



CLINICAL PSYCHOLOGY IN EUROPE

The Official Academic Journal of the
European Association of Clinical Psychology
and Psychological Treatment

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Shifting Our Perspective for the Future of Assessment and Intervention Science

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A big chunk of my early years in graduate school was spent learning about psychopathology and the diagnostic systems that categorize these. We learned about prevalence, contributing factors, how to assess and differentially diagnose individuals with psychopathological problems. When I started my clinical work, I was shocked to encounter that the reality of clinical practice was far from the information I learned in my psychopathology courses. Almost all clients, would not fit properly under one diagnosis, comorbidity was the norm, and I discovered that assigning a diagnosis was not particularly helpful for my case conceptualizations and choice of treatment. Since those days, even though I have seen hundreds of patients, I am still looking for the classic book example of a panic patient. As for depression, it is fascinating to me that I can give the same diagnosis to a patient who presents with loss of appetite, low energy, excessive sleepiness, and catatonic-like symptoms, as to a patient who presents with concentration difficulties, increased appetite, difficulty sleeping, and restlessness. How does our training in a topographical approach to psychological suffering with the search for syndromes (collection of signs and symptoms) prepare us for clinical practice and effective intervention? What are our diagnostic systems useful for? Interestingly, even the task force on DSM-5 ([American Psychiatric Association, 2013](#)) acknowledges the shortfall of this approach in “uncovering etiologies”, recommending intervention strategies, and have gone as far as to propose that a “paradigm shift may need to occur” ([Kupfer, First, & Regier, 2002](#)).

Beyond assessment and diagnosis, in the realm of treatment, psychological intervention training is driven by theories, traditions, or schools of thought (e.g., cognitive-behavioral, humanistic, psychodynamic). In training and education, we focus on teaching students’ tools, techniques, and approaches, almost like cookbooks, ignoring that the



reality of practice or even cooking, is far from the strict following of a specific mechanistically applied set of tools. Inflexible and strict devotion to a particular approach has hindered scientifically based development of psychotherapy, has propagated bias and impeded progress and communication among therapists, and has prevented the investigation of common mechanisms that may drive therapeutic changes in individuals who suffer and seek services (Hofmann, 2020; Rief, 2021). Going back to the reality of human suffering, if we examine the World Health Organizations' top 10 diseases causing the most deaths worldwide (WHO, 2020a, 2020b), we will notice that these include heart disease, stroke, chronic obstructive pulmonary disease, respiratory infections, neonatal conditions, lung-related cancers, Alzheimer's and dementia, diarrheal diseases, diabetes, and kidney diseases. What is common among all these top killers? Common to all these are maladaptive health-related behaviors, dysfunctional coping, and behaving and all can be aided with the realm of the work we do as clinical psychologists- behavior change. Yet, despite important scientific advances, current treatments are hindered by these dysfunctional behaviors and clinicians' inability to help patients overcome them. Therefore, a change of perspective is needed on how we approach human suffering, and under what circumstances, how and where we intervene.

One such new perspective shift came from The National Institute of Health (NIMH, 2021) RDoC framework. This approach aimed to examine psychopathology as dysregulation of particular neurobiological and behavioral systems, including affective valence systems, cognitive systems, social systems, attachment processes, and arousal systems (Cuthbert, 2014). The goal is to translate progress in behavioral and neuroscience to improve understanding of psychopathology and develop new and tailored treatments. It remains to be seen whether this framework will prove helpful in remedying the problems posed above. Another recent development comes from Hofmann and Hayes (2019, p. 47), who are extending the question posed by Gordon Paul in 1969 and ask: "What core biopsychosocial processes should be targeted with this client given this goal, in this situation, and how can they most efficiently and effectively be changed?". With this question and their new conceptual developments of a process-based approach couched within the umbrella of evolutionary science, they raise a different claim (see Hayes, Hofmann, & Ciarrochi, 2020). In this approach, assessment procedures and therapy can and should be linked via mechanisms of action implicated in the maintenance and treatment of suffering and the promotion of well-being.

Research from my laboratory and others around the world are presently attempting to establish necessary parameters so as to be able to result in directly linking mechanisms of action (change processes via which psychotherapeutic change can occur) with intervention choices and outcomes in an iterative, bottom-up manner. We recently proposed that a successful coupling of assessment and treatment depends on the basic core mechanisms of action identified and measured (Gloster & Karekla, 2020). Such candidate mechanisms need to: 1) be malleable and amenable to experimental manipulation, 2)

demonstrate robustness across contexts, 3) be tested across time ideographically, and 4) be tested across multiple levels of analysis (e.g., biological, genetic, psychophysiological, and behavioral). Adopting such a multi-method, multi-level perspective in the exploration of mechanisms of action can move us towards functional process-based alternatives to approaching human suffering. When this is couched within a coherent theory such as that of evolutionary science (see Hayes, Hofmann, & Ciarrochi, 2020), we may be able to achieve meaningful progress towards our aim of better serving the humans who suffer and seek our services. I hope that as a field we will shift our perspective to a more functional, contextualistic, and process-based approach for the future of our assessment and intervention science.

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Widespread Recommendations Can Change Our Habits of Hand-Washing and Physical Distance During the COVID-19 Pandemic

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Supplementary Materials: Materials [see [Index of Supplementary Materials](#)]



Abstract

Background: Habits and behaviors in everyday life currently need to be modified as quickly as possible due to the COVID-19 pandemic. Two of the most effective tools to prevent infection seem to be regular and thorough hand-washing and physical distancing during interpersonal interactions.

Method: Two hundred and eighty-four participants completed a short survey to investigate how previous habits regarding hand-washing and physical distancing have changed in the general population as a function of the current pandemic and the thereby increased information and constant recommendations regarding these behaviors.

Results: Participants aged 51 and older reported a greater change in everyday hand-washing behavior than younger participants. In addition, participants aged 31 and older selected significantly greater distances to have a conversation than younger participants. However, that was not the case if participants had to actively stop their conversational partner from approaching.

Conclusion: Participants aged 51 years and older seem to be well aware of their at-risk status during the current pandemic and might therefore be willing to change their behavior more strongly than younger survey participants. Nevertheless, they seem to struggle with enforcing the current rules towards others. The group aged between 31 and 50 years, however, reports a



comparable level of fear, but no corresponding change in hand-washing behavior. Future surveys should try to provide more insight into why this might be the case.

Keywords

COVID-19 pandemic, everyday habits, hand-washing, physical distancing

Highlights

- Habits and behaviors need to be modified quickly during the current COVID-19 pandemic.
- Participants aged 51 years and older seem to be willing to change their behavior more strongly.
- However, they seem to struggle with enforcing some of the current rules towards others.

The current COVID-19 pandemic forces us to change our everyday lives and associated habits as quickly as possible. Regular thorough hand-washing and physical distancing have been recommended as two of the most effective tools to prevent infection (Bundeszentrale für gesundheitliche Aufklärung, 2020). Habits regulating these behaviors, however, are triggered by similar contextual circumstances, can be implemented using minimal resources, and can be used to predict future behavior in a similar situation (for a review see Ouellette & Wood, 1998). Habitual behavior thus needs to be modified by consciously inhibiting previously established habitual behavior and implementing alternative responses (for a review see Gardner, 2015). Social psychological models furthermore suggest that social behavior is not only driven by a reflective system based on consequences and probabilities, but also by an impulsive system based on spreading activation (Strack & Deutsch, 2004), which can cause fear to at least co-determine behavior.

Regular thorough hand-washing is already recommended during periods of increased probability of infections to prevent the spreading of infectious diseases like influenza (Bundeszentrale für gesundheitliche Aufklärung, 2018). Previous population-based research, however, does not show a clear reduction in influenza transmission (Simmerman et al., 2011) or acute respiratory tract infections (Merk, Kühmann-Berenzon, Linde, & Nyrén, 2014) as a function of self-reported hand-washing. Of note, the latter investigation suggested a protective effect for health-care workers, leading the authors to conclude that the knowledge regarding adequate hand-washing might be insufficient in the general population.

We implemented a short survey to investigate how previous habits regarding hand-washing were changed in the general population as a function of the current pandemic and the thereby increased information and constant recommendations regarding adequate hand-washing. We also assessed whether the general public is aware of and able

to follow further recommendations, particularly with regard to physical distancing in interpersonal situations.

Method

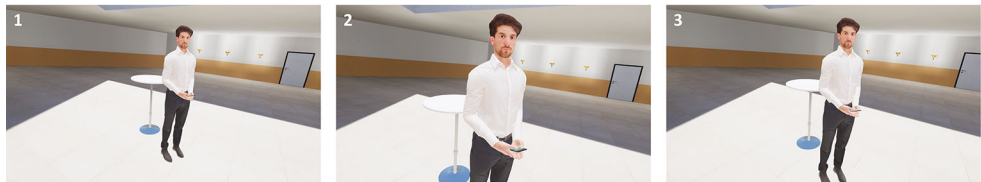
Assessment

Data were collected for the duration of twelve days, starting on the day of the implementation of movement restrictions in Bavaria (March 21st, 2020) and ending on April 1st. The questionnaire was implemented via EvaSys (Electric Paper Evaluationssysteme GmbH, Lueneburg, Germany), an online questionnaire tool operated by the University of Regensburg. It consisted of seven questions assessing the frequency of hand-washing in different situations as well as possible changes since the outbreak of the corona virus SARS-CoV-2. Situations were chosen to cover a range of everyday situations, in which hand-washing is recommended (before eating, after entering your flat/house, after blowing your nose, after coughing/sneezing in your hand, after touching another person not living in the same household, after touching an object that is also touched by other people) as well as a baseline item (after using the bathroom). Participants were asked to report both the frequency of and the change in hand-washing in these situations on a five-point scale (“0 = never” to “4 = always” and “0 = unchanged” to “4 = very much more”, respectively). Data were aggregated to form mean scores across situations with self-reference (before eating, after entering your flat/house, after blowing one’s nose, after coughing/sneezing in your hand) and with other-reference (after touching another person/an object touched by other people), both for frequency and change since the outbreak of the virus.

In addition, the questionnaire assessed the use of soap/disinfectant, the adherence to further recommendations to avoid infection (not touching one’s face and physical distancing), the subjective importance of following the recommendations regarding hand-washing, and the attention to observing adequate physical distance during interactions. Participants were also asked to select interpersonal distances where they a) were currently most comfortable with (passive distancing) and b) would stop someone else from approaching (active distancing) from one of three standardized virtual reality pictures showing an agent at the distances of 1m, 1.5m, and 2m (see [Figure 1](#)), which were taken as still frames from a Virtual Reality scenario (VTplus GmbH, Würzburg, Germany). Furthermore, participants’ fear of COVID-19 for themselves and for relatives as well as the incidence of pathological hand-washing as occurring in obsessive compulsive disorder (OCD; i.e. washing one’s hands more frequently and longer than necessary) were assessed.

Figure 1

Virtual Reality Pictures Used in the Assessment of Physical Distancing



Note. Standardized pictures from virtual reality with an agent at the distances of 1.5m (1), 1m (2), and 2m (3) taken from an experimental VR-paradigm, joint project OPTAPEB. ©VTplus.

Participants were informed beforehand that participation in the survey was entirely voluntary and that they could end the survey at any time, in which case no data were transmitted. To comply with current regulations of data protection and to ensure de facto anonymity, age was only collected in the form of age ranges (5 years per range except for 18 to 21 years). Care was furthermore taken to keep the survey as short as possible and to not include questionnaires that might cause distress in survey participants (e.g. assessing mental health problems). All participants gave their informed consent to participate in the survey.

A link to access the questionnaire was distributed via personal contacts, social media, university mailing lists, and a press release on the university's home page.

Participants

A total of 284 adults (205 women) between 18 and 75 years of age participated in the survey. While participants' place of residence was not obtained to ensure anonymity, 93.7% of the sample (266 participants) reported movement restrictions at their place of residence when taking the survey. As this was not the case for 62.5% of the German federal states at the time of data collection (Steinmetz, Batzdorfer, & Bosnjak, 2020), it is likely that most participants lived in Bavaria at the time of the survey. Overall, 72.2% of participants were aged 40 years or younger, with the largest percentage of participants (30.6%) in the 21 to 25 years age group. To facilitate analyses, participants were assigned to one of the age groups: "young age" (YA, 18-30 years of age; 150 participants); "middle age" (MA, 31-50 years of age; 86 participants), and "best/older age" (OA, >50 years of age; 48 participants). The category "best/older age" was chosen to include all participants with a theoretically increased risk for severe or critical course of COVID-19, as the Robert Koch-Institute lists older people as having a steadily increased risk for a severe course of the disease, starting at age 50 to 60. (Robert Koch-Institut, 2021). There was a trend for a greater proportion of women in the YA group, $\chi^2(2) = 5.2, p = .074$; see Table

1 for descriptive data. Most participants (78.9%) reported high-school level education (*Abitur*), with 39.4% of the sample currently attending university.

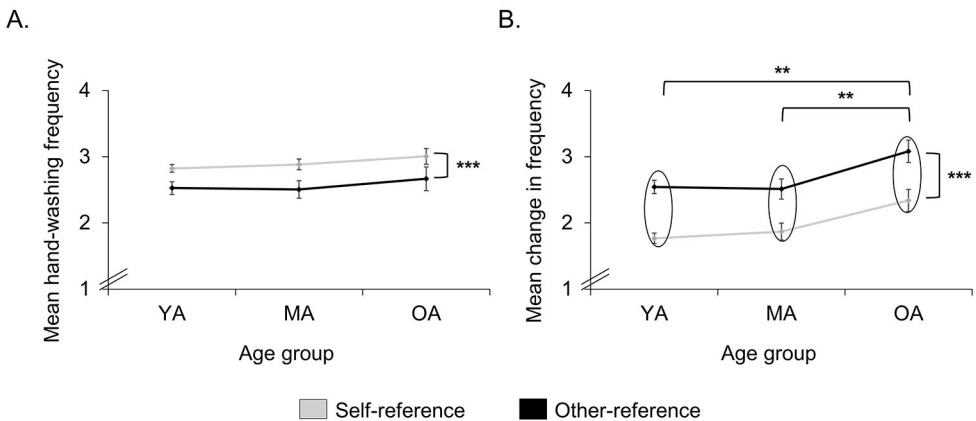
Results

Descriptive data showed a mean frequency of hand-washing across all age groups and situations slightly below the “3 = often” scale point ($M = 2.7$, $SD = 0.8$) on a five-point scale (“0 = never” to “4 = always”), and a mean change in hand-washing frequency slightly above the “2 = somewhat changed” scale point ($M = 2.3$, $SD = 1.0$), also on a five-point scale (“0 = unchanged” to “4 = very much more”).

A repeated measures analysis of variance (ANOVA) for frequency of hand-washing with the factors *Age Group* (YA, MA, OA) and *Situation* (self-reference, other-reference) showed a main effect for *Situation*, with participants reporting more frequent hand-washing in situations with self-reference as compared to situations with other-reference, $F(1, 281) = 18.50$, $p < .001$, $\eta_p^2 = .062$. There was no significant main effect of *Age Group* ($p = .474$) and no significant interaction ($p = .879$; see Figure 2, Panel A).

Figure 2

Mean Hand-Washing Frequency and Change



Note. Mean hand-washing frequency (A.) and mean change in hand-washing frequency (B.) in situations with self-reference and other-reference for the three age groups (young age, middle age, and best/older age). Mean hand-washing frequency on a scale from “0 = never” to “4 = always” (A.) and mean change in hand-washing frequency on a scale from “0 = unchanged” to “4 = very much more” (B.). Error bars denote standard error of the mean.

** $p < .01$. *** $p < .001$.

A repeated measures ANOVA for change in hand-washing with the factors *Age Group* (YA, MA, OA) and *Situation* (self-reference, other-reference) also showed a main effect for *Situation*. Participants reported a greater change of hand-washing in situations with other-reference as compared to situations with self-reference, $F(1, 281) = 67.37, p < .001, \eta_p^2 = .193$. In addition, there was a significant main effect of *Age Group*, $F(2, 281) = 6.24, p = .002, \eta_p^2 = .043$. Post-hoc *t*-tests for independent samples revealed a greater change in the OA group as compared to the YA group ($p = .001$) and the MA group ($p = .003$). The YA and the MA groups were not significantly different ($p = .788$). There was no significant interaction of *Age Group* and *Situation* ($p = .756$; see [Figure 2](#), Panel B).

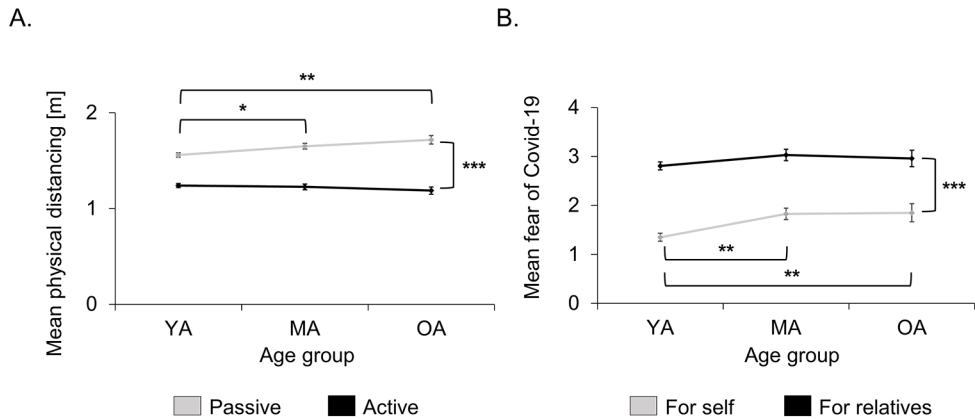
Importantly, the univariate ANOVA for the baseline item (after using the bathroom) showed no significant effect of *Age Group* for either frequency of ($p = .130$) or change in ($p = .834$) hand-washing.

The repeated measures ANOVA for everyday physical distancing with the factors *Age Group* (YA, MA, OA) and *Distancing* (passive, active) showed a main effect for *Distancing*, $F(1, 281) = 337.75, p < .001, \eta_p^2 = .546$, with participants selecting greater physical distances in passive than in active distancing. There was no main effect of *Age Group* ($p = .222$). There was, however, a significant interaction of *Age Group* and *Distancing*, $F(2, 281) = 7.28, p = .001, \eta_p^2 = .049$. Post-hoc *t*-tests for independent samples showed significantly higher passive distancing in the OA group compared to the YA group ($p = .001$) but not to the MA group ($p = .200$), which also showed higher passive distancing than the YA group ($p = .022$). In contrast, there were no significant differences between the three groups for active everyday distancing (all $ps > .2$; see [Figure 3](#), Panel A).

A repeated measures ANOVA for fear of COVID-19 with the factors *Age Group* (YA, MA, OA) and *Fear Target* (self, relatives) showed a main effect for *Fear Target*, with participants reporting more fear of COVID-19 for relatives than for themselves, $F(1, 281) = 404.54, p < .001, \eta_p^2 = .590$, and a main effect of *Age Group*, $F(2, 281) = 4.61, p = .011, \eta_p^2 = .032$, with the YA reporting less overall fear than the MA group ($p = .007$) and the OA group ($p = .039$). In addition, there was a significant interaction of *Age Group* and *Fear Target*, $F(2, 281) = 3.32, p = .037, \eta_p^2 = .023$. Post-hoc *t*-tests for independent samples showed significantly lower fear for themselves in the YA group compared to the MA group ($p = .001$) and the OA group ($p = .005$), which were not significantly different ($p = .882$). In contrast, there were no significant differences between the three groups for fear for relatives (all $ps > .1$; see [Figure 3](#), Panel B).

Figure 3

Mean Passive and Active Physical Distancing and Mean Fear of COVID-19



Note. Mean passive and active physical distancing (A.) and mean fear of COVID-19 for self and for relatives (B.) for the three age groups (young age, middle age, and best/older age). Mean fear of COVID-19 on a scale from “0 = not at all” to “4 = very much”. Error bars denote standard error of the mean.

* $p < .05$. ** $p < .01$. *** $p < .001$.

General fear of COVID-19 was further investigated by calculating bivariate correlations with change in hand-washing frequency, physical distancing, and pathological hand-washing across all participants. Of note, there were significant associations of change in hand-washing frequency and passive physical distancing with both participants’ fear for themselves, $r(282) = .19$, $p = .002$ and $r(282) = .19$, $p = .002$, respectively, and for relatives, $r(282) = .26$, $p < .001$ and $r(282) = .17$, $p = .005$, respectively. Participants reporting higher fear levels also reported greater changes in hand-washing frequency and more passive physical distancing. In contrast, active physical distancing was not associated with general fear of COVID-19 (both $ps > .08$). In addition, general fear of COVID-19 for both themselves as well as for relatives was correlated with pathological hand-washing, $r(282) = .22$, $p < .001$ and $r(282) = .20$, $p = .001$, respectively. Participants reporting higher fear levels also reported washing their hands more frequently and longer than necessary (see [Supplementary Materials](#) for group-specific correlations).

