-management. This type of tailoring may require adapting by whom the intervention is delivered. It may require a multidisciplinary approach involving experts in the field of physical activity counseling as well as mental health. This is in line with recommendations for the pandemic of physical inactivity in general, stating the need for a systems approach taking the complex interplay of physical activity correlates into account (Kohl et al., 2012). Additionally, this is in line with the more holistic definition of physical activity taking cerebral, social, situated, and political aspects of physical activity into account (Piggin, 2020). This may be of particular importance for participants experiencing the

PACINPAT intervention in a stagnant way, whose attempts at initiating and maintaining physical activity are hampered by the struggle with chronic and co-morbid illness (Cody et al., 2022b). The concept of tailoring physical activity counseling according to MDD-specific self-management is supported in further qualitative literature. It was found that the nature of MDD and comorbidities was one of the major factors linked to the initiation of physical activity. Authors conclude that physical activity promotion programs for people with MDD need to be personalized and integrated into the management of their MDD (Machaczek et al., 2022). A multidisciplinary lifestyle intervention led by psychiatrists, nurses, activity counselors, team leaders and dieticians has been implemented in in-patients with severe mental illness with the aim of reducing sedentary behavior, increasing physical activity, and improving eating habits. Data collection after 18 months of the intervention showed a significant increase in accelerometer-based MVPA ($\beta = 1.8\%$, $p = 0.03$) in the intervention group (Deenik et al., 2019). Additionally, according to a systematic review, combining physical activity with psychological treatment is recommended and is evidenced to yield more positive effects compared with treatment as usual (Thomas et al., 2020). From the perspective of mental healthcare, a multidisciplinary approach is also being urged. The recognition that physical and mental health are inextricably linked has led to the suggestion that mental health services should monitor physical health and health behaviors including lifestyle interventions to support physical activity, healthy eating and sleep hygiene in early stages of treatment (Rosenbaum et al., 2021).

2.4. Outlook on long-term effects and scaling up

In a next step, the long-term outcomes of the PACINPAT intervention will be evaluated. In this analysis, changes in the main PACINPAT study outcome accelerometer-based physical activity levels, along with physical activity determinants and cardiorespiratory fitness after the one-year physical activity counseling will be compared between the intervention and control group. This will provide insight into intervention effects delivered over a longer time period and may represent behavior in the more stable every-day life of the participants. Based on the design of the intervention, the hypothesis is that levels of physical activity and fitness will increase and physical activity determinants will be more favorable in the intervention group compared with the control group. Further intervention effects will be analyzed based on the intervention dose, which may enable a conclusion on the dose-response of physical activity counseling in this population. Besides the most frequently applied BCTs, which have already been identified, the most effective BCTs for people with MDD may be detected by analyzing intervention content in relation to long-term physical activity levels. Additionally, the other intervention elements such as the use of the mobile application and receipt of text messages can be evaluated.

Furthermore, intervention effects according to MDD severity, which has been identified as a potential moderator, will be investigated. Further mediator analyses will be conducted to see whether potential changes in physical activity levels were mediated by psychosocial determinants of and implicit attitudes towards physical activity and whether said determinants had predictive power of physical activity in the long-term. Lastly, a cost-effectiveness analysis may be conducted with data pertaining to number and duration of coaching sessions as well as the potential dose required for effectiveness. According to a systematic review of physical interventions in the mental health care setting, there is a lack of cost-effectiveness evaluations, which are necessary for the translation of research to practice (Czosnek et al., 2019). The translation of research to practice is a known issue in this field, because there is increasing evidence on the treatment of mental disorders, yet little change is observed (Stewart, 2015). In line with this, it is said that adapting and scaling up health interventions is an important step to benefit maximally from research findings and that few effective interventions are scaled up to date (Lane et al., 2021). In the public health research progression model, it is suggested that after testing for efficacy, as is done in the PACINPAT study, replication and dissemination tests should follow to increase the scale and reach of the intervention. Replication studies should focus on practical aspects of implementing an efficacious intervention in a new population or real-world setting. Dissemination studies should examine a wide roll-out in communities and systems (Milat et al., 2011). For the PACINPAT study this could mean, in a next step, that refinements as described in the Discussion of this thesis could be made and tested in more psychiatric clinics. Following refinements resulting in an efficacious intervention design a dissemination study could be conducted analyzing the new design of physical activity counseling for in-patients with MDD as an add-on to standard psychiatric treatment in Switzerland. The focus here would no longer be primarily on the outcome of the counseling intervention but on the systems in which it would be implemented and ideal conditions for long-term implementation (Bauman & Nutbeam, 2013). According to a qualitative analysis of scaling up health interventions from the perspective of policy-makers, an important factor for deciding to scale up is the support of practitioners in the health system (Lee et al., 2020). Hence, involving clinic personnel in the next step of implementation is key to ensure physical activity counseling is in line with the working environment and practitioners are in favor of a more wide-spread implementation. This includes establishing accountability structures and engagement mechanisms for the participation in the intervention (Lee et al., 2020). It is to be kept in mind, that intervention effects may reduce in a scale-up study, the so called “scale-up penalty”, which may in part be because of the real life setting in which a scale-up is

