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Division of Clinical Psychology and Psychological Treatment
Department of Psychology
Philipps-University of Marburg
Marburg, Germany
email: rief@uni-marburg.de

&

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Department of Psychology
Philipps-University of Marburg
Marburg, Germany
email: weise@uni-marburg.de

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Editorial

Is Singing Under the Christmas Tree Psychologically Recommended? A Scientific Evaluation

Philipp Kanske[1], Winfried Rief[2]

[1] *Clinical Psychology and Behavioral Neuroscience, Faculty of Psychology, Technische Universität Dresden, Dresden, Germany.* [2] *Division of Clinical Psychology and Psychotherapy, Department of Psychology, Philipps-University of Marburg, Marburg, Germany.*

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Corresponding Author: Philipp Kanske, Technische Universität Dresden, Faculty of Psychology, Clinical Psychology and Behavioral Neuroscience, Chemnitzer Str. 46, 01062 Dresden, Germany. Phone +49 (0)351 463-42225. E-mail: philipp.kanske@tu-dresden.de

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Clinical Psychology in Europe CPE wants to present latest scientific findings, but also highlight their societal impact, and practical relevance. Following the tradition of our first three years, we integrate these aims in a special Christmas editorial, that can be taken seriously, but there is no need to be overly serious with it.

Many European families build a Christmas tree into a living room, although this room was kept clean and proper for the other times of the year, and no dirt from outside was allowed. This surprising activity for inside decoration follows old Egyptian, Chinese, Jewish and Northern tribal traditions to put some green into buildings during cold winter days. However, it is unique that these trees seem to trigger some urgent need to sing along, preferably together in families. We will analyze whether, from a psychological perspective, it can be recommended to follow this urgent need, or whether we should give priority to stop this tradition.

It is not easy to find someone who does not know at least one Christmas carol. Why is that? If anything, it suggests that singing under the Christmas tree is not particularly aversive. In fact, for most people singing is surprisingly fun; using a pre- to post-design to evaluate singing, your mood seems to improve (Schladt et al., 2017). And it is not the same if you just listen to music, singing yourself is what seems to do the trick (Kreutz et al., 2004). So, dig up all those Christmas carols from memory and sing to your heart's content?

Now there is one further ingredient that may make the festive singing so pleasurable. The positive mood effect is considerably increased by singing together with others

(Schladt et al., 2017). This could be due to a whole range of social effects of joint singing. Singing with others seems to have an “ice-breaker effect”. Faster than other group activities like crafting, it will increase social bonding and felt closeness (Pearce et al., 2015), potentially because performing music together, requires a considerable amount of social coordination. In order to really sing together, you need to anticipate the sounds produced by others, divide attention between yourself and others and constantly adjust your timing to that of the group (Keller, 2008). This social attentiveness and adaptation increases group cohesion and accordingly, group singing even promotes feelings of social inclusion (Welch et al., 2014).

Christmas is the feast of charity. According to Christian tradition, Jesus was born in a stable and the big churches take the occasion of Christmas to collect money for people in need. Singing could actually benefit such altruistic behavior. It enhances empathy, the capacity to share others’ suffering, and also compassionate feelings for others (McDonald et al., 2022). These social emotions, in turn, increase people’s willingness to help, especially when the other is in need (Lehmann et al., 2022). Maybe this is a reason why churches of different traditions also encourage to sing along.

You probably learned the songs that you are singing already as a child. And this is part of the reason why Christmas carols may have a particular magic about them. In contrast to music that we encountered later in life, the songs we were exposed to as children have a special potential to calm us in the face of stress and act as emotional regulators (Gabard-Durnam et al., 2018). Already at six months of age, we seem to prefer our mother singing to us compared to her speaking (Nakata & Trehub, 2004). And singing with others leads to spontaneous cooperative and helpful behavior in four-year-olds (Kirschner & Tomasello, 2010). So take some time to sing with your kids. It will not only improve your mood, but also help in creating some peace and harmony in the family. This could be a helpful game changer if other education attempts have failed.

Even on a bodily level, music in general and singing in groups in particular have astonishing effects. It increases secretory immunoglobulin A, a marker of immune competence that can only be helpful at the height of the latest flu wave when winter really hits and in the late outbreaks of the COVID pandemic (Kreutz et al., 2004).

The broad positive effects of singing have led to the development of a number of clinical interventions making use of mainly group singing for diverse health conditions ranging from somatic (e.g. Reagon et al., 2017) to neurodegenerative (Baird, 2018) and mental health conditions (Williams et al., 2018). Among others, depression could be shown to be reduced during an eight weeks group singing intervention (Petchkovsky et al., 2013). Meta-analytically, group singing effects for mental health conditions reach moderate to large effect sizes in wellbeing and mental health improvements, mainly attributable to improved emotional states, sense of belonging and self-confidence in patients (Williams et al., 2018).

There seems to be little to no downside to singing and given that almost everyone knows a Christmas carol, Christmas might really be the one occasion to actually do it, for yourself, your family, your children and their children, since it is the early songs we learn that we will never forget. Therefore, the conclusion of this scientific evaluation is quite straight forward: just do it, let's sing together.

On behalf of the whole CPE editorial board, we wish you a relaxing time of the year, and a happy and peaceful new year 2023.

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Research Articles

Psychological Processes Associated With Resilience in UK-Based Unpaid Caregivers During the COVID-19 Pandemic

Emma Wilson [1,2,3], Juliana Onwumere [1,4], Colette Hirsch [1,4]

[1] *Department of Psychology, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, United Kingdom.* **[2]** *Health Service and Population Research, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, United Kingdom.* **[3]** *ESRC Centre for Society and Mental Health, King's College London, London, United Kingdom.* **[4]** *South London and Maudsley NHS Foundation Trust, London, United Kingdom.*

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Corresponding Author: Colette Hirsch, Department of Psychology, Institute of Psychiatry, Psychology and Neuroscience, King's College London, De Crespigny Park, London SE5 8AF, UK. Phone: +44 207 848 0697. E-mail: colette.hirsch@kcl.ac.uk

Supplementary Materials: Materials [see Index of Supplementary Materials]

Abstract

Background: Unpaid caregivers have faced and dealt with additional challenges during the COVID-19 pandemic. Understanding the psychological processes associated with their resilience is warranted. The objective of this study was to examine the associations between resilience with mental distress, emotion regulation strategies (i.e., reappraisal and suppression) and interpretation bias in adult caregivers.

Method: Participants were living in the UK, aged 18+, and consisted of 182 unpaid caregivers of an adult aged 18+ living with a long-term health condition, and 120 non-caregivers. Data were collected in an online study during the first national UK COVID-19 lockdown (May and September 2020). Hierarchical multiple regression analyses explored whether emotion regulation strategies and interpretation bias explained unique variance in levels of resilience in caregivers whilst controlling for anxiety and depression.

Results: Compared to non-caregivers, caregivers reported higher levels of anxiety, depression, negative interpretation bias and lower levels of resilience. Emotion regulation strategies did not differ between groups. Within caregivers, greater resilience was associated with lower mood disturbance, a positive interpretation bias, and greater use of cognitive reappraisal and lower use of suppression strategies to regulate emotions. Emotion regulation and interpretation bias together predicted an additional 15% of variance in current levels of resilience.

Conclusion: Our findings indicate that psychological mechanisms such as emotion regulation strategies, particularly reappraisal, and interpretation bias are associated with resilience in caregivers. Although preliminary, our findings speak to exciting clinical possibilities that could form the target of interventions to improve resilience and lower mental distress in unpaid caregivers.

Keywords

resilience, interpretation bias, emotion regulation, informal carers, unpaid caregivers, COVID-19

Highlights

- Negative interpretation bias, alongside use of emotional regulation strategies (i.e., suppression; reappraisal), and their association with resilience was investigated in unpaid caregivers for the first time.
- Caregivers report lower levels of resilience and higher levels of anxiety and depression compared to non-caregivers during the COVID-19 pandemic.
- The tendency to interpret information in more positive ways, and to use reappraisal as a way to regulate emotions, were associated with greater resilience in caregivers.
- Interpretation bias and reappraisal could form the target of future caregiver tailored interventions to improve resilience.

Data suggests the United Kingdom (UK) is facing an increase in negative mental health outcomes due to the impact of the COVID-19 pandemic (Li & Wang, 2020). Unpaid caregivers (also called informal carers, herein ‘caregivers’) have been defined as ‘anyone, including children and adults who looks after a family member, partner or friend who needs help because of their illness, frailty, disability, a mental health problem or an addiction and cannot cope without their support’ (NHS England, 2014). Pre-pandemic, caregivers represented around 7% of the UK population (Department for Work and Pensions, 2020) and Carers UK (2020) has suggested that numbers doubled from 6.5 million to 13.6 million during the COVID-19 pandemic. Compared to the general population and pre-pandemic, caregivers were at greater risk of anxiety and depression and poorer health outcomes (Smith et al., 2014). This is observable across different illness groups; for example, when caring for someone with dementia (Papadopoulos et al., 2019), cancer (LeSeure & Chongkham-ang, 2015), multiple sclerosis (McKeown et al., 2003), and a mental health condition (Young et al., 2019).

On 23rd March 2020, the UK government introduced a nationwide lockdown with measures aimed to restrict transmission of the virus and mitigate pressure on the National Health Service (NHS). Measures included staying at home with few exceptions (e.g., essential purposes), working from home unless designated a ‘key worker’ and always maintaining social distancing rules. People in at-risk groups were asked to ‘shield’ by remaining indoors. Caregivers had to navigate the changes to their own routine and consider their own pre-existing health conditions and life situation (Onwumere, 2021; Vahia et al., 2020). Hence, in a group already at a heightened risk of social isolation (Hayes et al., 2015) and lower life satisfaction compared to non-caregivers (Naef et al., 2017), distress was exacerbated by social distancing rules and inability to access support from friends and family or formal services in their caring role (Baker & Clark, 2020; Whitley et al., 2021). Understanding how the psychological wellbeing of caregivers, relative to their non-caregiver peers, was impacted during the pandemic and the key mechanisms driving their presentations is an important step in informing future targeted interventions. However, these types of investigations have been limited. Nevertheless, emerging data suggests reduced psychological wellbeing (e.g., heightened anxiety/depressive symptoms, stress/distress related to caregiving, care burden) among family caregivers (Gallagher & Wetherell, 2020; Muldrew et al., 2022), although the psychological mechanisms driving these mood states remain less researched in the literature.

One psychological factor associated with better psychological functioning (i.e., positive adaptation) is resilience (Luthar et al., 2015; Seery et al., 2010), commonly defined as the ability to bounce back from adversity (Rutter, 1985, 1987; Southwick et al., 2015). This psychological process can fluctuate over time and across contexts, so one person may be resilient to certain adversities but not others (Egeland et al., 1993; Pooley & Cohen, 2010). Windle and Bennett’s (2012) theoretical resilience framework for caregivers also highlights how resilience is influenced by interactions in the environment and draws on social resources. Restricted access to important resources in health and social care during periods of lockdown, combined with the threat from the virus to the most vulnerable, may have impacted caregivers in particular, threatening their capacity to remain resilient. Identifying factors that may foster lower levels of distress and higher levels of resilience in caregivers during times of extra stress, such as a pandemic, could help us identify those who are likely to need extra support and better tailor future interventions; particularly when resources are limited (Rapado-Castro & Arango, 2021).

Resilience is associated with higher quality of life, better regulation of emotions, more positive emotions, and less perceived stress, anxiety and depression (Balmer et al., 2014; Troy & Mauss, 2011). In caregivers, reduced mood disturbance (e.g., lower levels of anxiety and depression) is recorded in those reporting higher levels of resilience (Simpson et al., 2015). Moreover, systematic review data suggests that higher resilience levels are linked to reductions in the risk of stress and care burden and supports greater role adaptation (Palacio González et al., 2020). To determine whether caregiver and non-caregiver populations in the UK differed in levels of resilience during early stages (first 3 months) of a global pandemic, data were collected using a widely used, multidimensional self-report measure of resilience with good psychometric properties (Connor & Davidson, 2003; Pangallo et al., 2015).

Given the potential importance of resilience to caregiver wellbeing and outcomes, it would seem important to also identify modifiable psychological mechanisms that can foster resilience, such as emotion regulation approaches (Palacio González et al., 2020). Common approaches include cognitive reappraisal (occurs before an emotion is experienced; seeking alternative perspectives in situations that may change the emotional response) and suppression (purposively attempting to suppress expressive behaviour while emotionally aroused, such as trying not to display anger or annoyance; Gross, 1998; Gross, 2014; Gross & Levenson, 1993). Reappraisal is seen as an opportunity to grow in times of adversity by reducing maladaptive appraisals (e.g., self-blame), whereas suppression involves the avoidance of expressing one's feelings and may lead to negative outcomes (Gross & John, 2003; John & Gross, 2004). The links between emotional regulation and resilience are yet to be explored despite a hypothesised relevance between two concepts that are arguably connected (Kay, 2016). The limited work in this area has suggested that high levels of cognitive reappraisal may serve as a protective factor that fosters resilience after adverse situations (Polizzi & Lynn, 2021; Troy & Mauss; 2011), while expressive suppression may have a negative effect on resilience (Hong et al., 2018; Mouatsou & Koutra, 2021).

Another psychological mechanism that might potentially expand our understanding of resilience in caregivers is interpretation bias, which is the tendency to draw negative conclusions from ambiguous information (Hirsch et al., 2016). There is already data to suggest that lower levels of interpretation bias are linked to greater resilience in groups such as women living beyond breast cancer (Booth et al., 2022; Gordon et al., 2022) and in adolescents (Booth et al., 2022). Such findings support a cognitive model of psychological resilience (Booth et al., 2022), whereby interpretation bias influences levels of resilience and is a key mechanism for maintaining internalising disorders such as mood conditions. Moreover, interpretation biases may interfere with certain protective emotion regulation strategies (e.g., reappraisal), impacting the regulation of negative affect (Joormann & Siemer, 2011). It was therefore anticipated that cognitive reappraisal would be associated with interpretation bias, and suppression associated with more negative interpretation biases of ambiguous situations. Given the challenges faced by unpaid caregivers, it is important to explore the relevance to their wellbeing of these potentially modifiable psychological mechanisms and by doing so, potentially inform the development of targeted and care focused support interventions.

Study Aims

First, we sought to examine caregivers reports of depression, anxiety and resilience, alongside their levels of negative interpretations and compare these to non-caregiver populations. Second, we wanted to assess whether more negative interpretations and suppression of emotions, as well as less use of reappraisal, are associated with, and help predict, resilience levels in UK caregivers between May to September 2020 of the COVID-19 pandemic.

Hypothesis 1

Caregivers compared to non-caregivers will have lower levels of resilience, and higher levels of anxiety and depression. Exploratory analysis will see if negative interpretation bias, emotion regulation (reappraisal and suppression) varies between caregivers and non-caregivers.

Hypothesis 2

Within the caregiver population, greater resilience will be associated with lower levels of negative interpretation bias and expressive suppression, and greater use of cognitive reappraisal.

Hypothesis 3

Within the caregiver population, emotion regulation and interpretation bias will contribute extra and unique variance in levels of resilience in a model which controls for factors known to be associated with resilience – anxiety and depression.

Method

Participants

Participants were aged 18+ and living in the UK. We recruited 182 caregivers and 120 non-caregivers. Caregivers could participate if they were not in a paid caring role (except for any state benefits/financial support for carers), had been in a caring role for 6 months or more, for someone aged 18+ who has a long-term condition commonly associated with caregiving (i.e., dementia, cancer, multiple sclerosis, and any mental health condition). Participants were recruited through social media, online message boards, charities (e.g., webpages or newsletters), the Join Dementia Research forum and Call for Participants.

Materials and Measures

Demographic Questions

Participants completed several demographic questions regarding age, ethnicity, gender, employment status and relationship status. Questions were completed about their experience of the pandemic, including whether they believed they had had COVID-19, were currently self-isolating/quarantining (i.e., not leaving the house or having visitors), and whether they were a paid keyworker (i.e., paid workers in certain key sectors defined as critical to the COVID-19 response; Department for Education, 2021).

Caregivers were asked additional questions about the people they provide care for (i.e., number they care for, their relationship to them, their condition). If caregivers selected more than one medical condition, caregivers were asked to stipulate whether it was the primary condition of the person they care for. For caregivers caring for more than one person, they were asked to respond in relation to the person they currently spent most time caring for. Questions covered specific diagnosis, gender, age, employment status of the person cared for, estimated number of hours spent in this caregiving role per week, whether they live together and duration of their caring role. Caregivers were also asked if they had people to confide in and if so, how many. See Supplementary Materials 1 for full list of questions.

Questionnaire Measures

Connor-Davidson Resilience Scale (CD-RISC) — This 25-item questionnaire (Connor & Davidson, 2003) measures resilience over the past month on a 5-point Likert scale (1 = *not at all* to 5 = *true nearly all the time*). Total scores range from 0 – 100 with higher scores reflecting greater resilience. Example item: *'I tend to bounce back after illness, injury, or other hardships'*. The CD-RISC has demonstrated high internal consistency in previous studies with caregivers of older adults (α = .94; Ong et al., 2018), people with dementia (α = .89; Ruisoto et al., 2020), and severe mental illness (α = .93; Mulud & McCarthy, 2017). Present sample Cronbach's α = .91.

Generalized Anxiety Disorder 7 (GAD-7) — This 7-item questionnaire (Spitzer et al., 2006) measures symptoms of anxiety over the past 2 weeks and asks participants 'how often have you been bothered by the following problems?' on a 4-point Likert scale (1 = *not at all* to 4 = *never*). A sum score is calculated, and scores assigned to the following categories of anxiety: Minimal (< 4), mild (5-9), moderate (10-14), severe (15-21). Example item: *'worrying too much about different things'*. The GAD-7 has been found to have high/good internal reliability in the general population (Löwe et al., 2008) and in carers (α = .93; Lappalainen et al., 2021). Present sample Cronbach's α = .91.

Patient Health Questionnaire 9 (PHQ-9) — This 9-item questionnaire (Kroenke & Spitzer, 2002) measures symptoms of depression over the past 2 weeks and asks participants 'how often have you been bothered by the following problems?' on a 4-point Likert scale (1 = *not at all* to 4 = *never*). The sum of scores indicates the following depression severities: None (<4), mild (5-9), moderate (10-14), moderately severe (15-19), severe (20-27). Example item: *'little interest or pleasure in doing things'*. The PHQ-9 has been found to be a valid and reliable measure of depression (Kroenke et al., 2001) and is widely used in caregiver studies (Kishita et al., 2020; Ping Pang et al., 2020). Present sample Cronbach's α = .91.

Emotion Regulation Questionnaire (ERQ) — This 10-item questionnaire (Gross & John, 2003) measures how individuals use two emotional regulation strategies in daily life: cognitive reappraisal and expressive suppression. The reappraisal scale contains six items (e.g., '*when I'm faced with a stressful situation, I make myself think about it in a way that helps me stay calm*') and suppression contains four items (e.g., '*I control my emotions by not expressing them*'), using 7-point Likert scales (1 = *strongly disagree* to 7 = *strongly agree*). The score for each subscale is the mean of the items (range 1 – 7) and the ERQ has been used in carer populations (α range from .67 to .84; Aerts et al., 2019; Lamothe et al., 2018). Present sample Cronbach's α = .74.

Interpretation Bias Task

Scrambled Sentences Test (SST) — Adapted from Wenzlaff and Bates (1998, 2000) and used in Hirsch et al. (2020); in 20 trials, participants select 5 words from 6 randomly presented words to form a grammatically correct sentence. Potential completions are positive or negative interpretations of self-referent statements. The task is completed over five minutes while holding a six-digit string in mind. The digit string has been used previously to add a cognitive load, allowing latent biases to be observed and limit participants from guessing the purpose of the sentence scrambling task, reducing the risk of answers being subject to demand characteristics such as social desirability (Krahé et al., 2022; Schoth & Liossi, 2017). An interpretation bias score is created by dividing the number of grammatically correct positively unscrambled sentences by the number of correct negatively unscrambled sentences. Index scores range from 0 to 1, with higher scores denoting a more positive interpretation bias.

Procedure

The survey was hosted on Qualtrics with all data collected between May and September 2020, between the middle of the first COVID-19 lockdown and the start of the UK home nations gradually reopening. Both caregiver and non-caregiver groups completed the same core survey (questionnaires, SST), and caregivers completed additional demographic questions about the person(s) they care for. The survey took 35 – 50 minutes to complete and participants could enter a prize draw for Amazon vouchers: 1 of 20 £10 prizes, 1 of 2 £50 prizes, or 1 of 2 £100 prizes. The study was approved by the King's College London Research Ethics Committee (approval number: HR-19/20-14617) and participants provided consent and data electronically.

Statistical Analysis

Bivariate descriptive statistics were used to describe sample characteristics and summarise scores of study measures. Continuous variables were expressed as means (standard deviation, SD). Two-tailed *t*-tests for continuous variables (e.g., age) and chi-squared tests for categorical variables (e.g., gender) were used to test for group differences in sociodemographic factors and study variables (H1). Effect sizes were calculated using Cohen's *d* for *t*-tests, and Phi and Cramer's V for chi-squared tests. Associations between study variables in caregivers were quantified using Pearson's correlation coefficient (H2). In the caregiver sample, a hierarchical regression tested the hypothesis that emotion regulation strategies (i.e., reappraisal and suppression) and interpretation bias would contribute significant variance, beyond anxiety and depression, in predicting levels of resilience (H3). Anxiety and depression were entered as independent variables in the model's first step. Emotion regulation and interpretation bias were entered into the second step as independent variables. Resilience was the outcome variable. Statistical significance was set at $p < .05$. SPSS versions 26 and 27 were used to conduct all analyses.

Results

See Table 1 for participant demographics and Table 2 for characteristics of the individuals that caregivers were caring for and their caregiving role. Participants were predominantly women and White British, with a higher proportion in the caregiver group. The higher rates of women as caregivers is similar to levels reported in the literature (Tur-Sinai et al., 2020). Other demographic characteristics were well-matched. Caregivers most often cared for someone with dementia (66%) and lived with the person they cared for (61%). Mental health conditions included depression ($n = 8$), anxiety ($n = 4$), psychosis/schizophrenia, ($n = 3$), PTSD ($n = 2$), bipolar disorder ($n = 2$), personality disorder ($n = 2$), eating disorder ($n = 2$), OCD ($n = 1$), other/multiple conditions including autism and learning difficulties ($n = 12$), not reported ($n = 8$).

Several post hoc power analyses were conducted to test for the power of the analyses conducted for each of our hypotheses (e.g., *t*-test, correlation, multiple regression). Except for two *t*-tests with small effect sizes (i.e., ERQ-R, ERQ-S; see Table 3), the minimum power achieved for all analyses was .82.

