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Editorial

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Towards a 21st Century Definition of Mental Health – Emerging Trends in Bringing Practice and Research Together

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Mental health is typically defined in clinical contexts through categorical systems such as the DSM (Diagnostic and Statistical Manual of Mental Disorders) or ICD (International Classification of Diseases). These categorical systems are based on medical standards, where a specific diagnosis is either met or not met (e.g., a Major Depressive Episode is either present or absent). Despite the potential communicative benefits of categorical systems in clinical settings, these classification systems fall short in capturing the complex, multi-faceted nature of mental health (Rief et al., 2023), thereby leading to frustration among practitioners who struggle to reconcile the nuances of human experience with the limitations of existing diagnostic frameworks (e.g., Jensen-Doss & Hawley, 2011).
In the context of the rapid advancements in information processing and data sciences, the limitations of existing classification systems are becoming increasingly pronounced. A gap is emerging between the precision in measuring and representing mental health and the above-mentioned, rather crude categorical classification systems for mental disorders. Recent innovations can be illustrated by three developments, among others: The transition from categorical to dimensional, hierarchically structured understanding of mental health severity; the definition of mental health with both individual problems and strengths; and the representation of mental health in a psychosocial and structural context.

Transition From Categorical to Dimensional, Hierarchically Structured Understanding of Symptom Severity

While a multidimensional understanding of personality disorders has become well established in classification systems, mental health diagnoses with high prevalence rates in the anxiety and depression spectrum continue to be strongly categorical in nature. The HiTOP model presents a counterpoint to this approach and proposes a hierarchical understanding of mental health (Kotov et al., 2021). At a higher level of this hierarchy, internalizing and externalizing behaviors can be defined – a distinction that has been established in the field of child and adolescent psychology for some time (Vergunst et al., 2023). The newer hierarchical understanding of mental health can be illustrated by pathological worrying, for example. In contrast to the DSM and ICD models, which categorize pathological worrying as a primary symptom of generalized anxiety disorder (GAD), the HiTOP model assumes that this symptom may be a key feature of a more general stress factor that crosses traditional diagnostic categories. This view is supported by meta-analytic evidence summarizing the association between worry and mental health based on 138 correlational studies (Vîslă et al., 2022). Notably, the link between worry and mental health was not significantly different between samples of individuals with GAD and those with major depressive disorder, supporting the notion that worry is a common symptom of a broader, generalized distress factor. These findings have important implications for the treatment of worry, suggesting that interventions focusing on worry may be beneficial for a wider range of psychopathologies. This example serves as one of several illustrations demonstrating how a dimensional understanding of mental health can inform the nuanced and sophisticated clinical thinking of practitioners (Hopwood & Sharp, in press).

Definition of Individual Mental Health Problems and Strength

Mental health is more than merely a response to individual distress. Two-dimensional models of mental health postulate that mental health is more accurately described by two related, but still distinct overall dimensions: Psychological burden (assessed by the degree of psychopathological suffering) and positive mental health, which includes various facets of patient strengths and resources such as subjective life satisfaction, hedonic pleasure, positive affect in everyday life, self-acceptance, personal growth, or finding purpose in life (Schürmann-Vengels et al., 2023). The two affect-related dimensions are not opposites and not strongly related, as two recent meta-analyses demonstrate. Individuals with severe psychological impairments also experience positive states, relatively

independent of the severity of their anxiety symptoms (Flückiger et al., 2025) or of depressive moods (Schürmann-Vengels et al., 2025).

Traditional psychotherapies consistently emphasize the importance of strengths and resources as catalysts for therapeutic progress. Moreover, many practitioners acknowledge the limitations of a solely problem-focused understanding of the individuals who come into therapy. A current intersectional task force evaluates capitalization of patient strengths and resources as a 'demonstrably effective' method in terms of therapeutic progress through to treatment termination (Flückiger et al., 2023). This systematic review and meta-analysis examined the effectiveness of strength-based methods in psychotherapy and revealed an association with more favorable immediate outcomes, as well as a small but significant effect on post-treatment outcomes compared to psychotherapy conditions without strength-based personalization. The findings indicate a potential benefit in capitalizing on patient strengths and resources while working on the problems and challenges, specifically by virtue of the systematic and regular assessment of an individual's abilities and motivational readiness, and the corresponding adjustment of mental health interventions. This approach fundamentally redefines the clinical concept of mental health, emphasizing the importance of leveraging an individual's inherent strengths and capacities in the pursuit of psychological well-being.

Representation of Mental Health in Psychosocial and Structural Contexts

Mental health encompasses more than the symptoms and abilities of an individual person. Mental suffering is caused and experienced in and with others. Mental health issues develop and are maintained within a social context where factors like relationship dynamics (e.g. within families, peers, at work or school) and chronic social stress exposure (ex. conflicts, social exclusion, discrimination, low socioeconomic status) negatively influence an individual’s well-being. Severe stress exposure of family members such as critical life events (e.g. the birth of a child or physical health issues of a family member) can not only increase the risk of mental health issues in individuals but also in their partners and children.

In turn, developed mental health issues can negatively impact an individual’s social environment by straining relationships, perpetuating stigmatization and/or provoking social exclusion. As another example, numerous studies have shown that marginalized groups experience disproportionate levels of mental distress due to additional stressors, such as discrimination, arising both from their immediate social environments and from broader societal structures (Hatzenbuehler et al., 2024). These examples demonstrate that the definition of mental health should not just be reduced to individual-level factors and instead reflect a complex psychosocial phenomenon that needs to be captured in future mental health assessments (Chronister et al., 2021).

The above-mentioned three trends highlight the need for a reciprocal exchange of knowledge between research and practice to define mental health, where practice is informed by current research, and research, in turn, is grounded in the everyday realities and challenges of clinical practice. These developments, however, also provide compelling evidence that the convergence of research and practice is considerably advancing.

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Research Articles

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Attitudes Towards Digital Health Interventions in Germany: Findings From a Population-Based Representative Survey

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Supplementary Materials: Materials [see Index of Supplementary Materials]

Abstract

Background: Digital (mental) health interventions have the potential to address barriers in mental health care. However, attitudes towards these interventions are a crucial factor to their successful implementation. Therefore, this study aims to assess those in a representative sample of the German adult population.

Method: A total of N = 2,519 participants took part in the survey as part of a larger study. Following a structured face-to-face interview, participants completed a self-administered questionnaire under the supervision of the interviewer. The questionnaire was based on the E-Therapy Attitudes Measure (ETAM) and the Attitudes towards Psychological Interventions Questionnaire (APOI). Results were analyzed by means of Pearson's product moment correlation coefficients and Spearman's ρ statistics. Supplementary open-ended questions explored

participants' utilization of digital health interventions for specific conditions, the conditions they perceived as suitable for those, and the perceived barriers to their adoption. Replies on open-ended questions are summarized descriptively.

Results: While a majority of participants (34.0%–41.5%) indicated partial agreement with the potential usefulness and advantages of digital health interventions (Items 1-3), a substantial proportion (45.8%, 95% CI [43.8%, 47.7%]) expressed an entire refusal to use them for future psychological problems (Item 4). Older individuals and those with lower educational status expressed particular critical views. Key barriers identified by participants comprised the absence of personal contact, technical issues, and concerns related to data privacy and security.

Conclusion: The results of this study indicate that while participants acknowledge the potential benefits of digital health interventions, the observed limited acceptance rates and identified barriers are to be addressed, in order to fully harness their potential.

Keywords

e-health, acceptance, UTAUT, digital psychotherapy, online therapy

Highlights

- A substantial proportion expressed an absolute reluctance to use digital health interventions.
- This reservedness decreases with younger age and higher educational status.
- Key barriers include the absence of personal contact, technical issues, and data privacy and security concerns.
- There was, however, a subsample that would rather use digital than regular face-to-face treatment.

While the precise prevalence rates of common mental conditions differ across countries, they are consistently high worldwide – with female gender, younger age, living without a partner, and low socio-economic status representing important risk factors (Baumeister & Härter, 2007; GBD 2019 Mental Disorders Collaborators, 2022; Jacobi et al., 2014; World Health Organization, 2022). Mental conditions are associated with substantial individual and societal costs and efficacious interventions to treat them are theoretically present, but only a fraction of affected individuals receive an evidence-based treatment (Mack et al., 2014; Wang et al., 2007). Possible reasons for the low uptake rates of mental health care include logistical barriers, fear of stigmatization, and a shortage of actually available treatment options (Brakemeier & Herpertz, 2019; Hansen et al., 2002; Lambert, 2017).

Expanding the provision of digital health interventions has repeatedly been linked to the promise to overcome these barriers (Andersson & Titov, 2014; Domhardt, Cuijpers, et al., 2021; Torous et al., 2021). Digital health interventions, defined as interventions using the Internet as a medium for the delivery of psychotherapeutic treatment, have been found to be efficacious and effective for a variety of mental conditions in a variety

of populations (Domhardt et al., 2019, 2020; Domhardt, Schröder, et al., 2021; Edge et al., 2023; Kolaas et al., 2024; Lecomte et al., 2020; Moshe et al., 2021; Plessen et al., 2025; Steubl et al., 2021). These interventions make therapeutic content available digitally – with the help of for example audios, videos, texts, downloads, and questions. A recent framework provides information on how to implement and study them (Smith et al., 2023). Of note, while video-based psychotherapy (i.e., synchronous therapy via videoconferencing) is also Internet-delivered, it differs from the types of digital interventions primarily referred to in this study and is therefore not the main focus of the present analysis.

Compared to conventional face-to-face treatments, digital health interventions may be easier to access, integration into the patients' daily lives may be more flexible and the provision may be easily scalable and cost-efficient (at least compared to non-bonafide comparisons) once developed (Andersson & Titov, 2014; Gega et al., 2022; Kählke et al., 2022; Titov et al., 2015; Warmerdam et al., 2010). However, there are two issues that have been repeatedly associated with limited implementation success of digital health interventions into routine health care: low uptake and low adherence (Kählke et al., 2022; Lambert, 2017).

One suggested reason for these issues may be the possible low level of patients' acceptance of digital health interventions. This is in line with the basic assumption of the so-called Unified Theory of Acceptance and Use of Technology (UTAUT), an overarching framework that combines eight models and postulates that acceptance is a direct predictor of the future use of digital interventions (Venkatesh et al., 2003). Along with several moderators (e.g., gender, age, voluntariness), UTAUT hypothesizes four determinants of intention to use as a predictor of behavior (i.e., usage): 1) the degree to which an individual believes that the technology will help them (*Performance Expectancy*), 2) the expected effort of using the technology (*Effort Expectancy*), 3) the influence of the opinion of significant others (i.e., peers or others, *Social Influence*), and 4) the degree to which necessary resources and support are seemingly available (*Facilitating Conditions;* Venkatesh et al., 2003). The UTAUT concept has been widely and successfully used in multiple areas, including digital health (Dwivedi et al., 2020).

A scoping review found evidence that digital health interventions were perceived as less beneficial compared to traditional face-to-face interventions (Apolinário-Hagen, Kemper, et al., 2017). Furthermore, the intentions to utilize digital health interventions in the future were generally lower in comparison to face-to-face services. Damerau et al. (2021) assessed the acceptance of digital health interventions following the UTAUT model in patients with diabetes in Germany, resulting in moderate acceptance ratings. Hereby, gender and having a mental disorder had a significant influence on acceptance, with participants with mental disorders having a significantly higher acceptance than those without. More broadly, Philippi et al. (2021) conducted secondary analyses on primary data of ten studies from Germany that examined participants' acceptance of

digital health interventions using the UTAUT framework. It was found that the most appropriate model resembled the fundamental structure of UTAUT, with performance expectancy emerging as the most influential predictor (Philippi et al., 2021). On average, the level of acceptance observed was categorized as low to moderate, primarily being drawn from a segment of the population that was close to hand (i.e., convenience sampling; Philippi et al., 2021). All included studies focused on specific disorders or populations (i.e., depression, diabetes and comorbid depression, chronic pain, well-being and health in the elderly, gastrointestinal problems, aftercare for inpatients, multiple sclerosis, psychotherapists' acceptance towards blended therapy; Philippi et al., 2021). However, another recent study on the acceptance of digital health interventions for depression care in Germany focusing on the perspective of patients, their relatives, and health professionals resulted in general openness towards the use of those interventions (Hafner et al., 2022). More precisely, about 80% of the participants reported being open to using a digital health intervention for depression (Hafner et al., 2022). Similar results have been found in two survey studies in Germany (Apolinário-Hagen et al., 2018; Apolinário-Hagen, Vehreschild, et al., 2017) concluding that the majority of participants regard digital health interventions as potentially helpful. Nevertheless, intentions to use are low and face-to-face treatments are preferred overall (Apolinário-Hagen et al., 2018; Apolinário-Hagen, Vehreschild, et al., 2017).

While these results shed some light on the attitudes towards digital health interventions – in the German population and in other western countries – they are still limited and inconclusive regarding attitudes towards digital health interventions in specific population groups, where acceptance levels are particularly high or low, and how this correlates with sociodemographic characteristics. Not only do the rates of acceptance diverge, there are also important limitations when it comes to the recruitment of survey participants. In particular, even recruitment for studies focusing on the general population was often convenience- and web-based and took place through digital advertisements (Apolinário-Hagen et al., 2018; Apolinário-Hagen, Vehreschild, et al., 2017) potentially leading to biased findings of prior research. This may restrict the generalizability of these findings to the general population. Therefore, this study aims to assess general attitudes towards digital health interventions exemplified in the German population by means of a representative and randomly chosen sample, in order to inform future efforts to integrate those interventions into routine health care.

Method

The present study analyzes relevant parts of the data from a large, representative survey conducted in Germany. The survey was approved by the Ethics Committee of the Medical Faculty of the University of Leipzig (approval number: 298/21-ek). The implementation of the survey and data collection was performed by an independent

institute (USUMA, Berlin) between December 2020 and March 2021. To put the data collection period into perspective, it is important to note that the first DiGA (i.e., a certified health application that can be reimbursed by German health insurances) was available in October 2020 (Ludewig et al., 2021). Regional areas were first predefined using the ADM-Sampling-System (Heckel & Hofmann, 2014). Next, target households were selected by means of a random route procedure. For multi-person households, one person was randomly selected. This multi-stage recruitment strategy ensures representativity of included individuals (Heckel & Hofmann, 2014). No financial compensation or other incentives were provided to participants. All randomly selected participants were first informed verbally about the research background of the study as well as the voluntary nature and the right of later withdrawal of their own participation. Experienced and trained interviewers then conducted face-to-face interviews with 2,519 participants representative for the German population over the age of 15 and supervised also the accomplishment of the self-report questionnaires after participants gave their informed consent. The data predominantly relevant for this study was obtained in the self-report questionnaires.

Measures

Relevant sociodemographic information (i.e., age, gender, marital status, level of education, religious affiliation, current stress, prior experience with digital health interventions) was collected from all participants.

Attitudes towards digital health interventions were assessed using four items (Items 1-4; 5-point Likert scale; 1 = absolutely no, 2 = rather no, 3 = partly, 4 = rather yes, 5 = absolutely yes) that were based on the "E-Therapy Attitude Measure" (ETAM; Apolinário-Hagen, Vehreschild, et al., 2017) and the "Attitudes towards Psychological Interventions Questionnaire" (APOI; Schröder et al., 2015) following the UTAUT model. Additionally, they were asked if they would use routine face-to-face psychotherapy for psychological problems in the future (5-point Likert scale, Item 5). Furthermore, three open questions were included in order to complement the quantitative measures and provide further exploratory insights. They assessed (1) the conditions for which participants already use digital health interventions, (2) the conditions participants could imagine to use digital health interventions in the future, and (3) possible barriers for the personal usage of digital health interventions. All questions were administered in German. To make sure patients understood what we conceive as digital health interventions, a short explanation was prefaced stating that the interventions in question are administered via the Internet (e.g., PC, tablet, smartphone) and can be used for the treatment of mental disorders, such as anxiety and depression, but also for other (mental and somatic) conditions. A translation of the full questionnaire, including the initial instruction, can be found in the Supplementary Materials (see Steubl et al., 2025S).

Statistical Analyses

Statistical analyses were performed using R Studio (version 4.2.2; R Core Team, 2022). To classify attitudes towards digital health interventions descriptive analyses were used. Potential predictors (i.e., age, gender, highest level of education, current stress) were explored using Pearson's product moment correlation coefficients and Spearman's ρ statistics. Hereby, the four questions assessing attitudes towards digital health interventions were combined to one sum score. Results from open questions were qualitatively analyzed using a structured approach informed by conventional content analysis. One rater developed a coding scheme based on the content of the responses (LSS), which was then independently applied by a second rater (AF). Disagreements were resolved through discussion until consensus was achieved.

Results

Of the 2,519 study participants, 1,322 participants self-rated their gender as female (52.5%), 1,130 as male (47.4%), and four as diverse (0.2%). The mean age was 50.3 years (*SD* = 18.1). Further characteristics of the study sample are described in Table 1.

Table 1

Characteristics of the Study Sample

Variable	*n* (%) or *M* (*SD*)
Age (*M*, *SD*)	50.3 (18.1)
Gender (*n*, %)	
Male	1,193 (47.4)
Female	1,322 (52.5)
Diverse	4 (0.2)
Marital status (*n*, %)	
Married, living together	1,076 (42.7)
Married, living apart	65 (2.6)
Single	757 (30.1)
Divorced	370 (14.7)
Widowed	243 (9.7)
German citizenship (*n*, %)	2,425 (96.3)
Highest level of education (*n*, %)	
In school	47 (1.9)
No graduation	57 (2.3)
Year 9 lower secondary school certificate)	679 (27.0)
Year 10 lower secondary school certificate	822 (32.7)
Graduated from polytechnical high school	240 (9.6)

Variable	*n* (%) or *M* (*SD*)
Graduated from technical college with no accreditation	101 (4.0)
Entrance qualification for technical college/university	277 (11.0)
College/university studies completed	274 (10.9)
Other	3 (0.1)
Currently stressed (*n*, %)	
Absolutely no	1,388 (55.1)
Rather no	507 (20.1)
Partly	364 (14.5)
Rather yes	189 (7.5)
Absolutely yes	51 (2.0)
Previous usage of digital health interventions (*n*, %)	
Yes	17 (0.7)
No	2,497 (99.1)
Not stated	5 (0.2)
Heard of digital health interventions (*n*, %)	
Yes	873 (34.7)
No	1,593 (63.2)
Not stated	53 (2.1)

Attitudes Towards Digital Health Interventions

The distribution of responses with regard to attitudes towards digital health interventions can be found in Figures 1, 2, 3, 4, and 5.

Figure 1

Attitudes Towards Digital Health Interventions: Item 1

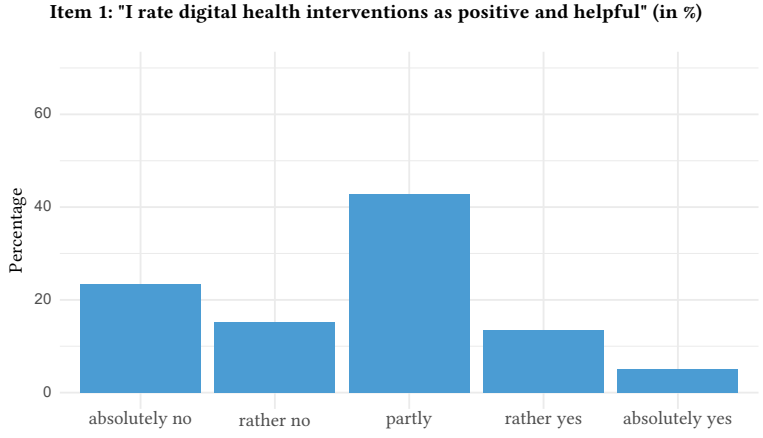


Figure 2

Attitudes Towards Digital Health Interventions: Item 2

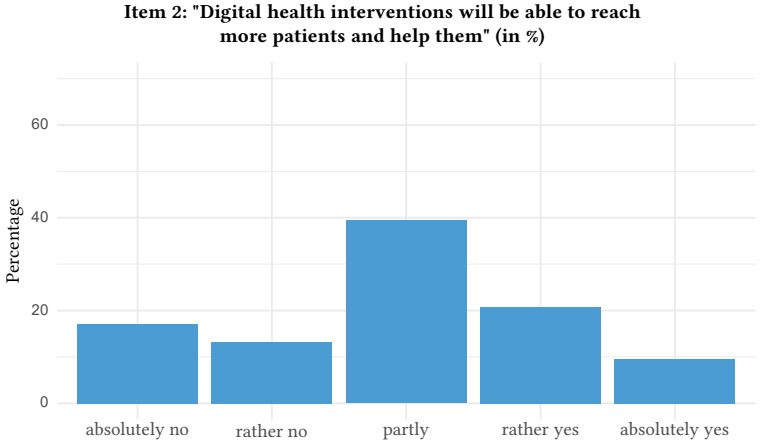


Figure 3

Attitudes Towards Digital Health Interventions: Item 3

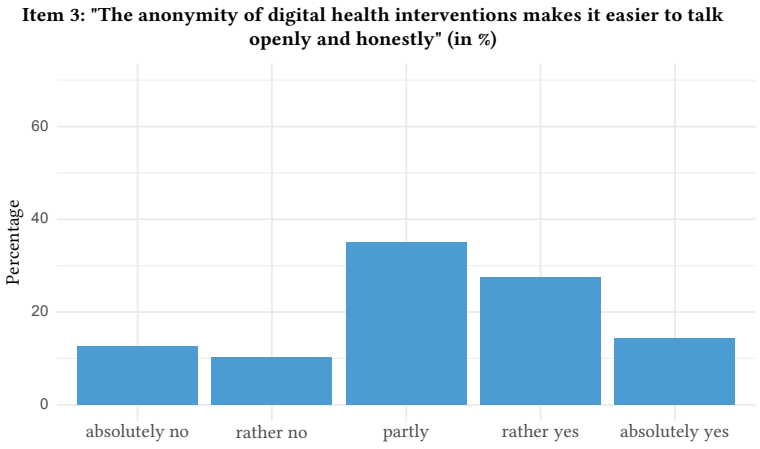


Figure 4

Attitudes Towards Digital Health Interventions: Item 4

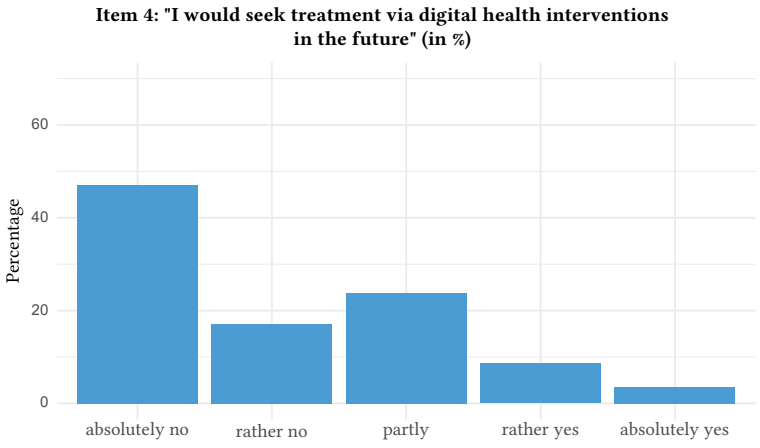
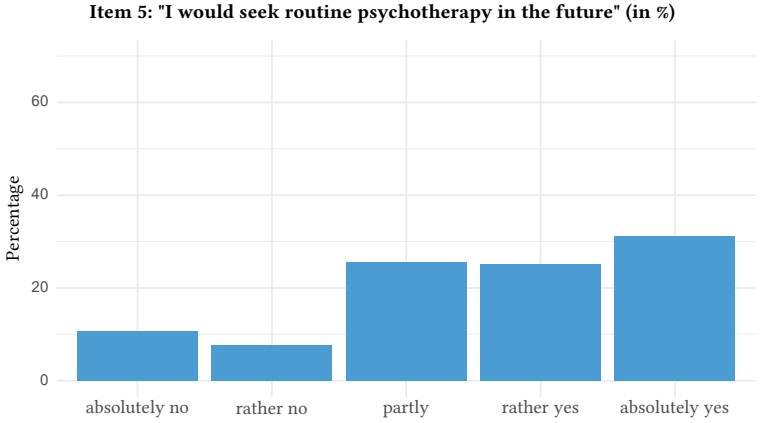


Figure 5

Attitudes Towards Routine Face-to-Face Psychotherapy: Item 5



In detail, when asked if they would agree that they rated digital health interventions positively and as helpful, a majority of participants indicated partial agreement (i.e., rated Item 1 with 3 = partly, n = 1,046, 41.5%, 95% CI [39.6%, 43.4%]). Likewise, the statement that digital health interventions will reach and help more patients was approved partly by the majority of the participants (i.e., rated Item 2 with 3 = partly, n = 959, 38.1%, 95%

CI [36.2%, 40.0%]). The majority also indicated partial agreement towards the statement that the anonymity of digital health interventions makes it easier to speak openly and honestly about important problems (i.e., rated Item 3 with 3 = partly, *n* = 854, 34.0%, 95% CI [32.1%, 35.8%]). Nevertheless, the majority of participants stated that they will "absolutely not" use digital health interventions for future psychological problems (i.e., rated Item 4 with 1 = absolutely no, *n* = 1,153, 45.8%, 95% CI [43.8%, 47.7%]). In contrast, the majority absolutely agreed that they would use routine face-to-face psychotherapy in case of future psychological problems (i.e., rated Item 5 with 5 = absolutely yes, *n* = 760, 30.2%, 95% CI [28.4%, 32.0%]). Of note, 10.2% of the participants (*n* = 256, 95% CI [9.0%, 11.3%]) rated Item 4 higher than Item 5, which indicates a preference for digital health interventions over routine face-to-face psychotherapy. The mean age of the subsample preferring digital health interventions was 42.8 (*SD* = 16.1).