Univariate ANOVAs with the factor *Age Group* (YA, MA, OA) yielded no age group differences with regard to the use of soap ($p = .103$) or disinfectant ($p = .448$), trying not to touch one’s face ($p = .699$), the average amount of people not belonging to one’s household met per day ($p = .633$), or pathological hand-washing ($p = .248$; see [Table 1](#) for all means and standard deviations).

Table 1*Descriptive Data for the Younger Age (YA), Middle Age (MA), and Best/Older Age (OA) Groups*

Behavior	YA		MA		OA	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Use of soap	3.8	0.4	3.7	0.6	3.9	0.5
Use of disinfectant	1.4	1.1	1.2	1.0	1.3	1.1
Trying not to touch one's face	2.6	1.0	2.6	1.0	2.7	1.1
Average number of people met per day ^a	3.2	10.6	2.1	5.9	2.5	3.8
Pathological hand-washing	1.4	1.1	1.1	1.1	1.4	1.3
Importance of observing hand-washing	3.6	0.7	3.6	0.6	3.9	0.4
Attention to physical distance	3.4	0.7	3.6	0.6	3.8	0.5
	<i>n</i>	<i>n female</i>	<i>n</i>	<i>n female</i>	<i>n</i>	<i>n female</i>
	150	116	86	59	48	30

Note. Means and standard deviations for use of soap and disinfectant, trying not to touch one's face, average amount of people met per day, pathological hand-washing, subjective importance of hand-washing, and attention to physical distancing (on 5-point scales starting at 0) for the three groups.

^anot belonging to one's household.

There was, however, a marginally significant main effect of *Age Group* for the subjective importance of observing the recommendations regarding hand-washing, $F(2, 281) = 2.88$, $p = .058$, $\eta_p^2 = .020$, with the OA group perceiving the observation of these recommendations as significantly more important than the YA group ($p = .025$) and the MA group ($p = .032$). In addition, there was a significant main effect of *Age Group* for attention to observing adequate physical distancing during interactions, $F(2, 281) = 5.09$, $p = .007$, $\eta_p^2 = .035$, with the OA group reporting significantly more attention than the YA group ($p = .002$) and also marginally more attention than the MA group ($p = .076$).

Discussion

This survey provides some insight into how health behavior habits in different age groups recently changed based on the actual pandemic situation and current recommendations for the prevention of infections. Importantly, the survey shows an increase in hand-washing after situations carrying a direct risk of infection by others (touching another person or an object touched by other people). However, conditions might still not allow for consistent hand-washing in these situations as the overall hand-washing is still lower than after situations that do not involve direct contact with others. This should urgently be investigated in further surveys.

Importantly, overall change in hand-washing frequency was highest in the best/older age group, compared to both the young and the middle age group. It could thus be

hypothesized that the best/older age group is well aware of their at-risk status and is therefore willing to change their behavior more strongly than the younger survey participants. Indeed, general fear of COVID-19 correlated positively with changes in hand-washing frequency and with passive physical distancing. In addition, the best/older age group reports a significantly higher fear of contracting COVID-19 than the younger age group. In contrast, the middle age group reports a comparable level of fear, but no corresponding change in behavior. However, when fear of contracting COVID-19 was included as a covariate, effect sizes decreased but the reported results still retained significance.

Previous research showed increased health behavior when the framing of the health message matched participants' emotional states (Gerend & Maner, 2011). Given the uncertain situation and the emphasis on age as the main risk factor at the beginning of the pandemic, it is understandable that older participants were generally more scared than younger participants. The initial "loss-framed" campaigns focusing on the risk of insufficient hand-washing and physical distancing thus might have led to stronger behavior changes in this age group. Should the pandemic worsen again in the future, it might therefore be worthwhile to also focus on "gain-framed" campaigns for the younger age groups stressing the (societal) benefits of hand-washing and physical distancing. In addition, health behavior can be promoted by correcting misperceptions of injunctive norms (Reid & Aiken, 2013). It might therefore be helpful to provide self-tests of hand-washing frequency and physical distancing that allow people to compare their own perceptions of acceptable behavior to the parameters actually considered acceptable by a representative sample.

With regard to age group differences, the young age group is somewhat less consistent implementing physical distancing in real life. When confronted with a selection of varying physical distances in an interpersonal situation, 12% of survey participants aged 30 or younger chose a distance of only 1 meter to have a conversation. This percentage was significantly lower in both older age groups. However, all participants seem to struggle with enforcing an appropriate physical distance when their conversational partner is not following recommendations. About half of the younger participants (53%) would actively stop their conversational partner from approaching any further at a distance of only 1 meter, with this percentage rising in the middle age group (57%) to almost two thirds (65%) of the best/older age group. As this group is most at-risk for complications from COVID-19, clinical psychologists might be called upon to provide assistance by instructing the general public on socially acceptable assertive behavior (e.g. based on Hinsch & Pfingsten, 2007).

Clinical psychological research should also monitor the incidence of compulsive washing as seen in obsessive compulsive disorder (OCD). It seems worrisome that fear of contracting COVID-19 was associated with self-reported more frequent and longer hand-washing than necessary across all age groups in our sample. According to the

classic model of OCD by [Salkovskis \(1985\)](#), the reduction of anxiety through neutralizing behavior (i.e. hand-washing) provides powerful negative reinforcement, thereby increasing the likelihood of its occurrence in the future. As the knowledge about OCD in the general public is still rather low ([Coles, Heimberg, & Weiss, 2013](#)), clinical psychologists should try to offer expert opinions on the chance of increasing rates of OCD in the wake of the pandemic whenever possible. On a related note, recommendations regarding physical and social distancing could be detrimental for people suffering from depressive disorders or social phobia. This should also be closely monitored in the future.

There are also several limitations: The sample in this survey is rather small, self-selected, and probably highly educated, with many participants reporting a high degree of formal schooling and almost 40% attending university at the time of data collection. It would therefore be worthwhile to investigate a larger and more representative sample. As our current sample was too small for meaningful analyses with regard to gender, it would be especially informative for future surveys to examine how the general recommendations are perceived and implemented in men as compared to women and if this changes with increasing age. Unfortunately, we did not inquire whether participants were experiencing COVID-19 symptoms at the time of taking the survey. Future surveys should include this question to allow for more in-depth analyses. In addition, the observed findings were quite likely heavily influenced by the time period of data collection as infections were rising quickly and it was uncertain if and how the epidemic could be controlled in Germany at the time. While it is important to have assessed the data for this period in the pandemic, it would be worthwhile to revisit the survey questions at present (after many of the restrictions have been lifted) and examine if the behavioral changes reported earlier are still being maintained. In addition, results might be specific for Germany, as government reactions to the pandemic differed in different countries. It would therefore be informative to gather and compare similar data from other countries.

Overall, it has to be noted that all age groups rate their observance of recommendations regarding hand-washing and physical distancing as very important and that the use of soap during hand-washing was very high in this sample, suggesting a good knowledge and acceptance of the current recommendations ([Bundeszentrale für gesundheitliche Aufklärung, 2020](#)). A sharp decrease on this year's influenza rates also testify to the effectivity of the current overall measures with regard to physical distancing ([Buchholz, Buda, & Prahm, 2020](#)). Our results furthermore show that recommendations given in a pandemic situation can in fact break through relevant habits. Whether this effect is mainly based on reflective decision-making (e.g. salient recommendation) or on impulsive processes (e.g. actual fear) should be further investigated. An additional challenge is now the long-term maintenance of these new adaptive behaviors as well as the management of potential negative effects of physical distancing and increased hand-washing on mental health.

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Supplementary Materials

The Supplementary Materials contain the English translation of the items analyzed in the manuscript (the original items are available from the authors upon request) and group-specific correlations and *p*-values for fear and age group (for access see [Index of Supplementary Materials](#) below).

Index of Supplementary Materials

Biehl, S. C., Schmidmeier, M., Wechsler, T. F., Kroczeck, L. O. H., & Mühlberger, A. (2021). *Supplementary materials to "Widespread recommendations can change our habits of hand-washing and physical distance during the COVID-19 pandemic"* [Additional information]. PsychOpen. <https://doi.org/10.23668/psycharchives.4558>

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Argentinian Mental Health During the COVID-19 Pandemic: A Screening Study of the General Population During Two Periods of Quarantine

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Abstract

Background: Due to the COVID-19 pandemic, Argentina has been under mandatory quarantine. We have aimed to investigate the state of mental health of the Argentine population and the behaviours adopted to cope with mental distress during quarantine.

Method: An online survey was conducted using a probabilistic sampling technique and stratified according to the geographic regions of the country. The survey covered days 7-11 ($n = 2,631$) and days 50-55 ($n = 2,068$) after compulsory quarantine. The psychological impact was measured using the 27-item Symptom CheckList (SCL-27), which provides a Global Severity Index (GSI). An ad hoc questionnaire registered problematic, healthy and other behaviours. Two network models were estimated using a Mixed Graphical Model. Data from the two periods were compared and analysed.

Outcomes: Higher GSI scores and greater risk of experiencing mental disorder were found in Period 2 as compared with Period 1. The lowest GSI scores were associated with physical activity in both periods, and meditation and yoga in Period 1. Drug users reported the highest GSI scores in both periods. The Network Comparison Test confirmed a significant change in symptomatology structure over the two quarantine periods.

Conclusion: This study showed that psychological symptoms and the risk of experiencing mental disorder increased significantly from Period 1 to Period 2. Network analysis suggested that the quarantine might have brought about changes in the relationships between symptoms. Overall



results revealed the relevance of mental health and the need to take mental health actions upon imposing quarantine during the current COVID-19 pandemic.

Keywords

COVID-19 pandemic, mental health, Argentina, quarantine

Highlights

- The length of the quarantine is associated with increased psychological symptoms.
- The youngest, the ones with a low income and females reported the most symptoms.
- Physical activity is less associated with psychological symptoms.
- Access to mental health assistance is crucial to minimize the psychological impact of quarantine.

Pandemics are *epidemics* on a large scale which affect people in multiple countries and which sometimes, as is the case of the current COVID-19 pandemic, can spread globally (World Health Organization [WHO], 2010). There is a long history of fighting epidemics and pandemics (Huremovic, 2019). It is pertinent to highlight that, in the absence of adequate biomedical treatments, behavioural methods such as good hygiene practices and social distancing have been frequently implemented to reduce morbidity and mortality (Taylor, 2019). *Quarantine* is the restriction of movement of people who have been exposed to an infectious disease to determine if they have been infected and thus, reduce the risk of spreading the disease. *Isolation*, on the other hand, is the separation of people who have been diagnosed with an infectious disease from those who have not (Centers for Disease Control and Prevention [CDC], 2017; Hurtado & Frías, 2010). Recently, *quarantine* has been implemented against the coronavirus disease 2019 (COVID-19) outbreak.

On March 3, Argentina confirmed its first COVID-19 case. School classes were suspended on March 16 with a strong non-mandatory recommendation for social isolation and, as of March 20, the mandatory quarantine came into effect; exemption was secured for health professionals, security and defence personnel, journalists and media professionals, and the food industry (Decreto Necesidad y Urgencia [Emergency Decree, Argentina], 2020). At the beginning of the quarantine, 30 cases and 3 deaths by COVID-19 were confirmed in Argentina (Ministerio de Salud [Ministry of Health, Argentina], 2020). The quarantine was enforced through police controls; city and town limits and provincial borders were closed, resulting in a 54.78% reduction in public transport usage (reaching 86%) (Google, 2020).

The *psychological effects* of quarantine have been studied in different past occasions and countries. From previous epidemic and pandemic studies, it appears that *the longest quarantine studied was a 21-day quarantine instituted in 2015 in Liberia, a country in*

West Africa, on account of an Ebola virus outbreak. Three studies showed that prolonged quarantine was associated with symptoms of post-traumatic stress, avoidance behaviours and anger, among the most prevalent (Brooks et al., 2020). Also, an association between higher levels of psychological symptoms and low income, job and financial insecurity, and healthcare workers was also established (Holmes et al., 2020). Studies of recent and dramatic experiences with COVID-19 show similar or more serious results. (de Girolamo et al., 2020; Wang et al., 2020; Williams, Armitage, Tampe, & Dienes, 2020).

Although mental health aspects of the COVID-19 crisis play an important role in managing the pandemic, there is a pre-existing lack of mental health research studies in Argentina. Given factors such as quarantine duration, culture, politics and economic situation are unique to this study. This study, which aims to determine the psychological impact of these factors on the Argentine population, was carried out 55 days after imposition of mandatory quarantine and 72 days after the first confirmed COVID-19 case. More specifically, it intends to establish the impact of the pandemic and quarantine on psychological symptomatology in the Argentine population, and its relationship with certain behaviours, defined as healthy, problematic and others. We also aim to establish whether quarantine duration is related to symptom severity. Apart from investigating changes in symptom severity, we are likewise interested in the changes in symptomatology structure as well as in the relationships between symptoms and reported healthy and problematic behaviours as the quarantine period is extended. Network models are used for studying unique relationships between individual symptoms and the reported behaviours (Borsboom, 2017; Borsboom & Cramer, 2013). Furthermore, symptom network models show the unique associations between behaviours and symptoms, elucidating the possible pathways via which healthy or problematic behaviours can (negatively or positively) influence specific symptom development (Isvoranu, Borsboom, van Os, & Guloksuz, 2016). To this means, we will attempt to identify changes in symptomatology structure and symptom-behaviour relationships between the early and later quarantine phases by constructing a network model of psychological symptoms and behavioural variables.

Method

Study Design and Participants

We adopted a survey design to assess the impact of COVID-19 and quarantine by using an anonymous online questionnaire. The sample was probabilistic and stratified according to geographic regions of Argentina and its population distribution (see Table 1 and Table 2). The online survey was conducted on days 7-11 (from March 27 to 31, 2020) and days 50-55 (May 8 to 12, 2020) of the compulsory quarantine.

Table 1*Sample Characteristics of the Period 1 (Days 7-11 of Quarantine) and 2 (Days 50-55 of Quarantine)*

Participants' characteristics	Period 1 (n = 2631)		Period 2 (n = 2068)	
	n	%	n	%
Age				
18-20	113	4	119	6
21-29	472	18	321	15
30-39	750	28	439	21
40-49	469	18	661	32
50-59	450	17	280	14
> 60	377	14	248	12
Gender				
Women	1210	46	1056	51
Men	1421	54	1012	49
Educational level				
Primary	143	5	80	4
Secondary	1056	40	777	37
Vocational	708	28	594	29
Higher	724	27	617	30
Income				
Low	1201	45	843	41
Middle	1281	49	1072	52
High	149	5.5	153	7

Table 2*Samples' Geographic Distribution of the Period 1 (Days 7-11 of Quarantine) and 2 (Days 50-55 of Quarantine)*

Region	Period 1 (n = 2631)		Period 2 (n = 2068)	
	n	%	n	%
Buenos Aires Metropolitan Area	1159	44	1011	49
Buenos Aires province	409	16	257	12
Córdoba	322	12	257	11
Rosario	269	10	178	9
Mendoza	246	9	157	8
Tucumán	226	9	111	5
Neuquén	–		132	6

Psychological Symptomatology

The psychological impact of COVID-19 was measured using the 27-item *Symptom Check-List* (SCL-27; [Hardt & Gerbershagen, 2001](#)). The SCL-27 has been adapted and well-validated to the Argentine population ([Castro Solano & Góngora, 2018](#)). Two indexes were calculated: 1) the *Global Severity Index* (GSI -27), which is the total item mean scores; and 2) the *Risk of Mental Disorder Index*, which included participants who answered over 50% of the items (14 or more out of the 27 items in this instrument) with the options "quite" or "much"; these participants being thus regarded as at risk of developing mental disorders.

Problematic, Healthy and Other Behaviours

Through an *ad hoc* questionnaire, problematic behaviours (alcohol, illegal drug and tobacco abuse), healthy behaviours (sports and physical activity, sex life and religious practice) and other behaviours (use of over-the-counter and prescription drugs, yoga or meditation practice) were registered. Associations with these behaviours and their changes during mandatory quarantine were analysed with GSI-27 indicators and the "risk of mental disorder" index provided by SCL-27.

Procedures

After completing the informed consent process, participants filled an online questionnaire sent through a social network. It contained a socio-demographic section, the SCL-27 ([Castro Solano & Góngora, 2018](#)), and an *ad hoc* questionnaire on healthy, problematic and other behaviours mentioned below.

Statistical Analysis

In order to compare the GSI-27 between the two periods, we conducted a paired-samples *t*-test. In addition, we compared risk of mental disorder and suicidal thoughts in the two periods through the *Z*-test for population proportions. In order to compare the effects of sex, age, and income on GSI in each period, we performed a one-way between-subjects ANOVA.

For the purpose of comparing the effects of problematic behaviours (tobacco, drug, and alcohol use), healthy behaviours (sports and physical activity, sex life and religious practice), and other behaviours (medication use, yoga or meditation practice) on GSI in each period, we carried out an independent-samples *t*-test. In an attempt to examine the relation between yoga practice and the risk of mental disorder, we performed a chi-square test of independence. Data were analysed using the Statistical Package for the Social Sciences (SPSS), version 18.0.

The network model was estimated with a Mixed Graphical Model (MGM), using the "mgm" implementation in the "bootnet" package in R ([Epskamp, Borsboom, & Fried,](#)

2018; Haslbeck & Waldorp, 2020). This model combined the use of categorical and Gaussian variables which allowed us to combine behaviours and symptoms into one network model. The MGM is not yet available for ordinal data, so we used the “Gaussian” option for the 5-point Likert scale symptom data, as suggested by Haslbeck and Waldorp (2020). Relationships between variables were statistically estimated based on conditional dependencies of the data. In order to test if symptomatology structure significantly changed from Period 1 to Period 2, we conducted the Network Comparison Test (NCT; van Borkulo et al., 2021) by using the “NCT” software package in R (van Borkulo, Epskamp, & Millner, 2016). The NCT compared the symptom networks from the two periods based on their structure and overall connectivity (i.e., the strength of statistical associations between symptoms). This test cannot be performed on mixed data, which is why we conducted it on symptom networks only containing the SCL-27 symptom data (i.e., without behaviours).

Results

2631 participants completed the online survey in Period 1 and 2068 participants completed it in Period 2.

Psychological Symptomatology

Firstly, it was evaluated if the psychological symptoms differed between Period 1 and Period 2. In addition, the risk of experiencing a mental disorder and suicidal ideation in both periods was estimated. A significant difference was observed in GSI scores, $t(2067) = -50.664$, $p < .001$, between the two periods; Period 2 yielding the highest score. We also identified a significant difference between the two population proportions according to the Mental Health Risk Index, $z = 3.48$, $p < .01$. During Period 1, 4.86% of participants were at risk of mental health disorder, while during Period 2, 7.2% of participants were at risk.

An independent-sample t -test comparing GSI values of individuals with suicidal thoughts and individuals without suicidal thoughts showed a significant difference in Period 1, $t(2629) = 18.16$, $p < .001$, (individuals with suicidal thoughts [$M = 1.9$, $SD = 0.82$] and individuals without suicidal thoughts [$M = 0.81$, $SD = 0.61$]). Important differences were also detected in Period 2, $t(2066) = 18.03$, $p < .001$, (individuals with suicidal thoughts [$M = 2.96$, $SD = 0.71$] and individuals without suicidal thoughts [$M = 1.9$, $SD = 0.66$]). A Z -test for population proportions was performed between the two periods for suicidal thoughts (*ad hoc* question). Significant differences were found; Period 2 yielding the highest score ($z = 3.28$, $p < .01$, Period 1 = 4.22%; Period 2 = 6.53%).

Regarding sleep disturbances, Period 1 showed that 73.7% of the sample had sleep related problems. In Period 2, 76.06% of the sample reported sleep disorders. Concerning

sex life, 43.97% in Period 1 and 44.39% in Period 2 reported sexual dissatisfaction. No significant differences were observed. See [Table 3](#).

Table 3

Screening Symptomatology Comparing Samples of the Period 1 (Days 7-11 of Quarantine) and 2 (Days 50-55 of Quarantine)

Measure, index and symptomatology	Period 1 (n = 2631)	Period 2 (n = 2068)	p
Mean GSI-27 (SD)	0.85 (0.66)	1.96 (0.71)	< .001 ^b
SCL-27 mental disorder risk	128/2631 (4.86%)	149/2,068 (7.2%)	< .01 ^a
Suicidal thoughts	111/2,631 (4.22%)	135/2,068 (6.53%)	< .01 ^a
Sleep disturbance	1,572/2,631 (73.7%)	1,939/2,068 (76.02%)	ns
Sexual life dissatisfaction	1,157/2,631 (43.97%)	918/2,068 (44.39%)	ns

Note. GSI-27 = Global Severity Index of SCL-27; SCL-27 = Symptom Check List-27. SCL-27 mental disorder risk = participants who choose score 3 or 4 in at least 50% of the items; ns = Not significant.