Table 1

Demographic Characteristics

	Caregiver sample (*n* = 182)	**Non-caregiver sample (*n* = 120)**	**Statistical test, significance value and effect size**
Baseline Characteristic	***n* (%)**	***n* (%)**	
Age – *M* (*SD*)[a]	56.36 (13.48)	53.76 (17.65)	$t(207.98) = 1.37$, $p = .172$, $d = .166$
Ethnicity			Non-White British vs. White British, $\chi^2(1) = 7.64$, $p = .006$, $\varphi = -.159$
Arab	–	1 (0.8)	
Bangladeshi	1 (0.5)	–	
Black British	3 (1.6)	–	
Chinese	1 (0.5)	1 (0.8)	
Indian	3 (1.6)	1 (0.8)	
Pakistani	1 (0.5)	–	
Other	1 (0.5)	22 (18.3)	
White and Asian	1 (0.5)	1 (0.8)	
White and Black Caribbean	1 (0.5)	1 (0.8)	
White British	159 (87.4)	90 (75.0)	
White Gypsy or Irish Traveller	1 (0.5)	–	
White Irish	5 (2.7)	3 (2.5)	
Gender[b]			$\chi^2(1) = 12.19$, $p = .001$, $\varphi = .201$
Woman	155 (85.2)	82 (68.3)	
Man	26 (14.3)	37 (30.8)	
Employment status			$\chi^2(3) = 1.68$, $p = .641$, V = .075
Full-time employment	25 (13.7)	23 (19.2)	
Part-time employment	34 (18.7)	22 (18.3)	
Retired	62 (34.1)	39 (32.5)	
Other	61 (33.5)	36 (30.0)	
Relationship status			$\chi^2(3) = 11.15$, $p = .011$, V = .192
Married/ domestic partnership	108 (59.3)	49 (40.8)	
Cohabiting	23 (12.6)	18 (15.0)	
Single	26 (14.3)	31 (25.8)	
Separated, divorced, widowed	25 (13.7)	22 (18.3)	
COVID-19 questions			
Caregiver has had COVID-19[c]	25 (13.7)	19 (15.8)	$\chi^2(1) = 0.96$, $p = .327$, $\varphi = -.063$
Self-isolating/ in quarantine[de]	20 (11.0)	18 (15.1)	$\chi^2(2) = 2.59$, $p = .274$, V = .093
Considered a ‘key worker’[fg]	36 (19.8)	22 (18.3)	$\chi^2(1) = .08$, $p = .781$, $\varphi = .016$

[a]Declined to say: *n* = 1. [b]Other: *n* = 2. [c]Respondents asked: *n* = 245. [d]Declined to say: *n* = 1. [e]By self-isolating/ in quarantine we mean not leaving the house for any reason and avoiding contact with anyone outside the household. [f]Declined to say: *n* = 1. [g]A ‘key worker’ was defined as someone who worked in: health and social care, education and childcare, key public services, local and national government, food and other necessary goods, public safety and national security, transport, utilities, communication and financial services. Phi (φ) and V (V) are measures of effect size for chi-square tests.

Table 2

Characteristics of the Person/People Caregivers Cared for and the Caregiving Role

Characteristics	**Participants (*n* = 182)**
Number they care for, *mean (SD)*	1.25 (0.62)
Primary condition, *n* (%)[a]	
Dementia	120 (65.9)
Multiple sclerosis	8 (4.4)
Cancer	10 (5.5)
Mental health condition	44 (24.2)
Relationship, *n* (%)	
Spouse/partner	66 (36.3)
Son/daughter	62 (34.1)
Parents	34 (18.7)
Other relative/friend/neighbour	20 (11.0)
Hours per week in caregiving role, *n* (%)	
0 – 19	60 (33.0)
20 – 49	49 (26.9)
50 – 90	24 (13.2)
Over 100	49 (26.9)
Duration of caregiving role, *n* (%)	
Under 12 months	18 (9.9)
1 – 5 years	75 (41.2)
5 – 10 years	45 (24.7)
Over 10 years	44 (24.2)
Live with person cared for, *n* (%)	
Yes	111 (61.0)
No	71 (39.0)
Has someone to confide in, *n* (%)	136 (74.7)
Number of confidents, *mean* (*SD*)	3.32 (2.51)

[a] If more than one condition listed, participant asked to provide primary condition of person they care for.

Do Caregivers Exhibit Lower Levels of Resilience and Higher Levels of Distress Than Non-Caregivers and Is Interpretation Bias More Negative in Caregivers?

The mean scores for all questionnaires are presented in Table 3. In keeping with Hypothesis 1, caregivers demonstrated lower levels of resilience, higher levels of anxiety, depression and interpretation bias with small to medium effect sizes (*d* = 0.36 to 0.74). Exploratory analysis found that emotion regulation techniques did not differ significantly between groups.

Table 3

Scores for Questionnaires and Interpretation Bias Measure, by Group

Measures	Caregiver group (n = 182) M (SD)	Non-caregiver group (n = 120) M (SD)	t-test and significance value
Questionnaire			
Resilience (CD-RISC)	62.21 (13.86)	66.98 (12.58)	t (300) = -3.04, p = .003, d = 0.36
Anxiety (GAD-7)	6.91 (5.44)	4.03 (4.63)	t (281.09)* = 4.92, p < .001, d = 0.57
Depression (PHQ-9)	8.95 (6.60)	4.63 (5.00)	t (294.30)* = 6.47, p < .001, d = 0.74
Emotion Reappraisal (ERQ-R)	4.44 (1.18)	4.62 (1.03)	t (300) = -1.33, p = .183, d = 0.16
Emotion Suppression (ERQ-S)	3.77 (1.35)	3.54 (1.23)	t (300) = 1.49, p = .137, d = 0.18
Interpretation bias (SST)	0.67 (0.24)	0.76 (0.20)	t (285.26)* = -3.60, p < .001, d = 0.42

Note. CD-RISC = Connor-Davidson Resilience Scale; GAD-7 = Generalised Anxiety Disorder Questionnaire; PHQ-9 = Patient Health Questionnaire; ERQ-R = Emotion Regulation Questionnaire – Reappraisal; ERQ-R = Emotion Regulation Questionnaire – Suppression; SST = Scrambled Sentences Test.
*Equal variances not assumed.

Is There an Association Between Resilience, Emotion Regulation Techniques and Interpretation Bias in Caregivers?

To examine how resilience may be associated with emotion regulation techniques and more negative interpretations (H2), we conducted Pearson's correlations; see Table 4 (non-caregiver sample on request). As expected, caregivers reporting greater resilience had a more positive interpretation bias, and greater use of cognitive reappraisal and lower use of suppression strategies to regulate emotions. Furthermore, greater resilience was associated with lower levels of anxiety and depression symptoms.

To determine whether emotion regulation and/or interpretation bias helps account for levels of resilience, we conducted a hierarchical multiple regression (see Table 5). In Step 1, processes known to be covariates of resilience were entered: anxiety and depression. In Step 2 emotion regulation via reappraisal, emotion regulation via suppression and interpretation bias scores were entered into the model. In Step 1, the model accounted for 33% of the variance in resilience, $F(2, 179) = 44.69$, $p < .001$ (see Table 5). When emotion regulation techniques and interpretation bias were added in Step 2, an additional 15% of variance of resilience was explained (Adjusted R^2 = .48), $F(5, 176)$ = 33.96, p < .001. Furthermore, both interpretation bias (β = .35, p < .001) and cognitive reappraisal (β = .28, p < .001) significantly predicted independent variance in resilience, but not emotion regulation via suppression (β = -.05, p = .385). Results did not change when other covariates associated with caregiving were added into the model (i.e., gender, age, ethnicity, time caring per week, duration of caregiving role; see Supplementary Analyses 2).

Table 4

Correlations Between Resilience, Anxiety, Depression, Emotion Regulation and an Interpretation Bias Measure (SST) in Caregiver Participants

Measure	1	2	3	4	5
1. CD-RISC					
2. GAD-7	-.50***				
3. PHQ-9	-.57***	.80***			
4. ERQ-R	.49***	-.31***	-.31***		
5. ERQ-S	-.21**	.23***	.293**	-.03	
6. SST	.64***	-.65***	-.75***	.41***	-.26***

Note. n = 182; CD-RISC = Connor-Davidson Resilience Scale; GAD-7 = Generalised Anxiety Disorder Questionnaire-7; PHQ-9 = Patient Health Questionnaire-9; ERQ-R = Emotion Regulation Questionnaire – Reappraisal; ERQ-S = Emotion Regulation Questionnaire – Suppression; SST = Scrambled Sentences Test.
$^{**}p$ < .01. $^{***}p$ < .001.

Table 5

Hierarchical Regression Analysis Testing the Influence of our Predictors on Resilience

Predictor variable	*B*	*SE*	β	*t*
Step one				
GAD-7	-0.33	0.26	-.13	-1.28
PHQ-9	-0.98	0.21	-.47	-4.59***
Step two				
GAD-7	-0.10	0.23	-.04	-0.42
PHQ-9	-0.37	0.22	-.18	-1.69
ERQ-R	3.26	0.69	.28	4.71***
ERQ-S	-0.51	0.58	-.05	-0.87
SST	20.35	4.90	.35	4.15***

Note. n = 182. B = unstandardized coefficient; SE = standard error; β = standardised coefficient; GAD-7 = Generalised Anxiety Disorder Questionnaire; PHQ-9 = Patient Health Questionnaire; ERQ-R = Emotion Regulation Questionnaire – Reappraisal; ERQ-R = Emotion Regulation Questionnaire – Suppression; SST = Scrambled Sentences Test.
$^{***}p$ < .001.

Discussion

This study aimed to investigate reported levels of resilience and wellbeing in unpaid adult caregivers of a person aged 18+ with a long-term condition (specifically, multiple sclerosis, dementia, any mental health condition, and/or cancer) compared to non-caregivers during a period of additional stress – the COVID-19 pandemic – and what role, if any, potentially modifiable psychological mechanisms (i.e., interpretation bias, emotion regulation via reappraisal and suppression) had on carers' reported levels of resilience. To the best of our knowledge, this represents the first investigation of its kind.

As predicted and in keeping with non-pandemic data, caregivers reported lower levels of resilience and greater levels of depression and anxiety compared to non-caregivers (our control condition). Our pattern and direction of findings for these higher levels of caregiver emotional distress and lower resilience support published findings using samples from before (Onwumere et al., 2017; Smith et al., 2014; Windle & Bennett, 2012) and during the pandemic (Kalb et al., 2021).

Our study confirmed for the first time that caregivers' resilience levels were associated with greater levels of positive interpretation bias, greater levels of reappraisal emotion regulation techniques and, to a lesser extent, lower levels of suppression. A more positive interpretation bias as well as greater use of cognitive reappraisal accounted for an additional 15% of the variance in resilience scores, with interpretation bias and use of reappraisal to regulate emotions both accounting for independent variance in resilience. To support a more nuanced understanding of these findings, an investigation with a similar sample outside of a global pandemic would be indicated.

Cognitive reappraisal and expressive suppression are independent constructs within the area of emotion regulation (Moore et al., 2008). Reappraisal is central to managing one's emotional reaction to stressful situations, encouraging positive outcomes over time and important for understanding resilience, whereas suppression fails to address the emotion internally (Troy & Mauss, 2011). Although both forms were associated with resilience, the current data found reappraisal, a cognitive construct, more relevant to fostering resilience than suppression, a non-cognitive construct that is focused on changing only the outward expression of emotions (Gross, 2014). This supports recent literature, which has found more mixed findings for the relation between expressive suppression and resilience, suggesting that situational factors may influence the longer-term adaptive or maladaptive role of suppression (Polizzi & Lynn, 2021). As a first step, supporting caregivers with emotional reappraisal techniques may be more beneficial than targeting expressive suppression.

Our findings on interpretation bias add to a growing body of literature that explores the impact of this cognitive bias in other populations, including adolescents with eating disorders, individuals with anxiety disorders, pregnant women, parents and their offspring (Hirsch et al., 2021; Rowlands et al., 2020; Subar & Rozenman, 2021). All highlight the risk of negative outcomes for negative interpretation biases. Importantly, interpretation bias and reappraisal are known to be modifiable mechanisms that can be targeted in psychological interventions; fostering a more positive interpretation bias or facilitating greater use of reappraisal techniques to regulate emotions could be beneficial in increasing resilience in caregivers. Interventions to foster resilience both at an individual or familial level, and population level, are crucial for managing future pandemics and any longstanding negative impacts from COVID-19 (Ameis et al., 2020), as well as challenges associated with long-term caregiving in non-pandemic times.

It is notable that while resilience is lower in caregivers (62.21) than non-caregivers (66.98), scores are much lower than general populations prior to the COVID-19 pandemic (80.4; Connor & Davidson, 2003). Indeed, our caregiver sample have similar levels of resilience to patients commencing a trial for PTSD (62.0; Krystal et al., 2014) and psychiatric outpatients with a history of recent trauma (64.3; Glass et al., 2019), although not as severe as some other PTSD populations (e.g., 49.8 to 55.7; Davidson et al., 2006; McGuire et al., 2018). While the mean levels of anxiety and depression reported in caregivers fell within the non-clinical range (i.e., a score of 7 or below for the GAD-7 and 9 or below for the PHQ-9), levels were higher compared to non-caregivers ($p < .001$, $d = 0.57$ to 0.84) and 46.2% still reported clinical levels of anxiety and 25.8% reported clinical levels of depression. This remains consistent with current literature (Giebel et al., 2021; Li et al., 2021) and offers further support of the need to consider the wellbeing of caregivers.

The results offer early support for potential therapeutic avenues. Cognitive behaviour therapy (CBT), for example, fosters more positive interpretations by reducing maladaptive thinking (DeRubeis et al., 2008) and a greater use of reappraisal to regulate emotion (Smits et al., 2012). Another approach to increase positive interpretation bias is cognitive bias modification for interpretations (CBM-I); this involves repeated computerised practice in generating more positive interpretations (Menne-Lothmann et al., 2014). It is possible that a caregiver focused CBM-I intervention could be tailored to focus on promoting more positive interpretations of ambiguous and potentially negative situations that caregivers frequently encounter (e.g., uncertainty and ambiguity around implications for changes in symptoms in the person they care for). Future qualitative studies could explore the specific caregiver stressors contributing to negative interpretations and its sequalae, compared to those unrelated to caregiving, to see if there is a generalised or situation-specific bias.

There are limitations of the current study. Firstly, it is cross-sectional, with data collected data within four months near the start of the pandemic. It therefore does not provide information on trajectories of resilience over the longer term during the pandemic, nor provide information on the extent to which interpretation bias predicts later levels of resilience in the caregiver populations. Furthermore, we are unable to determine the extent to which general caregiver stress was exacerbated by the pandemic for a given individual in this sample due to lack of pre-pandemic data. While caregiving roles can be held by anyone, irrespective of demography, ethnic minority participants were largely underrepresented in our sample. This is important given that many of the key conditions in this study disproportionately affect some racial and ethnic minority groups, such as dementia, and caregiver experiences may differ across cultures (Liu et al., 2021). Consequently, the under-representation limits generalisability of findings to the wider population.

Additionally, our study did not look at the impact of looking after children during the pandemic. Managing home-schooling alongside other responsibilities such as work undoubtedly contributed to additional challenges. These have been considered in great depth elsewhere. Finally, participants could only be recruited and participate via the Internet and therefore less likely to represent the experiences of informal caregivers with no or limited access to the Internet, or those with less time to take part due to increase caregiving demands. In 2020, groups less likely to have internet access in the UK included the over 75s (46%), retired individuals (28.9%) and persons who self-assessed as having a disability (18.6%; Office for National Statistics, 2021).

As convenience samples, our groups were also not matched on all demographic variables. Specifically, control participants were more frequently European White, men and single, as compared to caregivers. The under representation of particular groups is part of a broader issue in UK health focused surveys (Harrison et al., 2020). Nevertheless, future studies should aim to better match the control group to the caregiver sample.

In summary, caregivers were reporting less resilience and higher levels of anxiety and depression compared to non-caregivers during the COVID-19 pandemic. Importantly, the tendency to interpret information in more positive ways and to use reappraisal as a way to regulate emotions was associated with greater resilience and could form the target of future caregiver interventions to improve resilience.

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Twitter Accounts: @MindfulEm

Supplementary Materials

The Supplementary Materials contain the following items (for access see Index of Supplementary Materials below):

- *Supplementary Materials 1*: Additional questions asked to unpaid caregivers
- *Supplementary Materials 2*: Hierarchical regression analysis testing the influence of our predictors on resilience while controlling for additional covariates

Index of Supplementary Materials

Wilson, E., Onwumere, J., & Hirsch, C. (2022). *Supplementary materials to "Psychological processes associated with resilience in UK-based unpaid caregivers during the COVID-19 pandemic"* [Additional information]. PsychOpen GOLD. https://doi.org/10.23668/psycharchives.9297

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Research Articles

Symptom Perceptions in Functional Disorders, Major Health Conditions, and Healthy Controls: A General Population Study

Angelika Weigel[1,2], Thomas Meinertz Dantoft[3], Torben Jørgensen[3,4,5], Tina Carstensen[2,6], Bernd Löwe[1], John Weinman[7], Lisbeth Frostholm[2,6]

[1] *Department of Psychosomatic Medicine and Psychotherapy, University Medical Center Hamburg-Eppendorf, Hamburg, Germany.* **[2]** *The Research Clinic for Functional Disorders and Psychosomatics, Aarhus University Hospital, Aarhus, Denmark.* **[3]** *Center for Clinical Research and Prevention, Bispebjerg and Frederiksberg Hospital, Capital Region of Denmark, Denmark.* **[4]** *Department of Public Health, Faculty of Medical Sciences, University of Copenhagen, Copenhagen, Denmark.* **[5]** *Faculty of Medicine, Aalborg University, Aalborg, Denmark.* **[6]** *Department of Clinical Medicine, Aarhus University, Aarhus, Denmark.* **[7]** *School of Cancer & Pharmaceutical Sciences, King's College London, London, United Kingdom.*

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Corresponding Author: Angelika Weigel, University Medical Center Hamburg-Eppendorf, Department of Psychosomatic Medicine and Psychotherapy, Martinistr. 52, 20246, Hamburg, Germany. Phone: 0049 40 7410 52996. E-mail: a.weigel@uke.de

Abstract

Background: The present study investigated differences in symptom perceptions between individuals with functional disorders (FD), major health conditions, and FDs + major health conditions, respectively, and a group of healthy individuals. Furthermore, it investigated the relevance of FDs among other health-related and psychological correlates of symptom perceptions in the framework of the Common Sense Model of Self-Regulation (CMS).

Method: This cross-sectional study used epidemiological data from the Danish Study of Functional Disorders part two (N = 7,459 participants, 54% female, 51.99 ± 13.4 years). Symptom perceptions were assessed using the Brief Illness Perception Questionnaire (B-IPQ) and compared between the four health condition groups. Multiple regression analyses were performed to examine associations between symptom perceptions, FDs, and other health-related and psychological correlates from the CMS framework.

Results: Individuals with FDs (n = 976) and those with FDs + major health conditions (n = 162) reported less favorable symptom perceptions compared to the other two groups, particularly regarding perceived consequences, timeline, and emotional representations (effect size range Cohen's d = 0.12-0.66). The presence of a FD was significantly associated with all B-IPQ items, even in the context of 16 other relevant health-related and psychological correlates from the CMS framework, whereas symptom presence last year or last week was not.

Conclusion: In the general population, symptom perceptions seem to play a more salient role in FD than in individuals with well-defined physical illness. Symptom perceptions should therefore be targeted in both primary and secondary interventions for FDs.

Keywords

symptom perceptions, functional disorders, epidemiological study, quality of life, common-sense model of illness, personality traits

Highlights

- Symptom perceptions were poorest in individuals with functional disorders with and without co-occuring major health conditions.
- Functional disorders in oneself and in the family were associated with symptom perceptions.
- Symptom presence last year or last week was not associated with symptom perceptions.

Experiencing physical symptoms is a common everyday phenomenon in the general population (Hinz et al., 2017). Their perception and appraisal are results of multidimensional processes that go beyond a recognition of peripheral bodily changes (Petersen et al., 2011). In major health conditions (e.g., cancer, heart attack), the relationship between peripheral bodily dysfunctions and self-reported symptoms is weaker in chronic multisymptomatic than in acute monosymptomatic diseases (Janssens et al., 2011). In functional disorders, i.e., bothersome physical conditions that are not better explained by physical diseases or mental disorders and are associated with reduced health-related quality of life, evidence suggests a weaker relation between physical parameters (e.g., respiratory changes after gradually increased ventilation) and symptom perceptions (e.g., perceived dyspnea) compared to healthy controls (Bogaerts et al., 2010). These varying associations between peripheral bodily changes and symptom perceptions underline the relevance of cognitive and emotional processes in symptom perception and appraisal (Van den Bergh et al., 2017).

Symptom perceptions describe dynamic mental representations and personal ideas that individuals generate to make sense of and respond to their symptoms (Broadbent et al., 2015). Among numerous empirically tested theoretical models of symptom perception and appraisal (Whitaker et al., 2015), the Common-Sense Model of Self Regulation is particularly established (CSM; Leventhal et al., 2016). According to the CSM, individuals' mental models of experienced symptoms include cognitive representations of the symptom identity (lay diagnosis), the coherence and the perceived timeline, the control over and consequences of the experienced symptoms as well as emotional representations of symptom concerns and emotional reactions. Symptom perceptions thereby directly affect the coping efforts that may be more or less beneficial. Individuals then appraise the effects of these coping efforts, which may result in changes to their cognitive representations and emotional responses in a feedback loop. However, while healthy individuals can form their symptom perceptions based on their experience that symptoms are usually non-threatening and short-lived everyday phenomena and individuals with chronic diseases usually receive a biomedical explanation of their symptoms and a diagnostic label with an associated treatment rational, individuals with functional disorders lack these aspects. Instead, individuals with functional disorders are often confronted with inconclusive medical findings and receive no diagnostic label or external information about the possible course of the disease, which might negatively influence their symptom perceptions.

Symptom perceptions have an impact on health outcomes in both mental and somatic disorders (Dempster et al., 2015; Hagger et al., 2017). For example, one methodologically rigorous study that investigated illness perceptions in a primary healthcare sample with diverse new health complaints provided evidence for the impact of symptom perceptions on quality of life (Frostholm et al., 2007). Furthermore, there is a large body of literature on the influence of symptom perceptions in clearly defined medical conditions on various health outcomes (Aalto et al., 2006; De Gucht, 2015; O'Donovan et al., 2016; Tiemensma et al., 2016; Timmers et al., 2008; Tribbick et al., 2017; van Erp et al., 2017; Xiong et al., 2018). Despite valuable insights into the relevance of symptom perceptions on health outcomes, previous studies have rarely investigated symptom perceptions in individuals with functional disorders with potential co-occuring medical conditions. Research into this area is crucial as suggested by a Dutch epidemiological study showing that the functional impairments associated with functional disorders are similar in severity to those in major health conditions (Joustra et al., 2015). In addition, more negative symptom perceptions have been observed in individuals with functional gastrointestinal disorders compared with patients with peptic ulcer or reflux esophagitis (Xiong et al., 2018) and functional disorders might co-occur with medical conditions (Halpin & Ford, 2012).