Correlational Analyses of Attitudes Towards Digital Health Interventions

There was no significant correlation between attitude towards digital health interventions and gender (i.e., sum score of Items 1-4; $r = .002$, $p = .937$) or current psychological stress ($r = 0.000$, $p = .998$). The correlation between age and attitude was moderate ($r = -0.296$, $p < .001$), with younger age being associated with higher acceptance of digital health interventions. The correlation between highest level of education and attitude towards digital health interventions showed a small positive association (rho = 0.14, $p < .001$). Responses to all individual items depending on gender and categorized by age groups can be found in the Supplementary Materials (see Steubl et al., 2025S).

Open Questions

Out of the total number of participants, 17 (0.7%) stated that they have previously used a digital health intervention. Conditions mentioned included borderline personality disorder (*n* = 2; 11.8%), anxiety disorders (*n* = 2; 11.8%), depression (*n* = 2; 11.8%), obsessive-compulsive disorder (*n* = 2; 11.8%), addiction (*n* = 1; 5.9%), migraine (*n* = 1; 5.9%), burnout (*n* = 1; 5.9%), kleptomania (*n* = 1; 5.9%), and stroke (*n* = 1; 5.9%). The remaining six participants (35.3%) did not specify for which condition.

A total of 582 (23.1%) participants listed one or more conditions for which digital health interventions were considered as suitable treatment options. Most frequently listed were depression (*n* = 225, 38.7%) and anxiety disorders (*n* = 123, 21.1%). Other conditions mentioned were medical conditions (e.g., cancer, diabetes; *n* = 96, 16.5%), addictive disorders (*n* = 55, 9.5%), psychotic disorders (*n* = 15, 2.6%), obsessive-compulsive disorders (*n* = 13, 2.2%), eating disorders (*n* = 11, 1.9%), suicidal ideation (*n* = 8; 1.4%), personality disorders (*n* = 6, 1.0%), somatoform disorders (*n* = 4, 0.7%), and trauma-rela-

ted disorders (n = 3, 0.5%). Additionally, 111 (19.1%) participants mentioned psychosocial problems not directly associated with medical or mental conditions.

Altogether, 822 participants (32.6%) stated possible barriers to initiating treatment via digital health interventions. Most commonly stated barriers were the absence of personal contact (e.g., no personalization, no therapeutic relationship, anonymous treatment, n = 285, 34.7%), technical aspects (e.g., no soft- and hardware, no Internet connection, problems with Internet in general, n = 164, 20.0%), and mistrust because of data privacy and security concerns (n = 124, 15.1%). Other mentioned barriers were not enough experience or competence in the use of such interventions or the Internet in general (n = 106, 12.9%), integrity of interventions (n = 98, 11.9%), costs of digital health interventions (n = 27, 3.3%), limited offer of digital health interventions (n = 23, 2.8%), limited perceived effectiveness (n = 23, 2.8%), health reasons (e.g., symptom severity, n = 7, 0.9%), and assessments that need to take place in-person (e.g., electrocardiogram; n = 3, 0.4%).

Discussion

This representative study shows that attitudes towards digital health interventions in Germany are rather restrained. This holds particular significance because even the most effective digital interventions have limited impact if they are underutilized due to negative attitudes and lack of acceptance. Specifically, 45.8% of the representative sample in this study explicitly expressed an absolute reluctance to use digital health interventions for mental health in the future. In particular, older people and people with a lower level of education rated digital health interventions for mental health problems with reservation. This is in line with previous results suggesting that especially older adults experience a variety of barriers to the uptake of digital health interventions for mental conditions including the lack of trusted facilitators (Pywell et al., 2020; Wykes & Brown, 2016). However, even though there are concerns, there is still considerable acceptance in certain groups that also offers the opportunity to bring more individuals with mental conditions into treatment. For example, when looking at the youngest age group (< 20 years) this percentage drops to 27.3% with the majority (28.4%) stating that they would partly seek treatment via digital health interventions in the future (for details see Supplementary Materials [Steubl et al., 2025S]). Additionally, there is also a subsample (n = 256, 10.2%) that seems to prefer digital health interventions over routine face-to-face psychotherapy and a considerable number of participants (n = 595, 23.6%) listed mental health conditions they could see digital health interventions being used for. Accordingly, the frequently expressed barriers assessed within the survey (i.e., absence of face-to-face therapeutic relationship with personalization, technical aspects, and data privacy and security concerns) are of particular importance.

Hereby, the primary concern lies in the absence of a genuine therapeutic relationship and the perception that digital health interventions are unable to provide the same

level of personalized treatment as traditional face-to-face psychotherapy. However, it is well established that it is indeed possible to form a therapeutic relationship in (guided) digital health interventions (Berger, 2017; Flückiger et al., 2018; Pihlaja et al., 2018). Additionally, emerging viewpoints suggest that while a stable therapeutic relationship is of importance in conventional treatment, digital health interventions may extend beyond this and be applied for alternative purposes (e.g., micro interventions or to support significant others; Baumel et al., 2020; Baumel & Tamir, 2022). These novel applications appear to diminish the significance of the therapeutic relationship, as perceived by patients (Baumel & Tamir, 2022). Moreover, there is a variety of new approaches to make digital health interventions more personalized and engaging with possible approaches include just-in-time adaptive interventions, gamification, chatbots, and interventions that are personalized and tailored to the individual (Baumeister et al., 2023; Baumeister & Montag, 2023; Domhardt, Cuijpers, et al., 2021; Torous et al., 2021). While the issue of missing technical prerequisites (e.g., an Internet connection) cannot be solved that easily, the ubiquitous digital change may lessen this issue in the future.

Finally, privacy and security concerns are certainly to be taken very seriously as digital health interventions are dealing with private and sensitive data. However, this problem may be of special relevance when using digital health interventions from unknown sources. Fortunately, there is a wide range of digital health interventions from reputable and well-established sources with a high level of data protection efforts on the market. Additionally, there are platforms available online that rate interventions with regard to for example data privacy and security details (e.g., Mobile Health App Database, mhad.science [Stach et al., 2020] or https://onemindpsyberguide.org/). Moreover, patients in Germany have the opportunity to use so-called DiGAs. These digital interventions are subject to certain data privacy and security regulations to protect users' personal health information (Ludewig et al., 2021). Patients can obtain DiGAs with a prescription by their consulting physician, medical doctor or psychotherapist and use them as part of their treatment plan (Ludewig et al., 2021). Nevertheless, the exemplary regulation of digital interventions in Germany and other countries like Sweden or Australia does not refer to all available digital health interventions and many reviews of publicly available mobile health apps show considerable limitations when it comes to data privacy and security (Domhardt, Messner, et al., 2021; Simon et al., 2023; Steubl et al., 2022).

Taken together, the barriers seem to reflect low scores on the UTAUT dimensions *Facilitating Conditions* and *Effort Expectancy*. Interestingly, only a minority of participants explicitly questioned the effectiveness of digital mental interventions (2.8%) and none mentioned the influence or opinions of others as a reason for non-use (0.0%), despite *Performance Expectancy* and *Social Influence* being core factors within the UTAUT model. While the emphasis on the absence of personal contact could also reflect a broader skepticism regarding the performance of digital interventions, and thus relate to *Performance Expectancy*, these findings suggest that efforts to increase acceptance and uptake

may benefit from a focus on improving perceived usability, trust, and the integration of relational elements, rather than solely emphasizing efficacy.

Of note, the majority of participants (67.4%) did not provide any response when asked about potential barriers to using digital health interventions. This may reflect a lack of specific concerns among many respondents, but it could also be due to the open-ended nature of the question, which typically yields lower response rates compared to closed questions with multiple choice answers provided. Additionally, participants may have lacked detailed knowledge about such interventions, which could limit their ability to anticipate barriers.

Nevertheless, it seems evident from the aforementioned points that there exist valid reasons for patients to hold a more positive stance towards reputable digital health interventions than it is currently the case. Fortunately, there are numerous ways to influence and develop patients' attitudes positively (Bauer & Kirchner, 2020). For example, as a persuasive strategy, proponents have advocated the incorporation of future users and individuals with lived-experience in the developmental and implementation phases of digital health interventions (i.e., participatory development; Geirhos et al., 2021; Hochmuth et al., 2020). Moreover, there have been successful efforts to offer acceptance-facilitating interventions to both patients and therapists (Baumeister et al., 2014; Ebert et al., 2015). In general, it seems likely that a (corrective) experience with a digital intervention or more knowledge on the matter (e.g., through educational campaigns) is necessary to alleviate concerns or apprehensions. This should be addressed in depth in future studies and efforts.

In addition to promoting acceptance of digital health interventions, our findings may also inform future strategies on how to implement these interventions within the healthcare system. Specifically, the results highlight the importance of offering a variety of treatment formats (e.g., face-to-face/on-site, video-based/remotely delivered, fully digital/stand-alone) in routine mental health care. Given that individual preferences – such as the desire for personal contact – can shape attitudes and acceptance, providing freedom of choice and for example blended therapy formats (Baumeister et al., 2018) may help align treatment settings with patients' expectations and increase engagement.

It is worth highlighting that in contrast to attitudes toward digital interventions, a substantially larger proportion of participants indicated that they would be willing to use routine face-to-face psychotherapy in the case of future psychological problems. These results reflect the alignment between public attitudes and the current organization of the mental health care system, in which face-to-face psychotherapy remains the standard form of service delivery next to (rudimentary) mental healthcare provided by general practitioners (e.g., with medication). It also shows greater familiarity and comfort with traditional treatment modalities, as well as a general preference for direct personal contact, which was also a commonly cited barrier to using digital intervention formats. These results further underscore the continued importance of offering and extending

face-to-face treatment options – while addressing some limitations of on-site treatments like long waiting times at the same time – and highlight that digital health interventions may complement, rather than replace, conventional care in mental health services (e.g., as in blended therapy formats; Baumeister et al., 2018) and may represent a low-threshold component in stepped mental healthcare (Domhardt & Baumeister, 2018).

Limitations

While the results of this study shed light on the acceptance of digital health interventions, there are some important limitations to consider. First and foremost, the term digital health intervention is very broad and participants were only provided with a concise description comprising two sentences. In the following, some participants might have had a very limited or unrealistic understanding of the concept resulting in differences in attitudes. Additionally, blended therapy approaches (i.e., the combination digital health interventions with traditional face-to-face therapy) were not explicitly mentioned in the survey. Given that such formats are generally associated with higher acceptance compared to stand-alone digital interventions (Schuster et al., 2018), the incorporation of this treatment format into the survey might have had an additional influence on participants' responses. While the decision not to prime participants with specific interventions may have certain advantages (e.g., not focusing on one certain intervention), it might be beneficial for future studies to actually present participants with one or two examples (similar to the aforementioned acceptance-facilitating studies; Baumeister et al., 2014; Ebert et al., 2015). This is especially important, as a considerable amount of the replies to the open questions might have focused on video-based therapy. While this is certainly an important and already widely used form of a digital intervention as outlined previously in this paper, it might not provide the same advantages (e.g., cost-effectiveness, scalability) and disadvantages (e.g., limited guidance, concerns regarding therapeutic relationship) as other digital health interventions (i.e., IMIs) and might have to be viewed separately (for a more detailed discussion on this issue: Steubl & Baumeister, 2023). Second, the reported statistical analyses provide predominantly a descriptive picture of the gathered data. Longitudinal designs and examining changes over time would be highly worthwhile. Third, potentially relevant individual characteristics were not assessed (e.g., digital literacy, stigmatization of mental conditions, ethnic background) due to the broader scope of the overall study of which our survey represents a specific sub-analysis. As a result, our ability to examine how these factors may influence attitudes towards digital interventions is limited, and this may affect the generalizability of our findings to all segments of the population. Last, this study assesses attitudes towards digital health interventions, but considering the use of certain offers in a questionnaire might be different to actually using them. However, the UTAUT model on which the employed questionnaires are based strongly suggests that assessed acceptance is a direct predictor of use of digital offers (Venkatesh et al., 2003).

Conclusion

This study suggests that a majority of adults in Germany would (rather) not use digital health interventions. However, this reservedness decreases with younger age and there is a subsample of individuals who would rather use digital health interventions than regular face-to-face treatment. The identified barriers for the usage of digital interventions (i.e., absence of personal contact, technical issues, and concerns related to data privacy and security) need to be addressed in order to fully harness the potential of digital health interventions in routine care.

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Competing Interests: LBS, AB, HB, and MD have received payments for talks and workshops in the context of digital health interventions. AB and HB are principal investigators of several third party funded projects on digital health interventions. All other authors declare no competing interests.

Previously Presented: Parts of the results presented in this article were previously shared in a poster presentation at the EABCT 2023 Conference in Antalya, Turkey (https://social.hse.ru/data/2023/11/01/2051848124/EABCT2023-Book.pdf). The current manuscript expands upon that presentation.

Ethics Statement: The study was approved by the Ethics Committee of the Medical Faculty of the University of Leipzig (approval number: 298/21-ek).

Social Media Accounts: *Lena Sophia Steubl:* LinkedIn.

Preregistration: The present study analyzes selected data from a large, population-based representative survey conducted in Germany. As the analyses were conducted retrospectively based on an existing dataset, the study was not preregistered.

Reporting Guidelines: The paper follows the JARS–Quant guidelines for quantitative research.

Data Availability: Data, code, and materials can be obtained by contacting the first author upon reasonable request.

Supplementary Materials

The Supplementary Materials contain the following items (for access, see Steubl et al., 2025S):

- Table 1. Full questionnaire (translated)
- Figure 1. Attitudes towards digital health interventions depending on gender
- Figure 2. Attitudes towards routine face-to-face psychotherapy depending on gender

- Figure 3. Attitudes towards digital health interventions depending on age group
- Figure 4. Attitudes towards routine face-to-face psychotherapy depending on age group

Index of Supplementary Materials

Steubl, L. S., Büscher, R., Sander, L. B., Baumel, A., Barck, K., Sachser, C., Fegert, J. M., Brähler, E., Baumeister, H., & Domhardt, M. (2025S). *Supplementary materials to "Attitudes towards digital health interventions in Germany: Findings from a population-based representative survey"* [Full questionnaire and additional figures]. PsychOpen GOLD. https://doi.org/10.23668/psycharchives.18889

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IBD-Specific Cognitive Behavioral Therapy: Sustainability of Effect After Three Years

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Supplementary Materials: Preregistration [see Index of Supplementary Materials]

Abstract

Background and Aims: 'Inflammatory Bowel Disease (IBD)-specific-Cognitive-Behavioral Therapy' (CBT) is effective in improving Quality of Life (QoL) and in decreasing anxiety and depression in IBD-patients with poor mental QoL, one month after completing CBT. Main aim was to examine the sustainability of treatment effects up to three years after treatment with CBT.

Method: Participants (n = 118) of a previously conducted randomized-control-study on the effects of 'IBD-specific-CBT' for IBD-patients were contacted for a long-term follow-up assessment on main outcomes: generic and IBD-specific-QoL (SF-36, IBDQ), anxiety and depression (HADS, CES-D) and DSM-IV disorders (SCID-I). Change over time was examined with multilevel-regression-analyses.

Results: Three years after finishing 'IBD-specific-CBT', 61 IBD-patients (response rate 52%) completed the follow-up SCID-I assessment and 52 patients (response rate 44%) completed the

assessments for symptomatology. There were no differences between dropouts and participants at three year follow-up, except for a longer disease duration in dropouts. At three-year follow-up the chance of patients having a DSM-disorder significantly decreased with an estimated 48% (from 87% at baseline to 38% at follow-up). Multilevel analyses showed a significant improvement between baseline (n = 118) and follow-up measurements (n = 52) on outcomes: IBDQ-Total (Cohen's d effect-size = .89), SF-36 Physical (d = .54), and SF-36 Mental (d = .69), HADS-A (d = -.77), HADS-D (d = -.65) and CES-D (d = -.55); all p < .01. QoL outcomes showed further improvement between completion (n = 90 for IBD-specific QoL and n = 91 for generic QoL) and follow-up measurements, with significant improvements for IBDQ-Total (d = 0.31) and SF-36 Physical (d = 0.32).
Conclusions: Sustainable positive effects of 'IBD-specific-CBT' for IBD-patients with poor mental QoL were found and the prevalence of mental conditions substantially decreased over three year follow-up.

Keywords

Cognitive Behavioral Therapy, Inflammatory Bowel Disease, three year follow-up, quality of life, anxiety, depression

Highlights

- IBD-specific-CBT showed lasting benefits on QoL, anxiety, and depression three years post-treatment.
- Patients further improved, even after completion of therapy regarding IBD-specific QoL and generic physical QoL.
- Comorbid psychiatric disorders at baseline had decreased at long-term follow-up three years after ending 'IBD-specific-CBT'.
- Larger studies are needed to confirm these findings.

The unpredictability of the chronic relapsing and remitting inflammatory bowel diseases (IBD) ulcerative colitis (UC) and Crohn's disease (CD), may impact psychological well-being profoundly. Whereas the exact mechanisms by which IBD is developed remains unclear, it is assumed that the disease develops due to an interaction of genetic predispositions, enviromental and dietary factors, gut microbiome and a dysregulated immune response (Lee & Chang, 2021).

Patients with IBD report a poor quality of life (QoL) and psychiatric complaints such as anxiety and depressive disorders (Bennebroek Evertsz', Thijssens, et al., 2012). Moreover, a recent systematic review and meta-analysis demonstrated a high prevalence of symptoms of common mental health disorders in patients with IBD. According to validated screening instruments, one-third of IBD-patients are affected by symptoms of anxiety and a quarter by symptoms of depression in the previous 10-15 years (Barberio et al., 2021). Moreover, patients with active IBD were also found to have a higher probability of experiencing both anxiety and depression symptoms compared to patients with inactive IBD (Barberio et al., 2021). Although the causal pathway remains unclear,

associations between depression, anxiety and disease activity are well demonstrated (Mikocka-Walus et al., 2016). Additionally, anxiety and depression were found to exacerbate disease outcomes in IBD patients (i.e. higher rates of surgery, hospitalization and corticosteroid use) (Keefer, 2021). Moreover, anxiety related irrational beliefs may lead IBD patients to disengage from regular restrictive physical activity (Gravina et al., 2023) and anxiety itself may reduce their therapeutic adherence, as was documented during the COVID pandemic (Pellegrino et al., 2022). Various studies point to a bidirectional link between the brain-gut axis (Gracie et al., 2018). This bidirectional link has been proven to affect the natural course of the disease along with mental health (Fairbrass et al., 2022; Peppas et al., 2021). Furthermore, individuals with a history of depression may show an increased risk of developing subsequent new-onset IBD (Piovani et al., 2024). A recent study found that IBD patients with anxiety and depressive symptoms have a higher risk of developing steroid resistance and IBD related poor outcomes (Duan et al., 2023). Additionally, two recent systematic reviews and meta-analyses (Naude et al., 2023; Seaton et al., 2024) have shown that psychological treatments, including CBT addressing mood disorders, also improve inflammatory biomarkers in IBD (i.e. faecal calprotectin and C-Reactive Protein). Consequently, an effective psychological intervention to target both anxiety and depression in IBD patients is important. Hence, we designed an 'IBD-specific cognitive behavioral therapy (CBT)' (Bennebroek Evertsz', Bockting, et al., 2012), that targets anxiety, depression, Post Traumatic Stress Disorder (PTSD) and adjustment disorders for IBD patients with poor mental QoL. The beneficial effects were measured one month after 'IBD-specific-CBT' treatment as studied in a multi-center randomized control trial (QL!C study) (Bennebroek Evertsz' et al., 2017). The QL!C-study consisted of an experimental group receiving immediate CBT (n = 59), and was compared with a wait-list control group receiving standard medical care followed by CBT (n = 59) (Bennebroek Evertsz' et al., 2017). At baseline, (before starting the 'IBD-specific-CBT') we measured the prevalence of psychiatric disorders (SCID I), generic and disease specific QoL (SF-36, IBDQ), anxiety and depression (HADS, CES-D) in this IBD-patient group with poor mental QoL (Bennebroek Evertsz' et al., 2017, 2020). We found a positive effect of 'IBD-specific-CBT' on disease specific QoL, generic QoL, depression and anxiety symptoms, one month after completion. Currently, the evidenced based 'IBD-specific-CBT' intervention for IBD patients has been implemented and disseminated in several hospitals in the Netherlands and showed comparable positive short–term effects on IBD-specific QoL, anxiety and depression (Bennebroek Evertsz' et al., 2024).

Study Aims

The primary aim was to investigate whether treatment gains of 'IBD-specific-CBT' (Bennebroek Evertsz' et al., 2017) were sustained up to three years after treatment with

CBT, particularly with respect to psychiatric disorders, disease specific QoL, generic quality of life, anxiety and depressive symptoms.

Materials and Method

Procedures

Three years after completion of the 'IBD-specific-CBT' from the QL!C-study (Bennebroek Evertsz' et al., 2017), IBD-patients 'who participated in the QLIC-study' were asked to participate in a follow-up study during the period July 2013 and June 2015.

Before participating in the previous QL!C study (Bennebroek Evertsz' et al., 2017), all the participants had provided written informed consent, including permission to be approached for follow-up research measuring the long-term effect of 'IBD-specific-CBT'. The patients met the criteria of the diagnoses of Crohn's disease or ulcerative colitis at the start of the original study. IBD was diagnosed based on the usual clinical criteria, comprising clinical history, physical examination, laboratory findings, negative stool cultures, radiological imaging and endoscopic and histological examinations as assessed by IBD-experts, at least 3-6 months before entry in the QL!C-study (Maaser et al., 2019). Potential participants of the former QL!C study (n = 118) were contacted by telephone by a research assistant. If they were interested in receiving more information, we sent them a letter with information about the follow-up study and an invitation for participation. The invitation letter was sent without an initial phone call, if only a postal e-mail address was known. Once patients agreed to participate, an appointment was made for a telephone interview to administer the SCID-I. The questionnaires were sent by mail or e-mail (with a link to the online version of the questionnaires). A reminder was sent if the participant did not return the completed questionnaires by post or e-mail within two weeks. When participants declined participation, they were asked for their permission by phone to fill in the declaration form with the reasons for refusal, demographic- and clinical characteristics.

The QL!C study was approved by the local Medical Ethics Committee of the Amsterdam University Medical Centre (location AMC: dossier number: MEC 08/295) and the long term follow-up study was approved as an amendment of the QL!C study (location AMC: dossier number: MEC NL22948.018.08).

Outcomes

Psychiatric disorders were assessed with the Structural Clinical Interview for DSM-IV Disorders (SCID-I) (First et al., 1999), by psychologists who received a specific training.

All other assessments were based on self-report questionnaires, which are the same as the questionnaires used in the original trial (QL!C-study) (Bennebroek Evertsz' et al., 2017). The primary outcome was the total score on the Inflammatory Bowel Disease

Questionnaire (IBDQ) – 32 items assessing four domains; bowel symptoms, systemic symptoms, and emotional and social functioning (Russel et al., 1997). Where higher scores indicate a better health related QoL. Secondary outcome was generic QoL assessed with the SF-36 (Ware, 1992). The SF-36 items can be aggregated into a Physical-Component-Summary (PCS) score and a Mental-Component-Summary (MCS) score. With higher scores indicating better health related QoL. Tertiary outcomes were depression and anxiety, which were assessed using the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). The HADS is considered to be unbiased by the presence of a somatic illness. Its 14 items were combined to form an anxiety (7 items) and depression scale (7 items), without including physical symptoms. With higher scores indicating more symptoms. The Depression Scale (CES-D) consisting of 20 items, assesses depressive symptomatology in the general population was also used to examine the difference between these two questionnaires on depression (Radloff, 1977).

Statistical Analysis

Data analyses were performed using IBM SPSS (version 28.0.1.1 (15)). The threshold for significance was $p < .05$ (two tailed). Demographic and clinical characteristics were analyzed using frequencies, percentages and median scores. Baseline differences between the group responders and non-responders were compared with Chi-square or Wilcoxon tests. Normality assumptions were checked using the Shapiro-Wilk test and inspection of histograms, appropriate non-parametric tests (i.e. Wilcoxon tests) were applied if needed. Scores on disease specific and generic QoL, anxiety and depression symptoms at baseline (before starting the IBD-specific-CBT) were compared with scores one month after completion and three years after CBT. Additionally, the prevalence of mental condition and co-morbid mental conditions at baseline and three years after CBT were compared. To analyze differences over time we used multilevel regression analyses (Heck & Thomas, 2020). Multilevel modeling takes into account the relationship between measures of the same individual across time and allows for including all available data (i.e. also data from participants who did not complete all measurements). Multilevel logistic regression was used to assess the difference between psychiatric disorders (DSM-IV) as assessed at baseline and the three-year follow-up measurements. The analysis yields estimated probability of having a psychiatric disorder at both measurements, where the odds-ratio (*OR*) is used to assess the difference between these two probabilities. When the upper bound of the 95% confidence interval of the estimated odds-ratio is below "1" this indicates that the chance of having a psychiatric disorder has significantly decreased with $p < .05$. Differences between scores on baseline, completion (post-CBT) and three-year follow-up measurements of IBD-specific and generic QoL, anxiety and depression symptoms were assessed with multilevel regression analysis. Comparison between baseline and three-year follow-up was used to measure change over time, and between CBT completion and follow-up was used to assess whether the treatment effectiveness was sustained after

three years. This analysis yields estimated mean differences between assessments, where confidence intervals of the estimated effects can be used to assess statistical significance of the difference. When the 95% confidence interval does not include zero, this indicates that the estimated difference is statistically significant at alpha = .05. The estimated effects can also be used to calculate a Cohen's *d* effect size (ES with 0.3, 0.5 and 0.8 indicating a small, moderate and large effect, respectively) while taking into account the correlation between measurements using the design-effect (Hox et al., 2018). The multilevel analyses were performed using the package lme4 (v1.1-34) (Bates et al., 2015) in R (R Core Team, 2021). Assumptions of homogeneity of variances and normality of residuals were assessed using an Anova on squared residuals within participants and by inspecting QQ-plots respectively. Assumption of (log)linearity does not apply as the comparisons involves only two measurement occasions. We added an ad-hoc analyses to measure the effect of gender, age and disease type.