^aZ-test. ^bt-test.

Age, Sex and Income

We compared GSI values with socio-demographic characteristics (i.e., age, sex, and income). The lowest GSI values corresponded to the eldest participants in the sample, in both periods, $F(5, 2625) = 31.322$, $p < .001$, and $F(5, 12.88) = 26.67$, $p < .001$. The highest scores corresponded to women, also in both periods: Period 1, $t(2618) = 10.77$, $p < .001$, and Period 2, $t(2055) = 8.91$, $p < .001$.

Lowest income participants reported the highest GSI scores as compared to middle and high- income participants in both periods: Period 1, $F(2, 2349) = 29.65$, $p < .001$, and Period 2, $F(2, 6.82) = 13.45$, $p < .001$). See [Table 4](#) for post hoc analysis and descriptive results.

Table 4*GSI Post Hoc Comparisons Using HSD Test on Age, Sex and Income, in Period 1 and 2*

Participants' characteristics	Period 1: GSI-27		Period 2: GSI-27	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Age				
18-20	1.05	0.06	2.41	0.80
21-29	1.02	0.03	2.18	0.73
30-29	0.96	0.02	2.01	0.74
40-49	0.85	0.03	1.90	0.66
50-59	0.69	0.03	1.84	0.67
60 or more	0.58	0.03	1.68	0.71
Sex				
Men	0.77	0.58	1.80	0.66
Women	1.00	0.71	2.10	0.73
Income				
Low	0.98	0.71	2.06	0.69
Middle	0.75	0.59	1.90	0.69
High	0.74	0.59	1.87	0.66

Note. In Period 1, post hoc comparisons using the Tukey HSD test indicated that the mean score for the 18-20 and 21-29 years old subgroups had significantly more symptoms than the 40-49, 50-59, and 60 plus years old subgroups. Also, the 40-49 years old subgroups had a higher GSI than the 50-59 and 60 plus years old subgroups. In Period 2, the 18-20 years old subgroup had significantly more symptoms than 21-29, 30-39, 40-49, 50-59 and 60 plus years old subgroups. The 21-29 subgroup had significantly more symptoms than 30-39, 40-49, 50-59 and 60 plus years old subgroups. Also, the 30-39 years old subgroup had a higher GSI than the 50-59 and 60 plus years old subgroups. The 40-49 years old subgroup had more symptoms than the 60 plus subgroup. In Period 1, post hoc comparisons using the Tukey HSD test indicated that the mean score for the low-income participants had a significant difference with the middle and high-income participants. In Period 2, the low-income participants reported the highest GSI score. Low-income participants had a significant difference with the middle and high-income participants.

Problematic, Healthy and Other Behaviours

With respect to problematic, healthy and other behaviours, lower GSI scores were found in individuals who did physical activity both in Period 1, $t(2629) = -6.63, p < .001$, and in Period 2, $t(2066) = -6.46, p < .001$. In a similar manner, lower GSI scores were found in those who practiced meditation in Period 1, $t(2629) = -3.19, p = .001$. Again in Period 1, lower proportions of participants in the Risk of Mental Health Index were associated with the practice of yoga, $\chi^2(1, N = 2630) = 9.94, p < .01$. Regarding religious practice, we did not find considerable differences.

Drug users reported the highest GSI scores in Period 1, $t(2601) = 4.93, p < .001$, and Period 2, $t(2033) = 3.54, p < .001$. Tobacco users showed higher GSI scores during Period 1, $t(2629) = -3.76, p < .001$.

Alcohol was consumed by 37.51% of participants ($n = 987$) in Period 1 and 41.15% of participants ($n = 851$) in Period 2. 27.43% ($n = 271/988$) of participants in Period 1 and 33.73% ($287/851$) in Period 2 referred that their alcohol consumption had increased. Differences were not significant.

Over-the-counter and prescription drugs were used by 33.33% ($n = 877$) of participants in Period 1 and 33.12% ($n = 686$) in Period 2. Differences were not significant. More participants used prescription drugs for coping with distress (anxiety, “nerves”, relaxation, sleep) in Period 2 than in Period 1, but we did not find a marked difference.

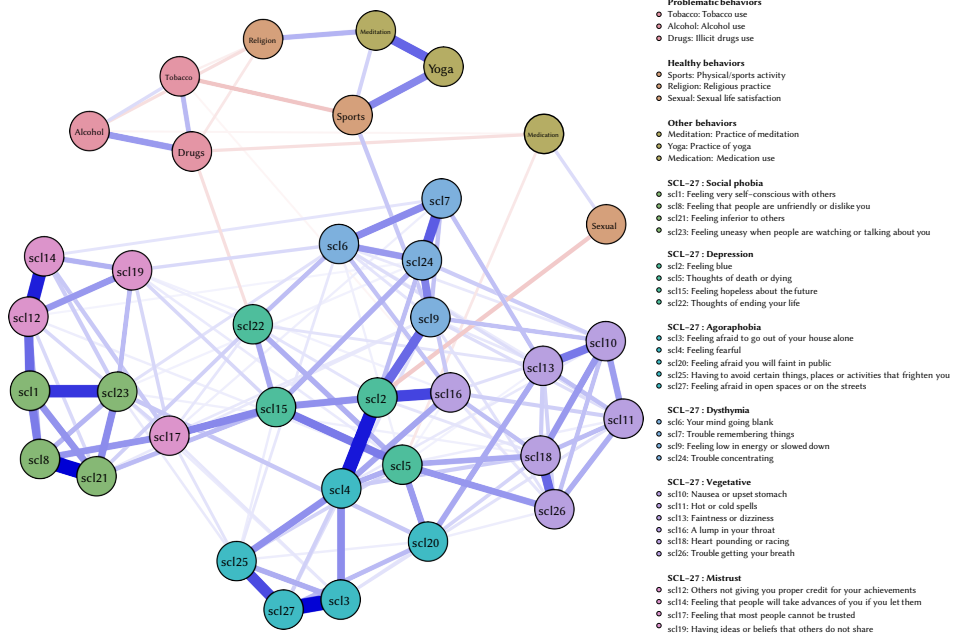
Considering mental health care, in Period 2, 14.02% ($n = 290$) of participants were in psychological treatment and 37.55% ($n = 668$) of responders that were not receiving mental health care considered that they needed treatment but pointed to difficulties in accessing mental health care systems.

Network Analysis

Figure 1 and Figure 2 show the estimated network models for both periods.

Figure 1

Estimated Network Model – Period 1



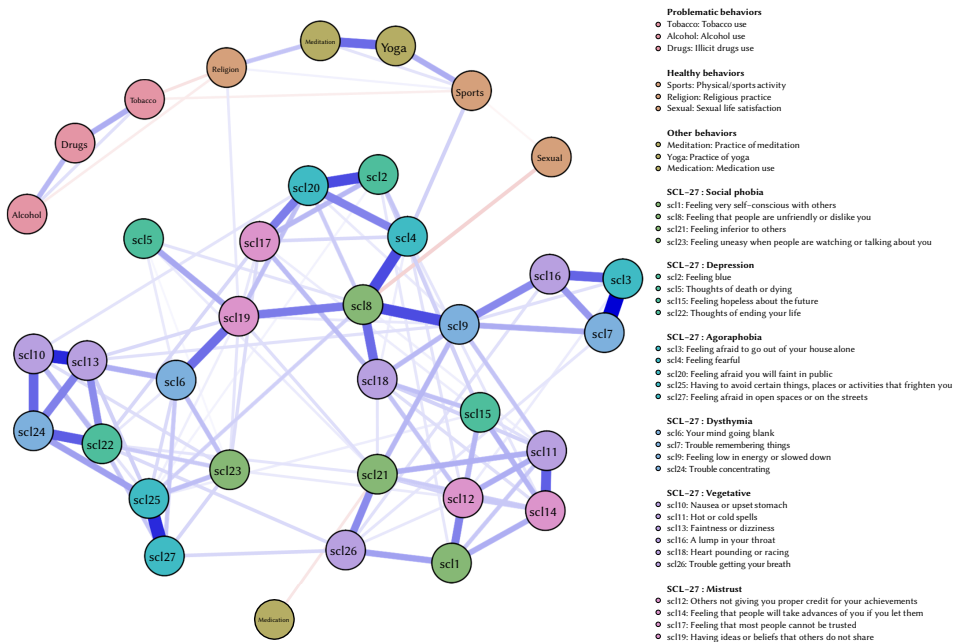
Note. The estimated network model includes the SCL-27 variables and behavioural variables for quarantine Period 1. The nodes in the figure represent the variables, and the lines between the nodes represent the edges, which encode the statistical associations between variables. The colour

of the edges represents the nature of this association: blue edges represent positive associations; red edges represent negative associations. Thickness of edges represents the strength of associations.

Regarding the structure of symptom network models, the network model for Period 1 shows that symptoms cluster together according to their domain: this means that the items designed to measure the same domain have indeed strong positive associations amongst each other.

Figure 2

Estimated Network Model – Period 2



Note. The estimated network model includes the SCL-27 variables and behavioural variables for quarantine Period 2.

However, this does not apply to the network model for Period 2. Here, symptoms no longer cluster together according to their domain and symptom relations are interchanged.

Results from the NCT confirm the change in symptom structure: the structure of the symptom networks changed substantially over the two quarantine periods ($p < .01$). However, the global connectivity of the symptom networks was not altered ($p = .98$). This

means that associations between different symptoms changed significantly over the two periods, but overall associations between symptoms did not increase or decrease.

Discussion

This study is limited in the sense that participants were recruited through a social network and completed an online survey; therefore, individuals lacking access to the Internet or an electronic device, or presenting more severe symptoms, have not been included in the sample (Pierce et al., 2020). This is particularly important in Argentina, as it is a country with high poverty rates (Instituto Nacional de Estadísticas y Censos [INDEC, 2019]). However, the number of registered cell phone users in Argentina exceeds its total population. Nevertheless, this study is a contribution to the understanding of the mental health impact of COVID-19 pandemic and its subsequent mandatory quarantine.

This study showed that symptom indicators notably increased as the quarantine was extended. In addition, there is an indication that the risk of mental health disorders is also increased. Whereas diffuse symptoms may require lower intensity interventions, deep seated psychological problems call for more complex interventions by mental health professionals. Individuals with mental disorders were identified as the most vulnerable group, and the literature endorses the need to approach this group with a more comprehensive evaluation (Duan & Zhu, 2020).

The percentage of participants having suicidal thoughts increased greatly from Period 1 to 2. This surge is correlated with the increase in clinical psychological symptoms and risk of mental disorder mentioned above. Although certain symptoms are expected to increase in such extraordinary circumstances, there is concomitant risk that increased mental disorders lead to pathological behaviours such as self-harm, suicide and domestic violence (Holmes et al., 2020). A recent US study on COVID-19 and suicide mortality reported the highest rates since 1941 (Reger, Stanley, & Joiner, 2020). Preventing suicide risk is a priority which requires immediate interventions and actions (Gunnell et al., 2020).

In regard to participant's sex life, our findings were consistent with evidence in the scientific literature which reports higher levels of overall prevalence of psychological symptoms in women compared to men (Mazza et al., 2020). In addition to biology-based roles, women in Latin America exhibit greater levels of stress on account of the number of tasks they perform and the social pressure to which they are subjected, as well as their exposure to gender discrimination and violence (Economic Commission for Latin America and the Caribbean [ECLAC], 2020). In both periods, younger women reported more symptoms than older women. In Argentina, 35.5% of the general population and 42.5% of its youth live below the poverty line (INDEC, 2020). Young people are therefore more vulnerable, have greater job instability, and fewer resources in general. The pre-existing Argentine economic recession has been exacerbated by the adverse economic

effects of the quarantine on the entire population. Indeed, our study confirmed that lower income sectors experienced higher risk of mental disorder. This population is more exposed to labour, housing and economic uncertainty, factors that can impede quarantine compliance. Hence, the official slogan "stay at home" was adapted to the reality of these vulnerable areas and became: "stay in your neighbourhood". For the middle class sector, monthly rent fees became an additional stressor in the face of financial uncertainty and, in fact, during the quarantine, the Argentine government issued a controversial decree for the suspension of payment of rental fees and yet another decree which prohibited dismissals. Higher income sectors presented less symptoms possibly resulting from its access to greater resources to face the mandatory restrictive measures for the quarantine period and the loss of income during the pandemic. Besides, this social sector has access to health insurance or prepaid health coverage, which can prove crucial during the COVID-19 crisis.

According to our findings, more than half of the population did not engage in the healthy behaviours considered. Furthermore, as quarantine duration kept getting moved, a tendency to dismiss them was observed. It should be borne in mind that the mandatory quarantine during the period studied only allowed people to go outside their homes to get food and medicines. In addition, given that sport facilities and recreational areas remained closed, the population was forced to seek more restrictive alternatives such as video tutorials, online learning and workout classes in small spaces at home. Despite the fact that healthy behaviours could decrease the emotional impact of quarantine (e.g., those who did physical activity showed less psychological symptomatology in both periods), only a small percentage of the population resorted to these protective conducts, and this became accentuated as the quarantine progressed. Furthermore, the decrease in healthy activities can also be explained as a consequence of the changes in psychological symptomatology. The network analysis conducted provided an insight into the specific relationships between symptoms and behaviours. Domain-specific symptoms clustered together during the first period, but were significantly interchanged during the second period. This means that quarantine might have changed the symptom relationships which govern the specific symptomatology from which participants might suffer. Although there was no significant increase in global connectivity (i.e., associations between the symptoms of the network as a whole did not increase), this change in symptomatology structure, where the symptoms decreased in their domain-specific clustering, might indicate a worsening in symptomatology. Decrease in model fit regarding underlying symptom clusters has been related to a worsening of depression symptoms (Elhai et al., 2013). However, future research should focus on the implications of change in symptomatology network structure on symptom severity.

Sleep disturbances affected about 75% of participants in both periods of this study. Sleep problems are highly prevalent in both anxiety disorders and depression. Decreased physical activity and low exposure to sunlight in large cities alter sleep cycles. Over-

sleeping was the most frequent sleep disturbance recorded in Period 1 of the study, while insomnia predominated in Period 2.

Regarding sex life satisfaction, almost 45% of participants in the present research reported that their sex life worsened during both Period 1 and 2. In comparison to the previous year, 35% considered that their sex life had deteriorated (Etchevers, Garay, Castro Solano, & Fernández Liporace, 2019). Sexuality is regarded as a healthy behaviour, together with physical activity and social life. Diminished sex life is associated with discomfort rates and widespread social restriction. Mandatory quarantine hinders sexual encounters for single or divorced / separated persons. It is to be expected that once the quarantine is over, these bonding difficulties will persist out of fear of contagion. Even in consolidated couples, human sexuality can be explained in the tension between presence and absence, which increases fantasy and desire. However, this item should be regarded with caution, because the great majority of respondents preferred not to provide an answer.

Our results showed that alcohol consumption increased as the quarantine progressed. The same was not observed with respect to tobacco or illegal drugs. Consumption of substances constituted one of the problematic behaviours adopted to deal with psychological distress. Although they provide relief by altering the effects of neurotransmitters, thus producing feelings of pleasure or sedation, prolonged use eventually results in general health deterioration.

About 40% of participants reported the need for mental health treatment but pointed out to barriers to access mental health care. Among the reasons for this, they stressed personal financial problems together with a set of barriers associated with lack of medical coverage and lack of response from nearby health centres. Additionally, partial closure of mental health services, which provided only emergency consultations, together with the fact that clinical psychologists have not yet been authorized to resume face-to-face therapy sessions, made it even more difficult for the population to get access to psychological care. To the best of our knowledge, like it was discussed (Andersson, Berg, Riper, Huppert, & Titov, 2020), the problems that can be effectively addressed through distance modality (i.e., tele-psychiatry or tele-psychology) and there is evidence that digital psychological interventions are moderately effective in Low-Income and Middle-Income Countries according to a recent meta-analysis (Fu, Burger, Arjadi, & Bockting, 2020). Although the number of professionals adequately trained in this modality in Argentina have yet to be determined. The percentage of the population having the digital resources to access these approaches has not been established either. Improving the population's access to mental health care is a priority at this point in the quarantine. Our findings emphasize the need to improve monitoring of the psychological impact of the quarantine and pandemic, and to evaluate crisis interventions or approaches and face-to-face and non-face-to-face treatments in order to identify and implement optimal models. Likewise, it is essential to identify the degree of psychological support required

by health care workers on the front line and its accessibility since this population is at greater risk of suffering psychological consequences.

The general results of this study show the relevance of mental health and the need to take action to protect it when implementing mandatory quarantine measures during the COVID-19 pandemic. Increased psychological symptomatology and the risk of mental disorder can in turn increase alcohol consumption or other risky behaviours for oneself or others, and medium-term quarantine compliance depends on the level of understanding and emotion regulation ability of the quarantined population. As the COVID 19 pandemic continues to sweep the world and mandatory quarantine in Argentina is extended, more methodologically rigorous studies need to be conducted in order to determine how to reduce their impact on mental health.

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Dysfunctional Cognition in Individuals With an Increased Risk for Mania

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Abstract

Background: There is still a lack of knowledge about attitudes and cognitions that are related to bipolar disorder. Theoretically, it was proposed that exaggerated beliefs about the self, relationships, the need for excitement, and goal-related activities might lead to mania in vulnerable individuals, however, the few studies that examined this hypothesis provided mixed results. One of the unresolved issues is if such a cognitive style is associated with current mood symptoms or with different stages of the illness, i.e. at-risk versus diagnosed bipolar disorder. Therefore, the present study aimed at evaluating depression and mania-related cognitive style in individuals at-risk for mania.

Method: In an online survey, we collected data of 255 students of the University of Klagenfurt, Austria. All participants completed the Hypomanic Personality Scale (HPS), the Cognition Checklist for Mania – Revised (CCL-M-R), the Dysfunctional Attitude Scale (DAS), the Beck Depression Inventory (BDI), and the Internal State Scale (ISS).

Results: In a hierarchical regression, HPS was positively related to scores of all subscales of the CCL-M-R. The HPS did not significantly predict scores of the DAS. Current manic and depressive symptoms significantly contributed to the models.

Conclusion: The present results suggest that a trait-like risk for mania is associated with mania-related but not depression-related cognitions.

Keywords

bipolar disorder, hypomania, hypomanic personality, dysfunctional attitudes, cognition, vulnerability



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Highlights

- Individuals at-risk for mania show mania-specific rather than depression-specific thinking patterns.
- Current subclinical mood symptoms are related to mood-congruent attitudes and cognitions.

Bipolar spectrum disorders, which include bipolar I, bipolar II, and subthreshold bipolar disorder, affect about 2.4% of the population worldwide (Merikangas et al., 2011) and can be highly disabling. Compared to other psychiatric illnesses, bipolar disorder (BD) is the fifth leading cause of years lived with disability (Ferrari et al., 2016), it is associated with social disruption (e.g., Depp et al., 2010) and an increased risk of suicide (e.g., Nordentoft et al., 2011). Psychological treatments for BD combined with pharmacological strategies yielded better outcomes than pharmacological treatment alone (Miklowitz et al., 2007). For example, structured psychological treatments, such as cognitive behavioral therapy (CBT) seem to be effective (Chiang et al., 2017), but this effect might be specific for depressive symptoms (Oud et al., 2016). One reason for this result might be that cognitive behavioral interventions for BD stem from CBT that was originally developed in the context of major depression (Lam et al., 2010), and usually psychotherapy does not focus on decreasing activation, changing self-confident thoughts or lowering elevated mood. In addition, there is still relatively little knowledge about cognition specifically related to BD and mania.

One of the few cognitive theories specifically developed for BD was proposed by Beck et al. (2006). They state that individuals possess schemata defined as underlying cognitive structures for organizing perceptions of the world. These schemata can be detected by asking people about their beliefs and attitudes. If a negatively biased schema is activated by a stressful life event, the individual might develop even more negative thoughts and subsequently experience depressive symptoms. For example, an underlying belief “I am incompetent” can be represented in the conscious thought “I can’t do it” when asked to handle a difficult situation, which then might lead to an increase in depressive symptoms (Beck & Haigh, 2014). Parallel, a different set of dysfunctional beliefs might lead to manic episodes. These mania-specific cognitions relate to exaggerated beliefs about self-worth, to grandiose beliefs about interpersonal relationships, to erroneous beliefs about needing excitement caused by high-risk situations, and unrealistic beliefs about having high energy levels for undertaking goal-driven activities (Beck et al., 2006; Newman et al., 2002).

