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Rapid commentary: Ethical implications for clinical trialists and patients associated with COVID-19 research

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Abstract

Pandemics disrupt clinical trials worldwide, with lasting effects on research. It can severely impact clinical trialists ability to conduct safe and ethically uncompromised trials. Hence, the mounting pressure results in ethically and morally distressing decisions faced by clinical trial professionals during pandemic situations. Whilst clinical trialists attempt to think about preparedness and responses during a pandemic, the need to have an ethical framework that has real-world applicability is imperative. Pandemics are a challenging time for all, however, the safety and access to support for clinical trialists and patients within clinical trials should be at the forefront for their organisations and the government.

Key Words: COVID-19; Pandemic; Ethics; Clinical trials; Patients; Trialists

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Core Tip: This commentary provides an important facet and argues the ethical implications surrounding clinical research practices and staff during pandemic

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situations. Clinical trial professionals face ethical dilemmas whilst conducting trials safely at an unprecedented rate given the clinical urgency. This commentary highlights the detrimental impact of not having a protocol for pandemic-driven clinical research, as well the lack of an ethical framework with *real-world* applicability to support the clinical trial workforce. Unethical behaviours and practices could be introduced in the current pressurised climate in order to rapidly respond to coronavirus disease 2019 research in particular.

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INTRODUCTION

A pandemic is a time to focus on containing the clinical situation, ensuring deaths are minimised, reviewing the causation and developing treatments. However, the ethical implications surrounding clinical research practices and staff may be less considered. Ethically and morally distressing decisions may be faced by many clinical trial professionals during pandemic situations. These decisions, which could be seen as "moral injury", may impact upon an individual's ethical and moral code and may develop into feelings of shame and guilt^[1]. In the current coronavirus disease 2019 (COVID-19) pandemic, the wider psychosocial and psychological impact of the pandemic amongst Clinical Trialists is yet to be explored. Whilst there is an argument that there could be personal factors that may contribute to this, Clinical Trialists have had to reprioritise their work regimes to deliver research around severe acute respiratory syndrome coronavirus 2.

A useful document that has aided Clinical Trialists in particular is the World Health Organisation's (WHO) pandemic preparedness document. Interestingly the National Institute for Health Research also provided guidance and paused non-COVID related research as of March 20, 2020. The WHO's pandemic preparedness framework was a result of a workshop conducted in 2018 amongst the Global Health Ethics Team and the African coalition for Epidemic Research, Response and Training. The purpose of this workshop was to discuss and identify empirical processes and procedures in relation to ethics reviews and preparedness during pandemics. This included five key areas in particular; pre-review of study protocols (including multi-country reviews), coordination between national ethics committees, statistical and stakeholder considerations, data and outcome sharing, as well as transfer of samples to share knowledge and develop future proofed interventions. Another key development to come out of this workshop were standard operating procedures (SOPs) for ethical reviews, in part to protect staff and their time while conducting pandemic research. These SOPs were to provide clarity on terminology and expectations of the pre-review of protocols and to agree a specific set of standards to speed up the process. Whilst these recognised a number of complex ethical issues could be raised during pandemics, it is also imperative to consider both research and clinical staff resources. Various other aspects such as quality assurance, regulatory requirements and operational delivery of the required research, which arguably could have ethical implications due to the by-stander effect this generates, were not well discussed and reported. This should be a fundamental aspect to consider with any future pandemic preparedness documentations as well as any associated procedures. Additionally, ethical implications for specific staff groups should be considered, to ensure policy makers are able to develop relevant guidelines.

Ethical implications associated with pandemics have significantly evolved over the centuries, but developing fit for practice ethical guidelines universally applicable to policy makers, healthcare systems and clinical trial units appears to have been challenging. Furthermore, ethical implications and principles may be driven by the pandemic itself. A good example would be to consider research conducted during the H5N1 influenza endemic. A significant limitation with H5N1 research was that longitudinal data was scarce and so its wider use and applicability was constrained. In

order to aid future pandemic management plans or to better understand transmission of a virus on the scale of a pandemic, existing data could have been used as part of prediction model, to support research staff. Whilst, the infection was managed in various ways, clinical trial staff had a different set of ethical considerations that were needed to have been addressed. Currently, there is no evidence to suggest these ethical considerations for trial staff were explored and reported. The vulnerability in this situation, of course, is that addressing the needs of a pandemic alongside the need for clinical research to develop treatments and vaccines, has to sit alongside access to care and the ethical obligations of research and to our clinical research staff.

IMPACT OF PANDEMIC RESEARCH ON CLINICAL TRIALISTS

All clinical trials testing licensed or unlicensed drugs and vaccines are mainly led by clinicians and clinical academics and there are staff from many disciplines working as Clinical Trialists. Therefore, the research associated with a pandemic, resourcing levels and the mental and physical impact varies considerably. Whilst there is a wide acceptance resource issues in the NHS, this has been exacerbated during the current pandemic. As a result, there appears to have been a heavy reliance on clinical and non-trial staff to deliver some clinical trials, which could impact their mental wellbeing in the long term, although this hypothesis would require further investigation.

Interestingly, Alperovitch and colleagues^[2] stipulated whilst there is a need for research to be conducted during a pandemic, the major implications are in respect to managing the ethical principles pertaining to the studies themselves, research participants and Clinical Trialists. A key issue to consider is the informed consent aspect. Some studies have had deferred and/or waived consent models when conducting clinical trials during previous pandemics^[2]. Whilst participants, clinicians and researchers often agree emergency research consent could be waived in some urgent situations, this method isn't suitable and acceptable for all. Clinical Trialist based research requires informed consent, and recognition that an electronic method of conducting a trial could be an efficient way to gather insightful data to further evaluate this is often missed. For example, the European Medicines Agency has provided clarity that informed consent must be taken before enrolling any patients into COVID-19 clinical trials taking place in Europe. Gobat and colleagues^[3] discussed this issue further in their systematic review, and highlighted that patients accept clinicians acting as surrogate arbitrators. However, research regulators were more judicious if studies had substitute consenting procedures. Also, while further recommendations around study setup and protocol design need to be fit for purpose for any pandemic-driven clinical research such research should comply with both research and practice ethics. Alternative consent models could also have major psychological impact on Clinical Trialists and research to this effect remains limited.

Balancing clinical care and research to manage pandemic preparedness

Another common ethical argument presented during pandemics is that clinical care for current patients outweighs clinical research around non-pandemic issues. This may impact both patients and ongoing clinical care in a multitude of ways. Currently there are clinical trials taking place to test the use of Lopinavir, Ritonavir or Dexamethasone for COVID-19 (*via* the RECOVERY Trial); all of which are licenced treatments for other diseases. As there is clinical and adverse effect data already available for these drugs, there are minimal risks and ethical and moral implications for staff conducting these trials, when compared with COVID-19 vaccine studies or first in human trials. However, there could be unlicensed drugs that may also be suited to combating a new infection or a modified strain of a known infection such as COVID-19.

Another facet to pandemic preparedness is whether countries have ample research capacity to ensure an efficient and effective response in terms of research. The requirement for ethical principles and merit of incorporating these into research and clinical practices using specific guidelines could be endorsed during public health emergencies and it is widely recognised this could be a cost effective way to further operational capacity for Clinical Trialists in particular. As such, policy makers, clinicians, researchers and stakeholders need to identify time and resources to provide immediate treatment and maintain other activities, inclusive of an integrated approach for research as part of a pandemic response. In situations such as the COVID-19 pandemic, developing research and clinical practice "ethics preparedness" can help provide an efficacious response.

Challenges with implementation

Whilst ethical preparedness has the potential to cover an array of factors, a key challenge is the applicability of ethical standards between the “individual” and “group”. There may be conundrums around duty to act to preserve lives of patients and the general public, *vs* the personal risks of those providing clinical care. It is clear that those in frontline clinical positions put themselves at risk in order to save lives and that this is morally acceptable. However, there may be others who may feel, as a healthcare professional, their right to conduct their role in a safe manner is compromised due to the very obligations of the role they play during a pandemic.

Identifying specific risks for staff

COVID-19 has a unique aspect, that is, the infection having particular effects on the black, Asian and minority ethnic (BAME) population based on the current data reported specifically within the United Kingdom. 44% of the NHS workforce belongs to the BAME population and to date, several reports state approximately 62%-75% of the 181 healthcare worker deaths were of BAME descent^[4-6]. Ethnicity has the potential to influence the disease transmission through societal, cultural and behavioural differences^[7]. The Francis report^[8] found the frontline doctors who are of ethnic minorities may feel more vulnerable to raising concerns at work, thus BAME staff may not have vocalised concerns around their health risks and lack of access to personal protective equipment (PPE) during the pandemic. Minimal or lack of PPE has been found to correlate with increased anxiety levels in healthcare professionals^[1]. As the causation of the ethnic bias in COVID-19 is yet to be understood, this introduces ethical implications for those serving in the frontline and in COVID-19 related research and potentially needs further investigation before this impacts other frontline BAME staffing groups.