Results

Of the 57 (48%) IBD-patients who did not participate in this follow-up study (dropouts), 42 (74%) refused participation with no reason, 9 (16%) did not respond to letters and/or telephone calls, 2 (3%) persons indicated to be physically not able to participate and 4 (7%) persons were not able to participate due to time constraints. The dropout analyses (comparing baseline measures of the 61 patients participating at three-year follow-up vs the 57 dropouts) showed no significant differences regarding demographic and clinical characteristics and psychiatric disorders (DSM-IV) (data not shown). Dropouts had a significantly longer median disease duration of 11 years at time of baseline while participants who participated at follow-up' had a 'median' disease duration of 5 years (p = .03).

The demographic- and clinical characteristics of 61 IBD-patients (response rate 52%) who completed the three year follow-up SCID-I telephonic interview assessment, are summarized in Table 1. Median age at long term follow-up was 36 years (IQR 28-47), 35 patients are female (57.4%) and almost more than two-fifth of our participants are married or living together (44.3%). Of the 61 participating IBD-patients there were 52 (85%) IBD-patients who also completed IBD-specific and generic QoL, anxiety and depression symptoms at three-year long-term follow-up. Median age was 35 years (IQR 28-47), 30 patients were female (57.7%) and nearly half of them were married or living together (43.4%) (see also Table 1). There were also no significant differences regarding demographic and clinical characteristics (and neither disease duration; p = .07) between the n = 52 participants who completed follow-up and patients lost to follow-up (data not shown). Assumptions of homogeneity of variances and normality of residuals were met for all multilevel analyses.

Table 1

Demographic and Clinical Characteristics

Variable	IBD (n = 61) Baseline and 3 year follow-up Completion of Psychiatric Disorders	IBD (n = 52) Baseline, post-CBT and 3 year follow-up Completion of IBDQ, SF-36, HADS, CES-D
Gender		
Female	35 (57.4%)	30 (57.7%)
Age in years (Median [IQR])	36 (28-47)	35 (28-47)
Marital status		
In a relationship	27 (44.3%)	23 (43.4%)
Level of education		
Low (Primary or Secondary)	24 (39.4%)	23 (40.4%)
High (College or University)	32 (52.5%)	26 (50%)
Otherwise	5 (8.2%)	3 (5.7%)
Employment		
Employed or studying	34 (55.7%)	28 (53.8%)
Unemployed	27 (44.3%)	24 (46.2%)
Sickleave	12 (19.7%)	10 (19.2%)
Hospital type		
Academic	36 (59%)	29 (55.8%)
Diagnosis		
Ulcerative colitis	26 (42.6%)	22 (42.3%)
Crohn's disease	35 (57.4%)	30 (57.7%)
Disease duration in years (Median IQR)	5 (3 – 13)	6 (3 – 13)
Number of operations		
None	43 (70.5%)	36 (69.2%)
≥1	18 (29.5%)	16 (30.8%)
Stoma	1 (1.6%)	0 (0%)
Medication with side-effect depression		
Prednisone	12 (19.7%)	9 (17.3%)
None	49 (80.3%)	43 (82.7%)

Multilevel regression analyses showed a significant decrease in estimated probability of overall psychiatric disorders (baseline 86.7% (n = 51), follow-up 38.3% (n = 24), p < .01), mood disorders (baseline 45.4% (n = 25), follow-up 20% (n = 13), p < .01), anxiety disorders (baseline 35.1% (n = 21), follow-up 10.7% (n = 8), p < .01) and adjustment disorders (baseline 30.6% (n = 23), follow-up 11.5% (n = 7), p < .01) (see Table 2). For the other psychiatric disorders, including eating disorder, alcohol related disorder and psychotic disorder, the number of participants with the disorder at baseline was very low (n < 5), precluding further analyses.

Table 2

Frequencies of Psychiatric Disorders of IBD Patients at Baseline and at 3 Year Follow-Up

	Baseline (n = 118)		3 year follow-up (n = 61)		
Psychiatric disorder	***n***	**%[a]**	***n***	**%[a]**	***OR* [95% CI]**
DSM-IV	51	86.7	24	38.3	0.10 [0.02, 0.23]**
Mood	25	45.4	13	20.0	0.30 [0.13, 0.62]**
Anxiety	21	35.1	8	10.7	0.22 [0.07, 0.52]**
Adjustment	23	30.6	7	11.5	0.30 [0.11, 0.68]**

Note. Psychiatric disorders were only assessed at baseline and at 3 year follow-up and are not available immediately at post-CBT.

[a]Percentages are based on the estimated odds from the multilevel logistic regression model.

**$p < .01$.

Additionaly, analyses showed a significant improvement in IBD-specific QoL between baseline and follow-up among 52 patients after three years (IBDQ total score: Cohen's d = .89, IBDQ bowel: Cohen's d = .69, IBDQ systemic: Cohen's d = .79, IBDQ emotional: Cohen's d = .79, IBDQ social: Cohen's d = 73). Also there was a significant positive long-term effect on generic QoL (SF-36 physical: Cohen's d = .54 and SF-36 mental: Cohen's d = .69). Strikingly, patients showed significantly further improvement three years after completion of 'IBD-specific-CBT', concerning IBD-specific QoL total, IBDQ bowel, IBDQ social and generic physical QoL (completion versus follow-up IBDQ total score: Cohen's d = .31; IBDQ bowel: Cohen's d = .34, IBDQ social: Cohen's d = .33, SF-36 physical: Cohen's d = .32) (see Table 3).

Anxiety and depression symptoms remained decreased three years after completion of 'IBD-specific-CBT' (baseline versus follow-up HADS-A: $p < .01$, Cohen's d = -.59; HADS-D: $p < .01$, Cohen's d = -.41 and CES-D: $p < .01$, Cohen's d = -.66). However, these results did not further significantly improve after completion of the therapy (completion versus follow-up HADS-A: p = .42, Cohen's d = -.12; HADS-D: p = .67, Cohen's d = -.06; CES-D: p = .20, Cohen's d = -.19).

Ad hoc explorative analyses showed that there were some effects of disease-type (i.e., UC versus CD). Participants with CU showed a larger improvement between baseline and three year follow up on IBDQ total ($p < .05$), and the improvement between completion and three-year follow up for SF36-MH was only statistically significant for participants with CU (but not for participants with CD). There were no effects of age and gender. There were also no effects of gender, age and disease-type on the decrease of psychiatric disorders over time.

Table 3

Comparison of QoL, Anxiety and Depression Between Baseline (n = 103) and 3 year Follow-Up (n = 52), and Completion (Post-CBT; n = 91 (IBDQ) or n = 90 (Other PROMs)) and Follow-Up Assessments (Total n = 106)

	Baseline vs Follow-up		Completion (post CBT) vs Follow-up	
Assessment	**MD[a] [95% CI]**	**Cohen's *d*[b]**	**MD[a] [95% CI]**	**Cohen's *d*[b]**
IBDQ Total	25.11 [17.92, 32.31]**	0.89	8.85 [1.60, 16.05]**	0.31
IBDQ Bowel	6.8 [4.26, 9.33]**	0.69	3.41 [0.86, 5.95]**	0.34
IBDQ Systemic	4.53 [3.00, 6.06]**	0.79	1.34 [-0.19, 2.87]	0.23
IBDQ Emotional	10.1 [7.01, 13.19]**	0.79	2.32 [-0.79, 5.42]	0.18
IBDQ Social	3.72 [2.37, 5.07]**	0.73	1.67 [0.32, 3.02]**	0.33
SF-36 Physical	2.07 [1.01, 3.14]**	0.54	1.22 [0.16, 2.28]*	0.32
SF-36 Mental	3.75 [2.49, 5.03]**	0.69	0.8 [-0.48, 2.08]	0.15
HADS Anxiety	-3.23 [-4.29, -2.18]**	-0.77	-0.85 [-1.90, 0.21]	-0.20
HADS Depression	-2.39 [-3.39, -1.39]**	-0.65	-0.67 [-1.66, 0.33]	-0.18
CES-D	-3.83 [-5.52, -2.14]**	-0.55	-1.56 [-3.26, 0.15]	-0.22

Note. Cohen's *d* .3 is small, .5 is medium and .8 is large. IBDQ = Inflammatory Bowel Disease Questionnaire; SF-36 = MOS 36-item Short Form Health Survey; HADS = Hospital Anxiety and Depression Scale; CES-D = The Center for Epidemiologic Studies Depression Scale.

[a]Mean difference (MD) is based on the estimated effect in the multilevel regression model. [b]Cohen's *d* is based on the estimated parameters from the multilevel regression model.

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

Discussion

We found a sustainable positive effect up to 3 years follow-up of 'IBD-specific-CBT' on IBD-specific and generic QoL, anxiety- and depressive symptoms among IBD patients with a priori poor mental QoL. Moreover, comorbid psychiatric disorders at baseline had decreased at long-term follow-up three years after ending 'IBD-specific-CBT'.

Recent meta-analyses and reviews did find short term effectiveness of CBT for IBD on mental health problems (such as anxiety and depression) (Chen et al., 2021; Li et al., 2019). However, to date, positive sustainable effects of 'IBD-specific-CBT' have not been demonstrated.

After 24 months of observation, Mikocka-Walus et al. (2017) did not find a significant longterm effect of CBT on QoL, mental health or coping. A study of McCombie et al. (2016), that examined the long-term effect of computerized CBT, found an increased QoL at 12 weeks but the effect was not maintained after 6 months. In patients with other medical illnesses, little is known about the sustainable effects on mental symptomatology and mental condition as well as QoL after CBT (van Straten et al., 2010). However, sustainable effects of CBT have been reported for depressive disorder (Cuijpers et al., 2013, 2023; Furukawa et al., 2021; Legemaat et al., 2023).

We would recommend a number of amendments for future research to investigate the sustainable effects of 'IBD specific CBT'. First, employment of a larger sample size that would accommodate dropout, enabling the study of long-term effects. Furthermore, inclusion of multiple assessment points (e.g., 3, 6 and 12 months after completion) would enable a closer examination of the treatment effects over time. Even more so, in the first phase of this study we randomized CBT to a wait-list control group. Therefore we have no control group for the three year follow-up. We would recommend to use a different type of control-group. Namely comparison of 'IBD-specific-CBT' with IBD patients receiving only treatment as usual for longterm follow-ups. Fortunately, this research will be repeated with due observance of these recommendations.

Given these promising short-term and long-term results of 'IBD-specific-CBT' in IBD patients with poor mental QoL and the positive results of the aforementioned implementation study of 'IBD-specific-CBT' in four hospitals in the Netherlands (Bennebroek Evertsz' et al., 2024), there is an urgent need to disseminate standard stepwise screening and treatment of mental health disorders in IBD patients. As mentioned before CBT for patients living with IBD not only enhances psychological benefit, but may also improve their physical health (e.g. inflammation) (Naude et al., 2023; Seaton et al., 2024).

Moreover, providing integrated psychological care to IBD patients in need for mental health can reduce costs, particularly by decreasing visits to emergency departments (Lores et al., 2021). However, untill now the integration of mental health care in general IBD care is still insufficient and a challenge in daily clinical practice (Fairbrass & Gracie, 2021; Peppas et al., 2021).

Conclusions

IBD patients with initial poor mental QoL were found to experience a sustainable positive effect of the 'IBD-specific-CBT' on IBD-specific and generic QoL, anxiety and depressive symptoms, three years after ending CBT. Morover, a significant reduction of the prevalence of mental conditions was found (83.6% 1 month after CBT to 39.3% with a mental health condition at three year follow-up). The prophylactic effect of CBT seems also to hold for IBD-specific problems, since patients further improved, even after completion of therapy regarding IBD-specific QoL and generic physical QoL. This gives an indication that this therapy may not only have sustainable positive effects, but also generate further improvement over years after completion. This is in line with other findings on Preventive Cognitive Therapy in depression (Bockting et al., 2018; Furukawa et al., 2021; Legemaat et al., 2023) and CBT in anxiety disorders (van Dis et al., 2020).

We can therefore conclude this 'IBD-specific-CBT' was found to have sustainable effects in decreasing mental health problems and mental conditions in IBD-patients on the long term. Moreover this study shows the first indications of long-term sustainable effects. Larger studies are needed to confirm these findings.

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Competing Interests: The authors (FBE, FLSG, PCFS, RS, MV, MAGS and CLHB) declare that they have no competing interests.

Author Contributions: FBE was the chief investigator grant holder of the three years follow-up QL!C study. She drafted the final manuscript (which was added and modified by all other authors), wrote the original treatment manual 'IBD-specific-CBT' (which was added to and modified by CLHB) and she was responsible for the training and supervision of the psychotherapists. MAGS was the study's principal investigator. The statistical analysis plan was set up by FBE, MV and FLSG. MV is responsible for the statistical analysis and reporting (adviser statistical analyses). MAGS, PCFS, RS, and CLHB supervised the study and contributed to its design and analytic strategy. FLSG supported in literature searches, reference preparation and reviewed early drafts of the article. FBE, MAGS and CLHB reviewed early drafts of the article. All authors read and approved the final manuscript. FBE had full access to all data in the study and had final responsibility for the decision to submit for publication.

Ethics Statement: This long term follow-up study design has been approved by the Medical Ethics Committee of the Amsterdam UMC as an amendment of the QLIC study (location AMC: dossier number: MEC NL22948.018.08). Participants of the follow up study were properly instructed and they gave informed consent. The manuscript has been read and approved by all authors.

Reporting Guidelines: Clinical trial, intervention study following the CONSORT statement.

Preregistration: Before start of the study the trial was registered at the Overview of Medical Research in the Netherlands (OMON), the formerly Dutch Trial Register. Trial registration number of the original randomized control trial (TC = 1869) (see Bennebroek Evertsz', 2025S).

Data Availability: The corresponding author FBE had full access to the study data and material. The data underlying this article will be shared on request to the corresponding author. Code availability: Non applicable.

Supplementary Materials

The Supplementary Materials contain the preregistration for the study (see Bennebroek Evertsz', 2025S).

Index of Supplementary Materials

Bennebroek Evertsz', F. (2009). *Enhancing the quality of life of patients with inflammatory bowel disease: A multi-center study investigating cognitive behavioral therapy* [Preregistration; Trial registration number = 1869]. Overview of Medical Research in the Netherlands (OMON). https://www.onderzoekmetmensen.nl/nl/trial/19981

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A Remote Adapted Physical Activity Intervention for Women With Breast Cancer and Severe Depressive or Anxiety Symptoms: Series of N-of-1 Trials With Ecological Momentary Assessment

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Supplementary Materials: Code, Data, Materials, Preregistration [see Index of Supplementary Materials]

Abstract

Background: Women with breast cancer live with the burden of the disease, its treatment, and the psychosocial consequences of illness, often contributing to the experience of psychological distress. At this end, physical activity (PA) is an evidence-based strategy to decrease depressive and anxiety symptoms. However, no study has yet investigated how those psychological symptoms fluctuate and vary during a PA intervention at the individual level, especially for individuals with severe psychological distress. Thus, the aim of the present study was to examine the short-term effects of a 12-week remote PA intervention on daily level of depressive and anxiety symptoms among women with breast cancer and severe depressive or anxiety symptoms.

Method: A N-of-1 study followed an ABA' design was conducted. Each A phase (2-week) represents pre- and post-intervention phase and B phase (12-week) represents the intervention phase. For the whole 16 weeks, participants received a daily prompt to report their depressive and anxiety levels. The intervention combined two to three (un)supervised remote PA sessions per week coupled with weekly text messages.
Results: Sixteen participants completed the intervention. A significant decrease of depressive and anxiety symptoms was found for nine and seven participants, respectively. Different temporal patterns of depressive and anxiety were observed during and after the intervention. Interestingly, the impact of PA intervention was generally not immediate and gradual.
Conclusion: This study supports the utility of remote PA intervention to improve depressive and anxiety symptoms in women with breast cancer and poor mental health.

Keywords

psychological distress, cancer, physical exercise, tele-health, single case experimental study

Highlights

- A remote physical activity intervention is beneficial for adults experiencing severe psychological distress.
- N-of-1 coupled with EMA is a solid method to observe the fluctuation of mental health symptoms.
- Physical activity benefits on mental health symptoms are not immediate but gradual.

Poor mental health is a major clinical issue during and post-breast cancer treatment (Caruso et al., 2017; Kissane, 2014; Niedzwiedz et al., 2019). Previous meta-analyses have reported that the prevalence of anxiety and depressive symptoms among women with breast cancer (BC) reached 44.2% and 28.9% for moderate levels and 20% and 13.2% for severe level, respectively (Hashemi et al., 2020; Pilevarzadeh et al., 2019). Severe depressive or anxiety symptoms are associated with higher risk of mortality and cancer recurrence (Wang et al., 2020) but also with lower cancer treatments adherence, higher health related costs and impaired quality of life (Mausbach et al., 2015, 2018; Mitchell et al., 2013).

Regarding treatment options, psychological therapies and antidepressants can decrease the symptoms' intensity among women with a BC and moderate levels of depressive and anxiety symptoms. However, the effectiveness of these interventions is very modest (Vita et al., 2023; Xiao et al., 2017) and, in most cases, women with severe depressive and anxiety symptoms were excluded from clinical trials (Carvalho et al., 2014). Therefore, new interventional strategies must be explored and applied to women with BC and moderate to severe depressive and anxiety symptoms.

At this end, high level of evidence revealed that physical activity (PA) interventions are effective treatments to help adults with moderate or severe depressive or anxiety dis-

orders (Ravindran et al., 2016). For BC, the American College of Sport Medicine (ACSM)'s guideline highlighted that PA interventions are an evidence-based strategy to decrease the risk of depressive or anxiety symptoms (Campbell et al., 2019). Meta-analyses including more than thirty randomized controlled trials, suggested that PA interventions decrease the depressive and anxiety symptoms during and after BC treatment (Carayol et al., 2013, 2015). However, none of these trials included women with a severe level of depression or anxiety (Bernard & Carayol, 2015). One reason is that designing an adapted PA intervention for those women is very challenging because the presence of depressive and anxiety symptoms decreases the PA engagement and adherence rate (Bullard et al., 2019). So, it is crucial to individualize and personalize the PA intervention, according to preferred PA modalities in women with BC (Schmitz et al., 2019) and in using behavioral change techniques during the intervention.

Furthermore, the daily fluctuations of those symptoms are complex to observe with a simple pre- and post-intervention measurement (Bentley et al., 2019). An appropriate method, such as single case experimental study (or N-of-1) is necessary to examine the evolution of depressive and anxiety symptoms during the intervention (Bentley et al., 2019). N-of-1 has received an increasing interest in oncology (Sequeira et al., 2023), PA (Lapointe et al., 2023), and mental health research (St-Amour et al., 2024). This design consists in collecting data regularly form participants as they progress through different phases of the study, i.e., the first phase measures the baseline of the interest variables and the subsequent phase serve to introduce the intervention. The data from the intervention phase are compared to the baseline phase, providing strong internal validity for each participant. In addition, conduction N-of-1 combined with Ecological Momentary Assessment (EMA) is a solid methodological approach to examine the effects of a clinical intervention on depressive and anxiety symptoms at individual level. EMA has been recommended to improve the ecological validity and reduce recall bias (St-Amour et al., 2024).

The goal of the present study was to examine the short-term effects of a 12-week supervised adapted PA intervention on daily levels of depressive and anxiety symptoms among women with BC and severe depressive or anxiety symptoms. We hypothesize that (1) daily level of depressive and anxiety symptoms will decrease during the intervention and (2) intervention effects were maintained 2 weeks after its end.

Method

This research protocol has been approved by the Ethics Boards of the *Eastern Montreal Integrated University Health and Social Services Centre* (2022-4319). This manuscript was written according to the *Single-Case Reporting Guideline in BEhavioural Interventions* (SCRIBE; Tate et al., 2016). The SCRIBE checklist is provided in the Supplementary Materials (Bernard, 2025S).

Study Design

This N-of-1 study followed an A-B-A design (representing the three phases of the study) and lasted 16 weeks. No randomization nor blinding were used due to the nature of the study. Each A phase (2-week each) represents the pre- and post-intervention baseline measures, and the B phase (12-week) represents the intervention phase. For the whole 16 weeks, participants received a daily EMA prompt to report their depressive and anxiety levels. The intervention (B phase) included two to three (un)supervised remote PA sessions per week coupled with motivational and educational text messages.

Recruitment

Participants were recruited from Maisonneuve Rosemont or Santa Cabrini Hospitals (Montreal, Canada). Flyers, outlined the study aims, inclusion criteria and contact information for the research coordinator, were distributed through psycho-oncology consultations and shared to patients on the psycho-oncology unit waitlist and on the oncology center website and social networks. Potential participants were screened by telephone and included if they: 1) were diagnosed with a non-metastatic BC and currently completing treatment or completed treatment at least three months prior; 2) reported a high level of self-reported depressive (Patient Health Questionnaire score ≥ 15) or anxiety symptoms (General Anxiety Disorder's questionnaire score ≥ 15); 3) were aged 18 to 65 years; 4) were considered inactive (less than 150 minutes per week or Godin's questionnaire score < 23; Amireault et al., 2015); 5) possessed a smartphone. Participants were excluded if they: 1) reported a psychotic or schizophrenia disorder diagnostic; 2) answered positively to the PA Readiness Questionnaire for Everyone; 3) received a weekly psychological treatment from a clinician; 4) reported a major functional or physical disability; 5) were unable to provide consent. The consent form was sent via e-mail before the initial evaluation. Participants were rewarded $150 CA upon study completion.

Physical Activity Intervention

The intervention combined a remote adapted PA intervention, supervised by a kinesiologist, coupled with weekly text messages for 12 weeks. The characteristics of this intervention were based on the ACSM recommendations, identified behavioral change techniques and PA preferences in interventional context among women with BC (Caudroit, Chevance, et al., 2025). The detailed description of the intervention development and content have been previously published (Caudroit, Lapointe, et al., 2025). This intervention has been found as feasible, acceptable, and associated with high adherence rates (Caudroit, Lapointe, et al., 2025).

Participants had three supervised remote PA sessions from week three to six. From week seven to 14, participants had two supervised remote PA sessions, with the choice

between supervised or unsupervised sessions for the third weekly session. The supervised PA sessions included: 1) combination of behavioral change techniques and aerobic exercise with resistance or yoga exercises (participants' choice); 2) the durations of sessions ranged from 30 (weeks 3-6) to 60 minutes (weeks 7-14) but actual durations were adaptable based on participants' self-reported fatigue level; 3) the effort intensity was selected by the participant, guided by the proposed intensity of the day provided by the kinesiologist, explained through the rate of perceived exertion, progressively increasing, and varying between 1 and 8 (different for aerobics, resistance, yoga) on a scale of 10 during the 14 weeks. The unsupervised PA sessions could be based on previous supervised sessions or personalized after discussions with the participant (e.g., 2 weekly walks of 30 minutes).

Measures

Online questionnaires and EMA were used to measure our variables of interest during the phases of our study. In line with the SCRIBE, we used validated questionnaires to describe participants demographic characteristics and clinical features (Tate et al., 2016). A research-oriented app was installed (EthicaData) on participants' smartphones to obtain self-measured daily rating of depressive and anxiety symptoms.

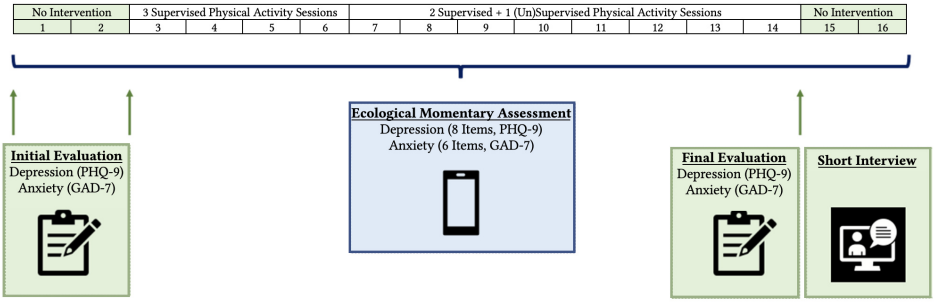
Questionnaires

Before the intervention, online questionnaires collected information on age, educational achievements, marital status, income, number of children, date of diagnosis, treatments, current medications, and history of cancer. According to the SCRIBE recommendations, generalization measures were also performed to increase the external validity of the study. Thus, GAD-7 and PHQ-9 were filled by participants three times during the study (details in Figure 1; Tate et al., 2016). The respective validated thresholds of these scales were used to describe the individual scores (see details in the Supplementary Materials [Bernard, 2025S]). The Patient Health Questionnaire (PHQ-9) is a screening instrument with nine items, developed to assess the severity of depression (Kroenke et al., 2001). For each item, the respondent is asked to rate how often each symptom occurred over the last two weeks, on a Likert scale ranging from 0 "not at all" to 3 "nearly every day". The sum score (range to 0 to 27) indicates the degree of depression with score of ≥ 15 representing severe levels of depression (Howell et al., 2015). The Generalized Anxiety Disorder (GAD-7) is a one-dimensional instrument created to detect symptoms of generalized anxiety disorders (Spitzer et al., 2006). Core symptoms within the past two weeks were queried with seven items on a four-point Likert scale rated from 0 (not at all) to 3 (nearly every day). The total GAD-7 score can range from 0 to 21 and a score ≥ 15 represents severe anxiety symptoms levels (Howell et al., 2015). PHQ-9 and GAD-7

are both recommended questionnaires by the Canadian Association of Psychosocial Oncology (Howell et al., 2015).