To tap into mania-related dysfunctional beliefs Beck et al. (2006) developed the Cognition Checklist for Mania – Revised (CCL-M-R) that comprises four subscales, i.e. ‘Myself’, ‘Relationship’, ‘Pleasure/Excitement’, and ‘Activity’. Based on Beck’s model, all four dimensions of the CCL-M-R should be elevated in manic states. However, the

few studies conducted so far have yielded mixed results. Beck et al. (2006) found that currently manic patients indeed reported more mania-related cognition with regards to 'Myself', 'Relationship', and 'Activity' compared to patients in depressed and mixed states, whereas another study found that only the 'Pleasure/Excitement' subscore was related to manic symptoms (Fulford et al., 2009). In addition, it is unclear whether this specific set of cognitions is associated exclusively with manic states or if they persist in other bipolar states as well, e.g., remission or prodromal. While two studies mentioned before concluded that certain mania-related cognitions were linked only to acute manic states (Beck et al., 2006; Fulford et al., 2009; Ruggero et al., 2015) showed that individuals with a history or current diagnosis of BD reported elevated levels of mania-related cognitions, irrespective of current symptoms. Also, mania-related cognitions might be present and prevalent in different stages of the disorder, i.e. at-risk stages or symptomatic BD (Fulford et al., 2009). For example, beliefs relating to self-confidence in the CCL-M-R were increased in individuals at risk for BD but not in those diagnosed with BD. In contrast, cognitions relating to interpersonal problems were increased in individuals diagnosed with BD but not in those at high risk for BD.

A few more studies examined depression-related cognition in BD. In this context, one of the most widely used instruments is the Dysfunctional Attitude Scale (DAS; Weisman, 1979). However, the results of the studies that used the DAS were mixed. Some studies found no differences in overall dysfunctional attitudes between healthy controls and individuals diagnosed with remitted BD (Alatiq et al., 2010; Lex et al., 2008; Lex et al., 2011; Mansell et al., 2011). Other studies found elevated DAS scores in patients with remitted BD relative to healthy control groups (Hollon et al., 1986; Jones et al., 2005; Scott et al., 2000; Tosun et al., 2015). However, dysfunctional attitudes refer to different areas, for example, achievement, dependency, and goal attainment. Since mania involves increased goal-directed activity (American Psychiatric Association, 2013) some researchers argued that it would be essential to focus on assessing beliefs relating to goal attainment. In line with this, Lam et al. (2004) found evidence that dysfunctional attitudes related to goal attainment were indeed more pronounced in individuals with BD compared to unipolar depression. However, this was not found in all studies (e.g., Jabben et al., 2012).

Despite the recent increased efforts to understand cognitive processes in BD, studies are still sparse and their results are mixed. For example, it still remains unclear whether these dysfunctional cognitions are tied to depressive or (hypo)manic states of BD or if they are part of the underlying diathesis of BD. One possibility to examine this question would be to assess these cognitions among individuals at-risk for mania. Risk for BD can be defined via a genetic vulnerability (Ruggero et al., 2015) or via a constitutional predisposition. Hyperthymic temperament represents such a constitutional predisposition for mania and can be assessed by the Hypomanic Personality Scale (HPS; Eckblad & Chapman, 1986) because there is evidence that people scoring high on the HPS are more

likely to develop symptoms of BD over time (Blechert & Meyer, 2005; Kwapil et al., 2000; Walsh et al., 2015).

Therefore, the present study aimed at examining, if mania related cognition depicted by the CCL-M-R were even present in at-risk states or if they were rather tied to acute manic symptoms. Also, we were interested if core beliefs related to goal attainment were associated with at-risk states for mania. Therefore, we hypothesized that risk for mania predicted mania-related cognition assessed with the CCL-M-R and the DAS subscale 'Goal Attainment'. We also expected that current manic symptoms were associated with mania-related cognition. We, however, did not expect such a relation for depression-specific cognition, i.e. DAS-subscale 'Dependency' and 'Achievement'.

Method

Participants and Procedure

At first, we contacted all students at the University of Klagenfurt, Austria, via their campus e-mail addresses. The e-mail contained general information on the study and a link to "Lime Survey". "Lime Survey" is a web application to conduct online surveys. If the students decided to participate, they provided informed consent, filled out the questionnaires, and provided demographic data. We also asked if they had been in psychotherapy before, because some psychological approaches might potentially alter cognitions related to mood symptoms. The participants remained anonymous and could leave the survey and delete their data at any time. At the end, the participants could optionally disclose their mail address to obtain course credit ($n = 68$). In total, we obtained data from 255 students. Most participants were female (80%) and had never been in psychotherapy before (63.5%). The demographic data is displayed in Table 1.

Measurements

Hypomanic Personality Scale (HPS)

The HPS (Eckblad & Chapman, 1986) is a self-rating scale and includes 48 true-false items covering emotions (e.g., "I frequently get into moods where I feel very speeded-up and irritable"), behavior (e.g., "At social gatherings, I am usually the 'life of the party'"), and energy level, (e.g., "There have often been times when I had such an excess of energy that I felt little need to sleep at night") one feels at most times of his/her life. It assesses hyperthymic temperament, was used in clinical and non-clinical samples before, and is predictive of bipolar disorder and (hypo)manic symptoms (Blechert & Meyer, 2005; Kwapil et al., 2000; Walsh et al., 2015). In the present study, we used the total score to operationalize a constitutional risk to develop mania. Scores can range between 0 and 48, and individuals scoring above 26 are considered at high risk for mania (Meyer & Baur, 2009). The German version (Meyer et al., 2000) showed an internal consistency of $\alpha = .89$.

Table 1*Characteristics of the Sample (N = 255)*

Variable	<i>M</i>	<i>SD</i>	<i>Minimum</i>	<i>Maximum</i>
Age	28.27	9.56	18	65
HPS	16.28	8.25	1	42
BDI	10.25	9.36	0	48
ACT	142.88	95.22	0	466
CCL-M-R				
Myself	8.42	4.12	1	19
Relation	4.05	2.92	0	14
Pleasure/ Excitement	9.87	4.00	0	20
Activity	7.80	3.39	0	18
Thwarting	0.90	1.38	0	6
Total	30.14	11.12	1	60
DAS				
Goal Attainment	20.27	4.82	3	35
Dependency	8.27	4.84	0	22
Achievement	9.80	6.60	0	29
Total	60.58	18.03	20	117

Note. ACT = Internal State Scale Activation Subscore; BDI = Beck Depression Inventory; CCL-M-R = Cognition Checklist Mania; DAS-24 = Dysfunctional Attitude Scale; HPS = Hypomanic Personality Scale.

Hyperthymic temperament was a stable trait over time ($r_{tt} = .87$ [2 years]; Hofmann & Meyer, 2006). In the present sample the reliability was adequate (Cronbach's $\alpha = .87$), and 34 participants were considered at high risk for mania (HPS > 26).

Cognition Checklist for Mania – Revised (CCL-M-R)

The CCL-M-R (Beck et al., 2006; Goldberg et al., 2008) includes 29-items assessing beliefs associated with mania one had had during the past two days and has been used in clinical and non-clinical samples (Fulford et al., 2009). The questionnaire contains four subscales. The 'Myself' subscale contains 7 items and assesses cognition related to the self (e.g., "I am the best"), the 'Relationship' subscale contains 7 items and assesses interpersonal issues (e.g., "I love everyone"), the 'Pleasure/Excitement' scale contains 9 items exploring excitement seeking (e.g., "It is OK to take risks"), and the 'Activity' subscale comprises 6 items and assesses goal-driven activities (e.g., "I have got to get the job done while I can"). A 'Thwarting' subscale can be derived from the 'Relationship' scale by summing two items ("I could accomplish great things, if people did not get in my way" and "Other people stand between me and my goals"; Fulford et al., 2009). Inde-

pendent back-translation was used by two of the authors (R. U. and C. L.) and a native English speaker to obtain a German version of the CCL-M-R. Internal consistencies in the present study were adequate (Total CCL-M-R score: Cronbach's $\alpha = .89$, 'Myself': $\alpha = .80$, 'Relationship': $\alpha = .64$, 'Pleasure/Excitement': $\alpha = .83$, 'Activity': $\alpha = .70$) and comparable to the English version (Beck et al., 2006; Ruggero et al., 2015).

Dysfunctional Attitude Scale (DAS-24)

The DAS (Weisman, 1979; German version: Hautzinger et al., 1985) is designed to assess depression-specific beliefs that individuals have about themselves, others, and their environments most of the time. Although the DAS has been widely applied in clinical samples, it is also used with analogue samples (e.g., Perez & Rohan, 2021). Lam et al. (2004) used a 24-items DAS version in their study from which 3 factors could be derived: 'Goal Attainment' (6 items e.g., "I ought to be able to solve problems quickly"), 'Dependency' (4 items, e.g., "If others dislike you, you cannot be happy", and 'Achievement' (5 items, e.g., "People who have good ideas are more worthy"). These subscales showed good internal consistency. In the present study, we adapted the German DAS in order to parallel the DAS-24 by Lam et al. (2004). We obtained Cronbach $\alpha = .83$ for the total score, for 'Goal Attainment' $\alpha = .44$, for 'Dependency' $\alpha = .65$, and for 'Achievement' $\alpha = .80$.

Beck Depression Inventory (BDI)

The BDI (Beck et al., 1961; German version: Hautzinger et al., 1995) measures the severity of self-reported depression during the past 2 weeks and is used in clinical and non-clinical samples (Richter et al., 1998). It consists of 21 items and each item is scored on a 4-point scale, e.g. "0 - I do not feel sad; 1 - I feel sad; 2 - I am sad all the time and I can't snap out of it, 3 - I am so sad and unhappy that I can't stand it". Scores can range from 0 to 63, and higher scores indicate more severe depressive symptoms. In the present study, we used the validated German version that has comparable psychometric properties to the English version (Hautzinger et al., 1995).

Internal State Scale (ISS)

The ISS (Bauer et al., 1991, 2000; German version: Meyer & Hautzinger, 2004) is a self-report measure that consists of 16 items that are rated on a visual analogue scale (0 - "not at all" to 100 - "totally") incorporating 4 subscales (Activation, Well Being, Perceived Conflict, Depression Index). The Activation subscale (ACT) contains 5 items. It reflects self-reports of manic symptoms within the last 24 hours by assessing behavioral and formal cognitive activation (e.g. "I feel overactive", "My thoughts are going fast"). It correlates positively with self- and expert ratings of mania (Bauer et al., 1991, 2000) and has been used in clinical and non-clinical samples (e.g., Kelly et al., 2016).

Statistical Analysis

To examine if high risk for mania predicted depression- and mania-specific cognition we calculated hierarchical regression analyses using IBM SPSS Statistics for Macintosh, Version 25.0. Scores of the CCL-R-M and DAS-24 were used as dependent variables. All analyses controlled for age and gender in Block 1, for current manic and depressive symptoms in Block 2, and for a prior history of psychotherapy in Block 3. Scores of the HPS were entered in Block 4 after accounting for the other variables of interest. Prior to interpreting the models, the relevant assumptions for linear regressions and potential biases were examined. First, the visual inspection of all scatter plots depicting 'standard residuals' vs. 'standard predicted value' revealed no specific pattern, hence the assumptions of linearity and heteroscedasticity were met. Second, the correlations between the predictors were low (all $r < |.5|$), and the multicollinearity statistics (i.e., Tolerance and VIF) were all within the tolerable limits (Field, 2009). Third, histograms and P-P plots showed that the standard residuals were normally distributed. Forth, the assumption of independent errors was met because all Durbin-Watson results were close to 2 (between 1.83 and 2.14). Finally, we identified the presence and significance of outliers by looking at the standard residuals, the Mahalanobis distance and the leverage effect (i.e., Cook's distance). Cases with standard residuals values below -2 and above 2 were defined as outliers. However, the proportion of identified outliers was less than 5% in all analyses and was, therefore, tolerated (Field, 2009). In order to examine this issue in more detail, we also looked at the Mahalanobis distance. Eleven cases were defined as outliers because their values of the Mahalanobis distance were above 22.59 (for the cut-off value see Stevens, 1984). However, the leverage effects of these 11 cases were small (i.e., Cook's distance < 1); therefore, the cases were not deleted from the analyses (Field, 2009, p. 309).

Results

First, the final overall models including all predictors for *mania-related cognitions* (CCL-M-R) are reported. The final overall model for the composite CCL-M-R score was significant $F(6, 248) = 23.96, p < .001$. Also, the final overall models for the specific dimensions of the CCL-M-R were significant: 'Myself' $F(6, 248) = 22.56, p < .001$, 'Relationship' $F(6, 248) = 18.05, p < .001$, 'Pleasure/Excitement' $F(6, 248) = 14.52, p < .001$, and 'Activity' $F(6, 248) = 15.40, p < .001$. Looking at the ΔR^2 , it became evident that BDI, ACT, and HPS scores significantly increased the explained variance in all five models (Table 2).

Table 2
Final Model (Step 4) of the Hierarchical Regression Analyses for Cognition Related to Mania

Predictor	CCL-M-R Total			CCL-M-R Myself			CCL-M-R Relationship			CCL-M-R Pleasure/Excitement			CCL-M-R Activity		
	B	SE _B	β	B	SE _B	β	B	SE _B	β	B	SE _B	β	B	SE _B	β
Block 1															
Sex	2.02	1.45	0.07	0.45	0.54	0.04	0.94	0.40	0.13*	0.06	0.56	0.01	0.56	0.47	0.07
Age	0.06	0.06	0.05	0.00	0.02	0.00	0.02	0.02	0.08	-0.01	0.02	-0.02	0.04	0.02	0.12*
Block 2															
BDI	-0.11	0.06	-0.09	-0.17	0.02	-0.39***	0.12	0.02	0.37***	0.01	0.02	0.01	-0.06	0.02	-0.17**
ACT	0.03	0.01	0.22***	0.01	0.00	0.14**	0.00	0.00	0.05	0.01	0.00	0.20***	0.01	0.00	0.26***
Block 3															
Therapy	0.00	0.00	-0.01	0.00	0.00	0.00	0.00	0.00	-0.05	0.00	0.00	-0.06	0.00	0.00	0.08
Block 4															
HPS	0.65	0.08	0.48***	0.23	0.03	0.46***	0.10	0.02	0.28***	0.18	0.03	0.36***	0.14	0.03	0.35***

Note: CCL-M-R Total: $R^2 = .01$ for Block 1; $\Delta R^2 = .18^{***}$ for Block 2; $\Delta R^2 = .01$ for Block 3; $\Delta R^2 = .17^{***}$ for Block 4; CCL-M-R Myself: $R^2 = .01$ for Block 1; $\Delta R^2 = .19^{***}$ for Block 2; $\Delta R^2 = .00$ for Block 3; $\Delta R^2 = .15^{***}$ for Block 4; CCL-M-R Relationship: $R^2 = .03^*$ for Block 1; $\Delta R^2 = .21^{***}$ for Block 2; $\Delta R^2 = .01$ for Block 3; $\Delta R^2 = .05^{***}$ for Block 4; CCL-M-R Pleasure/Excitement: $R^2 = .01$ for Block 1; $\Delta R^2 = .14^{***}$ for Block 2; $\Delta R^2 = .01$ for Block 3; $\Delta R^2 = .10^{***}$ for Block 4; CCL-M-R Activity: $R^2 = .02$ for Block 1; $\Delta R^2 = .16^{***}$ for Block 2; $\Delta R^2 = .00$ for Block 3; $\Delta R^2 = .09^{***}$ for Block 4.
ACT = Internal State Scale Activation Subscore; BDI = Beck Depression Inventory; CCL-M-R = Cognition Checklist Mania; HPS = Hypomanic Personality Scale; Therapy = Prior Psychotherapy.
* $p < .05$. ** $p < .01$. *** $p < .001$.

More specifically, ACT positively predicted cognition related to 'Myself' ($\beta = 0.14$), 'Pleasure/Excitement' ($\beta = 0.20$), and 'Activity' ($\beta = 0.26$), BDI positively predicted cognition related to 'Relationship' ($\beta = 0.37$), and HPS scores positively predicted all CCL-M-R dimensions as well as the total CCL-M-R score. An exploratory hierarchical regression model for the Thwarting subscale was also significant, $F(6, 248) = 10.63, p < .001$ (final model). Specifically, BDI ($\beta = 0.40, p < .001$) and HPS scores ($\beta = 0.16, p = .01$) predicted Thwarting.

Next, the final overall models including all predictors for *depression-related cognitions* (DAS-24) are reported. The final overall model for the composite DAS-24, $F(6, 248) = 18.30, p < .001$, as well as the final overall models for the specific dimensions of the DAS-24 were significant: 'Achievement' $F(6, 248) = 15.20, p < .001$, 'Dependency' $F(6, 248) = 13.63, p < .001$, 'Goal Attainment' $F(6, 248) = 4.52, p < .001$. The BDI significantly predicted attitudes related to 'Achievement' ($\beta = 0.45$), 'Dependency' ($\beta = 0.46$) and the total DAS-24 score ($\beta = 0.49$). The ACT ($\beta = 0.20$) and sex ($\beta = 0.17$) significantly predicted 'Goal Attainment'. The HPS score could not increase the explained variance in any of the regression models (Table 3).

Table 3

Final Model (Step 4) of the Hierarchical Regression Analyses for Cognition Related to Depression

Predictor	DAS-24 Total			DAS-24 Achievement			DAS-24 Dependency			DAS-24 Goal Attainment		
	B	SE _B	β	B	SE _B	β	B	SE _B	β	B	SE _B	β
Block 1												
Sex	3.98	2.45	0.09	1.66	0.92	0.10	0.13	0.69	0.01	2.06	0.75	0.17**
Age	-0.02	0.10	-0.01	0.02	0.04	0.03	0.00	0.03	-0.01	0.03	0.03	0.06
Block 2												
BDI	0.95	0.11	0.49***	0.32	0.04	0.45***	0.24	0.03	0.46***	0.03	0.03	0.05
ACT	0.02	0.01	0.11	0.01	0.00	0.11	0.00	0.00	0.04	0.01	0.00	0.20**
Block 3												
Therapy	0.00	0.00	0.00	0.00	0.00	-0.03	0.00	0.00	0.04	0.00	0.00	-0.03
Block 4												
HPS	0.13	0.13	0.06	0.06	0.05	0.07	0.05	0.04	0.08	0.04	0.04	0.06

Note. DAS-24 Total: $R^2 = .02^*$ for Block 1; $\Delta R^2 = .28^{***}$ for Block 2; $\Delta R^2 = .00$ for Block 3; $\Delta R^2 = .01$ for Block 4; DAS-24 Achievement: $R^2 = .02$ for Block 1; $\Delta R^2 = .24^{***}$ for Block 2; $\Delta R^2 = .00$ for Block 3; $\Delta R^2 = .01$ for Block 4; DAS-24 Dependency: $R^2 = .01$ for Block 1; $\Delta R^2 = .23^{***}$ for Block 2; $\Delta R^2 = .00$ for Block 3; $\Delta R^2 = .01$ for Block 4; DAS-24 Goal Attainment: $R^2 = .03^{**}$ for Block 1; $\Delta R^2 = .06^{***}$ for Block 2; $\Delta R^2 = .00$ for Block 3; $\Delta R^2 = .01$ for Block 4.

* $p < .05$. ** $p < .01$. *** $p < .001$.

Discussion

The present study examined the relation between an increased risk for mania, current mood symptoms and cognition specifically related to depression and mania. The risk for mania was assessed with the HPS. In line with our hypotheses, risk for mania significantly predicted mania-specific but not depression-specific cognitions. However, while we had expected that risk for mania would be specifically related to one aspect of dysfunctional attitudes, i.e., ‘Goal Attainment’, this was not the case. Current manic and depressive mood also contributed significantly to the regression models.

The association between high risk for mania and elevated levels of mania-specific cognition was proposed by [Beck and his colleagues \(2006\)](#) as a logical extension of the original theory of depression ([Beck et al., 1979](#)). In line with this theory, we found that the CCL-M-R total score as well as all subscores were associated with increased vulnerability for mania. [Beck et al. \(2006\)](#) also found evidence for their theory regarding most types of mania-specific cognition, however, they failed to find elevated scores on the CCL-M-R subscale ‘Pleasure/Excitement’. As they point out, they tested inpatients who had few opportunities to engage in exciting, high risk behavior while admitted to the hospital. In contrast, our sample consisted of university students who had much more chances for potentially risky behavior to fulfill their need for excitement. This is consistent with [Fulford et al. \(2009\)](#) who also found that HPS scores were related to a modified ‘Pleasure/Excitement’ score of the CCL-M-R in a college student sample.

The CCL-M-R assesses mania-specific beliefs and although it explicitly asks to focus on the last days, it might capture more long-standing beliefs and attitudes about the self, the interaction with others, the engagement of high risk behavior to feel excitement, and the attainment of high goals. This would explain why an indicator of vulnerability for BD would be related to these beliefs, even after accounting for current symptoms. In contrast, [Ruggero et al. \(2015\)](#) found no difference in CCL-M-R scores between individuals at-risk for mania and those with no elevated risk. There are several differences between the studies. We used continuous scaling, whereas [Ruggero et al. \(2015\)](#) used between group differences, i.e. high-risk group vs. low risk group, which could reduce the variance in the predictor group. In addition, their sample was much smaller and might have lower power.¹ Finally, contrary to [Ruggero et al. \(2015\)](#), we assessed current mood symptoms and found associations to the CCL-M-R, therefore, not differentiating between current symptoms and vulnerability could also affect the results. Finally, it might be that the CCL-M-R and the HPS show some construct overlap. Although designed to tap into emotion, behavior, and energy levels, some items of the HPS might also assess cognition, e.g. “I expect that someday I will succeed in several different professions”.²

1) We thank an anonymous reviewer for these comments.