RISKS OF PREDICTION MODELS

Historically, the rate of deaths during a pandemic depends on the number of those infected, the virulence of the infection and the efficiency and effectiveness of the preventative measures^[9]. In addition, accurate mortality rates can be challenging to establish. However, this may be because the use of Artificial intelligence (AI) methods, coupled with data science and its influence on healthcare, has been minimal until now. Therefore, another facet to complicate ethical implications for staff could be that prediction models for COVID-19 are AI instead of traditional statistics. Whilst, AI methods and statistics have their own strengths and weakness, the rapid reviews being conducted to develop these prediction models could lack quality and perhaps be poorly reported, which would contribute to increasing bias. This was highlighted in a recent systematic review conducted by Wynants and colleagues^[10]. Therefore, there is an argument that unethical behaviours and practices could be introduced in the current pressurised climate due to the rapid response-based research conducted. Whilst conducting “rapid reviews” is very much appropriate and is a time sensitive matter, academia maybe overloading the journals with a large number of papers in a bid to put their views across and to support healthcare practitioners. This could raise more confusion within frontline services than anything else. In fact, this counter productivity itself could be deemed unethical. Furthermore, an already overstretched healthcare system may feel overwhelmed and may also have very limited time to use this evidence in a meaningful manner.

CONCLUSION

It is anticipated that national research ethics committees, research consortia, funding agencies, healthcare organisations and policy makers will work towards promoting better recommendations and for conducting effective research during a pandemic, whilst still protecting our clinical trial workforce. A key factor that must remain at the forefront as we think about preparedness and responses during a pandemic, is that, despite theoretical and conceptual debates, the real-world applicability of any ethical frameworks is imperative. This is vital to keep in mind when decisions are made with regard to research and supportive strategies for clinical research staff working during pandemics.

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Exorcising memories of internalised stigma: The demons of lived experience

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Abstract

Public stigma and self-stigma impact negatively on the lives of people with mental health issues. Many people in society stereotype and discriminate against people with mental ill-health, and often this negative process of marginalisation is internalised by people with lived experiences. Thus, this negative internalisation leads to the development of self-stigma. In this article, I reflect on my own experiences of shame and self-stigma as a person with mental ill-health socially bullied by peers from my community and social groups. I present a personal narrative of both public and self-stigmatisation which I hope will enable me to exorcise memories of internalised stigma, which are encountered as my demons of lived experience. Using reflexivity, a process used widely in health and social care fields, I consider how social bullying shattered my fragile confidence, self-esteem, and self-efficacy in the early days of my recovery; the impact of associative stigma on family members is also explored. Following this, the potential to empower people who experience shame and stigma is explored alongside effective anti-stigma processes which challenge discrimination. I connect the concept of recovery with the notion of empowerment, both of which emphasise the importance of agency and self-efficacy for people with mental ill-health. Finally, I consider how the concepts of empowerment and recovery can challenge both the public stigma held by peers in the community and the self-stigma of those with lived experiences.

Key Words: Stigma; User-led narrative; Reflexivity; Empowerment; Recovery; Mental health

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by a person with lived experience of mental ill-health. It explores how both public stigma and self-stigma can shatter fragile confidence and impact negatively on both self-efficacy and self-esteem. Connections with the importance of empowerment and recovery in mental health are considered, and how they can overcome the sense of shame and self-pity experienced by people with mental ill-health who encounter social bullying by peers in their community.

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INTRODUCTION

Stigma is at the centre of the experiences that many service users encounter when in contact with their peers and with the communities they belong to^[1-3]. The word stigma originates from ancient Greek and means ‘a mark of shame or discredit’^[4]; this defines the exclusion and marginalisation that many people with mental ill-health experience. Two elements to stigma have been defined: Public stigma and internalised stigma^[1]. Public stigma involves the construction of stereotypes about excluded groups. This process leads to prejudice which is translated into active discrimination and marginalisation against this population^[1]. Self-stigma^[1,5] involves the internalisation and acceptance of negative beliefs about mental illness. These elements interact^[5] because people who live with conditions such as schizophrenia may also endorse stereotypes about themselves, leading to “self-discriminating behavior” such as self-imposed isolation derived from the stereotype held by others about their “risky and dangerous” behaviours. Self-stigma reduces individuals’ self-efficacy and self-esteem^[1,5]; moreover, internalized stigma can disrupt mental health treatment-seeking intentions and behaviours and can lead to delayed help-seeking^[6]. Stigmatisation processes can also affect family members of people diagnosed with mental ill-health.

This article will explore my lived experiences of stigma as a person with a diagnosis of mental-ill health and reflect on the response by peer groups to my condition. It asks questions about the nature of both public and internalised stigma^[1,5] and investigates the lack of understanding of mental health symptoms. I explore the processes that can challenge both public and internalised stigma and suggest how anti-stigma campaigns can confront discrimination. I finally propose how acts of empowerment and the concept of recovery can both challenge stigma and promote greater understanding of mental ill-health.

METHOD OF REFLECTION

I am both a social work academic and service user expert with a diagnosis of schizophrenia. Both these identities are central to the construction of this article as I reflect and analyse my experiences about the nature of stigma. At the centre of social work is the process of reflection and reflexivity, a method used to enable professionals to understand and make sense of their experiences^[7]. Reflexivity enables a person to explore his/her experiences and interpret them to gain greater understanding of the context to the situation around him/her^[7]. A useful method that enables reflexivity is a process that explores the art of writing and reflection in investigating practice^[8]. This approach connects the narratives of lived experiences told through personal reflections to the context of practice^[8], exploring the links between local encounters and the wider circumstances. I thus relate my lived experiences of stigma and illuminate their significance for understanding the wider environment through a process of reflection. This method has been used in health, social care, and education and can facilitate an investigation of the significance of personal reflection in the setting of professional practice^[8].

MY REFLECTIONS

This is for me a frightening and revealing reflection. It focuses on my sense of shame and stigma as a person with mental ill-health. It is hard to write as this process reveals details of experiences I have not spoken of before or allowed to bubble to the surface. These are accounts which I have hidden deep and buried in forgotten memories. They are embarrassing and shameful-and best forgotten. But at times they can't be forgotten and come to the surface.

At the time of the experiences described in this reflection, I was very paranoid and found it difficult to manage my mental health symptoms. I heard conversations and thought that people were talking about me. I translated the words I heard into what I wanted to hear - words that had been unsaid. These are my demons of lived experience through the shame and embarrassment I encounter as I remember them.

I experienced a mental health crisis involving extreme paranoia and psychosis at the age of 18-years-old. This happened at university in the North of England in the early 1990s. At the time I was studying at university far away from home. I had no personal experience of mental ill-health and had no inkling or understanding of its manifestation. At that time, I believed that mental illness happened to "mad" people, and was not something I would experience; moreover none of my peers or tutors recognised the signs of a pending mental health crisis until the illness was quite advanced.

My parents came to visit me at my university; this visit coincided with my first episode of mental health crisis. My mother stayed in the university as my mental health was deteriorating. I eventually had an appointment to see a psychiatrist and was admitted voluntarily for a short hospital stay and prescribed medication. On leaving hospital, I continued to take medication and returned to university. I continued to experience paranoia and low levels of psychosis and was eventually diagnosed with schizophrenia two years later. I continued my university studies, with great difficulty, and finally graduated. I was awarded a lower degree classification than previously predicted; however, completion of my university degree was a real achievement.

However, alongside this success at completing my degree, I also experienced many episodes that caused (and still cause) me shame and embarrassment. I remember back to experiences of when I was unwell, and I cringe. After leaving university I returned home to live with my parents. I was very lonely and isolated and craved a relationship with somebody who would like me for who I was, support me and take care of me. I was naïve, dependent, and overweight, because of the increased appetite associated with taking the prescribed anti-psychotic medication. I had little self-confidence and felt a sense of shame at who I was. I so much wanted to be valued.

There are so many memories that cause shame and embarrassment. I remember. I really liked somebody. This person was in a social club which I joined at the age of 23-years-old. The social group was a small group of 10 people for those aged 20-30-years-old (It wasn't a mental health peer group, but a social group in the community). There were some people who became my friends in the group; they were kind and thoughtful, but some who were unkind and found a mental health issue to be amusing. The group members all had more "success" than me. I was still living at home, undertaking additional study, and trying to forge a life for myself. But I was still dependent on my parents, and I lacked self-worth. This person who I liked didn't like me. I couldn't accept it and I believed that he liked me.

I listened like a snake to the conversations of other people. I listened to their conversations for evidence that he liked me. I heard things the people didn't say, and when I would go over their words, I would hear the words that he liked me. Words that hadn't been said, but I remembered as being said. Few people without lived experience of mental ill-health, can understand how paranoid beliefs may be perceived as a true representation of the world; my peers couldn't understand that I believed these thoughts to be true. At times people in this group teased me because I was a sad and very lonely person. They would say that he liked me, but he didn't; some people teased me because I couldn't seem to accept the obvious. During this period, I was like a ship, lost at sea, hurtling from one wave to another. I always ask the question: Did those people treat me unkindly and without compassion, or did they just not understand? As I remember I cringe with embarrassment and shame. Was it my fault? I had a mental health illness. They didn't understand the impact on me.

To my lasting shame and stigma, I had a pattern of such behaviour. I would latch onto somebody and believe he liked me. I was lonely and isolated and so wished for somebody to care for me. Previously to this experience, I kept such thoughts silent and did not share them, but this situation was different as I truly believed he liked me. I

was a persistent re-offender! My behaviour wasn't obvious, and I didn't harass him, I was a bit of a "silly nuisance"! He didn't understand my pain and embarrassment, I don't think he noticed me, only I experienced the shame.