Figure 1

Study Design



Daily Assessments

Every day during the Phase B, participants rated the severity of depressive and anxiety symptoms using a 0-100 visual analog slider (0: not at all – 100: as much as possible). Participants rated the severity of depression symptoms with 8 adapted items from the Patient Health Questionnaire (PHQ-9, Kroenke et al., 2001). The severity of anxiety symptoms was measured with 6 adapted items from the GAD-7 (Spitzer et al., 2006). All EMA items are presented in Table 1.

Internal Validity

Single case experimental studies may be subject to rival hypotheses that can explain changes in the dependent variables like maturation, question-behavioral effect, and other external factors (St-Amour et al., 2024). To ensure the internal validity (i.e., the observed change is attributable to the intervention rather than other factors), participants were questioned at the end of Phase B about important event having occurred in their life during the phase they just finished that could have a prolonged (positive or negative) impact on their mental health symptoms.

Statistical Analyses

A piecewise linear regression has been performed for each participant. This analysis is particularly well-suited for time series with Gaussian or Poisson distribution (Lapointe et al., 2023; Wilbert, 2021). We considered the auto-correlation between symptoms data only for models with a Gaussian distribution because it was implemented only for the

Table 1

Ecological Momentary Assessment Items

Variable / Item
Depressive symptoms
Today, I feel depressed
Today, I feel guilty
Today, I had difficulties in concentrating
Today, I feel tired
Today, I feel like I am in slow motion
Today, I have a good appetite
Today, I felt hopeless
Today, I have little interest or pleasure in what I am doing
Anxiety symptoms
Today, I have a feeling of fear
Today, I feel angry
Today, I feel worried
Today, I feel restless
Today, I feel irritable
Today, I am feeling muscle tension

latter in the scan package (Wilbert, 2021). Through those analyses, we compared the daily depression and anxiety level during and after the intervention to baseline measures. Each piecewise regression was carried out to examine the level effects (i.e., the difference between the mean of symptoms in Phase A with Phase B and A', divided by the standard deviation of the residuals) and test the slope effects (i.e., the continuous change of symptom levels due to the PA intervention). Two models were systematically compared by including or not the trend. The model with the highest R^2 was finally selected for each dependent variable.

Transparency and Openness

The study protocol was registered a priori with OSF registries (see Supplementary Materials [Bernard et al., 2022S]). Analyses and graphics have been performed with R 4.3 and ggplot2, and scan packages. Data, open materials, and R scripts are available online (Bernard, 2024S-a).

Results

Participants Characteristics

Between 2022 May and 2023 June, 18 participants (10 during treatment and eight post-treatment) were included. Baseline sociodemographic, health and cancer-related information, and PA adherence sessions rates are in Table 2. Two participants were dropped during this study. Some participants postponed the beginning of their intervention phase due to events out of their control making some A phases longer for some than others. Regarding scores on PHQ-9 and GAD-7, all participants experienced severe psychological distress (score ≥ 15 on, at least, one scale) with 13 patients who had severe depressive disorders, one who had severe anxiety disorders and four who had severe depressive and anxiety disorders. The EMA adherence rates were ranged from 48% to 88%, with eight participants with a rate above 70%.

Table 2

Study Participant Characteristics

ID	Age	Marital status	Education	Working status	Incomes (k$)	BMI	Cancer stage	In treatment[a]	Smoking	GAD7	PHQ9	Adherence
id1	44	Single	Coll	SL	40-60	23	I	Yes	No	13	17	62
id2	43	Single	Coll	SL	40-60	DK	III	No	No	15	17	100
id3	59	Married	Coll	FTW	>80	25	II	Yes	No	14	16	85
id4	29	Married	High S	SL	>80	48	IV	Yes	No	10	18	97
id5	38	Married	Univ	SL	20-40	30	II	Yes	No	12	15	94
id6	44	Married	Univ	SL	>80	27	I	Yes	No	12	15	88
id7	61	Single	Univ	PTW	40-60	14	I	Yes	No	13	21	82
id8	45	Single	Coll	FTW	60-80	55	III	No	Yes	12	18	91
id9	30	Married	Univ	SL	>80	37	III	Yes	No	15	19	97
id10	50	Other	Coll	SL	40-60	32	II	Yes	No	17	18	100
id11	52	Married	Coll	PTW	20<	40	I	Yes	Yes	22	13	32
id12	47	Single	Univ	SL	40-60	14	DK	Yes	No	11	17	91
id13	29	Single	Colle	FTW	>80	21	II	No	No	9	16	88
id14	37	Divorced	Coll	SL	20<	28	II	No	No	11	19	94
id15	45	Divorced	Univ	SL	40-60	41	II	No	No	18	18	94
id16	60	Other	Coll	SL	20-40	74	II	No	No	11	21	38

Note. DK = Don't know; Univ = University; Coll = College; High S = High school; SL = Sick leave; FTW = Full-time work; PTW = Part-time work; BMI = Body Mass Index; PHQ = Patient Health Questionnaire; GAD = General Anxiety Disorder; Adherence = Number of adapted physical activity sessions realized.
[a]Chemotherapy or radiotherapy.

Intervention Effects

Figures 2 and 3 present the daily mean of depression and anxiety symptoms for all participants and local regressions. Table 3 and 4 present the results of piecewise regressions. The level regression coefficient indicates a mean level change after the beginning of

intervention. The slope regression coefficient indicates the daily decrement following the beginning of intervention.

A significant decrease of depressive symptoms during the intervention has been found among 10 participants (id2, id3, id4, id5, id8, id13, id10, id11, id12, id15, see details in Table 2). As presented in Figure 2, different patterns of symptom reduction can be observed. For id4, id5, id8, id12, a negative and significant effect was found for level and slope. In other words, benefits from our intervention were quick and progressive. For id2, id3, id13, the beginning of intervention was associated with a significant higher level of symptoms, however, these symptoms gradually decreased (i.e., negative slope) during the intervention. A significant reduction of daily depressive symptoms was observed only for the level (id10, id15) or slope (id11).

Figure 2

Depression Scores in Three Conditions With Regression Lines for Each Phase

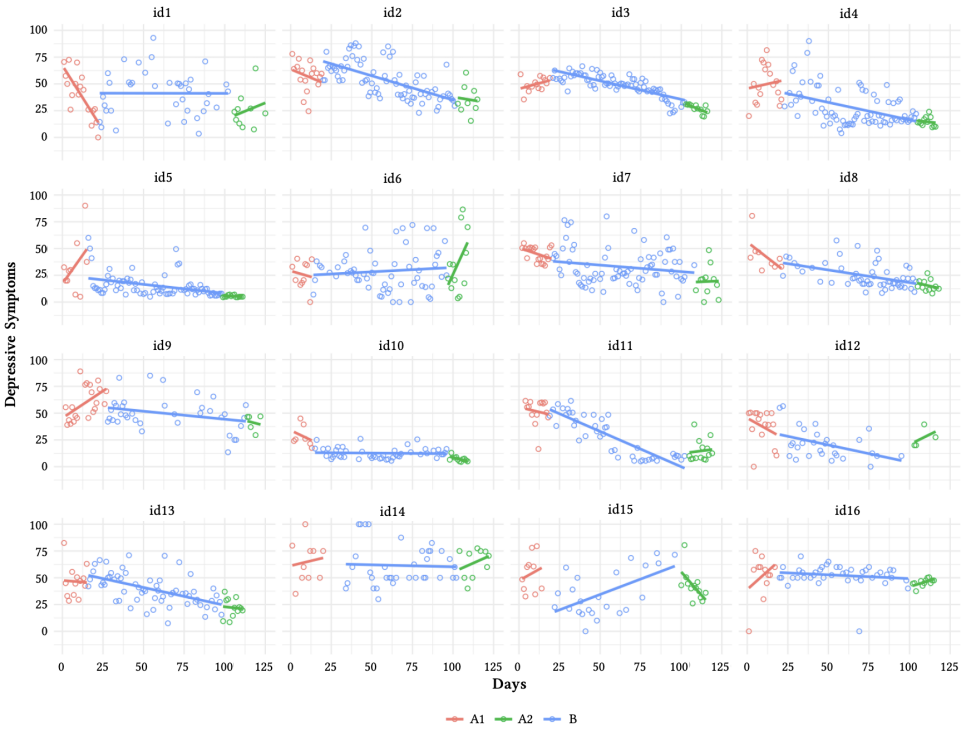
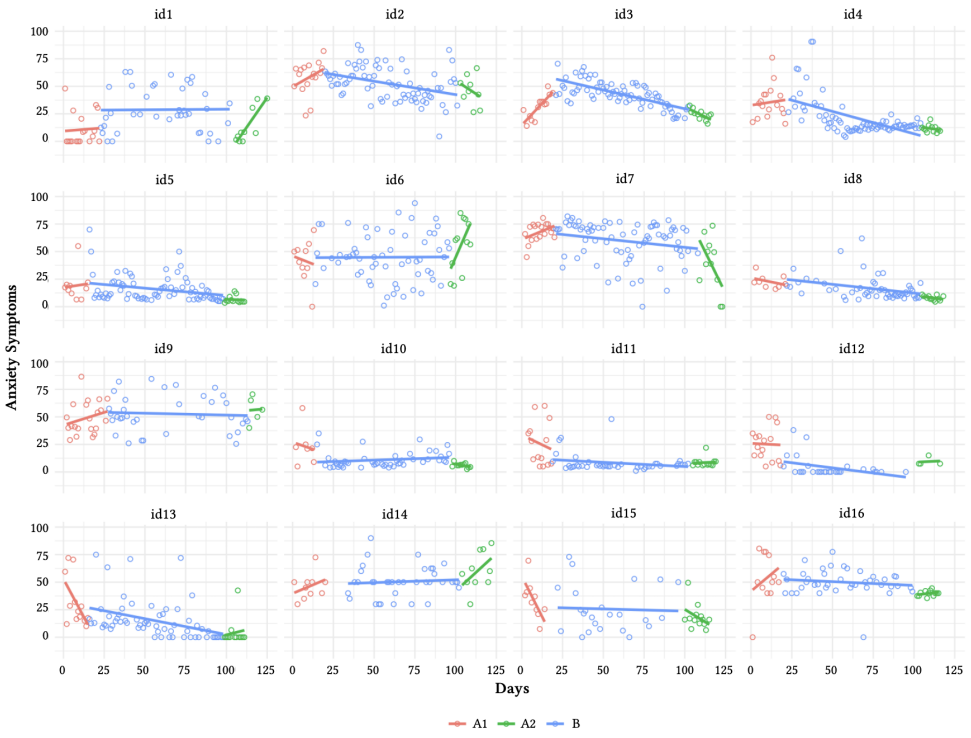


Figure 3

Anxiety Scores in Three Conditions With Regression Lines for Each Phase



A significant decrease of anxiety symptoms following the introduction of the intervention has been found for nine participants (id1, id2, id3, id4, id5, id10, id11, id12, id13, see details in Table 3). Different patterns of symptom reduction have also been found (see Figure 3). For id12, a negative and significant effect was found for level and slope. For id3, the beginning of intervention was associated with significant a higher level of anxiety symptoms, however, these symptoms gradually decreased during the intervention. A significant reduction of daily anxiety symptoms was observed only for the level or slope for id10, id11, and id1, id2, id4, id5, id13, respectively.

In summary, a significant reduction of depression and anxiety symptoms was found among seven participants (id2, id3, id4, id5, id10, id12, id13). A no significant effect of our intervention on mental health symptoms was found for four participants (id6, id9, id14, id16). Also, id6 showed a significant progressive increase of depressive and anxiety symptoms during the follow-up phase.

Table 3

Results of Piecewise Regressions for Depressive Symptoms

	Phase B vs A						Phase A2 vs A					
	Level			Slope			Level			Slope		
ID	*B*	2.5%	97.5%	*B*	2.5%	97.5%	*B*	2.5%	97.5%	*B*	2.5%	97.5%
1	14.36	-9.73	38.45	1.19	-.06	2.45	68.32	-27.02	163.66	3.14	-1.04	7.32
2	15.27*	4.81*	25.73*	-.48*	-.63*	-.33*	-16.67	-37.32	3.98	-.88	-4.46	2.71
3	9.62*	2.48*	16.76*	-.30*	-.43*	-.17*	-17.86*	-29.59*	-6.14*	-.58	-1.47	.31
4	-.40*	-.56*	-.23*	-.03*	-.04*	-.02*	-3.38*	-4.45*	-2.32*	-.03	-.07	.01
5	-.66*	-.84*	-.48*	-.08*	-.09*	-.05*	-7.46*	-9.26*	-5.65*	-.05*	-.09*	-.01*
6	.40	-18.73	19.53	.15	-1.13	1.42	-10.76	-131.59	110.07	3.37*	.98*	5.76*
7	-9.99	-22.93	2.94	-.08	-.27	.11	-32.09*	-55.81*	-8.37*	.30	-3.42	4.02
8	-.17*	-.32*	-.03*	-.01*	-.01*	-.01*	-.94*	-1.21*	-.68*	-.01	-.03	.01
9	-3.60	-13.23	6.04	-.52	-1.67	.62	-41.06	-95.19	13.06	1.84	-7.65	11.33
10	-15.81*	-20.70*	-10.91*	-.01	-.08	.06	-19.95*	-26.85*	-13.05*	-.21	-.68	.26
11	2.26	-5.91	10.42	-.86*	-1.03*	-.69*	-39.12*	-51.51*	-26.73*	.39	-.94	1.72
12	-12.99*	-16.80*	-9.18*	-.36*	-.50*	-.22*	-20.94*	-38.72*	-3.17*	4.35	-7.43	16.14
13	7.00*	.58*	13.43*	-.35*	-.45*	-.26*	-22.92*	-33.91*	-11.93*	-.07	-1.44	1.29
14	-2.59	-19.37	14.18	-.08	-.31	.15	2.19	-23.44	27.81	-.49	-2.71	1.74
15	-23.85*	-43.17*	-4.53*	.47*	-.05	1.00	3.10	-18.50	24.70	-.96	-2.26	.34
16	1.29	-12.16	14.73	-.25	-1.28	.79	-25.21	-118.30	67.88	.31	-1.22	1.84

*$p < .05$.

Significant slope changes were observed more often than level changes (8/10 for depressive and 7/9 anxiety symptoms), indicating that the impact of PA on mental health was generally gradual. Seven participants with a significant reduction of depressive symptoms during the intervention showed maintained benefits during the follow-up phase (id, 3, id4, id5, id8, id11, id12, id13). Four women experienced maintained benefits in terms of anxiety (id1, id4, id5, id13). The statistical modeling of time series explained 15% to 74%, and 12% to 54% of the variance for depressive and anxiety symptoms, respectively (more details are provided in the Supplementary Materials [(Bernard, 2025S]).

A visual analysis of repeated PHQ-9 and GAD-7 scores (see Figure S.1. and S.2. in the Supplementary Materials [Bernard, 2024S-b]) shows that most of the participants (with complete data) had a score below the clinical cut-off at the end of intervention.

Table 4

Results of Piecewise Regressions for Anxiety Symptoms

	Phase B vs A						Phase A2 vs A					
	Level			Slope			Level			Slope		
ID	*B*	2.5%	97.5%	*B*	2.5%	97.5%	*B*	2.5%	97.5%	*B*	2.5%	97.5%
1	7.70	-7.68	23.08	-.96	-1.70	-.21	-80.52	-138.72	-22.33	2.20	-.87	5.28
2	2.81	-8.38	13.99	-.23*	-.41*	-.06*	-8.18	-28.24	11.88	-1.03	-4.22	2.16
3	19.86*	10.50*	29.23*	-.27*	-.41*	-.13*	-2.47	-17.16	12.23	-.77	-2.02	.49
4	-.16	-.35	.03	-.05*	-.06*	-.04*	-3.98*	-5.23*	-2.73*	-.05*	-.09*	.00*
5	-.10	-.32	.12	-.06*	-.08*	-.03*	-5.48*	-7.63*	-3.32*	-.04*	-.08*	.00*
6	6.80	-5.74	19.33	-.03	-.20	.15	-8.73	-28.43	10.96	3.38*	1.45*	5.31*
7	-2.56	-13.39	8.26	-.14	-.30	.02	-11.71	-33.53	10.11	-3.75*	-7.27*	-.23*
8	4.84	-4.43	14.11	-.01	-.30	.27	.81	-35.27	36.90	.01	-.49	.51
9	6.78	-2.22	15.78	-.89	-1.92	.14	-40.63	-89.36	8.11	3.83	-5.02	12.68
10	-17.71*	-24.55*	-10.88*	-.17	-.68	.33	-37.82	-83.46	7.82	-.28	-.95	.40
11	-11.82*	-19.83*	-3.81*	.43	-.46	1.33	20.40	-44.40	85.20	.41	-.74	1.56
12	-21.19*	-27.05*	-15.34*	-.72*	-1.23*	-.20*	-45.22*	-85.39*	-5.06*	-1.19	-11.24	8.86
13	.06	-.20	.09	-.02*	-.02*	-.02*	2.57*	-3.22*	-1.99*	.08*	.01*	.15*
14	4.94	-6.39	16.28	-.02	-.17	.13	1.24	-17.48	19.97	1.44	-.25	3.13
15	-10.21	-22.74	2.32	-.14	-.46	.17	-9.41	-23.57	4.76	-.75	-1.85	.34
16	-.79	-8.00	6.41	-.08	-.20	.04	-14.47	-28.91	-.04	.08	-1.48	1.64

*$p < .05$.

Personal Event During Intervention

Eleven participants were available for the short interview at the end of intervention. The reported personal events are presented in the Supplementary Materials (Bernard, 2025S).

Discussion

The primary aim of this study was to evaluate the short-term effects a 12-week remote adapted PA intervention on daily levels of depressive and anxiety symptoms among women with BC and severe depressive or anxiety symptoms. We hypothesized that daily level of depressive and anxiety symptoms would decrease during the intervention and that these benefits would be maintained two weeks after intervention. Our findings show that our program progressively decreases the depressive and anxiety symptoms among 10 and nine participants, respectively. This significant decrease of symptoms could be considered as clinically relevant because observed benefits were corroborated with the decrease PHQ-9 and GAD-7 after the intervention. After Phase B, most of our patients showed improvement, moving from a severe to a moderately severe or moderate depression score, and from a moderately severe to a moderate anxiety score. Overall, this study supports the utility of remote PA intervention to improve depressive

and anxiety symptoms in women with BC and poor mental health. It is difficult to compare our results to previous studies as no other study has examined the effect of PA in this specific population. However, our positive findings are in line with previous meta-analyses suggesting significant benefits of physical activity on mental health in women with breast cancer (Carayol et al., 2013, 2015).

The remote format of our intervention is particularly promising because physical distance from care and the disproportionate distribution of mental healthcare providers are two major barriers for patients with cancer and severe psychological distress (Deshields et al., 2021). Another important finding is that the benefits from PA were generally not immediate, i.e., not associated with the beginning of intervention. It is in line with the Canadian treatment guidelines for mood disorders concluding that PA interventions length has to be superior to 10 weeks to decrease the depression severity (Ravindran et al., 2016). This progressive effect is also in line with previous n-of-1 studies examining the benefits of PA in young adults with high depressive symptoms (McFadden et al., 2017) or women with major depressive disorders (Doyne et al., 1983).

Our intervention did not show significant effect for all included women. The absence of mental health benefits from our intervention could be partially explained by personal events during the intervention: cancer treatment (id16) or mourning experiences (id14). Other factors could also be associated with responsiveness to the intervention such as a low adherence rate (e.g., id16), intensity of PA session (Bernard et al., 2013), or type of exercise. Indeed, Carayol et al. (2015) suggested that yoga related activities led to greater decrease of depressive and anxiety symptoms rather than aerobic/resistance-PA during BC treatment. The fear of cancer recurrence (Savard & Ivers, 2013) might also play a moderating role in the effectiveness of PA intervention for this population. Future studies should consider this factor as a judgment or inclusion criterion to optimize the benefits of PA program.

To our knowledge, this is the first study examining the effects of a PA intervention among women with BC and severe depressive or anxiety symptoms. Although this study employed a robust method, our results have to be replicated with a larger sample to understand the PA intervention response heterogeneity. Also, more complex models should also be used to examine the daily dynamic of mental health outcomes (Batley, 2024).

While our results are promising, this study is not without limitations. Firstly, repeatedly asking study participants about their mental health symptoms with EMA may increase their awareness about them (Runyan et al., 2013), thus influence outcomes and threat the internal validity in our N-of-1. Secondly, women with metastatic BC were excluded from our study because we could not fully guarantee the safety of these patients during remote PA sessions. Future studies should investigate how to implement a safe remote PA intervention for this population, who is less aerobically fit, more symptomatic and report higher levels of fatigue and dyspnea (Yee et al., 2014). Thirdly,

the collection of information regarding impactful life events that could influence our result was missing for 4 participants. Consequently, we could not check the internal validity our findings.

In conclusion, the present study is the first to report on the short-term effect of remote adapted PA for the treatment of severe depressive or anxiety symptoms. Future investigations could assess the efficacy of several strategies to improve the maintenance of mental health benefits, such as offering additional booster sessions as needed. Our findings are relevant for clinical practice, as they suggest that our intervention can be easily implemented for women with BC living far to psycho-oncology services.

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Competing Interests: No potential conflict of interest was reported by the author(s)

Ethics Statement: The research protocol has been approved by the Ethics Boards of the Eastern Montreal Integrated University Health and Social Services Centre (2022-4319).

Social Media Accounts: *Paquito Bernard:* Mastodon, Bluesky

Preregistration: The study protocol was registered a priori (see Bernard et al., 2022S).

Reporting Guidelines: This manuscript was written according to the Single-Case Reporting Guideline in BEhavioural Interventions.

Data Availability: Data, open materials, and R scripts are available online (see Bernard, 2024S-a, 2024S-b, 2025S).

Supplementary Materials

The Supplementary Materials contain the following items:

- Preregistration (Bernard et al., 2022S)
- Research data and R code (Bernard, 2024S-a)
- Additional figures (Bernard, 2024S-b)
- Additional information:
  - Detailed statistic findings (Bernard, 2025S)
  - SCRIBE checklist (Bernard, 2025S)
  - Interview findings (Bernard, 2025S)

Index of Supplementary Materials

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Assessing Perinatal Psychiatric Morbidity: Implications for Maternal Mental Health Care in Italy

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Supplementary Materials: Materials [see Index of Supplementary Materials]

Abstract

Background: Traumatic births impact women's long-term health, family dynamics, and healthcare systems, underscoring the need for prevention and effective interventions. Despite Italy's universal healthcare, perinatal mental health services and guidelines, especially for childbirth-related PTSD (CB-PTSD), remain underdeveloped. This study aims to investigate the prevalence of CB-PTSD, postpartum depression (PPD), and anxiety in Italian women 6-12 weeks postpartum, and assess the impact of comorbidities on mother-child bonding.

Method: The study was part of a broader longitudinal research that involved 175 Italian mothers 6-12 weeks postpartum, recruited from birthing centers. Participants completed measures for childbirth-related PTSD (City BiTS-IT), depression (EPDS), anxiety (PSAS-IT), and mother-child bonding (PBQ).

Results: Prevalence rates were 1.1% for CB-PTSD, 18.6% for depression, and 30.2% for anxiety. Depression was significantly associated with anxiety ($\chi^2(1, N = 159) = 9.131$, $p = .003$) and CB-PTSD ($\chi^2(1, N = 171) = 11.689$, $p < .001$). Hierarchical regression showed that depression and general PTSD symptoms significantly impaired mother-child bonding, explaining 36.3% of the variance ($R^2 = 0.363$).

Conclusion: The findings highlight the prevalence and complexity of perinatal psychiatric morbidity, emphasizing the critical need for comprehensive assessment tools tailored to the Italian context. These results contribute to a deeper understanding of maternal mental health challenges during the perinatal period.

Keywords

post-traumatic stress disorder, birth, recommendations, policy, perinatal, screening

Highlights

- 1.1% met full diagnostic criteria for childbirth-related PTSD, 68.4% had one or more symptoms.
- CB-PTSD was associated with depression and comorbidity impaired mother-infant bonding.
- Screening for CB-PTSD is often neglected. This paper offers a validated screening tool.

Pregnancy and childbirth bring significant physical, psychological, and social changes. The perinatal period, which extends from the beginning of pregnancy to one year postpartum, is a complex and vulnerable time that presents various challenges for both women and men in the transition to parenthood (Parfitt & Ayers, 2014).

Research suggests that approximately 1 in 3 births are perceived as psychologically traumatic (Alcorn et al., 2010) and meta-analyses show that 4% of women who give birth later develop childbirth-related PTSD (CB-PTSD), while clinically significant CB-PTSD symptoms are observed in 17% of women (Heyne et al., 2022).

The mother-child bond, the emotional and cognitive connection between a mother and her child, is of central importance for the child's development and the mother's well-being. Previous research has shown that poor parent-child attachment has been associated with impaired emotional, behavioural and cognitive development in the child, as well as affective disorders in adulthood (Dekel et al., 2020). Although previous studies have shown how postpartum depression and anxiety can affect mother-infant bonding (Dekel et al., 2020), less is known about the potential impact of birth-related PTSD.

Traumatic birth experiences and the resulting CB-PTSD symptoms can cause considerable distress and have a significant long-term impact on the health of women, their babies and their families. It is now well established that maternal CB-PTSD can affect both maternal and spousal relationships (Garthus-Niegel et al., 2018; Hairston et al., 2018) and can also lead to long-term negative effects on child behaviour and development (e.g. Cook et al., 2018).