2) See Footnote 1.

The same study found that the Hypomanic Attitudes and Positive Prediction Inventory (HAPPI; Mansell, 2006) differentiated between individuals at-risk and those with no elevated risk. The HAPPI assesses hypomania-specific positive and negative appraisals relating to high and low activation internal states, e.g., an emotion one feels in a specific situation (e.g., Kelly et al., 2017). Given the few studies, it remains unclear whether cognition relating to internal states as measured by the HAPPI or cognition potentially relating to more long-standing cognitive factors as measured by the CCL-M-R is more relevant for at-risk stages in BD. Furthermore, the way risk for BD is defined might be essential, as well. In the present study, we focused specifically on risk for mania by assessing temperamental traits (e.g., Blechert & Meyer, 2005; Kwapil et al., 2000), whereas Ruggero et al. (2015) defined the risk for BD genetically (offspring of parents diagnosed with BD). Speculatively, individuals scoring high on the HPS who might never have been exposed to actual BD might be less familiar with its presentation and more likely to endorse items on the CCL-M-R than individuals whose parents have expressed such mania-related attitudes and beliefs while being (hypo)manic. Internal processes, such as appraisals might be less shared with others even if they influence actual behaviors. Or perhaps, offspring of parents with BD might have been exposed to challenging situations due to their parent's disorder during their childhood and therefore be more cautious to endorse, for example, grandiose statements or behaviors that are considered risky as asked in the CCL-M-R.

In the present study, risk for mania did not predict cognitions related to goal attainment as measured with the DAS. Although Lam et al. (2004) found that the 'Goal Attainment' subscale of the DAS differentiated between patients with remitted BD and patients with remitted unipolar depression, most previous studies found little evidence for increased scores on the 'Goal Attainment' subscale of the DAS in remitted BD (e.g., Alatiq et al., 2010; Lex et al., 2008). This is interesting because there is evidence that a dysregulation of goal-directed behavior and goal striving is an important aspect in BD (Alloy et al., 2012; Urošević et al., 2008) and life events relating to goal attainment caused increases in manic symptoms (Johnson et al., 2000, 2008; Tharp et al., 2016). Subsequently, it would make sense that individuals at-risk for mania endorse exaggerated beliefs about goal attainment. In the present study risk for mania predicted elevated scores on the 'Activity' subscale of the CCL-M-R but not on the 'Goal Attainment' subscale of the DAS. One possible reason for this could be that the items of the DAS 'Goal Attainment' subscale are worded more generally, e.g. "I should be happy all the time", while the items on the CCL-M-R 'Activity' scale are targeted at more specific events, e.g., "I have new goals". Additionally, there is evidence that dysfunctional attitudes might be latent outside of acute mood episodes and must be activated before individuals endorse them (Babakhani & Startup, 2012) or are state-dependent (Alloy et al., 1999; Hollon et al., 1986; Lex et al., 2008, 2011; Reilly-Harrington et al., 1999; Scott et al., 2000). We actually found an association between current manic symptoms and the DAS subscale 'Goal At-

tainment'. Although one has to keep in mind that the reliability for the 'Goal Attainment' subscale was low, this result suggests that manic mood, rather than risk for mania, might be more closely related to dysfunctional attitudes related to goal attainment.

We also found that current subthreshold manic symptoms predicted the mania-related cognition, even though to a lesser degree than the risk for mania. This is consistent with previous studies (Fulford et al., 2009). However, our data also revealed an unexpected association between current depressed mood and the CCL-M-R subscale 'Relationship'. This is in conflict to previous evidence and to the theoretical background (Beck et al., 2006; Fulford et al., 2009). It might be that some of the items of the 'Relationship' scale might relate to depressed mood, e.g., "People treat me like I am sick" and "They do not understand me". However, even if only those two items of the 'Relationship' scale were extracted, that focus on interpersonal behavior most relevant in BD, namely being thwarted by others in the attainment of goals (Fulford et al., 2009), we still found that the level of depression was a significant predictor.

The present study focused on risk and cognitions associated with mania. However, in most cases BD also includes depressive mood episodes. Based on our results we cannot explain how depressive symptoms might arise, which could be a limitation of the present study. In terms of methodical limitations, first, our data was collected online. This approach bears some disadvantages, e.g., limited control regarding the test setting (Wright, 2005). However, there is evidence that paper-and-pencil and Internet data collection methods are equivalent (Weigold et al., 2013). Second, our participants were not asked if they had been diagnosed with an affective or any other psychiatric illness before or if they were experiencing an acute illness episode at the time of their participation. However, in order to control for psychological problems we asked them if they had ever been in psychological therapy and found no relation to mania-specific cognition. Third, we had a mainly female non-clinical sample that might not be representative of people developing BD. However, several reviews emphasize the relevance of analogous samples to understanding clinical phenomena (Abramowitz et al., 2014; Ehrling et al., 2011). At last, we used a hierarchical regression design in a cross-sectional approach because we aimed at examining a directional association. It might be that this approach missed longitudinal developments and changes of our target variables.

Despite these limitations, the present study showed that risk for mania was associated with mania-specific dysfunctional cognition. This finding points toward the importance to identify mania-specific cognitions in early or at-risk states of BD in order to help individuals to question and modify these cognitions to potentially prevent more severe symptoms. Future studies should assess mania-specific beliefs in different phases of BD in order to examine the relation between mania-specific cognitions and current mood, perhaps even looking at specific symptoms, such as elated versus irritable mania. Also, longitudinal studies are highly awaited in order to test if dysfunctional cognitions

increase the risk of acute bipolar episodes or if they interact with life events or other factors (e.g., Lex et al., 2017).

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The Cooperative Revolution Reaches Clinical Psychology and Psychotherapy: An Example From Germany

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Supplementary Materials: Materials [see [Index of Supplementary Materials](#)]



Abstract

Background: Psychology is at the beginning of a cooperative revolution. Traditionally, psychological research has been conducted by individual labs, limiting its scope in clinical samples and promoting replication problems. Large-scale collaborations create new opportunities for highly powered studies in this resource-intensive research area. To present the current state of a Germany-wide platform for coordinating research across university outpatient clinics for psychotherapy.

Method: Since 1999, over 50 such clinics were created in Germany. They represent a unique infrastructure for research, training, and clinical care. In 2013, a steering committee initiated a nationwide research platform for systematic coordination of research in these clinics (German abbreviation “KODAP”). Its main goal is to aggregate and analyze longitudinal treatment data – including patient, therapist, and treatment characteristics – across all participating clinics.



Results: An initial survey (100% response rate) yielded recommendations for improved integration of data collection. Pilot data from 4,504 adult (16 clinics) and 568 child and adolescent patients (7 clinics) proved feasibility of data transfer and aggregation despite different data formats. Affective, neurotic, stress, and somatoform (adults) and anxiety and behavioral (children and adolescents) disorders were most frequent; comorbidity was high. Overcoming legal, methodological, and technical challenges, a common core assessment battery was developed, and data collection started in 2018. To date, 42 clinics have joined.

Conclusions: KODAP shows that research collaboration across university outpatient clinics is feasible. Fulfilling the need for stronger cumulative and cooperative research in Clinical Psychology will contribute to better knowledge about mental health, a core challenge to modern societies.

Keywords

psychotherapy research, outpatient clinics, collaborative research, replication crisis

Highlights

- Data from 4,504 adult and 568 child and adolescent patients were successfully aggregated across 23 outpatient clinics.
- Affective, neurotic, stress, and somatoform (adults) and anxiety and behavioral (children and adolescents) disorders were most frequent; comorbidity was high.
- Legal, methodological, and technical challenges were overcome, and a common core assessment battery was developed.
- 42 clinics have joined a Germany-wide research platform for systematic coordination of research in these clinics. Longitudinal data collection started in 2018.

Psychology and psychotherapy are at the beginning of a cooperative revolution (Chartier et al., 2018; Spellman, 2015). Traditionally, research in these fields has been conducted by individual labs, limiting its scope in clinical samples and promoting replication problems. In response to the so-called “replication crisis” in medicine, psychology and related fields (Camerer et al., 2018; Dumas-Mallet et al., 2017; Ioannidis, 2005; Open Science Collaboration, 2015; Pashler & Wagenmakers, 2012), the search for causes revealed methodological issues including insufficient sample sizes (Button et al., 2013; Flint et al., 2015; Rossi, 1990; Simmons et al., 2011) and the “file drawer problem” (aka publication bias; Kirsch et al., 2002; Rosenthal, 1979; Turner et al., 2008). These proximal causes are worsened by misaligned incentives in a context of dwindling research funding and increasing pressure to publish or perish (Margraf, 2015; Spellman, 2015). In addition, basic aspects of our academic cultures may serve as major contributors to the crisis by accelerating a race that, under the motto “winner takes all”, favors fundamentally undesirable developments (Fang & Casadevall, 2012b). These “cultural” aspects include an exaggerated cult of originality (Fang & Casadevall, 2012a) and the “toothbrush problem” (Mischel, 2008): We

tend to treat other peoples' theories like toothbrushes — every decent person uses one but no self-respecting person wants to use anyone else's. If getting and keeping your job and status requires achieving “originality” by not building on anyone else's work, it may directly undermine the goal of building a cumulative science (Mischel, 2008). The conflict applies not only to theories but also to therapies: The field is full of overstated claims of originality and uniqueness, leading to ill-founded distinctions and misguided competition that impede fruitful cooperation. As a result of this “disconnect between what is good for scientists and what is good for science” (Nosek et al., 2012, p. 616) we have a situation, where “most published research findings are false” (Ioannidis, 2005) and “most clinical research is not useful” (Ioannidis, 2016).

We cannot, however, simply deplore external pressures and individual misconduct, we must also devote our critical attention to the cult of originality and priority and the overemphasis on individual contributions that underlie them. We need to pursue an academic community that works collectively, albeit competitively, to advance theory and therapy. This requires developing common shared tools and a more serious quest for robust, replicable and consequential findings (Mischel, 2009). The importance of teamwork in science has never been greater (Fang & Casadevall, 2012a). Teams increasingly dominate science and are contributing the highest-impact and most reliable research. Collaborations, consortia and networks are essential for tackling many of the most important challenges in psychotherapy and psychosomatics. Luckily, scientists in psychology and medicine recently have opened up much more to new forms of increased collaboration, allowing them to initiate projects at a scale previously unattained. Perhaps the most visible hallmark of the cooperative revolution has been the rapid increase in large-scale collaborations such as ManyLabs, ManyBabies, Open Science Collaboration, Psychological Science Accelerator, Registered Replication Reports, and StudySwap (Chartier et al., 2018). Our research questions as well as our often still inadequate measurement accuracy typically require very large samples (Margraf, 2015). Large joint projects and individual projects coordinated with them must complement each other, and the necessary infrastructure must be developed. This should create new opportunities for highly powered studies even in resource-intensive areas such as psychotherapy research.

The present article describes the example of an innovative approach to collaborative psychotherapy research from Germany (Hoyer et al., 2015; In-Albon et al., 2019; Velten et al., 2017, 2018). Since Germany established the legal basis for psychotherapy outpatient clinics at university departments of Clinical Psychology in 1999, over 50 such clinics devoted to research (i.e., research clinics) and to clinical training of psychotherapists (i.e., training clinics) were created. Each year, many thousand patients across all age and clinical groups are treated under routine clinical conditions as well as in circumscribed research projects (In-Albon et al., 2019; Velten et al., 2018). Together, they represent a unique infrastructure for research, training and clinical care that rapidly has proven to be an important facilitator of research in psychotherapy and mental health. The clinics

routinely gather a large amount of data on therapy outcomes as well as on patient and therapist characteristics (Velten et al., 2017). High standards of quality assurance are achieved in these outpatient clinics through regular, standardized diagnostic assessments. These data can also be used for research, in particular psychotherapy research (e.g., Ziem & Hoyer, 2020). In spite of this remarkable track record, the full potential of synergetic gain from a systematic coordination of research at the clinics had until recently not yet been sufficiently exploited. The scientific evaluation of treatment data is particularly difficult for clinics with a smaller number of cases: Patients and therapists often invest time and effort to answer questions about symptoms, the course of therapy or therapeutic relationships without sufficiently large samples for quantitative analysis. Up to now, the combination of the collected data with other clinics has been an exception that was limited to individual multicenter research projects (e.g., Gloster et al., 2011; Hoyer et al., 2016; Lutz et al., 2009). Nonetheless, the chances of an aggregation of research data across clinics are manifold.

Research coordination would involve a standardization in diagnostic documentation, a standardized reporting system and consequently the possibility of aggregating data from several or all outpatient clinics. Proposals for practice research networks have already been discussed on various occasions (e.g., Borkovec et al., 2001; Castonguay, 2011). A collaborative approach offers a number of important advantages: With the aggregated basic data, research with a large number of cases can be carried out in a short time. If necessary, comparatively rare disorders or their variants (e.g., Skin Picking Disorder, Depersonalization/Derealization Disorder, Sexual Dysfunctions; Balon, 2017; Sierra & David, 2011; Velten et al., 2021) even those not yet explicitly defined in classification systems (e.g. Facebook Addiction Disorder; Brailovskaia et al., 2018, 2019) can be investigated. In the case of more frequent disorders, the high number of cases allows subgroup comparisons and valid benchmark analyses to be carried out. Current topics such as the investigation of therapist data, discontinuation rates, the hotly debated topic of failures and side effects (Jacobi et al., 2011), transgenerational psychotherapy effects (Schneider et al., 2013) or groundbreaking developments in basic research (such as in the area of therapygenetics; Coleman et al., 2017; Rayner et al., 2019; Roberts et al., 2017, 2019; Wannemüller et al., 2018a; Wannemüller et al., 2018b) could be addressed more quickly with highly visible studies based on large clinical data sets. Ultimately, the collaborative database provides a valuable starting point for applying for major projects.

In 2013, an initiative group began to lay the groundwork for the systematic coordination of research in the German university outpatient clinics for psychotherapy in order to create a nationwide research platform for clinical psychology and psychotherapy (German abbreviation “KODAP” for “Coordination of Data Acquisition at Research Clinics for Psychotherapy”). This platform will allow the aggregation and analysis of longitudinal treatment data – including patient, therapist, and treatment characteristics – across all participating clinics for adults, children and adolescents. The short-term goal

of KODAP was to establish the feasibility of large-scale coordinated research. Medium to long-term goals of the project are the advancement of theory, practice, and dissemination of psychotherapy and clinical psychology. The present article describes the steps taken, the challenges that had to be overcome and four feasibility studies that were carried out.

Overview of Feasibility Studies

Immediate goals of Study 1 (Hoyer et al., 2015) were (a) to gather information on the core characteristics of the clinics and on this basis (b) to develop proposals for better integration of research efforts. In order to estimate the size and clinical composition of potential populations for future studies the number of patients initiating treatment in the participating KODAP outpatient clinics in 2016 as well as their diagnoses and psychopathological complaints together with the database, research and administrative software used in the clinics were recorded. Immediate goals of Study 2 (Velten et al., 2017) were (a) to develop a comprehensive catalogue of the considerable logistical, technical and legal data protection challenges facing the planned research collaboration, (b) to use this to examine the workability of cross-clinic collection of patient, therapist and therapy data and (c) to plan the third and fourth pilot studies. Study 3 (Velten et al., 2018) and Study 4 (In-Albon et al., 2019) aimed (a) to actually aggregate patient data across a pilot sample of clinics (Study 3: adults, Study 4: children and adolescents) treated in 2016 and use this (b) to test all the processes necessary for data preparation, transmission and aggregation at the cooperation partners and the central coordination center. The focus was on the frequency distribution of treatment diagnoses to answer the following research questions: Which disorders are frequently treated, which are rarely? How high is the proportion of severely distressed patient groups with more than one disorder diagnosis, at least one personality disorder or severe symptoms?

Study 1 (Hoyer et al., 2015)

Method

A complete list of outpatient clinics at German university departments of clinical psychology and psychotherapy for the psychotherapeutic treatment of adults, children and adolescents (referred to as “clinics” in the following) was compiled in 2014 (Hoyer et al., 2015). This yielded 53 institutions whose scientific and managing directors were contacted by e-mail in May 2014 with the request to complete a short survey form. A questionnaire was developed by the initiative group to record the characteristics of the clinics. It asked for the diagnostic instruments, disorder-specific and general clinical questionnaires, as well as the patient and therapist variables of interest. In addition, the type, strengths and weaknesses of the clinical, research and administrative software used was assessed by open questions. Finally, the clinics reported the annual number of pre

and post therapy datasets of all patients (i.e., defined as any person for whom a patient file was created) treated in 2013. Case numbers for adults and children and adolescents were asked separately.

Results

All 53 clinics contacted provided data on their institution by November 2014 (100% response rate). Whereas some of the clinics were still in the planning or construction stage or could not provide reliable data on current patient numbers for technical reasons, 49 clinics were able to provide information on their annual number of patients. Estimates (some of the clinics were able to provide only approximate data) for patients treated in 2013 yielded 8200 pre- and 5400 post-therapy data records for adults, and 2400 pre- and 1100 post-therapy data records for children and adolescents.

There were clear overlaps in the methods used for the diagnosis of mental disorders as shown in Table 1. Given the large number of different mental disorders treated in the clinics, it is not surprising that more than 150 different disorder-specific instruments were identified by the survey.

Table 1

Diagnostic Assessments Utilized Routinely in Outpatient Clinics (Instruments Used by at Least 15% of Clinics).

Instrument	% of clinics using instrument
Instruments used for ICD/DSM diagnoses	
<i>Adults</i>	
Structured Clinical Interview for DSM-IV ^a , SCID	89.2
International Diagnostic Checklist ^b , IDCL	21.6
Diagnostic Interview for Mental Disorders ^c , DIPS	16.2
<i>Children and adolescents</i>	
Diagnostic Interview for Mental Disorders in Childhood and Adolescence ^d , Kinder-DIPS	85.7
General clinical instruments	
<i>Adults</i>	
Brief Symptom Inventory ^e , BSI	62.2
Symptom Checklist 90-Revised ^f , SCL 90-R	45.9
Inventory of Interpersonal Problems ^g , IIP	27.0
Clinical Global Impressions Scale ^h , CGI	24.3
<i>Children and adolescents</i>	
Child Behavior Checklist ⁱ , CBCL/6-18R	64.3
Youth Self-Report of the Child Behavior Checklist ⁱ , YSR/11-18R	57.1
Teacher Report Form ⁱ , TRF/6-18R	50.0
Inventory for the Assessment of Life Quality in Children and Adolescents ^j , ILK	42.9

Instrument	% of clinics using instrument
Disorder-specific instruments	
<i>Adults</i>	
Beck Depression Inventory ^k , BDI I or BDI II	89.2
Body Sensations Questionnaire, Agoraphobic Cognitions Questionnaire, Mobility Inventory ^l	64.9
Screening for Somatoform Symptoms 2 ^m , SOMS 2	56.8
Eating Disorder Inventory 2 ⁿ , EDI 2	48.6
Social Interaction Anxiety Scale ^o , SIAS	48.6
Hamburg Obsessive/Compulsive Inventory ^p , HZI	45.9
Social Phobia-Scale ^q , SPS	43.2
Posttraumatic Stress Diagnostic Scale ^r , PSD	40.5
Impact of Event Scale ^t , IES	35.1
Eating Inventory ^s , FEV	29.7
Borderline-Symptom-List-23 ^t , BSL-23	29.7
Yale Brown Obsessive Compulsive Scale ^u , Y-BOCS	27.0
<i>Children and adolescents</i>	
Children's Depression Inventory ^v , DIKJ	64.3
Fear Survey Schedule for Children – Revised ^w , PHOKI	57.1
Social Phobia and Anxiety Inventory for Children ^x , SPAIK	35.7
Anxiety Questionnaire for School Students ^y , AFS	35.7

^aWittchen et al., 1997. ^bHiller et al., 1997. ^cMargraf et al., 2017; Schneider & Margraf, 2011. ^dMargraf et al., 2017; Schneider et al., 2009. ^eDerogatis & Spencer, 1993; Franke, 1997. ^fDerogatis, 1992; Franke & Derogatis, 1995. ^gHorowitz et al., 2000. ^hGuy, 1976; Kadouri et al., 2007. ⁱDöpfner et al., 2014. ^jMattejat & Remschmidt, 2006. ^kHautzinger et al., 2000, 2009. ^lEhlers et al., 2001. ^mRief et al., 1997. ⁿPaul & Thiel, 2004. ^oStangier et al., 1999. ^pZaworka et al., 2003. ^qGriesel et al., 2006. ^rMaercker & Schützwohl, 1998. ^sPudel & Westenhöfer, 1989. ^tWolf et al., 2009. ^uHand & Büttner-Westphal, 1991. ^vStiensmeier-Pelster et al., 2014. ^wDöpfner et al., 2006. ^xMelfsen et al., 2001. ^yWiczerkowski et al., 1981.

