

Development and validation of a questionnaire to assess the psychological impact and fearfulness of COVID-19 among Human Immunodeficiency Virus (HIV) patients

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Abstract

The outbreak of COVID-19 has led to a serious and uncertain condition, including an abrupt national economy and increased psychological distress especially among vulnerable population such as people living with HIV (PLHIV). Fear of infection, prolonged lockdown and isolation, and stigma merged with mental health burden for this group. This study aims to develop and validate a questionnaire assessing the psychological impact and fearfulness related to COVID-19 among HIV patients. The questionnaire was developed through a comprehensive literature review, followed by expert validation and statistical reliability testing. Content and face validity were conducted by medical, psychological, and public health professionals. Internal consistency and test-retest reliability were analysed using Cronbach's alpha and Spearman correlation. The final questionnaire included two domains: psychological impact (10 items) and fearfulness (14 items), each with a Scale-Content Validity Index (S-CVI) of 1.0. Face validity scores exceeded 90% in clarity, readability, and layout. Cronbach's alpha for psychological impact and fearfulness was 0.81 and 0.92, respectively. A test-retest correlation coefficient of 0.728 indicated strong stability. In conclusion, this validated questionnaire is a reliable tool for measuring psychological and emotional responses to COVID-19 among HIV patients, offering insight into their mental health needs during public health crises.

Keywords: *fearfulness, impact of COVID-19, mental health, psychological, questionnaire*

Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic, caused by the novel SARS-CoV-2 virus, first emerged in Wuhan, China, in late 2019. Characterised by both respiratory and non-respiratory symptoms, the virus rapidly spread across the globe, prompting the World Health Organization (WHO) to

declare it a Public Health Emergency of International Concern (AlSamman *et al.*, 2020). As of May 2023, more than 687 million cases were reported worldwide, with approximately 6.87 million deaths (World Health Organization, 2022).

In Southeast Asia, Malaysia ranked among the highest in terms of COVID-19 cases and deaths (Shah *et al.*, 2020). To curb

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transmission, the Malaysian government implemented strict public health measures including the Movement Control Order (MCO) and Conditional MCO (CMCO). While these interventions were essential to flatten the epidemiological curve, they also triggered profound socio-economic disruptions. Prolonged lockdowns led to business closures, job losses, and economic instability, particularly among vulnerable populations (Tzur Bitan *et al.*, 2020).

Beyond the economic impact, the pandemic had significant psychological consequences. Uncertainty, social isolation, and continuous exposure to distressing news created a climate of fear and stigma, particularly among unprepared communities (Brooks *et al.*, 2020; Liu *et al.*, 2021; Serafini *et al.*, 2020a). Individuals reported heightened anxiety, stress, irritability, and depression due to disruptions in daily routines, loss of income, and restricted access to social support and healthcare (Serafini *et al.*, 2020a; Shah *et al.*, 2020).

These challenges were especially severe for people living with HIV (PLHIV), who were already at risk of mental health issues due to stigma, treatment burden, and chronic illness (Hong *et al.*, 2023; Lusher *et al.*, 2023). The intersection of HIV and COVID-19 may have compounded psychological distress, yet there remains a lack of validated tools to assess these impacts (Å & El-masri, 2005).

Therefore, this study aims to develop and validate a questionnaire to assess the psychological impact and fearfulness related to COVID-19 among PLHIV. Such a questionnaire is crucial to support targeted mental health interventions and inform public health preparedness in future crises (Armstrong, 2019).

Materials and Methods

Ethical approval and study design

This study was conducted over a six-month period, from November 2022 to March 2023, encompassing the development, validation,

reliability testing, and distribution of the questionnaire. Ethical approval was obtained from the National Medical Research Register (NMRR) with ID NMRR-22-02745-2NM (IIR). A prospective cross-sectional survey design was employed to explore the psychological impact and fearfulness associated with COVID-19 among people living with HIV (PLHIV). Data collection was carried out using a validated, self-administered, closed-ended questionnaire.

Questionnaire development

i) Literature search

A systematic literature review was conducted between August and September 2022 using PubMed, Scopus, and ScienceDirect. Search terms included "COVID-19", "psychological impact", "fear", "mental health", and "people living with HIV (PLHIV)", using Boolean operators to refine results. The inclusion criteria encompassed studies published from 2019 to 2022, in English or Bahasa Malaysia, focusing on psychological or emotional impacts of COVID-19 among PLHIV. Exclusion criteria included articles not related to mental health or fear, and non-research materials such as commentaries or editorials.