Traumatic births can also affect medical staff (Uddin et al., 2022), resulting in significant costs to healthcare systems and potential economic consequences for society (Bauer et al., 2014). Therefore, the prevention of traumatic births and CB-PTSD is a global priority. This mandate is in line with the United Nations Millennium and Sustainable Development Goals for better health for women, mothers and children (United Nations DESA, 2022), the World Health Organisation's call for dignified and respectful maternity care for every woman (WHO, 2015) and the Council of Europe and European Parliament's resolution on the importance of women's sexual and reproductive rights (European Parliament, 2022). Although a recent systematic review of the cost-effective-

ness of interventions for perinatal disorders, including CB-PTSD, concluded that screening, psychological or social support and specialised treatment programs are all effective and cost-effective interventions to address these issues (Verbeke et al., 2022), screening for CB-PTSD is often neglected among perinatal mental disorders (PMDs). Currently, only a handful of countries have developed strategies to prevent traumatic births and treat CB-PTSD (Thomson et al., 2021). Even in the World Health Organisation's recommendations on maternal and newborn care for a positive postnatal experience (WHO, 2022), only depression and anxiety are mentioned in the few lines dedicated to mental health. The lack of clear policies or guidelines means that many people have limited access to the services they need (Sperlich et al., 2017).

Since 1978, the Italian National Health Service (Servizio Sanitario Nazionale, SSN) has guaranteed universal access to healthcare. The central government determines the national core benefits package and provides funding for the regional healthcare systems. The 19 Italian regions and two autonomous provinces are responsible for funding, planning and providing services at the local level, supported by a network of around 100 local health authorities (Signorelli et al., 2020). Significant differences exist in the provision of healthcare services across the country (Cicchetti & Gasbarrini, 2016). In Italy, there is no specialised service for perinatal mental health, so mental health care for women of childbearing age is provided by mental health departments (MHDs; Grussu et al., 2020). Family Care Centres (FCCs), which are integrated into SSN community services, provide free support to women during pregnancy and in the postnatal period and focus on the early identification of perinatal mental health problems (Grussu et al., 2020). A national guideline for perinatal mental health care is currently not available (Lega et al., 2024). In addition, healthcare providers often have limited training in selecting the most appropriate screening tool and determining the appropriate cut-off point for specific time periods (Cena et al., 2020). Despite these findings, recent research suggests that the prevalence of perinatal mental disorders (PMDs) in Italy is similar to other European countries (e.g. Camoni et al., 2023; Ciuffo et al., in preparation), so there is currently a lack of knowledge about how the national mental health service supports women during the perinatal period. The first study providing insights into the availability of evidence-based best practices for perinatal mental health (PMH) within the Italian mental health service dates back to 2024 (Lega et al., 2024). However, recommendations on prevention and screening for CB-PTSD are still lacking.

The predominant perinatal mental disorders that occur in women during pregnancy and postpartum are depressive syndromes and anxiety syndromes (Cena et al., 2020). Comorbidity of these disorders is common, reaching 40% in some studies (i.e., Misri & Swift, 2015). Research indicates that CB-PTSD is often comorbid with depression and anxiety disorders (i.e., Horesh et al., 2017), which increases the likelihood of postpartum psychiatric problems in women with CB-PTSD. Of women diagnosed with PTSD, 65% also exhibit symptoms of postpartum depression (PPD), while 22% of women with PPD

also exhibit symptoms of PTSD (Söderquist et al., 2006). Due to the frequent overlap of these syndromes, it is important to consider how these factors interact with maternal mental health (Grisbrook & Letourneau, 2021). The failure to include recommendations for CB-PTSD screening in existing guidelines may be due to a failure to recognise the prevalence and impact of CB-PTSD on maternal quality of life and family functioning, and the need for validated screening tools (Grisbrook & Letourneau, 2021).

Against this background, the present study aims to investigate the prevalence of CB-PTSD, PPD, and anxiety, along with their comorbidity, in a sample of Italian women 6–12 weeks postpartum, as well as to assess the impact of potential comorbidities on mother-child bonding.

Materials and Method

Ethics

Ethical approval was granted by the ethics committees of the Catholic University of the Sacred Heart (reference: 05-22) and the S. Giuseppe Hospital in Milan (reference: 550/2022). Before starting the survey, participants had to read an information sheet and electronically sign a consent form with Qualtrics. Data collection was conducted according to the principles of the Declaration of Helsinki and in accordance with the ethical guidelines of the IRB.

Procedure and Participants

The City BiTS-IT was included in a wider international project, the International Survey of Childbirth-related Trauma (INTERSECT), which has been registered at: https://www.researchregistry.com/browse-the-registry#home/registrationdetails/5ffc7453702012001b80a58c/

In Italy, the INTERSECT project was conducted by the Trauma Psychology Research Unit of the Catholic University of the Sacred Heart in Milan. The Italian component followed a longitudinal design with three waves of data collection. In the initial phase (T1), participants were recruited in birth centers, hospitals or clinics and completed the questionnaire via Qualtrics. They were then contacted 6-12 weeks after the birth (T2) and again 6 months after the birth (T3) for a follow-up survey. No social media or other online methods were used during recruitment to avoid self-selection bias. The inclusion criteria were: (i) participants in the third trimester of pregnancy, (ii) aged 18 years or older, (iii) with informed consent and (iv) proficient in Italian.

Measures

Alongside socio-demographic and obstetrical information, participants completed the following measures.

The City Birth Trauma Scale (City BiTS)

CB-PTSD was assessed using the validated Italian version of the City Birth Trauma Scale (BiTS; Ayers et al., 2018; Ciuffo et al., in preparation). The BiTS assesses PTSD symptoms based on DSM-5 criteria, including exposure to traumatic stressors, intrusive symptoms, avoidance, negative cognitions and mood, hyperarousal, and dissociative symptoms. The scale also assesses symptom occurrence, duration, distress, impact on daily life and possible physical causes. The total score resulting from criteria B-E ranges from 0 to 60. You can find more detailed information about the BiTS in the Supplementary Materials (Ciuffo et al., 2025S).

The Edinburgh Postnatal Depression Scale (EPDS)

Maternal depression was assessed using the Italian version of the Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987; Benvenuti et al., 1999). This self-report questionnaire assesses the severity of maternal depression during the postpartum period. Scores range from 0 to 30, with a score between 9 and 10 indicating clinically significant depression. The internal reliability was $\omega = 0.84$. Detailed information on the evaluation can be found in the Supplementary Materials (Ciuffo et al., 2025S).

The Postpartum Specific Anxiety Scale (PSAS)

The mothers' anxiety was assessed using the Italian version of the Postpartum Specific Anxiety Scale (PSAS; Fallon et al., 2016; Ionio et al., 2023). This questionnaire comprises 51 items that were developed to assess anxiety symptoms in the postpartum phase. The scale measures four areas of anxiety. Scores range from 51 to 204, with a threshold score of 112 indicating clinically significant anxiety. Further details about the PSAS can be found in the Supplementary Materials (Ciuffo et al., 2025S).

The Postpartum Bonding Questionnaire (PBQ)

Maternal and paternal attachment was assessed using the Italian adaptation of the Post-Birth Attachment Questionnaire (PBQ; Brockington et al., 2001; Busonera et al., 2017). The questionnaire comprises four subscales and uses a six-point Likert scale to assess attachment difficulties. Further information about the PBQ can be found in the Supplementary Materials (Ciuffo et al., 2025S).

Statistical Analyses

The analyses were carried out with IBM SPSS Statistics Version 29.0. Descriptive statistics (means, standard deviations, frequencies) were calculated to summaries the characteristics of the sample and the prevalence rates of psychiatric disorders. Recommended cut-offs were used to analyse the rates of depression and anxiety. Diagnostic criteria were used to calculate the prevalence of PTSD. Participants were categorised based on

their scores. Comorbidity of CB-PTSD, PPD and anxiety was analysed using cross-tabulations and chi-square tests to determine the proportion of women suffering from multiple disorders simultaneously. Hierarchical regression analyses were performed to examine the influence of CB-PTSD, PPD and anxiety (independent variables) on mother-infant attachment (dependent variable). Previous mental disorders, complications for the mother or child during labour and mode of delivery were included as covariates in the model.

Results

The sample consisted of 175 Italian women with a mean age of 32.75 years (*SD* = 4.68). The majority were either married or cohabiting (93.7%), and 60.6% had attained higher education. In terms of employment, most participants were engaged in professional, office, or technical occupations, while a small percentage were unemployed or homemakers. All participants were primiparous, and the majority (74.0%) had a vaginal birth, with 34.7% experiencing minor maternal complications during delivery. Infant complications were reported in 11.1% of cases. Additionally, 28.2% had experienced a previous pregnancy loss, and 12.8% reported uncertainty regarding a past diagnosis of mental illness. Table S1 (Supplementary Materials – see Ciuffo et al., 2025S) summaries the main demographic characteristics and obstetric information of the mothers.

Table 1 shows the prevalence rates of psychiatric disorders and the distribution of specific diagnostic criteria to provide a comprehensive understanding of symptom patterns and diagnostic thresholds.

The cross-tabulation analysis between postnatal depression and anxiety showed a significant correlation. Of the 175 participants, 159 gave valid responses (90.9%), while 16 were missing (9.1%). Of the women with valid data, 84 met the criteria for either depression or anxiety: 46 women met the criteria for anxiety but not for depression, 27 women met the criteria for depression but not for anxiety, and two women met the requirements for both. The remaining nine cases were women who did not fulfil the criteria for either disorder. The chi-square test for independence showed a statistically significant relationship between depression and anxiety, $\chi^2(1, N = 84) = 9.131$, $p = .003$. This was further confirmed by the likelihood ratio, $\chi^2(1, N = 159) = 11.258$, $p < .001$, and Fisher's exact test, p (bilateral) = .002. These results suggest that the presence of depression is significantly associated with an increased likelihood of anxiety in postpartum women.

The association between CB-PTSS and anxiety was examined in 158 valid cases (90.3%) and 17 missing cases (9.7%). The distribution was as follows: 33 women met criteria for neither CB-PTSS nor anxiety, 19 women met criteria for anxiety but did not have CB-PTSS, 78 women met criteria for CB-PTSS but not anxiety, and 28 women met criteria for both. The chi-square test showed no statistically significant association between PTSS and anxiety, $\chi^2(1, N = 158) = 1.711$, $p = .191$. The likelihood ratio, $\chi^2(1,$

$N = 158$) = 1.680, $p = .195$, and Fisher's exact test, p (bilateral) = .200, also showed no significant association. This suggests that the presence of PTSD symptoms related to childbirth was not significantly correlated with anxiety in this sample.

Table 1

Distribution of Psychiatric Disorder Diagnostic Criteria and Prevalence Rates

Characteristic	Percentage
CB-PTSD Criterion A: exposure to traumatic stressor	14.3
CB-PTSD Criterion B: Re-experiencing	58.6
CB-PTSD Criterion C: Avoidance symptoms	12.6
CB-PTSD Criterion D: Negative cognitions and mood	35.6
CB-PTSD Criterion E: Hyperarousal	61.1
CB-PTSD Criterion F: Duration	53.1
CB-PTSD Criterion G: Distress or impairment	57.5
Having one or more symptoms of trauma	68.4
Full criteria for CB-PTSD met	1.1
Depression above the cutoff	18.6
Anxiety above the cutoff	30.2

Note. The total sample for this table included 175 participants.

For the relationship between CB-PTSS and postnatal depression, there were 171 valid cases (97.7%) and 4 missing cases (2.3%). The results of the contingency table were as follows: 52 women did not meet criteria for either CB-PTSS or depression, two women met criteria for depression but not CB-PTSS, 87 women met criteria for CB-PTSS but not depression, and 30 women met criteria for both. The chi-square test showed a statistically significant association between CB-PTSS and depression, $\chi^2(1, N = 171) = 11.689$, $p < .001$. The likelihood ratio, $\chi^2(1, N = 171) = 14.541$, $p < .001$, and Fisher's exact test, p (bilateral) < .001, confirmed this significant association. These results suggest that women with postnatal depression are more likely to experience PTSD symptoms related to childbirth.

Finally, a hierarchical regression model was developed to examine the effects of individual and comorbid disorders on mother-infant attachment 6-12 weeks postpartum. In Step 1, depression was used as a predictor of attachment, in Step 2 anxiety was integrated, in Step 3 the CB-PTSS (birth-related symptoms and general symptoms) and in Step 4 the covariates were added. Depression was found to be a significant predictor of disturbed mother-infant attachment and explained 28% of the variance. This suggests that higher levels of postpartum depression are associated with poorer attachment. The addition of anxiety did not significantly improve the model, suggesting that anxiety is not a strong predictor of mother-infant attachment in this sample. When birth-related

and general PTSD symptoms were added, the model improved significantly, with general PTSD symptoms being a particularly strong predictor. This model explained 34.8% of the variance, suggesting that trauma-related symptoms play a significant role in mother-infant attachment. The inclusion of additional covariates (such as type of birth and pre-existing mental health diagnoses) did not further improve the model, suggesting that these variables do not have a significant impact on mother-infant attachment in this context. The following table (Table 2) summaries these results.

Table 2

Hierarchical Regression Predicting Mother-Child Bonding

Predictor	*B*	*SE B*	β	*t*	*p*
Step 1 (R^2 = 0.280)					
Depression	1.073	0.137	.529	7.836	< .001
Step 2 (R^2 = 0.280)					
Depression	1.072	0.138	.529	7.741	< .001
Anxiety	-0.002	0.032	-.004	-0.055	.957
Step 3 (R^2 = 0.348)					
Depression	0.740	0.167	.365	4.435	< .001
Anxiety	0.015	0.031	.031	0.465	.643
Birth-related PTSD symptoms	-0.257	0.187	-.100	-1.374	.171
General PTSD symptoms	0.592	0.148	.337	4.002	<.001
Step 4 (R^2 = 0.352)					
Depression	0.753	0.171	.371	4.412	< .001
Anxiety	0.015	0.032	.031	0.461	.645
Birth-related PTSD symptoms	-0.255	0.193	-.099	-1.323	.188
General PTSD symptoms	0.565	0.152	.322	3.708	< .001
Vaginal delivery	1.350	2.466	.062	0.547	.585
Assisted vaginal delivery	-0.257	3.517	-.006	-0.073	.942
Emergency CS	2.276	2.999	.079	0.759	.449
Pre-existing Diagnosis	-0.623	1.943	-.022	-0.321	.749

Note. Mode of delivery includes four categories: vaginal delivery, assisted vaginal delivery, emergency CS, and planned CS. Dummy coding was applied, with planned CS as the reference category. Pre-existing mental health diagnosis is a binary variable (yes/no).

Discussion

Perinatal mental disorders are widespread and represent a major health problem. Awareness, prevalence rates and treatment of these mental disorders vary greatly from country to country (i.e., Dikmen-Yildiz et al., 2017). The present study aimed to investigate the prevalence and comorbidity of CB-PTSD, PPD and anxiety in a sample of Italian

women 6-12 weeks postpartum. In addition, the effects of these potential comorbidities on mother-infant bonding were investigated.

In terms of prevalence rates, depression and anxiety were similar to previous literature (i.e., Hahn-Holbrook et al., 2018), while CB-PTSD was slightly lower than the observed global pooled prevalence (Heyne et al., 2022), albeit similar to previous studies (i.e., Dikmen-Yildiz et al., 2017). Although only 1.1% of women met the full diagnostic criteria for CB-PTSD, the vast majority of mothers (68.4%) had one or more CB-PTSS, demonstrating how prevalent this pathology is in this population. In addition, the results confirmed the co-occurrence of childbirth-related PTSD symptoms and depression in 17.54% of the sample, similar to previous research in this field (Dekel et al., 2020), suggesting that women with depression are more likely to have CB-PTSS and vice versa. In our sample, we found no significant association between CB-PTSS and anxiety. However, previous studies (Dikmen-Yildiz et al., 2017) have found increased comorbidity between these disorders 6 months postpartum. This suggests that the co-occurrence of these disorders becomes more evident later in the postpartum period as conditions become more structured. Longitudinal studies are needed to investigate these associations throughout the postpartum period. The presence of comorbidities indicates that if depression or PTSD is suspected, it is important to look at other symptoms for treatment purposes. It may also be beneficial to consider these disorders as part of a continuum of stress and to use the term 'postnatal mood disorders' proposed by Matthey et al. (2003), which includes birth-related PTSD. There is extensive evidence that early assessment of PPD can predict maternal attachment difficulties up to one year postpartum (e.g. Kasamatsu et al., 2020), but there is considerably less research examining the relationship between attachment and other psychopathologies such as CB-PTSD. Women with comorbid mental disorders are more likely to have impaired functioning and experience higher levels of stress than women with only one disorder (e.g. Horesh et al., 2017). Although PPD is widely recognised as a significant risk factor for poor attachment, the relationship between CB-PTSD and attachment is less well understood. Some studies have found a clear association between CB-PTSD and impaired attachment (Parfitt et al., 2014), while others have not observed such an association (Nakić Radoš et al., 2020). This inconsistency may be due to differences in the definition of CB-PTSD, the methods used to measure it, and the consideration of other factors, such as comorbid depression (Davies et al., 2008). Our findings suggest that the effects of CB-PTSD on attachment may vary from person to person. In particular, symptoms of CB-PTSD, especially when combined with depression, appear to disrupt emotional bonding between mothers and their infants. In contrast, birth-related PTSD symptoms alone appear to have less of an impact on attachment. This is consistent with recent research that distinguishes between birth-related and more general PTSD symptoms (e.g. Nakić Radoš et al., 2020), with general PTSD symptoms showing a stronger association with impaired attachment.

As mentioned above, the lack of recommendations for CB-PTSD screening in existing guidelines may be due to a lack of awareness of the prevalence and impact of CB-PTSD on maternal quality of life and family functioning, as well as the need for validated screening tools (Grisbrook & Letourneau, 2021). Indeed, a recent systematic review (Ciuffo et al., 2025) highlighted that a challenge in screening for CB-PTSD is the limited availability of validated questionnaires specifically designed to assess this disorder.

The lack of customised instruments also makes it difficult to determine the true prevalence of the disorder, which remains poorly researched and overlooked in Italian maternity facilities (Ciuffo et al., in press). Screening needs to take into account organisational factors that affect implementation as well as the availability of valid measurement tools to accurately identify the disorder. To date, the City Birth Trauma Scale (City BiTS; Ayers et al., 2018) is the only self-report specifically designed to measure CB-PTSD according to DSM-5 diagnostic criteria and validated for the Italian population (Ciuffo et al., in press). The City BiTS-IT has good reliability and strong psychometric properties. It is a quick and straightforward instrument, making it highly recommended for the early detection of childbirth-related PTSD (Ciuffo et al., in press).

In 2019, an international consortium of researchers and clinicians specialising in traumatic birth and CB-PTSD was established to advance knowledge and practise in this area (European Commission Cooperation in Science and Technology (COST Action grant CA18211). This group developed recommendations for practise, research and policy (Ayers et al., 2024). In terms of research, the use of "CB-PTSD validated, diagnosis-based instruments is required. To determine diagnoses and prevalence, cut-off values need to be established and adapted to different cultural settings". Substantial evidence of the prevalence and consequences of CB-PTSD will facilitate the assessment of the economic burden associated with this condition, thus providing a sound rationale and financial motivation for prioritising prevention and intervention efforts in areas that are currently under-supported in health systems worldwide (Ayers et al., 2024).

Strengths and Limitations of the Study

This study has several limitations. First, it relies on self-reported measures, which may be subject to response biases such as social desirability or memory distortions, which could affect the accuracy of reported symptoms and experiences. On the other hand, the questionnaires are easy to administer and score, making them ideal for early assessment and prevention of PMDs. Second, the cross-sectional design limits the possibility of establishing causal links between psychiatric disorders and disrupted mother-child attachment. While our results suggest significant associations, the direction of these associations remains unclear. For example, it is unclear whether psychiatric symptoms directly affect attachment or whether attachment difficulties exacerbate maternal psychological distress. Longitudinal data would provide a more comprehensive understanding of the trajectory of maternal mental health and attachment over time. Future research should

use longitudinal studies to track the development of symptoms, identify potential mediators or moderators in this relationship, and assess the long-term impact on maternal and infant well-being. Second, the cross-sectional design may limit the ability to draw causal conclusions. Future research should consider longitudinal studies to better understand possible pathways of comorbidity of these disorders as well as their long-term effects on family functioning. Finally, study participants were recruited in birth centers, hospitals and clinics without using social media or other online methods. While this approach helps to reduce self-selection bias, it may also exclude women who do not seek inpatient care or are less familiar with these healthcare facilities. This study uses validated measures, ensuring a reliable and standardised assessment. Furthermore, to the best of the authors' knowledge, this is the first study to investigate the prevalence and impact of CB-PTSD and its comorbidities in the Italian context, providing new insights into perinatal mental health in Italy.

Conclusions

The high rates of mental disorders after birth emphasise several important implications for policy and clinical practice. Effective perinatal screening is crucial for identifying women with mental health problems. Early detection and intervention can reduce the likelihood of postnatal mental disorders. Timely treatment of women affected by these disorders is important to ensure their mental well-being and that of their families and to prevent these disorders from becoming chronic. National and international guidelines on maternal mental health are needed to raise awareness of perinatal mental health problems, including CB-PTSD, and to present evidence-based, practical strategies for detection, prevention and treatment. Future research and policy statements should also include men and/or other birth partners.

This review adds to the literature highlighting the great need to prioritise women's mental health in both research and clinical practice, and reflects calls for greater attention to this area within the psychological community (e.g. Ayers et al., 2024). Our study, which focuses on the prevalence of perinatal psychiatric disorders and their impact on mother-infant attachment, provides a foundation for future research and policy decisions aimed at improving women's mental health. This could be a first step in addressing a historically overlooked aspect of public health and ensuring that women receive the support they need during this critical stage of life.

Overall, this research has shown that a significant number of women in Italy suffer from significant depression, anxiety, CB-PTSD or a combination of these conditions during the perinatal period. Healthcare providers and policy makers should recognise the significant psychological distress experienced by Italian women during the perinatal period and the potential long-term impact on women and their families.

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Author Contributions: Conceptualisation: [GC, CI]; Methodology: [GC, CI]; Formal Analysis: [GC]; Investigation: [CI, GC] Writing – Original Draft: [GC]; Writing – Review & Editing: [GC, ML, CI]; Supervision: [CI].

Ethics Statement: Women who chose to participate in the study gave their informed consent. All procedures used in human subjects research followed the ethical requirements of the institutional and/or national research committee and the 1964 Declaration of Helsinki and its subsequent revisions or comparable ethical standards.

Related Versions: This research was conducted as part of the International Survey of Childbirth-Related Trauma (INTERSECT, www.intersectstudy.org).

Reporting Guidelines: This paper was written following STROBE reporting guidelines (Strengthening the Reporting of Observational Studies in Epidemiology).

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Preregistration: This study is part of the broader international project *International Survey of Childbirth-related Trauma (INTERSECT)*, which was preregistered on the Research Registry. The preregistration includes the general study aims and methodological framework of the international survey and is publicly accessible at: https://www.researchregistry.com/browse-the-registry#home/registrationdetails/5ffc7453702012001b80a58c. However, the analysis of the Italian subsample and the specific research questions addressed in the present article were not preregistered.

Data Availability: The raw data supporting the conclusions of this article, as well as the code used for data analysis and the materials employed during the study are available from the authors upon reasonable request. These resources will be provided directly to researchers who contact the corresponding author, without undue reservation.

Supplementary Materials

Supplementary File 1 – Table 1 and Measures (see Ciuffo et al., 2025S): This Supplementary Material includes a table summarizing the demographic characteristics and obstetric information of the 175 Italian mothers who participated in the study. It provides details such as maternal age, region of residence, marital status, occupation, educational attainment, and various obstetric variables, including mode of delivery and maternal/infant complications during birth.

Additionally, the Supplementary Material offers detailed information on the self-report questionnaires used in the study: the City Birth Trauma Scale (City BiTS), the Edinburgh Postnatal Depression Scale (EPDS), the Postpartum Specific Anxiety Scale (PSAS), and the Postpartum

Bonding Questionnaire (PBQ). Each measure is described in terms of its structure, scoring, and internal reliability.

Index of Supplementary Materials

Ciuffo, G., Landoni, M., & Ionio, C. (2025S). *Supplementary materials to "Assessing perinatal psychiatric morbidity: Implications for maternal mental health care in Italy"* [Additional information]. PsychOpen GOLD. https://doi.org/10.23668/psycharchives.21076

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Appendix: List of Abbreviations

CB-PTSD – Childbirth-related Posttraumatic Stress Disorder
CB-PTSS – Childbirth-related Posttraumatic Stress Symptoms
PPD – Postpartum Depression
PMDs – Perinatal Mental Disorders
PMH – Perinatal Mental Health
MHDs – Mental Health Departments

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The Context of COVID-19 at 18 Months in Relation to Depression, Anxiety, Insomnia: The Emerging Role of Post COVID-19 Symptoms

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Abstract

Background: The COVID-19 pandemic naturally raised concerns about mental health and wellbeing around the world. As time passed, persisting physical and mental symptoms of post COVID-19, referred to as Post COVID Condition (PCC), have become an increasing concern. The aim of this study was to investigate the stability of symptoms of mental ill health in Sweden in the late phase of the pandemic and the prevalence of persistent symptoms post COVID-19 and interrelations between them.

Method: We measured depression, anxiety, and insomnia, through a one-time online survey in Sweden (n = 1,482, mean age 47.6 years; 89.5% women) and used correlation and regression analysis to study potential predictors and their interrelations with PCC symptoms.

Results: Compared to our previous study during the pandemic (May – June 2020), a marginal decrease was found for depression (27% versus 30%), a larger decrease for anxiety (16% vs 24%), and an increase for insomnia (45% vs 38%). Persistent symptoms were frequently reported, with 84.5% reporting at least one symptom, and 49.7% attributing one or more of these to COVID-19 infection. A history of poor mental health and COVID-19 related worry appeared as the strongest risk factors for mental ill health. Persistent symptoms also predicted these outcomes.