implemented, which is usually controlled for in efficacy studies. According to a systematic review a median of 59% of effect size may be lost in the scale-up of physical activity interventions (Lane et al., 2021)

2.5. Strengths and limitations

The main strength of this thesis is that multiple methods were used to evaluate the intervention. The quantitative evaluation of short-term intervention outcomes assessed physical activity levels both objectively and via self-report and physical activity determinants explicitly and implicitly. The qualitative evaluation of intervention outcomes entailed the lived experience of depression and experience of the intervention from the participants' perspective. Despite the issue with the discrepancy between objective and self-reported physical activity levels described in the discussion, information can be gained from both assessment methods. Explicit psychosocial determinants of physical activity were assessed with validated and reliable questionnaires, which have been used in prior physical activity counseling research. Implicit attitudes towards physical activity were assessed via reaction-based Single Target Implicit Associations Test (ST-IAT). This is an important distinction, because self-reports are inherently at risk of social desirability bias (Van de Mortel, 2008), whereas reaction time is more difficult to influence consciously (Libet, 1993). Furthermore, the ST-IAT as opposed to traditional Implicit Association Tests entails only a single target (Bluemke & Friese, 2008), physical activity, which is considered on a continuum (Cheng & Mao, 2016), hence presenting an opposed target is conceptually challenging. Emoticons (smileys and frownies) were used as target categories, instead of traditionally used words "good" and "bad" to ensure test accuracy irrespective of verbal abilities. Finally, the pictures selected to represent the target concept were individuals displaying no affect performing leisure time physical activity such as walking, cycling and yoga and did not have an overly athletic look, to increase the level of identification of the study sample with the target concept (Gerber et al., 2018a). Beyond intervention outcomes, its implementation and contextual influences were assessed as proposed by the MRC (Moore et al., 2015). Hence, even though the PACINPAT study is an efficacy study, typically primarily examining outcomes, the process as well as contextual factors were examined and presented in this PhD thesis.

The multifaceted intervention is a further strength of this thesis. It was based on two theoretical frameworks, tailored to the individual, delivered by trained physical activity coaches, included in-person aspects important for relationship building (Phillips et al., 2020) as well as remote aspects important for time and location efficiency (Foster et al., 2013) and was supplemented by a mobile application for self-monitoring, considered one of the most important techniques

for self-regulation and effective behavior change (Michie et al., 2009). Additionally, the intervention delivery was documented in a detailed manner by the physical activity coaches to gain insight into the active ingredient of the counseling sessions. Regular meetings with the coaches were put in place to ensure intervention fidelity and to reduce potential inter-coach variability of intervention delivery (Borrelli, 2011).

Nevertheless, there are limitations to be considered. Firstly, there is a risk of selection bias. The study population exhibited relatively high levels of MVPA both at baseline and post data assessment (Cody et al., 2023). This may be, as described, because of structured clinical setting and an increased external locus of control, however there also may be a selection bias. That is to say, those who enrolled in the PACINPAT trial, may have been more eager to increase physical activity levels and / or had a history of being physically active. This is to be considered a possibility because the physical activity inclusion criteria only took the week prior to in-patient treatment into account. Secondly, there was heterogeneity regarding duration and type of in-patient treatment as well as participation in other exercise programs offered by the clinic or privately. Specifically, in-patients were recruited at varying stages of their treatment and it could be hypothesized that this may have influenced their decision to enroll in the study and may explain some differences observed at baseline. Additional exercise programs were not controlled for in the study, yet the randomization should reduce any associated negative effect. Both the potential selection bias and heterogeneity mean that the presented results are not strictly generalizable to all in-patients with MDD. Thirdly, according to the study design the control group was not a treatment as usual group because they did receive two counseling sessions in which the health benefits of regular physical activity were discussed. This may have sufficed to elicit behavior change in some individuals. That is to say, a comparison between those who received an intervention and no intervention at all is not possible. However, this may also be seen as a strength because this is the closest form of a placebo control group in a behavioral intervention and the possibility of a nocebo effect is present in a treatment as usual group. Fourthly, also according to study design, self-reports were used to assess physical activity, psychosocial determinants and depression severity. These are all subject to recall and social desirability bias (Van de Mortel, 2008; Althubaiti, 2016). However, as described above, this risk was countered by objective methods. Namely accelerometers and a ST-IAT were used and depression symptoms were also elicited via clinical interview using the Hamilton rating scale (Hamilton, 1967). Fifthly, according to the study designs of the manuscripts relating to COVID-19 (Cody et al., 2021) and the association between physical activity determinants and MDD severity (Cody et al., 2022a), cross-sectional data were used. To definitively identify

