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Editorial



Clinical Psychology in Transition: Taking Responsibility and Broadening the Scope

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For many of us, December is the time to look back to what happened during the year. Very often we end up remembering all the challenges, difficulties, worries and burdens that have accompanied us throughout the year. This is also the case this year and not without a reason: The world is full of wars, there are crises and unstable political conditions in many countries around the globe, and not to forget the climate change that is speeding toward catastrophe (Lenton et al., 2023).

But... Should we really leave this Editorial's review of the year at that? We don't think so. Even if we have seen a lot of miserable things happen in 2023, there are also a lot of positive activities going on. Or in the words of Haruki Murakami:

"Where there is light, there must be shadow, and where there is shadow there must be light. There is no shadow without light and no light without shadow." (Haruki Murakami, 1Q84)

In the ever-evolving landscape of clinical psychology, 2023 has witnessed remarkable strides that signal a paradigm shift in the discipline. This year has been marked by an expanded scope that addresses global challenges such as climate crises and wars, a heightened emphasis on patient and public involvement, and the establishment and fortification of crucial research initiatives. These positive developments not only signify the forward-thinking nature of clinical psychology but also underscore its relevance and adaptability in addressing contemporary societal issues.

Addressing Global Challenges: In response to the psychological impact of global challenges, the field of clinical psychology has expanded its purview. We are delighted



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to see that researchers in clinical psychology are taking responsibility and suggest ways how to improve mental health. In this issue, an Editorial by Pandi-Perumal and researchers from an impressive number of 22 different countries points to the consequences of war on mental health (Pandi-Perumal et al., 2023). The authors clearly express the need for international efforts to promote peace, humanitarian aid and mental health care. In an earlier issue, Asbrand, Michael, and colleagues (2023) discussed the impact of current challenges such as wars, societal polarization, and climate crisis on mental health in adolescents. The key recommendations of their paper include not only developing and expanding effective prevention and intervention programs, but also making a joint effort at various levels of society to enable effective changes. But also the activities of the field to overcome vaccination hesitancy to improve COVID-19 management indicated that clinical psychological concepts and intervention approaches are more and more considered relevant for tackling global challenges (Asbrand, Gerdes, et al., 2023; Bagarić & Jokić-Begić, 2022; Hysing et al., 2023; Lincoln & Rief, 2021; Wilson et al., 2022)

Emphasizing Patient and Public Involvement: The commitment to patient and public involvement in clinical psychology research is exemplified by initiatives mandated by renowned institutions such as the European Research Council (ERC) or the National Institute for Health Research (NIHR). For instance, the ERC, as a driving force in funding cutting-edge research across Europe, has been instrumental in promoting patient and public involvement as an integral component of research applications. Researchers seeking ERC grants are now required to demonstrate how they actively engage with patients and the public throughout the research process. Similarly, leading academic journals encourage researchers to engage with patients in the design, conduct, and dissemination of studies, recognizing the value of incorporating diverse perspectives to enhance the relevance and impact of medical and psychological research. These international initiatives not only elevate the standard of clinical psychology research but also align the discipline with a global ethos of inclusivity, ensuring that the voice of the patient and the public resonates in the development and implementation of mental health interventions.

Establishing and Strengthening Research Initiatives: This year has also seen the fortification of several research initiatives fostering mental health. These initiatives are characterized by their collaborative and cross-European nature, bringing together experts from diverse fields to tackle complex issues. Notable examples include projects focusing on the intersection of technology and mental health, initiatives aimed at reducing mental health disparities, and endeavors exploring the long-term impact of the global pandemic on mental well-being. The backbone of clinical psychology and psychiatry, namely the classification of mental disorders, is more and more challenged with suggestions for improvement or revision (see also our Special Issue "Innovations in ICD-11", (Maercker, 2022a, 2022b) and the manuscript in this paper (Rief et al., 2023)). Intervention techniques and trainings in psychological treatments are searching for new frameworks, that help to overcome barriers of traditional psychotherapy theories (see our Special



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Issue on "Transtheoretical psychological treatments" that will be published early 2024). Our association, the European Association of Clinical Psychology and Psychological Treatment (EACLIPT) has emerged as a central force in promoting collaboration and advancing clinical psychology practices across Europe. Most importantly, the EACLIPT campaigns for better policies at a European level (e.g. by reporting to and building a direct exchange with members of the European Parliament). In addition, the series of EACLIPT webinars featuring renowned experts who present research on hot topics in clinical psychology and psychological treatment. In 2023, O'Connor talked about the psychology of suicide risk and Neuner focused on trauma treatment in refugees (Neuner, 2023; O'Connor, 2023).

As the year draws to a close, we are pleased to announce the completion of the **fifth volume** of Clinical Psychology in Europe. This milestone is a proof of the vibrant landscape of clinical psychology and would not have been possible without the collective support of our community.

Our heartfelt thanks go to our brilliant publisher, whose commitment to excellence and open science has been fundamental to our success. Our thanks also go to the reviewers for their careful evaluations and to the authors who entrust us with their groundbreaking work.

We look forward with enthusiasm to the forthcoming CPE volumes. Thank you for being an essential part of our journey.

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Editorial



Harbingers of Hope: Scientists and the Pursuit of World Peace

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Abstract

The ongoing wars in many regions—such as the conflict between Israel and Hamas—as well as the effects of war on communities, social services, and mental health are covered in this special editorial. This article emphasizes the need for international efforts to promote peace, offer



humanitarian aid, and address the mental health challenges faced by individuals and communities affected by war and violence.

Keywords

SDGs, UN, UNHCR, COVID-19, global health diplomacy, Hamas, Israel, mental health, psychiatry, Middle East, military invasion, Palestine, peace, scientist, sustainable development goals, war

"Now I am become Death, the destroyer of worlds"
- The Bhagavad Gita

The world has recently endured COVID-19, followed by the Russian invasion of Ukraine, the worldwide outrage about unprovoked invasions and subsequent deaths of civilians, and, currently, the deadly war between Israel and Hamas in Gaza appears to have no end in sight. In the context of a long duration of bad blood between Palestinians and Israelis, Hamas attacked Israel in early October, an invasion which was evidenced by videos of murder, rape, torture, and kidnapping of civilian hostages. At the time of writing, while Hamas continues its rocket attacks on Israeli cities, Israel has responded with a ground invasion and massive bomb strikes, activities that have resulted in incremental deaths among civilians, a particular heart-wrenching tragedy in Gaza, with its very high population ratio of children and youth. The massive death and destruction have raised alarms among all nations. What is badly needed is humanitarian assistance in Gaza, where the population lacks food, water, and fuel. Israel, in the meanwhile, has lost the hostages in Gaza but also many of its young men and young women who are now waging war on five fronts.

Fear reigns on both sides. More civilians are being killed every day, injured, displaced, bereaved, traumatized, and deprived of home and livelihood. Fear of the outbreak of a regional conflict has spread beyond Gaza and Israel, and large-scale public demonstrations are taking place around the world, especially on Western university campuses where Palestinians are viewed as the underdogs in an unequal war.

We, as scientists and clinicians, have the means, whenever possible, of relieving anxiety and emotional distress. Hence, we feel the need to make our voices heard in the midst of this crisis. There are turning points in history that require the dissemination of good sense.

Armed conflicts significantly undermine the economic vitality of conflict-affected nations (Seleznova et al., 2023) and severely harm their social, physical, and human capital, both during and after the conflict is over. If international organizations are not given the opportunity and support to take urgent action, a humanitarian disaster will take place in Gaza. Amidst overwhelming despair and a general feeling of helplessness, we want to use our experience in researching the consequences of war and violence on mental health to lay out the facts regarding the impact of war on civilization.

The effects of violence, from Israel and Gaza to Afghanistan, Cambodia, the Democratic Republic of Congo, Iraq, Libya, Syria, Yemen, Myanmar, Nepal, Rwanda, Sri Lanka,



Syria, South Sudan, Sudan, and Ukraine, have all been well studied (Familiar et al., 2021; Kienzler & Sapkota, 2020; Razjouyan et al., 2022; Sá et al., 2022). History has supplied unambiguous evidence of the lasting harm of warfare (Hyseni Duraku et al., 2023; Leshem et al., 2023; Saw et al., 2023; Thomas et al., 2023). International wars, civil wars, proxy battles, conflicts, invasions, and insurgencies all end badly. They are all accompanied and followed by disruptions in the delivery of basic social services, especially access to healthcare, which has led to epidemics and spikes in infection and diseases, critical battle-related injuries, and chronic disability (Blais et al., 2023), acute malnutrition, acute and chronic mental health conditions, and horrific deaths (Sher, 2023). Wars always result in widespread suffering, enduring stress, trauma, loss, and population displacement, which can reverberate and scar the well-being of future generations. This, in turn, leads to the continuation of violence across generations (Betancourt, 2015; Castro-Vale et al., 2019; Dashorst et al., 2019). In longstanding conflicts, past injustices are used as rationales for future retribution and aggression. Human beings tend to ruminate over past grievances and, thus, view retaliation as justified. Continued violence rips at the social fabric of society, and healing is difficult, but can be achieved (Kapshuk & Deitch, 2023). It was achieved, against all odds, in Northern Ireland (Uluğ et al., 2023).

Living in war-torn countries has been associated with physical handicaps, and mental and psychological anguish (due to exposure to death). Complaints such as post-traumatic stress disorder (PTSD), anxiety, depression, sleeplessness, nightmares (Birhan et al., 2023; Pavlova et al., 2023; Rogowska & Pavlova, 2023), alcohol and substance abuse (Dissanayake et al., 2023), suicidal thoughts, tendencies, and attempted suicides (Blais et al., 2023; Sher, 2023) sexual and non-sexual violence (Hladik et al., 2023), and psychosomatic disorders all have been reported. These will have long-lasting effects on affected individuals. Both aggressors and victims face immense mental challenges: war trauma, violations of human rights, social exclusion, discrimination, spiralling rates of family violence, poverty, and loss of social support.

Women and children are disproportionately impacted because they are unable to flee from danger due to their socioeconomic dependence on men (Bendavid et al., 2021). Parental loss and family disruption negatively affect children throughout their adult lives, partly because the memory of the terrors of war impairs the parenting abilities of survivors (Ugurlu et al., 2016). Children grow up with attachment difficulties and personality problems and remain, throughout life, at high risk of suicide. Soldiers who serve in combat are increasingly reported as suffering from the often-catastrophic effects of injuries, medical problems such as chronic pulmonary disorders, as well as post-traumatic stress (Jordans et al., 2009).

Decades of rehabilitation and rebuilding work are always required to aid in the recovery of individuals impacted by war as well as in the restoration of communities and the rebuilding of means of subsistence. Many losses, not only of life but also of cultural traditions and meaningful religious symbols and structures, are irreversible.



When examining the effects of war on mental health and well-being, the results are invariably catastrophic whether for winners or losers, combatants or civilians.

One of the most visible impacts of living in war-torn countries has been physical disability. Wars disrupt the supply chain of food and potable water, contributing to malnutrition, gastrointestinal and respiratory problems, as well as an increase in community infectious diseases. Wars disrupt youth development and education (Gómez-Restrepo et al., 2023), leaving lasting transgenerational impacts on individuals and society. A notable concern is the mental health of first, second, and third generations of survivors.

Refugees are highly susceptible to trauma. As noted by the United Nations High Commissioner for Refugees (UNHCR), the main reasons for fleeing one's country are related to war, the threat to survival, and the violation of human rights. These situations undermine mental health. Fleeing brings with it the need to embrace a survival journey that involves abandoning one's identity and self-worth, leaving one's family and friends, subjecting oneself to dangerous, illegal crossings, and often needing to rely on unreliable human smugglers. Parental loss and family disruption adversely affect migrants for life (Raturi & Cebotari, 2023). The inhumane conditions in which people seeking asylum are forced to live while awaiting international protection are disastrous for mental health. We know that human beings are resilient (Purgato et al., 2020) but eventually, a limit to resilience is reached.

In the present world situation, we need to prepare for the worst. Specific physical, psychological, and mental health promotional help will be needed. Psycho-educational, psychological, and other integrated health services will be required, as suggested by the recently released World Mental Health Report (World Health Organization, Noncommunicable Diseases and Mental Health Cluster, 2005). Actions are needed to scale up interventions that are effective and sustainable in promoting mental health and preventing the development of mental disorders (Tol et al., 2023). As proposed by WHO, in civil societies, basic training in mental health and mental health first aid for people in civil societies should be a concern of all governments. Thousands of persons will be displaced and dispersed in host countries (Teixeira-Santos et al., 2023). There will be resource constraints and cost escalations. All sides in a conflict must make concessions, and this is difficult when there are wide differences in social, religious, and cultural norms, traditions, and values. A large influx of internally displaced people fleeing from violence at home is increasingly putting strains on the healthcare systems, other social services, and economies of countries that welcome refugees (Somasundaram et al., 2023). There are compromises that civilians, host governments, and communities need to make so that refugees can integrate into the host society and contribute to their new country's economic growth. If such an agenda fails, it will put pressure on the existing fabric of our global system and this usually leads to political unrest down the road.

Disinformation campaigns spread misinformation, disinformation, mal-information, tendentious information, and alternative facts on both sides of a war conflict. As a result,



even the well-intentioned fall prey to incorrect certainties, which they convey through their social networks. This results in unnecessary polarization and pitches neighbour against neighbour, destroying social networks that would be needed to re-establish the backbone of societies. The authors of this paper, as scientists and medical professionals, believe that our efforts are best focused on (i) averting conflicts among ourselves as a global community of scholars, scientists, and practitioners (not an easy feat); (ii) analyzing the effects of war; (iii) assisting in the creation of relief efforts, (iv) developing and studying the beneficial effects of new mental health promotion and prevention strategies; and (v) planning for mental health resources for now and for the (ideally quick) return of peace.

This special editorial has briefly highlighted some of the ramifications of war. When a conflict occurs in any part of the world, it triggers ripple effects that render us all vulnerable to fear. To combat fear, we unite as scientists to voice our opposition to war in general, as contrasted to protesting the rightness of one cause versus another.

As scientists, we strongly encourage international leadership and diplomacy among statesmen as a path to enduring peace (Pandi-Perumal et al., 2022). Scientific evidence has the power to improve the world's health, equality, justice, resilience, and prosperity for all. Negotiations and compromise among partners in dialogue lead to far better outcomes than mutual killings. International helping organizations and impartial, well-respected international leaders are crucial agents in advancing peace initiatives and giving civilians in war-torn regions, refugees, and internally displaced persons the much-needed assistance they require. As Nelson Mandela pointed out:

"Negotiation and discussion are the greatest weapons we have for promoting peace and development."

The United Nations (UN) is the driving force behind the Sustainable Development Goals ("Addressing Sustainable Development through Economic Empowerment," 2019); this is an intergovernmental set of objectives that advocates for 17 goals and 169 targets, covering a wide range of sustainable development issues and measured through 230 individual indicators that are inextricably linked to peace and stability (United Nations, n.d.). The SDGs are imperiled by conflicts that derail the process and prevent the aspiration of achieving critical milestones; this affects not only the countries directly involved in the conflict, but all nations.

Peace means better quality of life and better mental health. There is abundant scientific evidence that vulnerable populations, the public, planetary health and safety, global security, and the global economy must be protected in these very dangerous times. As scientists, we are mindful of the challenging, intricate, multifaceted, and malignant consequences of wars. Apart from its impact on human health, it also hurts biodiversity, accelerates climate disasters, and intensifies social inequalities, inequities, and injustices.



Let's form a multi-stakeholder partnership involving scientists, policymakers, legislators, and regulators to facilitate a sustainable future for our planet Earth.

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Scientific Update and Overview



Health Scares: Tracing Their Nature, Growth and Spread

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Abstract

Background: Health scares are highly publicised threats to health that increase public concern and protective behaviours but are later shown to be unfounded. Although health scares have become more common in recent times, they have received very little research attention. This is despite the fact that health scares often have negative outcomes for individuals and community by affecting health behaviours and causing high levels of often unnecessary anxiety.

Method: In this paper we undertook a review and analysis of the major types of health scares as well as the background factors associated with health scares and their spread.

Results: We found most health scares fell into seven main categories; environmental contaminants, food, malicious incidents, medical treatments, public health interventions, radiation from technology and exotic diseases. For most health scares there are important background factors and incident characteristics that affect how they develop. Background factors include conspiracy theories, trust in governmental agencies, anxiety, modern health worries and wariness of chemicals. Incident characteristic include being newly developed, not understood or unseen, man-made rather than natural and whether the incident is out of personal control. We also identified the aspects of traditional and social media that exacerbate the rapid spread of health scares.

Conclusion: More research is needed to identify the characteristics of media stories that intensify the levels of public concern. Guidelines around the media's reporting of health incidents and potential health threats may be necessary in order to reduce levels of public anxiety and the negative public health impact of health scares.



Keywords

health scares, media, environmental incidents, technology, nocebo effect

Highlights

- Most health scares can be categorised into one of seven types.
- Underlying environment and social factors influence the development of health scares.
- Traditional and social media could reduce the negative public health impact of health scares.

We live in the age of health scares, defined as a highly publicised threat (or perceived threat) to health that causes increases in public concern, avoidance or protective behaviour but is substantially disproportionate to the risk involved (MacKrill, 2021). News stories frequently appear in the media that raise concern about common household products, food or medication. While the respective health risk appears frighteningly large initially, it turns out to be comparatively low or unfounded in retrospect (Hooker, 2010). The early stage of a health scare is characterised by an increase in concerns and public anxiety which is followed by the gradual reduction in the frequency and tone of coverage, until the event is no longer newsworthy. Consequently, it is the response of the public and the media that elevates a health incident into a scare (Whitworth et al., 2017).

Many health scares involve the unexpected dangers of modern or new technology, such as 5G or Wi-Fi. Others, such as in modern food production, are concerned with chemical additives, processing or colourings. Most countries have experienced some form of scare over artificial sweeteners, the overuse of antibiotics in food, and genetically modified ingredients. Modern medicine has also been implicated, with drugs and other medical treatments always being a prominent source of public concern. Anxieties about vaccination are as old as the intervention itself but have recently gained more visibility with the COVID-19 pandemic.

Understanding the nature of health scares has become more important with increasing recognition and numerous examples of the public health consequences they can have. For example, the COVID-19 crisis has provided many unfortunate illustrations of how unfounded health scares about the virus and its control can cause negative outcomes for individuals and communities. These included the belief that COVID-19 was spread by 5G towers, which lead to a number of towers being damaged (Ahmed et al., 2020). A related scare was that COVID-19 vaccines alter people's DNA and that the vaccine was developed to control individuals by placing a microchip inside them for easy tracking (Sanders, 2020). This has contributed to a greater hesitancy for some individuals to be vaccinated and consequently affected uptake and community immunity.

Health scares can be rapidly transmitted on informal social networks spreading further anxiety and negative expectations in a community (Southwell et al., 2019). Research



suggests that individuals who hold strong conspiracy beliefs also are more likely to believe that some of the same factors that are commonly associated with health scares also cause cancer, such as eating genetically modified food and microwave ovens (Paytubi et al., 2022). The transmission of these beliefs can establish negative expectations that may subsequently produce a nocebo effect when the individual has been exposed to the focus of concern (Crichton, Dodd, et al., 2014). A nocebo effect is defined as adverse effects that are caused by negative expectations rather than any physical effects from exposure to an object of concern (Petrie & Rief, 2019).

In this paper we start by providing a taxonomy of common health scares, followed by an analysis of the background factors and circumstances associated with their development, as well factors involved in their spread. We end with a discussion of areas for future research on health scares.

Taxonomy of Health Scares

Research on health scares identifies particular health interventions, consumer goods or features of modern life that are often the subject of unexplained adverse reactions or unfounded concerns. From our analysis of this literature, we found that health scares fell into seven main categories; environmental contaminants, food, malicious incidents, medical treatments, public health interventions, radiation from technology and exotic diseases (Table 1). Consistent across many health scares is the fact that they can arise from a legitimate concern but what distinguishes health scares is the disconnect between the level of perceived and actual risk.

The first category of environmental contaminants involves instances where the public believe they have been exposed to a noxious substance in the environment, such as infrasound from wind turbines or chemicals in drinking water. These exposures are unlikely to have a physical effect on health but people report symptoms due to the perception of harm (Crichton, Chapman, et al., 2014; David & Wessely, 1995).

Health scares relating to exotic diseases occur when it is retrospectively determined that the catastrophic outcomes initially predicted when the disease first appeared did not occur. For example, the World Health Organisation (WHO) warned in 2004 that the bird flu virus could kill millions of people (Bird, 2005), however, to date there has been 457 deaths globally (WHO, 2023). Potentially this category represents an important dilemma that robust and effective prevention strategies that are used to contain an outbreak or virus could potentially increase anxiety and contribute to the creation of a health scare, as the public may see preventative measures as a sign of a severe and imminent health threat.