According to the CSM, a number of contextual, health-related, and psychological factors may influence the formation of symptom perceptions. A recent systematic review on so-called modifiable correlates of symptom perceptions observed an association between higher symptom severity and less favorable symptom perceptions in different somatic conditions (Arat et al., 2018). The same review highlighted a negative influence of depression and anxiety on symptom perceptions, with the limitation that no differentiation was made between lifetime mental disorders and the current presence of symptoms. Only few studies have considered other mental comorbidities than depression and anxiety. Two studies investigated the influence of post-traumatic stress disorder (PTSD) on symptom perceptions in patients with a myocardial infarction and observed significantly less favorable symptom perceptions in patients with PTSD symptomatology compared with those without (Princip et al., 2018; Sheldrick et al., 2006). In contrast, many studies have investigated coping and symptom perceptions. A meta-analysis by Dempster and colleagues concluded that symptom perceptions and coping explain a valuable amount of variance in distress outcomes across a range of physical health conditions (Dempster et al., 2015).

One cross-sectional study investigated the association between Type D personality and illness perceptions in colorectal cancer survivors and observed significantly less favorable symptom perceptions in those with high Type D personality traits (Mols et al., 2012). However, the concept of Type D personality has been criticized in favor of the Big Five personality traits (neuroticism, extraversion, openness, agreeableness, conscientiousness; Horwood & Anglim, 2017). Furthermore, there is evidence that personality traits are more relevant to symptom perceptions than current illness severity (Goetzmann et al., 2005), and that symptom perceptions at least partially mediate the association between personality traits and coping (Rassart et al., 2014). Within this body of literature on correlates of symptom perceptions in the framework of the CMS, the possible influence of functional disorders in a patient or his/her significant others has not yet been investigated.

Knowledge of symptom perceptions within the CSM framework from a large representative general population sample can help shed light on the possible differences in symptom perceptions in functional disorders and somatic diseases, respectively. Such an investigation would increase the evidence base for the current theoretical understanding of the role of specific symptom perceptions in functional disorders. Furthermore, it may pave the way for the identification of intervention components to improve symptom management and improve health outcomes as has been shown in patients with myocardial infarction (Petrie et al., 2002) and severe functional disorders (Christensen et al., 2015).

The first aim of the present epidemiological study was to compare symptom perceptions in healthy individuals and individuals with either functional disorders, major health conditions or both. We hypothesized that there would be differences between the four health condition groups, with particularly less favorable symptom perceptions in individuals with functional disorders. The second aim was to examine whether the presence of a functional disorder in a participant or his/her significant others would explain meaningful variance in symptom perceptions besides a large number of other possible correlates of symptom perceptions from the CMS framework by means of an exploratory approach.

Method

Study Population

Data collection took place in the context of the “Danish study of Functional Disorders” (DanFunD; Dantoft et al., 2017). The complete DanFunD sample comprises a random sample of 9,656 participants aged between 18-76 years from the Danish general population living in the western part of greater Copenhagen (participation rate 33.7%). Recruitment occurred in two cross-sectional waves with the same eligibility criteria: DanFunD part one from 2011 to 2012 (2,308 participants) and DanFunD part two from 2012 to 2015 (7,493 participants). All DanFunD participants completed a general health examination and a self-report questionnaire battery at the Research Centre for Prevention and Health, Glostrup, Denmark. The DanFunD part two self-report questionnaire battery included a questionnaire on symptom perceptions, and this cohort was therefore eligible for the present study. All participants gave their written informed consent prior to study participation. The study was approved by the Ethical Committee of Copenhagen Country (KA-2006-0011, H-3-2011-081, H-3-2012).

Measures

Symptom Perceptions

The Danish version of the B-IPQ was applied to assess symptom perceptions with eight numerous rating scales (range 1–10, for item wording see Table 2, Broadbent et al., 2006). The B-IPQ uses a single-item scaling to measure symptom perceptions based on the CSM with five items related to cognitive perceptions, two items to emotional aspects and one item to the understanding of an illness. Participants were instructed only to fill out the B-IPQ items if they had experienced symptoms during the last year according to the BDS checklist (see below) or the last week (SCL-90 somatization subscale). As symptom perceptions were assessed with respect to physical symptoms and not to a certain illness, the B-IPQ item assessing illness *identity* was removed. Items assessing personal control, treatment control and coherence were reversed to facilitate interpretation, i.e., that higher scores indicate less control and less coherence.

Four Health Condition Groups

The questionnaire set comprised a predefined 22-item list that covered diagnosed major health conditions, functional disorders and mental health disorders that were categorically answered (yes/no) to the question “Has a doctor ever told you that you have/had…”. Participants were asked to answer this 22-item list with regard to themselves and each family member (i.e., fathers, mothers, siblings). Within this list, cancer, heart attack and thrombosis or embolism in the brain were operationalized as major health conditions. Fibromyalgia, chronic fatigue, irritable bowel syndrome, whiplash syndrome, and multiple chemical sensitivity were operationalized as functional disorders. Lifetime depression and anxiety were operationalized as mental disorders. Of note, the list did not include questions on mental disorders in the family. In each case, a major health condition, functional disorder, or mental disorder was evaluated as being present either in the patient or in the family if one of the respective items was answered positively. The four health condition groups were: functional disorders, major health conditions, functional disorders and major health conditions, and healthy (i.e., no major health condition or functional disorder).

Perceived Symptoms

The Bodily Distress Syndrome (BDS) checklist (Budtz-Lilly et al., 2015) uses a Likert-scale to assess 25 symptoms related to the cardiopulmonary, gastrointestinal, musculoskaletal and general symptom clusters of the diagnostic concept of the Bodily Distress Syndrome. The Danish version of the BDS checklist was applied to assess the presence of physical symptoms *during the last year*. As we focussed on the number of symptoms during the last year rather than the burden of each symptom, answers were dichotomized (0 = *not at all*; 1 = *little to a lot*) and summed up with higher values indicating a higher number of symptoms (range 0-32). Likewise, physical symptoms *during the last week* were operationalized through the 12-item sum score of the SCL-90 somatization subscale (range 0-12, Cronbach's alpha in this sample = 0.80; Olsen et al., 2004).

Psychological Factors

Current symptoms of depression and anxiety were assessed using the 8-item sum score of the SCL-90 mental distress subscale (range 0-24, Cronbach's alpha in this sample = 0.87; Fink et al., 2004).

Personality traits were operationalized based on the NEO-Five Factor Inventory that assesses the personality traits neuroticism, extraversion, agreeableness, openness, and conscientiousness through 60 Likert-scaled items (subscale range 0-48 points; Körner et al., 2002).

The number of adverse life events was operationalized through the Cumulative Lifetime Adversity Measure (range 0-37, additional item to mention specific life adversaries). The questionnaire asks respondents whether they ever experienced one or more of 37 different negative life events (Carstensen et al., 2020).

The 10-item Perceived Stress Scale with a Likert-scaled answering format was used to assess current stress (sum score range 0-40 points, Cronbach's alpha in this sample = 0.87; Cohen et al., 1983).

The 10-item General Self-Efficacy Scale with a Likert-scaled answering format was applied to assess coping abilities (sum score range 0-30 points, Cronbach's alpha in this sample = 0.91; Luszczynska et al., 2005).

Self-Perceived Health

One Likert-scaled item of the 12-item Short Form Health Survey (Ware et al., 1996) was applied to assess self-perceived health as an indicator of health related quality of life.

Objective Health Measures

Body mass index (BMI = kg/m^2) and waist-to-hip ratio were obtained.

Sociodemographic Aspects

Age, sex and years of school education (≤10 years = “elementary school education” >10 years = “beyond elementary school education”) were included.

Statistical Analyses

Participants with a minimum of four answered B-IPQ items (i.e., completers) and those with zero to three answered items were compared with regard to sex, age, marital status, and school education to identify potential selection biases. The four health condition groups were compared with regard to sociodemographic and clinical characteristics using χ^2-tests for categorical (sex, marital status, school education) and ANOVA for metric variables (age, BMI, waist-to-hip ratio, self-perceived health).

First study aim: B-IPQ items were compared between each of the four health condition groups applying an ANCOVA with age and sex as covariates and Bonferroni corrected post hoc tests. Adjusted means, standard errors (*SE*) and in case of significant differences effect sizes (Cohen’s *d*) are reported.

Second study aim: Seven multiple regression analyses with each including a total of 18 independent variables were applied to examine associations between the B-IPQ items and functional disorders (own; in the family) as well as other health-related (own major health condition or in the family, symptom presence in the last year and the last week) and psychological correlates of symptom perceptions (own mental disorder, mental distress, perceived stress, coping ability, number of adverse life events, personality traits) and sociodemographic variables (i.e., sex, age,) in the framework of the CMS. B-IPQ items were log10 transformed due to skewness and linearity.

No imputation procedure was applied on the study variables and the maximum available information was used in each analysis. IBM SPSS version 25 (SPSS Inc., Chicago, IL, USA) was used for all analyses. The significance level was set at $p < .05$ with adjustments in case of multiple testing.

Results

Among the 7,459 participants, 7% affirmed on the predefined list that a doctor told them they had cancer, 2% a heart attack and 2% thrombosis or embolism in the brain. Further

1% affirmed to have been told to have fibromyalgia, 1% chronic fatigue, 12% irritable bowel syndrome, 3% whiplash syndrome, and 2% multiple chemical sensitivity. Sociodemographic and clinical characteristics differed significantly between healthy individuals and the other three health condition groups with regard to age, sex, marital status, BMI, and waist-to-hip ratio (see Table 1). Within this total sample, 2,135 did not answer any B-IPQ items (84% healthy individuals, 9% major health conditions, 6% functional disorders, 1% both). An additional 107 answered one to three (76%, 10%, 6%, 3%,) and 5,217 participants answered ≥4 B-IPQ items (71% of the cohort).

Table 1

Sample Characteristics of Participants From the DanFunD Part Two Study Sample

Variable	**Healthy** $n = 5524$	**Major Health Condition** $n = 601$	**Functional Disorder** $n = 976$	**Major Health Condition + Functional Disorder** $n = 162$	**Statistics**
Sex % (*n*) female	51 (2821)	52 (311)	69 (672)	67 (108)	$\chi^2 = 117.377$, $p < .001$
Age *M* (*SD*)	50.49 (13.50)	59.94 (9.19)	53.29 (12.68)	60.21 (8.37)	$F = 125.064$, $p < .001$
Marital status % (*n*) married	64 (3544)	72 (429)	66 (639)	67 (109)	$\chi^2 = 95.259$, $p < .001$
School education % (*n*) > 10 years	56 (2972)	52 (303)	53 (496)	50 (80)	$\chi^2 = 9.103$, $p = .028$
Body Mass Index *M* (*SD*)	25.84 (4.53)	27.15 (4.57)	26.30 (5.06)	27.08 (4.60)	$F = 18.726$, $p < .001$
Waist-to-Hip Ratio *M* (*SD*)	0.88 (0.09)	0.91 (0.10)	0.87 (0.09)	0.90 (0.09)	$F = 22.888$, $p < .001$
Self-perceived health[a] *M* (*SD*)	2.39 (0.76)	2.76 (0.80)	2.86 (0.83)	3.17 (0.79)	$F = 166.024$, $p < .001$

Note. *M* = Mean; *SE* = standard deviation; Cancer, heart attack and thrombosis or embolism in the brain were operationalized as major health conditions from a predefined list of 22 diseases; Fibromyalgia, chronic fatigue, irritable bowel syndrome, whiplash syndrome, and multiple chemical sensitivity were operationalized as functional disorders from the same list of diseases.

[a] Increasing scores equal a worse self-perceived health.

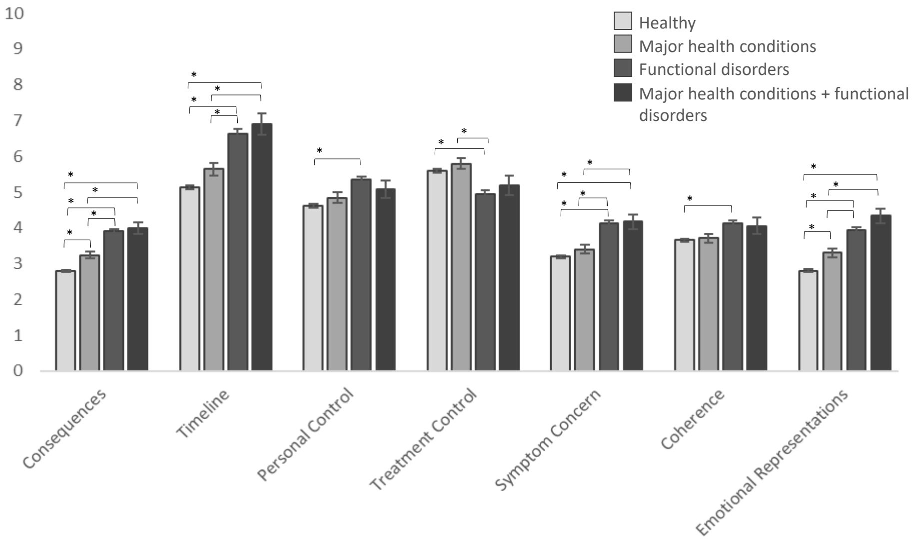
Aim 1: Comparison of Symptom Perceptions in the Four Health Condition Groups

All health condition groups differed significantly from each other with regard to the B-IPQ subscale items when controlling for age and sex (see Figure 1, Table 2 and Appendix).

Participants with **major health conditions** reported significantly less favorable *consequences* (Cohen's *d* = 0.20) and *emotional representations* (Cohen's *d* = 0.17) than healthy participants. Participants with major health conditions also reported significantly more favorable *consequences* (Cohen's *d* = 0.32), *timeline* (Cohen's *d* = 0.27), *symptom concern* (Cohen's *d* = 0.31), and *emotional representations* (Cohen's *d* = 0.45) as well as significantly less favorable *treatment control* (Cohen's *d* = 0.27) than participants with functional disorders. With the exception of *treatment control*, a similar picture occurred between participants with major health conditions and those with functional disorders and major health conditions (Cohen's *d* range = 0.30–0.37).

Figure 1

Mean Comparisons of Symptom Perceptions as Assessed With the B-IPQ in the Four Health Condition Groups Adjusted for Age and Sex



Note. x-Axis = Items of the Brief Illness Perception Questionnaire (B-IPQ), y-axis = Visual Analog Scale, range of 0-10. * = significant group difference. Error bars represent Standard Errors. Cancer, heart attack, and thrombosis or embolism in the brain were operationalized as major health conditions from a predefined list of 22 diseases; fibromyalgia, chronic fatigue, irritable bowel syndrome, whiplash syndrome, and multiple chemical sensitivity were operationalized as functional disorders from the same list of diseases.

Table 2

Symptom Perceptions as Assessed With the B-IPQ in Four Health Condition Groups Adjusted for Age and Sex

B-IPQ item	**Healthy** ***n*** **= 5524**	**Major Health Conditions** ***n*** **= 601**	**Functional Disorders** ***n*** **= 976**	**Major Health Condition + Functional Disorders** ***n*** **= 162**	**Statistics**
Consequences *M* (*SE*) *How much do your symptoms affect your life?*	2.79 (0.03)	3.24 (0.10)	3.90 (0.07)	3.99 (0.17)	$F = 77.670$, $df = 3$, $p < .001$
Timeline *M* (*SE*) *How long do you think your symptoms will last?*	5.13 (0.06)	5.64 (0.17)	6.64 (0.12)	6.89 (0.29)	$F = 50.959$, $df = 3$, $p < .001$
Personal Control[a] *M* (*SE*) *How much control do you feel you have over your symptoms?*	4.62 (0.05)	4.84 (0.15)	5.34 (0.10)	5.08 (0.25)	$F = 13.872$, $df = 3$, $p < .001$
Treatment Control[a] *M* (*SE*) *How much do you think your treatment can help your symptoms?*	5.50 (0.05)	5.80 (0.16)	4.95 (0.11)	5.18 (0.27)	$F = 10.959$, $df = 3$, $p < .001$
Symptom Concern *M* (*SE*) *How concerned are you about your symptoms?*	3.20 (0.04)	3.40 (0.12)	4.13 (0.08)	4.18 (0.20)	$F = 40.059$, $df = 3$, $p < .001$
Coherence[a] *M* (*SE*) *How well do you feel you understand your symptoms?*	3.66 (0.04)	3.71 (0.13)	4.13 (0.09)	4.06 (0.23)	$F = 7.687$, $df = 3$, $p < .001$
Emotional Representations *M* (*SE*) *How much do your symptoms affect your emotionally? (e.g. make you angry, scared, upset or depressed)*	2.81 (0.04)	3.31 (0.12)	3.95 (0.08)	4.34 (0.20)	$F = 69.459$, $df = 3$, $p < .001$

Note. B-IPQ = Brief Illness Perception Questionnaire; item wordings are in italics. *M* = Mean; *SE* = standard error. Cancer, heart attack and thrombosis or embolism in the brain were operationalized as major health conditions from a predefined list of 22 diseases; Fibromyalgia, chronic fatigue, irritable bowel syndrome, whiplash syndrome, and multiple chemical sensitivity were operationalized as functional disorders from the same list of diseases.

[a]Reversed item, age groups comprise missing values.

Participants with **functional disorders** reported significantly less favorable symptom perceptions than healthy individuals on all but one B-IPQ subscales (Cohen's *d* range =

0.16–0.56), i.e., treatment control was significantly more favorable in participants with functional disorders. Participants with **functional disorders and major health conditions** reported significantly less favorable *consequences* (Cohen's d = 0.32), *timeline* (Cohen's d = 0.58), *symptom concern* (Cohen's d = 0.42) and *emotional representations* (Cohen's d = 0.66) compared to healthy participants. Notably, participants with functional disorders and those with both major health conditions and functional disorders reported comparable B-IPQ subscale item scores.

Aim 2: Correlation Between Functional Disorders in Oneself and Significant Others and Symptom Perceptions in the Context of Other Possible Correlates From the CMS Framework

There was no evidence of multi-collinearity as assessed by tolerance values greater than 0.1 and VIF between 1.056 and 3.298. There was indepence of residuals as indicated by Durbin-Watson values between 1.958 and 2.041. The assumption of normality was met as assessed by Q-Q Plots.

Higher, i.e., more negative, perceived *consequences* were significantly associated with own and family functional disorders, own major health conditions, mental disorders, higher mental distress and perceived stress, and more adverse life events (for regression coefficients, standard errors, 95% confidence intervals and model summary, see Table 3).

Higher, i.e., more negative, perceived *timeline* was significantly associated with own and family functional disorders, own major health conditions, higher levels of mental distress, more adverse life events, and lower levels of extraversion.

Higher, i.e. less, perceived *personal control* was significantly associated with own functional disorders, higher levels of mental distress, and perceived stress as well as a lower coping ability, lower levels of conscientiousness, and female sex.

Higher, i.e. less, perceived *treatment control* was significantly associated with, own functional disorders, the absence of functional disorders in the family, lower levels of extraversion and agreeableness, and younger age.

Higher, i.e. more negative, perceived *symptom concerns* were significantly associated with own and family functional disorders, higher mental distress and perceived stress and female sex.

Higher, i.e. less, *coherence* was significantly associated with own functional disorders, the absence of a mental disorder, higher levels of mental distress and perceived stress as well as a lower coping ability, higher levels of neuroticisms and lower levels of openness and agreeableness, younger age and female sex.

Higher, i.e. more negative, *emotional representations* were significantly associated with own and family functional disorders and major health conditions, mental disorders and higher levels mental distress, perceived stress, and neuroticism.

Table 3

Summary of Multiple Regression Analyses to Predict Symptom Perceptions in a Danish Population-Based Sample

	Consequences			**Timeline**			**Symptom control**			**Treatment control**		
Variable	***B***	***SE***	**95% CI**	***B***	***SE***	**95% CI**	***B***	***SE***	**95% CI**	***B***	***SE***	**95% CI**
Functional Disorders and major health conditions												
Own functional disorders	1.26**	1.02	[1.15, 1,32]	1.34**	1.03	[1.25, 1.43]	1.14**	1.03	[1.08, 1.21]	1.06**	1.19	[-0.83, -0.95]
Functional disorders in family	1.05**	1.02	[1.20, 1.10]	1.06*	1.03	[1.00, 1.12]	1.04	1.03	[-0.99, 1.09]	-0.89*	1.03	[-0.89, -0.99]
Own major health conditions	1.07*	1.03	[1.01, 1.14]	1.09*	1.04	[1.00, 1.19]	0.99	1.04	[-0.92, 1.06]	-0.94	1.03	[-0.96, 1.12]
Major health conditions in family	1.02	1.03	[-1.01, 1.07]	1.05	1.04	[0.98, 1.13]	1.00	1.03	[-0.94, 1.07]	-1.04	1.04	[-0.92, 1.06]
Symptoms last year	1.00	1.00	[-0.97, 1.00]	1.00	1.00	[-0.99, 1.00]	-1.00	1.00	[-1.00, 1.00]	-0.99	1.04	[-1.00, 1.01]
Symptoms last week	1.00	1.00	[-0.99, 1.10]	-1.00	1.01	[-0.99, 1.01]	-1.00	1.01	[-0.99, 1.01]	-1.00	1.00	[-0.99, 1.01]
Psychological correlates of symptom perceptions												
Mental disorders	1.06*	1.03	[0.99, 1.12]	-1.04	1.04	[-0.96, 1.12]	-0.94	1.03	[-0.88, 1.00]	-1.00	1.01	[-0.88, 1.02]
Mental distress	1.03**	1.00	[1.00, 1.03]	1.02**	1.00	[-1.01, 1.03]	1.02**	1.00	[1.01, 1.02]	0.95	1.04	[-0.99, 0.00]
Perceived stress	1.01**	1.00	[1.02, 1.02]	1.00	1.00	[-1.00, 1.01]	1.02**	1.00	[1.01, 1.02]	1.00	1.00	[-0.99, 1.01]
Coping ability	1.00	1.00	[-1.01, 1.01]	1.00	1.00	[-1.00, 1.01]	-0.99**	1.00	[-0.99, -1.00]	-1.00	1.00	[-0.99, 1.00]
Adverse life events	1.01**	1.00	[1.00, 1.02]	1.02**	1.00	[1.01, 1.03]	1.01	1.00	[-1.00, 1.02]	-0.99	1.00	[-0.99, 1.00]
Neuroticism	1.00	1.00	[-1.01, 1.01]	1.00	1.00	[-1.00, 1.01]	1.00	1.00	[1.00, 1.01]	-0.99	1.00	[-0.99, 1.00]
Extraversion	1.00	1.00	[-1.00, 1.00]	-0.99**	1.00	[-0.99, -1.00]	-1.00	1.00	[-0.99, 1.00]	-0.99**	1.00	[-0.98, -0.99]
Openness	1.00	1.00	[-1.00, 1.00]	-1.00	1.00	[-0.99, 1.00]	-1.00	1.00	[-0.99, 1.00]	-0.99	1.00	[-1.00, 1.01]
Agreeableness	1.00	1.00	[-0.99, 1.01]	1.00	1.00	[-1.00, 1.01]	-1.00	1.00	[-0.99, 1.00]	-1.00**	1.00	[-0.99, -1.00]
Conscientiousness	1.00	1.00	[-1.00, 1.00]	-1.00	1.00	[-0.99, 1.01]	-0.99**	1.00	[-0.99, -1.00]	-0.99	1.00	[-0.99, 1.01]
Sociodemographic factors												
Sex	1.02	1.02	[-0.99, 1.07]	-0.98	1.03	[-0.92, 1.03]	-0.95*	1.03	[-0.91, -1.00]	-1.00	1.00	[-0.98, 1.09]
Age	1.00	1.00	[-0.98, 1.00]	1.00	1.00	[-1.00, 1.00]	-1.00	1.00	[-1.00, 1.00]	-1.03**	1.03	[-0.99, -1.00]
Model summary	$F_{18,4038}$ = 42.228, p = < .001 adj. R^2 = 0.155 Durbin-Watson = 1.988 VIF_{max} = 3.290 (Neuroticism)			$F_{18,3965}$ = 17.377, p = < .001 adj. R^2 = .069 Durbin-Watson = 1.967 VIF_{max} = 3.298 (Neuroticism)			$F_{18,\ 3986}$= 26.894, p = < .001 adj. R^2 = .104 Durbin-Watson = 2.041 VIF_{max} = 3.295 (Neuroticism)			$F_{18,\ 3971}$= 5.375, p = < .001 adj. R^2 = .019 Durbin-Watson = 1.958 VIF_{max} = 3.277 (Neuroticism)		