From an initial pool of 124 articles, 42 were reviewed in full, and 15 were ultimately selected to guide the development of the questionnaire. Key psychological themes extracted included anxiety, depression, social isolation, stigma, and fear of infection. This led to the initial drafting of 18 psychological impact items and 20 fearfulness items. After iterative refinement, 10 psychological and 14 fear-related items were finalised.

ii) Face and content validity

Face validity was assessed among 15 individuals from various backgrounds to evaluate the questionnaire's clarity, feasibility, wording, and layout. Each item was rated using a 4-point Likert scale. The

psychological impact section received average scores of 93.7% for readability, 91.7% for feasibility, 92.1% for clarity, and 92.2% for layout. The fearfulness section scored slightly lower in clarity and layout (both 90.0%) but higher in feasibility (96.0%). Based on this feedback, two items were revised and one was removed. The overall scale-level face validity index (S-FVI) was 0.92, suggesting strong agreement on comprehensibility.

Content validity was evaluated by 15 experts in medicine, pharmacy, psychology, and HIV care. Using Lynn's (1986) method, each item was rated for relevance on a 4-point scale. The content validity index (CVI) reached 1.00 for both psychological and fearfulness domains, exceeding the minimum threshold of 0.78. Based on this process, four items were revised, two were removed, and a total of 24 items (10 psychological, 14 fearfulness) were finalised for the questionnaire.

iii) Questionnaire evaluation for reliability

The revised questionnaire was administered to 30 randomly selected PLHIV at Klinik Kesihatan Tanglin, Kuala Lumpur. Internal consistency was assessed using Cronbach's alpha. The psychological impact domain yielded a value of 0.81, while the fearfulness domain recorded 0.92, both indicating excellent reliability (Cortina Jose M, 1993). Test-retest reliability was evaluated by re-administering the same questionnaire to the same participants after a three-week interval (3rd to 17th January 2023). Participants were identified and followed up via contact details gathered during the initial session. Spearman's correlation coefficient was used to assess temporal consistency, yielding a rho value of 0.728, indicating a moderate to strong positive correlation. The p-value was above 0.05, suggesting no significant difference between the two sets of responses, and confirming the questionnaire's temporal stability (Armstrong, 2019; Chen *et al.*, 2021).

Cross-sectional survey

A total of 250 PLHIV respondents were recruited from Klinik Kesihatan Tanglin and Klinik Kesihatan Petaling Bahagia. Eligible participants were adults (18 years and above) living with HIV, receiving treatment at the clinics, and able to understand either Malay or English. Those with severe psychiatric illness, cognitive impairment, or who declined to participate were excluded. Recruitment was conducted at the pharmacy counters, where patients were approached while waiting for their medication. The questionnaire was distributed in printed form and self-administered on-site. Data collection for this phase was conducted between February and March 2023.

Statistical analysis

Descriptive statistics were used to summarise demographic data and face/content validity results. Internal consistency was measured using Cronbach's alpha, while test-retest reliability was analysed with Spearman's correlation coefficient. To confirm construct validity, Confirmatory Factor Analysis (CFA) was conducted. CFA tested the model fit and factor structure of the questionnaire based on observed data. Key metrics including factor loadings, Average Variance Extracted (AVE), and fit indices were used to validate the hypothesised two-domain model of psychological impact and fearfulness.

Results

Demographic characteristics

A total of 250 respondents participated in this study. The majority of respondents were Malaysian citizens, consisting of 175 Malay respondents (70 percent), 40 Chinese respondents (16 percent), and 35 Indian respondents (14 percent). The respondents' ethnic backgrounds reflect the distribution in Malaysia. The mean age of respondents was 32.4 years (SD=6.7), with ages ranging from 17 to 67. The majority were male, 211 respondents (84.4 percent), and female, 39 respondents (15.6 percent).

In terms of employment status, the majority worked in the private sector/non-government, 168 respondents (67.2 percent), 25 respondents (10 percent) worked in the government sector, and 23 respondents (9.2 percent) were self-employed. The remaining respondents were unemployed, 18 respondents (7.2 percent), and 16 respondents (6.4 percent) were students. All respondents were HIV patients from Klinik Kesihatan Tanglin and Klinik Kesihatan Petaling Bahagia, Lembah Pantai, Kuala Lumpur. The median duration since diagnosis was 6 years and the median monthly income was RM 2700.00.