Conclusions: Based on comparison with pre-pandemic rates, it appears that the pandemic continued to exert a negative impact on mental health in Sweden. Persistent symptoms, associated with COVID-19 exposure, appear common and may represent a vulnerability factor for mental ill

health, along with other factors, including history of a mental ill health and specific pandemic worries.

Keywords

COVID-19, pandemic, mental health, depression, anxiety, insomnia, Post COVID-19 Condition

Highlights

- Mental health problems persist 18 months post-pandemic.
- High rates of depression, anxiety, and insomnia are documented.
- Symptoms of Post COVID-19 Condition appear highly prevalent, notably fatigue.
- Risk factors for persistent symptoms include health history and pandemic-related worries.

Background

During the COVID-19 pandemic mental health and wellbeing was a concern, especially for the most vulnerable (World Health Organization, 2020; Yu et al., 2021). Global mental health was rapidly studied during the early pandemic, documenting considerable suffering (Mukherjee et al., 2021). Years following the pandemic the question becomes what does the picture look over time? Did mental health and wellbeing worsen, or did people demonstrate resilience and adjust? Tentative evidence suggests that some recovery took place (Manchia et al., 2022; Yarrington et al., 2021). On the other hand, there is also evidence of persistent impacts 6 and 12 months later in COVID-19 survivors (Mazza et al., 2022; Taquet et al., 2021) suggesting long lasting effects. Thus, more careful study is needed to determine what has happened and what to do about it (Gruber et al., 2021; O'Connor et al., 2021; Tegnell, 2021).

During May and June 2020, we conducted a survey in Sweden with the purpose to assess mental health and wellbeing and factors related to these (McCracken et al., 2020). Based on responses from 1,212 adults we found high rates of depression, anxiety, and insomnia, at 30%, 24%, and 38%, respectively. We further found that these outcomes were associated with poor self-rated overall health, a history of mental health problems, presence of COVID-19 symptoms, and specific worries around health and finances (see also Rondung et al., 2021). It is not known whether circumstances improved or declined for mental health, in Sweden or globally, during the years that followed.

An unexpected result from the pandemic is a high rate of Post COVID-19 Condition or PCC (Fernández-de-las-Peñas et al., 2021; Nalbandian et al., 2021). This includes persisting symptoms potentially involving multiple organ systems, including fatigue, breathing problems, cognitive disturbance, problems with the gastrointestinal tract, joints, skin, problems with mood and sleep, and other problems, that follow infection by the coronavirus (Carfì et al., 2020; Hayes et al., 2021; SBU, 2020). The prognosis of persisting

symptoms remains unclear, and it appears that additional research and new models of care are needed (Nalbandian et al., 2021). It is unknown how these symptoms correlate with, or perhaps contribute to, mental health outcomes.

The purpose of this study was to repeat our study conducted in Sweden during June 2020 and reassess the state of mental health and wellbeing 18 months following the start of the pandemic using an independent population sample. The outcomes were levels of depression, anxiety, and insomnia as they are sensitive to stressful events and serve as important predictors of both emotional and physical health. The second purpose was to examine the prevalence of PCC (i.e., symptoms lasting for at least six weeks following infection (e.g., physical, and mental dysfunctions and cognitive impairments – see method section for full description) and their relations with mental health outcomes. Additional questions addressed included the identification of risk factors previously associated with health outcomes, such as a previous history of mental health problems and COVID-19 related worry.

Method

Data collection for this one-time cross-sectional survey in Sweden occurred from June to August 2021. Participants were recruited online via notices on social media and Uppsala University hospital and Uppsala university homepages. It was only required that participants were adults, living in Sweden, and able to respond to survey material online in Swedish. Study data were collected and managed using Research Electronic Data Capture (REDCap), a widely used electronic survey tool hosted locally at Uppsala University (Harris et al., 2009, 2019). Recruitment of participants continued until the rate of recruitment reduced and before the recruitment interval became extended beyond two months.

Participants

Initially, 1,657 people provided their consent and entered the survey. In general, there was an increase in missing data with each subsequent measure in the survey, due to dropout, as opposed to skipped or missed items. There was a 10.6% non-completion rate of the three mental health outcome measures and the sample size retained was n = 1,482. However, sample size varied slightly from analysis to analysis due to small amounts of missing data on other individual variables.

Participant characteristics are included in Table 1. Notably, the percentage of women who participated was 89.5%. Mean age of the total sample was 47.6 years, SD = 11.7, and range was 18 to 81. The participants were well educated with 61.1% having completed university or post graduate education. The vast majority of participants were from Sweden or another Scandinavian country, 90.1%. Most were married or in a relationship,

75.0%, or single, 18.3%, and a little less than half had young children, 45.9%. Most participants were working either full or part time, 80.3%, and the next largest category was retired, 6.8%. A substantial proportion reported a history of mental health difficulties, 43.2%. Fewer, 27.9% of the total sample, were currently experiencing these, and 23.9% reported they had a formal diagnosis.

Measures

Demographic variables included those detailed in Table 1. To further clarify, participants were also asked whether they (a) lived in suburbs, city, or countryside; (b) had children living at home; and (c) the number of people living in their home in total; whether (d) they had received a formal diagnosis of a mental health condition; (e) were experiencing one of these currently; or (f) were suffering with any of the identified conditions placing people at risk of a poor outcome from COVID-19, including age over 70, hypertension, angina, stroke, heart disease, diabetes, cancer, smoking, respiratory disease, and immune suppressant. Specific worries about COVID-19 were assessed with items used in our previous study (McCracken et al., 2020). Here participants rated their worries about their own health, others' health, their personal finance, world economy, and the future, on a 5-point scale from 1 (Not at all worried) to 5 (Extremely worried). The respondents' answers to the five worry items were summed up to calculate a total worry score (α = .77).

Persistent Symptoms

Persistent symptoms were defined as symptoms lasting for at least six weeks in one or more of 25 different domains. These were based on the PCC report from the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU, 2020) based on available literature at the time and reported on 21 December 2020. The following symptoms were included: fatigue, sleeping problems, problems with attention, joint pain, memory difficulties, depression, headache, impaired daily functioning, anxiety, shortness of breath, pins and needles, gut problems, heart palpitations, changes in smell, changes in taste, decreased lung function, chest pain/pressure, cough, nausea, skin changes, appetite loss, sore throat, weight loss, fever, and reduced quality of life. Participants were presented with the following: "Do you have one or more of the following long-term symptoms? With long-term symptoms we mean symptoms that have persisted for at least six weeks". If the participant answered "Yes" to any of the symptom questions, they were further asked whether they attributed symptoms they experienced to a previous COVID-19 infection.

Standardized Measures

Three well-established, widely used, and properly validated measures were utilized to assess depression, anxiety, and insomnia (see previous report for full descriptions;

McCracken et al., 2020, 2021). These measures included the Patient Health Questionnaire (PHQ-9; Kroenke & Spitzer, 2002) for depression, the Generalized Anxiety Disorder scale (GAD-7; Kroenke et al., 2007) for anxiety, and the Insomnia Severity Index (ISI; Bastien et al., 2001) for insomnia.

The PHQ-9 scores range from 0 to 21, with recommended cutoff points for depression severity set at 5 (mild), 10 (moderate), 15 (moderately severe), and 20 (severe) (Kroenke & Spitzer, 2002). In addition to the nine items on the PHQ-9, an additional global rating item assesses functional impairment. The GAD-7 scores also range from 0 to 21, with a cutoff score of 10 identified as optimal for sensitivity and specificity (Kroenke et al., 2007). The ISI total score ranges from 0 to 28 and is categorized as follows: absence of insomnia (0-7), sub-threshold insomnia (8-14), moderate insomnia (15-21), and severe insomnia (Morin et al., 2011).

Statistical Analysis

Data were analyzed using IBM SPSS version 26.0. First, sample characteristics including rates of infection, vaccination, other health-related descriptors, and rates of cases meeting clinical cutoffs for depression, anxiety, insomnia, and persistent physical symptoms were analyzed. Next Pearson correlation coefficients were calculated to identify background or health status factors significantly associated with depression, anxiety, and insomnia scores. Categorical background variables, such as work and relationship status, were dichotomized as labelled, for example, into "out of work" versus not, and "in a relationship" or not. A second set of correlation analyses included depression, anxiety, and insomnia with each of the individual persistent physical symptom reports and the summary of the total number reported, excluding sleep, depression, anxiety, quality of life, and daily functioning, to avoid inflating the correlations. Additional correlation analyses examined relations between participant attributions of symptoms to a COVID-19 infection, this time analyzing the full symptom set again examining whether the symptom was regarded as a direct result of infection with the COVID-19 virus or not. Finally, hierarchical multiple regression analyses were conducted, with depression, anxiety, and insomnia scores as the criterion variables. In these analyses, age, being in a relationship, being out of work, and having above average financial status were included as background variables in the first block of predictors, based on the correlation analyses. The second block of predictors included relevant health status variables, including self-rated physical health, reported mental health history, and a summary score of risk factors for poor COVID-19 outcome. The third block included reported infection with COVID-19. The fourth block included the summary score for COVID-19-related worry. And finally, a selected set of persistent physical symptom reports plus the summary total of symptoms reported was included in the final block of predictors. The included individual symptoms were selected based on having achieved a medium sized correlation or larger with either depression, anxiety, or insomnia in the correlation analyses.

Results

Descriptive Statistics

Table 1 includes descriptive statistics on COVID-19 infection and vaccination related data.

Table 1

Sample Characteristics (N = 1,657) and Mental Health Results

Variable	*n*	%
Sample Characteristics		
Gender		
Female	1483	89.5
Male	154	9.4
Non-binary	6	0.4
Education		
Pre-secondary	39	2.3
Secondary	326	19.8
University	1206	73.5
Post graduate	71	4.3
Country of Birth		
Sweden	1430	87.1
Other Scandinavian country	49	3.0
Other European country	121	7.4
Other	41	2.6
Domestic Status		
Married	742	45.2
In a relationship	411	25.0
Single	301	18.3
Divorced/separated	99	6.0
Living apart	79	4.8
Widowed	10	0.6
Work Status		
Working full time	1072	65.3
Working part time	247	15.0
Retired	111	6.8
Student	77	4.7
Sick leave	69	4.2
Unemployed	31	1.9
Parental leave	29	1.8
Unpaid work	6	0.4

Variable	*n*	%
Self-Rated Economic Status		
Average	762	46.4
Above average	584	35.6
Below average	185	11.3
Much below average	58	3.5
Much above average	53	3.2
Self-Rated Health Status		
Good	595	37.0
Average	568	35.3
Very good	239	14.9
Poor	177	11.0
Very poor	30	1.9
History of a Mental Health Condition		
No	927	56.8
Yes	705	43.2
COVID-19 Vaccine		
Two dose	862	53.6
One doses	407	25.3
Three doses	339	21.1
Infected with COVID-19		
No	784	48.8
Yes, diagnosed	580	36.1
Yes, unconfirmed	242	15.1
Physical Risk Factors[a]		
None	1065	66.5
One	380	23.7
Two	118	7.4
Three or more	39	2.4
Mental Health Outcome Results		
Depression (PHQ-9; *M* = 6.8, *SD* = 5.9)		
Minimal (Range 0 – 4)	630	44.7
Mild (Range 5 – 9)	393	27.9
Moderate (Range 10 – 14)	221	15.6
Moderately severe (Range 15 – 19)	107	7.6
Severe (Range 20 – 27)	59	4.2
Anxiety (GAD-7; *M* = 4.9, *SD* = 4.8)		
None (Range 0 – 4)	810	57.0
Mild (Range 5 – 9)	380	26.8
Moderate (Range 10 – 17)	190	13.4
Severe (Range 15 – 21)	30	2.8

Variable	*n*	%
Insomnia (ISI; *M* = 9.4, *SD* = 6.5)		
None (Range 0 – 7)	629	44.5
Sub-threshold (Range 8 – 14)	474	33.6
Moderate (Range 15 – 21)	235	16.6
Severe (Range 22 – 28)	75	5.3

[a]Sum of risk factors: age over 70, hypertension, angina, stroke, heart disease, diabetes, cancer, smoking, respiratory disease, and immune suppressant.

Mental Health Results

Table 1 includes summary results from the measures of depression, anxiety, and insomnia. Mean values fall in the mild or subthreshold range, and most people fall below the clinical cutoff in each case. On the other hand, 27.4%, 16.2%, and 45.0%, met criteria for clinically significant depression, anxiety, and insomnia, respectively, based on cutoff scores $\geq$ 10. Further, 13.6% reported some frequency of thoughts of being better off dead or self-harm (PHQ-9 item 9), and 67.3% reported that depression symptoms were associated with some level of difficulty in work, home, or social activities (PHQ-9 item 10). For potential comorbid presentations of these three conditions, 50.6% met criteria for at least one, 25.6% for at least two, and 12.7% for all three. Naturally these measures are intercorrelated, with depression and anxiety scores correlated at r = .82, depression and insomnia at r = .67, and anxiety and insomnia at r = .65.

Data on worries about own health, health of friends or family, own finances, national or international finances, or the future, was provided on a scale from 1 to 5, from not at all worried to extremely worried. The highest area of worry was around health of friends or family, M = 2.85, SD = 1.25, followed by national or international economy, M = 2.68, SD = 1.19, and the future, M = 2.68, SD = 1.30. Worry about own health, M = 2.43, SD = 1.91, and own finances, M = 1.99, SD = 1.23, were lowest ranked.

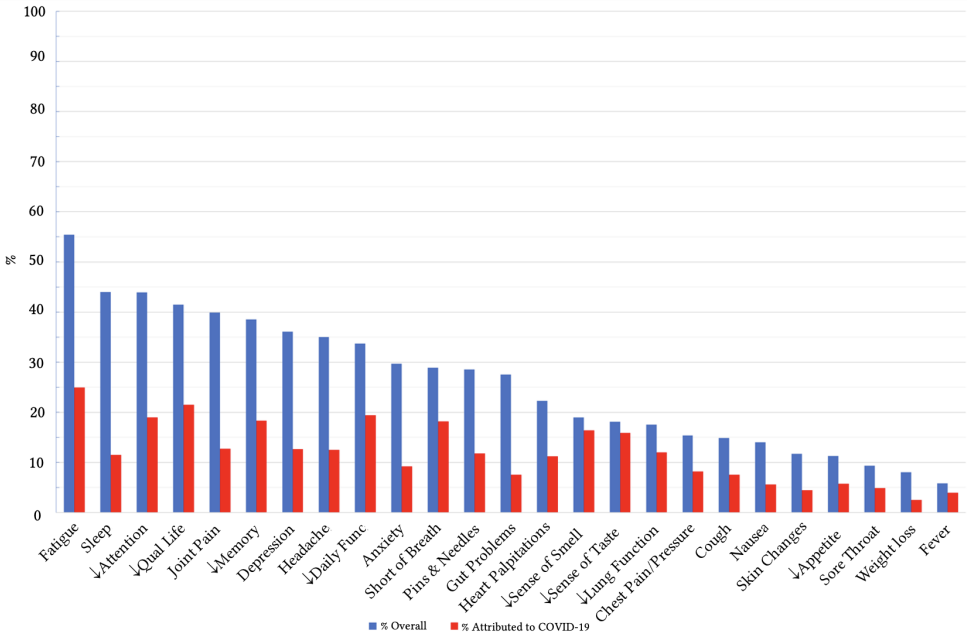
PCC Results

Overall, 84.5% of survey participants reported at least one persisting COVID-19 symptom from the set of 25 and the mean number of symptoms reported was M = 6.5, SD = 5.3. At least one symptom was reported by 78.0% of those who reported they were never infected with COVID-19 and 90.5% of those who reported that they had been. These percentages, although both high, were significantly different, $\chi^2(1, N = 1{,}552) = 46.3$, $p < .001$. With the removal of the symptom items related to sleep, depression, anxiety, quality of life, and daily functioning, high percentages of participants reported at least one of the remaining 20 symptoms, including 73.1% of those who reported never having COVID-19 and 88.2% of those who reported having it, $\chi^2(1, N = 1{,}552) = 57.0$, $p < .001$.

Figure 1 includes the percentages for persons reporting each of the 25 persistent symptoms potentially associated with COVID-19 infection. The figure includes both the percentage reporting the symptom and the percentage of those who attributed the symptom to COVID-19. The most frequent persistent symptom overall was fatigue, reported by 55.4% and 48.0% of those (24.9% of the overall sample), attributed the fatigue directly to COVID-19. A total of nine symptoms were reported by 30% or more of respondents, and these included, in addition to fatigue, sleep disturbance, difficulties with attention, reduced quality of life, joint pain, difficulties with memory, depression, headache, and reduced daily functioning. For about half of the respondents who reported decreased quality of life or daily functioning these effects were attributed to COVID-19. For all the other symptoms the percentage was lower. There were several symptoms where the majority of those who reported the symptom also attributed it to COVID-19, at rates all greater than 67%. These included shortness of breath, reduced sense of smell, reduced sense of taste, and reduced lung function.

Figure 1

Reported Rates (%) of 25 Symptoms Potentially Linked to COVID-19



Note. The downward arrow symbol (↓) indicates a reduction in that domain (e.g., ↓Attention = reduced attention, ↓Daily Func = reduced daily functioning, ↓Appetite = reduced appetite, ↓Qual Life = reduced quality of life).

Factors Associated With Mental Health Outcomes

Table 2 includes correlations between the depression, anxiety and insomnia scores with participant background and health status variables. Alpha was set at $p < .001$, given the large sample size and large number of correlations calculated.

Table 2

Correlations Addressing Potential Predictors of Depression, Anxiety, and Insomnia

Potential Predictor	Depression (PHQ-9)	Anxiety (GAD-7)	Insomnia (ISI)
Age	-.17*	-.21*	-.04
Gender (female)	.07	.06	.09
Education (University Graduate)	-.06	-.04	-.09
Married or in a relationship	-.11*	-.04	.10*
Unemployed	.20*	.16*	.18*
City dwelling	.05	.05	.02
Children at home	-.03	.01	.02
Self-rated finance above average	-.15*	-.13*	-.07
Self-rated health above average	**-.52***	**-.43***	**-.40***
History of a mental health condition	**.33***	**.35***	.25*
Current mental health condition	**.55***	**.57***	**.35***
Infected with COVID-19	.15*	.10*	.13*
Risk factors for poor COVID-19 outcome[a]	.10*	.07	.12*
Worry about own health	**.39***	**.38***	**.31***
Worry about others health	.28*	**.34***	.26*
Worry about personal finance	**.48***	**.45***	**.39***
Worry about world economy	.21*	.21*	.21*
Worry about the future	**.45***	**.41***	**.34***
Worry total	**.50***	**.49***	**.42***

Note. Correlations that reflect medium or large effect sizes in bold text.

[a]Sum of risk factors: age over 70, hypertension, angina, stroke, heart disease, diabetes, cancer, smoking, respiratory disease, and immune suppressant.

*$p < .001$.

There were several factors that were unrelated to the mental health outcomes, including gender, education, home setting (city versus suburbs or country), or having children at home. There were several other factors that achieved significant but small or inconsistent correlations, including age, relationship status, employment status, self-rated financial status, COVID-19 inflection, number of medical conditions increasing risk for poor COVID-19 outcomes, and worry about the world economy. Factors that achieved medium-sized or larger correlations included self-rated health, history of mental health problems,

current mental health, and worries about own health, others health, personal finances, and the future. Amongst all of these, reported history of mental health problems was the strongest correlate.

Table 3 includes correlations between depression, anxiety, and insomnia with the 25 persistent symptoms. Every symptom correlated with all three outcomes at $p < .001$, except for changes in sense of smell which failed to significantly correlate with anxiety.

Table 3

Correlations of Persistent Symptoms During COVID-19 and Depression, Anxiety, and Insomnia

Symptom	Depression (PHQ-9)	Anxiety (GAD-7)	Insomnia (ISI)
Fatigue	**.53***	**.43***	**.43***
Shortness of breath	.35*	.29*	.29*
Cough	.16*	.13*	.19*
Heart Palpitations	**.35***	**.33***	.26*
Weight Loss	.19*	.20*	.18*
Gut problems	**.31***	.27*	.29*
Memory problems	**.48***	**.39***	**.38***
Attention problems	**.55***	**.48***	**.40***
Chest pain or pressure	**.30***	.27*	.19*
Sleep difficulties	**.49***	**.45***	**.67***
Skin changes	.21*	.17*	.16*
Changes to sense of taste	.14*	.09*	.11*
Changes to sense of smell	.11*	.07	.11*
Joint pain	.29*	.23*	**.30***
Pins and needles in extremities	.29*	.27*	.26*
Nausea	**.34***	**.31***	.24*
Decreased lung function	.18*	.15*	.17*
Headache	**.35***	**.32***	**.30***
Decreased appetite	**.37***	**.27***	.23*
Fever	.19*	.15*	.13*
Sore throat	.18*	.12*	.11*
Depression	**.63***	**.56***	**.43***
Anxiety	**.53***	**.60***	**.34***
Decrease quality of life	**.51***	**.41***	**.36***
Decreased daily functioning	**.46***	**.36***	**.36***
Total number of symptoms[a]	**.59***	**.49***	**.48***

Note. Correlations that reflect medium or large effect sizes in bold text.

[a]Total number of symptoms here excludes items related to sleep, depression, anxiety, quality of life, and daily functioning.

*$p < .001$.

There were several symptoms that achieved medium or large correlations across all three outcomes. These included fatigue, memory problems, attention problems, sleeping difficulties, headache, depression, anxiety, decreased quality of life, decreased daily functioning, and the total number of symptoms.

Multivariate Prediction Analyses

Three separate hierarchical multiple regression analyses were conducted with depression, anxiety, and insomnia as dependent variables (see Table 4). These were to examine the combined role of background, health status, COVID-19 infection, worry, and persistent post-COVID-19 symptoms in accounting for variance in these outcomes.

Amongst these blocks of variables, history of COVID-19 infection was the least informative, accounting for less than 1% of variance in all cases. The four background variables, including age, relationship status, employment status, and self-rated financial status, accounted for 8.4%, 7.6%, and 4.1% of variance in depression, anxiety, and insomnia, respectively. Older age significantly predicted lower scores for depression and anxiety, and being single, unemployed, and, unexpectedly, being well off financially, each contributed significantly to higher score for insomnia, although the variance accounted for was modest.

The health status block including self-rated health, mental health history, and the summary score of physical conditions representing risks for poor COVID-19 accounted for 27.0%, 21.0%, and 17.0% of variance. Here the health rating and mental history were significant predictors, but the physical risk factors were not. The single best variable in the equations was the total COVID-related worry scores, accounting for 9.2%, 10.0%, and 7.5% of variance in the outcomes. With all other potential predictors included, on average the twelve persistent physical symptoms with medium effect sizes and the summary score for the number reported (adjusted to exclude depression, anxiety, sleeping problems or reduced quality of life or daily functioning) were relatively good predictors of outcomes as a set, accounting for 14.0% or variance in depression, 9.0% for anxiety, and 7.7% for insomnia. The specific symptoms most strongly related to the three outcomes were fatigue and headache, which both significantly predicted all three, and attention problems, which was a relatively strong predictor of both depression and anxiety, but not insomnia. Finally, we reran the regression analyses selecting only the participants who had reported a history of COVID-19 infection and the results did not change appreciably. For example, the variance accounted for by the persistent physical symptoms remained similar or the same, 14.0% for depression, 8.4% for anxiety, and 7.5% for insomnia.

Table 4

Multiple Regression Analyses of Depression, Anxiety, and Insomnia

		Dependent Variable					
		Depression		Anxiety		Insomnia	
Block	**Predictor**	**ΔR^2**	**β**	**ΔR^2**	**β**	**ΔR^2**	**β**
1	**Background**	.084**		.076**		.041**	
	Age		-.080**		-.11**		.010
	In a relationship		-.061**		-.00		-.068*
	Unemployed		.046		.027		.064*
	Finances above average		.023		.021		.067*
2	**Health status**	.27**		.21**		.17**	
	Health above average		**-.17****		**-.12****		**-.11****
	Mental health history		**.12****		**.17****		**.11****
	Physical risk factors		-.00		-.00		.00
3	**COVID**	.005*		.002		.005*	
	COVID infection		-.021		-.024		.010
4	**Worry**	.092**		.10**		.075**	
	Worry total		**.23****		**.26****		**.23****
5	**Persistent symptoms**	.14**		.090**		.077**	
	Fatigue		**.13****		**.073***		**.12****
	Shortness of breath		.078*		.069		.040
	Heart palpitations		.045		.094**		.010
	Gut problems		-.025		.010		.041
	Memory problems		.081*		.024		.067
	Attention problems		.20**		.21**		.054
	Chest pain/pressure		.035		.024		.050
	Joint pain		.039		.017		.076*
	Nausea		.065*		.078**		.010
	Headache		**.081****		**.094****		**.075***
	Decreased appetite		.17**		.081**		.037
	Total number symptoms		.12		.12		.040
Total R^2		**.59**		**.48**		**.37**	

Note. Regression coefficients that reflect significant effect sizes across all three dependent variables in bold text.
*$p < .01$. **$p < .001$.

Discussion

>The purpose of this study was to examine levels of depression, anxiety, and insomnia, in Sweden at 18 months following the start of the pandemic and compare to our findings from an independent population sample in 2020. We also examined persistent COVID-19 symptoms in terms of prevalence and associations with the mental health outcomes, as well as risk factors known to increase vulnerability for mental ill health in the pandemic context (McCracken et al., 2020; Zvolensky et al., 2020). Compared to previous reports of mental health from the early pandemic, we found a decrease in level of depression and anxiety and an increase for insomnia. We found a high rate of persistent COVID-19 symptoms, with 84.5% of the sample reporting at least one persistent symptom, with fatigue being the most common. It appears that at the late phase of the pandemic, people in Sweden were still suffering from mental health problems, and from persistent symptoms. In addition, these persistent symptoms seemed to play a role in mental health over and above risk factors such as demographics, general health status, and COVID-19 related worry.