COVID-19 elicited changes in psychosocial health, physical activity determinants and physical activity levels in in-patients with MDD, longitudinal data would be required. Regarding the associations between physical activity determinants and MDD severity, the direction of the association remains unclear because of the cross-sectional nature of the study. Lastly, according to the study design, the post data assessment took place only 6 weeks after completion of the MoVo intervention. This means that comparisons with other studies in which the duration between completion of the intervention and data assessment time point was longer need to be interpreted with caution. However, this will be addressed in the follow-up data assessment, which will take place after completion of this thesis.

Chapter 10 Perspectives & Conclusion

1. Perspectives

Looking beyond the PACINPAT study, there are advances being made in the area of physical activity counseling. Since the project preceding the PACINPAT trial named "Movingcall", in which telephone physical activity counseling was implemented and evaluated for insufficiently physically active adults (Fischer et al., 2019), a company named SalutaCoach AG was founded (https://www.salutacoach.com/). The aim is to provide individualized, holistic, and sustainable personal health coaching for increased physical activity, healthy eating, and stress management. The coaching is provided for a duration varying from 3 to 12 months, via telephone and video by trained physical activity coaches and is supplemented by a mobile application. Following a pilot project by the Swiss health insurance company SWICA in which personal health coaching was offered to employees, personal health coaching provided by SalutaCoach AG is now subsidized for those who have supplemental health insurance by not only SWICA, (https://www.swica.ch/de/magazin/themen/kundengeschichten/salutacoach) but also other Swiss health insurance companies such as Helsana and CSS. Another pilot project is being run at the Health Department of Basel-Stadt with the aim of introducing more physical activity at the workplace. In the year 2020 a Certificate of Advanced Studies (CAS) course with the title "Personal Health Coaching" was launched at the University of Basel. The curriculum includes basics of non-communicable diseases, intervention strategies, evidence for personal health coaching, behavior change theories and techniques, coaching tools, and fitness as well as health assessments. Upon successful completion of the one-year course, receipt of 12 ECTs, practical work experience and a written and oral final exam, participants of the CAS are certified personal health coaches (https://advancedstudies.unibas.ch/studienangebot/kurs/cas-personal-health-coach-238755). In 2021, personal health coaching was added to the Swiss registry for complementary medicine (Erfahrungsmedizinisches Register), which also counts as a quality label and means that certified personal health coaches are registered as official service providers in Switzerland. This registry also provides information regarding which health insurance companies partake in therapeutic costs (https://emr.ch/).

Additionally, physical activity counseling is being implemented and evaluated in different populations at the University of Basel. Since 2021, an Innosuisse funded project is being conducted providing remote physical activity counseling for people with type II diabetes. The aim of this study is to increase physical activity behavior and also promote healthy eating with

the main outcomes of objectively measured physical activity and glycated hemoglobin during a one-year intervention period including the use of a mobile application (Hohberg et al., 2022b). Furthermore, a pilot project is being planned to implement physical activity counseling in cardiac patients transitioning out of cardiac rehabilitation. These projects are being conducted with regular communication between the study coordinators to ensure, lessons learned from preceding projects are being implemented in ongoing and next projects.

In this sense, steps towards the promotion of physical activity counseling in industry including financial support within the health care system and adapted replications in different populations are being taken. However, there are still steps to be taken to bring physical activity counseling to the broader public, i.e., those typically without supplemental health care insurance as well as in primary care settings and psychiatric clinics. Along these lines, there are still open questions, which have not been addressed within the PACINPAT project. The dose-response relationship between physical activity counseling and behavior change is unknown. More specifically, the intervention duration and intervals for eliciting changes not only in outcome behavior but also of determinants said to influence behavior. This also goes for habit formation. It is not clear how long it may take people with MDD to form a habit for physical activity. Similarly, the PACINPAT study does not address the question of behavioral maintenance in people with MDD because the follow-up data assessment will take place with completion of the intervention not allowing for a no-contact period. Regarding the physical activity determinants more specifically, it remains unknown how explicit and implicit determinants of physical activity align in individuals with MDD. Finally, it would be of interest to conduct a qualitative analysis of those in-patients who were eligible to participate in the PACINPAT intervention yet decided not to participate. It would be valuable to find out what was not appealing about this specific intervention, and what would help to become more active in general.