This internalised failure is linked to the messages I reinforced to myself when I wasn't well. You can't do that. You aren't good enough to do that. You are no good. These are the demons of internalised stigma that say you can't achieve; that you are no good. This is a narrative of pain. I was bullied, undermined, and shamed as they laughed at me. Did they know the impact on me?

I managed the day-to-day stigma by convincing myself that I was of no value and self-reinforced the stigma others felt towards me; this meant my confidence plummeted. This was a negative coping mechanism which was effective because it dulled all hope and optimism; I couldn't be hurt anymore and couldn't fall any further because I had failed utterly.

What saved me from being this sad and lonely person? Eventually by engaging with learning, study, and being supported by mentors throughout my social work career, I began to achieve and to succeed. I studied for a Master of Arts degree in Social Work, then a PhD. Work for me was at the centre of my recovery journey and enabled me to fight the stigma; it led to a passion to change public stigma for those experiencing mental distress. Finding a wonderful and considerate and understanding man who became my husband was at the centre of my recovery. I am not now the person who was that person at that point in time described in my reflection. I cringe at my loneliness, my embarrassment, my shame, and my isolation. Was it my fault or was it part of my recovery journey?

DISCUSSION

The meaning of stigma and its impact on my life

In the following section I discuss my reflection and contextualise the experiences in the wider literature which seeks to explore the impact of mental health stigma in society. It is important to illuminate how stereotypes and prejudice impact on people with lived experience, and lead to their sense of shame and exclusion from society. **Figure 1** highlights different types of stigma encountered in my life which resulted in my low self-esteem, poor self-efficacy and which limited my recovery. It provides a framework to explore discussion in this article. The elements of stigma represented in **Figure 1** include: Public stigma, structural stigma, associative stigma, personal stigma, perceived stigma, and self-stigma. Alongside the cycle of stigma, my own experiences of double discrimination as both a woman and a person with lived experience of mental ill-health are depicted; these underpin the experiences of social bullying. Whilst parallel to these feelings, but outside of my direct encounters, the associative and affiliate stigma experienced by my family are identified. Finally factors that help to challenge stigma in society, such as protest, education, and contact push out against the cycle of stigma to counteract discrimination and marginalisation. These factors, captured in **Figure 1**, are elucidated in the article discussion.

The social identity of a person with mental ill-health is often negatively construed because the individual does not conform to social expectations of working and living independently^[9]; this thus leads to them being stigmatised and devalued and experiencing public stigma. Furthermore, as people absorb this negatively constructed social identity, this then leads to forms of internalised stigma, or self-stigma, in the individual because of negative attitudes aimed at them.

The stigma encountered by people with mental health issues has been widely explored in research^[1,2,5]; perhaps the most well-known forms of stigma are public and self-stigma^[1]. However, stigma exists in many forms across cultures^[2]: Within the individual (self-stigma), interpersonally (personal stigma), in the shared beliefs of a social group (public stigma), and in the policies and practices that structure society (structural stigma). **Figure 1** shows the elements of stigma which constrained my recovery, first exemplified in structural stigma derived from public stigma.

Structural stigma is an important concept to highlight as it expresses how stigma can exist throughout a culture and become endemic in a system^[9]. From my narrative, it seems clear that my peers believed that it was acceptable for them to tease me because I was a person with mental ill-health to be pitied and undermined. The acceptance of structural stigma^[9] allowed them to bully me because I was a person who was devalued and of no worth.

Furthermore, three different reactions^[10] by the community to people with mental health issues have been identified. Firstly, authoritarianism is the belief that people



Figure 1 Experiencing and challenging different forms of stigma.

with mental health issues are not able to take care of themselves and need other people to take control and direct their lives. Secondly, there is a response to people with mental ill-health that is based on fear and exclusion. This reaction is founded on the belief that people with mental health problems are dangerous and should be isolated from their communities. The final reaction generated in response to people with mental ill-health is benevolence. This response is based on the belief that people with mental health issues are innocent and naïve and not able to make decisions for themselves, resulting in paternalistic help being offered. Such a reaction from peers in their community is often compounded with feelings of annoyance and anger towards people with mental health issues.

Thus, in my experiences I was a person to be excluded and isolated; my peers also felt a benevolent response towards me. I was treated with paternalism as they directed annoyance and anger towards me. I was to be pitied but simultaneously an object unable to manage her own emotions, unable to live independently, of potential risk because I failed to respond in “normal” and socially acceptable ways to my peer group. The process of structural stigma led to a sense of low self-esteem and poor self-efficacy, as illustrated in Figure 1.

Furthermore, six further forms of public stigma have been highlighted^[11]; however only three are mentioned here which I particularly relate to in the context of this article. I thought I was unable to fulfil social positions (exclusionary sentiments); I believed my mental health treatment had negative effects on my social status; (treatment carryover concerns) and I believed my family experienced negative consequences from my mental health status (disclosure spillover).

Associative and courtesy stigma^[11,12] were encountered by my family members This type of stigma is a process in which a person is stigmatized by virtue of his/her association with another stigmatized individual. Additionally affiliate stigma occurs when care-givers’ psychological responses to caring are impacted by the public stigma that prevails in society and they internalise self-stigma^[13]. My parents supported me to the best of their ability, but they didn’t always understand the shame and stigma that I experienced. My family felt personally impacted by the negativity of my diagnosis; and were unable to talk to their peers in their community, encountering affiliate stigma^[13]. As shown in Figure 1, their experiences were encountered in parallel to my exclusion but were different to and outside of the stigma I suffered as a person with a diagnosis of schizophrenia. They sought support from peer and mutual aid support groups at moments in their caring journey. However, I felt uncomfortable with them attending such groups because I believed they talked solely about my mental ill-health in these environments. I didn’t recognise or acknowledge that they had their own needs as care-givers. However, eventually, the fears I expressed prevented them from accessing any forms of support. My parents were therefore further isolated through

the feelings of self-stigma; and, thus, stigma limited the recovery of both me and my social network.

These elements suggest that underpinning public stigma^[1] are elements of fear^[14], a desire to keep a social distance^[10], a devaluing of the role of people with mental health issues^[9]; fears that association with someone with a mental health issue can cause feelings of exclusion^[10] or “courtesy stigma” and associative stigma^[11,12]. These elements connect to the process of self-stigma in both myself and my parents^[1,11] associated with internalising the notions of social exclusion and the inability to manage an independent life^[14]. These elements of exclusion led to the belief that I was deserving of pity, that I was shameful and thus deserving of stigma.

The issue of perceived stigma may also be in play in this context^[15,16]. Perceived stigma concerns how a person with mental ill-health anticipates a negative reaction from others about their diagnosis; it is particularly relevant to those people who want to be open about their diagnosis^[15]. Moreover, this interacts with a sense of self-stigma as indicated in **Figure 1**. I anticipate a negative reaction from some people in my social circles and thus choose not to disclose my diagnosis. For example, I have not shared my diagnosis with some close family members from a fear about how they might react-I perceive that the diagnosis of schizophrenia is often linked to notions of dangerousness and anticipate a negative response. However, although I choose not to reveal my diagnosis in many social settings, I often divulge these experiences in many academic circles^[17]. I have a passion to use my expertise-by-experience to change mental health services for the better and yet feel a need to protect myself from people who don't understand mental ill-health. This decision about when to reveal my diagnosis leads to an anomaly of when I choose to disclose my status and when I choose not to^[17].

Returning to my experiences of exclusion, women with mental health conditions^[18] often experience social devaluation through a double disadvantage based on the intersection of being both a woman and a person with a mental health condition. Such discrimination was reflected in the historical devaluing of women through the early diagnosis of hysteria, labelled as a mental health condition linked to women's health and reproductive cycles^[18]. Women with mental illness, who have experienced trauma, highlighted more difficulties with low self-esteem and the stigma connected to lived experiences than women who have not experienced trauma^[18]. The trauma and social bullying that I received ripped out my sense of self-esteem and self-efficacy, limiting my recovery and leaving me a pitiable and empty shell. This process of stigma is depicted in **Figure 1**, whilst the double discrimination of being a woman and having lived experience of mental ill-health is illustrated as existing alongside these feelings.

Furthermore, the connection between perceived stigma and experiences of victimisation for people with mental health needs has been considered in other studies^[19]. Perceived stigma and victimization are significantly associated, and the stigma attached to mental illness^[19], from being perceived as being dangerous, violent, or undesirable, is a statistically significant predictor of victimization experiences. However, there is little understanding of the experiences of those with mental health issues; particularly as women with mental ill-health often experience an intersection of stigma and victimisation by their peer and friendship groups^[18,19], as I describe above.

More widely, the cultural heritage of people with mental ill-health can impact negatively on their experiences of acceptance in their peer and friendship groups^[10,20]. Public from Eastern countries ascribed more moral attributions to people with mental illness than from Western cultures^[10], thus increasing the potential to discriminate. Moreover, people from Western countries endorsed higher stigma (prejudice and discriminatory potential) and made more moral attributions when the target was a minority (as compared with majority) group member. Furthermore, concern for loss of face in Eastern cultures is part of the process preventing individuals from seeking help from mental health providers to prevent shaming one's family^[20], because mental health conditions are highly stigmatized in Chinese communities. In the United Kingdom, there has been an ongoing national anti-stigma campaign, Time to change, which has sought to challenge stigmatisation and discrimination against people who experience mental ill-health^[21]; it has achieved some limited success.