Descriptive analysis of psychological impact and fearfulness

A descriptive analysis investigated the distribution of responses to the psychological impact and fearfulness related to the COVID-19 pandemic. The questionnaire were assessed using a 6-point Likert scale ranging from 1 = Not at all to 6 = Always, allowing for a more detailed evaluation of the respondents' emotional, cognitive, and behavioral reactions in the week of the study.

i) Psychological impact

Findings from the ten item questionnaire provided significant insights into respondents health. The majority of respondents (58%, n = 145) said they occasionally found it difficult to focus on their work. The majority of respondents (64.0%, n = 160) said they could make decisions with reasonable ease. Significant emotional anguish was highlighted by the large majority (75.2%, n = 188) who said they frequently or always felt helpless to tackle their challenges. Although more analysis is required for a more accurate assessment, 55.2% (n = 138) of respondents stated that they had a moderate to high aptitude to handle difficulties.

Regarding emotional reactions, the majority of participants (60.8%, n = 152) said they felt glad occasionally to frequently when things were going well. Most respondents ranked

their level of life satisfaction as moderate. Furthermore, over half (56.0%, n = 140) believed that their mental health was moderately to strongly impacted by a healthy physical environment.

But there were also indications of exhaustion and a lower standard of living. The fact that over half of the respondents (53.6%, n = 134) hardly ever had the energy to complete everyday tasks suggests that they were either physically or emotionally exhausted. The majority (60%, n = 150) also stated that they seldom ever had time for leisure activities. Besides, 46.0% (n = 115) of participants said they occasionally to fairly frequently had headaches.

ii) Fearfulness towards COVID-19

The results of the 14 questions indicated a rise in COVID-19-related anxiety and avoidance behaviour. The findings indicated that respondents' levels of fear and anxiety around the COVID-19 pandemic had increased. A sizable portion (75.2%, n = 188) reported feeling uneasy when thinking about COVID-19 frequently to continuously. Additionally, 57.0% (n = 142) exhibited bodily symptoms of anxiety, such as sweating palms, and 60.5% (n = 151) feared infection-related death. A significant number of respondents (80.0%, n = 200) reported feeling anxious when exposed to COVID-19-related news or stories on social media, indicating that outside information sources significantly influenced emotional states.

Physiological reactions were also frequent; among those who imagined being infected, 50.0% (n = 125) reported experiencing palpitations in their hearts. 65.2% (n = 163) of individuals reported sleep difficulties brought on by infection-related worry, while 68.0% (n = 170) reported social interaction anxiety. The most common concern, expressed by 85.2% (n = 213) of respondents, was the danger of infecting family members.

Moreover, 62.0% (n = 155) acknowledged that they frequently overthink the possibility of getting the virus, and 54.5% (n = 136) said they are afraid of getting infected when they go to clinics or hospitals for regular check-

ups. Concerns also included dangers associated with employment and vaccinations; 55.0% (n = 138) were concerned about losing their jobs, and 59.0% (n = 148) were reluctant to have the COVID-19 vaccine because of possible adverse effects. Furthermore, 61.0% (n = 153) were worried of developing a chronic illness following infection, and 63.5% (n = 159) were afraid of infection symptoms.

Content validation: Confirmatory Factor Analysis (CFA)

i) Psychological impact

The results of the Confirmatory Factor Analysis (CFA) indicate that the measurement model for the psychological impact of COVID-19 demonstrates a good model fit. All factor loadings exceeded 0.60, suggesting that each item strongly reflects the underlying construct. The Root Mean Square Error of Approximation (RMSEA) value was 0.066, which falls within the acceptable range (<0.08), indicating a reasonable approximation error. Additionally, both the Comparative Fit Index (CFI = 0.91) and Tucker-Lewis Index (TLI = 0.903) surpassed the minimum threshold of 0.90, suggesting a good fit of the model to the observed data.

The chi-square to degrees of freedom ratio ($\chi^2/df = 2.528$) further supports the model's adequacy, as values between 1 and 3 are typically considered acceptable. Convergent validity was confirmed, with Average Variance Extracted (AVE) values exceeding 0.50 for all constructs. Furthermore, Composite Reliability (CR) values were above 0.60, indicating good internal consistency. These findings confirm that the questionnaire is both valid and reliable in measuring the psychological effects of COVID-19.

ii) Fearfulness towards COVID-19

The CFA results for the fearfulness dimension related to COVID-19 also indicate a strong and well-fitting model. All items demonstrated factor loadings above 0.60, supporting the one-dimensionality of the construct. The RMSEA value of 0.071 reflects

an acceptable model fit. Moreover, the TLI (0.958) and CFI (0.965) both exceeded the stringent 0.95 threshold, indicating an excellent fit between the hypothesised model and the data.