2. Conclusion

This thesis constitutes a process evaluation of a theory-based, tailored physical activity counseling intervention for in-patients with MDD delivered in-person and remotely, which was implemented within the PACINPAT trial. The development and implementation of this intervention was motivated by the fact that individuals with MDD in particular exhibit less physical activity behavior compared with peers without MDD and do not meet physical activity recommendations (Schuch et al., 2017), despite the potential therapeutic effect of physical activity (Stubbs et al., 2018). Increasing physical activity levels in this population could lead to

decreases in MDD-specific symptoms and risk of future relapses (Hoffman et al., 2011; Mammen & Faulkner, 2013; Kvam et al., 2016); increased quality of life (Zamani Sani et al., 2016); protection against other chronic illness and all-cause mortality (Katzmarzyk et al., 2022) and decreased health care costs (Hafner et al., 2020). To date, physical activity counseling, an effective method of physical activity promotion, has not been implemented and evaluated during and after in-patient treatment for people with MDD. This thesis provides insights, not only into the efficacy of physical activity counseling on accelerometer-based physical activity levels but also into contextual factors shaping how the intervention works, implementation of the intervention, and the mechanism of impact. Thus providing a comprehensive understanding of the intervention in this population and setting.

In conclusion, the COVID-19 induced lockdown, which took place approximately one year into the three-year recruitment period, seemed not to elicit differences in psychosocial health, psychosocial determinants of and implicit attitudes towards physical activity or self-reported physical activity levels. Severe MDD symptoms were associated with lower levels of self-efficacy, intrinsic motivation and action and coping planning as well as higher levels of introjected and external motivation, negative outcome expectancies and perceived barriers compared with those with mild and moderate MDD symptoms. The intervention dose varied among participants and those who already dropped out after the first two counseling sessions, were recognizable by shorter counseling sessions and different intervention content (physical activity plans were discussed less frequently) compared with those who continued with the remote intervention. Varying experiences of the intervention were identified: (i) expansive with increased well-being and maintained physical activity, (ii) adoptive with fragile well-being with relationship-dependent physical activity, (iii) stagnant with declining well-being with a shift away from physical activity and (iv) confirmatory with unchanged well-being and physical activity behavior. Finally, MVPA and step count in the intervention group decreased less from baseline to post data assessment compared with the control group while psychosocial determinants of and implicit attitudes towards physical activity remained seemingly unchanged by the intervention.

Suggestions for intervention refinement were made including supplementing physical activity counseling with an in-person structured physical activity session, tailoring according to MDD severity and self-management, taking a multidisciplinary delivery approach, targeting other health behaviors, and starting with sedentary behavior counseling. Additionally, the importance of translating research into practice and steps taken so far were presented.

Overall, this thesis provides knowledge regarding intervention design with concrete suggestions for refinement and further implementation of physical activity counseling in in-patients with MDD, a population for which there are scarce guidelines to date.

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Appendix

Contributors

The PACINPAT trial was a cooperation between two divisions of the Department of Sport, Exercise and Health at the University of Basel, namely the Sport Science Division led by Prof. Dr. Markus Gerber and the Exercise and Movement Division formerly led by Prof. Dr. Lukas Zahner and currently by Prof. Dr. Oliver Faude (*ad interim*). Also, it involved the commitment of four psychiatric clinics, namely the Adult Psychiatric Clinics (UPKE) of Basel represented by Prof. Dr. med. Undine Lang and Dr. med. Nina Schweifruth, the Psychiatric Clinic Sonnenhalde AG represented by Dr. med. Anja Oswald, PD Dr. med. Johannes Beck and Dr. Anja Rogausch, the Psychiatric Services in Solothurn represented by Prof. Dr. med. Martin Hatzinger and PD Dr. med. Thorsten Mikoteit, and the Private Clinic Wyss represented by Dr. med. Christian Imboden and Dr. Sarah Mans. Funding was acquired from the Swiss National Science Foundation by Prof. Dr. Markus Gerber as principal investigator along with Prof. Dr. Lukas Zahner, Prof. Dr. Oliver Faude, PD Dr. Serge Brand and Prof. Dr. med. Undine Lang. The Neurobiological Laboratory of the University of Basel led by Prof. Dr. Anne Eckert was involved in processing and assessing blood samples. Prof. Dr. Lars Donath, from the German Sport University Cologne and PD Dr. Sebastian Ludyga from the Department of Sport, Exercise and Health at the University of Basel were involved in the study design and added their expertise in the development of the manuscripts. Dr. Xenia Fischer, who designed, implemented, and evaluated the preceding project “Movingcall” served as an advisor for the proceedings in the PACINPAT study. Sofia Rey contributed to the initial setup of the PACINPAT study. Jan-Niklas Kreppke contributed to the implementation of the intervention, participant recruitment and data collection as part of his doctoral dissertation. Dr. Dunja Nicca contributed her valuable time and expertise in developing and overseeing the embedded qualitative study. Daniel Vogel and Andrew Usov developed the PACINPAT mobile application. Finally, the physical activity coaches who implemented the intervention are: Marcia De Witte, Sara Fischer, Adina Hauser, Michael Christensen, Sira Heimgartner, Arnold Marti, Anja Wigger, Reto Maurer, Lilja-Sophie Rhodius, Laura Wechsler and Nadine Kügerl.