The systematic collection of essential patient characteristics such as age, gender and diagnosis (see Table 2) is a standard in all participating clinics. In addition, most clinics also record level of education, marital status and the number of therapy sessions. The documentation of therapist characteristics is limited to therapist gender, age and training status in most clinics. A large number of different software programs for patient data maintenance, room planning and billing as well as other administrative purposes are used by the clinics. These include programs from commercial providers as well as individual database solutions created in-house. The three most frequently cited software tools were PsychoEQ (PsychoWare Software), AMBOS (Therapy Organization Software) and self-developed SPSS or Microsoft Excel databases. The most frequently named strengths of the respective software solutions are their individual adaptability to the needs of the clinic, easy exportability of the data, simple operation and good support from the manufacturer. Frequently mentioned weaknesses of the programs are the susceptibility to errors, the limitation of data export only via employees of the manu-

facturer as well as the missing possibility to record specific variables such as therapist characteristics.

Table 2

Patient and Therapist Characteristics Reported in Feasibility Study 1

Variable	% of clinics giving information
Patient characteristics	
Age	100
Gender	100
Diagnosis (ICD-10)	100
Level of education	95.9
Marital status	93.9
Number of treatment sessions	93.9
Index diagnosis	89.8
Therapist characteristics	
Gender	77.6
Age	69.4
Training status (fully licensed vs. in training)	65.3

Study 2 (Velten et al., 2017)

Method

The results of the first pilot study were evaluated by the initiative group¹ in several face-to-face meetings as well as in telephone and Skype conferences in 2015 and 2016. Two subgroups dealt with the variables for adults and for children/adolescents, respectively. This led to the following structure of the catalogue of logistical, technical and legal data protection challenges facing the planned research collaboration: (1) organizational framework conditions, (2) cooperation agreement, (3) Steering Group, (4) coordination center, (5) initial set of variables to be collected for adults and for children and adolescents, (6) process to expand the dataset in the future, (7) data protection of transmitted information and ethical approval, (8) planning of the final feasibility study (Velten et al., 2017). For each of these sections specific recommendations were formulated on the basis of unanimous decisions. In addition, the procedures for patient informed consent and ethical approval of the project had to be developed.

1) C. Bennecke, M. Berking, J. Hoyer, T. In-Albon, T. Lincoln, W. Lutz, J. Margraf, A. Schlarb, H. Schöttke, U. Willutzki.

Results

Based on the results of Study 1, the initiative group for the development of research cooperation derived recommendations regarding the catalogue of challenges for the cooperation project listed below. All recommendations were formulated on the basis of unanimous decisions by the initiative group.

(1) Organizational framework conditions — The planned research cooperation requires a solid organizational basis that must be supported by a legal entity. On 20 March 2017, *Unith.ev* began to serve as the organizing institution of the KODAP project. *Unith.ev* (the network of German university outpatient clinics for psychotherapy) is a registered non-profit association (the German “ev” stands for registered association, “unith” combines “university” and “therapy”). The sponsorship by a registered association clarifies the continued legal responsibility, and the non-profit character underlines the non-commercial character of its research, which serves the common good.

(2) Cooperation agreement — In order to legally secure the ambitious project, a cooperation agreement was drafted which regulates the rights and obligations of all participating clinics. It specifies the subject matter of the contract and provides the relevant information on the duration, confidentiality, liability and termination of membership in the project. In order to ensure the effective execution of the scientific and operational work of the research network, a steering group and a coordination center had to be established. Their respective tasks are also defined in the cooperation agreement (in German language, available from the first author on request).

(3) Steering group — The tasks of the steering group include the development, support and conception of KODAP’s research activities. At present (mid-2020), the steering group consists of most members of the initiative group, which was formed in October 2013 at the annual meeting of German university professors of clinical psychology and psychotherapy. So far, the group met about three times a year, addressing the essential steps of the project, taking decisions by consensus. It currently consists of 8 members, representing 8 different universities. Rules of procedure were adopted in January 2017 to govern the rights and duties of the steering group (in German language, available from the first author on request) and contain guidelines for publications based on KODAP data.

(4) Coordination center — The main tasks of the coordination center are the collection, storage, quality control, aggregation and statistical analysis of the data obtained. The data sets which the participating clinics provide annually for the KODAP project are aggregated and stored in the coordination center. This task was taken over by the Mental Health Research and Treatment Center of Ruhr University Bochum. Regular reports,

which serve to keep the partners continuously informed about the progress of work, are prepared by the coordination center. The rights and duties of the coordination center are set out in the cooperation agreement (in German language, available from the first author on request).

(5) Initial set of variables – The initial core data set defined is presented in Table 3.

Table 3

Initial Core Set of Variables to be Collected for Adults and for Children and Adolescents

Patient characteristics
All
Age (years)
Gender
Previous psychological or psychosocial treatments
Index and additional diagnoses (ICD-10, before and after therapy) based on structured or standardized clinical interviews
Level of education
Clinicians Global Impression Scale ^a , CGI
Adults
Marital status
Brief Symptom Inventory ^b , BSI or Symptom Checklist 90-Revised ^c , SCL 90-R
Beck Depression Inventory ^d , BDI I or BDI II
Children and adolescents
Child Behavior Checklist ^e , CBCL
Youth Self-Report of the Child Behavior Checklist ^e , YSR 11-18R
Psychosocial stressors (max. 5)
Living situation
Parent variables: BSI ^b or SCL-90-R ^c , level of education, partnership status
Therapist characteristics
Gender
Age
Training status (fully licensed vs. still in training)
Treatment variables
Number of therapy sessions
Type of treatment performed
Current treatment status (ongoing, discontinued, regular termination)

^aGuy, 1976; Kadouri et al., 2007. ^bDerogatis & Spencer, 1993; Franke, 1997. ^cDerogatis, 1992; Franke & Derogatis, 1995. ^dHautzinger et al., 2000, 2009. ^eDöpfner et al., 2014.

The aim of assessing only a limited number of variables was to minimize the additional burden of data collection for KODAP and to allow clinics to continue using established assessments. Since the psychometric instruments are given before and after treatment, it is possible to evaluate therapy outcome.

All patient and therapist data are collected in pseudonymized form. Special consideration needs to be given to the problem of personal data, as is emphasized in Article 26 of the basic EU data protection regulation (see Regulation [EU] 2016/679; [European Parliament and Council, 2016](#)), which became effective in May 2018. KODAP follows the recommendations of a task force of the German Society of Psychology. As a consequence, the KODAP project does not collect data that are used in combination by a "person at his or her own discretion [...] to identify the natural person directly or indirectly" (Article 26). In order to ensure that individual patients - even those with rare disorders - cannot be identified on the basis of personal characteristics such as occupation or date of birth, only basic characteristics (level of education, age in years, gender, pre- and post-therapy diagnoses) are to be collected in the KODAP project. This procedure enables the storage of different data for a given patient over several years necessary for the longitudinal data collection, one of the central goals of KODAP. The same considerations also apply to the selection of therapist variables; therefore only information on age, gender and training status are recorded. With respect to treatment variables, the current treatment status (ongoing, completed or discontinued therapy), number of sessions and type of psychotherapeutic procedure are stored.

(6) Process to expand the dataset in the future – Since the success of KODAP essentially depends on smooth and reliable data collection and combination, only a manageable number of patient, therapist and therapy variables should be transmitted at the start of the project. However, a particular strength of a large-scale collaborative project is that it allows the investigation of rare disorders or therapy phenomena as well as new survey instruments. An extension of the initial data set is therefore planned for the future. It is relatively easy to extend the data set with instruments or variables, of which we know from Study 1 ([Hoyer et al., 2015](#)) that the majority of clinics already use them (e.g., SPS, SIAS, SOMS 2, EDI 2). In the long term, the survey can be expanded by follow-up data through multiple measurements across the course of therapy as well as freely available psychometric instruments. Similar to the British Improving Access to Psychological Therapies (IAPT) ([Clark, 2018](#)) program, KODAP will also serve to develop and establish public domain instruments. In addition, all participating project partners are free to propose additional time-limited research questions. If an additional variable that is relevant for many patients is specifically collected over a clearly defined period (e.g., 3 or 6 months) in all clinics, large, clinically well-documented samples can be obtained in a very short time.

(7) Data protection and ethical approval – As the variables to be collected in the clinic include sensitive treatment and health data special attention had to be given to data protection aspects in the run-up to the project as discussed in section (5) above. With regard to data transmission, various technical implementations were examined by the steering group. The solution needed to ensure longitudinal data collection, secure data transmission and storage, easy application by the clinic and low maintenance in the coordination center. In order not to delay the start of the project due to costly and time-consuming technology, we decided to merge the data records into one SPSS data record. A corresponding SPSS template (for adults or children and adolescents) is provided to all participating clinics at the start of the project, which will be sent back to the coordination center on encrypted data carriers at the end of the first project year. The data are stored in secured form on the server of the coordination center. In order to ensure that the transfer of patient data in KODAP is ethically acceptable, an informed consent form was developed, which has to be signed by the patients before the start of treatment (in German language, available from the first author on request). Before the start of the project, the ethics committee of the Faculty of Psychology at Ruhr University Bochum approved the project. The clinics are, however, free to additionally secure their participation in the project by submitting their own applications to their local ethics committees.

(8) Planning of the final feasibility studies – The first transmission of data, which form the basis for longitudinal analyses over several years, was planned to take place between the clinics and the coordination center in January 2019. At this point, the core data of those patients whose treatment started in 2018 were to be transmitted. Before this, however, it was planned to pilot the processes necessary for data preparation, transmission and aggregation at the cooperation partners and the coordination center. For this purpose, the clinics that joined the project by September 2017 provided the patients' core data sets from 2016 for two final (the third and fourth) feasibility studies. The benefits of these feasibility studies go far beyond the mere optimization of the project processes as descriptive statistics of patient data (e.g., distribution of diagnoses, age structure, type and number of co-morbidities and severity of treated disorders) are not yet available for German psychotherapy clinics.

Study 3 (Velten et al., 2018)

Method

As of June 2018, 32 clinics from 15 locations had joined the KODAP project (26 for adults and 6 for children and adolescents). These were invited to contribute the initial core set for adult patients (see Table 3). All patients treated in the participating clinics in 2016 as well as their therapists were to be included, no other inclusion or exclusion criteria applied. A total of 16 clinics for adults were able to provide data sets (Velten et al., 2018).

Reasons for non-participation were the lack of data due to the recent establishment of clinics and the missing approval by ethics committees for the transmission of data from 2016 because of a lack of coordinated consent forms. The participating clinics checked their internal data for completeness and compatibility and assessed the time and personnel required to process and transmit the data. In the coordination center data quality and ease of data transmission were tested. Faulty data points were reported back to the clinics. In addition, study protocols with precise information on all variables were sent to the clinics, which were to be returned to the coordination center together with the quantitative data set. A qualitative evaluation of the study protocols was used to check the variables for conclusiveness and to identify difficulties in data collection.

In order to prevent possible personal identification, some variables (e.g., occupation, exact time of treatment, transgeneriness) were not collected. ICD-10 F diagnoses (Dilling, Mombour, Schmidt, & Weltgesundheitsorganisation, 2005; World Health Organization, 1993) at the beginning of treatment were recorded separately for the initial or index diagnosis (defined as the main reason for presentation) and for additional diagnoses. Reported diagnoses had to be derived from a standardized diagnostic tool or a structured interview according to ICD-10, DSM-IV or DSM-5. In addition to the patient, therapist, and therapy variables listed in Table 3, the average number of patients treated during the study period was computed.

Results

Of the 26 KODAP adult clinics, 16 clinics (61.5%) from ten locations (Humboldt-Universität zu Berlin, Freie Universität Berlin, Bochum, Dresden, Greifswald, Hamburg, Landau, Mainz, Trier, Osnabrück) provided data on 4504 individuals treated in 2016 (start of treatment could have been in 2016 or earlier). The number of records transmitted per clinic ranged from 24 to 756. The completeness and quality of the data (e.g. with regard to the coding of the response options) were checked in the clinics. With the support of the coordination center, all clinics were able to adapt their internal data collection in such a way that all defined variables for the future longitudinal study could be transmitted in an adequate form. All participating clinics were able to provide the time and personnel resources needed for the preparation and transfer of the data records. All clinics transmitted the data sets to the coordination center in compliance with data protection regulations (Velten et al., 2017).

Patient sociodemographic – The majority of the persons treated (mean age = 37.87; $SD = 13.47$; Range = 15–86 years) were female ($n = 2937$, 65.3%) and currently in a partnership ($n = 2383$, 67.5%). Marital status was reported as 49.4% ($n = 1777$) single, 29.4% ($n = 1058$) married and 9.2% ($n = 332$) divorced. The highest school degree attained was the German “Abitur” (equivalent to A-level or International Baccalaureate Diploma) for 48.2% ($n = 1518$), intermediate school certificate (German “Mittlere Reife”) for 29.4%

($n = 926$) and basic school certificate (German “Hauptschulabschluss”) for 18.1% ($n = 570$). At the start of treatment, 68.7% ($n = 803$) of the patients were able to work. In addition to the 18.6% ($n = 217$) disabled patients, 5.5% ($n = 64$) received a retirement pension and 3.1% ($n = 36$) an invalidity pension.

Patient diagnoses – Nearly all clinics stated that the diagnosis at the beginning of treatment was confirmed by structured or standardized interview procedures. Only one outpatient clinic reported that an interview was not always used. A total of 7947 diagnoses were assigned to 4266 patients. Neurotic, stress and somatoform disorders (F4) were the most common category, followed by affective disorders (F3). A recurrent depressive disorder, currently a moderate episode (F33.1), was diagnosed 844 times, making it the most common disorder. With 651 and 539 assigned diagnoses, social phobia and the moderate depressive episode were the second and third most common disorders. Personality and behavioral disorders were diagnosed a total of 563 times. At least one personality disorder (F60 or F61) was present in 10.8% of all patients. The distribution of index diagnoses, which were defined as treatment causes in this study, differed from that of the overall distribution of all diagnoses assigned. Although F4 diagnoses were the most frequently assigned, affective disorders (F3) were by far the most frequent index diagnoses with 39.4% ($n = 1682$). Phobias (F40.-) and other anxiety disorders (F41.-) accounted for 14.2% ($n = 607$) of the initial diagnoses. Also frequently given were index diagnoses in the area of somatoform disorders (F45.-) with 5.5% ($n = 233$), post-traumatic stress disorder (F43.1) with 4.5% ($n = 190$), adaptation disorders (F43.2) with 4.5% ($n = 190$), eating disorders (F50.-) with 4.4% ($n = 186$) and emotionally unstable personality disorder: borderline type (F60.31) with 2.6% ($n = 113$). However, patients with bipolar affective disorders ($n = 42$; 0.9%), schizophrenia ($n = 44$; 1.0%) and sexual dysfunction ($n = 8$; 0.2%) as index diagnoses were rarely treated. The average number of diagnoses given was 1.84 ($SD = 0.99$, range = 0-7). Thus, multimorbidity was found in the majority of cases. 43.1% ($n = 1865$) had only one diagnosis, 33.4% ($n = 1448$) had two and 21.6% ($n = 942$) had three or more. Only 1.7% ($n = 74$) had no diagnosis at the start of treatment or no diagnosis was recorded in the system. The most frequent comorbidity pattern was the co-occurrence of affective disorders (F3) and neurotic, stress and somatoform disorders (F4). For example, 581 patients (13.7%) with F4 index diagnosis had an additional F3 diagnosis. The reverse pattern, F3 as first diagnosis and F4 as second and/or third diagnosis, applied to 546 patients (12.8%). [Figure 1](#) shows the proportion of patients treated in research and training clinics by index diagnosis (ICD-10).

Figure 1

Proportion of Patients Treated in Research and Training Clinics by Index Diagnosis (ICD-10)

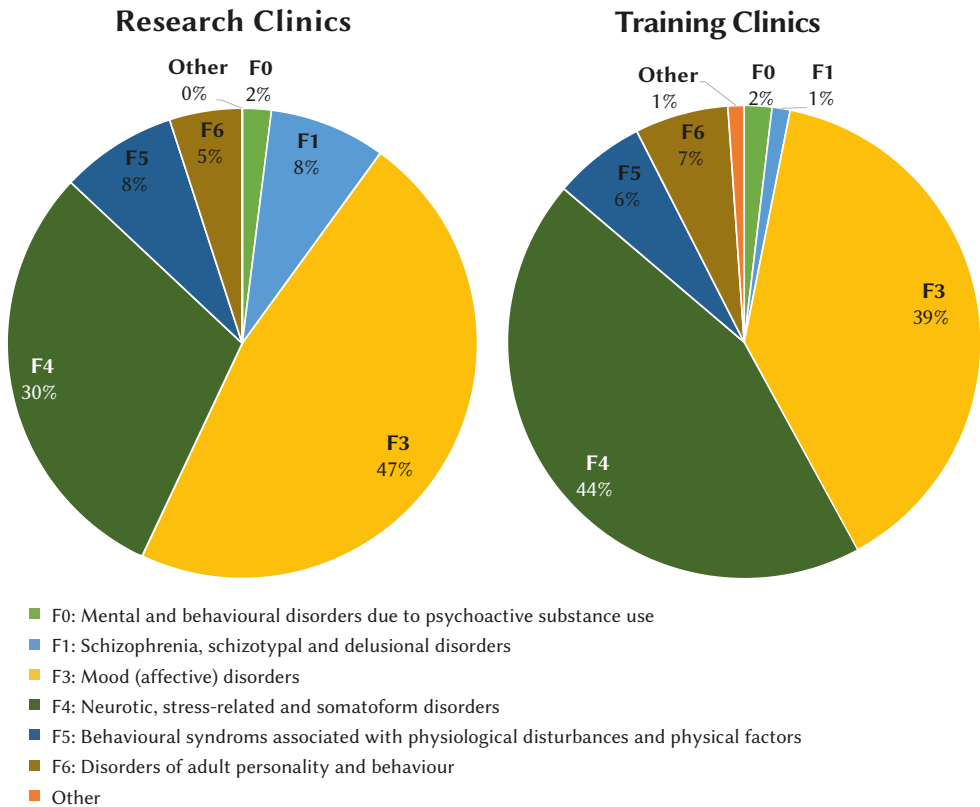


Table S1 in the [Supplementary Materials](#) shows the 50 most frequently assigned diagnoses, broken down by main disorder categories. Table S2 in the [Supplementary Materials](#) shows the 50 most frequently assigned index diagnoses, which were defined as treatment causes in this study. Table S3 in the [Supplementary Materials](#) shows the most frequent diagnostic combinations or comorbidity patterns after ICD-10-F disorder sections.

Patient psychopathological symptoms – Four clinics ($n = 844$ patients) provided data on the severity of the impairment at the start of therapy as assessed by the CGI. According to their therapists, 0.1% of the patients were not ill at all, 1.1% were borderline cases of mental disorder, 5.9% were only mildly ill, 28.9% were moderately ill, 49.8% were markedly ill, 12.1% were severely ill and 0.7% were among the most extremely ill patients. [Table 4](#) shows the BSI and BDI values at the start of therapy. At the start of treatment, clinically relevant elevated BSI values ($GSI > 0.61$) were present in 76% ($n =$

2823), clinically significant BDI values (total values in BDI-I or BDI-II > 14) in 70% ($n = 2298$) of the treated persons. Severe depression symptoms (total values in BDI-I or BDI-II > 29) were reported by 24.3% ($n = 797$) of patients at the start of treatment.

Table 4

Level of Patients' Psychopathological Symptoms at the Beginning of Treatment

Instrument	<i>n</i>	<i>M</i>	<i>SD</i>
Brief Symptom Inventory^a, BSI	3753	0.89	0.77
Somatization	3757	1.47	0.87
Obsession-Compulsion	3758	1.44	1.00
Interpersonal Sensitivity	3760	1.36	0.93
Depression	3754	1.14	0.83
Anxiety	3760	0.96	0.76
Hostility	3756	0.85	0.88
Phobic anxiety	3760	1.10	0.88
Paranoid ideation	3756	0.92	0.77
Psychoticism	3763	1.12	0.67
Beck Depression Inventory^b, BDI			
BDI-I	642	18.47	10.10
BDI-II	640	22.08	11.73

^aDerogatis & Spencer, 1993; Franke, 1997. ^bHautzinger et al., 2000, 2009.