Table 3 [continued]

Summary of Multiple Regression Analyses to Predict Symptom Perceptions in a Danish Population-Based Sample

	Symptom concerns			Coherence			Emotional representations		
Variable	***B***	***SE***	**95% CI**	***B***	***SE***	**95% CI**	***B***	***SE***	**95% CI**
Functional Disorders and major health conditions									
Own functional disorders	0.08**	1.03	[1.14, 1.27]	1.13**	1.03	[1.07, 1.20]	1.04**	1.15	[1.17, 1.29]
Functional disorders in family	1.06*	1.02	[1.01, 1.11]	1.02	1.03	[-0.98, 1.08]	1.23**	1.03	[1.02, 1.12]
Own major health conditions	1.02	1.04	[0.95, 1.10]	-0.97	1.04	[-0.90, 1.05]	1.07**	1.02	[1.04, 1.18]
Major health conditions in family	1.03	1.03	[-0.98, 1.10]	1.03	1.03	[-0.96, 1.09]	1.11	1.03	[-0.95, 1.06]
Symptoms last year	1.00	1.00	[-1.00, 1.01]	-1.00	1.00	[-0.99, 1.00]	1.01	1.03	[-1.00, 1.00]
Symptoms last week	1.00	1.00	[-0.99, 1.01]	1.00	1.01	[-0.99, 1.02]	1.00	1.00	[-0.99, 1.01]
Psychological correlates of symptom perceptions									
Mental disorders	-0.98	1.03	[-0.92, 1.04]	-0.91*	1.03	[-0.86, -0.98]	1.00**	1.00	[1.03, 1.15]
Mental distress	1.04**	1.00	[1.03, 1.05]	1.01**	1.00	[1.01, 1.02]	1.09**	1.03	[1.04, 1.06]
Perceived stress	1.01**	1.00	[1.01, 1.02]	1.01**	1.00	[1.00, 1.02]	1.05**	1.00	[1.01, 1.02]
Coping ability	1.00	1.00	[-0.99, 1.00]	-0.99**	1.00	[-0.98, -0.99]	-1.02	1.00	[-0.99, 1.00]
Adverse life events	1.01	1.00	[-1.00, 1.01]	-0.99	1.00	[-0.99, 1.00]	1.00	1.00	[-1.00, 1.01]
Neuroticism	1.00	1.00	[1.00, 1.01]	1.01*	1.00	[1.00, 1.01]	1.00**	1.00	[1.01, 1.02]
Extraversion	1.00	1.00	[1.00, 1.01]	-1.00	1.00	[-0.99, 1.00]	1.01	1.00	[-1.00, 1.01]
Openness	1.00	1.00	[-0.99, 1.00]	-0.99**	1.00	[-0.99, -1.00]	-1.00	1.00	[-0.99, 1.00]
Agreeableness	1.00	1.00	[-1.00, 1.00]	-0.99**	1.00	[-0.99, -0.99]	-1.00	1.00	[-1.00, 1.00]
Conscientiousness	1.00	1.00	[-0.99, 1.00]	-0.99*	1.00	[-0.99, -1.00]	1.00	1.00	[-1.00, 1.01]
Sociodemographic factors									
Sex	-0.95*	1.02	[-0.91, -0.99]	-0.95*	1.03	[-0.90, -1.00]	-1.00	1.00	[-0.96, 1.04]
Age	1.00	1.00	[1.00, 1.00]	-1.00*	1.00	[-1.00, -1.00]	1.00	1.02	[-1.00, 1.00]
Model summary	$F_{18,\ 4006}$ = 39.014, p = < .001 adj. R^2 = .145 Durbin-Watson = 1.986 VIF_{max} = 3.271 (Neuroticism)			F18, 3993 = 25.125, p = < .001 adj. R^2 = .098 Durbin-Watson = 1.992 VIF_{max} = 3.269 (Neuroticism)			F18, 3998 = 85.396, p = < .001 adj. R^2 = .274 Durbin-Watson = 1.996 VIF_{max} = 3.302 (Neuroticism)		

Discussion

This large population-based study observed more negative symptom perceptions in individuals with functional disorders with and without co-occuring major health conditions than in those with major health conditions only or healthy individuals. More specifically, individuals with functional disorders judged their symptoms to affect their life and their emotional well-being more and to last longer than the other health condition groups. They expressed less symptom understanding, less treatment control, but higher personal control than those with major health conditions.

These results have three important implications. Firstly, the higher levels of negative cognitive representations and emotional reactions observed in individuals with functional disorders confirm previous research that perceptual, cognitive, and emotion regulation processes may play a more salient role in functional disorders as compared to well-defined physical illness (Henningsen et al., 2018; Okur Güney et al., 2019). Secondly, our results support previous findings from clinical samples that functional disorders in some cases are comorbid with major health conditions (Duffield et al., 2018; Halpin & Ford, 2012). Our results extend the existing evidence by showing that this comorbidity results in more negative symptom perceptions and more negative self-perceived health. Thirdly, more research is needed to investigate the consequences of these more negative symptom perceptions in individuals with functional disorders on relevant outcomes such as symptom burden, symptom course, and individual symptom management.

In terms of correlates of symptom perceptions from the CMS framework, our results indicate that not only the presence of a functional disorder in oneself was associated with symptom perceptions but also functional disorders in family members, albeit to a lesser extent. Interestingly, the presence of a major health condition in the family was not associated with more negative symptom perceptions. These results might indicate that the experience of an illness or symptoms in significant others does not in itself lead to a more negative evaluation of present symptoms but that particularly in functional disorders, learning of illness behavior, and beliefs within families seem to be crucial (Brace et al., 2000; Palermo et al., 2014).

It is of note that the presence of a major health condition, but neither the number of symptoms in the last year, nor the number of symptoms during the last week, was associated with current symptom perceptions in the multivariate regression models. On the one hand, this result might be interpreted in light of former evidence on a weaker association between health states and symptom reports in chronic health conditions (Janssens et al., 2011). On the other hand, the inclusion of functional disorders in the analyses might have erased the impact of symptom reports.

With regard to personality traits, extraversion, openness, and agreeableness were all significantly associated with more favorable symptom perceptions, whereas neuroticism was (to a lesser extent) associated with more negative associations. Notably, conscientiousness was associated with lower personal control. One may speculate that persons with high conscientiousness may need a more controlled environment to feel in control and therefore be prone to appraise less control when experiencing symptoms. Overall, interpretating these results from the perspective of a recent meta-analysis, extraversion, openness, and agreeableness might be regarded as resilience factors in the context of symptom perceptions (Oshio et al., 2018).

In line with the accumulating evidence from other research fields (Anda et al., 2006), multiple experiences of adverse life events were associated with more negative symptom perceptions. Additionally, our results indicate that current symptoms of depression and anxiety as well as perceived stress and coping abilities were psychological correlates of most symptom perceptions. This result was in line with evidence derived from a systematic review on so-called modifiable correlates of symptom perceptions in samples with somatic diseases (Arat et al., 2018) and indicates that these variables might be considered as potential moderators or mediators in future studies.

Taken together, our results support the notion from the perspective of the CSM that a range of biopsychosocial factors are involved in the formation of symptom perceptions (Leventhal et al., 2016), i.e., broadly speaking, that a person's life experience is involved in how the person reacts to and copes with symptoms and illness. Extending on previous evidence, the present study found significant associations between functional disorders in significant others and oneself for the formation of symptom perceptions. Still, the emerging picture is somewhat complex, as it remains challenging to judge which factors might be of particular relevance, given that each B-IPQ subscale displayed an individual pattern of significant biopsychosocial correlates.

From a clinical perspective, screening for functional disorders in individuals with major health conditions may be a valuable approach to identify vulnerable patients that might be at risk for more complex illness trajectories and to personalize the given treatment rationale with psychosocial interventions to challenge symptom perceptions if needed. Derived from the observed associations of symptom perceptions in the present cross-sectional study, these interventions should address present symptoms of depression, anxiety, and current stress and should aim at improving coping skills.

The present study was to the best of our knowledge the first to investigate symptom perceptions and their correlates in a population-based sample. This approach enabled a sufficient sample size and high representativeness. However, the results of the present study should to be interpreted in light of the following limitations. Firstly, the cross-sectional design of the present study prevented us from making any causal/temporal interpretations of our results. Secondly, the participation rate in the DanFunD study was rather low (30%), which is a challenge for all epidemiological studies (Galea & Tracy, 2007). Further, there seemed to be a selection bias, which has also been observed in other epidemiological studies (Keeble et al., 2015), with females and more educated individuals being more likely to participate. Thirdly, the four health condition groups were operationalized through self-report with a predefined list of health conditions. In doing so, some participants may not have indicated a diagnosis of a functional disorder because they disagree with it. Also, other major health conditions not included in this list might have explained some of the perceived symptoms. Fourthly, the present study applied a crude measure of school education. Therefore, the effect of educational level (i.e., vocational training) on the outcome measures has to be investigated in future studies. Fifthly, the B-IPQ uses a single scale approach, which does not allow the determination of internal validity and might be more prone to random measurement error than multi-item scales. Additionally, a scale deviating from the original scale was used and the B-IPQ was answered in terms of symptoms in general, so the item assessing symptom identity was removed. These aspects and large amounts of missing responses on the B-IPQ items decrease the comparability with other studies. Last, further major health conditions or functional disorders and treatment related variables, such as prior illnesses and treatment, symptom duration or severity might be further relevant correlates of symptom perceptions but were not included in the present study.

Conclusions

Researchers can benefit from the results of the present study with respect to expectable differences in symptom perceptions in healthy individuals and those with functional disorders and major health conditions. Further, the present study identified potential moderators and mediators of symptom perceptions that might be worth further investigation in experimental and treatment studies. Clinicians and health policy makers can benefit from the results in that the present results could inform the future development of preventive interventions in the context of symptom perceptions.

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Competing Interests: The authors declare that they have no conflicts of interest.

Ethics Statement: All study procedures were approved by the Ethical Committee of Copenhagen Country (KA-2006-0011, H-3-2011-081, H-3-2012). All participants provided written informed consent.

Data Availability: The datasets generated during and/or analyzed during the current study are available on reasonable request from the DanFunD project leader Thomas Dantoft by email: Thomas.Meinertz.Dantoft@regionh.dk

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Appendix

Table A.1

Adjusted Mean Comparisons of B-IPQ Subscales Between the Four Health Condition Groups

	Healthy vs. MHC			Healthy vs. FD			Healthy vs. MHC + FD			MHC vs. FD			MHC vs. MHC + FC			FD vs. MCH + FD		
B-IPQ subscale	M_{diff}	95% CI	*d*	M_{diff}	95% CI	*d*	M_{diff}	[95% CI]	*d*	M_{diff}	[95% CI]	*d*	M_{diff}	[95% CI]	*d*	M_{diff}	[95% CI]	*d*
Consequences	-0.43*	[-0.72, -0.16]	0.20	-1.11*	[-1.31, -0.90]	0.56	-1.20*	[-1.66, -0.73]	0.61	-0.66*	[-0.98, -0.34]	0.32	-0.75*	[-1.27, -0.23]	0.35	-0.09	[-0.58, 0.40]	
Timeline	-0.51	[-0.98, -0.03]		-1.51*	[-1.86, -1.15]	0.47	-1.76*	[-2.54, -0.97]	0.58	-1.00*	[-1.55, -0.46]	0.27	-1.25*	[-2.13, -0.37]	0.37	-0.25	[-1.08, 0.58]	
Personal control	-0.22	[-0.63, 0.19]		-0.73*	[-1.03, -0.42]	0.24	-0.46	[-1.14, 0.21]		0.51	[-0.98, -0.04]		-0.24	[-1.01, 0.52]		0.26	[-0.45, 0.98]	
Treatment control	-0.20	[0.64, 0.24]		0.64*	[0.32, 0.97]	0.21	0.41	[-0.32, 1.14]		0.85*	[0.34, 1.35]	0.27	0.62	[-0.20, 1.44]		-0.23	[-1.00, 0.54]	
Symptom concern	-0.20	[-0.52, 0.13]		-0.93*	[-1.17, -0.69]	0.40	-0.98*	[-1.52, -0.44]	0.42	-0.73*	[-1.11, -0.36]	0.31	-0.78*	[-1.40, -0.18]	0.33	-0.05	[0.62, 0.52]	
Coherence	-0.05	[-0.42, 0.32]		-0.47*	[-0.73, -0.20]	0.16	-0.40	[-1.01, 0.21]		-0.42	[-0.84, 0.00]		-0.35	[-1.03, 0.33]		0.07	[-0.57, 0.71]	
Emotional representations	-0.50*	[-0.83, -0.18]	0.17	-1.15*	[-1.38, -0.91]	0.50	-0.53*	[-2.07, -1.00]	0.66	-0.65*	[-1.01, -0.28]	0.45	-1.03*	[-1.63, -0.43]	0.30	-0.39	[-0.95, 0.18]	

Note. MHC = majore health condition, i.e. cancer, heart attack and thrombosis or embolism in the brain; FD= functional disorders, i.e. fibromyalgia, chronic fatigue, irritable bowel syndrome, whiplash syndrome, and multiple chemical sensitivity; *d* = Cohen's d effect size of significant difference; Mdiff = mean difference; 95% CI = 95% confidence interval, Range of B-IPQ subscales = 1-10.

*Significant at Bonferoni corrected *p*-value for multiple comparissons.

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Open-Label Placebo Effects on Psychological and Physical Well-Being: A Conceptual Replication Study

Anne-Kathrin Bräscher[1], Ioanna-Evangelia Ferti[1], Michael Witthöft[1]

[1] *Department of Clinical Psychology, Psychotherapy, and Experimental Psychopathology, Johannes Gutenberg University of Mainz, Mainz, Germany.*

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Corresponding Author: Anne-Kathrin Bräscher, Department for Clinical Psychology, Psychotherapy, and Experimental Psychopathology, Johannes Gutenberg-University of Mainz, Wallstr. 3, 55099 Mainz, Germany. Phone: +49 6131 3939209. E-mail: abraesch@uni-mainz.de

Supplementary Materials: Materials [see Index of Supplementary Materials]

Abstract

Background: Contrary to traditional placebos, open-label placebos (OLP) abstain from deception, i.e., participants are openly informed to receive an inert substance. Studies in clinical and healthy samples evidence the efficacy of OLPs. This study aims to conceptually replicate and expand findings of a recent OLP study in healthy participants while implementing a within-subject design and daily instead of retrospective assessments. Additionally, the effect of a brand name on the medicine container is tested and possible predictors of the OLP effects are explored.
Method: Healthy participants (N = 75) received OLP and no placebo for 5 days each (randomized sequence) and answered daily questionnaires on sleep quality, bodily symptoms, mental well-being, and psychological distress. The medicine container of half the participants had a brand name, the remaining did not. Different personality traits and situational factors were assessed.
Results: Mental and physical well-being did not differ between OLP and control phase, i.e., overall, no OLP effect emerged. Contrast analysis indicated that an OLP effect emerged for sleep quality and psychological distress when no brand name was present. Further, an OLP effect emerged in persons with higher expectations for bodily symptoms (r = .23, p = .046) and psychological distress (r = .24, p = .037).
Conclusions: Methodological differences to the original study are discussed as an explanation for the failure to induce overall OLP effects. Future studies should continue to replicate previous findings and determine the exact conditions of successful implementation of OLP effects in healthy as well as clinical samples.

Keywords

open-label placebo (OLP) effect, expectation, brand name, personality traits, healthy sample

Highlights

- The attempt to replicate an open-label placebo effect on well-being in healthy participants failed.
- Possibly, differences in the design and time-points of assessments explain the negative findings.
- Presence of a brand name on the medicine container and possible moderators were tested.

Due to deception, the application of traditional placebos (i.e., “interventions that, owing to their intrinsic properties, are ineffective for a particular condition or symptom(s), but which may be (…) administered (…) with the aim of eliciting placebo effects”, p. 18, Blease & Annoni, 2019) in patient care can go along with ethical and legal problems as well as with a loss of trust in the therapist-patient relationship (Bundesärztekammer, 2010; Miller et al., 2005). Open-label placebos (OLP) might solve these issues since patients are openly informed about the placebo treatment, rendering deception unnecessary.

Numerous studies evidence the efficacy of OLP in different clinical contexts and two meta-analyses indicate large effect sizes (Charlesworth et al., 2017; von Wernsdorff et al., 2021). Studies in healthy participants have been conducted less frequently, although they can 1) help to shed light on underlying mechanisms of OLP effects that remain unclear to this point and 2) target primary endpoints as the improvement of well-being and physical or cognitive performance (Kleine-Borgmann et al., 2021; Saito et al., 2020). Along these lines, some studies in healthy samples explored OLP effects in experimentally induced pain (Disley et al., 2021; Kube et al., 2020; Locher et al., 2017; Schafer et al., 2015; Schneider et al., 2020; Wei et al., 2018). Few studies focused on areas other than pain perception (El Brihi et al., 2019; Guevarra et al., 2020; Kleine-Borgmann et al., 2021). Especially, El Brihi and colleagues (2019) showed that the intake of placebo pills on five subsequent days compared to not taking placebo pills can reduce psychological distress and bodily symptoms and increase mental well-being and sleep quality in healthy participants. While the dose (i.e., taking one vs. four pills each day) did not influence the OLP effects, positive expectations and adherence were significant predictors.

The primary aim of the present study was to conceptually replicate the findings of El Brihi et al. (2019) on physical and mental well-being in healthy participants. As a stricter test of the OLP effect, a within-subject design was implemented (i.e., all participants pass through a control phase without taking placebos and a placebo phase), since a control group that does not receive OLPs might be disappointed and thus artificially boost OLP effects. Further, instead of a singular retrospective assessment of relevant constructs, assessments were collected daily to avoid potential memory biases.

Knowledge on situational and personality factors that moderate OLP effects is scarce. Dispositional optimism has shown to be associated with deceptive but not open-label placebo effects (Locher et al., 2019). Yet, studies on the impact of personality factors are rare even in the investigation of deceptive placebo effects, and results tend to be inconsistent (Kern et al., 2020). Beyond that, evidence shows the influence of aspects like price, appearance, branding, and labeling on deceptive placebos (Meissner & Linde, 2018), but studies in this realm focusing on OLP effects are missing. Expanding the conceptual replication, we aimed to additionally explore whether the presence of a brand name on the medicine container would influence the OLP effect, as suggested by El Brihi and colleagues (2019), who did not vary the brand name ("placibax") in the original study. We hypothesized that healthy participants would show OLP effects in physical and mental well-being, which would be further enhanced when the medicine container is equipped with a brand name instead of no label. Further, we exploratively assessed a range of different psychological and situational factors to potentially identify predictors of the OLP effect.

Method

Sample

Participants were recruited by notes on campus, social media, and e-mail distribution lists, already indicating that the study investigated the influence of placebos on well-being. In total *N* = 75 participants (*n* = 49 females, 65.3%; *M* = 32.00, *SD* = 12.75 years) were included in the study (for exclusion criteria and further information cf. Appendix A, Supplementary Materials). All participants gave their written informed consent before commencing the study. All procedures were approved by the local ethics committee (2019-JGU-psychEK-001).

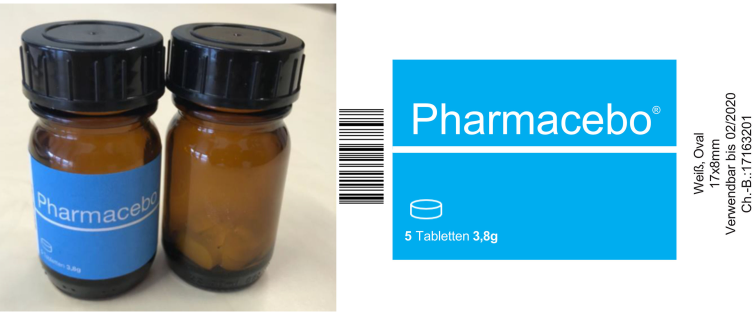
Experimental Procedure

In the first part of the study, participants came to the lab and filled in several psychometric questionnaires and a questionnaire on demographic information via the online platform SosciSurvey (Leiner, 2018). Suggestibility was assessed with the Creative Imagination Scale (cf. below). Subsequently, participants watched a 10-minute animated video (generated with videoscribe; cf. Appendix B, Supplementary Materials, for the narrative), addressing the four key aspects that are always communicated in OLP studies (Kaptchuk, 2018): remove the stigma of placebo effects; automatic nature of placebo responses; no requirement to believe; taking the pills is critical. The video also stressed that studies have shown beneficial effects on psychological and bodily well-being in healthy persons.

After that, participant’s questions were answered and expected effects on sleep quality, bodily symptoms, mental well-being, and psychological distress were assessed using a scale from 0 (“I do not expect any effect at all”) to 10 (“I expect a very strong effect”), respectively. Finally, participants received a closed envelope containing an amber glass with five placebo pills. Half of the amber glasses (*n* = 37) had a label inscribed with “pharmacebo”, the other half of the amber glasses (*n* = 38) did not have a label (randomized; cf. Figure 1). The experimenter was blind to the kind of amber glass, which the participant received. Further, participants were informed when they should start taking the placebo pills.

Figure 1

Picture of the Medicine Container



Note. Medicine container with and without a label (left) and display of the label with the brand name (“pharmacebo”), including information on the size and weight of the pills as well as the expiration date.

The second part of the study always started on the Monday following the lab appointment, to avoid interference with weekend days. Participants either started with the placebo phase and were instructed to take a placebo every morning for five consecutive days (Monday to Friday) and then switch to the control phase (again from Monday to Friday), or they started with the control phase and switched to the placebo phase the week after. The order of placebo and control phase was randomized (random.org). During those ten days, participants received an e-mail every evening containing the link to questionnaires they were asked to fill in to assess the OLP effects as well as a question on adherence (“Did you take the placebo pill at least 6 hours ago?” yes/no). On the last day of the placebo phase, they were additionally asked how many placebo pills they had to spare. Further, on the day before the start of the placebo phase, the expected effects on all outcome measures were assessed again, using the expectancy scale.

Outcome Measures

The following questionnaires were filled in daily. The instructions were changed where necessary to refer to the current day (instead of a longer period).