Curriculum Vitae

Robyn Cody

1. Personal information

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Nationality: Swiss and Irish
Date of birth: March 14th 1991
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Twitter: @robyn__cody

2. Education

June 2018 – Jan 2023	**PhD Candidate**, Department of Sport, Exercise and Health, University of Basel, CH Supervisors: Prof. Dr. Markus Gerber & Prof. Dr. Lukas Zahner Member of the PhD Program Health Sciences (PPHS) Dissertation title: Process evaluation of a lifestyle physical activity counseling intervention for in-patients with major depressive disorders
Sep 2015 – Sep 2017	**Master of Arts in Health Sciences**, University of Lucerne, CH Final grade 5.49/6, supervisors: Prof. Dr. Armin Germperli & Dr. Stefan Essig
Sep 2011 – Sep 2015	**Bachelor of Science in Midwifery**, University of Applied Sciences, Winterthur, CH Final grade 5.19/6, supervisor: Regula Hauser

3. Employment history

June 2018 – Jan 2023	**Research assistant & PhD candidate** in SNSF funded project: Physical activity counseling in in-patients with depression (PACINPAT) - a multi-centred randomised controlled trial (PI/advisor: Prof. Dr. Markus Gerber) Department of Sport, Exercise and Health, University of Basel, CH
Aug 2017 – Feb 2018	Employment in hospitality industry, SPiS AB, Kiruna, SE
June 2016 – Sep 2016	**Graduate research assistant**, Institute for Primary and Community Care, Lucerne, CH, Advisor: Dr. Stefan Essig
Aug 2014 – Sep 2015	**Midwife**, Kantonsspital Basel-Land, Basel, CH
June 2011 – July 2011	**Administrative assistant**, Recruitment Services, Syngenta Crop Protection AG, Basel, CH

4. Institutional responsibilities

Since 2022	Member of the emergency and event organization team

5. Approved research projects

Not applicable

6. Supervision of junior researchers

Sep 2019 – Oct 2022	4 Master theses (Reto Maurer, Arnold Marti, Michael Christensen, Laura Wechsler) 4 Bachelor theses (Sira Heimgartner, Michael Christensen, Matteo Gini, Flavia Bachofer)

7. Teaching activities

Dec 2018 – Oct 2022	Personal Health Coaching seminar for Bachelor students: Physical activity counseling for people with depression, University of Basel
Sep 2020 – Aug 2022	Personal Health Coaching for Certificate of Advanced Studies: Behavior change theories and tailored health communication, University of Basel

8. Memberships in panels, boards and individual scientific reviewing activities

Sep 2019	BMC Women's Health
June 2022	International Journal of Nursing Studies
August 2022	International Review of Sport and Exercise Psychology
October 2022	Frontiers in Sports and Active Living
December 2022	Psychology of Sport and Exercise

9. Active memberships in scientific societies

Since 2021	Swiss Society for Sport Science (SGS)
Since 2021	Swiss Society for Sport Psychiatry and Psychotherapy (SGSPP)
Since 2021	German Society for Sport Psychology (ASP)

10. Organization of conferences

Not applicable

11. Prizes, awards, fellowships

Feb 2022	University of Basel for participation in the Antelope Career Program (4'000 CHF)
Aug 2021	Swiss Society for Sport Science for organization of an online Seminar titled "From behaviour change theory to interventions and their implementation - what is needed to promote physical activity?" (500 CHF)
Oct 2021	Travel fund for young academics University of Basel for attendance at a Junior Research event organized by the German Society for Sport Psychology (ASP), Eberhard Karls Universität Tübingen (D) (160 CHF)