Psychotherapeutic treatments — In accordance with German psychotherapy regulations, a limited number of sessions are reserved for diagnostic procedures including case history and indicative decisions (so called probatory sessions). An average of 4.77 probatory sessions ($SD = 0.85$; range = 0-13) were performed. An outlier analysis showed only 1.5% of the treatments involved more than five probatory sessions. The number of regular therapy sessions after the probatory sessions was 35.01 ($SD = 22.28$, range = 0-117). While 42.7% ($n = 1371$) of the therapies were terminated consensually by patient and therapist (mean duration 43.09 therapy sessions, $SD = 17.09$), 23.3% ($n = 748$) were still ongoing at the time of data retrieval and 32.9% ($n = 1057$) of patients had dropped out of treatment (mean duration 23.8 sessions, $SD = 22.04$). In all cases, cognitive behavior therapy was used as therapeutic procedure. In the vast majority, only individual therapy sessions took place (90.9%, $n = 2683$), combined individual and group therapy were applied in 9.0% ($n = 284$) of the treatments.

Therapists — A total of 675 persons (mean age = 30.91 years, $SD = 5.82$, range = 22-58) were involved as therapists. Most therapists were female ($n = 502$, 83.3%) and the majority ($n = 427$, 70.6%) in advanced psychotherapy training (not licensed yet). On average, therapists treated 6.67 patients ($SD = 5.75$, range = 1-54) during the study period.

An average of 5.19 ($SD = 6.94$, range = 1-43) patients per therapist were treated in the research clinics and 6.80 ($SD = 5.29$, range = 1-54) patients per therapist in the training clinics. An outlier analysis showed that 95% of therapists were responsible for less than 17 patients.

Study 4 (In-Albon et al., 2019)

Method

This study characterized the patient population treated in 2016 in seven university outpatient psychotherapy clinics for children and adolescents (In-Albon et al., 2019). These submitted the initial core data set for children and adolescent patients (see Table 3). Completeness and quality of the data were checked in the clinics as well as in the coordination center as described in Study 3. Descriptive data on the diagnoses and comorbidity patterns of the patient population as well as sociodemographic information of their parents and therapists were analyzed. For the CBCL/6-18R and YSR/11-18R, t -values adapted for age and gender for a total, an externalizing and an internalizing score are reported.

Results

Study 4 characterized the patient population treated in 2016 in seven university outpatient psychotherapy clinics for children and adolescents. For the year 2016, data from 568 children and adolescents between 3 and 20 years of age ($M = 11.89$, $SD = 3.68$; 46.6% female) were available. The most frequent diagnoses were anxiety disorders (F40, F41, F93; $n = 317$, 35.30%) followed by attention-deficit hyperactivity disorders and conduct disorders (F90, F91, F92; $n = 195$, 21.71%). In 45.6% of the patients, there was at least one additional comorbid diagnosis. The mean t -value of the CBCL/6-18R (mother reports) was 67.60 ($SD = 9.94$) for the total score, 67.03 ($SD = 10.70$) for internalizing problems, and 61.84 ($SD = 12.01$) for externalizing problems. The mean t -value of the YSR/11-18R was 61.35 ($SD = 10.23$) for the total score, 63.43 ($SD = 12.75$) for internalizing problems, and 54.88 ($SD = 9.53$) for externalizing problems. All of these are above the clinical cut-off ($t > 60$; based on German norms; Döpfner et al., 2014). Therapist CGI severity scores classified the vast majority of patients as mentally ill (15.1% mildly, 46.6% moderately, 28.8% markedly, and 5.5% severely) and only few patients as not at all (1.4%) or borderline mentally ill (2.7%). Of the 126 therapists (83.1% female, mean 29.76 years, $SD = 5.04$), the majority (78.9%) were still in psychotherapy training (not licensed yet). Each therapist was responsible for a mean of 4.51 patients (range 1-13). Cognitive behavior therapy was used for all patients, and almost all treatments (99.3%) were conducted in an individual setting (combination of individual and group setting in 0.8%). An average of 6.93 probatory sessions ($SD = 1.59$, range 1-13) were performed. Most of the treatments (52.3%) had not yet been terminated. Overall, this study indicated the feasibility of consolidating and

evaluating research data across university outpatient psychotherapy clinics for children and adolescents.

Discussion

While other fields of research, such as physics, astronomy and genetics, have been practicing collaborative research on a large scale for some time, their value in the field of psychotherapy and mental health has only been increasingly recognized in recent years (Margraf, 2015). With the establishment of university outpatient clinics at departments of Clinical Psychology and Psychotherapy in Germany in 1999, a unique infrastructure for research, training and clinical care became available, offering opportunities for a collaborative approach. Since 2013, a steering committee works towards a systematic coordination across clinics in order to create a nationwide research platform. This platform will allow to aggregate and analyze longitudinal treatment data for adults, children and adolescents across all participating clinics and thereby contribute to the advancement of theory, practice and dissemination of psychotherapy and mental health research.

The feasibility of large-scale coordinated research was investigated in a series of four descriptive studies. An initial survey with 100% response rate (Study 1) in 2014 identified the most relevant features of the then 53 clinics and led to recommendations for improved integration of data collection. Already in 2014, the annual number of patients reported by the clinics surpassed 10,000 children, adolescents, and adults, with a strongly growing trend. Based on these results, we defined a catalogue of challenges facing the planned research collaboration and gave unanimously derived recommendations (Study 2). Study 3 collected data on 4,504 patients from 16 clinics treated in 2016 allowing for the first time to systematically describe patients, therapists and treatments available for collaborative research in the German psychotherapy outpatient clinic network. Finally, Study 4 analyzed data of 568 child and adolescent patients from seven clinics starting treatment 2016 providing the first description of this patient population within KODAP.

Adult Patients

Diagnoses are based on evaluated, structured or standardized interviews whose validity and reliability exceed clinical judgment and other non-standardized diagnostic procedures (Margraf et al., 2017). The most frequently treated diagnostic groups in the KODAP clinics in 2016 were neurotic, stress and somatoform disorders (F4) and affective disorders (F3), the latter also yielding the most frequent index diagnoses and cause of treatment. This is in line with previous studies of psychotherapy outpatient clinics in Germany and England (Clark, 2018; Jacobi et al., 2011; Richter et al., 2013; Victor et al., 2018). The majority of KODAP patients (55%) had several mental disorders at the start of treatment. This is more than previously reported in non-university clinics (Victor et al.,

2018), individual university clinics (Peikert et al., 2014; Richter et al., 2013) or routine care by practicing psychotherapists (Köck, 2012). While patients with almost all diagnoses and degrees of severity are treated, severe disorders (e.g., severe depressive episode, borderline disorder, chronic pain disorders, post-traumatic stress disorder) are very frequent. In addition, a sub-sample of four clinics showed that almost two thirds of the patients were rated by their therapists as markedly, severely or extremely ill. The fact, however, that psychotic disorders accounted only for one percent of treatment reasons (34th rank) calls for an increased proportion of this patient group in outpatient training settings (Schlier et al., 2017). Further investigation of the 7% of patients labeled by their therapists as borderline or only mildly ill may help to determine whether these patients may not have been in need of psychotherapy or whether some patient characteristics (e.g., certain diagnoses or symptoms, age, gender) may result in therapists' underestimation of patient distress. While patients on average had a high level of education, a lack of comparative values prevented a direct comparison with earlier studies. The results for age and gender as well as the BSI and BDI scores show that the patient population in KODAP clinics is largely comparable to other German outpatient clinics and routine care by fully licensed behavior therapists (Jacobi et al., 2011; Köck, 2012; Lutz et al., 2013; Richter et al., 2013; Victor et al., 2018).

Child and Adolescent Patients

The most frequently assigned diagnoses were anxiety disorders and behavioral disorders. This is in line with epidemiological studies, e.g. a meta-analysis (Polanczyk et al., 2015) indicating a prevalence rate of 6.5% for anxiety disorders, 5.7% for disruptive disorders, and 3.4% for ADHD. As in the adult clinics, the diagnoses are based on validated structured clinical interviews. The results of the questionnaires CBCL/6-18R and YSR/11-18R are comparable with a clinical control group of an outpatient sample in a child and adolescent psychiatric clinic (Walter et al., 2018). The categorical and dimensional diagnostic assessments as well as the comorbidity rate of almost 50% underline the clinical severity and the breadth of the problems treated in the participating child and adolescent clinics. The age range of 3 to 20 years reflects the legal restrictions for child and adolescent psychotherapists in Germany who may treat patients up to the age of 21. In contrast to the adult patient samples where roughly two thirds of the patients were female, girls and boys were equally distributed in the child and adolescent clinics.

Therapists

The high proportion of female therapists (83%) is comparable with that of non-university training institutes (Victor et al., 2018) and somewhat higher than for practicing fully licensed psychotherapists in Germany (74.4%), or psychologist in the USA (73%) (APA Center for Workspace Studies, 2015). This reflects an ongoing international trend toward

more women entering psychotherapy training and practice (APA Center for Workspace Studies, 2015). Because most of the reported treatments took place in training clinics, the majority of the therapists were not yet fully licensed. The fact that therapists treated an average of seven patients in training clinics during the study period underlines the intensity and structure of psychotherapy training in the participating clinics. Variability in number of patients treated per therapist in our data reflects the different training models (part-time vs. full-time training).

Treatments

With an average of 43 treatment sessions for adults and 36 sessions for children and adolescents (regularly terminated therapies), the length of treatment is identical to that reported in other German outpatient clinics (Victor et al., 2018). This duration, however, is higher than internationally reported as the optimal dose for routinely delivered psychological therapies (Robinson et al., 2020). Patients dropped out in about one third of the treatments. Although this figure appears high, these values are comparable with termination rates reported in similar treatment settings (Hiller et al., 2009). In order to record the proportion of quality-relevant (e.g. low therapeutic success) in comparison to non-quality-relevant drop-outs (e.g., change of residence, low level of suffering), the reasons for early termination or non-execution of approved sessions should be systematically and uniformly documented in the future.

Limitations

Although a large number of the clinics in question have already joined the KODAP project and more than half of the current member clinics contributed data to the last two feasibility studies, it is unclear to what extent the clinics included in this study are representative of all German university outpatient clinics for psychotherapy. Causes for non-participation of KODAP clinics in this study or reasons for missing variables in the transmitted data sets were not systematically documented. A more detailed, quantitative analysis of feasibility aspects related to data processing in clinics was therefore not possible. In addition, this study did not examine the extent to which clinics differ in terms of process and structural quality. Due to ethical and data protection considerations, only a limited number of personal variables of patients and therapists can be evaluated across clinics. A detailed analysis of the influence of specific personal variables, such as occupation or place of residence, is therefore not possible. Instead, this study deliberately focuses on a description of the patient population and treatment diagnoses at the beginning of treatment. The majority of clinics use the BDI-II, while two clinics still use the BDI-I. The comparability of the pre-treatment depression values across clinics with different BDI versions is therefore limited. Since the primary focus of this study was the estimation of feasibility aspects, the clinics were free to decide whether this first data

transmission included variables already collected at the end of therapy. The analysis of treatment outcomes is planned for the longitudinal data collection that has been ongoing since the beginning of 2018.

Opportunities and Challenges

The network provides a distinctive, unprecedented infrastructure for research, training and clinical care in psychotherapy and mental health. Clinical research designs, field experiments, and multicentric randomized controlled trials can be implemented rapidly and with large samples (e.g., 20 clinics per condition, inclusion of 1,000-5,000 patients), hence systematically solving typical problems such as recruitment issues, the lack of standardized assessments, and replicability.

Challenges for the collaborative project include expanding the core data set (e.g., behavioral data, social and biological variables), agreeing on new questions (e.g., long-term follow-up, systematic causality testing of predictors with experimental designs), and last but not least, full-cost funding of the joint research. A transfer of the network into a national structure would be desirable; a first application for consideration in the planned future National Research Center for Mental Health has already been submitted. The proof of a successfully established patient flow and the smooth realization of the cooperation will also improve the chances of success for acquisition of further third-party funding.

Conclusions

Despite different data formats, data transfer and aggregation proved feasible. Affective, neurotic, stress, and somatoform disorders accounted for most of the diagnoses within the adult patients and anxiety and behavioral disorders within the child and adolescent patients. In both groups, comorbidity was the rule rather than the exception. Overcoming legal, methodological, and technical challenges, a common core assessment battery was developed and data collection for KODAP started in 2018. As of today, 42 clinics have joined and 30 already have provided data. The compilation of selected core data from the participating clinics makes it possible to answer important scientific and technical questions. These include but are not limited to the provision of normative data on patient, therapist, parents (for the child sample) and treatment characteristics, the interactions of such variables (e.g., success in specific subgroups, interaction of patient and therapist characteristics), treatment outcomes under routine conditions, dropout rates as well as failures and side effects in therapy, rare disorders, subgroup analyses of frequent disorders, special comorbidity patterns, specific age groups (e.g., preschool age, primary school or adolescent age; older patients) and high-powered studies for the development of new instruments and treatments. The first steps of KODAP reported here show that research collaboration across university outpatient clinics is feasible, provided that clin-

ics invest time and effort for data collection, data checking and data transfer. Fulfilling the need for stronger cumulative and cooperative research in psychotherapy and related fields will contribute to better knowledge about mental health, a core challenge to modern societies.

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All authors except for the first, second, and last are listed in alphabetical order.

Statement of Ethics: This research complies with the guidelines for human studies and was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. All patients gave their written informed consent and that the study was approved by the ethics committee of the Faculty of Psychology at Ruhr University Bochum.

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Supplementary Materials

The Supplementary Materials include three tables listing the diagnoses of patients in Study 3 (for access see [Index of Supplementary Materials](#) below).

Index of Supplementary Materials

Margraf, J., Hoyer, J., Fydrich, T., In-Albon, T., Lincoln, T., Lutz, W., & Velten, J. (2021).

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Examination of the New ICD-11 Prolonged Grief Disorder Guidelines Across Five International Samples

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Supplementary Materials: Materials [see [Index of Supplementary Materials](#)]



Abstract

Background: Prolonged grief disorder (PGD) is a new disorder included in the 11th edition of the International classification of diseases (ICD-11). An important remit of the new ICD-11 is the global applicability of the mental health disorder guidelines or definitions. Although previous definitions and descriptions of disordered grief have been assessed worldwide, this new definition has not yet been systematically validated.

Method: Here we assess the validity and applicability of core items of the ICD-11 PGD across five international samples of bereaved persons from Switzerland (N = 214), China (N = 325); Israel (N = 544), Portugal (N = 218) and Ireland (N = 830).

Results: The results confirm that variation in the diagnostic algorithm for PGD can greatly impact the rates of disorder within and between international samples. Different predictors of PGD severity may be related to sample differences. Finally, a threshold for diagnosis of clinically relevant PGD symptoms using a new scale, the International Prolonged Grief Disorder Scale (IPGDS), in three samples was confirmed.



Conclusions: Although this study was limited by lack of questionnaire data points across all five samples, the findings for the diagnostic threshold and algorithm iterations have implications for clinical use of the new ICD-11 PGD criteria worldwide.

Keywords

prolonged grief disorder, ICD-11, psychometric validity, global applicability

Highlights

- The first study to explore core items of the ICD-11 PGD definition in five large international samples
- Comparison of three different diagnostic algorithms
- Preliminary analysis of different thresholds for diagnosis in different groups
- Preliminary estimates of PGD prevalence

In 2019 prolonged grief disorder (PGD) was included in the International Classification of Diseases (ICD-11) for the first time. The diagnostic criteria for a disorder of grief have a long history and there are several previous definitions and iterations (Prigerson et al., 2009; Shear, 2015; Wagner & Maercker, 2010). The current definition represents a new focus of the World Health Organization (WHO) on the clinical utility and global applicability of the disorder (Maercker et al., 2013). The rationale for the updated iteration in the new ICD-11 definition was to standardize this diagnosis internationally, however, the validity of the diagnostic criteria across different international samples has yet to be established. In this brief report, we test, for the first time, the core items of the PGD ICD-11 criteria in five international datasets.

The WHO working groups for the ICD-11 adopted a two-phase strategy to update disorder definitions. The first phase involved developing the structure of the definition based on a large international survey of psychologists and psychiatrists (Evans et al., 2013; Reed, Correia, Esparza, Saxena, & Maj, 2011). They called for flexible diagnostic guidelines, recognition of cultural factors, and fewer disorder categories with no subtypes. The resulting PGD definition included two core symptoms (intense yearning or preoccupation with the deceased), examples of emotional pain (i.e. anger, sadness, guilt), at least 6 months duration since loss, and an impairment criterion. For a full description see Killikelly and Maercker (2017). Importantly, the working group also included a cultural caveat whereby symptoms of grief must exceed expected socio-cultural norms. The second phase in the WHO's research approach was to evaluate the usability (clinical utility) of these guidelines in diagnostic decision making. Recent field studies have been conducted to explore the clinical utility and validity of PGD through clinicians' assessments of vignettes (Keeley et al., 2016; Reed et al., 2018) and proposals for further evaluation (Gureje, Lewis-Fernandez, Hall, & Reed, 2019). These studies confirmed that,

when compared with the ICD-10, the current ICD-11 including PGD improved the diagnostic sensitivity of grief related psychopathology, especially once the duration since loss criteria was included. However, until now this evaluative phase is limited and there are large scientific gaps in establishing the validity of the new ICD-11 PGD, particularly in a global context (Boelen, Spuij, & Lenferink, 2019; Eisma & Lenferink, 2018).

Previous research has confirmed that PGD may have different prevalence rates in different samples. For example, worldwide rates of a disorder of grief may range from 1% to 10% (Kristensen, Weisæth, & Heir, 2012; Lundorff, Holmgren, Zachariae, Farver-Vestergaard, & O'Connor, 2017). In a recent scoping review we found that the rates of disordered grief appear to be much higher in Asian countries compared to countries in Europe and North America (Stelzer, Zhou, Maercker, O'Connor, & Killikelly, 2020). This may depend on different factors including heterogeneity in the diagnostic criteria used, the sample characteristics, and, perhaps, specific cultural factors that may influence the assessment and reporting of grief symptoms. In this study, we sought to eliminate the methodological variability of previous studies by directly comparing some of the same diagnostic criteria items across multiple national samples, as well as exploring the sample characteristics and their influence on PGD symptoms.

This paper explores core items of the new ICD-11 PGD disorder criteria along with some of the supplementary items indicating emotional distress, across five international samples. The aims include: firstly, the examination of rates of possible PGD caseness using the same core items and diagnostic formulations in each country. Secondly, examination of criterion validity through the identification of predictors of PGD across and between countries. Thirdly, to find provisional cut-off scores and assess the thresholds for the best sensitivity and specificity in each country using the receiver operating characteristic analysis (ROC).

Method

Participants

Data from participants who experienced the loss of a loved one were analyzed. Data sets were obtained from five different countries: Switzerland ($N = 214$), China ($N = 325$), Israel ($N = 544$), Portugal ($N = 218$), and Ireland ($N = 830$). For demographic information see [Table 1.1](#). For additional demographic characteristics for each sample please see Tables 1-4 in the [Supplementary Materials](#).

Recruitment and Sampling

Across all of the studies participants were recruited using online survey methods. In addition, the Portuguese data also includes a clinical outpatient sample. *Switzerland*: Data was collected using an online survey (Qualtrics). Participants were recruited through

online and in person fliers posted at German speaking grief and bereavement support groups, online forums and community services (i.e. churches, townhalls, libraries). *China*: Participants were recruited to participate in an online survey (Qualtrics) using social media (WeChat) and online bereavement forums. *Israel*: Participants were recruited as part of a large national online survey using stratified and random sampling methods. *Ireland*: A nationally representative sample were recruited using the company Qualtrics. Stratified sampling methods were used to select participants based on sex, age and geographical location. *Portugal*: The 'general' group were recruited using Limesurvey anonymous online survey protocol using the snowball method. The 'clinical group' is based on participants from a Hospital setting (Centro Hospitalar Tâmega e Sousa) where participants received outpatient support for grief difficulties. Participants in this group were referred to the Grief Consultation Service part of the Clinical Psychology Unit and had completed informed consent procedures. This service is focused on supporting parental and perinatal losses and data was collected in face-to-face interviews with self-evaluation questionnaires.