We found that 27% of our sample reported clinically significant levels of depression, whereas the rates for anxiety and insomnia were 16% and 45%, respectively. In our previous study (McCracken et al., 2020), the rates for the same mental health problems, were 30% for depression, 24% for anxiety, and 38% for insomnia. Although we observed a decrease for depression, this change is small and may be practically non-significant. On the other hand, the results for anxiety are in line with other reports indicating that the world is beginning to slowly recover from the mental health impacts associated with the pandemic (Manchia et al., 2022; Yarrington et al., 2021). The high rate of significant insomnia was unexpected, and the cause for this increase is unclear. In one study, insomnia during the pandemic was more common in women (Goncalves et al., 2022) and considering that 89.5% of our sample identified as women could be a factor. We note that the percentage meeting criteria as having significant insomnia is the same as the 44% who endorse sleeping problems in the list of persistent symptoms, the second most frequent complaint. Perhaps not surprisingly, our regression analyses showed that COVID-19-related worries were a strong predictor of insomnia.

The higher rates of depression, anxiety, and insomnia in Sweden are consistent with global prevalence of these identified in a systematic review and meta-analysis, calling prevalence rates “very high compared to normal times” (Mahmud et al., 2021) and with longitudinal data suggesting long term psychological disturbances in COVID-19 survivors (Mazza et al., 2022). Practically speaking, 67% of the participants meeting criteria for depression reported that this was having an impact on their daily functioning suggesting significant real-life consequences for the individual and society.

As a whole, the persistent symptoms assessed occurred very frequently, with 84.5% of the participants reporting at least one symptom lasting for at least six weeks, and there was a high rate of these symptoms even among those who reported no prior infection

with COVID-19, 78%. Important to note is that some of the symptoms are likely entirely coincidental to the COVID-19 infection, but we have no clear way to specifically identify those that are and those that are not.

In our study, fatigue was the most common persistent symptom, with a prevalence of 55.4% and approximately half of these, 48%, attributing it directly to COVID-19. This finding corroborates consistent results across European studies on persistent COVID-19 symptoms, with prevalence rates of fatigue between 50-70% (Fernández-de-las-Peñas et al., 2021; Lopez-Leon et al., 2021). This is not to lose sight of the wider range of symptoms and that 30% of the participants reported having all of a total of nine symptoms including fatigue, sleep disturbances, difficulties with attention, reduced quality of life, joint pain, difficulties with memory, depression, headache and reduced daily functioning.

Looking at potential vulnerability factors, numerous participant characteristics were associated with at least one of the three mental health outcomes, including age, relationship status, employment status, financial status, risk for poor COVID-19 outcome, and worry about the world economy (see Table 3). Given the small correlations, practical implications for these results may be limited and findings should be replicated. However, factors that appeared more robustly linked to depression, anxiety and insomnia, presenting medium effect sizes, were self-rated overall health, history of mental health problems, current mental health status, and current worries. Amongst these, reported current mental health status was the strongest correlate.

The results from the multivariate analyses showed that history of COVID-19 infection was the least informative in explaining variance for depression, anxiety and insomnia, accounting for less than 1% of all three outcomes. Thus, contracting COVID-19 infection did not seem to impact on level of mental health in the pandemic context perhaps pointing to other contextual factors as more important. Background variables – age, relationship status, employment status, and self-rated financial status –, as a set, significantly predicted all of the three mental health outcomes, explaining 8.4%, 7.6%, and 4.1% of the variance in depression, anxiety, and insomnia, respectively. Older age seemed to function as a protective factor against increased levels of depression and anxiety. This also suggests that younger people are more vulnerable to mental ill health in the pandemic context, a result which has been well documented throughout the pandemic (McCracken et al., 2020; Pierce et al., 2020).

The health status variables, including, overall rated health, mental health history, and a summary score of physical conditions was the strongest predictor of risk for poor outcome in depression, anxiety and insomnia, accounting for close to half of the explained variance for each outcome. Overall health and mental history appeared similarly important whereas physical risk did not contribute at all. The relation between a previous history of mental ill health and higher levels of poor mental health in all outcomes, suggests increased vulnerability for mental ill health during the pandemic in those already burdened with the impacts of mental ill health

We found that the best single predictor of the mental health outcomes was COVID-19-related worry scores, accounting for 9.2%, 10.0%, and 7.5% of variance in depression, anxiety and insomnia. This finding may mean that for many people cognitive and emotional responses to the pandemic situation represent an underlying mechanism of the elevated levels of significant depression, anxiety, and insomnia.

Controlling for all other predictors, the 12 selected persistent symptoms and the summary score for the number reported (adjusted to exclude depression, anxiety, sleeping problems or reduced quality of life or daily functioning) accounted for 14.0% or variance in depression, 9.0% for anxiety, and 7.7% for insomnia. The symptoms most strongly related to the three outcomes were fatigue and headache, which both significantly predicted all three, and attention problems, which was a relatively strong predictor of both depression and anxiety, but not insomnia. We attempted to examine whether it mattered if the symptoms seemed to emerge directly from diagnosed COVID-19 exposure or not. We did this in two ways, by analyzing the COVID-19 attributions related to the symptoms and by analyzing the specific COVID-19 diagnosis groups. In either case it did not make any difference whether there was a direct link with COVID-19 infection or not. This may mean that these symptoms are not specific or uniquely linked to COVID-19 infection but may be caused by people's experiences in the pandemic context, as mentioned before, in combination with other vulnerability factors. In fact, the nature of many of the symptoms included is that they are frequently associated with stress. These persistent symptoms are interesting, because their link with mental health outcomes seems stronger than their links with COVID-19 itself. We hasten to add that none of this is to deny the legitimacy of the symptoms nor to express an opinion on their genesis in any particular case.

One obvious limitation of this study is the relative absence of men, with 89.5% of participants identifying as women. This result was unexpected. One explanation may be related to the reported gender gap in COVID-19 risk perceptions, with men having lower estimates of their COVID-19 related risks compared to women (Lewis & Duch, 2021). This could lead to greater interest in pandemic research among women and, consequently, increased participation. Nevertheless, the uneven gender distribution limits what we can say about the experience of men. However, analyses of gender differences in mental ill health based on data from our previous pandemic survey (McCracken et al., 2020, 2021) showed no gender difference in the prevalence of the same mental health outcomes. Yet another unexpected result was the 100% vaccination rate in participants, leaving us unable to examine the role of this variable or to assume generalizability to those who are unvaccinated.

This survey, like our previous one (McCracken et al., 2020) is a cross sectional study and did not technically track the same people prospectively. There could be differences in the samples recruited that confound our comparison despite our intention to avoid these. Either way, we are unable to assess any direction in relations observed. Finally, we

must acknowledge the inherent bias of self-report measures and the potential selective recruitment bias entailed through the use of social media. In fact, it may be this social media context that led to the recruitment of more women than men. In light of these limitations our results reported here need to be regarded as provisional.

To summarize, about 18 months after the pandemic began Swedish people continued to report a great deal of suffering and reduced health. Half of those who responded in this study appeared to suffer significant problems in at least one of the domains of depression, anxiety, or insomnia. In addition, many participants, 84.5%, reported one or more persistent symptom defined as potential effects of COVID-19. The most apparent risk factors for lower mental health included negative overall self-rated health, history of mental health problems, worries related to the pandemic, and persistent physical symptoms. It may be important to study whether symptoms and other negative health outcomes persist long term post pandemic, whether these represent a significant health burden, and might need to be addressed. In conclusion, this study emphasizes the need for comprehensive, long-term mental health strategies that address both psychological and physical health issues, particularly for vulnerable populations, as the world continues to recover from the COVID-19 pandemic.

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I'm Still Standing: Body Sway, Interpersonal Distance, and Social Anxiety – A Proof of Principle

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Abstract

Background and Objectives: Cognitive models suggest that individuals with high degrees of social anxiety (SAs) tend to incorrectly interpret (ambiguous) social cues as negative evaluations and thus justifying their fears. It is assumed that subtle behaviors of SAs may give rise to factual negative evaluations, but it is unclear which kind of behaviors that may be. We tested whether automatic motivational behavior becomes disrupted when degree of social anxiety increases, expecting higher social anxiety to be associated with more threat-related 'freezing' (reduction of body sway) and backward leaning (avoidance).

Method: Of 87 participants with varying degrees of social anxiety, body sway was recorded by means of a stabilometric platform, while a fe-/male experimenter was gradually approaching.

Results: Higher levels of social anxiety were related to an *increase* of body sway at an interpersonal distance of 260 to 120cm. No avoidant backward-leaning occurred.

Limitations: Predictability of set-up and knowledge of escape options may have undermined participants' experience of the situation as highly socially threatening. Unease-, rather than fear-related behavior may have been the result.

Conclusions: The results indicate that SAs seem to show an increase in uneasy, nervous movement when approached by strangers. Whether that provokes the negative evaluation SAs fear most, still needs to be investigated.

Keywords

social anxiety, freezing behavior, interpersonal distance, stabilometric force platform, body sway, avoidance

Highlights

- Stranger approach paradigm was used to study freezing and avoidance behavior in social anxiety.
- Objective changes in body posture were assessed by a stabilometric force platform.
- Higher social anxiety was related to increased body sway during stranger approach.
- Freezing behavior was associated to state but not to (trait social) anxiety.

Social anxiety disorder (SAD) is a common and highly distressing disorder (e.g., Fehm et al., 2005; Kennedy et al., 2009; Perry et al., 2016) that is characterized by an excessive fear of negative evaluation by others in social or performance situations (American Psychiatric Association, 2013, 2022). Until recently, it has been predominantly conceptualized as a condition of 'distorted or biased information processing' (Clark & Wells, 1995; Hofmann, 2007; Rapee & Heimberg, 1997) based on the idea that individuals with high degrees of social anxiety (SAs) have a tendency to see social danger where in fact there is none. This tendency is thought to cumulate and eventually maintain SAD (Beard & Amir, 2008; Heeren et al., 2012; Schmidt et al., 2009).

Yet, there is growing evidence that SAs *are* truly evaluated in a negative way. Heerey and Kring (2007) found that interactions with SAs were characterized by, e.g., nervous fidgeting, or poor reciprocity of smiling (Heerey & Kring, 2007). As a consequence, conversations with SAs evoked increased negative affect in interaction partners (Alden & Wallace, 1995; Creed & Funder, 1998; Meleshko & Alden, 1993; Voncken & Bögels, 2008).

While the above-mentioned behaviors are more of a deliberate nature, the question remains whether SAs show disruptions in *subtle*, more automatic behaviors in social interaction. Research by Asher et al. (2020) showed that non-verbal behavioral synchrony increased in non-anxious couples during conversation while it decreased in anxious/non-anxious dyads. As behavioral synchrony is associated with increased positive affect (Tschacher et al., 2014) and increased sense of rapport (Miles et al., 2009), a lack of syncing with others may actually lead to the effect that SAs fear most.

In a different line of research, Givon-Benjio and Okon-Singer (2020) reported that increased degrees of social anxiety were related to a preference for larger interpersonal distance (IPD) *and* a tendency to underestimate interpersonal distances to strangers when compared to friends (see Givon-Benjio et al., 2020 for replication in individuals diagnosed with SAD).

While keeping more IPD *to* others may be a means to downregulate anxiety, breaches of an SA's personal space *by* others should increase anxiety (Perry et al., 2013). Accordingly, Wieser et al. (2010) showed that high social anxiety was associated with avoiding the gaze of a virtual male agent at 1.5m IPD, while the gazes of male agents were avoided irrespective of degree of anxiety at 0.5m. SAs also showed avoidance in the form of subtle backward head-movements irrespective of IPD (Wieser et al., 2010). In

addition, closer IPD and direct gaze were associated with heart rate deceleration. These last findings are particularly intriguing as decelerations have been linked to orienting and freezing responses in the past, while *accelerations* is thought to indicate fearful or phobic responding (Klorman et al., 1977; Ruiz-Padial et al., 2005; for critical discussion, see Barry & Maltzman, 1985).

It is only since this millennium, that researchers have started to investigate human freezing behavior as reflected by reduced body sway in response to threat (Azevedo et al., 2005; Hagenaars et al. (2014a); Roelofs, 2017; Volchan et al., 2017). It is proposed that a common response to imminent (unavoidable) threat is to 'freeze', *before* flight or fight responses are triggered (Blanchard, 2017; Bracha, 2004; Fanselow, 2022; Fanselow et al., 1987; Hagenaars et al., 2014a). Eilam (2005), however, argued that freeze and flight responses are mutually exclusive but may, nevertheless, alternate quickly, dependent on the situation. In the same line, Hagenaars et al. (2014a), suggested that when freeze/fight/flight responding had evolved for survival purposes, it must be dynamic and flexible rather than being characterized by chronological order and lack of overlap. Accordingly, Fanselow (2022) postulates that, under more, context, type and direction of approaching threat determines the 'adaptive defense threshold' and thus the timing, kind and magnitude of responding.

A few studies investigated freezing-like behavior in response to social threat. Roelofs et al. (2010a) and Noordewier et al. (2020) placed healthy participants on a stabilometric force platform and/or measured their heart-rates while passively viewing neutral, angry, and happy facial expressions. Viewing angry faces was associated with freezing-related behavior, e.g., a reduction in body sway. Moreover, reduced body sway was associated with increased state anxiety. In patients with SAD, Levitan et al. (2012), found reduced body sway irrespective of stimulus type (neutral objects, social threat, generic threat). Niermann et al. (2017), investigated freezing behavior after a physiological and social stress induction (Smeets et al., 2012) and found associations between diminished recovery from freezing and increased internalizing symptoms (such as, e.g., social anxiety).

In sum, there is reason to assume that SAs show distinct postural behaviors in social interactions, and in particular when their interpersonal space is breached. Yet, research assessing postural changes in human beings has seldomly looked at the impact of a trait such as social anxiety. It is particularly remarkable that all studies used static stimuli while threatening situations are typically of a dynamic nature. To our knowledge, postural balance fluctuations have not, yet, been investigated when the cause of threat is gradually approaching.

In this proof-of-principle study we therefore investigated at what distances between participant and an approaching research assistant (RA), avoidance behaviors and/or freezing would occur and which role social anxiety would play herein. We expected increasingly marked backward swaying of the participant when the RA would come closer. Such impulsive backward swaying would indicate embodied negative evaluation

(Bargh & Chartrand, 1999; Niedenthal et al., 2005). In addition, we expected that freezing responses, indicated by reduced body sway, would increase with a decreasing distance between RA and participant. Finally, we expected that freezing and simultaneous avoidance would occur earlier (at a greater distances) with higher degrees of social anxiety. The stance of the RA (moving vs still) was controlled for.

Method

Participants

In total 87[1] students from Radboud University Nijmegen (67.8% female) participated in the study with a mean age of 21.75 years (*SD* = 3.17), ranging from 18 to 41 years. The whole sample consisted of 75.7% individuals from Dutch origin, 20.9% Germans and 1.1% from other countries. With 66.7%, psychology was the predominant field of studies, followed by law (10.3%) and pedagogical sciences (8%). The remaining 15% was distributed nearly even across five other fields of studies or did not indicate a direction. The experiment took about 20–25 minutes, and, after completion, participants received a candy bar or course credit.

Questionnaires

Before the personal space task, participants completed a general screening instrument to assess sociodemographic information (e.g., age, gender, native language, education) and their height in centimeters (cm). Prior to the experiment some state measures were assessed by means of *Visual Analogue Scales* (VASs; Bond & Lader, 1974). Participants had to indicate on a 10 cm wide slider ranging from 0 (*not at all*) to 100 (*extremely*) how anxious they were at the very moment, how tense they felt and how much they would like to escape the situation. Typically, VASs have good psychometric properties (Wewers & Lowe, 1990). In the present study Cronbach's α was .55.

After the experimental task, participants were asked to answer questions to correct for possible experimenter related variables. Participants had to indicate by means of four VASs how friendly, sympathetic, and attractive they evaluated the research assistant (RA) ranging from 0 (*not at all*) to 100 (*very much*). In addition, they were asked to evaluate

1) In the time that the study was conducted, preregistrations and a priori power analyses were rather uncommon, and thus not done for the current study. For power estimations, it was common to rely on the sample sizes of comparable studies (Lakens, 2022). For the present study, thematically related articles indicated sample sizes between 20 (Rinck et al., 2010) and 148 (Kaitz et al., 2004). We strove to recruit as many participants as possible within two semesters, but at least 80. Post hoc power analyses indicated that with an effect size of $\eta^2 = .25$ (Wieser et al., 2010) and a power of $\alpha = .80$ a necessary sample size of 87 was calculated with g*power (Faul et al., 2009) which coincidentally is the number of participants that we recruited."

the body scent of the RA, ranging from 0 (*very unpleasant*) to 100 (*very pleasant*). In the present study, Cronbach's α for these scales was .83.

Level of social anxiety was assessed with the Dutch self-report version (van Vliet, 1999) of the *Liebowitz Social Anxiety Scale* (LSAS; Liebowitz, 1987; Oakman et al., 2003). The participants indicated for 24 social situations (e.g., "Talking to people in authority") on a 4-point Likert-type scale, ranging from 0 (*none*) to 3 (*severe*) how anxious they would be in these situations and how much they would avoid them from 0 (*never*) to 3 (*usually*). The psychometric properties of the scale are generally considered good (dos Santos et al., 2013; Heimberg et al., 1999) but the Dutch version has not been officially evaluated, yet (Lange et al., 2024). The internal consistencies of the total score of the LSAS measured by means of Cronbach's α was .93 in the present study.

In order to control for depressive symptomology often associated with social anxiety (e.g., Adams et al., 2016), participants completed the Dutch version of *Center for Epidemiological Studies Depression Scale* (CES-D; Ratloff, 1977). They had to indicate how often they had experienced each of the 20 listed symptoms (e.g., "I felt depressed") in the last week on a 4-point Likert scale ranging from 0 (*almost never*) to 3 (*almost always*). CES-D has good psychometric properties (Bouma et al., 2012). In the present study, Cronbach's α was .92.

Apparatus

The questionnaires were filled in online on a standard PC via the survey-platform Unipark (www.unipark.de). The stabilometric force platform (balance board [BB]) was a 1 m × 1 m custom-made strain-gauge force plate with a sampling frequency of 4 × 100 Hz, a resolution of 0.28 N/bit and a resonance frequency of 30 Hz. Changes in center-of-pressure (COP) were recorded in anterior-posterior (AP) direction as well as the medio-lateral (ML) direction by means of four pressure-sensitive sensors at each corner of the plate. As the BB was 16 cm high, a custom-made "catwalk" (3.20 m long and 50 cm wide) was used on which the RAs could approach the participants (Figure 1).

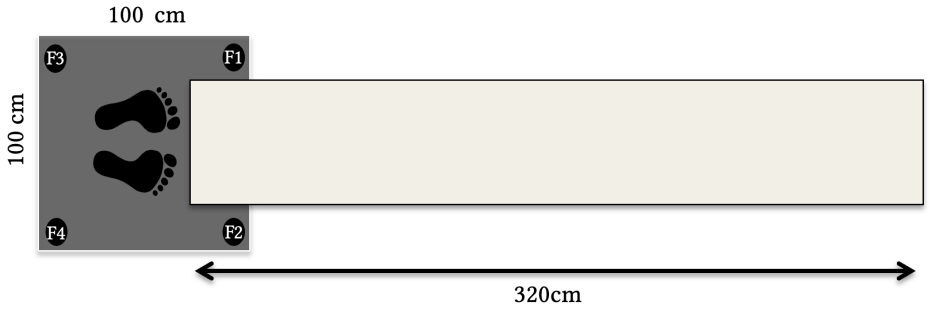
To mark the distance between participant and RA in the BB data, a bell-button with 5 m cable was connected to the laptop via a custom-made button box. All BB data were recorded by Presentation® software (www.neurobs.com). To record the participants' distance estimations an Olympus™ digital voice recorder was used.

Procedure

Prior to a test session, each participant was randomized to be tested by either the male or the female RA. Upon arrival participants were accompanied into the lab, were informed about the test session and were asked to give informed consent. After that, they filled in the sociodemographic information, while the RA left the room. After the RA's return, participants were informed that they were to judge the distances between themselves

Figure 1

Sketch of the Balance Board Set-up and Sensor Numbering



and the RA who would be approaching in small steps on the catwalk. Participants were instructed to not look for spatial cues in the room but to focus on the (neutral) face of the RA. Whenever the RA had completed a step, they were asked to speak their estimation out loud but would not receive any response. The RA also explained that s/he would eventually come very close, but that the participant was to stay on the platform.

When the participants indicated that they had understood the instructions, they were asked to take off their shoes and stand loosely but straight in the middle of the BB facing towards the "cat-walk". The RA started the software that recorded the BB signals and the voice recorder. S/He took a position on the catwalk at roughly 3.20 m from the participant (Figure 1) and held the bell-button in one hand. S/He asked if the participant was ready and if s/he could give the first estimate. Then the RA looked down, pressed the button to indicate the movement part of his approach in the data, moved a 20 cm step forward to a subtly marked point on the catwalk, released the button to mark the stationary part of her/his approach and looked up at the participant. After the participant had given her/his estimation of the distance, this procedure was repeated until the RA was standing right in front of the participant at a distance of about 20 cm. This led to 16 stationary and 15 movement markers. After the last estimate the RA stepped off the catwalk to stop data-recording, while the participant remained on the platform. The RA stepped back on the catwalk at about 1.5 m and asked the participant to indicate a distance that s/he would find comfortable/would prefer for an interaction, by instructing the RA to move closer or further away. This preferred interpersonal distance (PID) was marked on the catwalk. Finally, the participant put on her/his shoes and was asked to fill in the remainder of the questionnaires, while the RA left the room. At the end of the experiment, participants were debriefed, compensated, and thanked. After the participant

had left, the RA measured and noted the preferred IPS and wrote down the distance estimates by listening to the recordings.

Data Preparation

The raw data from the 4 BB sensors was processed with MATLAB™ software (The Mathworks Inc., Natick, MA). From every participant the first 20 data-points (0.2 sec) were deleted. To determine a baseline from the empty BB, the following 20 data points were averaged. This mean was subtracted from each data-point with the participant on the BB to calculate a value that was solely determined by the weight of the participant and not by that of the BB. The last trial, in which the RA stopped at about 20 cm from the participant, was discarded from analyses, as this trial was terminated quicker than the previous ones to minimize the discomfort of the participants. For each of the remaining 14 distances (steps of the RA), we first calculated the mean Center of Pressure (COP)[2] in the Anterior-Posterior (forward-backward; $COP_{AP\text{-}Mean}$) direction and in the Medio-Lateral (left-right; $COP_{ML\text{-}Mean}$) direction. $COP_{AP\text{-}Mean}$ was used to determine participants mean position/leaning towards the RA or backwards/away from the RA (i.e., "avoidance" per distance and per stance), COP_{AP} and COP_{ML} were both used to determine the general radius of body sway an indicator of the variability in body sway per distance and RA stance[3]. A reduction in posture mobility is typically seen as index of "freezing" responses (Azevedo et al., 2005; Hagenaars et al., 2012; Roelofs et al., 2010a).

Statistical Analyses

To investigate whether participants respond with avoidance and/or freeze behaviors when being approached and how these behaviors relate to degrees of social anxiety, separate Repeated Measures MANCOVAs were conducted: One for avoidance in AP direction with $COP_{AP\text{-}Mean}$ direction as dependent variable, and one for magnitude of movement with movement radius as dependent variable. Distance in steps (14 à 20 cm) and the RA's stance (move vs still) were independent within-subject variables. The total scores of LSAS and CES-D, participants' PID, as well as their ratings of the RAs' friendliness, sympathy, attractiveness, and body scent were added as covariates. Whenever the assumptions of univariate testing were violated in any of the analyses, more conservative tests with corrections of degrees of freedom were used (i.e., Huynh-Feldt).

2) COP_AP = ((F1 + F2) – (F3 + F4) / (F1 + F2 + F3 + F4)) * (1000/2). COP_ML = ((F1 + F3) – (F2 + F4) / (F1 + F2 + F3 + F4)) * (1000/2). For sensor numbering, see Figure 1; 1000 represents the distance between the BB sensors in millimeters.

3) $R = \sqrt{(COP\_x^2 + COP\_y^2)}$. We selected the radius because it provides a complete indication of changes in body sway (including diagonal movements), while the *SD* of, e.g, the COP_AP only indicates the radius of body sway in AP direction, deprived of the ML component.

Results

Participants and Research Assistants

First, randomization of participants to RAs had been successful: There was no difference in gender ratio allocated to the female (28 female:14 male) or male (31 female:14 male) RA, $\chi^2(1, N = 87) = 0.05$, $p = .83$. In addition, a One-Way-ANOVA was used to test whether age, questionnaire-scores, and state measures differed between female and male participants. There were no significant differences on any of these measures between the genders, all F's < 2.0, all p's > .16 (Table 1). By means of a MANOVA it was explored whether female and male participants evaluated the RA differently, regarding friendliness, sympathy, attractiveness, or body scent. Again, no significant differences emerged, all F's < 2.18, all p's > .08. Finally, as would be expected, Pearson's correlations revealed that degree of social anxiety ($LSAS_{min} = 5$, $LSAS_{max} = 93$) correlated positively with self-reported state anxiety at the beginning of the test session, $r(87) = .28$, $p = .01$, with tension/arousal, $r(87) = .26$, $p = .02$, and with number of depressive symptoms, $r(87) = .58$, $p < .001$.