This section has underlined the stigma and discrimination experienced by people with mental ill-health, highlighting the potential of victimisation to this group, and particularly to women who experience double discrimination. **Figure 1** captures how I have experienced different types of stigma which have limited and bounded my potential recovery journey, and that of my family. Subsequently, an acknowledgement of the importance of cultural heritage in this context has also been considered. In the next section the paper considers how society can challenge the stigma and marginalisation of those who experience mental ill-health.

HOW CAN SOCIETY CHALLENGE STIGMA?

People with mental ill health may sometimes challenge this sense of self-stigma through reactions of “righteous anger”^[1] about the negative social identity ascribed to them by their community. Moreover, a sense of righteous indignation, particularly associated with collective activism and group identity, can challenge both individual and group prejudice. For example, the experiences of 800 gay and bi-sexual men were explored^[2] and a sense of belonging and group activism was positively associated with improved self-esteem; indeed, extrapolating to mental health there may be “high feelings of self-esteem” from “experiencing group identity”^[1]. Despite this process of empowerment, individuals who are stigmatised can resist this label by claiming their own exceptionalism to the stereotypes, thus challenging stigma as an individual^[2].

A process of empowerment can help people to gain a sense of control in their lives and can foster independence and agency^[3], challenging the stigma they may experience that results in dependency and low self-efficacy. Indeed, “empowerment is the flip side of stigma, involving power, control, activism, righteous indignation, and optimism”^[3]. The importance of empowerment in tackling self-stigma is reinforced in the context of promoting control over treatment choices and the direction of one’s life^[23]. Empowering people in these choices can increase a sense of autonomy and agency, thus resulting in a positive effect on self-stigma.

Empowerment cannot happen without change in individuals and the systems around them. From their standpoint as art therapists^[24], the issues of stigma and shame met by people with mental health issues were surveyed in one study. This study noted how people with mental ill-health are often devalued in society and their role is seen as inconsequential. Such ideas in the field of mental health are related to the context of learning disability, where the importance of social role valorisation is explored, a concept^[25] developed to understand the need to empower people with learning difficulties and enable them to be respected and valued in their social role.

In the discussion above, it was identified that stigma against people with mental health needs derives from having a negatively construed social identity. The field of learning disabilities research offers a lot to learn in supporting the promotion of people with mental health issues as full and respected citizens with a valued social role. This leads to the question of how can society combat both public and self-stigma?

EFFECTIVE METHODS TO PROMOTE ANTI-STIGMA WORK

Three strategies to help overcome mental health stigma are explored in the literature^[10]: Protest, education, and contact. Firstly, protest is the process of challenging people’s negative beliefs through direct action. Secondly, education involves the provision of brief courses or facts to counteract prejudice. Finally, contact consists of directly promoting one-on-one contact between people with lived experience of mental ill-health and the public. Contact is found to be the most effective way of challenging stigma and changing attitudes. Moreover, “face-to-face contact with the person, and not a story mediated by videotape, had the greatest effect” at challenging stigma^[21]. The role of each of these factors in challenging stigma is illustrated in **Figure 1**, as they push out of the cycle of stigma that I depict as representing my experiences.

Anti-stigma campaigns need to balance wide and broad approaches that seek to challenge discrimination in a large population of people with more local campaigns which focus on challenging the opinions of small groups^[26]. This finding is reinforced by another study^[27] which suggests that such strategies could be developed to also reduce self-stigma in people experiencing mental health issues. However, little is known about what elements of contact are effective in challenging stigma^[10]; for example, is it equal status or promoting understanding about experiences of mental ill-health that makes contact-based strategies effective? It is essential to answer this to understand how to effectively tackle discrimination and marginalisation of people with mental ill-health.

Encouraging people with mental health needs to disclose their mental health condition may help to reduce stigmatization as individuals take control of information about their health condition and can become empowered^[3]. However, on one hand, disclosing psychiatric status can have negative implications because it can cause discrimination and prejudice, on the other, people who disclose often report lower levels of self-stigma, a greater sense of personal empowerment, higher self-esteem, and enhanced quality of life^[3]. Despite this, the value of disclosing a diagnosis such as schizophrenia is questioned because of the high stigma associated with this

condition^[28].

It appears that the process of “contact” to reduce stigma needs to be carefully managed. There needs to be further research about what elements of contact effectively challenge stigma^[40] and how people with a mental health condition can be appropriately supported through the process of disclosure^[28]. Empowerment is key to challenging self-stigma and enabling the person to challenge both self-stigma and public stigma. Moreover, difference and disdain are key measures of stigma; a recent study explored how to manage these issues in the context of mental health^[29]. They investigated how difference results in people with mental illness being alienated and othered making a separation of “us” from “them”. Consequently, this sense of difference leads to disdain because people with mental illness are devalued and disrespected. The study concludes that anti-stigma efforts may best be focused on tackling elements of disdain, rather than difference, because disdain seems to be the main driver of self-stigma^[29]. This focus on empowerment can be achieved by promoting messages such as: “I may be different, but I am not a person of lesser value.”

Moreover, in the United Kingdom, the anti-stigma campaign, Time to change^[21] has achieved some success in challenging stigma through publishing the personal narratives and stories of those who have lived experience of mental distress; this reflects the acceptance by service users that they may be potentially “different” from other people in society and may have different stories to tell, but that they are not of lesser value. Maybe other people without lived experience of mental distress come to acknowledge their own differences and idiosyncrasies as art of the process of learning about differences?

CONCLUSION

Empowerment through recovery

Such processes of empowerment build on the seminal work in the field of learning disability theory of social role valorisation^[25] that highlights the importance of having a respected and valued role in society. Furthermore, empowerment, enhancing service user control, and self-management of a mental health condition are at the centre of the recovery approach^[30] an aspirational practice in mental health that emphasises the importance of people with mental ill-health leading a good life despite the limitations of their illness^[31]. Indeed, recovery is, in itself, an “effective message” to combat stigma because it reinforces that “mental illness does not keep a person from achieving a full range of positive outcomes”^[30]. This process of empowerment through promoting recovery may be a key factor in challenging both the public stigma and self-stigma of people who have mental ill-health because recovery emphasises the importance of achievement, respect and value for this group^[31].

As my reflection shows, occupying a valued social role and beginning to follow my dreams enabled me to begin to reconstruct my brittle self-esteem and self-efficacy. Little by little, building on confidence and true friendship, I was enabled to take on a responsible role as an academic and increase my capacity to perform^[32,33]. Recovery was at the centre of my empowerment and led me to a place of increased confidence and self-esteem^[32,33] where I was able to combat my own sense of self-stigma and challenge the public stigma of being a person with a diagnosis of schizophrenia. This place led me to exorcise the demons of lived experience. Thus, drawing on the research presented in this article, it is suggested that increased contact between people with lived experiences, and their peers in the community, based on respect and value^[40,28], and the representation of stories of recovery^[32,33], may be at the centre of promoting the social value of people with mental ill-health.

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Case Control Study

Using eye movements in the dot-probe paradigm to investigate attention bias in illness anxiety disorder

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Abstract**BACKGROUND**

Illness anxiety disorder (IAD) is a common, distressing, and debilitating condition with the key feature being a persistent conviction of the possibility of having one or more serious or progressive physical disorders. Because eye movements are guided by visual-spatial attention, eye-tracking technology is a comparatively direct, continuous measure of attention direction and speed when stimuli are oriented. Researchers have tried to identify selective visual attention biases by tracking eye movements within dot-probe paradigms because dot-probe paradigm can distinguish these attentional biases more clearly.

AIM

To examine the association between IAD and biased processing of illness-related information.

METHODS

A case-control study design was used to record eye movements of individuals

patients gave informed consent.

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with IAD and healthy controls while participants viewed a set of pictures from four categories (illness-related, socially threatening, positive, and neutral images). Biases in initial orienting were assessed from the location of the initial shift in gaze, and biases in the maintenance of attention were assessed from the duration of gaze that was initially fixated on the picture per image category.

RESULTS

The eye movement of the participants in the IAD group was characterized by an avoidance bias in initial orienting to illness-related pictures. There was no evidence of individuals with IAD spending significantly more time viewing illness-related images compared with other images. Patients with IAD had an attention bias at the early stage and overall attentional avoidance. In addition, this study found that patients with significant anxiety symptoms showed attention bias in the late stages of attention processing.

CONCLUSION

Illness-related information processing biases appear to be a robust feature of IAD and may have an important role in explaining the etiology and maintenance of the disorder.

Key Words: Attention bias; Selective attention; Eye tracking; Dot-probe; Illness anxiety disorder; Disengagement

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Core Tip: This is the first study which has examined patients with illness anxiety disorder (IAD) having an attention bias that is mainly manifested as attentional avoidance at the early stage and overall attentional maintenance when presented with illness-related stimuli. They also have demonstrated vigilance of attention at the early attention stage and overall attentional maintenance when presented with disease and positive/neutral stimuli. In addition, this study found that patients with suspected disorders with significant anxiety symptoms show attention bias in the late stage of attention processing and struggle to dismiss the stimulus, showing delayed detachment. This study suggests that patients with IAD have attention bias and this may have provided a new way of identification of IAD symptoms using an eye-tracking evaluation method.