June 2019	Travel fund for young academics University of Basel for attendance at a Junior Research event organized by the German Society for Sport Psychology (ASP), Martin-Luther-Universität Halle-Wittenberg (D) (479 CHF)
Apr 2019	Travel fund for young academics University of Basel for attendance at a conference at the Centre for Behavior Change, University College London (UK) (325 CHF)

12. Personal skills

Languages	English: native proficiency German: native proficiency Swedish: intermediate proficiency
Computer	MS Office (Word, Excel, Outlook, Powerpoint) Stata, SPSS, MAXQDA

13. Career breaks

Not applicable

14. Additional training (20 ECTs)

Nov 2018	Fundamental concepts in epidemiology, Institute of Social and Preventive Medicine, Bern (2 ECTs)
Sep 2019	Composing attractive abstracts in natural and life sciences, University of Basel
July 2019	Junior Research Workshop, German Society for Sport Psychology (1 ECT)
Oct 2019	Articles in the life sciences and natural sciences, University of Basel
Nov 2019 – Dec 2019	Academic writing in health sciences, University of Basel (1 ECT)
Nov 2019	Introduction to statistical software Stata and electronic data capture software REDCap, Institute of Social and Preventive Medicine, Bern (1 ECT)
Feb 2020 – May 2020	Seminar: Statistics II – theory and application, University of Basel (3 ECTs)
Feb 2020	Intercultural communication, University of Basel (1 ECT)
Feb 2020 – May 2020	Higher education and research in the US, Europe and Switzerland, University of Basel (1 ECT)
July 2020	Introduction into multilevel modelling of clustered data, University of Basel (1 ECT)
Sep 2020 – Jan 2021	Teaching my first course with focus on digital teaching, University of Basel (1 ECT)
Oct 2020 – Nov 2020	Basics in literature research: PubMed and other resources, Swiss Tropical and Public Health Institute
Sep 2020 – Nov 2020	Cooperation in the perspective of evolutionary biology, economy, philosophy and theology, University of Basel (3 ECTs)
Feb 2021 – March 2021	Communicate efficiently – collaborate constructively, University of Basel (1 ECT)
July 2021	Observational epidemiology: advanced methods for data and exposure-response analyses, Swiss Tropical and Public Health Institute (2 ECTs)
Oct 2021	Verstehen verstehen: Einführung in die praktische Hermeneutik
Nov 2021	Ethics of science
Jan 2022	Behavior change interventions, University College London (1 ECT)
Jan 2022	Career planning for doctoral researchers, University of Basel (1 ECT)
Apr 2022 – May 2022	Science communication on social media
May 2022	How to deal with your data: research data management

Research Output List

Robyn Cody

1. Publications in peer-reviewed scientific journals

Cody R, Beck J, Brand S, Donath L, Faude O, Hatzinger M, Imboden C, Kreppke J-N, Land U E, Ludyga S, Mans S, Mikoteit T, Oswald A, Schweinfurth N, Zahner L, Gerber M. Short-term outcomes of physical activity counseling in in-patients with Major Depressive Disorder: Results from the PACINPAT randomized controlled trial. Frontiers in Psychiatry. **2023**; 13. Link: https://doi.org/10.3389/fpsyt.2022.1045158

Gerber M, Jakowski S, Kellmann M, **Cody R**, Gygax B, Ludyga S, Müller C, Ramseyer S, Beckmann J. Macronutrient intake as a prospective predictor of depressive symptom severity: An exploratory study with adolescent elite athletes. Psychology of Sport and Exercise. **2023**, 102387. Link: https://doi.org/10.1016/j.psychsport.2023.102387

Hohberg V & Kreppke J-N, **Cody R**, Guthold R, Woods C, Brand R, Dunton G, Rothman A, Ketelhut S, Nigg C. What is needed to promote physical activity? Current trends and new perspectives in theory, intervention, and implementation. Current Issues in sport Science. **2022**;7, 005. Link: https: https://doi.org/10.36950/2022ciss005

Cody R, Beck J, Brand S, Donath L, Eckert A, Faude O, Hatzinger M, Holsboer-Trachsler E, Imboden C, Kreppke J-N, Lang U E, Ludyga S, Mans S, Mikoteit T, Oswald A, Pühse U, Schweinfurth N, Zahner L, Gerber M. Depression severity and psychosocial determinants of physical activity behavior in in-patients with major depressive disorders. Psychology of Sport and Exercise. **2022**;63, 102294. Link: https://doi.org/10.1016/j.psychsport.2022.102294