Food scares involve concerns that additives in food or genetic modification cause health problems. Scares may also occur when there is a confirmed contamination case but the public responds by avoiding foods unrelated to the incident (Whitworth et al.,



 Table 1

 Taxonomy of Common Health Scare Areas With Examples of Health Concerns and Evidence for the Scare

Health Scare	Reference Examples
Environmental contaminants	
Building ventilation/sick building	Kinman & Griffin, 2008; Mendelson et al., 2000; Ooi & Goh, 1997
Water scares	Banner, 2018; David & Wessely, 1995; Petrie & Wessely, 2004; Roy et al., 2023
Wind turbine infrasound	Chapman et al., 2013; Crichton, Chapman, et al., 2014
Exotic diseases	
Swine flu	Klemm et al., 2016
SARS	Hooker, 2008; Tausczik et al., 2012
Food scares	
Genetically modified food	Frewer et al., 2002; Shaw, 2002
Food contamination	Jacob et al., 2011
Additives	Bearth et al., 2014; Haen, 2014
Malicious incidents	
Anthrax	Leask et al., 2003; Wills et al., 2008
Deliberate chemical or radiation poisoning	Rubin et al., 2007; Rubin & Dickmann, 2010; Rubin et al., 2020
Medical treatments	
Amalgam fillings	Dodes, 2001; Flanders, 1992; Molin, 1992
Generic drugs and medicine reformulation	Boone et al., 2018; Faasse et al., 2009; Faasse et al., 2012; MacKrill et al., 2019
Hormone replacement therapy	Bluming & Tavris, 2009; Haas et al., 2007
Public health interventions	
Vaccination programmes	Burgess et al., 2006; MacKrill, 2023; Petts & Niemeyer, 2004
Water fluoridation	Armfield, 2007; Carstairs & Elder, 2008; Howat et al., 2015
Radiation from technology	
Electromagnetic fields	Rubin et al., 2010
Wi-Fi	Bräscher et al., 2017; Bräscher et al., 2020; Witthöft & Rubin, 2013
5G	Foster, 2019
Mobile phones and towers	Burgess, 2004; Drake, 2006; INTERPHONE Study Group, 2010

Note. Adapted from MacKrill (2021).

2017). On a broader level various foods containing gluten, dairy, flavourings, lactose, and various additives, such as sulphites can also cause avoidance and anxiety from time to time (Haen, 2014; Vernia et al., 2010).

A further category is comprised of scares involving malicious incidents. This category is characterised by targeted attacks on individuals that involve methods like radiation that could potentially impact the wider community and cause significant public anxiety, even if the actual risk of harm to the wider public is low. After the poisoning of the former Russian secret service agent Alexander Litvininko in London in 2006, a survey found 12% of Londoners believed their own health was at risk due to the Polonium



poisoning (Rubin et al., 2007). More recently following the deliberate poisoning of an ex-Russian intelligence officer and his daughter with Novichok in Salisbury, 19% of a sample of Salisbury locals reported avoiding the city despite it being a targeted rather than random event (Rubin et al., 2020). A large number of people with anxiety and distress-induced symptoms seek medical care following a terrorist attack or other malicious incident (Engel et al., 2007).

Two categories relate to medical interventions, namely concerns about medical treatments, and worries about public health interventions. Scares involving medical treatments typically involve existing patient groups, where the treatment is subsequently revealed to have unexpected side effects or undergoes changes in ingredient formulation or appearance, which can elicit a nocebo response due to negative expectations (Faasse et al., 2009; Faasse et al., 2016). In regards to scares relating to public health interventions, these occur in non-patient groups receiving a medical treatment, such as in the case of large vaccination campaigns. This can foster worries and reluctance, as people experience no visible benefit, such as symptom reduction, and are instead exposing themselves or vulnerable others (such as in childhood vaccinations) to potential adverse reactions or the risk of unforeseen negative effects (Martin & Petrie, 2017; Petts & Niemeyer, 2004).

Scares involving radiation from technology centre on the perceived harm of invisible electromagnetic fields, such as those from mobile phones, Wi-Fi or 5G, which do not have a physical effect no health (Rubin et al., 2010). A previous study has shown that when highly anxious participants are shown a television documentary about the possible health effects of Wi-Fi they are more likely to report symptoms after exposure to a sham Wi-Fi signal and to decide they were sensitive to electromagnetic fields (Witthöft & Rubin, 2013).

The health scare taxonomy differentiates the primary areas of concern in seven main categories. Table 1 provides an illustration of the common health scares in each category, references to specific examples of health concerns, and evidence for the scare. However, we recognise this is to some extent an arbitrary categorisation. The categories could easily be divided further, which has been done for food scares by Page and colleagues (2006) and Whitworth et al. (2017) for environmental contaminations. It is important to note that health scares are typically wider and affect a greater number of people than incidents of mass psychogenic illness (MPI), which occur after a discrete event involving a closed community, such as a school or office building.

Background Factors

Health scares do not occur in a vacuum and are instead produced through the environment and social context that effects their development and spread. We term these the background factors, which shape an individual's interpretation of threat and expectations about how their health may be affected. In this section we discuss a number of factors in



the contemporary social environment as well as individual factors that influence the impact and spread of health scares, specifically: conspiracy theories, trust in governmental agencies, anxiety, modern health worries, and a wariness of chemicals.

Conspiracy Theories

While it is clear that conspiracy theories have been with us for as long as there have been theories, there is evidence that they increase during periods of uncertainty and threat as has been the experience for many during the COVID-19 pandemic (van Prooijen & Douglas, 2017). Often conspiracy theories, which ascribe events to malevolent people or powers, provide a ready-made explanation of events that may be threatening or anxiety provoking, providing a simplistic, albeit wrong, explanation of complex events (Aaronovitch, 2010).

A conspiracy mentality, or the tendency to believe conspiracy theories, has important health consequences and is likely to influence the spread of health scares. Oliver and Wood (2014) found medical conspiracy theories, such as the FDA is deliberately suppressing evidence about natural cures of cancer because of pressure from drug companies, to be common in the US population. Conspiracy beliefs are associated with a wide range of health behaviours, such as preferences for organic food and avoidance of mainstream medicine (Oliver & Wood, 2014). There is evidence that the acceptance of conspiracy theories is associated with a shunning of vaccination (Jolley & Douglas, 2014) and lower adoption of recommended preventative actions against COVID-19 such as wearing a face mask (Romer & Jamieson, 2020).

Trust in Governmental Agencies

A similar influential factor is the degree to which people trust governmental agencies. Suspicion and distrust of government institutions makes reassurance from official channels less effective following a health scare (Uscinski et al., 2016). Distrust in the health-care system is associated with a greater tendency to believe health misinformation (Scherer et al., 2021). In the Salisbury Novichok incident, lower trust in governmental agencies was associated with greater anxiety, perceived risk to self, and an increased likelihood of avoiding Salisbury (Rubin et al., 2020). Trust can also affect side effect reporting. In an experimental study, lower trust in pharmaceutical regulatory agencies was associated with a greater number of side effects being attributed to a placebo tablet (Webster et al., 2018). In a medicine brand change, lower trust in pharmaceutical agencies was associated with a lower belief in the efficacy of a new generic medicine (MacKrill & Petrie, 2018).



Anxiety

Anxiety is, by definition, associated with health scares. The publicization of health threats increases the general public's anxiety but existing trait anxiety can be an important background to factor in the development of health scares. Anxiety has a close relationship with the tendency to notice physical symptoms and to interpret them more negatively (Barsky et al., 2002; Watson & Pennebaker, 1989). It is this misattribution process that is key in health scares and research suggests individuals higher in anxiety not only experience a greater number of symptoms but there is a greater tendency to misattribute these to the effects of any given health scare (Faasse et al., 2009; Petrie et al., 2004; Witthöft & Rubin, 2013).

Modern Health Worries

Concerns related specifically to modernity or new technology have also been identified as a risk factor for health scares generally (Petrie et al., 2001). Modern health worries are surprisingly prevalent with a large proportion of people acknowledging concerns about the safety of food or the health effects of chemicals in household products. A German study found that 94% of people report some concerns about the effect of modernity on health and that this was associated with greater symptom reporting (Rief et al., 2012). Other studies have found higher levels of modern health worries to be associated with a greater use of organic food and alternative medicine (Devcich et al., 2007; Furnham, 2007). The influence of modern health worries in a particular health scare was examined in a prospective study looking at the health effects of an aerial pesticide spray programme to control an invasive moth species in New Zealand. Individuals with higher levels of modern health worries were found to attribute more symptoms to the spray programme and to also believe the spray caused more health problems for themselves, their children and pets compared to those with lower levels of modern health worries (Petrie et al., 2005).

Wariness of Chemicals

A related factor is an increase in the fear of chemicals or the association of chemicals with cancer, death and toxicity (Siegrist & Bearth, 2019). This has been called "toxicohistrionics" (Banner, 2018) and is often associated with the belief that modern manufacturing produces products that have dangerous levels of chemical substances that are hazardous to health (Saleh et al., 2019) and may be particularly associated with water and food-related health scares. Negative attitudes towards chemicals are associated with a greater preference for natural foods (Dickson-Spillmann et al., 2011). People with high levels of concerns about chemical substances that are present in food or the environment often do not consider the importance of dose (the dose makes the poison) or that the distinction between synthetic and natural chemicals is irrelevant when assessing chemical



risk in food (Paarlberg, 2021) or water (Roy et al., 2023). It seems that this concern is increasing while the risk of such exposures has decreased over time (Entine, 2011).

Incident Characteristics

Background factors are only one part of the foundation required to develop health scares. Health-related worries on their own will not manifest symptoms, rather a threatening event is also required to influence bodily awareness and the misattribution of symptoms to a particular category of scare. For instance, worry about power lines did not influence symptom reporting for people who did not live next to high voltage transmission lines, whereas for those living in these areas, the most worried respondents were more likely to report health problems (McMahan & Meyer, 1995). It seems logical that background factors alone can't create a health scare and that a threatening event is also necessary. However, not all health interventions or environmental events will be perceived as threatening. Incidents that often develop into larger health scares have certain characteristics that instil worry. These characteristics include: being newly developed, not well understood or unseen threats, natural versus man-made, and out of personal control (MacKrill, 2021).

Newly Developed

A frequent unifying factor of many common examples of health scares is that the event or medical intervention is modern or newly developed. Through history it is evident that health scares often follow the advent of a new form of technology. When the bicycle was created in the 1880s it was believed that the riding position would cause hernias and curvature of the spine and that women in particular could become possessed by 'cyclemania' (Whorton, 1978). As the novelty of the technology begins to decline so does concern; it is now accepted that cycling conveys many health benefits. Anxiety and concerns surrounding modernity still exist but the focus has shifted towards the latest technological advancement such as 5G (Elwood & Wood, 2019). It should be noted that this can also include changes to existing familiar interventions, such as medications, that take on a new form or colour (Faasse et al., 2009).

Not Understood and Unseen

It is often the case with newly developed technology that the underlying science is not be well understood by lay people. The general public may believe that the safety of the intervention has not been proven and unidentified negative effects might still occur. An example here is the new mRNA COVID-19 vaccines that use new technology to produce an immune response. The public's confusion and concern about the potential unknown effects of these interventions can be fuelled by the perception of 'unseen' harms. For



example, these interventions are often described as an invisible danger and people can be concerned that they are being unknowingly exposed to a perceived health threat (e.g., Owens & Feldman, 2004; Reekie, 2017).

This has also been the case for health scares about electromagnetic fields (EMFs), such as those from Wi-Fi, mobile phones and microwave ovens. Public discussion about the health effects of EMFs has focused on the radiation emitted, with claims that mobile phones or Wi-Fi can cause cancer (Swerdlow et al., 2011). Despite the widespread use of phones there has actually been a decrease in the diagnosis of brain and other nervous system cancers over the last 15 years in the United States (United States Food and Drug Administration, 2020). Confusion can be further exacerbated through factually correct albeit unclear information like the World Health Organisation (WHO) classifying mobile phones as "possibly carcinogenic" (WHO, 2014). While this sounds alarming to the general public, there are other normal, everyday things, like pickled vegetables and carpentry, that also share this classification.

Man-Made Versus Natural

In a similar vein is the differing perception of harm from natural versus man-made interventions. There is a common misconception that synthetic chemicals, at any concentration, are harmful (Entine, 2011). Chemicals of natural origin are perceived to be healthier and safer than synthetic chemicals, since the latter involve human intervention (Saleh et al., 2019). Even though a medicine's efficacy and safety may be clinically proven, patients can be fearful of putting 'unnatural chemicals' into their bodies and instead turn to untested 'natural' remedies (Petrie & Wessely, 2002).

Low Personal Control

If a situation is perceived to be out of an individual's control then this can also promote health scares. The perception of threat can be high when an incident is uncontrollable (Slovic, 1987). A feeling of lacking personal agency can occur through the government acting on behalf of the public. This is the case with water fluoridation, which despite the overwhelming evidence that fluoride is safe and effective at reducing tooth decay, is viewed as a violation of people's rights not to be subjected to compulsory medication (Reekie, 2017). When compulsory vaccination was introduced in Britain in the mid-19th century, opponents claimed that people's freedoms were being invaded by Parliament (Hussain et al., 2018). In mandatory medication switches from branded to generic medicines there are often backlash as patients fear side effects from the new brand and perceive their medicine options being removed due to a government cost-cutting strategy (Faasse et al., 2009). As a result, the nocebo effect frequently occurs in medicine brand changes (Weissenfeld et al., 2010).



Health Scare Spread

The concerns about and nocebo reactions to a perceived health threat initially start as an individual response. However, these issues can grow and be spread to a wider population through traditional and social media. As will be discussed in the next sections, it is this spread and publicity that transforms a health incident to a health scare.

Traditional Media

It has been claimed that the traditional media, such as newspapers and television, can turn a health incident into a crisis (Doeg, 1995). The media is central in the dissemination of health alarms (Burgess, 2008) and health scares are frequently characterised by mass media reporting creating panic about a health issue or intervention (Guillaume & Bath, 2004).

Observational studies clearly illustrate the impact of the media on spreading worry and adverse event reporting. Negative media coverage of the MMR vaccine by a local newspaper in the United Kingdom was associated with a decrease in vaccination rates by almost 14% in the area covered by the newspaper (Mason & Donnelly, 2000). Newspaper coverage of side effects was also found to be associated with an increase in adverse event reports from the HPV vaccination (Faasse et al., 2017). Media coverage discussing side effects from a generic antidepressant was associated with an increase in adverse event reporting, with television increasing the reporting rate by more than 210% compared to print media (MacKrill et al., 2019; MacKrill et al., 2020). Recently, the discussion of rare COVID-19 vaccine side effects in the media resulted in increased reporting of cardiac complaints, which were likely self-diagnosed (MacKrill, 2023). We identified two key factors responsible for the media's ability to spread nocebo responding and anxiety about a health event: 1) the faming of the news item; and 2) the process of social modelling.

The way the media frames issues can influence the public's expectations about a health event. The media is often people's first source of information about a health threat and because it is considered to be a trusted source, the reporting has the ability to shape long-lasting expectations (Guillaume & Bath, 2004). However, it is usually negative expectations that are developed, as the media is more interested in stories about an intervention causing harm than stories about benefit (Kitzinger, 1999). Tobert and Newman (2016) give the example of how "Statins have very few adverse effects" is not newsworthy, but "Cholesterol drugs taken by millions are dangerous" often is. This media focus has resulted in strong expectations in the general public that statins are associated muscle pain and other side effects, resulting in high discontinuation rates (Matthews et al., 2016).

There is often an imbalance between how much media attention a health issue receives and its actual public health significance (Cooper & Roter, 2000). News articles about health threats disproportionately discuss toxic and environmental causes of illness,



while neglecting lifestyle factors that are more common causes of illness (Frost et al., 1997). Even if experts or officials deny a link between a health event and an adverse reaction, the media have been known to report on an individual personal account of harm, allowing the perceived risk to enter public awareness (Kitzinger, 1998). Almost three quarters of British newspaper reports presented a mainly electromagnetic cause for complaints of symptoms from EMFs and used the experiences of particular people as examples (Eldridge-Thomas & Rubin, 2013).

Repeated reporting of a health issue can also be detrimental. The availability heuristic can influence people's estimation of the probability of events due to how readily confirmatory examples can be brought to mind (Kahneman et al., 1982). When the media continuously highlights a health issue, examples of harm can be readily recalled causing people to overestimate its incidence (Gollust et al., 2019). Additionally, artificial balance can be created by the media. In the United Kingdom, the media often gave equal coverage to both sides of the MMR-autism debate, which led the public to assume there was equal evidence for each argument (Hargreaves et al., 2003).

News stories often simplify a health issue (Seale, 2003). In the case of genetically modified food, media coverage reduced the complexity of this issue into a simple conflict between organic versus processed foods. Organic food has been framed as safe, natural and nutritious, while the alternatives that are created through new technology are artificial, threatening and untrustworthy, which has been linked to a rising anti-genetic modification attitude in the general public (Lockie, 2006).

Media coverage is also able to spread adverse reaction reporting through the process of social modelling. It has been well documented in experimental placebo studies that seeing another person report side effects can influence the treatment outcome in the observer (Faasse & Petrie, 2013). Seeing a study confederate report side effects from a placebo tablet results in a reduced placebo effect as well as increased side effect reporting (Faasse et al., 2015). Similarly, after inhaling an inert substance described as a toxin, female participants reported more side effects if they saw a model also report side effects (Lorber et al., 2007; Mazzoni et al., 2010). Watching a model display more pain after a placebo cream was applied resulted in participants also reporting greater pain (Vögtle et al., 2013).

Media coverage replicates this social modelling effect on a larger scale. The act of seeing someone in a media story report medication side effects can lead to increased expectations in the observer that they too will experience this response (Faasse & Petrie, 2016). When participants were shown television coverage of people reporting negative health effects from wind turbine noise, they reported more symptoms and of higher intensity than those who watched a neutral information video (Crichton, Dodd, et al., 2014). This effect has also been found in research investigating EMFs (Bräscher et al., 2017; Witthöft & Rubin, 2013; Witthöft et al., 2018). This can also occur with written information. Participants who read a leaflet containing media warnings about environ-



mental pollution and a case example of someone with Multiple Chemical Sensitivity, reported more side effects after inhaling an inert substance than those who did not receive prior warning (Winters et al., 2003).

Social Media

More recently, social media has been a key medium in the spreading of negative beliefs about health interventions. Unlike traditional media, social media has allowed opponents of medical interventions to directly share their concerns, which are not required to factually accurate (Wilson & Keelan, 2013). For example, the vaccine-autism link has been shown to be discussed more frequently on social media than in online mainstream news sites (Jang et al., 2019). Similarly, in the 2014 Ebola crisis, news shared on the social media platform Reddit amplified panic and uncertainty surrounding Ebola, while traditional newspaper coverage was significantly less likely to produce panic-inducing coverage (Brown et al., 2019). In another study, mothers who do not support childhood vaccination were more likely to share opinions and negative information on social media compared to those who did support vaccination (McKeever et al., 2016).

Negative health information appears to spread more readily on social media than accurate or positive public health appeals. An analysis of news stories on Twitter found that false stories spread faster and more broadly than true stories, potentially due to them containing more novel information (Vosoughi et al., 2018). Exposure to misinformation on the internet about health threats can lead to negative expectations, which further reinforces opposition (Crichton & Petrie, 2015).

Conclusion and Future Directions

This review provides the basis for how health scares are likely to develop and spread to wider populations. When a threatening incident occurs, background factors unique to an individual become more salient and influence expectations and health behaviours. Through examining health scare and nocebo effect literature, we identified specific influential background factors, namely conspiracy theories, trust in governmental agencies, anxiety, modern health worries, and a wariness of chemicals. Additionally, characteristics of incidents that appear to influence threat appraisals include being newly developed, not well understood or unseen threats, natural versus man-made, and out of personal control. Past research clearly shows that health concerns and adverse reactions can spread rapidly to a wider group of people through the attention of traditional and social media. This review has also provided a taxonomy to aid the grouping of health scares into common areas of concern. It is hoped that this taxonomy will help researchers differentiate between different types of health scares and encourage a greater analysis



of how different factors way be involved in the development and resolution of specific scares.

It is evident that more research is needed on interventions to reduce the development and spread of health scares, in particular identifying the characteristics of media stories that intensify the levels of public concern and increase the likelihood a story will be shared widely. A cardinal characteristic of health scares is the perceived level of risk is disproportional to the actual level of risk. Unlike many areas of health where researchers wish to increase the public's attention to risky behaviour or substances, in the case of health scares the need is to develop effective strategies to increase reassurance and alleviate public concern. It may be beneficial to provide an additional explanation of how beliefs and concerns can manifest symptoms and be misattributed to a treatment or other exposure, as this has been shown to be effective at reducing anxiety and symptom reporting (Crichton, Chapman, et al., 2014; MacKrill et al., 2021).

Social media has taken some steps to curb the spread of misinformation and scares by attaching a warning to posts that contain inaccurate information. In a similar vein, guidelines around the media's reporting of side effects and potential health threats may be necessary in order to reduce the effect of social modelling and the spread of anxiety. There needs to be a balance between creating a newsworthy story but not needlessly exacerbating worries. Future research will further our understanding of the role of psychology in intensifying perceived health threats, which will aid the development of strategies to reduce the likelihood of health scares occurring in the future.