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INTRODUCTION

Illness anxiety disorder (IAD) is a common, distressing, and debilitating condition, with the key feature being a persistent conviction of the possibility of having one or more serious or progressive physical disorders^[1]. IAD was formerly named hypochondriasis in DSM-4. Currently, the reported prevalence is approximately 1%^[2-5]. Patients manifest persistent somatic complaints or a persistent preoccupation with their physical appearance. They repeatedly seek assurance from medical advice for physical symptoms that they think they have, and frequently have doubt or fear about negative medical test results and doctors' explanations^[6]. This type of preoccupational thought persists despite appropriate medical evaluation and medical reassurance. The course of IAD is usually chronic and fluctuating, associated with costly and unnecessary medical reexaminations and the overuse of medical resources^[5].

According to cognitive-behavioral models of IAD^[1], IAD patients seem to hold faulty health beliefs. The dysfunctional assumptions about their bodily symptoms and

illness may be triggered by critical incidents. It has been argued that the dysfunctional beliefs about illness and misinterpretation of bodily symptoms appear to be specific and important for patients with IAD and to be a highly specific characteristic of IAD^[7,8]. They tend to show a more restrictive concept of good health than do anxiety patients and healthy people^[8]. They are hypervigilant to bodily symptoms or tend to amplify benign physical sensations^[9-11].

It has been proposed that these psychological processes may underpin the symptoms of IAD. A cognitive-behavior therapy (CBT) for IAD that is derived from W and S's model has been effective. CBT patients had lower levels of health-related anxiety and less impairment of social roles, but IAD somatic symptoms were not improved significantly by CBT^[11,12]. Other researchers have observed a positive correlation between the feature-positive effect (FPE) and illness anxiety concerns^[13]. The FPE is the bias of overweighing positive and underweighing negative information. The FPE may explain the interesting fact of the IAD's sensitivity to illness cues and insensitivity to medical reassurance or negative medical results, but it cannot fully explain the initial preoccupation with bodily complaints and health.

IAD is characterized by patients focusing their attention on one or two organs or systems of their body. They attend to information that confirms their worry and conviction, but simultaneously ignore and under-weigh negative results of medical investigations and evidence of good health. Thus, they display a type of information processing bias, and cognitive processes are considered relevant to the etiology and maintenance of IAD^[14].

Attention bias refers to the individuals who have different attention distribution to the corresponding threat or related stimulus, relative to the neutral stimulus^[15]. Researchers studying attention bias found patients with mental illness often allocate their attention towards concern-related or mood-congruent material. A key feature of attention biases is anxiety increasing patients' attention to danger and threat-related stimuli^[16]. Patients have attention bias in favor of stimuli referring to their specific disorder, and interpretational bias leads them to allocate their attention to these stimuli as more relevant. Thus, their bias is specific to the meaning of stimuli relevant to the disorder. In people with anxiety disorders, anxiety stimuli are likely to receive attention bias when they are danger or from threat-related stimuli, but in people with IAD, the content and disorder specificity of the stimuli is unclear. More recently, some non-illness-related attentional stimuli have been suggested to maintain IAD concerns; in other words, the attention bias may not be limited to illness-related stimuli but also include non-illness-related stimuli^[17,18]. In sum, empirical evidence regarding measuring attention bias in IAD is scarce and equivocal.

To date, a prominent means to evaluate visual attention is the emotional stroop task. Researchers have regarded increased color-naming latencies of emotional or concern-related words as an indicator of selective attention bias, but unfortunately the emotional stroop task cannot differentiate the two possible mechanisms a facilitated engagement or a delayed disengagement^[19,20]. So the precise course of such biases is obscured by the mixed nature of the test process. Alternative experimental paradigms regarding attention bias, such as the dot-probe investigation and the Posner cued-target paradigm, can distinguish these two possible biases more clearly^[21,22]. Because eye movements (EMs) are guided by visual-spatial attention, eye-tracking technology is a comparatively direct, continuous measure of attention direction and speed when stimuli are oriented. 'Persistent', the dot-probe experiment, which uses EM tracking, has been undertaken primarily to examine attentional processing among anxiety disorders and in pain-related research. Researchers have tried to identify selective visual attention biases by tracking EMs within dot-probe paradigms with success^[23,24]. These studies investigated individuals with high social anxiety, generalized anxiety disorder, and depressive disorder, using EMs and a modified probe detection task to pictures of faces. They found that anxiety individuals initially directed their gaze toward neutral faces more often, but were quicker to look at emotional faces and looked at emotional faces for less time. Therefore, anxiety individuals were consistent with a vigilant avoidant pattern of bias, compared with other people.

Using the dot-probe paradigm, our primary aim in the current study was to explore the specificity of attention bias in IAD. We hypothesized that patients with IAD, compared with healthy controls, show more attention bias for illness-related information when negative pictures, positive pictures, and neutral pictures are presented simultaneously. In addition, we hypothesized that patients display orienting attention biases, reflected by fixating first and more rapidly on illness stimuli than other alternatives. We analyzed differences in EM indices reflecting subsequent bias in attention maintenance, including duration of first fixation, average fixation and total gaze/first fixation, and overall gaze duration.

MATERIALS AND METHODS

Study design and participants

A case-control study design was used for the study, with the sample consisting of an IAD patient group and a healthy control (HC) group. Participants were recruited *via* e-mail and newspaper advertisement from Beijing An'Ding Hospital. The patient group fulfilled the criteria for IAD (DSM-5 and formerly named hypochondriasis in DSM-4) according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR)^[25]. Patients were screened with the Structured Clinical Interview for DSM-IV-TR Axis I Disorder (SCID-I) and Structured Clinical Interview For DSM-IV-TR Axis II Disorder (SCID-II)^[26] to affirm the initial axis I disorder diagnosis and axis II personality disorders. Interviews were led by independent, professionally trained clinical psychologists. The HC group was matched to the patient group in age, sex, ethnicity, and education. People who were unable to use their hands, or those with a serious head injury or psychiatric illness, were excluded from the study. All participants had normal or correct-to-normal vision and color vision and no neurological disease, psychiatric illness, or medication use for any psychiatric disorder. Their age ranged from 18 to 60 years, and their education level was 9 years or more.

Ethical approval for this research was obtained from the Beijing An'Ding Hospital, Capital Medical University Research Ethics Committee [Ethics number: (2014) Research (No. 38), Funding number: 20131107110012]. All participants were fully informed about the study research and provided with a general overview of the dot-probe task. All participants provided written informed consent before they agreed to participate in the research in compliance with the regulations of the institution and the guidelines of the Declaration of Helsinki. They were free to terminate the experiment at any time they wished.

Materials

The stimuli used in the dot-probe task consisted of 128 pictures; we collected these pictures through Baidu image search, a search engine in China, which were grouped into four main categories: Illness-related, social threat, positive, and neutral pictures. Illness-related pictures included pictures about patients in disease/hospitals/doctors/doctors threatening or checking patients and pictures about oral medicine. Social threat pictures included pictures about earthquake/quarrel/flood/wars/fires/explosion/traffic/fighting/bridge collapse/plane crash/chasing by animals. Positive pictures included mountain/flowers/children/bird/women/wedding/congratulation/dancing. Neutral pictures included pictures about furniture/meeting/beautiful scenery/shopping/roads/clothes. These pictures have clear meaning, clear content, and try to highlight the stimulus itself; at the same time, these pictures cover as wide range of meanings as possible. The color of the images was unified with Photoshop CS 6.0 about brightness, saturation and contrast. Illness-related and social threat pictures were included to determine whether IAD patients were associated with a specific threat-related attention bias or any threatening material. Positive pictures were included to examine whether a general emotional response accounted for any effects found. These images were randomly presented to participants for 2 s each. Each picture size had mean height of 4.6 cm and mean width of 6.5 cm.

Sixty healthy volunteers were recruited to classify the pictures into our four predefined categories in our pilot study. These volunteers had normal or correct-to-normal vision and color vision. They were not on any medication and had no diagnosed medical or mental health condition. Among 400 pictures, 272 (68%) pictures were excluded as they were not allocated to the correct picture category by at least 80% of the raters. The final number of selected pictures for trials was 128.

Apparatus

Stimulus pairs were presented on a DELL 19 inch TN screen, with 1980 × 1024 pixel resolution and a 60 Hz refresh rate.

EM data were recorded *via* an sr research eyelink 1000 device (sr research, Canada; <https://www.sr-research.com/>). The experiment was programmed and run with sr research experiment builder. The eye-tracker sampling rate was 1000 Hz, with a spatial accuracy greater than 0.5° and a resolution of 0.01° in the pupil-tracking mode. An infrared motion system tracked em/head motion. A forehead and chin rest kept viewing distance constant and minimized head movements. Participants sat 60 cm from the monitor screen, resulting in a 29 cm horizontal, 22 cm vertical visual field.

Prior to the task, a standardized 5-point calibration procedure was performed.

EM data were recorded during each trial, starting shortly before and terminating immediately after picture-pair presentation (Figure 1).