The chi-square/degree of freedom value ($\chi^2/df = 2.545$) was within the acceptable range, reinforcing the model's appropriateness. All AVE values surpassed the 0.50 benchmark, confirming good convergent validity. Additionally, the CR values exceeded 0.60, indicating strong internal reliability. Collectively, these CFA results validate the fearfulness subscale as a psychometrically sound measure of COVID-19-related fear.

Discussion

The COVID-19 pandemic has impacted vulnerable populations' mental health, especially people living with HIV (PLHIV) (Hong *et al.*, 2023; Serafini *et al.*, 2020b). A comprehensive tool to assess the psychological effects and fear associated with COVID-19 among PLHIV in Malaysia was designed and validated in this study (Å & El-masri, 2005; Armstrong, 2019). The information including individual demographics, treatment history, stigma experiences, and mental health indicators, this questionnaire provides a clear picture of how the epidemic has affected this population everyday functioning and emotional health. The study done by Liu *et al.*, 2021 emphasised the necessity of comprehensive evaluations to address the particular challenges faced by PLHIV during emergencies.

The questionnaire's robust psychometric results are a testament to its meticulous design. Each item's strong relevance is confirmed by the perfect content validity index (S-CVI = 1.0), while face validity scores more than 90% indicate that respondents perceived the questions to be understandable and straightforward. When working with various populations, this degree of clarity is crucial to ensuring that replies are accurate and meaningful (Å & El-masri, 2005).

From this, the results reveal alarming levels of psychological strain and fearfulness among respondents. Over 75 percent of participants reported feeling helpless in managing their challenges, while many experienced difficulty focusing, low energy, and reduced motivation to engage in leisure activities. These findings align with Serafini *et al.*, 2020b and Shah *et al.*, 2020, reported that prolonged lockdowns contributed to increased anxiety and depressive symptoms. Equally, this study reflects the finding by Hong *et al.*, 2023, which showed that the stigma and treatment difficulties faced by PLHIV have increased due to uncertainty, disruptions in daily routines, and worries associated with infection.

Based on these results, the confirmatory factor analysis (CFA) further supports the reliability of this tool in capturing two distinct but connected dimensions: the broader psychological impacts and the specific fears related to COVID-19. The high Cronbach's alpha values of 0.81 for psychological impact and 0.92 for fearfulness demonstrate excellent internal consistency, while the test-retest correlation of 0.728 confirms that the tool yields stable results over time. This level of consistency suggests the questionnaire can be confidently used in future monitoring or longitudinal studies to track mental health trends during and beyond major public health emergencies (Armstrong, 2019).

The degree to which COVID-19-related anxiety disrupted day-to-day functioning is indicated by the fear subscale. Many respondents noted physical symptoms including palpitations and disrupted sleep, postponed necessary healthcare visits, and expressed concern of spreading the infection to other members of their family. These results are consistent with the study finding by Brooks *et al.*, 2020, which showed that among high-risk groups, stigma, fear, and false information may hinder treatment compliance and interfere with public health initiatives.

By dealing with interrelated issues, this validated questionnaire equips researchers

and policymakers with a practical and robust tool to identify individuals who may be more vulnerable and to design interventions that genuinely respond to their mental health needs. Informative campaigns, enhanced community support systems, and steps to lessen stigma for PLHIV are a few examples of mental health interventions. These measures are essential for protecting PLHIV's mental wellness during current and upcoming crises (World Health Organization, 2022).

However, this study has several limitations, as data collection was limited to urban clinics, which may not fully capture the perspectives of PLHIV in rural or underserved communities. Moreover, the cross-sectional design makes it impossible to demonstrate a causal relationship between psychological outcomes and pandemic-related issues. Future research should use long-term approaches and broaden its scope to encompass a variety of contexts to have a more precise measure of how these mental health impacts change over time.

Conclusion

A rigorous and reliable questionnaire has been developed and validated in this study for assessing the psychological effects and fearfulness of COVID-19 among PLHIV in Malaysia. Strong reliability and validity have been demonstrated by the questionnaire, indicating that it is appropriate for use in research and continuous mental health monitoring. For the purpose of protecting PLHIV during this and subsequent crises of public health, these tools assist policymakers and healthcare professionals to gather important information that may help them to develop effective policies and provide mental health services.

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