Warwick-Edinburgh Mental Well-Being Scale

The questionnaire (Tennant et al., 2007; German version, Lang & Bachinger, 2017) contains 14 items and assesses general mental well-being (range [14-70]). It has shown good internal consistency (α = .89 to .91), content, convergent, and discriminant validity. The retest reliability is high (*r* = 0.83, Tennant et al., 2007). The German version has shown good validity and reliability, as well (Lang & Bachinger, 2017). Internal consistency in the current study ranged between α = .91 and α = .96.

Profile of Mood State (POMS)

The questionnaire (McNair et al., 1971; German short version, Dalbert, 1992) assesses the current mood through 19 items. Within the present work, the subscales sorrow, hopelessness, fatigue, and positive mood (reversely coded) are summoned to build the scale psychological distress (16 items; range [16-112]). The internal consistency is high and ranges between α = .83 and .94 for the different subscales (Dalbert, 1992). The internal consistency of the scale psychological distress in the current study ranged between α = .93 and α = .96.

Subjective Health Complaints (SHC)

The SHC lists 29 bodily symptoms, which can be rated on an intensity scale from 0 (not at all) to 3 (severe) (rang [0-87]). It has acceptable to good internal consistency (α = .75 to .82, Eriksen et al., 1999) and is associated with healthcare utilization (Filipkowski et al., 2010). The items have been translated by the authors. Internal consistency in the current study ranged between α = .70 and α = .80.

Groningen Sleep Quality Scale (GSQS)

This questionnaire (Leppämäki et al., 2003; Mulder-Hajonides van der Meulen et al., 1980) contains 15 items, which can be answered with yes and no, assessing sleep quality of the previous night. Larger scores indicate poorer sleep [range 0-14]. Internal consistency was α = .88 in a sample of depressed patients (current study: α between .15 and .55).

Measures of Psychological Factors

During the lab appointment, participants filled in the following questionnaires to assess different traits and psychological factors: State-Trait Inventory (STAI-T), NEO-Five Factor Inventory, Somatosensory Amplification Scale, Patient Health Questionnaire-15

(PHQ-15), Questionnaire on attitudes towards complementary medical treatment (QA-CAM). Further information on the questionnaires can be found in Appendix C, Supplementary Materials.

Creative Imagination Scale (CIS)

The CIS (Wilson & Barber, 1978) assesses suggestibility using standardized descriptions of ten different situations on visual, auditive, kinesthetic, and olfactory perceptions. While the experimenter reads out the descriptions, the participant is asked to imagine the situation and afterward evaluate inasmuch their imagination matched the real experience using one item for each of the ten situations. The internal consistency in the current study was $\alpha = .89$.

Statistical Analysis

Changes between the first and second assessment in expected OLP effects were tested using the Wilcoxon-signed-rank-test due to non-normally distributed data. Considering sleep quality, bodily symptoms, mental well-being, and psychological distress, respectively, as outcome variables, mixed 2x5x2-ANOVAs were performed to assess the OLP-effect (within-factor “condition”) and the influence of time (within-factor “day”) as well as brand name (between-factor “brand name”). Since the order of the phases (placebo intake or control phase in week one) did not significantly influence the results, this factor was not included in the reported analyses. Holm-corrected post hoc-tests were applied were appropriate. Contrast analyses were calculated to test the hypothesis that OLP effects were larger with a brand name. As measures of effect size, η^2 ($\eta^2 \geq 0.01$ small; $\eta^2 \geq 0.06$ medium; $\eta^2 \geq 0.14$ large) and Cohen’s d ($d \geq 0.30$ small, $d \geq 0.50$ medium, $d \geq 0.80$ large) are specified. As explorative analyses, to identify potential predictors of the OLP effect, Pearson correlations between psychological factors and the outcome measures (i.e., the difference between the average score during placebo and control phase) were calculated ($r \geq |.10|$ small; $r \geq |.30|$ medium, $r \geq |.50|$ large). The alpha level was set to 5%. Analyses were calculated with JASP version 0.14.1 (JASP Team, 2020).

Results

Expectation and Adherence

Adherence (i.e., intake of the placebos as instructed) was excellent. In only two instances, participants reported to have forgotten the intake once, which was confirmed by the question at the end of the OLP phase (“How many pills do you have to spare?”). Expected effects of the OLP effects were in the medium to low range of the scale and significantly decreased from the first to the second assessment (see Table 1).

Table 1

Expected Open-Label Placebo Effects

	Expectation after manipulation		Expectation before placebo phase		Test statistic for differences between both assessments		
Outcome	***M***	***SD***	***M***	***SD***	***W***	***p***	r_{rb}
Sleep quality	3.41	2.99	2.82	2.85	427.5	.040	0.33
Bodily symptoms	3.73	2.95	2.88	2.76	928.00	< .001	0.58
Mental well-being	4.41	3.12	3.34	2.95	1039.50	< .001	0.63
Psychological distress	3.77	3.01	2.86	2.84	874.00	.008	0.43

Note. Expectations assessed at the first assessment directly after the open-label placebo manipulation and at the second assessment the day before the first intake of the open-label placebo and difference test.

Open-Label Placebo Effects

Concerning sleep quality, placebo and control week did not differ significantly and this did not change over the five days, i.e., overall, no OLP effect emerged (see Table 2). Neither the main effect of day nor that of brand name were significant. A significant interaction effect between condition and brand name emerged (see Figure 2), but post hoc-tests were non-significant (all *p*s > .190). Contrary to the hypothesis, the contrast analysis showed that the difference between scores of the placebo versus the no treatment week was larger when no brand name was present, $t(73) = -2.42$, $p = .009$, indicating that a medicine container without a brand label led to an OLP effect but a medicine container without a brand label did not.

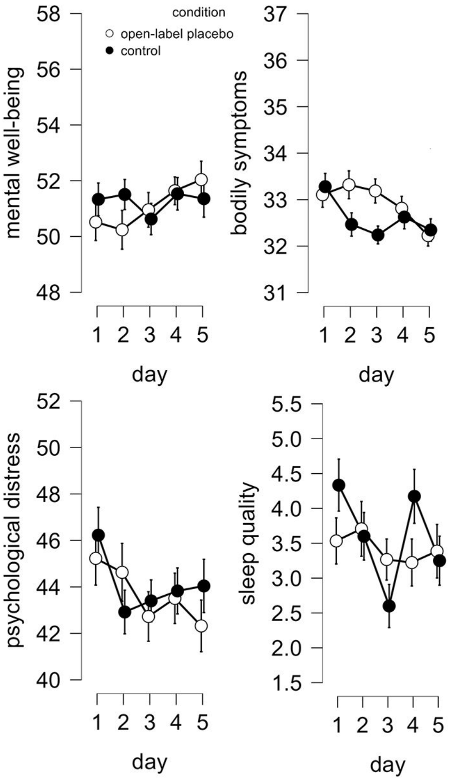
With regards to bodily symptoms, placebo and control week did not differ significantly (see Table 2). A significant interaction effect between condition and day emerged (see Figure 2), but post hoc-tests were non-significant (all $p > .240$). The five days differed significantly for reported bodily symptoms and post-hoc tests indicated that bodily symptoms decreased when comparing Day 1 to Day 5, $t(74) = 4.11$, $p < .001$, $d = 0.48$, remaining post hoc-tests all $p > .056$. Bodily symptoms did not differ significantly depending on the presence of a brand name and no significant interaction emerged between brand name and condition. The contrast analysis did not point to a differential effect depending on the presence of a brand name, $t(73) = -0.03$, $p = .490$.

Placebo and control week did not differ significantly concerning mental well-being (see Table 1, Figure 2) and this did not change over the five days, i.e., no overall OLP effect emerged. Neither the main effect of day nor of label, nor the interaction effect between label and condition reached significance. The contrast analysis did not point to a differential effect depending on the presence of a brand name, $t(73) = -0.94$, $p = .175$.

For psychological distress, similarly, placebo and control week did not differ significantly (see Table 2, Figure 2) and no significant interaction effect between condition and day emerged. No main effect of day and label reached significance. The interaction

Figure 2

Open-Label Placebo Effects



Note. Average scores of psychological distress, mental well-being, bodily symptoms, and sleep quality across five days each in the OLP (white) and control condition (black). Error bars represent the standard error.

effect between brand name and condition just reached significance, but post hoc-tests were non-significant (all *p*s > .561). Contrary to the hypothesis, the contrast analysis indicated that the difference between scores of the placebo versus the no treatment week was larger without the brand name, *t*(73) = -1.99, *p* = .025, indicating that a medicine container without a brand label led to an OLP effect but a medicine container without a brand label did not.

Table 2

Results of ANOVAs for the Respective Outcome Measures

Outcome / Factor	*df*	*F*	*p*	Effect size η^2
Sleep quality				
Condition	1	0.43	.512	< .001
Day of the week	4	2.18	.071	.010
Condition x day	3.48	2.32	.066	.008
Label	1	0.95	.334	.004
Condition x label	1	5.85	.018	.007
Bodily symptoms				
Condition	1	1.60	.210	.002
Day of the week	3.46	4.61	.002	.006
Condition x day	3.32	2.68	.042	.004
Label	1	< 0.01	.979	< .001
Condition x label	1	< 0.01	.979	< .001
Mental well-being				
Condition	1	0.13	.716	< .001
Day of the week	3.27	1.21	.306	.002
Condition x day	3.68	0.99	.408	.001
Label	1	0.10	.749	.001
Condition x label	1	0.89	.349	< .001
Psychological distress				
Condition	1	0.16	.693	< .001
Day of the week	3.51	2.50	.051	.003
Condition x day	3.68	0.71	.572	.001
Label	1	0.01	.910	.001
Condition x label	1	3.96	.050	.001

Identification of Predictors

Expectation assessed the day before the placebo intake (2nd assessment) significantly correlated with the difference between scores taken in the placebo versus the no treatment week for the outcome measures bodily symptoms (r = .23, p = .046) and psychological distress (r = .24, p = .037), respectively. The effect sizes of the remaining correlations with other psychological factors were partly in the small range but did not reach significance (Suppl. Table 1 in Appendix C, Supplementary Materials).

Discussion

This study aimed to conceptually replicate findings of a previous experiment (El Brihi et al., 2019) that demonstrated small to medium OLP effects (d = 0.28-0.50) on mental and physical well-being in healthy participants. Using a within-subject design and daily assessed sleep quality, bodily symptoms, mental well-being, and psychological distress, overall no significant OLP effect emerged in the present study. Other than hypothesized, a brand name on the medicine container hindered OLP effects in sleep quality and psychological distress. Explorative analyses hinted at expectation as a possible predictor of the OLP effects in bodily symptoms and psychological distress.

Several reasons might explain the failure to replicate the results of the original study. General issues refer to possible differences in the populations investigated (e.g., language, country, ethnicity, etc.). It is also possible that floor or ceiling effects prevented the development of OLP effects in this healthy sample, yet a comparison to normative values is hardly possible due to altered instructions (referring to the last day instead or a week or else). Further, the present study partly used other outcome measures than the original study (POMS, GSQS). The two most important differences to the original study refer to the design of the studies and the time points of assessment. Employing a within-subjects design has the advantage that every participant serves as their control group, i.e., no random differences will confound the effects of interest. This is especially important since concerns regarding the control group in OLP studies have been voiced (Blease et al., 2020). It can be speculated that the control group in the original study was less motivated or did not pay as much attention to the symptoms in question as the group that received placebos because they were neither reminded to attend to possible effects by taking a pill nor by filling in daily questionnaires, which might have artificially boosted OLP effects. Regarding the time points of assessment, the present study assessed symptoms daily, while the original study assessed symptoms once after five days of placebo intake or control phase. This retrospective assessment might have led to an overestimated OLP effect due to memory biases (Ebner-Priemer & Trull, 2009). Another potential reason for the non-existent OLP effects might be the mode of presentation of the information concerning OLP effects to the participants. To standardize this aspect of the study, participants watched an animated video that conveyed the relevant information. In other OLP studies, this information is given in a conversation between the experimenter and the participant. Research indicates that (open-label) placebo effects benefit from trustworthy, friendly and empathetic treatment providers (Gaab et al., 2019; Kube et al., 2021). Possibly, the therapeutic alliance between treatment provider and participant was adversely affected by implementation of the video instead of personal communication in the present study. Feasibly, participants in our study were not as attentive or engaged or the video just was less convincing than a personal conversation. Along these lines, expected OLP effects were somewhat lower in our study (range of M = 3.4 and M = 4.4) compared to the original study (M = 4.9). Interestingly, a recent study

(Kube et al., 2021) failed to find OLP effects in allergic rhinitis when information on OLP was conveyed in an online setting. This result emphasizes the importance of the mode of presentation.

Although many previous studies evidence OLP effects in clinical (Carvalho et al., 2016; Charlesworth et al., 2017; von Wernsdorff et al., 2021) as well as healthy samples, including those on mental and physical well-being (El Brihi et al., 2019; Guevarra et al., 2020; Kleine-Borgmann et al., 2021), some studies were only partly successful (context of itch, Meeuwis et al., 2019; Meeuwis et al., 2018) or failed to induce OLP effects, e.g., in chronic back pain (Ikemoto et al., 2020), nausea (Barnes et al., 2019), wound healing (Mathur et al., 2018), and allergic rhinitis (Kube et al., 2021). Future studies should find out, whether OLP effects can be reliably induced in healthy participants and which conditions are key.

We hypothesized that a brand name on the medicine container would increase the OLP effect because usually medication is labeled and in deceptive placebos, brand names lead to larger effects (Meissner & Linde, 2018). However, contrary to that, the difference in scores between placebo and control week tended to be increased when no brand name was present for two of the outcome measures, namely psychological distress and sleep quality, while the presence of a brand name did not influence the effects of the two remaining outcome measures. Possibly, when reading the label “pharmacebo”, participants were reminded that they are about to take a placebo, which might have counteracted conditioned effects based on previous experiences with medication. It would be worthwhile to replicate the present findings and to investigate the effect of a brand name that does not hint at the placebo context in future studies.

Several possible predictors of OLP effects were explored. Suggestibility, neuroticism, extraversion, openness, conscientiousness, habitual anxiety, somatization, somatosensory amplification, and a positive attitude towards CAM or conventional medicine were not significantly associated with the difference in scores of the placebo and control week. These findings are similar to those of a study on experimental heat pain in healthy participants that did not find associations of the OLP effect with optimism, pessimism, openness, locus of control, and positive attitudes towards CAM (Locher et al., 2019). Interestingly, relevant traits in the context of deceptive placebo effects do not necessarily play a role in OLP effects (cf. optimism, Locher et al., 2019). Thus, more research is needed to identify facilitating personality traits of OLP effects, should they exist.

In line with our assumptions, expectations were a significant predictor for the OLP effects in bodily symptoms and psychological distress. Results of previous studies concerning the role of expectations are inconsistent; whereas some studies showed a relationship between OLP effect and measures of expectation (El Brihi et al., 2019, not for sleep quality, however; Kleine-Borgmann et al., 2021) other did not (Guevarra et al., 2020; Kube et al., 2021). Possibly, the time point of assessment of the expectations is an important aspect to consider. In the present study, participants expressed higher expectations directly after the information about OLP effects and expectations significantly decreased in the second assessment before the placebo phase. Yet, only expectations of the second assessment were significantly associated with the OLP effects. Therefore, possibilities should be explored that keep expectations stable for a longer period of time, for example sending patients written information on the open-label placebo effect to boost expectations right before the intake of the placebos.

Some limitations need to be mentioned for the present study. The animated video was meant to increase standardization when giving participants information about OLP effects. It would have been helpful to validate the animated video in a pilot study, test whether the information was conveyed as desired and whether alliance would be affected. Since the placebo and control phases of the study took place in the field instead of in a controlled lab environment, we cannot be sure whether participants took the placebos as prescribed. Yet, this approach has higher ecological validity than most OLP studies that comprise healthy participants, as it closely resembles realistic conditions (i.e., taking medication at home). Further, besides asking about the intake of the placebo pills daily, we confirmed the participants' statements by asking how many pills they had to spare at the end of the study. The employed brand name "pharmacebo" might have not been optimally chosen, since it includes the term "pharma" and thus could be misleading. Yet, the results do not support this notion as participants whose medicine container did not have a label tended to benefit better from the placebos. It would be helpful to investigate the impact of different brand names and their connotations in a future study. Finally, analyses were based solely on self-report data. Assessing objective data, for example with the help of fitness watches tracking sleep parameters, could be a beneficial addition.

To conclude, open-label placebo effects are a promising phenomenon that has the potential to improve patient care while respecting patients' autonomy. Similar to other recent investigations, this study failed to find overall OLP effects in mental and physical well-being in healthy participants. It will be important to continue replicating previous findings and to determine the exact conditions of successful implementation of OLP effects in healthy as well as clinical samples.

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Twitter Accounts: @AnneKBraescher, @witthoef

Supplementary Materials

The Supplementary Material contains further information on the sample, the manualized narrative provided in the animated video, further information on questionnaires assessed, and a supplementary table with correlations of the difference between scores taken in the placebo versus the no treatment week of the outcome measures with psychological factors (for access see Index of Supplementary Materials below).

Index of Supplementary Materials

Bräscher, A., Ferti, I., & Witthöft, M. (2022). *Supplementary materials to "Open-label placebo effects on psychological and physical well-being: A conceptual replication study"* [Additional information]. PsychOpen GOLD. https://doi.org/10.23668/psycharchives.12173

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The Influence of Alcohol on Rumination and Metacognitions in Major Depressive Disorder

Lana Gawron[1], Anna Pohl[1], Alexander L. Gerlach[1]

[1] *Institute of Clinical Psychology and Psychotherapy, University of Cologne, Cologne, Germany.*

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Corresponding Author: Lana Gawron, Institute of Clinical Psychology and Psychotherapy, Pohligstraße 1, 50969 Cologne, Germany. E-mail: lana.gawron@uni-koeln.de

Supplementary Materials: Materials [see Index of Supplementary Materials]

Abstract

Background and Objectives: Comorbidity between major depressive disorder (MDD) and alcohol use disorder (AUD) is highly prevalent but reasons for this association are unclear. Rumination may activate metacognitive beliefs that contribute to the development and maintenance of rumination and depression. Negative metacognitions can further lead to other dysfunctional coping strategies (i.e., consumption of alcohol). We examined whether alcohol reduces (state) metacognitions, rumination and other disorder-specific processes in a group of individuals suffering from MDD.

Method: In an experiment with three randomized conditions we investigated whether the consumption of alcohol, placebo or no alcohol (orange juice) affects (meta-)cognitions, depressive symptoms and / or psychophysiological variables while participants ruminate.

Results: Voluntary rumination increased self-reported sadness, tension and rumination, tensed facial muscles and increased heart rate, but did not affect (state) metacognitions and heart rate variability. The consumption of alcohol did not influence rumination, metacognitions, depressive or psychophysiological measures.

Limitations: We recruited a depressed population but excluded pathological alcohol use due to ethical considerations.

Conclusions: We found no evidence that alcohol consumption affects rumination, metacognitions and other disorder-specific processes in MDD. However, rumination had a negative effect on various depression-specific processes, although it did not activate (negative state) metacognitions.

Keywords

major depressive disorder, rumination, metacognitions, alcohol consumption, self-medication, alcohol use disorder

Highlights

- The effect of alcohol on (meta-)cognitions, emotions, and psychophysiology was investigated with alcohol, placebo and a control group in MDD.
- No group differences were found both before and after alcohol consumption.
- Induced rumination did not activate (state) metacognitions, but affected various depression-specific processes.
- Future studies could activate metacognitions by providing false feedback about the controllability of such processes.

Rumination, the repetitive negative thinking about past events, possible causes and consequences of negative emotions (Nolen-Hoeksema, 1991), contributes to the development (e.g., Huffziger et al., 2009) as well as maintenance and severity of depressive episodes (e.g., Nolen-Hoeksema et al., 2008). Moreover, rumination has negative effects on somatic health, as illustrated by a number of psychophysiological changes such as decreased heart rate variability (HRV; e.g., Ottaviani et al., 2015), increased heart rates (HR; Ottaviani et al., 2016) and changes in muscular tension, e.g., in the corrugator EMG (Teasdale & Rezin, 1978).

According to the metacognitive model of rumination and depression (MCM), rumination is maintained by metacognitions reflecting on this type of perseverative thinking (Papageorgiou & Wells, 2003). Negative thoughts or other triggers initially activate positive metacognitive beliefs about the usefulness of rumination (e.g., “In order to understand my feelings of depression, I need to ruminate about my problems.”), and motivate further rumination. However, rumination prevents effective problem solving and intensifies negative affect. As a result, negative metacognitive beliefs emerge regarding the uncontrollability and harmfulness of rumination and its social consequences (e.g., “I cannot stop myself from ruminating.”; “People will reject me if I ruminate.”), thereby increasing the accessibility of negative and threatening information (e.g., negative thoughts or emotions), and thus exacerbating and maintaining depressive symptoms as well as promoting further rumination (Papageorgiou & Wells, 2004).

Both, clinical (e.g., Papageorgiou & Wells, 2003) and nonclinical studies (e.g., Solem et al., 2016) have shown that metacognitive beliefs about rumination are significant for the onset (Faissner et al., 2018; Papageorgiou & Wells, 2009) and maintenance (e.g., Solem et al., 2016) of depressive states / depression.

Negative metacognitions may also promote the use of dysfunctional behavioral strategies, such as the use of alcohol, to control or avoid recurrent negative thoughts. In the long term, however, these strategies may maintain negative metacognitions (cf. metacognitive model of generalized anxiety disorder; Wells, 2005; Wells, 2011). Although the MCM of generalized anxiety disorder focuses on worry and meta-worry, we assume that the assumptions regarding the use of other coping strategies can also be applied to the MCM for depression and rumination. Thus, we take a step beyond the original model by postulating that alcohol use functions as a cross-model coping strategy that can reduce rumination (see, e.g., Mollaahmetoglu et al., 2021) and possibly negative metacognitions (in the short term), making these thoughts and processes seem less uncontrollable and threatening.

According to the appraisal disruption model, alcohol can disrupt the appraisal of threatening information (i.e., cognitions; Sayette, 1993). More specifically, alcohol may interfere with the initial perception of stressful information by preventing negative memories and associated stressful concepts from being activated. Moreover, cognitive abstraction capacity is supposed to be reduced by alcohol (Sayette, 1993), which may also impede perseverative thinking and related metacognitions. Finally, when intoxication precedes a stressor, it can buffer the stress by attenuating appraisal, thereby protecting the person drinking from fully experiencing the stressor (Sayette, 2017). Applied to the context here, negative thoughts and processes promoted by metacognitions can also be defined as a type of threatening information whose appraisal can be attenuated by alcohol consumption. Furthermore, intoxication could prevent concepts associated with negative metacognitions, such as ruminative thoughts, from being activated, possibly leading to relief in terms of less threatening rumination or generally less aversive emotional states. Since this dysfunctional coping strategy is only helpful in the short term, alcohol may be consumed repeatedly in order to feel a facilitating effect (negative reinforcement). This could then lead to the development of a problematic drinking pattern or an alcohol use disorder (AUD).