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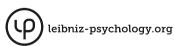
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Research Articles



How and Why the Choice of Success Criteria Can Impact Therapy Service Delivery: A Worked Example From a Psychological Therapy Service for Anxiety and Depression

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Supplementary Materials: Materials [see Index of Supplementary Materials]



Abstract

Background: Well-defined measures of therapeutic benefit are essential for evaluating therapies and services. However, there is no single gold standard for defining 'successful' outcomes. We therefore examined the potential impact of adopting different success criteria.

Method: We analysed data for 7,064 patients undergoing psychological therapy in a single UK IAPT (Increasing Access to Psychological Therapy) Service, each patient being assessed for depression (PHQ-9) and anxiety (GAD-7) both at the start and end of treatment. Predictors of successful outcomes based on these measures were analysed separately for three different success criteria: based either on assessing clinically significant change, or reliable change, in depression and anxiety.

Results: The choice of criteria had little bearing on which variables predicted successful outcomes. However, the direction of the relationship between initial PHQ-9 or GAD-7 score and outcome success reverses when the criteria used to judge success are changed: successful outcomes are less probable under clinically significant change criteria for patients entering the service with more severe depression and/or anxiety but are more probable for such patients under reliable change criteria.

Conclusion: Relevant for clinicians, researchers, and policymakers, the choice of success criteria adopted can substantially change the incentives for patient selection into a therapy service. Our



analysis highlights how the methods used to evaluate treatment outcomes could impact the priorities and organisation of therapeutic services, which could then impact on who is offered treatment. We recommend further investigations of success criteria in other conditions or treatments to determine the reproducibility of the effects we found.

Keywords

Increasing Access to Psychological Therapy (IAPT), therapy outcomes, clinically significant change, reliable change, payment by results, anxiety, depression

Highlights

- Changing the criteria for judging therapy success alters treatment incentives.
- The choice of success criteria changes which cases are likely to have successful outcomes.
- Incentives to treat a patient group are substantially affected by the success criteria chosen

Incentives in Healthcare Systems

Incentives abound in healthcare systems. Of course, the primary incentive is shaped by the goal of achieving good outcomes for patients. However, incentives can be created in numerous ways, and their (sometimes unintended) consequences are diverse. For example, one might expect that insurance-based systems and/or a culture of malpractice litigation encourage excessive use of diagnostic tests (e.g., additional testing with limited incremental predictive value) because the costs of testing are easily covered (by insurance companies) and extensive testing provides concrete evidence of due diligence in diagnosis (a defence against litigation). In the - mainly publicly funded - UK health system, 'payment by results' has become increasingly common (e.g., NHS England and NHS Improvement, 2017a) with the laudable goal of incentivising best practice to improve services and clinical outcomes, while also increasing efficiency (Horton, 2007; Taunt et al., 2015). However, anecdotes of weaknesses in such target-driven approaches are commonplace. These include removing wheels from trolleys to create 'beds' that meet targets designed to reduce patients' waiting-times on trolleys (Bevan & Hood, 2006) and having patients wait *outside* a hospital in ambulances to meet a maximum 4-hour waiting target in Accident and Emergency departments (Watts & Donnelly, 2012). Nonetheless, there is no a priori reason why well-designed financial incentives should not be used to improve the treatment that patients receive.

In 2017, NHS England and NHS Improvement issued detailed guidance to support service commissioners and providers to implement an outcomes-based payment approach for the UK's flagship (publicly funded) IAPT Service (*Increasing Access to Psychological Therapy*; NHS England and NHS Improvement, 2017b). This mandated the use of an outcomes-based payment model for IAPT services from 1 April 2018 onwards,



consisting of both a basic service price component reflecting activity *and* an outcomes payment component based on quality indicators and patient outcomes. The analysis presented in this paper primarily relates to the clinical outcomes element that comprises 50% of the outcomes payment component (with the other half of this component being based on performance against nine other quality and outcome measures). Note, however, that the application our analysis is not restricted to situations where payment by results is applied; but rather, to any situation where one clinical outcome measure is chosen in place of another or is given priority over another measure when outcomes are evaluated.

To illuminate the potential impact of the incentive structure created by the choice of clinical outcome measures, we analyse the clinical outcomes for both Depression and Generalised Anxiety Disorder from an IAPT service *prior to* the introduction of payment by results (PBR). To assess depression, IAPT services routinely use the Patient Health Questionnaire PHQ-9 (Kroenke et al., 2001) and for Generalised Anxiety Disorder the seven question GAD-7 measure (Spitzer et al., 2006). A quantitative assessment of the outcome of treatment is based on comparing pre- and post-therapy scores on the relevant clinical scale. However, there are different ways that this can be done in order to define a 'successful' treatment outcome (e.g., see Richards & Borglin, 2011). By considering three possible success criteria, and examining what predicts successful treatment outcomes according to each criteria in several thousand patients, we illustrate how the choice of success criteria could affect the incentives for patient selection for treatment. This is important because when incentives change, behaviour often changes – though not necessarily as hoped for by those creating the incentive structure (Gneezy & Rustichini, 2000).

Success Criteria in Psychological Therapy

Jacobsen and colleagues (Jacobson et al., 1984; Jacobson & Revenstorf, 1988; Jacobson & Truax, 1991) proposed two criteria to ascertain whether or not the change experienced by a patient/client is meaningful: *clinically significant change* (CSC) and *reliable change* (RC).

The notion of *clinical significance* (as distinct from statistical significance) in therapy has been conceptualised in various ways, including: the practical value of the effect of an intervention (Risley, 1970); an improvement in the client's everyday functioning (Kazdin & Wilson, 1978); a return to normal levels of functioning (Kendall et al., 1999; Nietzel & Trull, 1988) which is indistinguishable from that of their peer group (Kazdin, 1977). Operationalizing such considerations via standardised clinical assessments, Jacobson and colleagues proposed that *clinical significance* can be determined by the client's score at post-treatment falling within the range for the functional population as opposed to the dysfunctional one (at pre-treatment). However, this criterion does not take account of measurement error, which may therefore give rise to misinterpretation due to regression to the mean; and there can also be difficulties determining what cut-off score(s)



should divide the functional and dysfunctional populations (Tingey et al., 1996a, 1996b; Wampold & Jenson, 1986)

Measurement error is better dealt with in measures of (*statistically*) *reliable change*, which seek to determine whether a change is large enough to be considered meaningful. Such measures assess pre-post changes in scores on a clinical assessment relative to the standard error of that assessment tool (reflecting its reliability and the variability of scores in the normal/functional population). A reliable change can be said to have occurred if the pre-post change represents a statistically reliable improvement (or deterioration). Thus, the *size of change*, rather than whether change takes the patient across a threshold (as with CSC) is what determines success. This has the advantage of recognising improvements in symptoms even if the patient's scores remain within the dysfunctional range (Lunnen & Ogles, 1998).

In our analysis of treatment outcomes, we follow the implementations of CSC and RC used by Richards and Borglin (2011) for the PHQ-9 and GAD-7 measures (the tools for assessing depression and anxiety used by IAPT, and reflected in the clinical outcomes element of the IAPT PBR system). Additionally, we examine outcomes according to an IAPT recovery criteria. This is a variant of the CSC approach but specifies different threshold (cut-off) scores to those for Richards and Borglin's CSC implementation. The cut-off scores for this IAPT recovery criteria match the guidance given to general practitioners (GPs) regarding who to refer to an IAPT service (Clark et al., 2009) and are therefore important for determining which patients enter the IAPT service, how long they remain in it, and when they leave. This guidance dated from the set-up of the first IAPT services, and therefore precedes the introduction of PBR to IAPT by several years.

Method

Data

The anonymous dataset analysed (N = 7,064) comprised all patient cases undergoing therapy in a single IAPT service between 01 January 2009 and 14 February 2012 for whom both initial (start-of-treatment) and final (end-of-treatment) scores were available for both the PHQ-9 and GAD-7 measures. The data were provided by the IAPT Service in question. Scores for PHQ-9 and GAD-7 were used to categorise each case according to the three success criteria under consideration: IAPT recovery, clinically significant change and reliable change criteria.

Application of Success Criteria to the Data

It made little sense to analyse successful outcomes for patients who, because of their pre-treatment scores, could not achieve a criterion for 'success'. Therefore, for each of the three success criteria that we considered (Table 1) a subset of the data was created



containing only those patients that could (in principle) have a successful outcome to their treatment. The process of creating these three subsets is described below.

IAPT Recovery Criteria

IAPT services were set up to provide psychological therapy primarily for patients with anxiety disorders and/or depression that is *at least* moderate (Clark et al., 2009). Therefore, 'recovery' is classified as moving a service user from a score (at first appointment) that would identify them as suitable for GP-referral (PHQ-9 > 9 or GAD-7 > 7) to a score (at last appointment) that is too low to trigger GP-referral to the service (PHQ-9 < 10 and GAD-7 < 8). Thus, when a patient's initial score is close to the threshold specified by the IAPT criteria, a small reduction in their score is sufficient for a 'recovery' classification, e.g., from 10 to 9 for PHQ-9, and from 8 to 7 for GAD-7. However, much larger changes are required for a recovery classification when a patient's initial score is high (e.g., severe depression with PHQ-9 of 21) because for this classification the final score must fall below the specified threshold. Consequently, for the IAPT recovery criteria, we analysed cases with initial PHQ-9 scores above 9, or initial GAD-7 scores above 7 because these were the patients (N = 6,338) who *could* 'recover' on these criteria.

Clinically Significant Change (CSC) Criteria

Following the definition from Richards and Borglin (2011), a success under the CSC criteria for depression is when PHQ-9 is above 8 pre-treatment and then is below 9 post-treatment. GAD-7 scores were required to be above 9 at pre-treatment and below 10 post-treatment. Thus, the minimum changes for a 'success' classification on the CSC criteria are from 9 to 8 for PHQ-9, and from 10 to 9 for GAD-7. This means that 'success' cannot be defined by the CSC criteria when a patient's initial score is already below the specified threshold (i.e., PHQ-9 below 9, GAD-7 below 10). Therefore, for CSC, we analysed cases with initial PHQ-9 scores above 8, or initial GAD-7 scores above 9 (N = 6,127).

Reliable Change (RC) Criteria

For an outcome to be defined as showing reliable improvement, Richards and Borglin (2011) calculated that the PHQ-9 had to improve by 6 points or more and the GAD-7 by 5 points or more. Because the PHQ-9 and GAD-7 scales start at zero, a reliable change cannot be observed when a patient's initial score is smaller than the size of change specified by the RC criteria. Therefore, for the RC criteria, we analysed cases with an initial PHQ-9 score above 5 or an initial GAD-7 score above 4. For our joint analysis of success according to reliable change on both measures, reported below, only cases above *both* cut-offs (simultaneously) are included (*N* = 6,218).



Table 1Criteria Applied for the Analyses of Outcomes Defined by PHQ-9 and GAD-7 Scores (Analyses Are Reported in Tables 2-4)

Success criteria	Starting criteria ^a	Criteria to achieve a successful intervention	Number of cases analysed [available] ^b
IAPT recovery	Case has either a PHQ-9 > 9 or a GAD-7 > 7	Must record final scores of PHQ-9 < 10 and GAD-7 < 8	6,293 [6,338]
Clinically significant change (CSC)	Case has either a PHQ-9 > 8 or a GAD-7 > 9	Must record final scores of PHQ-9 < 9 and GAD-7 < 10	6,184 [6,229]
Reliable change (RC)	Case has both a PHQ-9 > 5 and a GAD-7 > 4	Must improve PHQ-9 score by 6 points or more and improve the GAD-7 score by 5 points or more	6,170 [6,218]

aStarting criteria represent the minimum score(s) needed to allow for the possibility of success; if scores fall below the specified cut-offs it is impossible to achieve a successful outcome with these criteria. bSome cases with complete data for PHQ-9 and GAD-7 scores could not be included in the regression analysis of predictors of success due to missing data for predictor variables. Missing data are for Deprivation, Age or Gender.

For all three of the assessment methods, we used the success on both affect scales considered in combination as criteria for being an overall success for the patient (Table 1).

Data Analysis

Within each data subset, each patient's outcome was coded for success (no vs. yes) according to the criteria for IAPT Recovery, CSC and RC. Next, using *SPSS* software, three analyses were conducted using binary logistic regression, one for each data subset. Each analysis used the same set of 10 predictor variables (see Table 2, 3, or 4) to determine the independent predictors of success (for each success criteria in turn). These variables are ones that had previously been found to predict engagement with treatment and/or final scores for PHQ-9 or GAD-7 within this patient cohort (Wheeler, 2018). For simplicity and transparency of reporting, PHQ-9 scores were re-coded into one of five categories: minimal (scores of 0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe (20-27). Four categories were used for the GAD-7: minimal (0-4), mild (5-10), moderate (11-15) and severe (16-21). Non-dichotomous categorical variables were dummy coded. For these variables, the reference category (i.e., 'baseline category', coded



'0') is shown in Tables 2, 3, and 4, together with the other category (coded '1') for each dummy variable.

 Table 2

 Successful Outcomes for IAPT Recovery Criteria by Patient Category, and Logistic Regression With Successful Outcome as the Dependent Variable

Predictor variable (Level)	Baseline characteristic	% patients	% success within category	p^{a}	Adjusted odds ratio	df	99% CI for adjusted <i>OR</i> (lower and upper limits)
		- In caregory	curegory		(01.)		пррег пппсо,
Gender	26.1						
Female	Male	33.4 66.6	39.0 38.9	.297	- 1.069	-	- 1 262
гешате		00.0	36.9	.297	1.069	1	0.907 - 1.260
Age in bands	16-24	15.9	33.3	-	-	-	-
Age 25-34 years		21.9	38.2	.516	1.066	1	0.827 - 1.374
Age 35-44 years		23.8	37.9	.677	1.042	1	0.810 - 1.340
Age 45-59 years		26.9	39.1	.309	1.102	1	0.861 - 1.411
Age ≥ 60 years		11.6	49.8	.020	1.348	1	0.967 - 1.878
Deprivation decile ^b	Decile 1-2	9.9	33.0	-	-	-	-
Decile 3-4		11.0	38.4	.218	1.172	1	0.841 - 1.635
Decile 5-6		32.5	38.6	.535	1.069	1	0.810 - 1.413
Decile 7-8		27.3	41.7	.080	1.213	1	0.913 - 1.610
Decile 9-10		19.4	38.6	.326	0.891	1	0.660 - 1.205
Employment ^c	In work	33.1	46.2	-	-	-	-
Unemployed seeking		17.0	42.1	.014	0.812	1	0.652 - 1.011
Students		20.8	25.8	< .001	0.490	1	0.393 - 0.611
Long term sick		7.8	28.9	< .001	0.535	1	0.391 - 0.733
Not actively seeking		19.5	42.5	.001	0.726	1	0.566 - 0.930
Retired		1.0	43.1	.304	0.754	1	0.372 - 1.530
Not known/stated		0.8	18.4	.005	0.317	1	0.109 - 0.919
Referral source ^c	GP	53.2	38.9	-	-	_	_
Self (i.e., patient)		41.0	40.7	.728	1.021	1	0.873 - 1.196
Secondary care		2.3	28.1	.056	0.675	1	0.398 - 1.146
Other source		3.6	25.3	< .001	0.535	1	0.340 - 0.843
Referral history	New referral	79.8	39.9	-	_	-	-
Re-referral		20.2	34.9	.381	.936	1	0.771 - 1.136
Psychotropic Medication	Not Prescribed	5.9	39.0	_	_	_	_
Prescribed, not taking		50.8	36.0	.853	1.024	1	0.740 - 1.416
Prescribed, taking		40.1	42.3	.596	1.070	1	0.771 - 1.484
Unknown/declined to say		3.3	44.2	.150	1.327	1	0.800 - 2.202
Initial PHQ-9 ^c							
Minimal		2.4	68.4	< .001	4.923	1	2.923 - 8.260
Mild		10.9	61.5	< .001	3.763	1	2.834 - 4.995
Moderate		26.7	48.6	< .001	2.322	1	1.859 - 2.901
Moderately severe		32.0	35.3	< .001	1.591	1	1.591 - 1.955
,	Severe	29.0	22.9	_	_	_	_



Predictor variable (Level)	Baseline characteristic	% patients in category	% success within category	p^{a}	Adjusted odds ratio	df	99% CI for adjusted <i>OR</i> (lower and upper limits)
Initial GAD-7 ^c							
Minimal		1.6	58.0	< .001	3.075	1	1.710 - 5.528
Mild		20.4	55.7	< .001	2.229	1	1.796 - 2.766
Moderate		35.8	41.9	< .001	1.448	1	1.211 - 1.730
	Severe	42.3	27.6	_	-	-	_
Engagement ^c	Less than 25%	4.1	14.8	-	-	-	-
26 - 50%		31.2	22.9	.007	1.681	1	1.027 - 2.750
51 - 75%		39.2	42.0	< .001	4.462	1	2.749 - 7.244
76 - 100%		25.5	57.5	< .001	8.563	1	5.228 - 14.025

Note. N = 6,293 patients with initial PHQ-9 > 9 or initial GAD-7 > 7, as defined by the IAPT recovery starting criteria. CI = confidence interval. Model fit: -2LL = 7135.5, Nagelkerke R^2 = .249, χ^2 (32, N = 6,293) = 1273.9, p < 001

^ap-values for significant differences (α = .01) from the baseline category are shown in bold face type. ^bPredictor variable is significant, p < .01. ^cPredictor variable is significant, p < .001.

Table 3Successful Outcomes for Clinically Significant Change (CSC) Criteria by Patient Category, and Logistic Regression With Successful Outcome as the Dependent Variable

Predictor variable (Level)	Baseline characteristic	% patients in category	% success within category	p ^a	Adjusted odds ratio	df	99% CI for adjusted <i>OR</i> (lower and upper limits)
Gender	Male	33.5	40.2	_	-	_	-
Female		66.5	39.5	.621	1.032	1	0.875 - 1.217
Age in bands	16-24	16.0	35.3	_	-	_	_
Age 25-34 years		21.8	38.9	.990	0.999	1	0.776 - 1.286
Age 35-44 years		23.8	38.8	.809	0.977	1	0.760 - 1.256
Age 45-59 years		27.0	39.4	.978	1.003	1	0.784 - 1.283
Age ≥ 60 years		11.4	50.3	.057	1.279	1	0.916 - 1.784
Deprivation decile	Decile 1-2	10.0	34.8	-	-	-	_
Decile 3-4		10.9	39.1	.297	1.144	1	0.821 - 1.593
Decile 5-6		32.4	39.0	.804	1.027	1	0.779 - 1.354
Decile 7-8		27.3	42.3	.163	1.164	1	0.879 - 1.542
Decile 9-10		19.3	40.2	.464	0.918	1	0.681 - 1.239
Employment ^b	In work	33.1	47.8	-	-	_	-
Unemployed seeking		16.9	41.9	.001	0.745	1	0.597 - 0.929
Students		21.0	27.0	< .001	0.485	1	0.389 - 0.603
Long term sick		7.8	28.3	< .001	0.473	1	0.345 - 0.649
Not seeking		19.3	43.0	< .001	0.704	1	0.549 - 0.903
Retired		1.0	42.9	.170	0.684	1	0.335 - 1.396
Not known/Stated		0.8	22.0	.012	0.380	1	0.141 - 1.024



Predictor variable (Level)	Baseline characteristic	% patients in category	% success within category	p ^a	Adjusted odds ratio	df	99% CI for adjusted <i>OR</i> (lower and upper limits)
Referral source ^b	GP	53.2	39.9	_	_	_	_
Self (i.e., patient)		40.8	41.3	.949	1.004	1	0.857 - 1.176
Secondary care		2.4	26.5	.007	0.571	1	0.335 - 0.972
Other source		3.6	27.4	.002	0.591	1	0.380 - 0.919
Referral history	New referral	79.7	40.8	_	_	_	_
Re-referral		20.3	35.5	.415	0.940	1	0.775 - 1.142
Psychotropic Medication	Not Prescribed	5.9	38.4	_	_	_	_
Prescribed, not taking		51.1	36.4	.437	1.104	1	0.796 - 1.531
Prescribed, taking		39.7	43.7	.140	1.208	1	0.868 - 1.681
Unknown/declined to say		3.3	47.3	.012	1.638	1	0.985 - 2.723
Initial PHQ-9 ^b							
Minimal		1.6	68.6	< .001	5.678	1	3.085 - 10.449
Mild		10.1	63.5	< .001	4.333	1	3.243 - 5.790
Moderate		27.1	49.8	< .001	2.552	1	2.044 - 3.185
Moderately severe		31.6	37.4	< .001	1.770	1	1.443 - 2.171
	Severe	29.5	23.2	-	-	-	-
Initial GAD-7 ^b							
Minimal		1.9	60.2	< .001	2.510	1	1.447 - 4.354
Mild		18.7	53.0	< .001	1.806	1	1.451 - 2.248
Moderate		36.4	44.0	< .001	1.377	1	1.154 - 1.643
	Severe	43.0	29.5	_	-	_	-
Engagement ^b	Less than 25%	4.1	15.0	-	-	-	-
26 - 50%		31.2	23.6	.003	1.762	1	1.079 - 2.880
51 - 75%		39.4	43.0	< .001	4.657	1	2.872 - 7.552
76 - 100%		25.4	58.4	< .001	8.912	1	5.445 - 14.58

Note. N = 6,184 patients with initial PHQ-9 > 8 or initial GAD-7 > 9, as defined by the CSC starting criteria. CI = confidence interval. Model fit: -2LL = 7083.0, Nagelkerke R^2 = .243, χ^2 (32, N = 6,184) = 1226.4, p < .001 a p-values for significant differences (α = .01) from the baseline category are shown in bold face type. b Predictor variable is significant, p < .001.