Selective attention task

Selective attention bias was assessed in a visual dot-probe paradigm. With traditional dot-probe tasks, stimulus pairs are presented in separate spatial locations (*e.g.*, left vs right side of computer screen) and replaced by a probe in the location previously occupied by one stimulus. For this study, the main focus was on EMs during stimulus presentation of different image types. Before the formal study, a brief training (four trials) was undertaken to increase familiarity with task requirements; training procedures were identical to those used in the formal study with the exception that different pictures were used for the present study. Participants were told that in each trial of the forthcoming spatial perception task, a triangle would appear in the right or left of the computer screen for 500 milliseconds (ms), followed by picture pairs to which they should carefully attend. Each trial of the task began with a central fixation cross (+) shown for 500 ms and then replaced by an image pair that appeared for 2000 ms. After 500 ms, the next trial began. The formal task included 224 pairs of cards presented in four blocks with 56 trials per block. The four blocks consisted of combinations of the four categories of picture meanings, including (1) Disease-neutral (*e.g.*, oral surgery vs rail), as shown in Figure 2; (2) Disease-positive (*e.g.*, infusion vs scenery), as shown in Figure 2; and (3) Disease-threat (*e.g.*, operating room vs traffic), as shown in Figure 2. Besides, there were four categories included as filling items in order to reduce the monotony of the test materials, including disease-disease, threat-threat, neutral-neutral, and positive-positive. Each pair of images was defined as a trial and each pair of pictures was presented randomly among the four blocks. Participants were given a 2-min break after the presentations of 56 pairs of pictures. On average, the task took 40 min to complete.

Procedure

After providing informed consent, participants were escorted to the eye-tracking experimental area. They were seated in a height-adjustable chair with their chin in a vertically adjusted chin rest. The chin rest was used to reduce participant head movements, ensuring that participants' eyes were level with the middle of the monitor on which the stimuli were presented, and to maintain participant eye distance from the monitor at 60 cm. They were instructed to free view the images at all times during each trial. Further, participants were asked to look at the fixation point before each trial to standardize the starting location of their gaze. On completion of the dot-probe task, participants were asked to fill in several questionnaires, including their self-reported measures of demographics. In addition, the Beck Anxiety Inventory (BAI)^[27], Beck Depression Inventory^[28], Illness Attitudes Scale^[29], and Whiteley Index^[30] were used to assess participants' clinical symptoms.

Statistical analyses

EM data was recorded using the Eyelink1000 tracking system (Canadian sr-research) and was processed by data retrieval. First, the trials affected by invalid calibrations and uncollected EM data were removed; as each pair had two stimulus-related trials, there are total 448 trials per participant, the average invalid trials in 30 IAD participants were 13.767 (3.07%), and the average invalid trials in HC participants were 13.500 (3.01%). Then, we used data viewer software to divide the positions of the two pictures in the same picture matrix into two interest areas and selected valid EM data, including the corresponding position of the first viewpoint, the first-fixation duration, the overall gaze durations, and the overall fixation frequencies in different interest areas. Then, they were exported to Excel (Microsoft) in text format and were collated and converted in Excel to obtain the following attention bias scores: The first-fixation direction bias score = number of views (the first view of a certain type of stimulus) / effective trials; First-fixation duration bias score: The average viewing time (the first view of a certain type of stimulus); Overall gaze duration bias score = total time gazing at a certain type of stimulus/total time gazing at all stimuli in the trial; Overall fixation frequency bias score = the total number of times (viewing a certain type of stimulus)/the total number of times of viewing all stimuli in the trial. The general demographic data and scores of each clinical scale were measured using the international business machines statistical package for the social sciences studies V21.0 software package. Metrological data were represented by mean \pm SD. All four EM indicators were statistically analyzed using independent sample *t*-test. The differences



Figure 1 Experimental setup for capturing eye-movement data.

between IAD group and HC group were compared on different types of images. The mean value of the group was compared with that of independent samples test, and $P < 0.05$ indicated that the difference was statistically significant.

Our study mainly examined four types of EM indicators: (1) First-fixation direction bias (%): The percentage of the number of first percentile points that an individual directs to the area of interest in which a certain stimulus is located as a percentage of the total number of active trials. It mainly examines the individual's initial attentional alert feature; (2) First-fixation duration bias (ms): In the disease-neutral, disease-threat and disease-positive image pairing, the difference reflects the early attention to the stimulation information in the area of interest; (3) Overall gaze duration bias (ms): During the entire experimental process, the total focus time of an individual on the area of interest of a certain type of stimulus accounts for the percentage of the total time spent staring at two pictures in the trial; and (4) Overall fixation frequency bias (%): Throughout the experiment, the total number of times an individual looks at the area of interest of a certain type of stimulus as a percentage of the total number of times a person looks at two pictures in the trial.

RESULTS

Table 1 depicts demographic characteristics and clinical symptoms of the IAD patient group and HC group.

Table 2 reports attention bias-related EM data, including first-fixation direction bias (%), first-fixation duration bias (ms), overall gaze duration bias (ms), and overall fixation frequency bias (%) in the IAD group and HC group (Figure 3).

First-fixation direction difference

When the participants were presented with the disease-neutral image pairs independent sample t -test showed there were significant differences in the first-fixation direction when presented with disease-related and neutral images in the HC group. When presented with disease-related images, the first-fixation direction of the IAD group was lower than that of the HC group ($t = -2.467$, $P = 0.017$); while presented with neutral images, it was higher than that of HC group ($t = 2.467$, $P = 0.017$).

First-fixation duration difference

When the participants were presented with the disease-neutral image pairs, independent sample t -test found that the first-fixation duration of the IAD group (280.476 ± 55.154) for the disease picture was significantly greater than that of the HC group (252.807 ± 45.075) ($t = 2.128$, $P = 0.038$). There was no difference in the neutral picture (IAD group: 288.280 ± 59.083 , HC group: 264.668 ± 47.270 ; $t = 1.709$, $P = 0.093$).

When the participants were presented with the disease-social threat image pairs, independent sample t -test found that the first-fixation duration of the IAD group (281.20 ± 61.472) for the disease picture was significantly greater than that of the HC group (246.40 ± 30.991) ($t = 2.769$, $P = 0.008$). There was also difference in the social threat picture (IAD group: 296.86 ± 58.129 , HC group: 266.37 ± 40.172 ; $t = 2.363$, $P =$

Table 1 Demographic characteristics and clinical symptoms of the illness anxiety disorder and healthy control groups

Item	Patient group: IAD group, <i>n</i> = 30	Control group: HC group, <i>n</i> = 30	<i>t</i> / χ^2	<i>P</i> value
Age in yr	30.03 ± 8.73	30.70 ± 8.61	-0.298	0.767
Sex, male/female	19/11	14/16	1.684	0.194
Educational background				
Junior high school	5	5		
Senior vocational/high school	4	4		
Junior college/university	20	20		
Master's degree or higher education	1	1		
IAS	47.53 ± 16.44	27.43 ± 13.07	5.240 ^c	< 0.001
WI	7.60 ± 3.83	3.13 ± 1.98	5.677 ^c	< 0.001
BAI	38.17 ± 12.09	24.57 ± 4.33	5.799 ^c	< 0.001
BDI	18.10 ± 9.65	6.13 ± 6.71	5.577 ^c	< 0.001

^c*P* < 0.001.

BAI: Beck anxiety inventory; BDI: Beck depression inventory; HC: Healthy control; IAD: Illness anxiety disorder; IAS: Illness attitudes scale; WI: Whiteley index.

0.022).

When the participants were presented with disease-positive image pairs, independent sample *t*-test showed there were no significant differences in the first-fixation duration bias when presented with disease-related and positive-related images between the IAD group and HC group.

Overall gaze duration difference

When the participants were presented with the disease-social threat, disease-positive, and disease-neutral pairs, independent sample *t*-test showed there were no significant differences between the IAD group and HC group.

Overall fixation frequency difference

When the participants were presented with the disease-positive image pairs, independent sample *t*-test results showed the overall fixation frequency of the two groups toward the illness-related and positive images were different. Independent sample *t*-test showed the overall fixation frequency bias toward the disease images in the IAD group was higher than in the HC group (*t* = 1.841, *P* = 0.071), and fixation frequency bias toward the positive images was lower than in the HC group (*t* = -1.841, *P* = 0.071).

Attention bias-related EM and clinical symptoms

Regression analysis was used to investigate the correlations between the characteristics of the clinical symptoms of the IAD group and their EMs with various image pairs. The results showed that when the participants were presented with the disease-threat image pairs, their overall gaze duration bias toward illness-related images and BAI were found to have a positive correlation with disease-related images (β = +0.156, *P* = 0.045) and negative correlation with threat-related images (β = -0.156, *P* = 0.045) (Table 3 and Figure 4).

DISCUSSION

With the changes of diagnostic criteria, discussion about IAD is increasing these years. This study discovered that in the early and late stages of attention, the IAD and HC groups were different in their information processing for illness-related images and had corresponding attention mechanisms at different stages of attention.