Empirical evidence suggests that these negative metacognitions are in particular associated with problematic alcohol use (e.g., Spada et al., 2007). The higher the levels of maladaptive metacognitions are, the more likely alcohol is consumed in response to unpleasant aversive states (Moneta, 2011). In line with this, rumination is associated with alcohol consumption (e.g., Devynck et al., 2019) and with increased alcohol-related problems (e.g., Willem et al., 2011). In a group of individuals with risky consumption, the direct effects of alcohol on rumination and mood were examined and it was found that alcohol reduced rumination directly and also indirectly by changing mood (Mollaahmetoglu et al., 2021).

Apart from the study of Mollaahmetoglu et al. (2021), most empirical evidence for the association of rumination, depressed mood and alcohol use (disorder) is correlative (e.g., Heggeness et al., 2019). Moreover, these relationships have mostly been examined in analogue samples (e.g., Bravo et al., 2018), and metacognitions have been assessed as a *trait* variable (e.g., Faissner et al., 2018; Papageorgiou & Wells, 2009). However, it has been argued that mimicking typical problematic situations may also provoke the presence of *state*-dependent metacognitive beliefs about perseverative cognitions as well as their consequences, especially in clinical populations (Andor et al., 2008). Consistent with this, negative metacognitions following worrying, so negative state metacognitions, were more pronounced in patients with generalized anxiety disorder compared with control participants when they received feedback that indicated arousal while being asked to relax (Andor et al., 2008).

In light of previous findings, we believe it is important to examine the direct effects of alcohol consumption on perseverative cognitions, such as rumination, and negative state metacognitions in an experimental setting: indeed, if it is shown that people with depression can alter cognitive processes with the help of alcohol, this could provide a significant clue to the mechanisms underlying the high comorbidity of major depressive disorder (MDD) and AUD (e.g., Brière et al., 2014), with, for example, odds ratios between 2.0 (Kessler et al., 1997) and 3.8 (Grant & Harford, 1995).

Namely, depression-related cognitive / ruminative and metacognitive processes that appear uncontrollable and threatening may erroneously appear controllable and less threatening after alcohol consumption, which may be relieving in the short term, thus promoting further consumption and the development of AUD.

To our knowledge, no study has yet examined the direct effects of alcohol on negative (meta)cognitions and depression in a clinically depressed sample. Our aim was therefore to examine these effects on rumination and metacognition in MDD. We specifically focused on (negative) state metacognitions (cf. Andor et al., 2008). The negative appraisal of these state metacognitions may be interrupted by alcohol consumption and consequently appear less threatening (cf. Sayette, 1993). For a holistic understanding of the effects of alcohol on disorder-specific processes, we also wanted to investigate the influence of alcohol on emotional states and psychophysiology (heart rate, heart rate variability, muscle tension). According to some studies, alcohol can lead to an increase in heart rate (Weise et al., 1986), a reduction in HRV (Koskinen et al., 1994), and a decrease in muscle tension (Stockwell et al., 1982).

Our hypotheses were as follows: given that rumination has an unfavorable impact on negative affect and psychophysiology (see, e.g., Ottaviani et al., 2016), we hypothesized that (H1) induced rumination has a negative effect on sadness, tension, and on the extent of rumination itself, as well as on psychophysiological processes. We also hypothesized that (H2) alcohol consumption reduces rumination, (H3) alcohol consumption reduces negative state metacognitions about rumination that, according to the MCM of rumination and depression, should be triggered by induced rumination, and (H4) alcohol consumption reduces negative emotions such as sadness and experienced muscle tension intensified by rumination. Finally, in addition to rumination, alcohol consumption may also affect psychophysiology, although the direction of the effect in MDD is still unclear. We assumed an increase in HR and a decrease in HRV and muscle tension in individuals with depression (H5).

Method

Recruitment

Participants were recruited online (e.g., via facebook), with publicly distributed leaflets, posters and at the outpatient treatment center for psychotherapy. All participants received a compensation of 8.50 euros per hour and were offered counselling. Exclusion criteria were current or past substance use disorder or AUD, complete abstinence of alcohol, GAD, current use of psychoactive medication, liver damage, current or past psychotic episodes, and pregnancy. GAD was excluded to ensure that the main problem with repetitive negative content was rumination and not worrying. All participants signed an informed consent. The ethics committee of the German Psychological Association approved this study (SS 042017).

Participants

Sixty-five participants (46 women) diagnosed with current MDD using a structured clinical interview (see Procedure) completed the study. Thirty-nine participants (40.5%) were diagnosed with additional comorbid disorders. Twenty-seven suffered from anxiety disorders (41.5%), ten from posttraumatic stress disorder (15.4%), three from obsessive compulsive disorder (4.6%), three from an eating disorder (4.6%), and five from somatic symptom disorders (7.7%). Sociodemographic data is presented in Table 1. Further characteristics can be found in Table A1 (Supplementary Materials). Power analyses according to G*Power 3 (Faul et al., 2007) indicated a required sample size of at least 54 participants, expecting a medium effect size f = .25 for the analysis of a repeated measures ANOVA (within-between interaction) at an alpha level of .05 and 95% power (cf. Andor et al., 2008; Stevens et al., 2017).

Procedure

Participants were telephone screened and then received information about the experiment. They had to agree to participate in the study irrespective of whether they would receive alcohol or not. Participants with depressive symptoms were invited for a 2 h diagnostic session using the German version of the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, 4th version (SCID-I; Wittchen et al., 1997). A trained clinical psychologist conducted the interviews. Participants with MDD then completed several questionnaires (see Baseline Questionnaires) and were invited for a laboratory session. At this point, participants were fully randomized to three conditions (see Drinking Procedure). At the beginning of the laboratory session, electrodes for physiological measurement were attached and participants estimated their blood alcohol level (BAL). Then the BAL was measured. A three-minute resting period (first baseline) and an additional three-minute task (Schandry, 1981) followed, which will not

Table 1

Demographic Data of all Participants Separated by Group

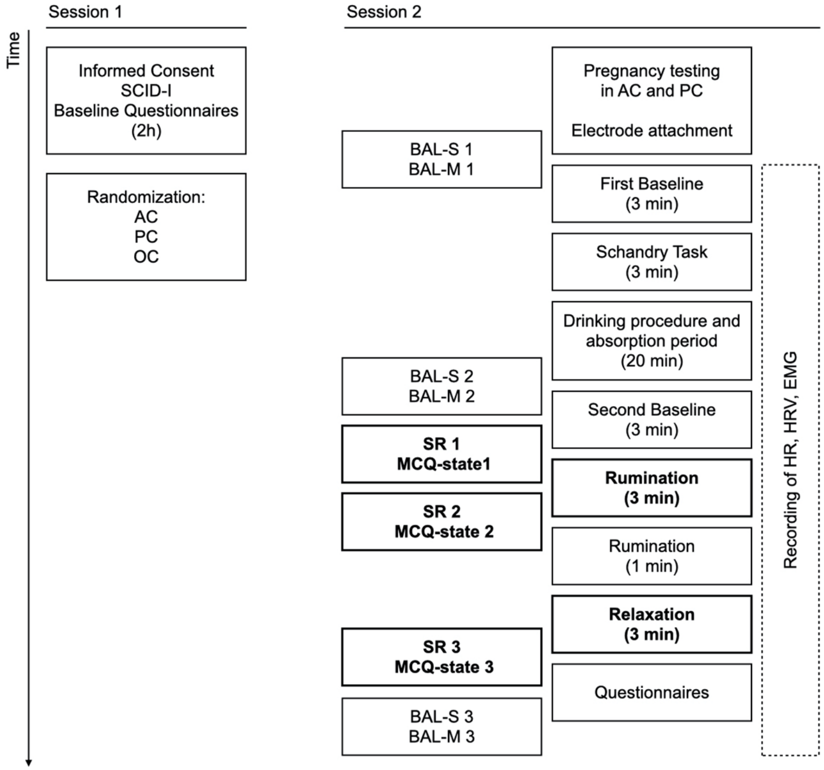
Variable	AC (*n* = 22)	PC (*n* = 22)	OC (*n* = 21)
Mean Age (*SD*)	33.6 (11.5)	30.2 (11.8)	30.7 (12.9)
Sex, *n* (%)			
Women	15 (68.2)	16 (72.7)	15 (71.4)
Men	7 (31.8)	6 (27.3)	6 (28.6)
Education, *n* (%)			
O level	4 (18.2)	16 (72.7)	1 (4.8)
Specialized A level	1 (4.5)	3 (13.6)	6 (23.8)
A level	15 (68.2)	3 (13.6)	15 (71.4)
Still attending school	2 (9.1)	–	–
Family status, *n* (%)			
Unmarried	17 (77.3)	20 (90.9)	17 (81.0)
Married – living together	1 (4.5)	1 (4.5)	3 (14.3)
Divorced	3 (13.6)	1 (4.5)	–
Registered civil partners	–	–	1 (4.8)
Widowed	1 (4.5)	–	–
Treatment, *n* (%)			
Current outpatient treatment	4 (18.2)	2 (9.1)	4 (19.0)
Past outpatient treatment	16 (72.7)	15 (68.2)	12 (57.1)
Past psychiatric inpatient treatment	7 (31.8)	7 (31.8)	5 (23.9)
Past antidepressant medication	5 (22.6)	7 (31.8)	8 (38.1)

Note. AC = alcohol condition; PC = placebo condition; OC = control / orange juice condition. O level = ordinary level high school certificate; A level = advanced level high school certificate. The groups did not differ significantly.

be reported here. Then, a drinking phase of 15 minutes drinking and a five-minute break allowing for absorption of the alcohol followed. Participants again estimated their BAL and it was also measured. After a second three-minute resting period (second baseline), participants estimated their level of rumination, sadness and tension, and completed the state metacognitions questionnaire (MCQ-state; Andor et al., 2008). The *rumination induction procedure* (a variant of the worry induction procedure; Borkovec & Inz, 1990) followed. Participants were asked to write down three topics they regularly ruminated about and were to choose the currently most troubling one. They were then instructed to ruminate about this topic “like they normally did”. After ruminating for three minutes (rumination episode), participants reported their rumination, sadness and tension again and completed the MCQ-state. They were instructed to ruminate for another minute and then asked to relax for three minutes (relaxation episode). Following the relaxation, participants completed the self-reports and MCQ-state a third time as well as the WBSI, TCQ-R and CAS-I (see Questionnaires Used During the Experiment). In the end, they estimated their BAL and the BAL was measured one last time. After the experiment, participants were debriefed. The procedure is visualized in Figure 1.

Figure 1

Procedure



Note. Timing and overview of the two sessions. The blood alcohol level (BAL) was measured at the beginning, after the phase of drinking and at the end of the experiment. Self-reports (SR) and MCQ-state were assessed at three time points: before rumination, after rumination and after relaxation. An overview of all baseline questionnaires and all questionnaires used during the experiment can be found in section Measurements. AC = alcohol condition (*n* = 22); PC = placebo condition (*n* = 22); OC = control condition / orange juice (*n* = 21). BAL-S = participants' estimated BAL before each measurement of BAL; BAL-M = measured breath alcohol level. SR = self-reports, i.e., estimated levels of sadness, rumination, and tension. MCQ-state = two subscales of the Metacognitions Questionnaire, German version. HR = heart rate; HRV = heart rate variability; EMG = facial electromyography.

Drinking Procedure

All participants were asked to eat a light meal, specified in a handout, four hours prior to the experiment and to forego food and drinks containing caffeine from then on. They were requested to abstain from alcohol 24 hours prior to the experiment. Participants in the control condition (OC) were told that they would receive orange juice. Participants in the alcohol (AC) and placebo condition (PC) were both given the information that they would receive alcohol and that they would have to be picked up or wait until their BAL decreased below 0.3 ‰. All participants were tested at 4:00 pm. Female participants in the AC or PC were pregnancy tested. None of the participants tested positive. Finally, height and weight were measured.

Participants in the AC consumed a drink of 1:2 vodka and orange juice. Following a modified version of the Widmark formula, participant's sex, weight, height and age was used to estimate the necessary amount of alcohol to reach a blood alcohol level of about 0.6 ‰ (Gerlach et al., 2006). The nonalcoholic beverage in the OC and PC was orange juice in comparable drinking quantity. In the PC, immediately before serving the beverages, a few milliliters of vodka were dropped on the orange juice and applied along the rims using a pipette (Stevens et al., 2014). Participants received three glasses with equal amounts of chilled beverage, each to be finished within five minutes. After drinking, participants waited five minutes.

Breath alcohol concentration was assessed by breathalyzer with an accuracy of +/- 0.03 mg/L (Dräger, Alcotest, 7410 plus). In the PC, the first measurement used a standard breathalyzer to ensure a BAL of zero. Then, a rigged breathalyzer with identical built was used giving a false feedback of 0.6 ‰ and then 0.7 ‰ BAL.

Measurements

Baseline Questionnaires

Alcohol Use Disorder Identification Test (AUDIT) — The AUDIT (Dybek et al., 2006) is a brief screening scale developed by the World Health Organization (WHO) for early detection of problematic drinking. The original as well as the German version includes 10 questions regarding alcohol consumption, dependency symptoms and alcohol related problems. For each question, one of five statements related to alcohol use in the past year can be selected on a 5-point Likert-type scale ranging from 0 ("never") to 4 (e.g., "daily or almost daily"). Cronbach's α = .76.

Simplified Beck Depression Inventory (BDI-S) — The BDI-S (Schmitt et al., 2003) assesses current depressive symptoms with 20 items on a 6-point Likert-type scale ranging from 0 ("never") to 5 ("almost always"), for example, "I feel sad.". Cronbach's α = .87.

Metacognitions Questionnaire 30 (MCQ-30) — The German version of the MCQ-30 (Arndt et al., 2011; a shortened version of the original Metacognitions Questionnaire; Cartwright-Hatton & Wells, 1997) is used to assess thoughts and beliefs (metacognitions) about worry. The questionnaire consists of five subscales (positive worry beliefs, beliefs about uncontrollability and danger, metacognitive efficiency, general negative beliefs, cognitive self-consciousness) assessed by 30 items (e.g., “Not being able to control my thoughts is a sign of weakness.”). Items/statements can be rated on 5-point Likert-type scales ranging from 1 (“not agree”) to 4 (“agree very much”). Cronbach’s α = .84.

Penn State Worry Questionnaire (PSWQ) — The German version of the PSWQ (Stöber, 1995) is a 16-item questionnaire assessing intensity, excessiveness and uncontrollability of worry (e.g., “I worry all the time.”) on a 5-point Likert-type scale ranging from 1 (“not at all typical of me”) to 5 (“very typical of me”). Cronbach’s α = .89.

Response Styles Questionnaire (RSQ) — The German version of the RSQ (Kühner & Weber, 1999) assesses people’s cognitive and behavioral strategies to cope with depressed mood with 32 items on 4-point Likert-type scales ranging from 1 (“almost never”) to 4 (“almost always”). The RSQ consists of the subscales rumination with 21 items (e.g., “When I am sad, I think about how sad I feel.”) and distraction with 11 items (e.g., “When I am sad, I go to my favorite place to get my mind off my feelings.”). Cronbach’s α = .69.

Questionnaires Used During the Experiment

Assessment of State Metacognitions (MCQ-state) — Since state-dependent changes in metacognitions can be assessed using the MCQ (cf. Andor et al., 2008), two subscales of the MCQ-30 (beliefs about uncontrollability and danger, general negative beliefs) were adapted to the experiential situation. An example is “My ruminating could make me go mad.”. Cronbach’s α = .97.

Rumination Score (RS) — The levels of sadness, tension and rumination were assessed on one rating scale each, ranging from zero (“absolutely not”) to 100 (“extremely so”) and then averaged. Cronbach’s α = .83.

White Bear Suppression Inventory (WBSI) — The German version of the WBSI (Fehm et al., 2000) measures thought suppression with 15 items (e.g., “There are things I prefer not to think about.”) on a 5-point Likert-type scale ranging from 1 (“strongly disagree”) to 5 (“strongly agree”). Cronbach’s α = .85.

Thought Control Questionnaire (TCQ) — The German version of the TCQ (Fehm & Hoyer, 2004) is a 30-item self-report measure assessing rumination, intrusive and unwanted thoughts. Items can be rated on 4-point Likert-type scales ranging from 1 (“never”) to 4 (“almost always”). Cronbach’s α = .67.

Cognitive Attentional Syndrome-Inventory (CAS-I) — The German version of the CAS-I (Wells, 2011) assesses maladaptive coping strategies (e.g., worrying, avoidance, use of alcohol/drugs) for dealing with negative thoughts, and negative and positive metacognitive beliefs. In total, the CAS-I consists of four questions. The first three questions are answered using a scale from 0 (“not at all”) to 8 (“all the time”) and refer to how much dealing with problems or worries about problems was done in the past week and how it was dealt with. The fourth question refers to positive and negative metacognitions, answered using a scale from 0 (“I do not believe in this belief at all.”) to 100 (“I am absolutely convinced that this belief is true.”). Cronbach’s $\alpha = .75$.

Psychophysiological Data Recording, Sampling and Analysis

Psychophysiological data (heart rate, respiration and facial muscle tension) were recorded using the Varioport (Becker Meditec, Karlsruhe, Germany). ECG was recorded at 512 Hz sample rate from three electrodes. The active electrodes were placed on the lowest left rib and on the right collarbone. Ground was affixed to the left collarbone. Respiration was assessed with a respiratory belt (128 Hz sample rate). Facial electromyography (EMG) was recorded in mV at 256 Hz sample rate over the *corrugator supercilii* on the left side of the face with two electrodes (TIGA-MED, Germany Ltd.). The EMG signal was preprocessed using an infinite impulse response high pass filter at 10 Hz. It was notch filtered at 50 Hz with a width of 3 Hz and rectified and smoothed using a two-step low pass filter with eight point moving average. For HRV, the root mean square successive differences (RMSSD) was calculated (cf. Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, 1996; Bertsch et al., 2012). Mean values were computed for each experimental 3-minute episode (baseline 2, rumination, relaxation).

Data Analysis

Group differences concerning sociodemographic characteristics and self-reported BAL were tested using an ANOVA[1] and Bonferroni-corrected post-hoc tests. Group differences concerning psychopathological variables (questionnaires) were analyzed using a MANOVA. A Pearson correlation was performed between problematic alcohol consumption (AUDIT) and the level of alcohol as a coping strategy (CAS-I). To test our hypotheses, we conducted several repeated measures ANOVAs[2] with Bonferroni-corrected post-hoc tests. Each ANOVA was analyzed by group (alcohol, placebo, orange juice).

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1) Initial exploratory analyses revealed a few outliers. However, there was no relevant change in the pattern of results when including vs. excluding outliers. Thus, results from the complete data set are reported. Deviations from the original data set are indicated in the data analysis (e.g., MCQ-state ratings).

2) The assumption of normality (ANOVA) or the equality of variances (repeated measures ANOVAs) was not met. Since the *F*-Test is relatively robust for violation of assumption (Finch, 2005; Tabachnick & Fidell, 2007), the ANOVA

To test H1 (rumination increases sadness, tension, rumination, and worsens psychophysiology) the measurement time points of all variables from “second baseline” to “rumination” were examined. H2 (alcohol reduces rumination) and H4 (alcohol reduces sadness and tension intensified by rumination) were tested in one model: for this, RS over time were analyzed. To test H3 (alcohol reduces negative state metacognitions), metacognitions ratings (MCQ-state) were analyzed. To test H5 (alcohol influences psychophysiology), EMG, HR and HRV over time were analyzed. In case sphericity was violated, the Greenhouse–Geisser adjustment was used.

Results

Manipulation Check

Coping Strategies

The correlation of AUDIT and CAS-I was significant ($r = .46$, $p < .001$). The most frequently used coping strategy was “to control emotions” ($M = 6.0$, $SD = 2.0$), followed by “the attempt not to think about anything” ($M = 5.2$, $SD = 2.2$), “to avoid situations” ($M = 2.8$, $SD = 2.5$), “to control symptoms” ($M = 4.2$, $SD = 2.2$), “to seek reassurance” ($M = 3.5$, $SD = 2.3$). The least used strategy was “to consume alcohol or drugs” ($M = 2.5$, $SD = 2.0$).

Self-Reported Alcohol Level and Measured Blood Alcohol Level

Compared to baseline, in both AC and PC self-estimated alcohol levels (in ‰) were higher after drinking ($M_{AC} = 0.6$, $SD = 0.2$, $M_{PC} = 0.2$, $SD = 0.1$) and after finishing the experiment ($M_{AC} = 0.7$, $SD = 0.2$, $M_{PC} = 0.4$, $SD = 0.2$). The manipulation in the PC can be considered successful: 20 of 22 participants believed that they had been given alcohol. Two subjects (PCs) were excluded because their self-estimated BAL was 0.0 ‰ at all measurement points and then assigned to the control condition for subsequent analyses. In the AC, the measured BAL was 0.8 ‰ ($SD = 0.2$) after the drinking period and 0.7 ‰ ($SD = 0.2$) at the end of the experiment (see Figure 2).

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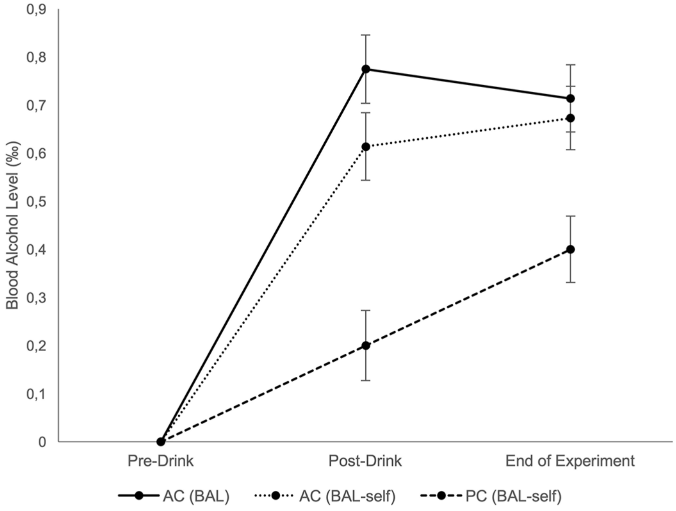
and the repeated measures ANOVAs were nevertheless conducted and results reported. Because the number of subjects varied across the variables, no repeated measures MANOVA could be calculated for the self-reports or for the biodata. Instead, several repeated measures ANOVAs were conducted with Bonferroni-corrected post-hoc tests.

Figure 2

Blood Alcohol Level



Note. Measured and estimated BAL. Data points represent values before and after the drinking procedure and at the end of the experiment; error bars depict 95% CI. AC = alcohol condition (*n* = 22); PC = placebo condition (*n* = 20). BAL = measured breath alcohol level in AC; BAL-self = participants' estimated BAL before each measurement of BAL. Control condition is not included.

Rumination Induction Procedure (H1, H5)

Self-report: An initial univariate ANOVA revealed no significant group differences in the self-reports ($F(2, 62) = .86$, $p = .427$) and MCQ-state-ratings[3] ($F(2, 42) = .26$, $p = .772$) before rumination induction. After rumination, RS were significantly higher (see Table 2 and Figure 3), whereas MCQ-state-ratings did not change (see Table 2).