Alpha was set to .01 to reduce the risk of capitalising on chance relationships (given the relatively large number of effects examined by each analysis), and as a conservative correction for the fact that there may be some dependence of observations that we could not remove from, or control for, in our anonymised dataset (e.g., two lines of data for a single individual representing two separate referral/treatment episodes; patients referred from the same GP surgery where we cannot rule out effects due to surgery-specific referral practices). Missing data were rare. If data were missing for variables included in an analysis, the case was excluded from that analysis. These exclusions never exceeded 0.8% of cases (see Table 1). To determine whether the conclusions are affected by our decision to analyse successful outcomes defined *jointly* by PHQ-9 and GAD-7 scores, we also conducted separate analyses for each affect scale using each of the three success cri-



teria. For the sake of brevity, these six analyses are reported in Supplementary Materials (Tables S1-S6).

 Table 4

 Successful Outcomes for Reliable Change (RC) Criteria by Patient Category, and Logistic Regression With Successful Outcome as the Dependent Variable

Duodiotou vouighlo (I ====\)	Baseline	% patients	% success	p ^a	Adjusted odds ratio (OR)	df	99% CI for adjusted OR (lower and
Predictor variable (Level)	characteristic	in category	category	<i>P</i>	(OK)	ат	upper limits)
Gender	Male	33.8	36.3	-	-	-	-
Female		66.2	36.6	.329	1.063	1	0.904 - 1.250
Age in bands	16-24	15.9	31.7	-	-	_	_
Age 25-34 years		22.1	36.1	.519	1.065	1	0.829 - 1.367
Age 35-44 years		23.6	37.3	.732	1.034	1	0.806 - 1.325
Age 45-59 years		27.1	37.2	.903	0.989	1	0.775 - 1.261
Age ≥ 60 years		11.2	41.1	.148	1.205	1	0.865 - 1.678
Deprivation decile	Decile 1-2	10.1	33.2	_	_	_	_
Decile 3-4		11.1	37.7	.187	1.178	1	0.855 - 1.623
Decile 5-6		32.6	36.6	.583	1.059	1	0.809 - 1.385
Decile 7-8		27.0	37.6	.358	1.103	1	0.838 - 1.452
Decile 9-10		19.2	35.7	.484	0.924	1	0.690 - 1.237
Employment ^b	In work	33.2	42.6	-	-	_	-
Unemployed seeking		17.2	36.0	< .001	0.737	1	0.591 - 0.918
Students		20.9	29.8	< .001	0.500	1	0.404 - 0.620
Long term sick		7.9	29.2	< .001	0.560	1	0.412 - 0.762
Not seeking		19.1	37.5	< .001	0.712	1	0.557 - 0.912
Retired		1.0	41.9	.594	0.864	1	0.426 - 1.751
Not known/Stated		0.8	16.3	.004	0.312	1	0.109 - 0.892
Referral source	GP	53.5	36.6	-	-	_	-
Self (i.e., patient)		40.6	37.6	.396	1.053	1	0.901 - 1.230
Secondary care		2.4	34.7	.558	0.894	1	0.547 - 1.461
Other source		3.5	25.5	.003	0.594	1	0.379 - 0.928
Referral history ^b	New referral	79.8	36.7	_	-	-	-
Re-referral		20.2	32.2	.003	0.802	1	0.662 - 0.972
Psychotropic Medication	Not Prescribed	5.8	40.2	-	_	-	_
Prescribed, not taking		51.1	36.2	.115	0.822	1	0.596 - 1.133
Prescribed, taking		39.8	35.9	.179	0.844	1	0.609 - 1.168
Unknown/declined to say		3.3	43.3	.381	1.185	1	0.720 - 1.950
Initial PHQ-9 ^b							
Mild ^c		13.2	21.1	< .001	0.395	1	0.294 - 0.530
Moderate		26.3	34.4	.014	0.814	1	0.656 - 1.010
Moderately severe		31.2	41.1	.640	1.035	1	0.856 - 1.252
•	Severe	29.3	40.6	_	_	_	_



for a successful outcome.

Predictor variable (Level)	Baseline characteristic	% patients in category	% success within category	p ^a	Adjusted odds ratio (OR)	df	99% CI for adjusted <i>OR</i> (lower and upper limits)
Initial GAD-7 ^b							
Mild ^c		22.5	23.2	< .001	0.456	1	0.364 - 0.572
Moderate		34.8	38.2	.038	0.870	1	0.733 - 1.034
	Severe	42.7	42.2	_	-	_	-
Engagement ^b	Less than 25%	4.1	13.4	-	-	_	-
26 - 50%		31.2	21.4	.001	1.896	1	1.146 - 3.136
51 - 75%		39.3	40.0	< .001	4.898	1	2.985 - 8.035
76 - 100%		25.4	53.5	< .001	8.740	1	5.284 - 14.454

Note. N = 6170 patients with both initial PHQ-9 > 5 and initial GAD-7 > 4, as constrained by the minimum size of RC. Model fit: -2LL = 7234.9, Nagelkerke R^2 = .178, $\chi^2(30, N$ = 6170) = 859.7, p < .001 *p-values for significant differences from the baseline category are shown in bold face type, though only when the overall effect for the variable is also significant (α = .01). *p-Predictor variable is significant, p < .001. *p-Mild was the lowest category analysed for PHQ-9 depression and GAD-7 anxiety because a successful outcome on the RC criteria cannot be achieved for patients with p-minimal depression or anxiety. This is because any initial score in the p-minimal category is already too low to allow for the size of reduction that the RC criteria require

Results and Discussion

Tables 2, 3 and 4 summarise each analysis of the predictors of success for the IAPT, CSC and RC success criteria, respectively, together with descriptive statistics for the distribution of patient characteristics and rates of successful outcomes across the levels of each predictor. These analyses suggest that there is 'nothing unusual' about the patient population that we have analysed. Consistent with other analyses of IAPT service populations, women outnumber men by a ratio of 2-to-1, and uptake rates are not particularly high among older individuals (Clark, 2018). Also consistent with previous analyses (e.g., Gyani et al., 2013) those who attend a higher proportion of the treatment sessions that they are offered have substantially better outcomes (see the 'engagement' predictor in Tables 2, 3, and 4). Perhaps unsurprisingly, some groups *not* in employment (e.g., long-term sick) are less likely to have a successful outcome, as is also the case in some analyses for those whose referral to the service did not originate from primary or community healthcare services.

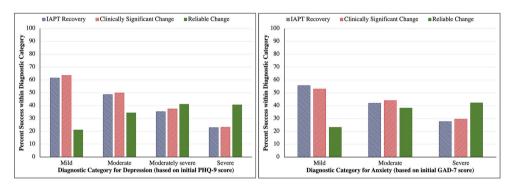
Importantly, each of Tables 2, 3 and 4 show that both initial PHQ-9 scores (for depression) and initial GAD-7 scores (for anxiety) significantly predict successful outcomes. This is true for each of the three success criteria. However, as seen by comparing treatment success rates for each level of depression or anxiety across Tables 2, 3, and 4, the *direction* of effect is *not* the same for all three criteria. Figure 1 illustrates this pattern of effects. For the IAPT recovery criteria, success rates are progressively lower for more severe levels of depression or anxiety: effects that are large, statistically significant, and



follow approximately linear progressions across different levels of PHQ-9 and GAD-7 (Table 2). An equivalent pattern and similar size of effect is seen for the CSC criteria: with the lowest rates of success found among those with severe depression and severe anxiety (Table 3). In contrast, this pattern is reversed when success is defined by RC: success rates are highest for those with severe depression or anxiety and lowest for those with mild depression or anxiety (Table 4). These effects are not so large as the equivalent ones for the IAPT recovery and CSC criteria. Nonetheless, the effects are statistically significant, both for depression and anxiety, and reveal that the recovery rate approximately doubles between the mild and severe categories on either the PHQ-9 or GAD-7.

Figure 1

Success Rate by Diagnostic Category for Each of Three Success Criteria, for (a) Depression [left] and (b) Anxiety [right]



Note. Minimal category not included because it is not examined in the analysis of the Reliable Change criteria.

The analyses reported in the Supplementary Materials confirm that initial scores for the affect measures also predict successful outcome when these outcomes are analysed separately for depression and anxiety. The direction of these effects reported in the Supplementary Materials (Tables S1-S6) match those described in the previous paragraph. Thus, consistent with the conclusions drawn from the analyses reported in Tables 2, 3, and 4 and illustrated in Figure 1, higher initial PHQ-9 scores are associated with a *lower* chance of successful outcome for depression when assessed on the IAPT recovery or CSC criteria, but a *higher* chance of successful outcomes for depression when assessed via RC criteria (Tables S1-S3). Likewise, the chances of a successful outcome for anxiety on the IAPT recovery or CSC criteria *reduce* as initial GAD-7 scores increase, but *increase* for the RC criteria as initial GAD-7 scores increase (Tables S4-S6). Moreover, the effects reported in the *Supplementary Materials* are always descriptively stronger than the corresponding effects reported in Tables 2, 3, and 4. That is, when predicting treatment



success for depression (Tables S1-S3) the odds ratios (*ORs*) for each level of the PHQ-9 are further from 1 (i.e., 'no effect') than the corresponding *ORs* reported for the PHQ-9 in Tables 2, 3 and 4. And likewise, when predicting treatment success for anxiety (Tables S4-S6) the *ORs* for each level of the GAD-7 are further from 1 than the corresponding *ORs* reported for the GAD-7 in Tables 2, 3 and 4. From this we infer that the findings reported in Tables 2, 3, and 4 are *not* an artefact of analysing success criteria based jointly on outcomes for depression and anxiety. Indeed, reporting analyses based on such joint criteria may have resulted in a conservative illustration of the general patterns that we find.

We assume that the implications of these findings are clear with respect to the incentives for which patients are prioritised for treatment, irrespective of whether those incentives are created by the goals that the service sets for itself, or derive from another source such as via payment by results (PbR). The choice of success criteria could impact on which patients are most worthwhile treating. When success is defined by the principles of clinically significant change (IAPT recovery and CSC criteria) the chances of success are better for those whose depression and/or anxiety is not so severe. If these criteria are adopted, the service is incentivised to treat the less severe cases and to encourage those with more severe depression and/or anxiety to seek treatment outside the service. When success is defined according to the principles of statistically reliable change, the chances of success are better for those whose condition is severe. If such criteria are adopted, this incentivises treatment of more severe cases, and therefore dis-incentivises taking the relatively less severe cases into the service. It is *not* necessary for service providers to be consciously aware of this incentive structure for the incentives to have this effect: changes in patterns of referral, acceptance into the service, and extension of treatment provision for those most likely to achieve 'success' (however defined) can all happen gradually (perhaps imperceptibly so) following a simple 'trial-and-improvement' or stimulus-reward mechanism.

To illustrate how such a mechanism might play out in a specific context, we consider one of the changes to service funding that occurred subsequent to the period in which our data were recorded. The Guidance from NHS England and NHS Improvement (2017b) for outcomes-related payments to IAPT services (which came into effect on 01 April 2018) gave precedence to statistically reliable change in payments to IAPT services for the *clinical outcomes* component. Payment that rewards the clinical outcome for a patient was *only* made if there was statistically reliable improvement. There was, however, some regard for the principles of clinically significant change in these payments because the full payment was only made if the patient's score drops below the cut-off for the IAPT recovery criteria. Failing that, payment was proportional to the degree of movement towards recovery. Given our analysis reported in this paper, such a PbR structure that emphasises reliable change seems to provide an incentive to prioritise treatment for those with more severe levels of depression and anxiety.¹



Such incentives may be entirely reasonable: prioritising intervention for those whose conditions are most severe may bring the greatest reduction in the 'global burden' (for individuals, on their families, and to the economy) associated with mental ill health; and financial rewards to a service for treating these patients may offset the costs of treating these patients who are likely to have longer-than-average programmes of treatment. That said, we note that the IAPT Programme was set up to provide a readily accessible service to those with at least moderate depression and/or anxiety disorders – and not necessarily to treat the most severe cases of these conditions (Clark et al., 2009). What our analysis illustrates is that the choice of success criteria – for whatever reason they are adopted – can be important for which patients a service targets and therefore treats.

It is, of course, a limitation that our analyses use a single dataset and focussed on only two clinical measures for two mental health conditions. We conjecture that the patterns we find arise from the principles that differentiate CSC from RC criteria, and should be apparent in other contexts. Nonetheless, further investigations should examine the reproducibility of our findings in other mental health conditions and for implementations of CSC and RC in clinical measures other than the PHQ-9 and GAD-7. Another area for future research is to examine whether and how patients' individual therapy goals map onto CSC or RC criteria. For example, can patients' goals be expressed in terms of changes or thresholds on clinical measures, how do those goals vary with a patient's starting point, and by what process do patients set their goals?

When considering how our findings relate to the academic literature on PbR in mental health services, it surprised us how small that body of literature seems to be. To illustrate, a search of the PUBMED database for "payment by results" [in article] AND "mental health" [in title/abstract] yielded only 13 articles². As best we could determine, all 13 articles had PbR *in UK* mental health services as their main focus. However, Mason et al. (2011) also examined what the UK NHS could learn from the experience of the small number of countries in which PbR for mental health services had been explored (Australia, Canada, New Zealand) or implemented (The Netherlands, USA). A few other articles also reflected on PbR in mental health in some of those countries (e.g., Tulloch, 2012) usually by drawing on Mason et al. (2011).

However, important for the analyses that we report, the 'results' in these PbR schemes were *service activity* not *clinical outcomes*. These PbR schemes set price tariffs for mental health services contingent on the features of the clinical populations being treated. Higher prices are set for patients whose treatment is judged likely to be cost-

²⁾ We are grateful to a reviewer for pointing us towards this literature. Our search, conducted in July 2023, identified one further article. However, this article was on homelessness, not mental health services, and its single reference to payment by results did not refer to mental health.



¹⁾ Additionally, the third largest component of the payment model, reducing disability and improved wellbeing (10% weighting), also has payments linked to statistically reliable improvement.

ly (e.g., because their diagnosis means treatment will probably be resource-intensive). Though rather different to the outcome-based PbR that we have focussed on in this article, our findings may point to a potential additional complexity associated with activity-based PbR. If treatment stops when a 'successful' outcome is achieved, but otherwise may continue, the choice of success criteria should impact what resources are allocated to a given patient. This is because - as our analyses show - the choice of success criteria impacts how condition severity relates to a 'successful' treatment outcome. Under CSC criteria, the chances of success are better for patients whose condition is less severe, and therefore these are the patients *least* likely to receive extended (costly) treatment. Conversely, a service that aims for 'success' under RC criteria will likely deploy more resources to treat these same patients because it will be more difficult (and therefore take longer) to achieve a successful outcome for their patients whose condition is less severe. Thus, when designing an activity-based PbR scheme, assuming one success criteria or another could (perhaps should) impact what price tariffs are set. And when operating under an established activity-based PbR scheme, the success criteria that a service adopts (explicitly or implicitly) in its clinical practice could affect whether or not service funding reflects service costs.

As a general point of application, our analyses illustrate that the question 'Which type of patients respond best to this treatment?' is *not* a context free question. Crucially, the answer to that question can depend on what criteria are used to measure a 'successful' response to treatment. Specifically, whether a successful outcome is determined according to a threshold for a clinical outcome measure (e.g., CSC) or according to the extent of improvement in such a clinical outcome (e.g., RC) can determine whether it appears that treatment is more successful for patients with less severe, or more severe, symptoms. Our goal is *not* to argue that one success criterion is best, or that another is inappropriate. Rather, we offer this analysis to emphasise that because incentives affect behaviour, success criteria must be chosen carefully if a therapy service is to operate according to its stated goals.

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Data Availability: Data are not publicly available due to the privacy policy of the Service in relation to patient data. For questions about the data or its analysis, please contact the corresponding author.



Supplementary Materials

The Supplementary Materials (see Wheeler et al., 2023) report analysis of the predictors of a successful treatment outcome, separately for each affect scale (PHQ-9 and GAD-7), and separately for each of the three success criteria. These six analyses, using logistic regression, serve as a 'check' on the conclusions from the three analyses that are reported in the article.

Index of Supplementary Materials

Wheeler, M. H., Orbell, S., & Rakow, T. (2023). Supplementary materials to "How and why the choice of success criteria can impact therapy service delivery: A worked example from a psychological therapy service for anxiety and depression" [Additional analyses]. PsychOpen GOLD. https://doi.org/10.23668/psycharchives.13964

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Research Articles



Mirror Exposure Training for Adolescents With Anorexia Nervosa (MIRADAN): Cognitive Mechanisms of Body Disturbance – A Study Protocol

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Abstract

Background: Anorexia Nervosa (AN) is a severe mental illness, which typically develops in adolescence and, if left untreated, often becomes chronic. Body dissatisfaction is a core characteristic of AN. Mirror exposure (ME) is an effective therapeutic technique to tackle body dissatisfaction in adult patients with eating disorders, but there is limited evidence for the effects of ME in adolescence. One potential mechanism underlying effects of ME on body dissatisfaction is change in body-related attention bias. However, this mechanism remains to be empirically tested. Accordingly, the aim of the current study is twofold: primarily, we aim to test if ME can reduce body dissatisfaction and associated symptoms in adolescent patients with AN. Additionally, we aim to investigate whether change in biased body-related attention due to ME is a possible mechanism of action.

Method: Adolescent patients with AN are randomized to either 12 sessions of ME (3 ME-sessions/week) or wait-list within four weeks. Main outcomes include body dissatisfaction and associated symptoms of AN. Moreover, body-related attention bias is assessed at baseline and post-treatment by means of eye-tracking with two paradigms. Further, process variables are collected weekly. In addition, 12 weeks after end of the study, the acceptability of the ME is assessed.



Discussion: The main aim of the study is to evaluate high-frequency and high-intense ME for treating body dissatisfaction in adolescents with AN. In addition, we would like to clarify whether change in attentional bias for body stimuli is a mechanism underlying change in body dissatisfaction due to ME.

Keywords

anorexia nervosa, body dissatisfaction, modifying attentional processes, mirror exposure, adolescence

Highlights

- Body dissatisfaction is a major risk factor for the development, maintenance, and relapse of AN.
- In this study we aim to test if mirror exposure reduces body dissatisfaction in young people with AN.
- A secondary aim is to test if change in body-related attention bias is a mechanism of change in body dissatisfaction.

Background

Eating disorders are highly prevalent among young women. For example, an 8-year longitudinal study found that 12% of female adolescents experienced some form of threshold or subthreshold eating disorder by age of 20 (Stice et al., 2009). Among people with a lifetime diagnosis of AN with early onsets (< 25 years), about 40% were diagnosed within the age range of 15 to 18 years, making this a prominent age to receive an AN diagnosis (Grilo & Udo, 2021).

AN has the lowest one-year remission rate (Stice et al., 2013) and current treatments of AN in adolescents show only moderate success, leaving room for further improvements (e.g. for an overview of the treatment of AN, Brockmeyer et al., 2018; Jansingh et al., 2020). This is particularly concerning because there was a highly significant increase of 40% in admission rates in the female children's and the adolescents' of typical and atypical AN between the pre- and peri-COVID-19 periods in 2019 and 2021, respectively, in Germany (Herpertz-Dahlmann et al., 2022). This illustrates how important it is to improve treatment options for adolescents with AN.

A disturbed body image is a core characteristic of AN. Body image disturbance is characterized by dysfunctional attitudes and emotions toward one's body, such as body dissatisfaction or fear of weight gain (Forrest et al., 2018; Mitchison et al., 2018). Research findings show that overaluation of shape and weight and the corresponding body dissatisfaction is a key risk factor for the development, maintenance, and relapse of AN (Glashouwer et al., 2019; Jacobi et al., 2004). Therefore, decreasing body dissatisfaction in AN is an important treatment target (DuBois et al., 2017).



Several meta-analytic reviews indicated that repeated confrontation with one's own body seems to have a positive influence on body image (Alleva et al., 2015) and that body exposure is an effective intervention for body disturbance in eating disorders (Griffen et al., 2018; Hartmann et al., 2021).