In the early stage of attention, when presented with different pairs of socially threatening, positive, illness-related, and neutral images, participants in the IAD group did not manifest an attention bias toward illness-related images, and no vigilance

Table 2 Attentional bias-related eye-movement data

Item	Image classification	IAD group, <i>n</i> = 30	HC group, <i>n</i> = 30	<i>t</i>	<i>P</i> value
First-fixation direction bias as %					
Disease–threat	Disease	49.90 ± 9.93	49.94 ± 8.96	0.341	0.734
	Threat	50.10 ± 9.93	50.94 ± 8.96	-0.341	0.734
Disease–positive	Disease	34.90 ± 12.23	32.92 ± 9.77	0.693	0.491
	Positive	65.10 ± 12.23	67.08 ± 9.77	-0.693	0.491
Disease–neutral	Disease	45.00 ± 7.81	50.21 ± 8.53	-2.467 ^a	0.017
	Neutral	55.00 ± 7.81	49.79 ± 8.53	2.467 ^a	0.017
First-fixation duration bias in ms					
Disease–threat	Disease	281.20 ± 61.47	246.40 ± 30.99	2.769 ^b	0.008
	Threat	296.86 ± 58.13	266.37 ± 40.17	2.363 ^a	0.022
Disease–positive	Disease	272.16 ± 61.83	246.20 ± 35.4	1.996	0.051
	Positive	259.41 ± 49.95	238.71 ± 48.83	1.623	0.110
Disease–neutral	Disease	280.48 ± 55.15	252.81 ± 45.07	2.128 ^a	0.038
	Neutral	288.28 ± 59.08	264.67 ± 47.27	1.709	0.093
Overall gaze duration bias in ms					
Disease–threat	Disease	44.90 ± 4.13	44.51 ± 3.86	0.388	0.700
	Threat	55.09 ± 4.13	55.49 ± 3.85	-0.388	0.700
Disease–positive	Disease	46.45 ± 5.3	44.35 ± 6.21	1.407	0.165
	Positive	53.55 ± 5.3	55.65 ± 6.21	-1.407	0.165
Disease–neutral	Disease	47.18 ± 4.13	46.97 ± 4.50	0.185	0.854
	Neutral	52.82 ± 4.12	53.03 ± 4.50	-0.185	0.854
Overall fixation frequency bias as %					
Disease–threat	Disease	45.63 ± 3.24	45.59 ± 3.83	0.051	0.960
	Threat	54.37 ± 3.24	54.41 ± 3.83	-0.051	0.960
Disease–positive	Disease	46.93 ± 4.43	44.67 ± 5.06	1.841	0.071
	Positive	53.07 ± 4.43	55.33 ± 5.06	-1.841	0.071
Disease–neutral	Disease	48.44 ± 3.78	48.76 ± 3.50	-0.341	0.735
	Neutral	51.56 ± 3.78	51.24 ± 3.50	0.341	0.735

^a*P* < 0.05.^b*P* < 0.01.

HC: Healthy control; IAD: Illness anxiety disorder.

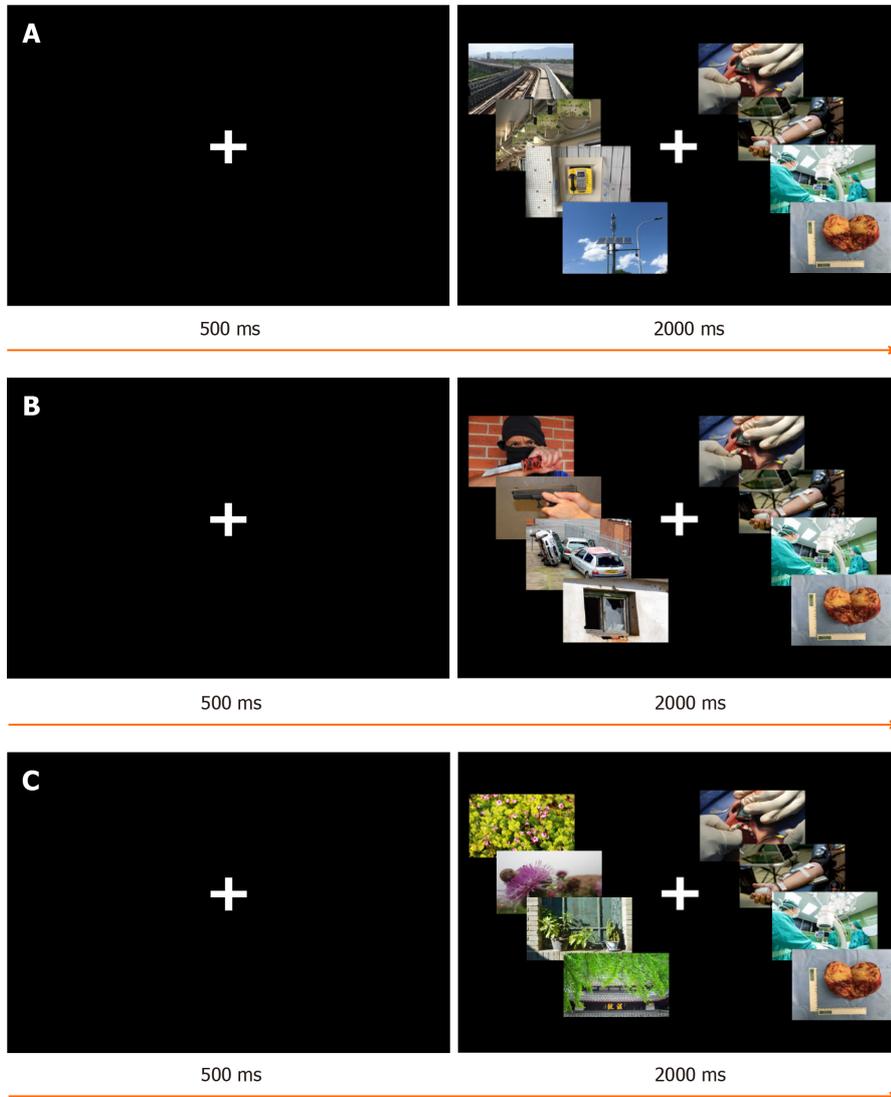
attention bias was observed. However, the first-fixation direction of IAD participants on illness-related images was shorter than that of the HC group, indicating that patients with IAD had an early-stage attentional avoidance bias on illness-related stimuli. Once the early visual attention of these patients was captured by symptom-related or socially threatening stimuli, they were less likely to disengage their attention to such stimuli, thus exhibiting delayed engagement bias. At the late stage of attention, participants with IAD presented a noticeable avoidance of illness-related images, which was manifested as a less overall fixation frequency on such pictures and more fixation frequency on positive, neutral and threat-related images. Therefore, the attentional pattern of patients with IAD was shown as an attentional delayed disengagement bias toward illness-related and socially threatening images, and an overall attentional avoidance bias to illness-related images.

The hypervigilance–avoidance hypothesis suggests that individuals tend to show instant vigilance, followed by swift avoidance, when presented with threatening

Table 3 Regression analysis of overall gaze duration bias (ms) and beck anxiety inventory

	Adjusted R-square	Regression coefficient (95%CI)	P value
Disease image	0.055	0.156 (0.004 to 0.308)	0.045
Threat image	0.055	-0.156 (-0.308 to -0.004)	0.045

CI: Confidence interval.

**Figure 2 Disease-neutral picture, disease-positive picture, and disease-threat picture presentation examples.** A: Disease-neutral (e.g., oral surgery vs rail); B: Disease-positive (e.g., infusion vs scenery); and C: Disease-threat (e.g., operating room vs traffic).

stimuli to prevent further processing of threatening information. This attentional mechanism allows individuals to detect more potentially threatening information during the early stage of attention. The attentional avoidance mechanism then hinders such information from being objectively evaluated, leading to a cognitive bias toward the threatening stimuli and creating a selective attention, judgment, and storage effect. For this reason, this study speculated that individuals with IAD have normal attentional processing mechanisms for stimuli related to neutral, positive and threat emotions. However, their longer attention engagement toward illness and threat-related information in the early attention stage and their overall avoidance mechanism in the late stage of attention may explain why they suffer from long-term processing failure of disease-related stimuli, and hence have psychological disorders.

Current research suggests that such an attentional maintenance bias in the early

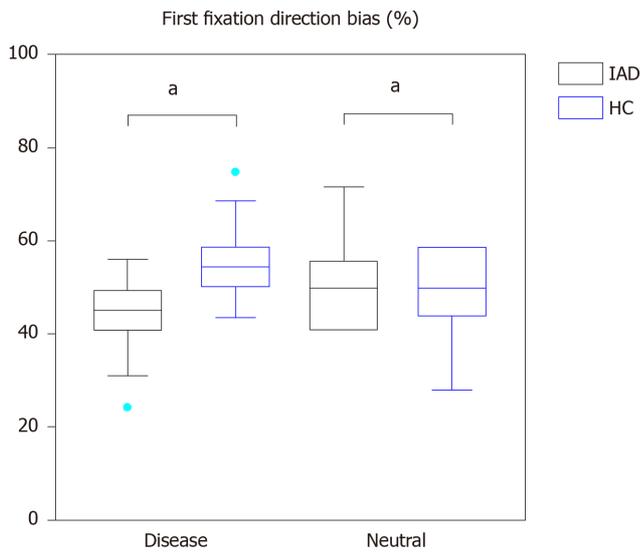


Figure 3 First-fixation direction bias of illness anxiety disorder and healthy subjects when presented with disease-related and neutral image pairs. HC: Healthy control; IAD: Illness anxiety disorder. ^a $P < 0.05$.