Psychophysiological measures: An initial univariate ANOVA[4] revealed no significant group differences in HR ($F(2, 61) = .37$, $p = .690$), HRV ($F(2, 61) = 1.46$, $p = .240$) or EMG ($F(2, 58) = .36$, $p = .702$) before rumination. HR and EMG increased significantly with rumination. Regarding HRV, there was no significant change in RMSSD during rumination or relaxation (see Table 2 and Figures 4, 5).

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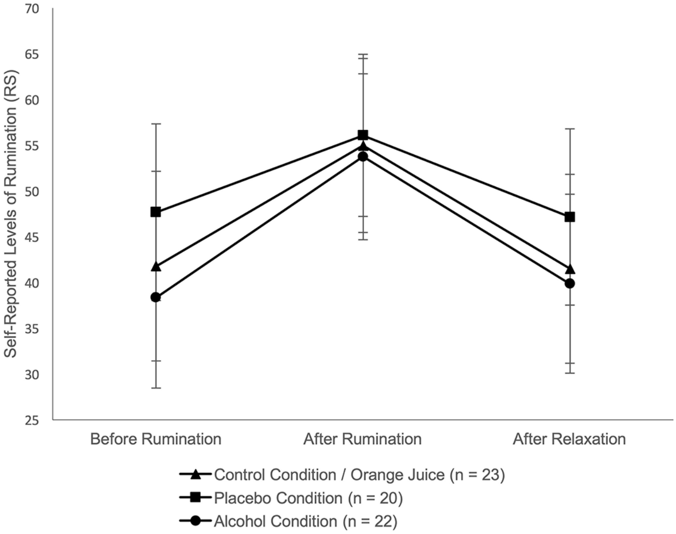
3) Since the first measuring time of the MCQ-ratings was subsequently integrated into the experiment, the repeated measures ANOVA was conducted with only *n* = 45.

4) Regarding EMG, three subjects (PC) were excluded from further analyses because they were identified as outliers in at least four of five relevant time intervals. Another subject was excluded because the recording of biodata failed. See Table A3 (Supplementary Materials) for an overview of all participants per condition.

Figure 3

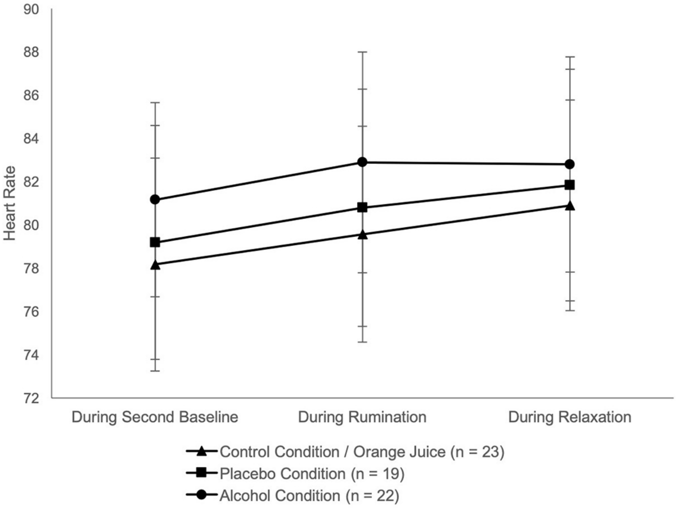
Results Over Time Separated by Group: a) Rumination Score



Note. Data points represent the mean values before, after the rumination induction and after relaxation; error bars depict 95% CI. Estimates of depression (sadness, rumination, tension) were rated on a scale from 0 to 100.

Figure 4

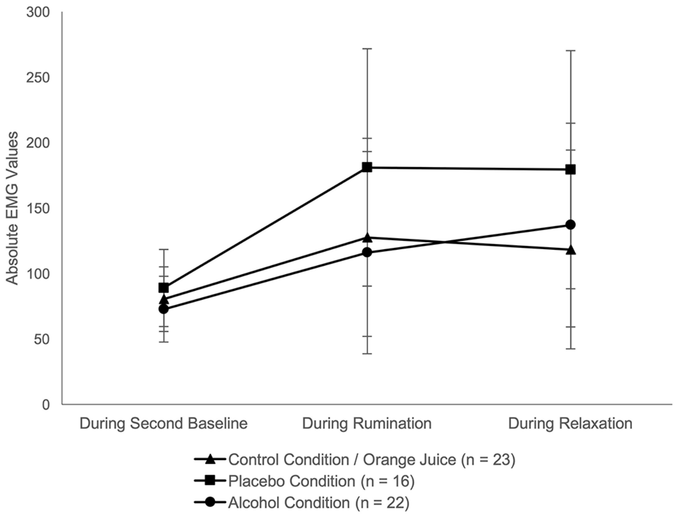
Results Over Time Separated by Group: b) Heart Rate



Note. Data points represent the mean values of three time intervals: during second baseline, rumination and relaxation; error bars depict 95% CI.

Figure 5

Results Over Time Separated by Group: c) EMG



Note. Data points represent the mean values of three time intervals: during second baseline, rumination and relaxation; error bars depict 95% CI.

Repeated Measures ANOVAs (H2-H5)

ANOVAs revealed a significant main effect of time for RS ($F(1.52, 94.38) = 16.45$, $p < .001$, $\eta_p = .21$), HR ($F(2, 122) = 14.12$, $p < .001$, $\eta_p = .19$), and EMG ($F(2, 116) = 5.41$, $p = .006$, $\eta_p = .09$). From “second baseline” (T1) to “rumination episode” (T2) there was a significant increase in RS, HR and EMG. From T2 to “relaxation” (T3) there was a significant decrease in RS (see Figure 3). From T2 to T3 there was no significant change in HR and EMG (see Figures 4, 5). No significant effect for group and no interaction effect for time × group was found in any variable (see Table 2 and A2, Supplementary Materials, for all significant and nonsignificant effects, Table A3, Supplementary Materials for mean values).

Table 2

Repeated Measures ANOVAs Results

Effects / Measures	*F*	*df*	*p*	η_p^2
Time				
RS	16.45	1.52, 94.38	< .001	.21
MCQ-state	.32	2, 84	*ns*	.01
HR	14.12	2, 122	< .001	.19
HRV	1.57	1.50, 91.26	*ns*	.03
EMG	5.41	2, 116	.006	.09
Group				
RS	.57	2, 62	*ns*	.02
MCQ-state	.31	2, 42	*ns*	.02
HR	.32	2, 61	*ns*	.01
HRV	1.08	2, 61	*ns*	.03
EMG	.74	2, 58	*ns*	.03
Time × Group				
RS	.38	3.05, 94.38	*ns*	.01
MCQ-state	.15	4, 84	*ns*	.01
HR	.56	4, 122	*ns*	.02
HRV	1.69	2.99, 91.26	*ns*	.05
EMG	.37	4, 116	*ns*	.01

Note. RS = Rumination score; MCQ-state = state version of the Metacognitions Questionnaire; HR = Heart rate, beats per minute (bpm); HRV = Heart rate variability, RMSSD; EMG = facial electromyography, absolute EMG values (uV). *ns* = nonsignificant.

Discussion

We directly studied if alcohol affects disorder-specific processes in individuals suffering from MDD. In particular, we wanted to understand whether and how alcohol affects rumination and state metacognitions about rumination. In addition, we were interested in determining the extent to which rumination negatively affects other disorder-specific processes, such as intensifying sadness, and in terms of the MCM, is associated with negative metacognitions.

The rumination induction was successful: self-reported levels for rumination, tension, and sadness increased, as did HR and muscle tension. However, HRV and state metacognitions did not change. We were able to successfully establish a placebo condition (i.e., induce the belief of having consumed alcohol) in almost all participants. In addition, participants who reported higher alcohol consumption were more likely to report using alcohol for coping. Yet, alcohol use was the least reported coping strategy for aversive states in our sample.

In contrast to our first hypothesis, we did not find an increase in negative state metacognitions after rumination. It is possible that the type and implementation of the rumination induction procedure influenced our result. The procedure was originally developed for the induction of worry (Borkovec & Inz, 1990). Given, however, that worry and rumination are often transdiagnostically conceptualized as two forms of perseverative negative cognitions (e.g., McEvoy et al., 2013), the procedure for inducing rumination should have been sufficient to induce metacognitions about rumination, just as inducing worry was sufficient to induce metacognitions about worry (Andor et al., 2008). Yet, Andor and colleagues (2008) studied individuals with generalized anxiety disorder whose negative (trait) metacognitions are more pronounced than in individuals with MDD (Sun et al., 2017). Participants in the Andor study received false arousal feedback during the relaxation phase, making it more likely to experience worry and relaxation as uncontrollable. In other words, it was directly suggested to the participants in this study that their condition was not controllable. It is likely that both the type of disorder and the type of manipulation influenced the intensification of metacognitions. One approach for future studies might be to examine both state and trait metacognitions in relation to rumination and depressive symptomatology and to directly induce a sense of uncontrollability to participants.

However, another consideration against the background of the MCM is conceivable. In the Andor study as well as in our experiment, negative metacognitions were measured via two subscales of the MCQ-30. These scales assess the uncontrollability and danger of worry (reworded to rumination in our study), but not negative metacognitions with regard to social consequences of rumination, which, in terms of the MCM, are also typical for the perpetuation of depression. After successful induction, we did not find more pronounced metacognitions in terms of uncontrollability and danger, but we might have found changes in terms of metacognitions related to the social consequences of rumination. One way to measure both types of negative metacognitive beliefs about rumination would have been to include the Negative Beliefs About Rumination Scale (NBRS; Papageorgiou & Wells, 2001) in our experiment. In this way, we would have been even closer to the original model and the respective measurement methods (cf. Papageorgiou & Wells, 2003).

Also, it is possible that negative metacognitions do not need to be reinforced in certain situations to have a negative effect on perseverative thinking. It may be sufficient that these assumptions exist in the first place to maintain depressive states (e.g., Papageorgiou & Wells, 2009). If negative (state) metacognitions cannot be intensified even with the use of other experimental procedures, we nonetheless consider it advisable to reassess the long-term effects of negative metacognitions on the development of depression in a vulnerable group of participants. This would allow to further investigate the extent to which negative metacognitions are causal in the development and maintenance of depression.

Contrary to our hypotheses (H2-H5), we could neither show that alcohol consumption reduced experienced rumination, sadness, or muscle tension, nor that it reduced state metacognitions about rumination. The three groups did not differ regarding their RS nor in their ratings of metacognitions. There were also no differences between groups in terms of psychophysiological data. Alcohol did not change the negative effect of rumination on psychophysiological variables, nor did it increase physiological reactivity. Thus, surprisingly, we did not find evidence of alcohol effects on any process potentially relevant for the formation and maintenance of depression.

Conger (1956) suggested that alcohol may be used because it reduces muscular tension. However, alcohol did not reduce muscle tension nor change other measures of arousal. Whereas Conger's notion can be found in many textbooks, the pharmacological (stress-reducing) effects of alcohol have only rarely been illustrated. According to a review of studies in social anxiety, for example, alcohol expectancy effects were more likely to be responsible for a reduction of aversive states such as anxiety than alcohol's pharmacological properties (Battista et al., 2010). Thus, people who consume alcohol and expect a stress and tension-relieving effect, may experience such an effect regardless of pharmacological effects. Such positive alcohol expectancies should have been evident in both the AC and PC in comparison to the OC. Yet, in both self-reports and EMG the numerically highest values (indicating distress) were found in the PC. Since Conger's hypothesis refers mainly to anxiety-provoking situations, it should be noted that these assumptions may not apply in situations where other emotions, such as depression or sadness, are prominent. Or possibly, individuals might assume that alcohol is a helpful strategy, but notice when drinking that the strategy proves unsuccessful.

Significant positive correlations have previously been found between metacognitions and alcohol consumption as well as between anxiety, depression and alcohol consumption (Spada et al., 2007). The consumption of alcohol can therefore be regarded as a conscious strategy for dealing with aversive states (Quitkin et al., 1972). In the AC, however, alcohol consumption did not result in feeling less emotionally distressed than in the other two groups. Thus, we found no evidence that alcohol consumption reduces rumination, state metacognitions, or sadness in depressed individuals. Interestingly, our findings are consistent with those of a recent study on social anxiety, in which alcohol consumption had no attenuating effect on negative (post-event) rumination (Hagen et al., 2020), although consumption reduced (social) anxiety (Stevens et al., 2014). Mollaahmetoglu and colleagues (2021) found that alcohol had an effect on ruminative thoughts and mood at a low dose (about 0.2 mg/L) but not at a high dose (about 0.6 mg/L). It is therefore worth considering whether the desirable effects of alcohol in our study would also have been observed if we had used a lower dose. A promising approach for further studies could be to examine alcohol effects on rumination, metacognitions and depressive mood depending on the dose administered. Also, the question arises to what extent the model assumptions on alcohol effects (for a review see Sayette, 2017), which were investigated in the context of anxiety (disorders), can be transferred to other disorders and / or other emotional states, such as depression. It should be noted, however, that according to Sayette's model (1993), appraisal disruption is expected only at higher levels of alcohol (i.e., at an amount of alcohol sufficient to cause cognitive impairment), and that we based our hypotheses on this model. Nonetheless, if alcohol may not be the usual choice for our participants, e.g., to control unpleasant cognitions, state metacognitions or emotions, it simply may not have this effect in the present sample due to selection bias. In order to ensure that alcohol is a preferred coping strategy, it would have been necessary to pre-screen, for example with the CAS-I (Wells, 2011).

Regarding the effects of alcohol consumption on (meta-)cognitive, emotional, and psychophysiological processes and its function in coping with depression, it can be stated that further research is needed to investigate these relationships in more detail.

Limitations

One limitation of our study relates to the sample size, due to which only moderate effects could be detected. However, compared to the results of other clinical studies dealing with the effects of alcohol (e.g., in social anxiety disorder), the sample size we recruited can be considered sufficient (cf. Stevens et al., 2017). Another limitation relates to our procedure, which can be considered rather exploratory, as the direct effect of alcohol on state metacognitions has not been investigated before and therefore we could only assume that alcohol consumption may prevent negative state metacognitions from being appraised as threatening (cf. Sayette, 1993). In addition, it would have been helpful to assess the expected effects of alcohol on rumination or metacognitions before or during the experiment to include trait and actual expectancies of alcoholic effects into statistical analyses. A final limitation relates to the assessment of rumination. Here, for example, a rumination-related questionnaire with better psychometric properties may have been more suitable, (e.g., the Brief State Rumination Inventory; Marchetti et al., 2018).

Conclusions

To our knowledge, this was the first study to directly examine the association between AUD and by assessing the effects of alcohol on rumination and state metacognitions in a sample of clinically depressed individuals. We did not find that alcohol reduced rumination, state metacognitions about rumination, or depressive symptoms. Thus, our results suggest that previous models of alcohol effects from the domain of anxiety disorders (e.g., Sayette, 1993) may not be easily transferable to the domain of depressive disorders.

Consistent with the findings of previous studies (see, e.g., Nolen-Hoeksema et al., 2008; Ottaviani et al., 2016), we were able to show that rumination negatively affects disorder-specific processes in MDD. Surprisingly, rumination did not elicit negative metacognitions about the uncontrollability and danger of rumination, although this would have been expected in terms of the MCM.

However, due to the novelty of this research approach, further studies are needed to further test existing models / theories linking depression and alcohol. For example, this could include studies with individuals who drink more and use alcohol more regularly for coping, with a modified paradigm, i.e., with other forms of rumination induction, with manipulated arousal feedback, or with a lower dose of administered alcohol, and / or with other (physiological) measurement methods.

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Author Note: This study was part of the first author's doctoral thesis (Gawron, 2022), which focused on the function of cognitive processes to explain the association of alcohol (consumption) and depression.

Supplementary Materials

The Supplementary Materials include the descriptive statistics of all questionnaires used, the results of the Bonferroni-Corrected Post-Hoc Tests for Repeated Measures ANOVAs, and the means of all measures across the three measurement time points (for access see Index of Supplementary Materials below).

Index of Supplementary Materials

Gawron, L., Pohl, A., & Gerlach, A. L. (2022). *Supplementary materials to "The influence of alcohol on rumination and metacognitions in major depressive disorder"* [Additional information]. PsychOpen GOLD. https://doi.org/10.23668/psycharchives.8391

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Competency-Based Training and Assessment of Listening Skills: A Waitlist-Controlled Study in European Telephone Emergency Services

Simone Jennissen[1,2], Stefan Schumacher[3], Diana Rucli[4], Melinda Hal[5,6],
András Székely[7], Derek de Beurs[8], Ulrike Dinger[1,2]

[1] *Department of General Internal Medicine and Psychosomatics, University Hospital Heidelberg, Heidelberg, Germany.* **[2]** *Department of Psychosomatic Medicine and Psychotherapy, Medical Faculty, Heinrich Heine University Düsseldorf, Düsseldorf, Germany.* **[3]** *TelefonSeelsorge Hagen-Mark, Hagen, Germany.* **[4]** *Studio Rucli Formazione e Consulenza organizzativa, Udine, Italy.* **[5]** *Department of Applied Psychology, Faculty of Health Sciences, Semmelweis University, Budapest, Hungary.* **[6]** *Szent Rókus Hospital, Psychiatry, Baja, Hungary.* **[7]** *Végeken Egészséglélektani Alapítvány, Budapest, Hungary.* **[8]** *Trimbos-instituut, Utrecht, The Netherlands.*

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Corresponding Author: Simone Jennissen, Department of Psychosomatic Medicine and Psychotherapy, Medical Faculty, Heinrich Heine University Düsseldorf, Moorenstraße 5, 40225 Düsseldorf, Germany. E-mail: simonejennissen@gmail.com

Supplementary Materials: Materials [see Index of Supplementary Materials]

Abstract

Background: Telephone emergency services (TES) provide an essential part of suicide prevention and emotional support services across different health care settings. TES are usually provided by paraprofessional counselors, who need specific training in listening skills to meet the demands of callers.

Method: This project developed a competency-based training for listening skills which was then evaluated in a randomized controlled waitlist study across four EU countries (Germany, Hungary, Italy, and the Netherlands). Each country provided one training group and one waitlist group. Across countries, a total of 71 (trained: n = 36, waiting: n = 35) counselor trainees were assessed in a standardized, simulated emergency call with an actor client either before or after training participation. Calls were audiotaped and competencies in listening skills were evaluated by external raters using a standardized rating form.

Results: Trained counselors showed significantly better listening skills than participants from the waitlist condition.
Conclusion: Results provide support for the efficacy of a competency-based training for listening skills in the field of TES across Europe. Furthermore, results demonstrated that a standardized competency-based assessment with an actor client is suitable to assess listening skills.

Keywords

listening skills, training, telephone emergency services, helpline, paraprofessional counselors

Highlights

- A competency-based training can improve paraprofessionals' listening skills in a relatively short training time.
- Listening skills can be assessed in a simulation with an actor client.
- The use of competency-based training and assessment methods could be expanded to the field of paraprofessional counseling.

Telephone Emergency Services (TES) form an important part of psychosocial health care, emotional support services, and suicide prevention (Dinger et al., 2019). TES are usually free of charge, available at all times, and do not require help-seeking individuals to disclose their identity. Thus, there is a small barrier for those in need to reach out to TES. This is also represented in the number of calls TES receive. In 2019, the German TES *TelefonSeelsorge* responded to 1.2 million calls (Telefonseelsorge, 2019). Similarly, the Australian *Lifeline* reports over one million calls yearly (Lifeline, 2020), the United Kingdom's *Samaritans* reported over 3.6 million calls in 2018 (Samaritans, 2019), and the United States' *National Suicide Prevention Lifeline* reported more than 22 million calls in 2018 (The National Suicide Prevention Lifeline, 2019), which underlines the widespread acceptance and need for TES. During the COVID-19 pandemic, TES have gained even more importance since there were both needs for social distancing as well as increased mental health burdens. TES responds well to both needs as a low-threshold mental health service that can be accessed even by high risk patients during times of rigorous infection control measures (Arenliu et al., 2020; Humer et al., 2021; Kavoor et al., 2020).

As opposed to psychotherapists, psychiatrists, and social workers who participate in year-long professional training curricula before providing mental health services, TES counselors are paraprofessionals with limited and regionally different training. A study conducted on the German *TelefonSeelsorge* showed that TES counselors receive training over the course of seven to 24 months (M = 13.3 months; Dinger & Rek, 2017). The *Samaritans*' conduct their training in five to ten sessions over the course of a few months (Samaritans, 2020). Despite having no formal medical or psychological education, TES counselors frequently deal with highly stressed callers. In 2019, 43.7% of callers in Germany presented suicidal thoughts, 6.6% stated an intent to commit suicide, and

7.1% had formerly attempted suicide (Telefonseelsorge, 2019). Most callers repeatedly contacted TES for emotional support, which could be an indicator of high mental strain. Frequently discussed topics included experiencing depression or anxiety, interpersonal difficulties, or physical health issues (Telefonseelsorge, 2019). Studies from the United Kingdom (Coveney et al., 2012), the United States (Ingram et al., 2008; Mishara et al., 2007), and Australia (Burgess et al., 2008) report similar contents. As such, the topics discussed in TES calls are comparable with the contents of psychotherapy sessions, despite TES counselors receiving far less formal training for handling difficult clients.

Training is important not only to provide adequate service to callers, but also for the well-being of TES counselors themselves. In a meta-analytic review, Hattie et al. (1984) showed that the amount of training that paraprofessionals received was associated with their effectiveness as counselors on a variety of outcome measures such as clients' self-reported change, clinical ratings by independent raters, information provided by significant others, work performance, or therapist improvement ratings. Paraprofessionals with "some experience" (e.g. hospital workers, medical students, or speech pathologists) were more effective than inexperienced paraprofessionals (e.g. college students, volunteer adults). A more recent review on the effectiveness of professional and paraprofessional counselors to deliver cognitive-behavioral treatment for depression and anxiety also concluded that training is important for paraprofessional counselors to deliver effective service (Montgomery et al., 2010). Furthermore, a qualitative survey suggests that paraprofessional counselors wish for more training in order to feel confident in dealing with difficult clients (Skoglund, 2006). Studies on psychotherapists show that training increases therapists' self-efficacy (Hess et al., 2006; Pascual-Leone & Andreescu, 2013). Note that while skills are defined as the ability to carry out an activity and competencies additionally include the knowledge of when and how to apply one's skills, self-efficacy encompasses one's *confidence* in one's own capabilities, but not actual skills or competencies (Bandura, 1977; Butler, 1978; Le Deist & Winterton, 2005). However, evidence from a systematic review suggests that counselor self-efficacy is related to counselor performance as assessed by trained raters and supervisors (Larson & Daniels, 1998). Thus, training is necessary to both directly increase counselors' efficacy as well as to boost their confidence in their own capabilities. Within TES, as there are large numbers of callers and limited resources, paraprofessionals' training is distinctively shorter than professionals' training.

Since TES are local organizations without uniform training standards, there is a need for more research on time-efficient, focused training opportunities that equip volunteer counselors with the key competencies they require. Listening skills form an integral part of many counselor trainings and are the core of TES trainings (Hill, 2009; Ivey et al., 1987). They comprise a variety of techniques such as active listening, showing empathy, supporting clients' self-efficacy, establishing rapport with the client, and exploring feelings of the client (Hill, 2009; Rogers & Farson, 1957). Listening skills may rather be categorized as competencies, since they also include the knowledge about when and how to apply a specific skill and refer to the broader concept of being able to listen to, soothe, and help another person (Butler, 1978; Le Deist & Winterton, 2005). However, since listening *skills* is an established term, this term will be used throughout the paper.