However, while in general ME seems to treat body image disturbances well in people with clinical and subclinical groups, research on the effectiveness of ME in patients with AN is still limited. One uncontrolled study showed that eight weeks of body image therapy with ME exercises in a group format (n = 9) compared to body image therapy without ME exercises (n = 6) significantly reduced body dissatisfaction, body anxiety and avoidance behaviors (Key et al., 2002). However, the reliability of these results is severely limited due to the particularly low power of the study (Nestoriuc et al., 2012). A larger uncontrolled study of Morgan et al. (2014) (n = 55) with exposure-based body image therapy (which included ME in seven out of ten group sessions) yielded significantly lower levels of body-related anxiety and worry, dysfunctional body and eating behaviors compared to baseline. It should be noted here that the two uncontrolled therapy studies by Key et al. (2002) and Morgan et al. (2014) examined patients with AN who were in partial remission with an almost healthy weight (BMI inclusion criterion ≥ 20.5 in Key et al., 2002; BMI inclusion criterion ≥ 17.5 in Morgan et al., 2014). Additionally, a case study showed that patients with AN (n = 3) in partial remission benefited from intensive Acceptance and Commitment (ACT) therapy with ME exercises (up to three sessions of 17 therapy sessions in total) in terms of their general pathology, eating symptomatology and body acceptance (Berman et al., 2009).

Additional evidence comes from studies investigating the therapeutic effects of ME in a mixed group of women with AN, Bulimia Nervosa and Eating Disorder Not Otherwise Specified: Results from these studies indicate that negative body-related thoughts and emotions decreased and overall body dissatisfaction and body-related avoidance behavior were reduced by confrontation-based body image therapies in women with eating disorders compared to the control group without therapy (Bhatnagar et al., 2013; Vocks et al., 2008). However, in these studies, ME exercises were part of a broader body image therapy (Bhatnagar et al., 2013: one out of five sessions with predominantly imaginary body exposure exercises; Vocks et al., 2008: three out of ten group therapy sessions), which makes it difficult to attribute effects to ME, specifically.

A functional magnetic resonance imaging (fMRI) study (Vocks et al., 2010) found no effects of body exposure (including ME-sessions) in self-reported measures of AN patients, but reported an increase in the activity of the extrastriate body area from pre- to post-treatment. The authors interpreted this finding as reduction of avoidant body-related processing in response to body image therapy, which may be one working mechanism of ME.

Recently a randomized control trial (RCT) was conducted in which young girls aged 11-17 years with a diagnosis of AN (n = 15) received body image therapy, including six



ME sessions (out of a total of 14 sessions) as add-on to their inpatient eating disorder therapy; (Biney et al., 2021). Compared to a group without additional body image therapy (n = 16, treatment as usual (TAU)), the experimental group showed significantly greater improvements in weight concerns, body-related avoidance behavior and fears of gaining weight. Again, all patients had reached their individual minimum healthy weight prior to body image therapy, including ME sessions. Moreover, the effects, especially for body-related avoidance behavior, observed in this study cannot be attributed to ME specifically, because other body image exercises were also included in the body image therapy received by the experimental group.

To summarize, there are first indications for the effectiveness of ME for patients with AN. However, sample sizes of previous studies were considerably low (ranging between 9 and 15 participants per group) thereby limiting the power of observed effects. Moreover, because ME was mostly applied as a component of a comprehensive "body-related" treatment, there is a lack of reliable randomized controlled data on the specific effect of ME in AN, especially for adolescent patients.

Even though evidence is accumulating the ME may be effective to target body dissatisfaction in AN, it is still unclear why ME may work. Empirical evidence suggests that one potential mechanism underlying body dissatisfaction is an aberrant attention bias to negatively-valenced body parts (for an overview see Jiang & Vartanian, 2018; Kerr-Gaffney et al., 2019; Rodgers & DuBois, 2016) and ME may specifically target this by changing attention processing of one own's body during repeated confrontations with the own body in the mirror. Accordingly, reducing body-related attention bias may be a working mechanism of ME.

However, experimental evidence for the causal relation of biased attention and body dissatisfaction as potential underlying mechanism of ME remains sparse and contradictory so far (Glashouwer et al., 2016; Krohmer et al., 2022a; Naumann et al., 2022). Initial evidence comes from a study by Smeets et al. (2011) demonstrating that directing attention towards subjectively positive body parts led to a reduction in body dissatisfaction in people with high body dissatisfaction. Similarly, Krohmer et al. (2022a) found that ME improved on body-related attention bias in in the female patients with Binge Eating Disorder compared to the waiting control group. In addition, change in attention bias correlated significantly with change in weight concerns. In a study by Glashouwer et al. (2016), five weeks of ME therapy (one session/week) in which women with high body dissatisfaction were instructed to focus on their subjectively attractive body parts also led to a reduction in self-reported body dissatisfaction. However, in this study, the instruction to direct attention towards subjective attractive body parts did not produce any changes in body-related viewing patterns (Glashouwer et al., 2016), even though body dissatisfaction improved. This finding, in particular, questions whether change in attention is an important mechanism underlying the effects of ME. As no clinical groups



were examined in Glashouwer et al. (2016), floor effects could have contributed to these results (Naumann et al., 2022).

Thus, the question remains whether dysfunctional attentional processes are maintaining mechanisms of body dissatisfaction and whether reducing this bias is a working mechanism of action of ME. Establishing whether changing biased attention towards the own body is a mechanism underlying the effects of ME in reducing body dissatisfaction in people with AN is therefore an important research target. In the present study, eye-tracking data, more specifically, tracking gaze on body stimuli, which has been successfully used in body image research as an objective measure of attentional bias (Bauer et al., 2017; Blechert et al., 2010; Jansen et al., 2005), is used to test whether the assumed selective gaze pattern of patients with AN on unattractive body parts can be successfully modified by a mirror exposure intervention, leading to a reduction in body dissatisfaction.

In a study of Bauer et al. (2017) all eating disorder subgroups had an attentive preference for body areas they find unattractive, with even longer fixation time on self-evaluated unattractive areas of one's own body compared to fixation time on the body of peer's. Participants with AN-R attended significantly longer to unattractive body areas in general and significantly shorter to attractive areas than the control groups (clinical control group with anxiety disorder and healthy controls). Therefore, we aim to investigate attention bias in different variations (single presentation vs. simultaneous presentation of own/other bodies as well as neutral stimuli), analyzing the areas of the bodies (most unattractive/attractive) to which the participants allocate their visual attention. Furthermore, we collect and analyze reaction times as an indirect measure of attentional biases through the cueing and dot-probe task (MacLeod et al., 1986; Posner, 1980).

Aims

The main aim of this randomized controlled trial is to test the efficacy of ME in adolescents with AN. We expect that ME significantly reduces body dissatisfaction compared to a waitlist control group. In addition, we will examine whether the change in body dissatisfaction relates to a reduction in the general eating disorder psychopathology. In exploratory analyses, we also aim to examine whether ME compared to a waitlist control group leads to a change of the behavioral components of body image disturbance (body checking and body avoidance).

Secondly, we expect that ME compared to a waitlist control group leads to a stronger reduction of body-related attention bias (pre-post comparison). Finally, we expect that changes in body-related attention bias are associated with changes in body dissatisfaction, body-related emotions and cognitions. Additionally, we want to explore possible process variables and predictors of treatment success.



Method

Trial Design

This feasibility study is designed as RCT (experimental: ME, control: waitlist) with preand post-comparison (6 weeks) and open follow-up (12 weeks). Participants are randomly allocated to receive either 12 sessions of ME (treatment group) in addition to TAU or to waitlist (control group), who will receive TAU only. TAU includes behavioral therapy interventions and nutrition management according to the German S3 Guideline for Diagnosis and Treatment of eating disorders. More detail regarding the randomization procedure is provided below. The study design is shown in Figure 1.

Ethical Approval and Trial Registration

Ethical approval has been obtained from the Ethics Committee of the Albert-Ludwigs-University in Freiburg, Germany (545/17). Participants received verbal and written (consent) information before participating. In the case of underage participants, their legal guardians are also informed and their consent to participate is obtained as well. The research is conducted in accordance with the Declaration of Helsinki. The study is registered on the German Clinical Trial Register (DRKS; registration number: DRKS0019104).

Participants and Recruitment

Participants are recruited via the Department of Child and Adolescent Psychiatry, Psychotherapy and Psychosomatics of the Freiburg University Hospital (director: Prof. Dr. Fleischhaker) and from the outpatient unit of the Institute of Psychology, Department of Clinical Psychology and Psychotherapy, University of Freiburg (head: Prof. Dr. Tuschen-Caffier).

Inclusion Criteria

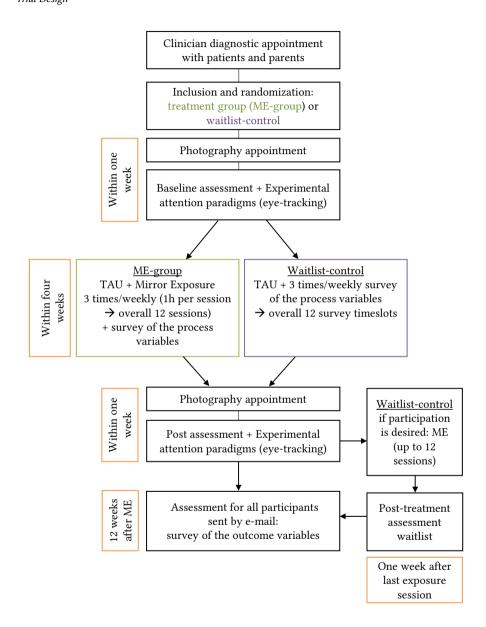
Girls and young women are eligible for participating if they are diagnosed with an ICD-10 of AN or atypical AN, age > 12 < 21. In addition, participants are not allowed to be currently tube fed and their weight must be above the 10th BMI percentile at the time-point of inclusion.

Exclusion Criteria

Exclusion criteria are high risk of suicide, co-occurring psychotic, bi-polar disorders, alcohol/substance dependence within the past six months, medical conditions that would affect the ability to participate, and pregnancy/lactation.



Figure 1
Trial Design



ME Procedure and Waitlist Control Group

The ME technique applied in the current study is based on the manual of Hilbert and Tuschen-Caffier (2010) as well as on the ME protocol used in Trentowska et al. (2013). ME sessions are delivered in an individual setting in standardized underwear (beige/white panty and top) by one of two post-graduate psychologists, who are enrolled in clinical CBT-training to become a licensed therapist.

Participants are instructed to look in a full-length mirror with double winged doors. The therapist stands outside the participant's view and asks her to describe her own body as precisely as possible from head to toe. During the ME, participants can freely express their positive and negative feelings and the therapist encourages the participant to name and persevere any upcoming feelings as part of the exposure rationale. ME sessions lasts 50-60 min and followed by a brief debriefing.

The waitlist control group receives TAU. TAU entails integral CBT-based treatment about nutrition management, eating behavior, stress management, social competence training and body-image treatment. However, participants in the waitlist control retain from receiving any body-image related treatment during the four weeks of study participation to prevent confounding of ME effects.

Therapist Training and Supervision

All ME therapists received an introduction to the ME rationale and treatment manual as well as ME practice sessions within the research group before starting with ME in the study. Regular supervision is provided to therapists by senior ME therapists. To ensure treatment adherence, ME sessions are video recorded and will be discussed during supervision. These are deleted after each supervision.

Outcome Measures

Since this is a feasibility study, a broad range of outcome measures is included to determine which are most sensitive for detecting a treatment effect. Table 1 provides an overview of outcome measurements.



 Table 1

 Schedule of Assessments

				Within-		Post-	After 3
Content	Assessment	Screening	Baseline	session	Post	treatment	months
Participant's information, informed consent		×					
Clinical and demographic information		×					
Chede		×					
K-SADS-PL		×					
Affective and cognitive components of body image disturbances	FFB		×		×	×	×
Behavioral components of	всо		×		×	×	×
body image disturbances	BIAQ		×		x	×	×
Attention-bias	exogenus cueing paradigm adapted version of the dot probe task		× ×		× ×		
Mood and body evaluation over course of ME	PANAS "Body-Questionnaire"		× ×	x x	× ×	X	×
others	BDI-II RSE		× ×		* *	* *	* *
questions about the conditions						×	×
treatment evaluation							×

Examination for children; ChEDE-Q = Child Eating Disorder Examination Questionnaire; FFB = Fragebogen zum Figurbewusstsein; K-SADS-PL = Kiddie Schedule Note. BDI-II = Beck Depression Inventory; BCQ = Body Checking Questionnaire; BIAQ = Body Image Avoidance Questionnaire; ChEDE = Eating Disorder for Affective Disorders and Schizophrenia Lifetime Version; PANAS = Positive and Negative Affect Scales; RSE = Rosenberg Self-Esteem Scale. 'Only for waitlist control who received ME.



Primary Outcome

Affective and Cognitive Components of Body Image Disturbances — To assess body dissatisfaction, as affective-cognitive component of body image disturbance, the German version of the Body Shape Questionnaire (BSQ; Cooper et al., 1987; German version: Fragebogen zum Figurbewusstsein, FFB; Waadt et al., 1992) is used. The FFB includes 34 items and is a widely used measurement tool to record numerous aspects of dissatisfaction with one's body shape with good psychometric properties (Pook et al., 2002).

Behavioral Components of Body Image Disturbances — Exploratory, behavioral components of body image disturbances are assessed with the Body Checking Questionnaire (BCQ; Reas et al., 2002; German version: Vocks et al., 2008) and the Body Image Avoidance Questionnaire (BIAQ; Rosen et al., 1991; German version: Legenbauer et al., 2007). The BCQ is a 23-item reliable and valid instrument for assessing body-related control behavior (Steinfeld et al., 2017). The BIAQ is a 19-item self-assessment tool for body-related avoidance and eating-related control behaviors with good psychometric properties (Legenbauer et al., 2007).

General Eating Disorder Pathology — ED symptomatology will be measured by the German version of the Child Eating Disorder Examination Questionnaire (ChEDE-Q; TODAY Study Group, 2007; German version: Hilbert et al., 2008). This child version of the Eating Disorder Examination-Questionnaire by Fairburn and Beglin (EDE-Q, 1994, 2008; German-version: Hilbert & Tuschen-Caffier, 2006, 2016) allows the assessment of the specific eating disorder psychopathology on four subscales (Restraint, Eating Concern, Weight Concern and Shape Concern) with 28 items. The German translation of the ChEDE-Q proved to be good internal consistency, convergent validity and retest reliability over a period of 7.5 months (Hilbert et al., 2008).

Secondary Outcomes

Attention Bias — Attention bias will comprise eye-tracking based attention processing of individually self-defined unattractive versus attractive body parts. Two attention paradigms (exogenous cueing paradigm and dot probe paradigm) are used to assess body-related attention biases. Both paradigms rely on the assessment of eye-tracking to index overt spatial attention allocation to body stimuli.

Stimulus Material — In both tasks, standardized photographs of the participants' own body and a control body matched in BMI and waist-to-hip ratio are used as body stimuli. Vases are used as neutral/non-body-related control stimuli (Krohmer et al., 2022b). Participants wear standardized underwear (beige/ white panty and top) and are photographed in standardized positions (hip wide stand, arms beside the body, back of



the hands forward with fingers extended) from four perspectives (front, left, right, back) without the face and feet being visible. The photos are transferred in black and white and presented on a gray background. Noticeable features (tattoos, scars) are removed.

Body-Related Exogenous Cueing Paradigm — In the exogenous cueing paradigm participants view their own body or a weight-matched control body on one side of the screen (either left or right) for 3000 ms and need to indicate the location of a cue appearing subsequently on either the left or right side of the screen (valid or invalid with the body's position). Accordingly, the paradigm consists of the following trial types: own body and other body in four perspectives (front, left, right, back) presented on right/left side with valid/ invalid cue = 32 trials, repeated in 4 blocks = 128 trials in total. The bias scores indexes attention allocation towards self-defined attractive and unattractive body parts of the own versus the other body without a direct competing stimulus. Frequency and duration of fixations on areas of interest (self-rated attractive vs. self-rated unattractive body parts of the own and the other body) are extracted for further analyses.

Body-Related Version of the Dot Probe Task — In this adapted version of the dot probe participants view stimulus pairs for 3000 ms and need to indicate the location of a cue appearing subsequently on either the left or right side of the screen, replacing one of the two stimuli. The following trial types are presented as stimulus pairs: own body/vase, other body/vase, own body/other body (each pair in 4 perspectives), presented on right/left side with valid/ invalid cue = 48 trials, repeated in 2 blocks = 96 trials in total. Gaze pattern during the presentation of these picture pairs indexes attention allocation towards the own body versus other body when a competing stimulus is presented at the same time. The bias scores of this paradigm indexes attention allocation towards own versus a direct competing neutral or another body stimulus. The frequency of the direction and the duration of the first and second fixation towards the own body when compared to a neutral stimulus or another body will be analyzed.

Mood and Body Evaluation Over Course of ME — To explore other potential processes of change during ME, we assess mood and the evaluation of one's own body over the course of ME. Mood is assessed using the German Version of the Positive and Negative Affect Scales (PANAS; Watson et al., 1988; German version: Krohne et al., 1996), which consists of 20 adjectives that describe different sensations and feelings (10 positive, 10 negative feelings). The German PANAS has very good psychometric properties (Breyer & Bluemke, 2016). The evaluation of one's own body is rated with the 'Body Questionnaire' (see e.g. Tuschen-Caffier et al., 2015), which assesses state body dissatisfaction and obtains attractiveness ratings of specific body parts based on photographs of participants as used in the attention paradigms.



Sample Characteristics — Age and duration of illness are measured. To assess severity of depression, the Beck Depression Inventory (BDI-II; Beck et al., 1996; German version: Hautzinger et al., 2006) is used, which is a 21-items self-report instrument for the severity of depressive mood over the last two weeks with high validity and reliability (Keller et al., 2022). Because self-esteem has been linked to body dissatisfaction and ED- symptoms, we assess self-esteem at baseline validly and reliably using the 10-item Rosenberg Self-Esteem Scale (RSE; Rosenberg, 1965); German version: von Collani & Herzberg, 2003).

Procedure

Potential participants are referred to the study by their clinician/therapists. Study researchers screen participants for eligibility. Once eligibility has been established, patient's and their parents', in the case of underage patients, written informed consents are obtained. Eligible participants are invited for a diagnostic session. Eating disorder diagnoses are established by means of the German version of the ChEDE (Bryant-Waugh et al., 1996; Hilbert, 2016). Other mental disorder diagnoses are assessed by means of the German version of the Kiddie Schedule for Affective Disorders and Schizophrenia Lifetime Version (K-SADS-PL; Delmo et al., 2001; Kaufman et al., 2000). If participants meet all inclusion criteria, participants are randomly allocated to the treatment or waitlist control group. Within one week, the photo appointment takes place, to create four standardized photos of participants, which are used as stimulus material in the attention paradigms.

Then, participants are invited to the baseline assessment, in which they complete the eye tracking paradigms and questionnaires on relevant outcome measures. If allocated to the ME condition, an initial session to explain the rationale and procedure of ME is scheduled first, followed by three sessions of ME per week for four weeks. Directly after each ME session, participants answer questionnaires assessing their body dissatisfaction and mood. In the waitlist control, participants also have three appointments per week, during which only body dissatisfaction and mood are assessed. After completing 12 sessions of ME or waitlist appointments, respectively, the post assessment takes place in the week following the last session. This outcome assessment of eye-tracking paradigms and questionnaires is identical to the baseline assessment. Participants in the waitlist control group are offered ME (at their own convenience) after completing post-treatment assessments.

Three months after the post assessment, participants who were allocated to the ME group receive an email containing a link to an online-questionnaire asked about the individually experiences and evaluation of ME regarding their subjective experiences of acceptability, satisfaction and recommendation. Participants from the waitlist control group who took up ME after post assessment evaluate their experience one week after their last ME session and again after three months.



Randomization

Before the start of the study, a randomization list was prepared by the project management. To ensure blinding during screening and diagnostics, the project management informs the researcher and the therapists on condition allocation only after inclusion of a patient.

Sample Size and Current Trial Status

Sample size calculation yielded with a power of $(1-\beta)$ = .80, a moderate to large effect (Cohen, 1988), based on previous results (Key et al., 2002; Morgan et al., 2014), of d = 0.8–1.3, α = .05 and a moderate correlation of within-effects the sample size – calculated over generic tests – at least around 42 patients with AN should be included. The study was initiated in September 2018. By January 2023, 24 patients have participated. The study recruitment has been repeatedly interrupted for various reasons (e.g., the Corona pandemic). With a study participation of 1-2 patients per month so far, the study is expected to run until December 2023.