Cody R, Christensen M, Kreppke J-N, Faude O, Gerber M, Nicca D. The experience of a physical activity counseling intervention among people with major depression within the PACINPAT trial – A reflexive thematic analysis. Mental Health and Physical Activity. **2022**; 23, 100464. Link: https://doi.org/10.1016/j.mhpa.2022.100464

Schilling R, **Cody R,** Ludyga S, Brand S, Faude O, Pühse U, Gerber M. Does dispositinal self-control moderate the association between stress at work and physical activity after work? A real-life study with police officers. German Journal of Exercise and Sport Research. **2022**;52(290-299).
Link: https://doi.org/10.1007/s12662-022-00810-5

Schnider L, Schilling R, Cody R, Kreppke J-N, Gerber M. Effects of behavioural skill training on cognitive antecedents and exercise and sport behaviour in high school students: a cluster-randomised controlled trial. International Journal of Sport and Exercise Psychology. **2022**:1-23.
Link: https://doi.org/10.1080/1612197X.2021.1877329

Cody R, Kreppke J-N, Beck J, Donath L, Eckert A, Imboden C, Hatzinger M, Holsboer-Trachsler E, Lang U E, Ludyga S, Mans S, Mikoteit T, Oswald A, Rogausch A, Schweinfurth N, Zahner L, Faude O, Gerber M. Psychosocial Health and Physical Activity in People With Major Depression in the Context of COVID-19. Frontiers in Sports and Active Living. **2021**;3(311).
Link: https://doi.org/10.3389/fspor.2021.685117

Coimbra M, **Cody R**, Kreppke J-N, Gerber M. Impact of a physical education-based behavioural skill training program on cognitive antecedents and exercise and sport behaviour among adolescents: a cluster-randomized controlled trial. Physical Education and Sport Pedagogy. **2021**;26(1):16-35.
Link: https://doi.org/10.1080/17408989.2020.1799966

Gerber M, Claussen M, **Cody R**, Imboden C, Ludyga S, Scherr J, Seifritz E, Känel R. Cardiovascular disease and excess mortality in depression: physical activity as a game changer. Deutsche Zeitschrift für Sportmedizin. **2021**(72):261-70. Link: https://doi.org/10.5960/dzsm.2021.498

Cody R, Gysin S, Merlo C, Gemperli A, Essig S. Complexity as a factor for task allocation among general practitioners and nurse practitioners: a narrative review. BMC Family Practice. **2020**;21(1):38.
Link: https://doi.org/10.1186/s12875-020-1089-2

Colledge F, **Cody R**, Buchner UG, Schmidt A, Pühse U, Gerber M, Wiesbeck G, Lang U E, Walter M. Excessive Exercise-A Meta-Review. Front Psychiatry. **2020**;11:521572.
Link: https://doi.org/10.3389/fpsyt.2020.521572

Colledge F, **Cody R**, Pühse U, Gerber M. Responses of fitness center employees to cases of suspected eating disorders or excessive exercise. Journal of Eating Disorders. **2020**;8(1):8.
Link: https://doi.org/10.1186/s40337-020-0284-9

Gerber M, Beck J, Brand S, **Cody R**, Donath L, Eckert A, Faude O, Fischer X, Hatzinger M, Holsboer-Trachsler E, Imboden C, Lang U, Mans S, Mikoteit T, Oswald A, Pühse U, Rey S, Schreiner A-K, Schweinfurth N, Spitzer U, Zahner L. The impact of lifestyle Physical Activity Counselling in IN-PATients with major depressive disorders on physical activity, cardiorespiratory fitness, depression, and cardiovascular health risk markers: study protocol for a randomized controlled trial. Trials. **2019**;20(1):367.
Link: https://doi.org/10.1186/s13063-019-3468-3

2. Peer-reviewed books/monograph (incl. published doctoral thesis)

Not applicable

3. Peer-reviewed conference proceedings

Not applicable

4. Contributions to books

Not applicable

5. Patents and licenses

Not applicable

6. Contributions to conferences

Oral presentation

Cody R, Kreppke J-N, Faude O, Gerber M. Short-term effects of in-person and remote physical activity counseling in people with depression. European Congress of Sport and Exercise Psychology in Padova, Italy in July **2022**. Presented by **Cody R**

Cody R, Kreppke J-N, Faude O, Gerber M. Physical activity coaching: How can behavior change be achieved by individually tailored coaching? International Conference on Sports Psychiatry online in January **2022**. Presented by **Cody R**

Cody R. What moves you? Das Bewegungsverhalten bei depressiven Störungen. German Society for Sport Psychology (ASP) Conference in Tübingen, Germany in September **2021**. Presented by **Cody R**