This study aimed to develop and evaluate a competency-based training for listening skills. To account for the heterogeneity of TES and extend the generalizability of our results, the study was conducted as an international multisite project in Germany, Italy, Hungary, and the Netherlands. Furthermore, while research in psychotherapy and counseling mostly relies on self-report measures, these are likely biased due to limited introspectiveness of respondents. Counselors, for instance, might over- or underestimate their skills depending on their level of self-criticism (Anderson et al., 2016). In psychotherapy research, recent studies have therefore employed competency-based assessments of therapist skills, such as the Facilitative Interpersonal Skills (FIS) performance test (Anderson et al., 2009). The FIS is used to assess therapists' interpersonal behavior in a standardized test situation. Therapists are asked to respond to challenging therapy situations that are presented to them either as video clips or with actor clients. Therapists' responses are filmed and later evaluated by trained judges according to a rating manual (Munder et al., 2019). In this study we intended to employ a competency test methodology similarly to the FIS. Specifically, we aimed to assess listening skills in a simulated TES call with an actor representing a typical TES client. As in the FIS, trained judges evaluate participants' listening skills based on recordings of the simulated calls using a standardized rating sheet. This allows a more objective assessment of paraprofessional counselors' listening skills in an ecologically valid setting, while also directly assessing the competencies needed in a TES call. We hypothesized that trained participants would demonstrate better listening skills in the standardized simulated emergency call than participants who had not received the listening skills training.

Method

The Ethics Committee (Institutional Review Board) of the department of psychology at Heidelberg University approved the study procedures (reference number: AZ Jenn 2020 1/1). Participants were informed about all study procedures by the local member of the research team and provided informed consent prior to participation.

Participants and Procedure

The study was designed as a randomized-controlled waitlist trial. Participants were recruited at local TES posts in Germany, Hungary, Italy, and the Netherlands via participating institutions in the Erasmus+ funded network EmPoWEring (Educational Path for Emotional Well-Being). As a widely known organization, TES posts are regularly contacted by individuals who are interested in becoming a volunteer counselor for TES. During our study period from November 2016 to April 2017, those who contacted TES about becoming a volunteer counselor were informed about the study and the opportunity to participate in the listening skills training. Those consenting to the study procedures were then cluster-randomized within site to start training either immediately (training group) or delayed (waitlist group). Within each country, the research team randomized each individual to either an immediate training group or a waitlist group. Participants in the training group immediately started the listening skills training. After the training groups had completed their training, listening skills of participants in both training and waitlist groups were assessed in a standardized, simulated emergency call with an actor client. After the assessment, the waitlist group received their listening skills training. Due to the naturalistic recruitment, there is no information available on the number of individuals who decided against participating in our study. There were no dropouts after enrollment.

Participants had to be 18 years or older to be eligible. A total of *N* = 71 volunteer counselors (*n* = 12 from Germany, *n* = 20 from Hungary, *n* = 20 from Italy, and *n* = 19 from the Netherlands) participated in our study. Each country provided on training group and one waitlist group. Across countries, a total of *n* = 36 participants were randomized to the training group and *n* = 35 were randomized to the waitlist group. The majority of participants (82%) were female. Participants' mean age was 38.51 years (*SD* = 15.86). About half of the sample (48%) reported a school diploma and 52% a university degree as their highest level of education. Participants were asked whether they had prior work experience as a "listener", either volunteering for a counseling or emergency service or as a professional therapist or counselor before participating in this study. About half (45%) of participants reported prior professional or voluntary work experience as a listener for a mean duration of 6.96 years (*SD* = 8.76). Descriptive characteristics by group (training vs. waitlist) are presented in Table 1. There were no significant differences between study groups regarding descriptive characteristics.

Listening Skills Training

A focus group of professionals in TES counseling and pastoral care developed a manual for the listening skills training. The 120 hr training is split into three parts: a 30 hr self-study online module to convey the theoretical basis of listening, a 40 hr practical group training in listening which is provided in 10 structured sessions, and a 50 hr module for in-depth practice and supervised training calls. Table 2 provides a more detailed overview of the training modules. Participants' attendance was monitored for all in-class events and there were no missed sessions. Attendance of the self-study online module was not assessed by the research team.

Table 1

Descriptive Characteristics for the Training and Waitlist Group

	Training group n = 36		**Waitlist group** n = 35		**Difference test**	
Characteristic	***M***	***SD***	***M***	***SD***	***t***	***p***
Age	40.1	15.7	36.9	16.1	-0.848	.400
Former experience in listening (years)	2.4	6.0	3.8	7.5	0.832	.408
	N	**%**	***N***	**%**	χ^2	***p***
Gender					2.53	.112
Male	4	11.1	9	25.7		
Female	32	88.9	26	74.3		
Highest educational level					1.283	.733
Basic secondary school	5	13.9	7	20.0		
High school	12	33.3	10	28.6		
Bachelor's degree	10	27.8	12	34.3		
Master's degree	9	25.0	6	17.1		
Former experience in listening					0.137	.712
Yes	17	47.2	15	42.9		
No	18	52.8	20	57.1		

Note. Former experience in listening refers to prior work experience as a "listener", either volunteering for a counseling or emergency service or as a professional therapist or counselor before participating in this study.

Assessment

Listening skills were assessed in a standardized, simulated emergency call with a trained actor client. The actor role represented a typical TES caller. Actors received a standardized role script with a detailed description of their role as well as instructions for a 15-minute TES call. There was one native speaking actor in each country. Before the assessment, actors prepared their role and practiced the simulated call with paraprofessional counselors of different experience levels. This ensured that actors were trained to respond realistically to a variety of possible interventions by participants. Furthermore, these practice calls were recorded and used as training material for the observer ratings of listening skills. During the assessment period, a local member of the research team listened to recordings of the standardized, simulated emergency call and gave feedback regarding role adherence to the trained actor client on a weekly basis.

Assessments were conducted by telephone to mimic a naturalistic TES setting. Calls were recorded for assessment purposes. Participants were called by blinded research assistants and instructed to be a good listener for an actor client for about 15 minutes.

Table 2

Description of Contents of the Listening Skills Training Modules

Module	Content
1. Self-study (30 hrs)	Using an e-learning tool, participants are provided with 100 multiple choice questions regarding the theoretical basis of listening. After each question, participants receive feedback on their selected answer(s) and are presented with a brief theoretical explanation. Topics include cognitive-behavioral, psychodynamic, systemic, and humanistic/client-centered theories.
2. Practical group training (40 hrs)	This part of the training is performed on site in groups of maximum 15 participants.
Session 1: Introduction	• focuses on a personal introduction of group members, self-reflection of training goals and motivations, and the assessment of existing knowledge and views on listening
Session 2: Active Listening	• teaches the principles of active listening (how to ask for thoughts/feelings/behaviors, give the other person space, and paraphrase meaningful contents)
Session 3: Emotional stability	• teaches ways to regulate one's own and the other person's feelings
Session 4: Respect and boundaries	• fosters acceptance of differences between people • teaches ways to set boundaries in the listening process
Session 5: Empathy	• fosters perspective taking and empathic responses to another person's story
Session 6: Mirroring	• teaches ways to reflect the other person's feelings or statements
Session 7: Self-reflection	• encourages reflection on own feelings, motivations, and resources
Session 8: Structuring conversations	• teaches the five-phase model of the listening process (welcome, exploration, goal setting, elaboration, conclusion)
Session 9: Strengths and resources	• teaches how to ask for resources and foster strengths of the other person
Session 10: Feedback and conclusions	• summarizes acquired listening skills and encourages reflection on personal progress
3. In-depth practice (50 hrs)	Having acquired the theoretical knowledge as well as practical experience in role plays and group exercises, the final part of the listening skills training is focused on supervised training cases. This module should be adapted to suit the needs of listeners in their specific work environment.

After assuring that the instructions were clear, the actor then took over the phone and presented herself as “Laura”, a 27-year-old office clerk, who was struggling in her relationship and also stressed out by her current job workload. “Laura” was calling TES when she was home alone in the evening and overwhelmed by her feelings. She was severely distressed, but not in an acute suicidal crisis. “Laura” was struggling to identify her own emotions, but she was willing to respond to the paraprofessional counselor's questions and able to benefit from the listening process.

Listening skills were assessed using an observer rating measure. The Listening Skills Scale (LSS) was developed by members of the research team (SJ, UD) based on several validated psychotherapy process scales, i.e. the Multitheoretical List of Therapeutic Interventions (MULTI; McCarthy & Barber, 2009), the Active Empathetic Listening Scale (AEL; Drollinger et al., 2006), the Working Alliance Inventory (WAI-SR; Hatcher & Gillaspy, 2006), and the Therapist Empathy Scale (TES; Decker et al., 2014) and adopted the methodology of the FIS performance test (Anderson et al., 2009). Items were modified to suit the TES environment (i.e. “client” instead of “patient”; “listener” instead of “therapist”) and to reflect an observer perspective. The scale consisted of 33 items representing listening skills such as perspective taking, respect, active listening, resource activation, and structuring the conversation. Higher values represent better listening skills. Items include “The listener sometimes finds it difficult to see things from the other person’s point of view *(inversed)*” or “The listener appreciates their client as a person”. Items are evaluated on a 5-point Likert scale (1 – *totally disagree*; 5 – *totally agree*) with one additional *N/A* category in case an item cannot be assessed from the information in the audio recording of the standardized simulated emergency call. Two items are reverse coded. Higher values represent better listening skills. Internal consistency of the scale was excellent in the present study (Cronbach’s $\alpha = .94$). The full scale is available in the online supplement.

Ratings were provided by at least on trained research assistant in each country. Recordings of practice calls from the actor training were used to train raters in the application of the LSS. During the assessment period, at least once per week the local member of the research team listened to recordings of the standardized, simulated emergency calls, gave feedback to the actor (see above), and supervised the local research assistant in ratings on the LSS. In the German subsample, all LSS ratings were performed by two independent observers. Interrater reliability of these two raters was excellent, ICC(3,1) = .86.

Data Analytic Strategy

As a first step, we explored missing data and investigated the factor structure of the listening skills scale as a basis for further analyses. We performed a principal component analysis (PCA) using the Scree criterion for factor retention to determine whether calculating a mean score for listening skills was appropriate. Next, we assessed whether our data was normally distributed. Since each of the four countries provided one training group and one waitlist group, groups were nested within country. We therefore assessed whether this introduced dependency in our data by calculating the intraclass correlation (ICC) within countries in a multilevel intercept only model. We intended to employ a multilevel model to assess group differences if there were an ICC $\geq .05$. An ICC $< .05$ would indicate that country does not affect outcome and therefore single level multiple regression models would be appropriate (Tabachnick & Fidell, 2014). We employed a stepwise modeling procedure. The first model tested for group differences in listening skills without covariates. To assess the robustness of results, the second model introduced age and gender as common covariates and the third model adjusted for years of previous experience as a listener outside of the TES environment. Effect sizes were calculated as standardized regression coefficients. A standardized regression coefficient of b = .10 is considered small, b = .30 is considered moderate, and b = .50 is considered large (Cohen, 1988).

Results

Preliminary Analyses

Missing data analysis demonstrated more than 5% missing values in six items of the LSS. We therefore excluded these items from the following analysis.

Next, we conducted a principal component analysis (PCA) to explore the factor structure of the LSS. The Kaiser-Meyer-Olkin score of KMO = .86 and the significant Bartlett's test of sphericity, $\chi^2(351) = 1562.15$, $p < .001$, demonstrated the adequacy of the data for PCA. The Scree plot was slightly ambiguous and showed inflexions that would justify both retaining one or two components. Inspections of the factor loadings indicated a higher-order general factor of "listening skills" which explained 48.58% of variance. We therefore decided to retain one component and calculate a mean value for listening skills as a basis for further analyses. Factor loadings are available in the online supplement. Based on a visual inspection of the histogram, negligible skew (-0.18) and kurtosis (-0.54), as well as a nonsignificant Kolmogorov-Smirnov test (p = .20), listening skills were normally distributed across participants.

Effect of the Listening Skills Training

Since groups were nested within countries, we first assessed the dependency in our data by calculating the ICC within countries in a multilevel intercept only model. With an estimated ICC of .01, the model suggested negligible dependency in the data. Hence, multiple regression was deemed an appropriate method to test for group differences. The first model predicted listening skills as measured by the LSS from group (waitlist group vs. training group). Group was a significant predictor of listening skills with a large standardized regression coefficient of b^* = .52 (see Table 3). Participants in the training group (M = 3.99, SD = 0.69) demonstrated significantly better listening skills than participants in the waitlist group (M = 3.20, SD = 0.62, see Figure 1). To assess the robustness of this effect, we next employed a hierarchical model introducing age and gender as covariates in the first step and group in the second step. While there was no significant effect of age or gender, group remained as a predictor of listening skills with a large standardized regression coefficient of b^* = .54 (see Table 3). Lastly, we assessed whether previous experiences in listening affected the observed listening skills. The final hierarchical model introduced years of previous experiences in listening outside of TES in the first step and group in the second step. Age and gender as nonsignificant predictors were dropped from this model. There was no significant effect of previous experience, while group continued to significantly affect listening skills with a large standardized regression coefficient of $b^* = .52$ (see Table 3).

Table 3

Linear Regression Models Predicting Listening Skills

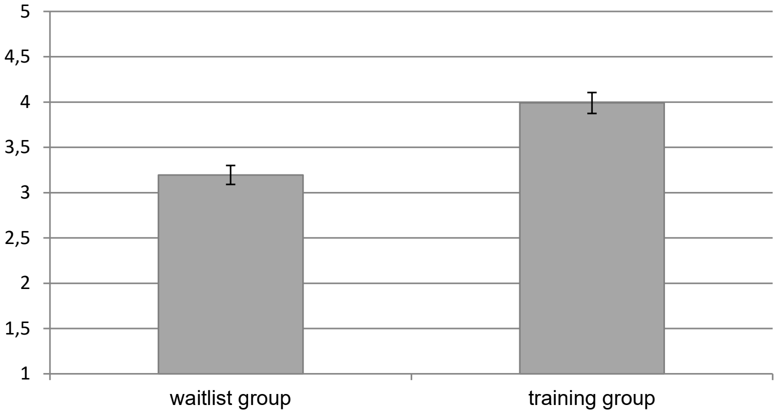
	Model 1		Model 2		Model 3	
Parameter	**Coefficient (*SE*)**	**95% CI**	**Coefficient (*SE*)**	**95% CI**	**Coefficient (*SE*)**	**95% CI**
Intercept	3.20 (0.11)*	[2.97, 3.42]	3.46 (0.27)*	[2.93, 4.00]	3.20 (0.12)*	[2.96, 3.45]
Age			-0.01 (0.01)	[-0.02, 0.00]		
Gender			-0.06 (0.21)	[-0.48, 0.35]		
Experience					-0.00 (0.01)	[-0.03, 0.02]
Group	0.79 (0.16)*	[0.48, 1.11]	0.82 (0.16)*	[0.50, 1.14]	0.79 (0.16)*	[0.47, 1.11]
Model Fit						
R^2		0.27		0.28	0.27	
Adjusted R^2		0.26		0.26	0.25	

Note. $N = 71$; Gender was dummy coded (0 – male, 1 – female). Experience = years of previous experience in listening outside of telephone emergency services. Group was dummy coded (0 – waitlist group, 1 – training group). Listening skills were assessed in a standardized, simulated emergency call using the observer-rated Listening Skills Scale (LSS).

$^*p < .05$.

Figure 1

Mean Listening Skills of Participants in the Training Group and the Waitlist Group



Note. $N = 71$ ($n = 36$ participants were randomized to the training group and $n = 35$ were randomized to the waitlist group). Error bars represent the standard error of the mean. Listening skills were assessed in a standardized, simulated emergency call using the observer-rated Listening Skills Scale (LSS). Scale values range from 1-5, where higher values indicate better listening skills.

The difference between the groups is significant ($p < .05$), see result of the linear regression model in Table 3.

Discussion

This study aimed to develop and evaluate a competency-based training for listening skills in an international multisite project across Europe. Results provide support for the efficacy of the 120 hr training. Trained individuals demonstrated significantly better listening skills than their untrained counterparts. The effect size for this group difference was large, which implies that this relatively short training makes a meaningful difference in paraprofessional counselors' abilities to adequately respond to TES calls. Furthermore, the effect of the training was independent from participants' age, gender, and previous experience as a listener in other contexts. Although approximately half of the participants reported previous experiences in the field of "listening", e.g. in their profession as social workers, nurses, or pastoral care workers, or as a volunteer for other services, these experienced participants benefitted as much from the training as inexperienced participants. This implies that the training is suitable for groups with different levels of expertise and equips paraprofessional counselors with specific competencies needed within TES. Listening on the telephone may require a different set of skills than listening in a face-to-face setting, such as the ability to fully rely on verbal expressions in understanding the client, without the option to consider nonverbal cues (Sötemann, 2019). The counselors themselves also have to convey their interest in the client, their caring and respectful attitude, and the comfort they provide solely through speech and voice modulation. Silence, which could serve a holding function in a face-to-face setting, might feel uncomfortable or even threatening to a client on the phone who has no means to determine whether the counselor is still with them. Lastly, the anonymity of TES could be unfamiliar to those who have never worked in listening of the phone and make it difficult to build a relationship at the beginning (Sötemann, 2019). These differences between face-to-face and telephone settings might explain while experiences in listening outside of the TES environment were not an advantage in our study and experienced participants also needed the training to acquire the specific competences needed to adequately respond to a TES call.

In this study, the assessment of listening skills was realized with an actor patient in a simulated emergency call. This method was chosen not only for a more objective assessment, independent of participants' ability to accurately report on their own listening skills, but also to tap into the exact competencies needed for the later task as a paraprofessional counselor in TES. Competency-based assessment methods have gained increased popularity in medical education and psychotherapy over the last decades (Anderson et al., 2016; Dannefer & Henson, 2007; Lurie, 2012). They are based on the insight that neither factual knowledge, nor self-evaluation are sufficient to guarantee the mastery of a practical task (Miller, 1990). To assure that trainees can perform their tasks competently, assessments should be performed in the context of the actual workplace or in a realistic simulation (Holmboe et al., 2010; Issenberg et al., 2005). Thereby, the assessment can include context factors from the real life setting and confirm that trainees are prepared for authentic encounters. The employed assessment method of a standardized, simulated emergency call with an actor client fulfilled these requirements. Participants were presented with a typical TES caller and could therefore demonstrate their competency as a paraprofessional counselor in TES. The assessment showed that the training sufficiently teaches listening skills as they a required in everyday practice at TES.

Limitations

This study is limited in generalizability by the recruited sample. Although we performed the study as a multisite project across four different European countries, TES operate internationally, and future studies will determine whether the listening skills training is effective in other than the investigated countries. However, investigating the training across four countries with very different local structures (Germany, Italy, Hungary, and the Netherlands) is a major strength of this study and the focus on European countries seems sensible since a large number of TES sites operate in Europe (IFOTES, 2020). Another limitation of this study is the small sample size within each country. Although the achieved power to detect the overall group difference was ≈ 1 (Faul et al., 2007), drawing statistical inferences at the country level would have proven difficult. However, by calculating the ICC we assured that outcomes did not differ depending on the country in which participants were assessed.

Next, although actors received a detailed role script, prepared their role thoroughly, and were trained and supervised frequently, the actors had to react flexibly to participants' interventions and therefore the assessment was not completely standardized. Future studies could investigate whether presenting pre-recorded audio sequences is a viable alternative, although this comes at the cost of a less ecologically valid assessment situation.

Furthermore, although participants received a standardized training of 120 hrs in total, their attendance in the 30 hr online module was not monitored by the research team and thus may have varied. Further evaluations of the training should assess attendance in all modules and control for missed classes in statistical analyses.

Next, though reliability measures within this study demonstrated excellent interrater agreement and internal consistency of the LSS, further validation of the scale, preferably with listening skills measures from different perspectives, would be useful.

Lastly, due to limited resources we designed the study as a randomized controlled waitlist trial with a single assessment in each group. Assuming randomization was successful, this procedure should result in correct effect size estimates for the training. However, a baseline assessment in the training group could have been used to examine the successfulness of randomization and could also have served as a more direct measure of existing knowledge than asking for previous experiences in listening. Furthermore, future evaluations of the listening skills training may want to include a follow-up assessment to examine long-term effects of the training.

Implications and Conclusion

Our findings have several implications. First and foremost, demonstrating the efficacy of the training in participants from several European countries suggests that the listening skills training can be used to train paraprofessional counselors at TES from different countries. The modular structure allows for flexibility while also providing an evaluated and effective basis. International TES sites may use the listening skills training as a basic curriculum and adapt it to their regionally different needs. To monitor their trainees' development of competencies, they could also make use of the assessment method with the standardized acting role. Although role-plays are typically part of the TES group training, introducing a standardized assessment could help trainers and trainees identify their specific needs while also providing a consistent background against which paraprofessional counselors' listening skills can be evaluated.

Furthermore, the increased demand for mental health services during the COVID-19 pandemic together with the necessity to reduce in-person contact between individuals has highlighted two core competencies of TES: they are widespread available and offer emotional support in a socially distant manner (Humer et al., 2021; Kavoor et al., 2020). Although trainings such as the helping skills training or postgraduate training programs for psychotherapists, psychiatrists, and social workers are well-established (Hill, 2009; Hill & Lent, 2006), the current rapid increase in demand for mental health services underlines the usefulness of short, effective trainings for listening skills.

Lastly, this study aimed to evaluate the use of competency-based training and assessment methods in the field of paraprofessional counseling. Although commonly accepted as beneficial in medical education (Lane et al., 2001; Scalese et al., 2008), competency-based methods are still rare in the field of psychotherapy and counseling. Similarly to simulation patients in medical education, this study introduced an assessment with a standardized actor client to a paraprofessional counseling environment. Future studies should investigate the use of an actor client to assess counseling competencies in the field of professional counseling and psychotherapy.

To conclude, this international multisite study demonstrated the efficacy of a competency-based training for listening skills across Europe. Trainees successfully acquired listening skills in the 120 hr course, as demonstrated in a standardized simulated emergency call with an actor representing a typical TES caller. Findings encourage the application of the training in TES to prepare volunteers for their tasks as paraprofessional counselors. Furthermore, results suggest that competency-based assessment in a simulated TES call is a suitable method to measure listening skills.

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Competing Interests: The authors have declared that no competing interests exist.

Supplementary Materials

Provides an observer-rating measure of listening skills (Listening Skills Scale). The Listening Skills Scale (LSS) was used by independent observers to rate listening skills of participants in simulated emergency calls (for access see Index of Supplementary Materials below).

Index of Supplementary Materials

Jennissen, S., Schumacher, S., Rucli, D., Hal, M., Székely, A., de Beurs, D., & Dinger, U. (2022). *Supplementary materials to "Competency-based training and assessment of listening skills: A waitlist-controlled study in European telephone emergency services"* [Measurement instrument]. PsychOpen GOLD. https://doi.org/10.23668/psycharchives.8308

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