Statistical Analysis

To determine quality, completeness and variability of the outcome measures, descriptive statistical analyses and graphical methods will be used. To test if ME significantly reduces body dissatisfaction compared to waitlist control group (first hypothesis) 2 x 2 one-way analyses of variance (ANOVA) with group (ME/waitlist) as between-subject factor, time (pre/post) as within-subject factor will be applied. In exploratory analyses we also aim to test if ME significantly reduces body checking and body avoidance compared to waitlist control group 2 x 2 one-way analyses of variance (ANOVA) with group (ME/waitlist) as between- subject factor, time (pre/post) as within-subject factor will be applied. For our secondary hypothesis (i.e. ME compared to wait-list results in reductions of body-related attention bias), a mixed 2 (group: ME/ waitlist) x 2 (time: pre/ post) x 2 (stimulus material: self/other) x 2 (body party: unattractive/attractive) ANOVA for both attention paradigms is planned. We will define areas of interest (AOI) based on participants' ratings of the most attractive and unattractive body part (for own/other body respectively). Bias scores for gaze duration, gaze frequency and number of initial fixations on each stimulus will serve as dependent variables. To clarify if change in attention bias is associated with change in body dissatisfaction, correlations between (changes) of attentional biases and body dissatisfaction, body checking and body avoidance will be conducted.

In exploratory analyses we also aim to capture processes of change in mood and body evaluation over the course of repeated ME sessions and how potential change in these measures relates to changes in relevant outcome variables such as body dissatisfaction, attention bias and global ED pathology. Finally, we will also explore how possible



participants' characteristics, such as age or self-esteem, relate to improvements in body dissatisfaction after ME.

Discussion

Dissatisfaction with one's own body is a major risk factor for the development, maintenance, and relapse of AN (Glashouwer et al., 2019; Jacobi et al., 2004). ME is an effective technique for treating body dissatisfaction in adults (Ziser et al., 2018). However, there is limited research on the effectiveness of ME therapy in AN, and even less research has been conducted on the effects of ME in children and adolescents with AN (Biney et al., 2021). The aim of this study is to address this research gap by examining the effects of ME on body dissatisfaction in children and adolescents with AN. The secondary aim is to clarify whether the change in attentional bias for body stimuli is the mechanism underlying the change in body dissatisfaction due to ME. In this feasibility RCT we will also strive to explore additional variables of interest, such as body-related emotions and cognitions.

Strengths

A strength of this study is conducting experimental psychopathology research in the field of adolescents with AN and in residential facilities because this is particularly difficult context for experimental studies (Glashouwer et al., 2020). Considering the high prevalence of AN among adolescents and minimal treatment effects in the treatment of AN (e.g. Zeeck et al., 2018), we know how important it is to conduct experimental research to test novel treatment options and to study working mechanisms of current treatment techniques as well as mechanisms contributing to the maintenance of AN. The present study achieves a greater understanding of ME as treatment technique for adolescents with AN as well as providing initial evidence for a potential working mechanisms of this technique (change in body-related attention bias) and maintaining factor of body dissatisfaction in this sample (i.e. dysfunctional body-related attention patterns). In addition, this experimental study conducted as an add-on to TAU offers the opportunity for patients to participate in and benefit from this treatment technique (ME). Another strength of the current study is combining a feasibility RCT in this context with multimethodological outcome assessment, including the direct assessment of overt spatial attention allocation by means of eye-tracking. This multimethod approach can inform on subjective as well as relatively automatic cognitive changes due to the treatment (ME). Eye-tracking has been established as a valid instrument to index visual attention processing (Blechert et al., 2009; van Ens et al., 2019).



Challenges

One major challenge remains consistent recruitment – even though there is the high number of people affected by AN in adolescence and in particular the prevalence of AN in adolescents amid the COVID epidemic and the demand for therapy are increasing. Consistent recruitment may also be challenging because facilitating research in an inpatient clinic during a pandemic has led to disruptions in concurrent recruitment procedures. In addition, the integration of a study in a clinical setting with a highly intensive therapy program for patients, is particularly challenging in the clinical context regarding logistics as well as time-planning organization.

Conclusion

To conclude, this paper sets out a protocol for an RCT that will enhance the current knowledge of the efficacy of ME to target body dissatisfaction as central core symptom for AN in adolescents.

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

Ethics Statement: Ethical approval has been obtained from the Ethics Committee of the Albert-Ludwigs-University in Freiburg, Germany (545/17).

Study Registration: The study is registered on the German Clinical Trial Register (DRKS; registration number: DRKS0019104).

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Systematic Reviews and Meta-analyses



Do We Need a Novel Framework for Classifying Psychopathology? A Discussion Paper

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Abstract

Introduction: The ICD-11 and DSM-5 are the leading systems for the classification of mental disorders, and their relevance for clinical work and research, as well as their impact for policy making and legal questions, has increased considerably. In recent years, other frameworks have been proposed to supplement or even replace the ICD and the DSM, raising many questions regarding clinical utility, scientific relevance, and, at the core, how best to conceptualize mental disorders.

Method: As examples of the new approaches that have emerged, here we introduce the Hierarchical Taxonomy of Psychopathology (HiTOP), the Research Domain Criteria (RDoC), systems and network approaches, process-based approaches, as well as a new approach to the classification of personality disorders.

Results and Discussion: We highlight main distinctions between these classification frameworks, largely related to different priorities and goals, and discuss areas of overlap and potential



compatibility. Synergies among these systems may provide promising new avenues for research and clinical practice.

Keywords

ICD-11, DSM-5, Hierarchical Taxonomy of Psychopathology HiTOP, Research Domain Criteria RDoC, network theory, personality disorders, process-based therapy PBT

Highlights

- The World Health Organization's International Classification of Diseases (ICD) and its latest revision ICD-11 offer the worldwide leading system for classification of mental disorders.
- Important proposals for rethinking classification came from the US National Institute
 of Mental Health's Research Domain Criteria (RDoC), the Hierarchical Taxonomy of
 Psychopathology (HiTOP) initiative, and the systems/network approach to mental
 disorders.
- More ideographic approaches such as process-based interventions have also been suggested.
- We present different ideas for classification before we suggest ways in which these
 approaches can inform each other, while respecting the different purposes that
 motivated their development.

The classification of psychopathology has been a topic of debate for decades, sometimes from a scientific perspective, sometimes more from the perspective of societal relevance, epidemiology of clinical conditions, or in terms of its general usefulness. However, the discussion about how best to classify mental disorders has been particularly intense during recent years. These are not new discussion, but they were further stimulated by Insel's assertion that the most widely used classification systems - the Diagnostic and Statistical Manual of Mental Disorders (DSM) and the International Classification of Diseases (ICD) - have not proven useful as a framework for research or in the development of new treatments targeted to underlying pathophysiological mechanisms (Insel et al., 2010). Since then, alternative approaches or extensions of these highly influential classification systems have been proposed and elaborated. Here, we will review various proposals for modifying the classification of mental disorders, including the most recent iteration of ICD's chapter on mental, behavioral and neurodevelopmental disorders (ICD-11). We highlight similarities and differences between proposed alternatives and different frameworks of classification (i.e., RDoC; HiTOP; the revised classification of personality disorders, network approaches, process-based approaches), and explore their advantages and challenges.

The worldwide leading systems for the classification of mental disorders are the World Health Organization's (WHO's) ICD, currently in its Eleventh Revision (ICD-11) (WHO, 2022) and the American Psychiatric Association's DSM, currently in its Fifth Edi-



tion (DSM-5-TR; American Psychiatric Association, 2022). Although they each have their own antecedents internationally, the ICD and the DSM have converged and diverged throughout their histories. The mental disorders chapter of the ICD-8 (WHO, 1967) and the DSM-II (American Psychiatric Association, 1968) were nearly identical and organized into the same three broad categories: psychoses; neuroses, personality disorders, and other nonpsychotic mental disorders; and mental retardation. Some of their basic concepts can be traced back to Pinel in 1798 (Postel & Quétel, 1994), Kraepelin (1893) and Bleuler (1911). The long history of concepts such as psychosis, schizophrenia, and depression could be attributed to the robustness of these concepts, or the resistance of the classification systems to change. The concepts were highly influential and the basis of research and treatment evaluations, but they were also misused (e.g., during mass murder campaigns like the "euthanasia program" in Nazi Germany). DSM-II integrated the numerical coding system of ICD-8. The descriptive, symptom-based approach that largely continues to characterize both the ICD-11 and the DSM was initially realized in the DSM-III (American Psychiatric Association, 1980), although there had been some parallel international developments. The DSM-III gained substantial international influence as a professional and commercial success, widely taken up by funders and researchers and selling a great many more copies than anticipated (Blashfield et al., 2014).

The ICD-11 classification of mental, behavioral and neurodevelopmental disorders and the DSM-5 were developed during overlapping periods of time and with substantial interaction between the WHO and the American Psychiatric Association. Intentional "harmonization" between the systems was most successful in terms of the overall organization of the classification, but the ICD and the DSM are currently more similar to one another than they have been in more than 40 years (for a detailed discussion see: First et al., 2021).

Most criticisms of categorical classification systems apply to both. These include questionable validity of many categories, dichotomization of dimensional features, high rate of use of "unspecified" or "other specified residual categories, lack of treatment specificity, excessive complexity and overspecification (Reed, 2010), reification (Hyman, 2010) (treating diagnostic categories as real and given without considering alternative approaches), heterogeneity of psychopathology / symptoms within diagnoses (e.g., Fried et al., 2016; Fried & Nesse, 2015; Hayes, Hofmann, & Ciarrochi, 2020), and stigma (Thornicroft et al., 2022), in addition to other issues that are explored in later sections of this article. Some aspects of the ICD-11 intended to address these issues and are explained in this article (e.g., secondary parenting, integration of dimensions, linkage to etiology, social and environmental determinants of health), and the solutions are based on the flexible digital infrastructure of the overall ICD-11 classification of diseases. At present, the ICD is more widely used in clinical systems around the world (Reed et al., 2011), whereas the DSM has been predominant in research.



The ICD and DSM classification systems are not intended or used for a single purpose (e.g., scientific validity), but rather have to achieve multiple goals at once. In part, they represent a pragmatic compromise among multiple competing demands and constituencies (Lilienfeld, 2014). From a clinical perspective, a key aim is to facilitate communication among clinicians and health system decision makers using the terms of the classification system. Diagnoses are meant to describe identifiable and meaningful clinical populations, a function that is intended to support treatment selection and clinical management. From a public health and policy perspective, an important priority is to communicate about the mental health of a population, and to quantify the need for treatment and governments responsibility to provide it. Economically, the definition of prevalence rates of specific syndromes and associated treatment costs, together with consideration of the disease burden and costs of untreated conditions, allow the proper allocation of limited financial resources. These policy and financial aims lead to highly influential decisions (e.g., allocation of financial budgets). And finally, the ICD must be acceptable and applicable all over the world to enable uniform global health statistics and to support comparability and focused prevention and intervention planning in support of global public health. The DSM, in contrast, is somewhat more bound to Western culture and in particular more influenced by the US legal and healthcare reimbursement systems.

Some experts now argue that the flaws inherent in these systems require a major shift in perspectives and principles for conceptualizing mental disorders. The Research Domain Criteria (RDoC) (Insel, 2014) advocates as a framework for research a focus on basic mechanisms of mental disorders that are based on scientifically well-defined psychological and neurobiological concepts. The Hierarchical Taxonomy of Psychopathology (HiTOP) (Kotov et al., 2017; Kotov et al., 2021) recommends using a more data-driven approach to define symptom clusters organised within broader dimensions. This approach has similarities to investigating the structure of personality traits, which resulted in the Big Five model (John et al., 2008). Meanwhile, these quantitatively based concepts enter more and more into the classification systems; the ICD-11's classification of personality disorder and related traits (Swales, 2022; Tyrer et al., 2015) and the DSM-5's Alternative Model for Personality Disorders (AMPD) (Zimmermann, Kerber, et al., 2019) are related examples.

Others reject these "nomothetic" classification approaches as they are predominantly oriented towards differences *between* persons, and instead highlight the importance of "ideographic" approaches studying processes *within* persons. This process-based approach not only advocates for a more individualized diagnostic process, but also a psychopathological understanding in the context of basic principles of evolutionary theory, focusing on aspects such as variation, selection and retention of psychological and social processes as typical and highly relevant adaptation strategies (Hayes, Hofmann, & Ciarrochi, 2020). Finally, and consistent with some of these frameworks, systems and network approaches view psychopathology as emerging from a complex system of



biopsychosocial variables and processes (Borsboom, 2017; McNally, 2021), and treatment as effecting dynamic changes in these networks. Dynamic network theory not only considers the relation and centrality of symptoms, social and environmental influences and biological processes, but also the dynamics of change processes. This framework aspires to describe, understand, predict, and intervene on psychological processes of mental disorders, and also inspires work on bridging levels of analysis, such as connecting neurobiological to behavioral systems (Blanken et al., 2021).

These approaches raise important criticisms and offer important insights for potential paths forward, but the key question remains whether they are viable alternatives for meeting the uses and demands of existing classification systems, or parallel systems that can inform the ICD and the DSM. How can they be integrated with the knowledge that is in the DSM and ICD? Or are these recommendations for innovations just scientific "l'art pour l'art", without relevant implications for clinicians or for public health?

In this article, we focus on these questions and hope to advance the scientific discussion concerning conceptualization of mental disorders, recognizing that the purposes of the ICD and DSM extend far beyond their use as a framework for research (International Advisory Group, 2011; WHO, 2019b). By bringing together authors working with very different theories and approaches, we introduce the background and rationales of these frameworks, starting with the reference system ICD-11 as a worldwide classification system with a long history and with important recent innovations in the classification of mental, behavioral, and neurodevelopmental disorders (Reed et al., 2022; Reed et al., 2019). We will investigate whether and how these new frameworks offer opportunities for improving the classification of mental and behavioral problems currently and over time.

International Classification of Diseases, 11th Revision (ICD-11)

The WHO is a specialized, semi-autonomous agency of the United Nations with primary responsibility for global health. Its highest governance body is the World Health Assembly, which comprises the Ministers of Health of WHO's 194 member states (countries). The WHO Constitution (WHO, 1948 reprinted in: WHO, 2020) provides a list of 22 specific responsibilities that were assigned to WHO at the time of its founding. Two of these are 1) to establish and revise as necessary international nomenclatures of diseases, of causes of death and of public health practices; and 2) to standardize diagnostic procedures as necessary.

The eleventh revision of the ICD, the ICD-11 (WHO, 2019a), was approved by the World Health Assembly on 27 May 2019 (WHO, 2019b). The ICD-11 represents the first major revision of the classification since the ICD-10 was published almost 30 years before (WHO, 1992) and incorporates major advances in research, practice, and



information and healthcare technology. The primary purpose of the ICD is to serve as a framework for the collection and reporting of health information by its 194 member states. Important statistical uses of data based on the ICD include monitoring epidemics and other threats to public health, the calculation of disease burden, and the identification of vulnerable or at-risk populations.

After adoption of new versions of the ICD, the new system is implemented by member states as a part of their administrative, clinical, and information systems over the subsequent several years. Beyond meeting reporting requirements, many member states use the ICD as a part of the framework for defining their obligations to provide fee or subsidized health care to their populations. A specific consequence of this is that, in most countries, having a particular diagnosis generally entitles the individual to receive a specific range of health care services (e.g., a particular medication, a surgical intervention, a course of psychotherapy) that would not be provided without a qualifying diagnosis. In this way, the ICD is used by WHO member states as a framework for defining the universe of health conditions that are an appropriate basis for reimbursed health services by appropriately qualified professionals. Because of the ICD's major implications for their health and health information and reporting systems, the pragmatic and statistical priorities of member states have a substantial influence on the ICD and its implementation. Member states are also invested in continuity across versions, so as not to undermine the usefulness of longitudinal health data.

The date of implementation of ICD-11 will vary by country, as it involves integration with laws, policies, health services and health data systems that vary considerably in scope and complexity. For example, the ICD-11 classification of mental disorders has been adopted clinically in Scottish mental health systems as of November 2022. Germany, on the other hand, intends to launch a fully integrated implementation covering both clinical and data systems in 2027.

Development of the ICD-11 Classification of Mental Disorders

Although validity was obviously a primary concern in evaluating the need for changes in the mental disorders chapter of ICD-10 (First et al., 2015), developing the ICD-11 was not purely a matter of attempting to capture as well as possible the scientific "truth" about the nature of mental disorders (International Advisory Group, 2011). In developing the ICD-11 classification of mental disorders, the WHO Department of Mental Health and Substance Use also placed substantial emphasis on *clinical utility* and *global applicability*, which were seen as critical to the Department's aim of reducing the global disease burden of these conditions (Reed et al., 2019). Detailed descriptions of different aspects of the development of the ICD-11 classification of mental disorders, its extensive program of integrated field studies, and its differences from the ICD-10 and from the DSM-5 have been provided elsewhere (First et al., 2021; First et al., 2015; Keeley et al., 2016; Reed et al., 2022; Reed et al., 2019).



In addition to the statistical version of the ICD-11 for Mortality and Morbidity Statistics (MMS) (WHO, 2023) the WHO Department of Mental Health and Substance Use developed Clinical Descriptions and Diagnostic Requirements (CDDR) for ICD-11 Mental, Behavioral and Neurodevelopmental Disorders. The CDDR are available on WHO's ICD-11 website (https://icd.who.int/dev11/l-m/en) and will be published in book form in 2024. To enable mental health and other health professionals to understand and apply this part of the classification in their work with patients, the CDDR describe the features clinicians can reasonably expect to see in all cases of a given disorder and how to differentiate disorders from non-pathological expressions of human experience and from other disorders including medical conditions (First et al., 2015). The CDDR describes additional clinical features that can assist in evaluating diagnoses across cultures, genders, and the lifespan. (See First et al., 2015 for additional information about the contents of the CDDR and its development.)

Benefits and Costs of Including Mental Disorders in the ICD

The ICD-6 (WHO, 1949) was the first version of the classification published by WHO, the first to include a classification of morbidity in addition to mortality, and the first to include a classification of mental disorders. (The ICD had previously been a classification of causes of death maintained by an international consortium. See Reed et al. (2016) for a historical perspective). The ICD-6 was therefore a major milestone in the recognition of mental disorders as valid health conditions and important causes of morbidity. In conceptualizing its approach to the development of the mental disorders classification in ICD-11, WHO's International Advisory Group (2011) stated, the inclusion of mental and behavioral disorders alongside all other diagnostic entities in health care is an important feature of the ICD, facilitating the search for related mechanisms of etiology, pathophysiology, and comorbidity of disease processes and providing a solid basis for the parity of psychopathology with the rest of the medical system for clinical, administrative, and financial functions in health care" (p. 87).

At the same time, integration in the ICD has brought with it certain limitations because the ICD classification of mental disorders must follow the same structural and taxonomic rules as the rest of the classification of diseases. Clark et al. (2017) explain that the ICD-11 "remains structured as a categorical taxonomic system because this format is necessary for its application as the classification system for global health statistics and, to a large extent, for its use in clinical systems (e.g., in treatment selection and the determination of eligibility for health care services)" (p. 105). These requirements impose different and much stricter restrictions on the classification model than other models discussed in this article. Nonetheless, the ICD-11 has been able to introduce substantial innovations that move beyond a strictly categorical classification in in the direction of greater dimensionality, while at the same time respecting rules and conventions that



have deep historical roots and are well accepted as the basis for classification in other areas of medicine.

The overall taxonomical rules inherent in the ICD — as a categorical classification system (and also inherent in the DSM, which in this regard is equivalent to the ICD) (Clark et al., 2017) — go back hundreds of years (Adriaens & De Block, 2013; Kendler, 2009) and have contributed to the reification or "essentialization" of mental disorder categories (Hyman, 2010). Specifically, it led to the illusion that ICD categories refer to discrete and non-overlapping disorders or subtypes of well-established validity, an illusion that has been further reinforced by the American Psychiatric Association's focus on increasingly precise operationalizations of diagnostic criteria as a part of the DSM. Randomized controlled trials were based on these precisely defined patient populations, de-emphasizing areas of overlap and commonality that are highly relevant to real-world implementation (Tucker & Reed, 2008). Another limitation is that, by definition, a classification of diseases or health conditions locates the pathology within the individual.

Moving Past Categorical Classification in the ICD-11

Structural and coding innovations introduced in the ICD-11, partly based on its fully electronic infrastructure, have made it possible to introduce classification innovations that expand beyond a strictly categorical approach to mental disorders. A core principle of taxonomic classification is that entities can be classified in one and only one place. ICD-11 uses a mechanism called "secondary parenting" to allow categories to appear in multiple places in order to improve clinical utility without sacrificing statistical integrity. For instance, Tourette syndrome is classified under movement disorders in the ICD-11 chapter on diseases of the nervous system but is also cross-listed under both neurodevelopmental disorders and obsessive-compulsive and related disorders in the chapter on mental, behavioral or neurodevelopmental disorders.

Moreover, the ICD-11 has made substantial progress in integrating a dimensional approach to the classification of mental disorders in the context of a categorical system (Bach et al., 2021; Clark et al., 2017; Gaebel, 2012; Reed, 2018). Classification entities were introduced that are not diagnoses on their own but can be appended to other diagnostic categories to characterize them by utilizing dimensional profiles. These include symptomatic manifestations of primary psychotic disorders (positive symptoms, negative symptoms, depressive mood symptoms, manic mood symptoms, psychomotor symptoms, and cognitive symptoms); prominent personality trait domains in personality disorders (negative affectivity, detachment, dissociality, disinhibition, and anankastia), and behavioral or psychological disturbances in dementia (psychotic symptoms, mood symptoms, anxiety symptoms, apathy, agitation or aggression, disinhibition, and wandering). Syndromal dementia diagnoses are rated for severity as well as these psychological and behavioral descriptors, and they are also linked to the presumptive underlying



etiology (e.g., cerebrovascular disease, chronic use of alcohol, Parkinson disease, HIV). This provides a multidimensional picture of the individual clinical presentation.