Table 1

Mean (M), Standard Deviations (SD), of Age, Questionnaires, State Measures and Ratings of the Research Assistants per Participant Gender

	♀	♂	♀	♂	♀	♂	♀	♂	♀	♂
n	**59**	**28**	**59**	**28**	**59**	**28**	**59**	**28**	**59**	**28**
	Age		**$LSAS_{Total}$**		**$CES\text{-}D_{Total}$**		**$VAS_{Anx.}$**		**$VAS_{Arousal}$**	
M	21.64	21.96	37.49	34.93	12.88	11.71	12.03	8.07	20.07	23.57
SD	3.41	2.63	17.90	13.22	10.03	8.02	16.35	7.88	17.85	21.41
	VAS_{Avoid}		**$RA_{Friend.}$**		**$RA_{Symp.}$**		**$RA_{Attract.}$**		**RA_{Odor}**	
M	11.08	8.57	73.69	74.36	68.27	69.14	37.53	42.64	58.10	54.71
SD	16.10	10.43	21.55	21.08	23.82	21.74	22.49	25.06	19.51	20.66

Note. LSAS = Liebowitz Social Anxiety Scale; CES-D = Center of Emotion Scale-Depression; $VAS_{Anx.}$ = Visual Analogue Scale (VAS) for State Anxiety; $VAS_{Arousal}$ = VAS for State Arousal; VAS_{Avoid} = VAS for State Avoidance; $RA_{Friend.}$ = Reseach Assistant (RA) rating of friendliness; RA_{Symp} = RA rating of sympathy; $RA_{Attract.}$ = RA rating of attractiveness; RA_{Odor} = RA rating of body odor.

Four participants had to be excluded from further analyses because of erroneous BB data recordings, resulting in 83 participants for testing the main research questions.

Interpersonal Distance, Social Anxiety and Avoidance (Leaning Backwards)

The only significant result concerned the three-way interaction of distance × RA stance × social anxiety on $COP_{AP\text{-}Mean}$, $F(12.04, 902.67) = 1.82$, $p = .041$, $\eta^2 = .024$. The remaining main effects and two-way interactions were not significant, all F's < 2.52, all p's > .11.

To explore the three-way interaction in more detail, identical analyses were conducted but for the 'moving' and the 'still' stance separately. The critical interactions of distance × social anxiety were not significant F's < 1.26, p's > .26. The parameter estimates reveal that numerous distances of moving RAs are tendentiously related to social anxiety, while only two are for stationary RAs (Table 2). This difference between moving and standing still *may* have caused the observed three-way interaction but the conclusion must be that, neither social anxiety, distance to the participant nor the stance of the RA had any effect on the $COP_{AP\text{-}Mean}$ (Figure 2: for *visualization* purposes participants were subdivided in three groups based on their LSAS scores: the 33.3% scoring lowest (score ≤ 29), 33.3% scoring highest (score ≥ 39), and those scoring in-between).[4]

Interpersonal Distance, Social Anxiety and Body Sway (Freezing)

There was a non-significant trend of social anxiety, $F(1, 75) = 3.57$, $p = .063$, $\eta^2 = .045$, indicating that increases in social anxiety were associated with more participant movement in general. The interaction of distance × social anxiety was significant, $F(8.19, 614.34) = 2.33$, $p = .017$, $\eta^2 = .03$. This indicates that, with increasing levels of social anxiety, participants' movability was increased as well, but only for some of the distances. All remaining main effects, two-way and three-way interactions were not significant, all F's < 1.26, p's > .10.[5]

The parameter estimates revealed (marginal) significant effects of social anxiety at different distances (Table 3). In sum, it seems that SAs tend to move about more, when being approached by an unknown other. This movability seems to peek at about 180 cm and 160 cm distance between RA and participant (for visualization see Figure 3).

4) Explorative analyses with these group divisions as between-subject factor revealed comparable results. In addition, based on suggestions of an anonymous reviewer, we conducted the originally planned analyses but added participant gender as between-subject factor and omitted preferred distance, RA friendliness, -sympathy, -attractiveness and -body odor as covariates. Again, the results did not change considerably.

5) Analyses conducted with the standard deviations of the COP_{AP} yielded similar results.

Table 2

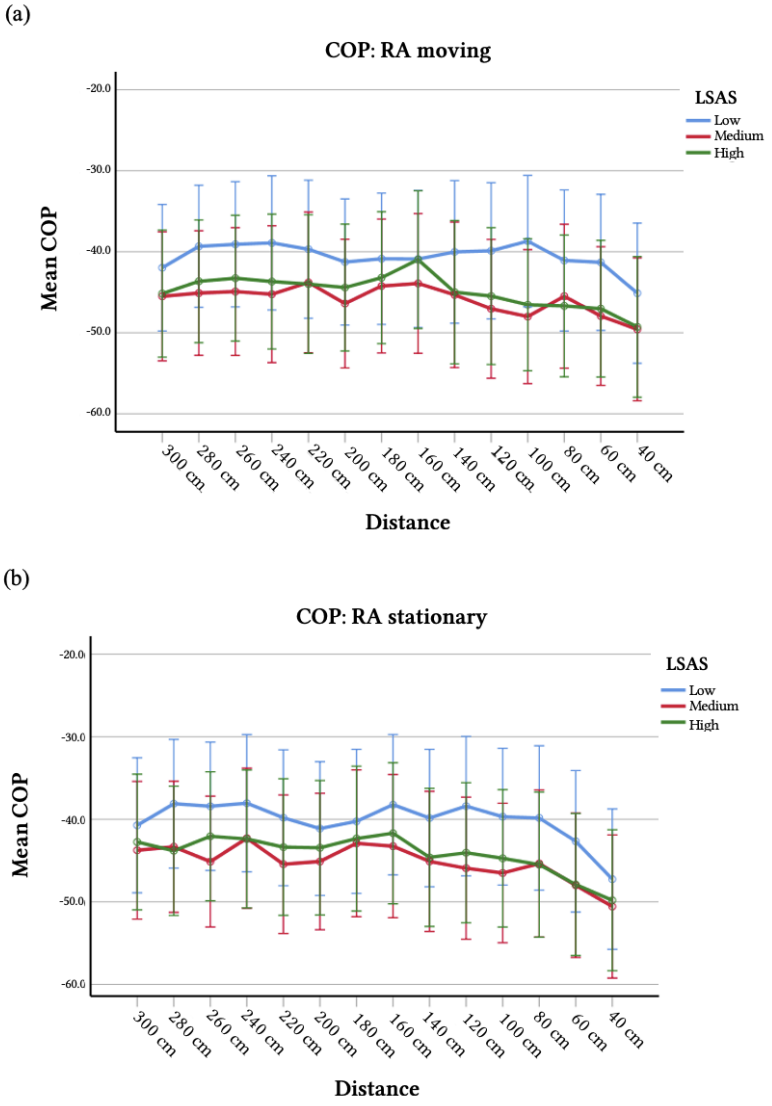
Parameter Estimates of Leaning Behavior per Distance and RA Stance Correlated With Social Anxiety Scores

					95% CI		
Stance and Distance	***B***	***SE***	***t***	***p***	***LL***	***UL***	η^2
- Still -							
300 cm	-.262	.177	-1.478	.144	-.615	.091	.028
280 cm	-.304	.170	-1.791	.077†	-.643	.034	.041
260 cm	-.230	.170	-1.351	.181	-.570	.109	.024
240 cm	-.294	.180	-1.635	.106	-.652	.064	.034
220 cm	-.316	.177	-1.785	.078†	-.670	.037	.041
200 cm	-.226	.176	-1.282	.204	-.577	.125	.021
180 cm	-.282	.190	-1.489	.141	-.660	.095	.029
160 cm	-.265	.185	-1.432	.156	-.635	.104	.027
140 cm	-.288	.181	-1.591	.116	-.648	.073	.033
120 cm	-.282	.184	-1.529	.130	-.650	.085	.030
100 cm	-.278	.180	-1.540	.128	-.637	.081	.031
80 cm	-.296	.190	-1.562	.122	-.674	.082	.032
60 cm	-.235	.187	-1.259	.212	-.608	.137	.021
40 cm	-.144	.186	-.770	.444	-.515	.228	.008
- Moving -							
300 cm	-.271	.168	-1.607	.112	-.606	.065	.033
280 cm	-.188	.166	-1.130	.262	-.519	.143	.017
260 cm	-.305	.168	-1.812	.074†	-.639	.030	.042
240 cm	-.324	.180	-1.804	.075†	-.682	.034	.042
220 cm	-.332	.183	-1.810	.074†	-.697	.033	.042
200 cm	-.289	.169	-1.709	.092†	-.626	.048	.037
180 cm	-.239	.177	-1.351	.181	-.590	.113	.024
160 cm	-.101	.187	-.539	.592	-.473	.272	.004
140 cm	-.339	.191	-1.774	.080†	-.719	.042	.040
120 cm	-.311	.183	-1.699	.093†	-.675	.053	.037
100 cm	-.342	.175	-1.948	.055†	-.691	.008	.048
80 cm	-.339	.189	-1.796	.077†	-.714	.037	.041
60 cm	-.250	.184	-1.361	.177	-.616	.116	.024
40 cm	-.229	.189	-1.212	.229	-.606	.148	.019

†$p < .1$. *$p < .05$.

Figure 2

Mean Center of Pressure per Distance



Note. Mean center of pressure in Anterior-Posterior direction ($COP_{AP\text{-}Mean}$) and standard errors per distance to participant and participants' degree of social anxiety as measured with Liebowitz Social Anxiety Scale (LSAS) for (a) Research assistant (RA) moving and (b) RA standing still. A more negative score reflects more leaning backwards/away from the RA.

Table 3

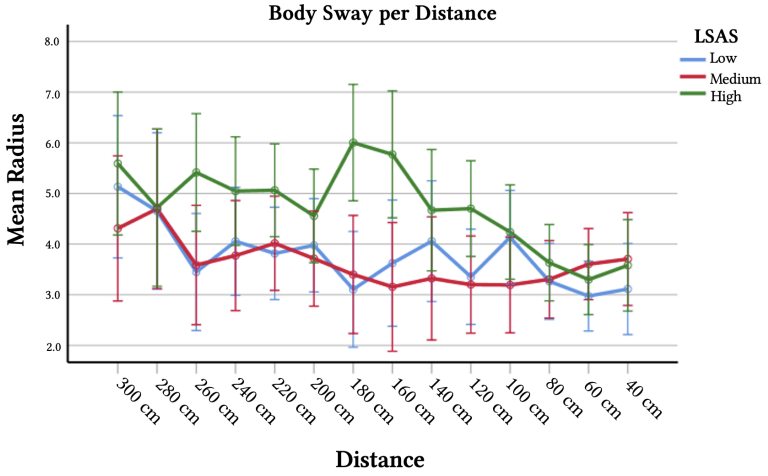
Parameter Estimates of Body Sway per Distance and RA Stance Correlated With Social Anxiety Score

					95% CI		
Stance and Distance	***B***	***SE***	***t***	***p***	***LL***	***UL***	η^2
- Still -							
300 cm	.009	.041	.215	.831	-.073	.090	.001
280 cm	.011	.051	.214	.831	-.092	.114	.001
260 cm	.078	.037	2.074	.042*	.003	.152	.054
240 cm	.010	.036	.285	.776	-.062	.083	.001
220 cm	.022	.026	.821	.414	-.031	.074	.009
200 cm	.008	.029	.260	.795	-.051	.066	.001
180 cm	.127	.039	3.244	.002*	.049	.206	.123
160 cm	.072	.028	2.530	.014*	.015	.129	.079
140 cm	.051	.039	1.324	.189	-.026	.128	.023
120 cm	.060	.025	2.401	.019*	.010	.110	.071
100 cm	-.019	.021	-.904	.369	-.061	.023	.011
80 cm	.030	.021	1.390	.169	-.013	.072	.025
60 cm	-.006	.017	-.351	.727	-.039	.028	.002
40 cm	.026	.027	.980	.330	-.027	.080	.013
- Moving -							
300 cm	-.004	.026	-.149	.882	-.056	.049	.000
280 cm	.024	.028	.853	.396	-.032	.079	.010
260 cm	.049	.023	2.138	.036*	.003	.095	.057
240 cm	.055	.023	2.368	.020*	.009	.102	.070
220 cm	.051	.027	1.938	.056†	-.001	.104	.048
200 cm	.024	.019	1.300	.198	-.013	.062	.022
180 cm	.019	.025	.784	.436	-.030	.069	.008
160 cm	.081	.039	2.107	.038*	.004	.158	.056
140 cm	.039	.019	2.011	.048*	.000	.078	.051
120 cm	.043	.022	1.991	.050†	-.000	.086	.050
100 cm	-.007	.029	-.229	.819	-.065	.051	.001
80 cm	.001	.018	.030	.976	-.035	.036	.000
60 cm	.012	.018	.689	.493	-.024	.049	.006
40 cm	-.017	.018	-.927	.357	-.053	.019	.011

†$p < .1$. *$p < .05$.

Figure 3

Mean Body Sway per Distance



Note. Mean radius (Body Sway) per distance to participant and participants' degree of social anxiety as measured with Liebowitz Social Anxiety Scale (LSAS). A higher score reflects more/larger movements in body posture irrespective of moving/stationary stance.

Preferred Interpersonal Distance and Social Anxiety

To explore the relationship between social anxiety and the preferred interpersonal distance (PID) when interacting with a stranger, Pearson's correlations were calculated, two-tailed. Participants' LSAS scores were not related to PID, $r(87) = -.02$, $p = .83$ (M = 73.37 cm, SD = 16.45; $IPS_{min} = 45$, $IPS_{max} = 157$).

Explorative Analyses

To explore effects that are not (directly) related to the current research question, several additional analyses were performed.

Correlations

PID was negatively correlated with how attractive the RA was found, $r(87) = -.26$, $p = .02$: The more attractive the RA was evaluated, the closer participants positioned the RA to indicate their comfortable interpersonal distance. With regard to body sway it was found that mobility and evaluations of the RA's body scent were positively correlated, $r(87) = .24$, $p = .03$: The more pleasant the RA's body scent was, the more the participants moved about. It was also found that state arousal and mobility were negatively correlated, $r(87)$

= -.22, p = .049: The more participants felt aroused and tense at the beginning of the test session, the less they moved about during the task.

Gender

To explore possible influences of participant gender, we also added this variable to the above-mentioned Repeated Measures MANCOVAs. This, however, had no influence on any of the statistical effects that were described above.

Distance Estimates

Finally, we explored whether the distance estimates that participants gave per step of the RA, were influenced by any of the relevant factors mentioned above. As would be expected, there was a main effect of distance $F(1.87, 147.7) = 5.23$, $p = .008$, $\eta^2 = .062$, indicating that participants' distance estimates declined with each step that the RA moved closer. No other relevant effect was found.

Discussion

We investigated if decreasing interpersonal distance was related to subtle avoidance (backward leaning) and increased freezing-like behavior (reduced body sway), as well as the role of social anxiety here in. To test this, we used a stabilometric platform to measure objective movements accurately and applied it to a dynamic stranger-approach paradigm in a proof-of-principle study.

Against expectations, the distance between the approaching RA and the participant had no general effect on avoidant body posture or freezing-like behavior. Typically, one would have expected that an approaching, unfamiliar person would make participants retreat, at least when their personal space was breached. This was indeed partially demonstrated by Wieser et al. (2010). In a VR setting, participants made backward head movements and avoided eye gaze of approaching male digital agents at an uncomfortable 50 cm distance. However, they used fixed distances where the agents stopped (0.5 and 1.5 m) instead of dynamic distance changes as used in our study and in our study gaze avoidance was undermined by instructing participant to look the RA in the eyes. Yet, our study could have shown similar results as backward head movements should be readily reflected in our sensitive measure of body posture.

Unexpectedly, social anxiety did *not* have any influence on avoidant body posture when the interpersonal distance decreased. This is not in line with the results of Wieser et al. (2010) and Rinck et al. (2010). The embodied cognition theory suggest that automatic evaluative/emotional responses towards environmental stimuli are readily reflected in associated impulsive bodily responding (and vice versa: van Dantzig et al., 2009). Thus, higher degrees of social anxiety should have increased the salience of the experimental situation as social and potentially threatening, which should have been

reflected in automatic bodily avoidance. Numerous studies using prototypical approach-avoidance tasks based on joystick-movements towards social stimuli, found such automatic avoidance behavior towards angry but not neutral faces in highly socially anxious individuals (e.g., Heuer et al., 2007; Lange et al., 2008; Roelofs et al., 2010b). It is possible that particularly angry faces as representation of prototypical threat evoke threat-related avoidance responses in SAs while approaching, neutral looking RAs might be merely unpleasant but inapt to evoke threat responding (Lange et al., 2014) as observed in our study.

Body sway, on the other hand, *was* influenced by participants' degree of social anxiety interacting with the distance of the RA. Interestingly, the pattern was opposite to what was expected: Participants with high levels of social anxiety showed increased bodily movement at 260cm, and between 200cm and 100cm distance, with a peak at 180cm. These results seem to contradict numerous previous studies that found reduced movement in response to threat in unselected samples (e.g., Azevedo et al., 2005; Hagenaars et al., 2014b; Roelofs et al., 2010a). Studies with participants showing characteristics related to *social* anxiety, however, reported more contradictory results. For example, while insecure attachment was associated with *increased* freezing-like responding (Niermann et al., 2015), internalizing symptoms were not (Niermann et al., 2017). Two studies found no effects of stimulus valence but instead general reductions of body sway throughout the experiment (social anxiety disorder: Levitan et al., 2012; panic disorder: Lopes et al., 2009), and one study found reduced body sway for blocks with painful stimuli, but not modulated by social context (Karos et al., 2020). Importantly, there is also evidence for a *lack* of freezing behavior in psychopathology. Stoffels et al. (2017), for example, reported reduced heart rate (typically associated with freezing) in response to aversive pictures in healthy controls but not in patients with borderline personality disorder. In the same line, Fragkaki et al. (2017) discovered attenuated freezing responses in patients with posttraumatic stress disorder. Finally, Hagenaars et al. (2015) found that heart rate reductions (indicative of freezing) were absent when participants were prepared for the aversive stimuli but not when being unprepared. Warning participants in the current study about the (very intimate) approach of the RA might have prevented the evaluation of the situation as threatening and may have undermined typical threat related responding. This is also compatible with Fanselow's (2022) idea that context and type of threat can influence the timing, type and degree of defensive responding. Taken together with Trower and Gilbert's (1989) evolutionary approach that social anxiety is not so much determined by imminent threat of death but more by survival related resources, freezing may be less likely in the approaching stranger context than other behavior that signals discomfort or unease.

Note that higher degrees of *state* anxiety at baseline, irrespective of social anxiety, *were* associated with decreased body sway/freezing, indicating that our measure was sensible enough to pick up freezing-like behavior when participants *are* stressed. This is

in line with previous work from, e.g., Hagenaars et al. (2014b) or Roelofs et al. (2010a). It might be that particularly state assessments of subjective experiences of stress/fear are more directly linked to physiological and automatic behavioral responding. Our assessment of SA, however, is more based on anxiety traits that may not necessarily be related to the stress levels in this particular situation. True is, that, in general, state stress and trait SA are positively correlated, but the predictability of our specific procedure may have evoked an attitude often observed with high functioning SAs: knowing the job, getting it done, with nervous fidgeting and restless movements indicating discomfort (Heerey & Kring, 2007; Voncken et al., 2008, 2012) but no pronounced fear reaction. In line with this notion, research has indicated that SA is a heterogeneous condition based, under more, on distorted interpretations and evaluations of environmental cues and social situations (Clark, 2001; Hofmann, 2007; Rapee & Heimberg, 1997). As indicated above, Fanselow (2022) as well as Trower and Gilbert (1989) acknowledge that decreases in adaptive defense thresholds are highly related to subjective evaluations and interpretations of the context. It is therefore thinkable that high degrees of social anxiety are generally related to increased stress in a situation, but that it is primarily the degree of SA in these healthy participants that allows for evaluating the situation as unpleasant but not threatening which then could determine their subtle behavior accordingly. It is important to note that the social anxiety levels of this particular sample were unexpectedly higher than is typical of a student sample. If the range between a score of 30–60 on the LSAS marks mild to moderate degrees of social anxiety then about 54% of the participants fall in that range. About 10% score 60 or higher which might be indicative of a clinically relevant degree of social fears (Mennin et al., 2002; Rytwinski et al., 2009).

In sum, increases of body sway may be more indicative of general unease with or nervousness in a situation rather than reflecting the expectation of eminent threat. For our understanding of social anxiety, this could mean that SAs show subtle signs of discomfort in a social situation. Once noticed by interaction partners they may feel uncomfortable themselves and may start disliking the situation, thereby fulfilling the SAs 'prophecy' of being disliked by others (Asher et al., 2020; Tschacher et al., 2014).

Remarkably, we found differences in body sway between high and low socially anxious individuals when the RAs were at a moderate distance. That is, RA-distance related changes in body sway were in the form an inverted U-shape. Especially on the uncomfortably short distances, one would have expected anxiety related effects to be strongest. This may have been a floor effect: The unnaturally close interpersonal distances are likely to be perceived as highly unpleasant for everyone, irrespective of social fears (Bailey et al., 1972; Dosey & Meisels, 1969; Hayduk, 1983). But exaggerated threat interpretations and resulting anxiety responses in social anxiety become primarily apparent in ambiguous situations and not necessarily in situations that actually *are* highly uncomfortable or threatening. In addition, subtle signs of discomfort and unease,

rather than obvious ones, would manifest in a distance range where normal social interactions take place and not at a far distance, when there is clearly no social threat.

Irrespective of these results, a few limitations need to be considered. As indicated above, the predictability of what participants could expect may have diminished the experience of threat and related behaviors. Luo et al. (2019) found indeed that task instructions can readily attenuate automatic responding to emotional stimuli. In addition, our participants were, of course, free to leave the situation whenever unbearable while freezing-like behavior may be more likely to occur without (knowledge of) escape options (compare: Clark, 1993; Sanderson et al., 1989). For example, Buss et al. (2004) found that children responded with more freezing to an approaching stranger when they were restrained in a high-chair instead of freely playing. Finally, while our setup was considerably more dynamic than, e.g., that of Wieser et al. (2010), approaching participants in steps rather than in a continuous motion in combination with distance judgements may still be suboptimal and decrease ecological validity. Future research should delineate specific responses to dynamic social interactions and distinguish social threat from social discomfort herein to provide the most ecologically validity when measuring subtle behavior. Although not consistently supported in SA research (e.g., Cheng et al., 2022), the addition of physiological measures to the current study setup may help to further the understanding of subtle behaviors in social interactions.

To conclude, with our new experimental setup, we found that high degrees of social anxiety were associated with deviations from subtle 'default' behaviors seen as normal in social interaction: SAs showed increased movement when their own personal space was intruded. Future research may explore whether such behavior elicits feelings of discomfort in others, and if so, whether that would lead to *true* negative evaluation of SAs. Treatments may target these subtle behaviors to break this vicious circle. If psychotherapy, "primarily tackles faulty cognitions while there is a considerable probability that the fear of negative evaluation is justified, chances of substantial and sustained recovery are undermined." (Lange et al., 2014, p. 360).

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Competing Interests: Neither of the authors has any conflict of interest regarding (the publication of) this research.

Ethics Statement: The current study was carried out in accordance with APA ethical principles and with the provisions of the World Medical Association Declaration of Helsinki (2013). It received a general approval by the Ethics committee of the Faculty of Social Sciences of Radboud University Nijmegen (The Netherlands) as education related research. This implies that no diagnosed, vulnerable and/or underage samples were tested, and no interventions/manipulations/stress inductions were taking place.

Reporting Guidelines: To the best of our knowledge we adhered to the JARS Quant guidelines of reporting quantitative research.

Preregistration: In the time that the study was conducted, preregistrations and a priori power analyses were rather uncommon, and thus not done for the current study.

Data Availability: Research material and data will be available upon request.

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Letter to the Editor, Commentary

Letter to the Editor: On the Critical Nature of Psychosomatics in Clinical Practice

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Highlights

- Scientific dialogue on current trends referred to psychosomatics results necessary.
- Fostering dialogue and dissemination represents scientific advancement.
- Clinical psychology deepening psychosomatics provides multifactorial results.

Dear Editors,

Acknowledging this journal's substantial commitment to advancing diverse applications in clinical psychology, this contribution aspires to cultivate a scientific dialogue within the psychosomatic domain.

Building upon this journal's publication concerning the work of Kleinstäuber et al. (2024), which highlighted the paucity of systematic contributions on comprehensive approaches and biopsychosocial models to inform the identification of aetiological factors, fostering dialogue and dissemination remains of paramount importance.

The current trends in clinical psychology seem to recognize the need for a multidisciplinary approach and increased communication (Kleinstäuber et al., 2023). These areas of interest have been addressed by the journal, thereby inspiring opportunities for initiating an innovative and international scientific discourse. The works of Fischer and Ehlert (2019), Frostholm and Rask (2019), as well as Weigel et al. (2022), have demonstrated considerable sensitivity to topics such as diagnosis, intervention, aetiological factors, and multidisciplinary approaches.

Differentiation between organic and endogenous causes, as well as psychological and ecological factors, is frequently observed. While these distinctions may still hold necessity, epistemological considerations remind us of their unitary status. Despite this, there remains a prevalent and persistent inclination to divide domains, thereby overlooking inherently inseparable unitary realities. Systems of thought continue to exist in which the notion of a dominant metaphysics over physics remains a common inclination.

A compelling illustration of this trend is evident in the psychosomatic field, particularly regarding genuine psychosomatic and chronic conditions. The concept of psychological factors exerting influence on biological systems is traditionally regarded as accurate within the classical framework of psychosomatic theory.

Nonetheless, this conceptual accuracy may still align with a system of thought that historically regarded psychological factors as extrinsic to the physical dynamics of a suffering body, perceiving them as mere epiphenomena. Epistemologically sustainable reconfigurations are warranted, as exemplified by contemporary neuroscientific integrative approaches.

This contribution seeks to underscore the fundamental importance of fostering a debate on these prevailing trends. It aims to establish a platform for dialogue through which processes may be refined to enhance the precision and relevance of daily scientific practice.

In conclusion, insights and exchange between clinical contexts belonging to different realities produces scientific advancement that emerges necessary.

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