Measures

To assess prolonged grief disorder, the International Prolonged Grief Disorder Scale with 15 items (Killikelly et al., 2020) and the Inventory of Complicated Grief-Revised with 8 items (ICG-R; Prigerson et al., 2009; Prigerson & Jacobs, 2001) were used. Both instruments include two core PGD symptoms (i.e. yearning for the deceased and preoccupation), emotional distress symptoms as well as a measure of functional impairment, and time since loss. For the items of the IPGDS please see Killikelly et al. (2020). The following 8-items of the ICG-R were assessed: core items 1) 'I think about him/her so much that it can be hard for me to do the things I normally do' 2) 'I feel myself longing and yearning for him/her'; accessory symptoms or examples of emotional distress, 3) 'I feel as if a part of me died' 4) 'I feel disbelief over his/her death' 5) 'Ever since he/she died, I find it difficult to move on with my life' 6) 'I am bitter over his/her death' 7) 'I feel that it is unfair that I should live when he/she died' and functional impairment criterion, 8) 'I believe that my grief has resulted in impairment in my social, occupational or other areas of functioning. Unlike the ICG-R, the IPGDS includes one cultural item (i.e. My grief would be considered worse, e.g., more intense, severe and/or of longer duration, than for others from my community or culture). Participants were asked to rate their grief symptoms on a five-point scale (i.e. "not at all" on IPGDS or "almost never" on ICG-R (1), "rarely" (2), "sometimes" (3), "often" (4), "always" (5)). When filling out the IPGDS, participants were asked to mark the answer that best describes their feelings, thoughts and behaviour during the last week. In case of ICG-R, they were requested to select an answer that best describes how they felt during the last month. PGD was assessed using the IPGDS in Switzerland, China, and Portugal, and the ICG-R in all five countries. Recently the IPGDS was confirmed to be psychometrically reliable and

valid with strong internal consistency (Cronbach's $\alpha = .92$), high concurrent and criterion validity (see Killikelly et al., 2020). Previously the 8-item ICG-R was shown to have good reliability (Cronbach's $\alpha = .94$) (Killikelly et al., 2019).

Predictors

Life Events Checklist (LEC) (Gray, Litz, Hsu, & Lombardo, 2004) and International Trauma Exposure Measure (ITEM) (Hyland et al., 2020) items were measured on a binary scale (0 = no; 1 = yes). For the LEC response options 1-2 (happened to me, witnessed it) were merged into 'yes' while all other response options were merged into 'no'. Information about traumatic events was not collected for the Portuguese sample. Furthermore, in the Portuguese sample, the duration since loss was not assessed and the data set revealed a high quantity of missing values (100 out of 218 participants) on the ICG-R scale. Therefore, the Portuguese sample was excluded from the data analysis when the association between predictors and PGD was investigated. The cultural item was collected only in Switzerland, China, and Portugal. The following variables were included in the data analysis as predictors of PGD:

1. Gender (measured in all 5 samples)
2. Age (measured in all 5 samples)
3. Cultural criteria (measured in Swiss, Chinese, Portuguese samples)
4. Severe human suffering (measured in Swiss, Chinese, Israeli samples with LEC, and in Irish sample with ITEM)
5. Sudden, violent or accidental death (measured in Swiss, Chinese, Israeli samples with LEC and in Irish sample with ITEM)
6. Serious injury, harm or death you caused to someone (measured in Swiss, Chinese, Israeli samples with LEC and in Irish sample with ITEM)

Statistical Analysis

To estimate possible PGD rates, three different diagnostic algorithms were applied; PGD strict criteria set, PGD moderate criteria set, and the criteria set according to Maciejewski et al. (2016). PGD strict criteria set requires the endorsement of at least one core item, at least one item of emotional distress symptoms, and functional impairment; all of which are rated as 4 (often) or higher. PGD moderate criteria set has almost the same requirements except all items are rated 3 (sometimes) or higher (Killikelly et al., 2020). Criteria according to Maciejewski et al. includes at least one of two core items, three or more emotional distress items (all rated 4 (often) or above), and no functional impairment. In all three diagnostic algorithms the same time criterion was applied (i.e., loss occurred 6 months ago or longer). The estimated rates of possible PGD were calculated across the five samples with 95% Confidence Interval (CI). However, it is important to note that some key items were missing in the datasets. In the Portuguese and the Israeli samples

the time criteria was not applied due to the absence of the data about time since loss and in the Portuguese dataset the functional impairment criterion was not evaluated. Therefore we can only examine estimates of possible PGD caseness not prevalence.

Logistic regression was used to examine the associations between PGD (strict criteria) and some items representing traumatic life events, gender (male/female), age, and cultural caveat item using odds ratio (OR) and 95% CI. The outcome was the endorsement of PGD strict criteria; coded as binary variable “yes, possible PGD caseness” (1) or “no” (2). Of note, due to the use of heterogeneous questionnaires across the samples, we could only include a few traumatic life event items. In terms of missing values, the default settings of SPSS were used whereby cases were deleted in a list wise manner. Third, Receiver operating characteristic analysis (ROC) was used to examine cut-off scores for the IPGDS and ICG-R, i.e. the threshold for the best fit in terms of sensitivity (high > .80) and specificity (.80). This analysis is presented as an initial exploration and may be highly dependent upon the samples used. ROC curves and logistic regression were calculated only for PGD strict criteria (i.e. 12 symptom items plus functional impairment). Statistical analyses were performed using SPSS version 23.

Results

Rates of PGD

The proportion of people in each sample who met the criteria for possible PGD caseness differed within the country depending on (1) whether strict, moderate or [Maciejewski et al. \(2016\)](#) diagnostic criteria were applied and (2) whether IPGDS or ICG-R were used to assess it. Furthermore, there was a difference in rates between the countries, even if assessed with the same diagnostic algorithm and the same measure instrument. For example using the strict criteria of the IPGDS the rates ranged from 6.9% to 12.6%, whereas for the ICG-R rates ranged from 2.0% to 21.1%. For detailed rates and confidence intervals (CI) see [Table 1.1](#) and [Table 1.2](#).

Table 1.1

Basic Sociodemographic Characteristics and Predictors in Five Samples

Variable	Swiss (<i>n</i> = 214) (<i>M</i> _{Age} = 38.7)		Chinese (<i>n</i> = 325) (<i>M</i> _{Age} = 33.3)		Israel (<i>n</i> = 544) (<i>M</i> _{Age} = 41.4)		Portuguese (<i>n</i> = 218) (<i>M</i> _{Age} = 32.8)		Irish (<i>n</i> = 830) (<i>M</i> _{Age} = 45.4)	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Gender										
Male	33	15.4	104	32	246	45.2	43	17.5	411	49.5
Female	178	83.2	212	65.2	298	54.8	203	82.5	419	50.5
Other	3		2		0		0		0	

Variable	Swiss (<i>n</i> = 214) (<i>M</i> _{Age} = 38.7)		Chinese (<i>n</i> = 325) (<i>M</i> _{Age} = 33.3)		Israel (<i>n</i> = 544) (<i>M</i> _{Age} = 41.4)		Portuguese (<i>n</i> = 218) (<i>M</i> _{Age} = 32.8)		Irish (<i>n</i> = 830) (<i>M</i> _{Age} = 45.4)	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Item										
Severe human suffering (LEC Item 13)	83	38.8	65	20.0	39	7.1	-	-	-	-
Sudden, violent death (LEC Item 14) ^a	62	29.0	53	16.3	71	13.0	-	-	-	-
Accidental death (LEC Item 15)	57	26.6	99	30.5	173	31.8	-	-	-	-
Serious injury, harm or death you caused (LEC Item 16)	6	2.8	49	15.1	11	2.0	-	-	-	-
Serious injury, harm or death you caused (ITEM Item 12)	-	-	-	-	-	-	-	-	35	4.2
Sudden, violent or accidental death (ITEM Item 13)	-	-	-	-	-	-	-	-	224	27.0

^aLEC items 14 and 15 were merged in the logistic regression. Data was not collected for the Portuguese sample.

Table 1.2

Estimates of Possible PGD Using Different Diagnostic Rules Across Five Countries

Scale	Swiss (<i>n</i> = 214)			China (<i>n</i> = 325)			Israel ^a (<i>n</i> = 544)			Portuguese ^b (<i>n</i> = 218)			Irish (<i>n</i> = 830)		
	95% CI			95% CI			95% CI			95% CI			95% CI		
	%	LL	UL	%	LL	UL	%	LL	UL	%	LL	UL	%	LL	UL
IPGDS															
Strict criteria	7.0	4.0	11.3	12.6	9.2	16.7	-	-	-	6.9	3.9	11.1	-	-	-
Moderate criteria	21.5	16.2	27.6	37.5	32.3	43.1	-	-	-	27.5	21.7	34.0	-	-	-
Maciejewski criteria	15.9	11.3	21.5	33.5	28.4	39.0	-	-	-	23.4	17.9	29.6	-	-	-
ICG-R															
										(<i>n</i> = 118) <i>Estimate only</i>					
Strict criteria	5.1	2.6	9.0	7.1	4.5	10.4	2.0	1.0	3.6	21.1	14.2	29.7	4.1	2.9	5.7
Moderate criteria	18.2	13.3	24.1	29.2	24.3	34.5	8.5	6.3	11.1	48.3	39.0	57.7	13.9	11.6	16.4
Maciejewski criteria	6.1	3.3	10.2	10.5	7.4	14.3	4.2	2.7	6.3	7.6	3.5	14.0	4.7	3.4	6.4

^aIn Israel dataset for ICG-R – no time criteria applied.

^bIn Portuguese dataset for ICG-R – no time criteria applied, no functional criteria (Item 8) applied; for IPGDS - no time criteria applied, pooled across the general and clinical groups.

Logistic Regression

Results from the logistic regression analyses showed that PGD assessed with IPGDS was significantly associated with the cultural caveat criteria in Switzerland, *OR* = 2.463, 95% CI [1.707, 3.554], and in China, *OR* = 3.152, 95% CI [2.361, 4.209]; with serious injury, harm or death to someone else, *OR* = 14.016, 95% CI [1.856, 105.854], in Switzerland, and

with gender (higher risk for women), $OR = 0.508$, 95% CI [0.259, 0.998] in China (see Table 2.1).

Table 2.1

Logistic Regressions for a Set of Predictor Variables Associated With PGD Measured With IPGDS

Variable	Swiss (<i>n</i> = 201)			China (<i>n</i> = 302)		
	OR	95% CI		OR	95% CI	
		LL	UL		LL	UL
IPGDS						
Gender ^a	1.240	0.331	4.646	0.508*	0.259	0.998
Age	1.018	0.989	1.049	1.022	0.996	1.048
Cultural criteria	2.463***	1.707	3.554	3.152***	2.361	4.209
Severe human suffering	2.321	0.898	6.000	1.256	0.507	3.111
Sudden, violent or accidental death	1.821	0.734	4.517	0.703	0.342	1.448
Serious injury, harm or death you caused	14.016*	1.856	105.854	1.471	0.534	4.055

^aFemale compared to male.

* $p < .05$. ** $p < .01$. *** $p < .001$.

When PGD was assessed with ICG-R, the logistic regression analyses revealed significant associations with the cultural caveat criteria within Switzerland, $OR = 8.148$, 95% CI [2.629, 24.782], and China, $OR = 4.501$, 95% CI [2.671, 7.586]; with serious injury, harm or death person caused to someone in China, $OR = 5.494$, 95% CI [1.309, 23.050]; with age, $OR = 0.964$, 95% CI [0.933, 0.966], severe human suffering, $OR = 5.095$, 95% CI [1.670, 15.547], and with sudden, violent or accidental death, $OR = 3.271$, 95% CI [1.178, 9.086], in Israel, and finally with gender, $OR = 0.993$, 95% CI [0.967, 1.020], and sudden, violent or accidental death, $OR = 0.297$, 95% CI [0.127, 0.694], in Ireland (see Table 2.2).

Examination of Provisional Cut-Off Scores

The ROC analysis was used to determine a cut-off score for those participants meeting the strict criteria for the IPGDS and ICG-R. The results can be found in Table 3. The Chinese sample required a slightly higher cut-off score (42.5) for the IPGDS when compared to the Swiss (37.5) and Portuguese (36.5) samples. Additionally, for the ICG-R the Portuguese sample had a lower cut-off (16.5) when compared with the Swiss (24.5), Chinese (25.5), Israeli (24.5) and Irish (22.5) samples.

Table 2.2*Logistic Regressions for a Set of Predictor Variables Associated With PGD as Measured by ICG-R*

Variable	Swiss (n = 201)			China (n = 302)			Israel (n = 544)			Irish (n = 830)		
	OR	LL	UL	OR	LL	UL	OR	LL	UL	OR	LL	UL
ICG-R												
Gender ^a	1.319	0.109	15.984	0.407	0.139	1.192	0.847	0.347	2.068	0.303**	0.967	1.020
Age	1.060	1.000	1.124	1.023	0.984	1.063	0.964*	0.933	0.966	0.993	0.133	0.692
Cultural criteria	8.148***	2.629	24.782	4.501***	2.671	7.586	–	–	–	–	–	–
Severe human suffering	1.495	0.290	7.708	0.286	0.057	1.428	5.095**	1.670	15.547	0.555	0.249	1.149
Sudden, violent or accidental death	0.779	0.147	4.117	0.809	0.247	2.648	3.271*	1.178	9.086	0.297**	0.127	0.694
Serious injury, harm or death you caused	19.536	0.266	1433.830	5.494*	1.309	23.050	0.964	0.079	11.748	0.339	0.102	1.131

^aFemale compared to male.* $p < .05$. ** $p < .01$. *** $p < .001$.**Table 3***Receiver Operating Characteristic Analysis (ROC)*

Scale	Swiss (n = 214)		China (n = 325)		Israel (n = 544)		Portuguese (n = 218)		Irish (n = 830)	
	cut-off [min; max]	sensitivity/ specificity	cut-off [min; max]	sensitivity/ specificity	cut-off [min; max]	sensitivity/ specificity	cut-off [min; max]	sensitivity/ specificity	cut-off [min; max]	sensitivity/ specificity
IPGDS	37.5 [13; 63]	0.933/ 0.814	42.5 [13; 65]	0.902/ 0.810	N/A	N/A	36.5 [13; 56]	0.933/ 0.818	N/A	N/A
ICG-R	24.5 [8; 40]	0.818/ 0.857	25.5 [8; 40]	0.957/ 0.854	24.5 [8; 40]	1.000/ 0.947	16.5 [7; 35]	0.920/ 0.871	22.5 [8; 40]	0.941/ 0.896

Discussion

This paper provides the first systematic exploration of core items of the new ICD-11 PGD criteria across five international samples. The results confirm large differences in the rates between and within samples depending on the diagnostic algorithm used; predictors of PGD severity may vary across samples due to the type of loss (violent or nonviolent) and the cultural caveat item of the IPGDS may be an important risk screening item; finally, a threshold for a clinically relevant diagnosis may be different depending on cultural group.

Core items of the new ICD-11 PGD criteria, as tested by the IPGDS (in Swiss, Chinese and Portuguese samples) and the ICG-R (in Irish and Israeli samples), revealed substantially different rates depending on the diagnostic algorithm used. Overall, the *strict criteria* for both the IPGDS and the ICG-R seems to capture the expected rates across the five samples, which ranged from 2-21.2%. However, substantially higher rates were found in the Chinese and Portuguese samples. There could be several explanations for these higher rates including sample differences and lack of cultural sensitivity of assessment measures (Stelzer, Zhou, & Maercker, et al., 2020). When the strict criteria of the IPGDS were applied, the Swiss (7.0%) and Portuguese (6.9%) samples had similar rates on the IPGDS, whereas the Chinese sample had a higher rate (12.6%) on the IPGDS. A higher rate in the Chinese sample is consistently found across all iterations of the IPGDS but also for most of the ICG-R comparisons. Conversely, when assessing the ICG-R the Swiss, Chinese, Israeli and Irish samples had similar rates, whereas the Portuguese sample was much higher (21.1%). The Portuguese sample also had high rates on the ICG-R for the strict and moderate criteria, perhaps due to the exclusion of the impairment criteria in this particular sample. Therefore, the results for the Portuguese sample must be interpreted with caution and it points to the importance of including the functional impairment item and ensuring consistency in the use of time criterion in the assessment measure. Additionally, the Portuguese sample included pooled data from the general and clinical sample. The inclusion of the clinical sample could increase the prevalence rates in the Portuguese data compared to the non-clinical samples obtained from the other countries.

The Portuguese sample consisted of a large proportion of bereaved people who experienced an unexpected loss (10%). Although not explicitly recorded, this would mostly include the unexpected loss of a child as participants were from the outpatient perinatal loss clinic. Loss of a child is known to predict high levels of PGD (Zetumer et al., 2015)

Lack of culturally sensitive assessment measures or items could explain differences in the symptom ratings and severity levels across the samples. For example, our previous study confirmed that Chinese bereaved may present with slightly different symptoms than those assessed by the ICD-11 (Killikelly & Maercker, 2017; Stelzer, Zhou, Merzhvynska, et al., 2020). The IPGDS standard scale does not explore somatic symptoms or culturally specific symptoms such as ‘a loss of a part of oneself’ (Stelzer, Zhou,

Merzhvynska, et al., 2020). Additionally, there could be a cultural bias in responding to these questionnaires which may lead to overreporting and overestimation of symptoms. Chentsova-Dutton et al. (2007) found that Chinese participants may overreport certain symptoms in order to ensure that they receive health care and support.

In terms of predictors of PGD severity we assessed a limited selection of predictors available across the datasets. Interestingly, when the cultural caveat item was included (e.g. endorsement of Item 14 of the IPGDs), violating the cultural norms for grief was found to significantly predict more severe grief scores on the IPGDS and the ICG-R. Although we only had the data for the Swiss and Chinese participants, further examination of this item might indicate its importance as a screening item for grief severity. In both the Israeli and Irish sample grief severity was predicted by sudden violent or accidental death whereas this was not found for the Swiss and Chinese samples. This may be due to differences in sampling. The Israeli and Irish data are from large nationally representative samples that may include more instances of sudden violent or accidental death. The Chinese and Swiss samples are mostly student populations who experienced the loss of older relatives. The larger Israeli and Irish datasets contain participants who experienced a high level of violent loss (more than 25%) and this could explain the differences in predictors. Previous research has confirmed that violent loss is a strong predictor of PGD severity and chronicity (Lobb et al., 2010; Schaal, Jacob, Dusingizemungu, & Elbert, 2010). Additionally, Israel and Ireland have recently experienced acts of terrorism that may preclude an added cultural vulnerability to trauma and loss (Duffy, Gillespie, & Clark, 2007; Silverman, Johnson, & Prigerson, 2001).

The final research question was to determine a possible threshold for establishing a clinically significant severity score on the IPGDS. All five datasets could not be compared with the IPGDS however across the Swiss, Chinese and Portuguese data, a score above 36.5 will most likely represent clinically significant PGD symptoms. As a control, the ICG-R was also examined and a score above 22 for all datasets was consistently found, except for the Portuguese sample (16.5). This attests to the variation that can occur across different samples, even with gold standard clinical assessments (Boelen & Lenferink, 2020).

Limitations

Due to inconsistencies in data collection across the five international samples it was not possible to directly compare the IPGDS or the ICG-R across all data sets. The full ICD-11 PGD criteria could therefore not be assessed. In particular the time criterion was not assessed consistently across the datasets for example not in the Portuguese or Israeli datasets. Therefore, a diagnosis of PGD is not possible. However, the core items of the PGD (yearning and preoccupation) as well as some supplementary items of emotional distress could be evaluated and indications of possible caseness implied. It is important to include the time criterion for disorder as individuals may experience severe

distress in the first weeks and months after a loss and this should not be pathologized. Importantly the estimates of prevalence rates for the Portuguese data must be interpreted with caution as there was a high amount of missing data. Furthermore, the Portuguese sample included a clinical subgroup. This may explain why the estimates of prevalence are significantly higher. Across the German, Portuguese and Chinese samples there is a high proportion of female responses. In the future it would be important to provide an analysis of a more representative sample. Additionally, there were only a limited number of similar predictors across all datasets. The data in each country was collected separately at different times, so only a cross sectional comparison is possible on some questionnaire items. Of note, the confidence intervals are very wide for some of the items in the logistic regression, particularly for the cultural criteria. This is perhaps due to a small number of values in some of the cells (response options). In the future a larger sample size should reveal more precise confidence intervals. Finally, in the future and with a more complete dataset the ROC analysis should also be conducted on the moderate and [Maciejewski et al. \(2016\)](#) criteria to provide a full estimate of possible thresholds for sensitivity and specificity.

Conclusion

This paper confirms the importance of establishing international guidance on the consistent use of a diagnostic algorithm for PGD in order to ensure reliability across heterogeneous samples. Currently, we recommend the use of the strict criteria as an indicator of PGD caseness, however this must be confirmed in a clinical sample. Future studies should examine the different PGD algorithms (moderate vs strict) in clinical and cultural samples and include important items that are missing in some of the current data (i.e. the impairment and time criteria as well as the cultural caveat). Additionally, clinicians should be aware of specific risk factors such as violent, sudden loss or screening 'yes' on the cultural caveat IPGDS item as these may predict clinically severe grief. In the future it may be important for clinicians to note that different cultural groups may need different cut-off thresholds for a clinical diagnosis on the IPGDS or other scales.

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Supplementary Materials

The supplementary information contains tables of additional demographic characteristics for each of the five samples (for access see [Index of Supplementary Materials](#) below).

Index of Supplementary Materials

Killikelly, C., Merzhvynska, M., Zhou, N., Stelzer, E.-M., Hyland, P., Rocha, J., . . . Maercker, A. (2021). *Supplementary materials to "Examination of the new ICD-11 prolonged grief disorder guidelines across five international samples"* [Additional information]. *PsychOpen*.
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