How Can Insights From Other Models Be Integrated – Incrementally – Into the ICD-11?

The ICD-11 is the first version of the classification that has been designed and built using a fully digital architecture. The coding system has changed from numeric (10 possible values per digit, i.e., 0-9) to alphanumeric (36 possible values per digit, i.e., 0-9 and A-Z), exponentially expanding the capacity of the system to contain information. Therefore, it is likely that the core architecture of the ICD-11 system will be in use for some time. Member states' interests and priorities for health information are also unlikely to change dramatically in the immediate future. So, discarding the entire classification of mental disorders and substituting a fundamentally different approach will not realistically be possible anytime soon.

However, there is a well elaborated and already functioning system for making more incremental proposals for changes to the ICD-11 based on emerging evidence. Proposals can be made by anyone registered on the ICD-11 maintenance platform at https://icd.who.int/dev11/l-m/en. There are different proposal forms to modify the name or definition or other descriptive properties of a category, to add or delete a category, or to alter the organization of categories within or among groupings. After triage to verify that they meet basic requirements, proposals are sent to the Classification and Statistics Advisory Committee (CSAC), which primarily comprises representatives of the health statistics agencies of WHO member states. When appropriate, CSAC requests consultation from the Medical and Scientific Advisory Committee (MSAC) to evaluate the scientific and clinical foundation of a proposal and make a recommendation to CSAC on that basis. For MSAC, important factors in the evaluation of proposals are: 1) the amount and quality of scientific and clinical evidence in support of the proposal; 2) the amount and quality of contradictory evidence; and 3) the extent to which the proposal represents an international and widespread professional consensus. If a goal of the developers or adherents to any of the models discussed in this paper is to influence the ICD, the ICD-11 maintenance platform provides the best way to do that. The change in question should be proposed at a point where sufficient supportive evidence has been developed and there is substantial agreement (e.g., among international scientific and professional societies) about the desirability of adopting the proposal.



A Paradigm Shift in Classifying Personality Disorders (PD)

A prime example of the advancement of ICD-11 is the section on PD. Research on PD has been at the forefront of challenging the validity of categorical classification systems in recent decades and has increasingly questioned their clinical utility (Bornstein & Natoli, 2019; Krueger, 2013; Widiger & Trull, 2007). For the ICD-11 PD Working Group, as well as for many other researchers in the field, the time was ripe for a radical change: developing a model that better represents the empirical evidence for the dimensional structure of PD (Hopwood et al., 2018). Although pragmatic concessions were made to certain stakeholders (e.g., by retaining the category of borderline PD), this goal was ultimately achieved (Tyrer et al., 2019). In this respect, the ICD-11 model for PD demonstrates that a paradigm shift within the established classification of mental disorders is indeed possible.

An important point of reference for the revision process was the AMPD, published in 2013 in DSM-5 Section III, which converges with some elements of the ICD-11 PD model. These include, for example, a refinement and substantiation of the general criteria for PD. Criterion A of the AMPD states that impairments in specific functions of the self (e.g., identity, self-worth, capacity for self-direction) and interpersonal relationships (e.g., capacity for empathy, cooperation, and intimacy) constitute PD and distinguish it from the state of mental health and other mental disorders. This definition is based primarily on the integration of various theories of PD (Livesley, 1998), but it is also compatible with the empirical finding that these features are particularly pure markers of the general factor of PD (e.g., Sharp et al., 2015). Furthermore, in the AMPD, the severity of PD takes centre stage and is directly represented diagnostically via a five-point rating scale—the Level of Personality Functioning Scale (LPFS: Zimmermann et al., 2023). The underlying evidence base included findings of the high predictive validity of severity with respect to future impairment, as well as its clinical usefulness in determining the amount of care required.

A particularly relevant element of the AMPD that converges with the ICD-11 PD model is using a dimensional trait model for describing the specific characteristics of PD. Here the goal was not to simply adopt an established model from personality psychology. The point was to adopt the predominant *methodological approach* of personality research by 1) aiming at efficient and precise description (rather than explanation), 2) collecting human judgments of hundreds of nuanced characteristics in thousands of self and other descriptions, and 3) conducting a comprehensive analysis of the covariation of those characteristics. Such a research program has contributed to a considerable integration of personality research since the 1990s. Most prominent examples are hierarchically structured personality models such as the Big Five (John et al., 2008) or HEXACO (Ashton & Lee, 2020), which encompass few broad domains and many specific, narrow facets. In line with this approach, the DSM-5 PD Working Group collected and defined 37 clinically relevant personality facets, created eight short descriptions per facet, submitted



the entire list of items to multiple samples in self-report format, and used factor analytic methods to develop the taxonomy so that individual items are organized according to their empirical covariation (Krueger et al., 2012). The result is the AMPD trait model, with the five superordinate domains Negative Affectivity, Detachment, Antagonism, Disinhibition, and Psychoticism, and 25 subordinate facets. The fact that many domains correspond to the domains of the Big Five model (e.g., Negative Affectivity can be considered as the opposite pole of Emotional Stability) is ultimately an empirical outcome of this methodological approach and not an arbitrary decision by experts.

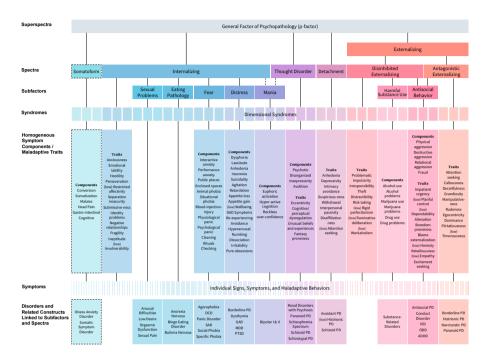
Some have called PD the "vanguard of the post-DSM-5.0 era" (Krueger, 2013). Indeed, the AMPD trait model has stimulated a large body of research over the past 10 years that tends to support its validity and clinical utility (Zimmermann, Kerber, et al., 2019, but also see: Clark & Watson, 2022), and the PD section in ICD-11 features for the first time a similar dimensional model in the main part of a classification system (Tyrer et al., 2019). Importantly, both models are based on a methodological approach that provides the template for creating a map for the totality of mental disorders, organized as they jointly emerge in the description of human raters. In this respect, the HiTOP initiative (Kotov et al., 2017) can be seen as an attempt to complete the work that has been started on revising the PD sections in DSM-5 and ICD-11.

HiTOP for a Better Classification of Mental Disorders

The Hierarchical Taxonomy of Psychopathology (HiTOP; Kotov et al., 2022; Kotov et al., 2017) represents a quantitative approach to the classification of psychopathology, extending the methodological approach of the AMPD described above. It is a hierarchical model of data-driven dimensions of psychopathology that have emerged in research on the structure of maladaptive personality as well as common and uncommon adult mental disorders (see Kotov et al., 2017 for the foundational review). The dimensions are based on patterns of co-occurrence or covariation among symptoms and disorders, and the hierarchy arranges these dimensions from individual signs and symptoms at the bottom all the way up to very broad dimensions at the top (e.g., a general factor of psychopathology, or p-factor; Caspi et al., 2014; Lahey et al., 2012). The model will be revised as the literature evolves and ultimately is intended to become a comprehensive framework articulating the empirical structure of all psychopathology (Forbes et al., 2023). The current model (Figure 1) is organised around six core *spectra* that largely mirror the personality domains described in the AMPD and the ICD-11 PD model. In this framework, diagnoses are not "present" or "absent"; individuals' symptom profiles indicate severity to guide intervention at the level of components, syndromes, and/or spectra (Ruggero et al., 2019).



Figure 1
The Current Official HiTOP Framework



Note. Dashed lines indicate dimensions included as provisional aspects of the framework. Abbreviations: ADHD, attention-deficit/hyperactivity disorder; GAD, generalized anxiety disorder; IED, intermittent explosive disorder; MDD, major depressive disorder; OCD, obsessive—compulsive disorder; ODD, oppositional defiant disorder; PD, personality disorder; PTSD, posttraumatic stress disorder; SAD, separation anxiety disorder. Reprinted from Forbes and Wright (2023), utilizing a Creative Commons 4 licence. See also HiTOP-system.org.

Motives for HiTOP

The primary aim of HiTOP is to provide reliable and valid description of the structure of psychopathology to overcome the limited reliability and validity of many traditional categorical diagnostic categories (Kotov et al., 2017). HiTOP dimensions have already been found to outperform traditional diagnoses in predicting important outcomes in research and practice (e.g., impairment, treatment-seeking, and suicidality) (Kotov et al., 2021) and can be used for a variety of purposes — spanning understanding individuals' symptom profiles, mapping the effect of a treatment to a specific domain of psychopathology, and quantifying risk factors that predict psychological ill-health and distress in the population (Conway et al., 2019). Further, the hierarchical nature of the framework provides a high degree of flexibility for researchers and clinicians to focus on the specific



level of detail relevant to their research questions or clinical context without needing to compromise on breadth of assessment (Ruggero et al., 2019).

Bridging the Gap Between Clinical Applications, Basic Psychology, Neuroscience, and Other Sciences

Due to its flexibility and breadth, HiTOP can act as a framework for disentangling the shared and unique features, processes, mechanisms, and causes of psychopathology for work spanning clinical practice, basic research, neuroscience, and other fields related to the study of mental disorders (Conway et al., 2023; Kotov et al., 2022; Kotov et al., 2021; Latzman et al., 2020; Perkins et al., 2020). Using reliable and empirically based constructs to operationalize psychopathology can offer a way forward that frees research in these fields from the limitations of traditional diagnostic categories and may present new opportunities for progress in understanding the mechanisms that underlie psychopathology, as well as for developing more effective treatments. While the official HiTOP measure is still in development (Simms et al., 2022), HiTOP constructs can be assessed using existing measures and analytic frameworks, reducing barriers to immediate implementation (e.g., Conway et al., 2019; Jonas et al., 2022).

Potential for a World-Wide, Transcultural, and Culture-Sensitive Approach

An important limitation of the evidence base for the HiTOP framework is the predominance of studies in homogeneous white and Western samples. There have been several large cross-cultural studies as well as some work on multi-group invariance by race, ethnicity, gender, age, and sexual minority status in US samples (Rodriguez-Seijas et al., 2023). However, these studies have typically been limited to examining the internalizing and externalizing spectra. Ultimately, the goal will be to have a classification system that has utility and is robust across sociodemographic and cultural groups, while also sensitive to differences between these groups. With more comprehensive research in this area, meaningful differences between groups may well emerge such that a more nuanced framework will be required that goes beyond a single structure. This is ongoing work in both the Diversity, Equity, and Inclusion Workgroup and the Revisions Workgroup in the HiTOP Consortium (Forbes et al., 2023; Rodriguez-Seijas et al., 2023).

Increasing the Acceptability and Utility of HiTOP in Practitioner Groups

Recent research shows mixed results regarding the acceptability and utility of HiTOP among practitioner groups; indeed, these were not the major goals for the development of HiTOP. For example, Balling et al. (2022) found that clinicians rated HiTOP as having better clinical utility than the DSM when applying both systems to a clinical vignette.



Raskin et al. (2022) also found support from psychologists for alternatives to the DSM-5 in principle, but in practice they were unfamiliar with HiTOP.

There is substantial work underway to increase the acceptability and utility of the HiTOP framework for practitioner groups. For example, there is work documenting the mapping between HiTOP constructs and existing interventions (Mullins-Sweatt et al., 2020); transdiagnostic treatments can be selected to target a range of related symptoms (e.g., Selective Serotonin Reuptake Inhibitors / SSRI or the Unified Protocol to treat symptoms across the internalizing spectrum; Kotov et al., 2017) or targeted treatments can be used for narrow symptom domains (e.g., exposure therapy for phobic anxiety or sleep restriction for insomnia). A Digital Assessment and Tracker (HiTOP-DAT) has also been developed that assesses symptoms and traits across the framework as well as functional impairment (Jonas et al., 2022). It can be used for scoring clients' symptom profiles at intake with reference to population norms, treatment planning, tracking progress over time, and cross-walking elevated HiTOP domains to ICD-10-CM codes for reimbursement and administrative purposes. Other clinical tools—such as links to existing 'HiTOP Friendly Measures' and explanations of how to use HiTOP in practice are available on the HiTOP Clinical Network website (HiTOP-system.org; see also HiTOP Consortium, 2023) and field trials are underway at nine clinical sites to identify and address gaps in clinical utility (Kotov et al., 2022).

RDoC for a Better Conceptualization of Mental Disorders

Motives for RDoC

Launched in 2009 by the National Institute of Mental Health (NIMH) in the US, the Research Domain Criteria (RDoC) represents a research framework – rather than a nosological system – developed to overcome serious limitations associated with symptom-based diagnostic categories. Among others, three problems inherent in categorical classification systems (e.g. DSM, ICD) fuelled the development of RDoC (Insel et al., 2010). First was the fact that DSM/ICD diagnoses remain generally agnostic with respect to underlying pathophysiology and etiology. Second was the amply documented observation that current diagnoses are characterised by a remarkable degree of clinical (and presumably, etiological and pathophysiological) heterogeneity and extensive comorbidity. And finally, a substantial body of evidence indicates that DSM/ICD diagnoses are poor predictors of treatment response and clinical course.

The RDoC research framework responded to these challenges by focusing on functional dimensions divided into seven domains ranging from normal to abnormal. These dimensions include negative valence systems, positive valence systems, cognitive systems, systems for social processes, arousal/regulatory systems, and sensorimotor systems.



tems. The investigation of these dimensions occurs across seven units of analysis: genes \leftrightarrow molecules \leftrightarrow cells \leftrightarrow circuits \leftrightarrow physiology \leftrightarrow behavior \leftrightarrow self-reports. This approach fosters a multi-faceted assessment of mental disorders. Additionally, the framework acknowledges that both neurodevelopment and environmental influences continuously shape and affect the domains and units of analysis. For more information about RDoC, see reviews by Cuthbert (2020); Morris et al. (2022).

In contrast to descriptive approaches for the classification of psychopathology, RDoC was launched from the premise that disorder categories should better consider diagnosis-relevant mechanisms. The first incarnation of the RDoC framework relied on the assumption that mental disorders are brain disorders that originate from dysfunctional brain neural circuits (Insel et al., 2010). A key underlying assumption was that such circuit-level abnormalities could be addressed by therapeutic interventions.

One foundational tenet of the RDoC is that studying mental disorders from the perspective of dimensions of measurable behavior and related neurobiological mechanisms could overcome some limitations of current nosological systems (Cuthbert, 2022). Accordingly, this approach starts from basic knowledge about functions (e.g., ability to learn from rewards, propensity to attend to threat, working memory abilities), which can be evaluated at neural, behavioral, or self-report levels of analysis, for example. Within this conceptualization, mental disorders can be studied as disruptions in these functions resulting in abnormalities across levels of analyses (and with varying degrees of disruption) (Morris et al., 2022).

Refinements, Misconceptions and Criticisms of RDoC

Partially due to early writings emphasising that mental disorders are fundamentally disorders of aberrant brain circuits (e.g., Insel et al., 2010), a misconception quickly arose that neural circuitry was considered the "primary focus" for RDoC (or stated differently, that neural units of analysis should be prioritized). This misconception has been clearly refuted in later writings (e.g., Kozak & Cuthbert, 2016), which have emphasized that no unit of analysis should have precedence or preferential consideration. With five of the seven units of analysis being biological, the RDoC retains a strong focus on biological mechanisms, but this should not be misconstrued as biological reductionism (since self-report and behavior are considered equally important). Rather, the RDoC framework emphasizes an approach in which mental disorders are studied simultaneously through observable (and quantifiable) behaviors as well as neurobiological variables.

Since its launch in 2009, the RDoC initiative has been criticized for several reasons, including insufficient attention to social determinants such as poverty, social inequality, and other environmental factors (e.g., Dean, 2019), particularly in earlier RDoC conceptualizations. Although an exhaustive discussion of such criticisms goes beyond the scope of the current review, a few selected key criticisms are discussed (Dean, 2019; Peterson, 2015; Ross & Margolis, 2019; Weinberger et al., 2015).



Perhaps among the most important criticisms, which goes to the core of the RDoC, is that serious mental disorders are not merely extreme forms of a dimensional continuum (Ross & Margolis, 2019; Weinberger et al., 2015), but rather qualitatively different states. Accordingly, serious mental disorders are thought to arise due to pathological processes that fundamentally disrupt normal neurobiological function (Ross & Margolis, 2019). Along similar lines, it has been argued that variables summarized in the RDoC matrix regulate normal brain function, rather than disease states. According to these views, RDoC's top-down approach rooted in seven predefined domains of functioning holds little promise towards better treatments. Instead, critics advocate for a bottom-up "disease model," which starts with identification of etiological factors (e.g., genetic variants), which in turn informs pathophysiological investigations and ultimately leads to a revised nosological system and targeted treatments. A second important criticism is that, owing to the fact that knowledge about the brain is still limited, the RDoC matrix focuses on well-established pathways and thus neglects emerging neurobiological targets discovered, for example, through recent GWAS studies of mental disorders (Ross & Margolis, 2019). As an example, Ross and Margolis (2019) highlighted that, as of Spring 2019, the RDoC matrix included 33 mentions of dopamine or serotonin, 36 mentions of GABA or glutamate, without any mention of molecules recently implicated in risk for major mental disorders. Although both criticisms are legitimate, it is important to emphasize that one important misconception is that the RDoC matrix is a fixed and prescriptive structure, focusing only on a subset of mental disorders. However, the RDoC leadership has been clear that the RDoC should be conceptualized as "a set of dynamic principles with which the field can build a cumulating knowledge base about psychopathology" (Cuthbert, 2020, p. 84). Thus, it is expected that the RDoC matrix will continue to evolve as knowledge is discovered and replicated.

To conclude, RDoC is an approach that bridges the gap between clinical applications, basic psychology, neuroscience, and other sciences. It has the potential of changing education and training programs for clinicians by moving the focus from diagnostic groups to mechanisms of change. However, at present, it has not yet developed to answer societal questions, health economic questions, or transcultural issues.

A Systems Perspective on Mental Disorder Research and Practice

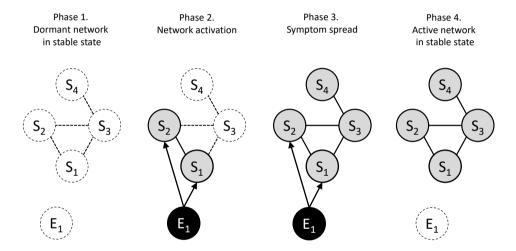
Five key insights are of particular relevance to the systems perspective. First, mental disorders are highly multifactorial, including biological, mental, social, and environmental determinants. This contrasts with oversimplistic, monocausal frameworks that have dominated our field. Second, people with the same determinants can develop different problems (multifinality), and people with different determinants may develop the same problems (equifinality). This means it is difficult to predict how a person's problems



will develop over time. Third, people with the same diagnoses can differ substantially in both the determinants and problems they experience. There are (next to) no simple homogeneous categories, and one-size-fits-all treatments have shown limited efficacy. Fourth, the problems people experience are often causally related: for example, injury \rightarrow pain \rightarrow insomnia \rightarrow decreased work performance \rightarrow negative affect \rightarrow relationship problems. Importantly, problems may persist even after determinants have subsided (see Figure 2). Overall, this calls into question simple cause-effect relationships as well as the clear separation of risk factors and symptoms. Fifth, mental disorders are dynamic: they rise and fall over time. Unfortunately, our knowledge of these dynamics is limited, largely owed to cross-sectional, between-subjects research designs.

Figure 2

The Development of Mental Disorders From a Systems Perspective According to Borsboom (2017)



Note. S = symptoms; E = environmental influences. According to the systems perspective, mental disorders go through several phases of development. Initially, there is an asymptomatic phase where the network is inactive (Phase 1). Then, an external event triggers some symptoms to manifest (Phase 2), which in turn enable other connected symptoms (Phase 3). If the network is highly interconnected, simply removing the external trigger does not result in recovery. This is because the network is self-sustaining and becomes trapped in an active, stable state (Phase 4). Figure reprinted with permission from Wiley & Sons Ltd.

A Framework for Description, Prediction, Explanation, and Control

These five insights have led some experts to conclude that rather than studying single, isolated disorders or components, we should study the *systems* from which mental disorders arise. The systems perspective (or network approach) to mental disorders proposes just that: to conceptualize mental disorders as complex systems, and to study



the systems (defined as components and relations among components) that give rise to mental disorders. The perspective has gained prominence in the last decade, and primers on the framework are available elsewhere (Borsboom, 2017; Fried, 2022; Olthof et al., 2023; Robinaugh et al., 2022; Roefs et al., 2022). This brief section serves as a summary of the core points and available resources. Broadly speaking, the perspective offers new theories and methods that aim to facilitate 1) description, 2) prediction, 3) explanation, and 4) control (i.e., prevention and intervention) of psychological systems.