Cody R, Beck J, Brand S, Donath L, Eckert A, Faude O, Fischer X, Hatzinger M, Holsboer-Trachsler E, Imboden C, Kreppke J-N, Lang U, Mans S, Mikoteit T, Oswald A, Pühse U, Rogausch A, Schweinfurth N, Zahner L, Gerber M. Vergleich der körperlichen Aktivität und deren Determinanten bei körperlich inaktiven, depressiven Patienten und körperlich inaktiven, gesunden Probanden. Swiss Society for Sport Psychiatry and Psychotherapy Conference online in July **2021**. Presented by **Cody R**

Cody R, Kreppke J-N, Faude O, Gerber M. Face-to-face and remote physical activity counselling in in-patients with major depressive disorders – The PACINPAT randomized controlled trial. Swiss Society for Sport Science (SGS) Conference in Basel, Switzerland in February **2020**. Presented by **Cody R**

Cody R, Beck J, Brand S, Donath L, Eckert A, Faude O, Fischer X, Hatzinger M, Holdboer-Trachsler E, Imboden C, Lang U, Mans S, Mikoteit T, Oswald A, Pühse U, Rey S, Schreiner A-K, Schweinfurth N, Spitzer U, Zahner L, Gerber M. Persönliche und telefonische Beratung zum Aufbau eines körperlich aktiven

Lebensstils bei depressiven Patienten in stationärer Behandlung: Die PACINPAT-Studie. PSY Congress in Bern, Switzerland in September **2019**. Presented by **Cody R**

Poster

Cody R, Christensen M, Kreppke J-N, Faude O, Gerber M, Nicca D. The lived experience of a physical activity counseling intervention to promote physical activity among people with major depression – A qualitative study. Swiss Society for Sport Science (SGS) Conference online in February **2022**. Presented by **Cody R**

Cody R, Rey S, Zahner L, Gerber M. Face-to-face and remote physical activity counselling in in-patients with major depressive disorders. German Society for Sport Psychology (ASP) Conference in Halle, Germany in May **2019**. Presented by **Cody R**

Cody R, Rey S, Gerber M, Zahner L. Face-to-face and remote physical activity counselling in in-patients with major depressive disorders. Centre for Behavior Change Conference in London, UK in April **2019**. Presented by **Cody R**

7. Outreach activities

Kreppke J-N, **Cody R**, Faude O, Gerber M. Freude durch Sport und Bewegung bei psychischen Erkrankungen. Praxis **2022**; 111(4): 200-204
Link: https://econtent.hogrefe.com/doi/10.1024/1661-8157/a003830

Cody R. Determinanten körperlicher Aktivität bei Personen mit depressiven Störungen. Referat SGPP 2021. Leading Opinion in Neurologie & Psychiatrie 5/**2021**.

Kreppke J-N, **Cody R**, Faude O, Gerber M. Sport als Therapie bei Depressionen. Fortbildung in Neurologie & Psychiatrie 1/**2021**. Link: https://www.rosenfluh.ch/media/psychiatrie-neurologie/2021/01/Sport-als-Therapie-bei-Depressionen.pdf

Cody R & Kreppke J-N. Die PACINPAT Studie – Zwischenresultate. Presentation in the clinic Sonnenhalde AG – Psychiatrie und Psychotherapie, **2021**. Presented by **Cody R.**

Cody R, Gerber M, Kreppke J-N, Faude O. Was bewegt Depressive – Sport und Depression. Kerbe - Forum für soziale Psychiatrie Heft 3, Themenschwerpunkt: Depression – erschöpftes Selbst, erschöpfte Gesellschaft. Publiziert: 17. Juli **2020**.
Link: https://www.kerbe.info/inhalt/kerbe-forum-fuer-soziale-psychiatrie-heft-3-2020/

Kreppke J-N, **Cody R**, Imboden C, Faude O, Gerber M. The PACINPAT study: physical activity counselling in in-patients with major depressive disorders. Sport & Exercise Medicine Switzerland Journal. Published online 24.08.**2020**
Link: https://sems-journal.ch/8497

8. General contributions to science

Not applicable

9. Other artefacts with documented use

Not applicable

10. Submitted but not yet accepted/published publications

Cody R, Maurer R, Kreppke J-N, Fischer X, Wechsler L, Rhodius L-S, Kügerl N, Faude O, Beck J, Brand S, Hatzinger M, Imboden C, Lang U E, Mans S, Mikoteit T, Oswald A, Schweinfurth N, Gerber M. An implementation evaluation of the physical activity counseling in in-patients with major depressive disorder (PACINPAT) trial. (submitted to BMC Psychiatry: August 2022, under review since Sepember 2022