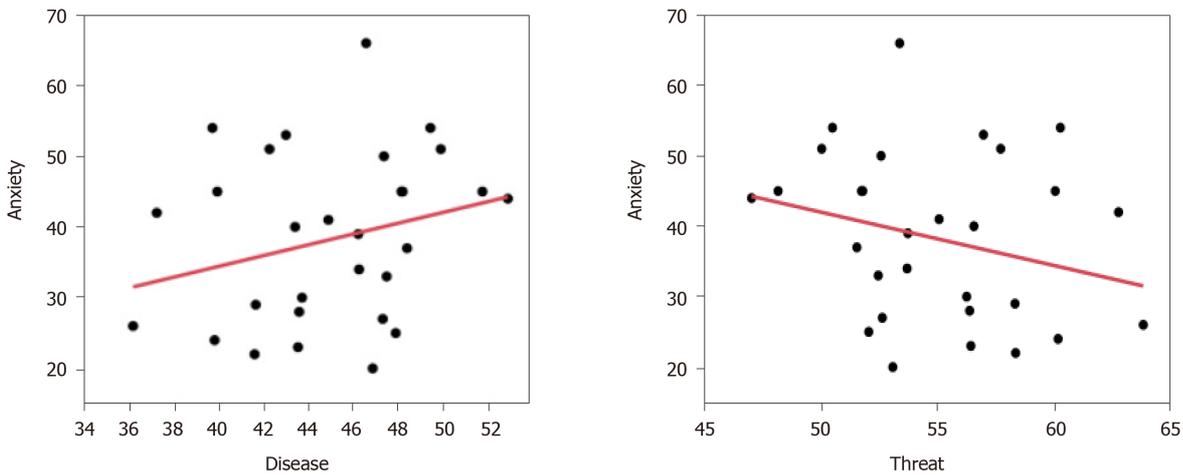


Figure 4 Total gaze duration to disease and threat in disease–threat image pairs.

attention stage may be due to the activation of disease-related schema within patients with IAD^[31]. Attention schema theory suggests that if the threat stimulus is consistent with the schematic contents of an individual, then such stimulus is more likely to be processed. In addition, the activation of schemata leads to the allocation of more attentional resources to the threat stimulus at the late stage of strategic processing, manifesting as a greater frequency of selective attention. According to Salkovskis’s cognitive-behavioral model of IAD, patients with IAD tend to overvalue illness-related information, giving it greater value and significance than reality, thereby inducing a cognitive bias such as selective attention. It is possible that illness-related information is more likely to activate the illness-related interpretation of the patients, leading to a longer processing period of such stimuli and the demonstration of a longer attention maintenance toward illness-related stimuli in the early maintenance stage.

At the late stage of attention, participants with IAD presented a noticeable avoidance of illness-related images, which was manifested as a shorter overall fixation duration on such pictures and a less overall fixation frequency. Therefore, the attentional pattern of patients with IAD was shown as an attentional avoidance bias toward illness-related images at the whole attention stage, but a delayed disengagement bias once attention captured by illness or threat information. The results demonstrate the attentional patterns of the participants when presented with illness-related, positive, and neutral stimuli. The findings revealed that patients with IAD showed different attentional patterns when presented with illness-related stimuli

and neutral stimuli. Specifically, patients showed an attentional maintenance bias in the early stage of attention and overall attentional avoidance toward illness symptom-related stimuli; however, they presented high levels of attention in the early attention stage and held their overall attentional maintenance when presented with normal stimuli (neutral information).

To further investigate the relationship between attention bias toward illness-related stimuli and the severity of symptoms among patients with IAD, this study utilized regression analysis. The results showed that the severity of anxiety symptoms had an impact on attention bias. In patients with mood disorder, there is a weakening of the ability to pay attention to the automatic processing of emotional information, resulting in defects and biases in the processing of emotional information^[32]. Beck^[33] believes that abnormal processing of emotional information in patients with mood disorders may be the main factor in the etiology of the disease and the maintenance of symptoms. Patients are sensitive to specific negative emotional information and alter their cognitive processing process, which may lead to symptom aggravation and maintenance. In many theories of clinical anxiety^[19,34]. These attention biases have been regarded as initiating and maintaining clinical anxiety.

In 2009, Olatunji *et al*^[35] proposed that the internal cognitive process indicates that IAD disorder may be related to anxiety disorder. The results also found that the more severe the anxiety symptoms, the more likely the disease stimulus attracts or occupies attention resources than other stimuli. Anxiety and IAD patients allocate excessive attention to disease information and struggle to dismiss the stimulus, showing delayed disengagement and attention bias; however, this feature is not obvious in their initial attentional stage.

Limitations and suggestions for future research

This study applied EM tracking technology to investigate attention biases of patients with IAD. Compared with past measurement methods based on participants' reactions, EM technology can effectively, directly, and continuously investigate the processing activities of attention of patients with IAD toward stimuli with threatening emotions, thereby differentiating the attention bias components more effectively. However, the method remains at the overt behavioral level and cannot analyze physiological parameters such as pupil changes and saccade during attentional processing. In addition, the method does not reveal the neurobiological mechanisms at play during attentional processing; hence, it is impossible to further explain the abnormality of brain function of patients with IAD. Future research is suggested to employ event-related potential technology (which has high time resolution) and functional magnetic resonance imaging technology (which has high spatial resolution) alongside eye-tracking technology to further investigate the characteristics of the attention bias and its mechanisms in patients with IAD. Furthermore, future study will use a machine learning classification method for the study to identify the IAD participants and estimate the accuracy of the eye-tracking method in identifying attention bias in patients with illness anxiety disorder.

CONCLUSION

Patients with IAD have an attention bias that is mainly manifested as an overall attentional avoidance when presented illness-related stimuli with disease, positive, and neutral stimuli, as well as avoidance of attention at the early attention stage; when presented with neutral stimuli, however, IAD performance showed higher delayed disengagement bias to illness and disease-related stimulus than in HCs. In addition, this study found that patients with suspected disorders with significant anxiety symptoms show attention bias in the late stage of attention processing, and struggle to dismiss the stimulus, showing delayed detachment. This study suggests that patients with IAD have attention bias and this may have provided a new way of identification of IAD symptoms using the eye-tracking evaluation method.

ARTICLE HIGHLIGHTS

Research background

Illness anxiety disorder (IAD) is a common, distressing, and debilitating condition with the key feature being a persistent conviction of the possibility of having one or

more serious or progressive physical disorders. Because eye movements (EMs) are guided by visual-spatial attention, eye-tracking technology is a comparatively direct, continuous measure of attention direction and speed when stimuli are oriented. Researchers have tried to identify selective visual attention biases by tracking EMs within dot-probe paradigms because the dot-probe paradigm can distinguish these attentional biases more clearly.

Research motivation

There are numerous studies that have investigated individuals with high social anxiety, generalized anxiety disorder, and depressive disorder, using EMs and a modified probe detection task to pictures of faces. However, no studies have provided an in-depth analysis of illness anxiety disorder using EMs.

Research objectives

Using the dot-probe paradigm, our primary aim in the current study was to explore the specificity of attention bias in IAD. In addition, we aimed to examine whether patients will display orienting attention biases, reflected by fixating first and more rapidly on illness stimuli than other alternatives.

Research methods

A case-control study design was used for the study, with the sample consisting of an IAD patient group and a healthy control (HC) group. Participants were recruited *via* e-mail and newspaper advertisement from Beijing An'Ding Hospital. The patient group fulfilled the criteria for IAD (DSM-5 and formerly named hypochondriasis in DSM-4) according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR). The stimuli used in the dot-probe task consisted of 128 pictures including 35 pictures from China internet sources, and 93 pictures selected from the International Affective Pictures System, which were grouped into four main categories: Illness-related, social threat, positive, and neutral pictures. These pictures were used to assess attentional bias in IAD patients. All four EM indicators were statistically analyzed using independent sample *t*-test. The differences between IAD group and HC group were compared on different types of images. The mean value of the group was compared with that of independent samples test, and $P < 0.05$ indicated that the difference was statistically significant.

Research results

When presented with disease-related images, the first-fixation direction of the IAD group was lower than that of the HC group ($t = -2.467$, $P = 0.017$); while presented with neutral images, it was higher than that of HC group ($t = 2.467$, $P = 0.017$). When the participants were presented with the disease-neutral image pairs, independent sample *t*-test found that the first-fixation duration of the IAD group (280.476 ± 55.154) for the disease picture was significantly greater than that of the HC group (252.807 ± 45.075) ($t = 2.128$, $P = 0.038$). When the participants were presented with the disease-social threat image pairs, independent sample *t*-test found that the first-fixation duration of the IAD group (281.20 ± 61.472) for the disease picture was significantly greater than that of the HC group (246.40 ± 30.991 ; $t = 2.769$, $P = 0.008$). There was also a difference in the social threat picture (IAD group: 296.86 ± 58.129 , HC group: 266.37 ± 40.172 ; $t = 2.363$, $P = 0.022$). Independent sample *t*-test showed the overall fixation frequency bias toward the disease images in the IAD group was higher than in the HC group ($t = 1.841$, $P = 0.071$), and fixation frequency bias toward the positive images was lower than in the HC group ($t = -1.841$, $P = 0.071$).

Research conclusions

Patients with IAD have an attention bias that is mainly manifested as an overall attentional avoidance when presented illness-related stimuli with disease, positive, and neutral stimuli, as well as avoidance of attention at the early attention stage when presented with neutral stimuli; however, IAD performance showed higher delayed disengagement bias to illness and disease-related stimulus than did the HCs. In addition, this study found that patients with suspected disorders with significant anxiety symptoms show attention bias in the late stage of attention processing, and struggle to dismiss the stimulus, showing delayed detachment.

Research perspectives

This study suggests that patients with IAD have attention bias and this may have provided a new way of identifying IAD symptoms using the eye-tracking evaluation

method.

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