Description

One of the first steps to gain a better understanding into complex systems is data description and visualization. Researchers in the last decade have implemented network methods from systems sciences that help psychologists estimate and visualize the relations between variables in datasets. Such methodological tools are available for cross-sectional data, panel-data (e.g., multi-wave epidemiological data), and time-series data (e.g., ecological momentary assessment data collected multiple times a day for several weeks using smartphones, or digital phenotype data collected using smartwatches or other wearable devices). A recent primer paper provides an overview of these methods and discusses challenges (Borsboom, Deserno, et al., 2021), which was followed by further discussion of methodological limitations (Borsboom et al., 2022; Neal et al., 2022). Importantly, some network methods allow one to distinguish processes that can only be identified at the individual level from those that generalize at the group-level (Beltz & Gates, 2017). These types of network models can start to bridge the gap between within-person and between-person perspectives, and highlight the importance of disentangling differences between and within persons.

Prediction

Recent work has suggested that studying the dynamic features of disorder systems over time may enable researchers to predict upcoming transitions into and out of mental disorders (Olthof et al., 2020; van de Leemput et al., 2014; Wichers et al., 2016). System features that are predictive of upcoming phase transitions are called early warning signals. Such signals have been widely and successfully studied in other literatures such as ecology, and one of the most commonly discussed early warning signals in the psychopathology literature is critical slowing down (van de Leemput et al., 2014; Wichers et al., 2016) – a feature that systems may exhibit before a phase transition occurs, such as from a healthy to a depressed state. Importantly, there is some evidence that critical slowing and other early warning signals can be detected some time before the symptoms of a person change, offering potentially novel opportunities for the prevention of mental disorders (Fried et al., 2023).



Control

Climate scientists conceptualize the global climate as a system, and variables of interest, such as the global temperature, emerge from interactions among system components. Climate scientists can simulate interventions on the system by implementing control mechanisms (such as reducing CO_2 emissions) and studying the outcomes for global temperature. Similarly, conceptualizing mental disorders *as systems* and quantifying components as well as relationships among components may afford our field novel tools to study interventions. Researchers in this field recently developed a toolkit for system interventions by combining the two disciplines of network psychometrics and control theory — the former is concerned with the estimation of network estimation in psychological data, the latter with the question of how to optimally control systems to achieve desired outcomes, such as reducing global temperature or mental disorders (Henry et al., 2022).

Explanation

In the summer of 2022, there were considerable shortages of sparkling water in Italy, and media also reported a potential beer production shortage in Germany-both "because" of the Ukraine war. This is the result of causal processes in a system: war \rightarrow increasing energy prices \rightarrow decreased ammonia (fertilizer) production that is very energy intensive \rightarrow decreased CO₂ production that is a byproduct of ammonia production \rightarrow CO₂ shortage that affects production of sparkling water and beer. Understanding these causal pathways helps with predicting future states of the system, as well as thinking of potential control operations (e.g., subsidizing ammonia production or finding alternative sources of CO₂). This also applies to psychological systems, where thorough descriptions of a system, along with theory building and testing, could help to properly map out components and relations within a system, and lead to a better understanding. Using a complex systems approach, Robinaugh and colleagues developed a theoretical model that aims to explain panic attacks and panic disorder (Robinaugh et al., 2022). This model specifies all relevant components and their relations in mathematical form, and the paper discusses in some detail the value of formalizing theories as systems (see also: Borsboom, van der Maas, et al., 2021; Haslbeck et al., 2022; Robinaugh et al., 2021).

Process-Based Therapy as a New Conceptualization of Problems and Treatments on an Individual Level

The Goal of a Process-Based Approach: The Individual Perspective

Process-based therapy is a new approach to psychopathology and treatment (Hayes, Hofmann, & Ciarrochi, 2020; Hofmann & Hayes, 2019; Hofmann et al., 2021). From



a process-based perspective, perhaps the most problematic approach of contemporary psychiatry and psychology is to study phenomena on a between-person level (group level), rather than on a within-person level (individual level), leaving idiographic issues buried in statistical variation (Fisher et al., 2018). By studying psychological phenomena almost exclusively at a between-person level (e.g., diagnostic categories), we miss out on the meaningful individual processes that are the main focus in clinical practice and might lead us to the actual underlying processes of treatment change.

A related problem, specifically related to psychotherapy, is the contemporary approach of studying treatment processes with traditional mediation analyses based on a cross-sectional view of group data, which assumes that treatment change is nomothetic (Baron & Kenny, 1986). Again, this assumption makes findings difficult to apply to individuals and has little relevance to clinical practice. To model processes of change, clinically meaningful intervention research needs to focus on variables longitudinally, allowing them to vary between and within individuals. Furthermore, the impact of therapy cannot reasonably be reduced to just one or a few mediators and moderators, nor by assuming that these variables are independent or that they form simple unidirectional, linear relationships (Hofmann et al., 2020). The process-based perspective instead posits that change processes can more accurately be described as patterns of multiple inter-related variables forming dynamic complex networks over time, in individuals.

The Process-Based Framework

For these reasons, Hofmann and colleagues have advocated for shifting towards processbased therapy, or PBT (e.g., Hayes & Hofmann, 2021; Hayes et al., 2019; Hofmann & Hayes, 2019) with the aim of discovering what change processes underlie psychopathology and its successful amelioration, and refining our understanding of these processes to facilitate treating individuals in a flexible, more precise way. In transitioning to a PBT framework, the focus in clinical psychology is shifting from determining "what treatments work?" to exploring "how treatments work and why." The goal of PBT is to gain a comprehensive understanding of two aspects: 1) identifying the essential biopsychosocial processes to target in an individual based on their specific goals and stage of intervention, and 2) determining the most effective methods for targeting these processes, utilizing functional analysis, complex network approaches, and identifying core change processes derived from evidence-based treatments (Hayes & Hofmann, 2018). PBT shares goals with classical functional analysis, including the consideration of context and the usefulness of specific behaviors. However, PBT encompasses a wider range of processes and is specifically designed to be applicable and beneficial for clinicians (Hayes et al., 2019).

PBT also highlights the importance of distinguishing between therapeutic procedures and processes. Therapeutic procedures refer to the specific techniques employed by a therapist with the aim of helping a patient to achieve their individual treatment



goals (Hayes & Hofmann, 2018). Processes occur primarily within the client, but they also involve interactions between the client and therapist, the client and other individuals, and even within the therapist themselves. These processes encompass dynamic, theory-based, progressive, and multi-level changes. PBT necessitates a comprehensive theoretical framework to encompass specific evidence-based therapeutic models, and it has adopted an extended evolutionary model to fulfill that requirement (Hayes, Hofmann, & Wilson, 2020). PBT views psychopathology as maladaptations to a particular context. From an evolutionary perspective, these maladaptations stem from issues related to variation, selection, and/or retention of specific biopsychosocial dimensions within that context. Within PBT, this framework is referred to as the Extended Evolutionary Meta-Model (EEMM). The EEMM serves as a tool for researchers and clinicians to identify, study, categorize, and address the processes involved in psychopathology. We have extensively described the key aspects of the EEMM, including variation, selection, retention, and context, and have applied these concepts across various domains (Hayes, Hofmann, & Ciarrochi, 2020).

Variation is the initial step toward adaptation (Hayes & Hofmann, 2018). It requires flexibility. Healthy selection is the second critical step in the process of adaptation. Even if there is healthy variation present, maladaptation can occur if beneficial psychological variants are not recognized and chosen. Selection processes include reinforcement, as well as the pursuit of goals, values, and attachment. Finally, retention involves intentionally developing and reinforcing adaptive patterns and habits to replace old maladaptive ones. Many evidence-based therapy techniques, such as homework assignments, aim to strengthen this aspect of adaptation. Often during the development of psychopathology, some behaviors and cognitive approaches tend to become habitual, resulting in a narrower range of variation. Thus, a dialectic relationship exists between variation and selective retention. Context serves as a moderating factor in this dialectic relationship, encompassing cultural, diversity, social support, and family factors. Psychological domains are not restricted to behaviors, but also include emotions, cognition, attention, self-perception, and motivational tendencies. Multilevel selection involves considering gene systems, behavioral classes, cognitive themes, physiological processes, and sociocultural influences. Together, these factors constitute the Extended Evolutionary Meta Model of change processes, as represented in Figure 3.

Treatment and Research Implications of the PBT Approach

In recent years, there has been a growing trend towards transdiagnostic approaches in the field. The process-based approach addresses the limitations of the latent-disease model present in current classification systems by (1) systematically incorporating treatment processes from various therapy modalities and (2) viewing the treatment focus in PBT as the removal of unhelpful processes rather than a specified disorder. This approach has been developed to analyze individual-level change processes. PBT places



Figure 3

Extended Evolutionary Meta-Model of Change Processes

Affective Cognitive Attentional Self Motivational Overt Behavioral Physiological Social/Cultural

Extended Evolutionary Meta-Model (EEMM)

Note. Figure from Hayes, Hofmann, and Ciarrochi (2020). For the meta-model, it was argued that variation, selection, retention, and context are constructs to explain whether adaptation processes to life challenges are successful or end up in psychopathological problems. The theory of evolution is used in all life sciences to explain complex living systems. It was argued by Hayes, Hofmann, and Wilson (2020) that evolutionary ideas have been underutilized by behavioral science. To introduce evolutionary thinking into the discourse, the extended evolutionary meta-model applies key concepts of variation, selection, and retention in different contexts to answer questions about the function, mechanisms, developmental pathways, and history of mental disorders. Six content dimensions, including affect, cognition, attention, motivation, self, and overt behavior, are discussed to specify adaptation processes, and to be essential for describing mental disorders. Figure reprinted with permission. Copyright S.C. Hayes and S.G. Hofmann.

emphasis on tracking the patient's progress over time, utilizing techniques such as ecological momentary assessment, wearables, and smartphones. By redefining symptoms as problems based on the patient's current experiences, the aim is to understand the processes that contribute to maintaining these problems and the functional relationship between them. Ultimately, the goal is to intervene effectively and predict future experiences.



To understand the individual, PBT encourages us to study the individual in all its complexities. This approach may lead to exciting new avenues for psychotherapy research, both in terms of identifying processes with empirical support and new data analytic advancements (Hofmann et al., 2016). Further research is necessary to investigate whether the utilization of a PBT approach truly results in enhanced effectiveness of psychological treatment. This is because the scientific evaluation of this conceptual framework is still in its early stages, involving initial single case studies (Ong et al., 2022).

Discussion

In this article, we have presented the different rationales and purposes of different approaches to the classification of mental disorders. After briefly summarizing these approaches, we will discuss how they can inform each other. It is clear that a major source of differences among the approaches presented relate to distinct goals and purposes. The primary aim of ICD-11 is as a tool for improving global public health, emphasizing usability and worldwide applicability. Given its foundational role in global health statistics, it has relevance for global development, economic evaluations, policy campaigns, legislation, and legal decisions. Currently, there is no real alternative that serves all these purposes. However, other approaches can stimulate changes and improvements that can either be integrated into the ICD-11 or can be further developed as a complementary or, perhaps eventually, alternative system.

HiTOP is an empirically-based proposal to organize symptoms according to a hierarchical and dimensional model. HiTOP has the potential to inform international classification systems because of its proximity to existing psychopathological concepts, but there is still a need for further evaluations based on HiTOP. The data underpinning the current HiTOP working model is heavily influenced by the traditional diagnostic categories it aims to improve, and the model does not yet capture sufficiently the diversity of populations. Further, previous research on HiTOP is largely focused on differences between persons, and such a nomothetic approach can suffer from limitations when being applied to individual cases (e.g., Fisher et al., 2018).

RDoC, at first glance, seems to be orthogonal to the classification approaches based on descriptive psychopathology. It follows the vision of identifiable, separable mechanisms that contribute to the development and maintenance of psychopathology. If such a system of identifiable mechanisms is further validated by empirical data, it can provide a breakthrough for moving primarily descriptive, psychopathological systems to a classification system that is characterized by central processes of mental disorders. However, many promises of RDoC have not been fulfilled yet. The definition of endophenotypes or the identification of central brain circuits responsible for mental disorders are progress-



ing only slowly, and effect sizes of pharmacological treatments continue to be in a low to moderate range (Cipriani et al., 2018).

Another critique on RDoC is the tendency to focus on single systems, functions and mechanisms. Alternatives may include dynamic network models that take into consideration that relevant processes are interdependent. Dynamic network models can be applied to mental/psychopathological symptoms and processes as well as to neurobiological circuitries. Although not unique to network approaches, they allow for integration of machine learning techniques, for example to improve prediction of changes. However, so far, network approaches have been applied only in an initial series of studies. It remains to be seen whether this approach will lead to relevant new insights and to a profound change of our understanding of mental disorders.

The process-based approach mainly points to the fact that most diagnostic and interventional procedures focus on the individual, although the knowledge they are based on is mainly derived from analyses of group differences (the nomothetic-idiographic dilemma). The PBT approach advocates the need to collect more data on an individual level, such as individual trajectories about symptom development and recovery with the goal to derive novel, homogeneous, and treatment-relevant groups (using an integration of nomothetic and idiographic approaches such as the Group Iterative Multiple Model Estimation / GIMME algorithm; Gates and Molenaar, 2012). While the PBT approach offers a novel perspective on mental disorders and employs innovative analytical techniques, it currently lacks sufficient empirical validation.

Opportunities and Barriers to Between-Framework Integration

HiTOP shares its methodological approach with the AMPD and ICD-11 trait models, resulting in high convergence between HiTOP spectra and extant trait domains (Wright & Simms, 2015). HiTOP is also similar to the ICD-11 in its focus on signs and symptoms and its prioritization of description as a foundation for explanation, and there is potential for more purposeful integration of HiTOP into ICD. One barrier will be the emphasis on pragmatism in the ICD-11 to ensure utility in health reporting and structuring clinical care, and also ICD's worldwide perspective. Additional dimensions of psychopathology could be integrated into ICD-11 where sufficient evidence for higher order spectra, empirical syndromes and other dimensional constructs accrues.

Other dimensions or units of analysis such as those contemplated in RDoC (e.g., negative valence systems, arousal/regulatory systems, circuits) could also be incorporated into what is called the "foundation layer" of the ICD-11 without changing the statistical version. For example, the MSAC is already considering how best to incorporate genomic information in the foundation layer. Although this would not be a part of the statistical version, if specific genomic variables were already part of the foundation they could easily be moved into the statistical version as evidence accumulates and there is a strong clinical or public health rationale for doing that.



To take another example, the systems approach (e.g., Fried, 2022; Fried & Robinaugh, 2020) explicitly includes consideration of factors in the interpersonal, social, and physical environment, so a classification model that focuses solely on disturbances within the individual would initially appear to be a poor fit. However, the ICD-11 includes an extensive chapter on factors influencing health status and encounters with health services, which covers many of the important social and environmental determinants of health. These include finances, education, employment, drinking water and nutrition, social or cultural environment, and relationships, among other areas. Proposals based on the systems perspective could potentially focus on refining these categories and organizing them in configurations shown to be useful by research. The increasing attention currently being devoted to issues of health equity, with the goal of addressing the overwhelming evidence of serious and unequal problems with access to healthcare services, quality of care received, and unequal outcomes among minoritized groups across numerous health and psychological parameters (Kelly, 2022; WHO, 2018) suggests that consideration of these issues as part of the predominant global classification system for health could be important and timely.

Integration of HiTOP and RDoC is also a potential natural progression for both systems. For example, Michelini et al. (2021) worked on an interface linking RDoC and HiTOP dimensions to strengthen both systems: RDoC's biobehavioral focus could improve research on the mechanisms and processes underpinning HiTOP constructs, and HiTOP constructs can be used as reliable phenotypes (clinical targets) to guide RDoC-informed studies. While reliable covariation does not necessarily indicate a shared cause among constructs, the flexibility of the HiTOP hierarchy can at least account for heterogeneity within traditional diagnostic categories and this integration of the two approaches offers a concrete path forward for determining whether and where biobehavioral mechanisms and processes map onto specific symptoms, broader components, or larger transdiagnostic dimensions (see also Tiego et al., 2023).

Despite the possibilities for integration between different frameworks, there are significant difficulties for integrating HiTOP and the systems perspective. One hurdle seems to be that the current HiTOP working model focuses on between-person differences, while the systems approach focuses primarily on within-person differences. However, it should be noted that HiTOP's underlying methodological approach of analyzing covariation in descriptions is also applicable to intensive longitudinal designs. In fact, similar to research on the Big Five as states (Borkenau & Ostendorf, 1998), the structure of within-person fluctuations in mental disorders is found to be largely compatible with the HiTOP spectra (Wright et al., 2023; Zimmermann, Woods, et al., 2019). In this respect, the HiTOP spectra could also have a heuristic value for the systems approach or PBT (e.g., regarding the selection of target dimensions or measures; Wright & Zimmermann, 2019). However, there are substantial philosophical and methodological differences between HiTOP and systems perspective frameworks. HiTOP – by design – searches for higher order latent



factors of psychopathology while the systems perspective takes a deflationary stance on the existence of latent factors as constituents of mental disorders and instead emphasizes e.g., the importance of contextual variables for the development and maintenance of mental disorders (e.g., Borsboom, 2017). In systems approaches, mental disorders *are* a system of interacting problems *without simple underlying latent causes*. HiTOP, however, is hierarchical and models latent constructs (supraspectra, spectra and subfactors) with the use of dimension reducing techniques (e.g., Conway, Forbes, et al., 2022). Ongoing methodological and philosophical discussions (e.g., Borsboom et al., 2022; Forbes et al., 2021) exemplify the considerable challenge in integrating the systems perspective on mental disorders, including PBT, and HiTOP.

For RDoC, there is emerging evidence indicating that utilizing the framework in conjunction with categorical diagnoses, such as from DSM or ICD systems, may improve treatment outcomes. In a recent multi-site study in MDD, Ang et al. (2020) reported that behavioral (relatively better reward learning ability, as assessed by the Probabilistic Reward Task) and neural (relatively stronger resting state functional connectivity between the nucleus accumbens and the prefrontal cortex) reward-related markers predicted treatment response to the atypical antidepressant bupropion after failing 8 weeks treatment with the first-line treatment sertraline (an SSRI). Critically, without a priori incorporation of these measures (including of the RDoC subdomain of reward learning), identification of treatment-specific markers (moderators) of treatment response would not have been possible. This is consistent with the RDoC's assumption that, by implementing quantifiable and granular assessments of fundamental dimensions of behavior that map onto precise neural circuitries (and computational parameters), we might be able to identify biologically more homogenous subgroups of individuals who might preferentially benefit from a given treatment strategy. For an important example of discovery of different "biotypes" in a study that used cognitive and electrophysiological variables to parse heterogeneity among a large group of individuals with schizophrenia, schizoaffective disorder, or psychotic bipolar disorder, see Clementz et al. (2016).

A systems perspective aims to identify shortcomings of traditional diagnoses, including inter-individual differences of people with the same diagnosis, lack of reliability and validity of categorical diagnoses, and an over-reliance on symptoms compared to other important factors. Generally, the systems perspective aligns well with PBT, given the explicit focus on studying networks of within-person processes. Methods from systems science can help to describe such systems, to describe their dynamic changes, and also to study to what degree systems generalize across people (Borsboom, Deserno, et al., 2021; Roefs et al., 2022). It also aligns with RDoC's transdiagnostic focus on mechanisms, and much of the work done by RDoC can be framed as studying disorder / health components and their interrelationships.

The systems perspective and PBT also share a focus on understanding mental disorders as dynamic processes that are shaped by complex interactions among various fac-



tors (Borsboom, 2017; Hofmann et al., 2020; Hofmann & Hayes, 2019). Both approaches emphasize the role of individual experiences and the importance of context in shaping the development and maintenance of mental disorders. PBT and the systems perspective share a goal of developing personalized and context-aware treatment approaches that consider the unique needs and circumstances of the individual (e.g., Fried et al., 2023; Ong et al., 2022). Despite the similarities there are also differences between the approaches. PBT is primarily a treatment approach, while the systems perspective is a broader framework for understanding mental disorders. While PBT draws on the systems perspective to inform its understanding of mental disorders, it is primarily focused on developing and implementing novel interventions. The systems perspective, on the other hand, seeks to provide a comprehensive understanding of mental disorders that can inform the development of a wide range of future treatments.

Conclusion

The field of diagnosis and classification of mental disorders is characterized by a rapidly developing discourse, the utilization of multiple novel frameworks, and efforts to effectively incorporate empirical data into the development of these models. As previously discussed, the main distinctions among the approaches result from their differing priorities and goals. However, many aspects of single frameworks can be integrated into one another, which could lead to promising new research programs and hopefully also spark ideas for effective psychological treatments along the way.



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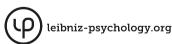
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