

Prevalence and Associated Factors of Treatment Regimen Fatigue Among People Living with HIV/AIDS in China: A Cross-Sectional Survey

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Introduction: Treatment regimen fatigue (TRF) is universal among people living with HIV/AIDS. Long-term adherence to treatment regimens is crucial to maintaining the health and life span of such individuals.

Objective: This study aimed to examine treatment regimen fatigue among people living with HIV/AIDS and the relevant factors.

Methods: This cross-sectional study was conducted between January and December 2019 at two designated AIDS medical institutions in Harbin, China. A total of 717 valid samples were included in the study. The Treatment Regimen Fatigue Scale was used to measure treatment regimen fatigue. The participants responded to several questions regarding their demographic characteristics, clinical characteristics, and social psychological characteristics. Multivariate logistic regression assessed the relationship between TRF and associated factors. Odds ratios (OR) and 95% confidence intervals (CI) for OR were calculated.

Results: The self-reported mean global score for the TRFS was -15.59 ± 22.90 . After adjusted location, education background and, monthly income, the logistic regression model indicated that depression (OR=3.177, 95% CI=2.180–4.629), other chronic diseases (OR=1.786, 95% CI=1.057–3.019), >3 years of treatment (OR=1.767, 95% CI=1.203–2.594), having an intimate confidant (OR=0.514, 95% CI=0.347–0.760), life satisfaction (OR=0.564, 95% CI=0.365–0.870), living area (OR=0.491, 95% CI=0.295–0.817), and an undergraduate or above education level (OR = 0.568, 95% CI=0.335–0.965) were associated factors for TRF.

Conclusion: The prevalence of TRF among PLWHA in China is relatively high and is influenced by multiple factors including psychosocial, clinical, and demographic characteristics. Social support, especially psychological support, for PLWHA should be strengthened. This study's findings highlight the need to develop multilevel interventions to reduce TRF, addressing the complex needs of PLWHA and mitigating the adverse impact of TRF on HIV treatment outcomes. Further longitudinal research on factors of TRF should be conducted to strengthen and broaden the current findings.

Keywords: treatment regimen fatigue, antiretroviral therapy adherence, HIV/AIDS, psychosocial factors

Introduction

Since the 21st century, the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) epidemic in China has grown rapidly. By the end of 2020, more than one million people were living with HIV/AIDS in China.¹ Although effective antiretroviral therapy (ART) has improved the survival and quality of life of people living with HIV/AIDS (PLWHA) and transformed HIV into a controllable infectious disease, the management of HIV/AIDS remains a critical challenge. For decades, adherence to recommended treatments has been a difficult issue in HIV/AIDS management, requiring strict compliance, continuous participation in health care, tolerance of adverse side effects, adaptive coping skills, and lifestyle adjustments. In a recent meta-analysis, Peng et al reported that the average rate of ART adherence among PLWHA in China was 86.01% to 87.12%;² however, the ART adherence rate decreased over the

study time period.³ Moreover, there remains a sizeable gap between the reported adherence levels and the benchmark for good compliance, which is 95%.⁴ One significant risk factor for the decline in HIV/AIDS adherence, which has been proposed but rarely studied, is treatment regimen fatigue (TRF).

PLWHA inevitably experience TRF during their long course of treatment. Claborn et al defined TRF as a decreased desire and motivation to maintain vigilance in adhering to prescribed treatment regimens.⁵ This definition incorporates the dimensions of psychological fatigue associated with long-term HIV treatment. TRF is nearly universal in the management of chronic diseases and has been observed in individuals with conditions such as diabetes, multiple sclerosis, and other chronic illnesses.^{6–8} These conditions usually require routine oral medication to achieve optimal treatment outcomes. Clinical observations of PLWHA have linked antiretroviral non-adherence to TRF,⁹ and patients with long-term treatment plans have identified TRF as a crucial structure of compliance.^{7,10} In addition, TRF has been identified as a precursor for drug noncompliance, possibly due to increased treatment workload.¹¹

Addressing the problems associated with TRF can prevent or minimize the potential negative health consequences for PLWHA, benefitting both the healthcare system and society at large. Although ART compliance literature often mentions TRF as a potential reaction to side effects, there is a notable lack of focused research on TRF. Factors contributing to TRF must be identified and managed to mitigate its effects. Consequently, this study aims to examine TRF among PLWHA in China. Understanding the factors influencing TRF is expected to aid the development of successful and contextually appropriate interventions for supporting ART adherence among PLWHA, thereby improving clinical outcomes and enabling the creation of strategies based on acquired knowledge.

Methods

Study Design and Study Participants

This study is part of a cross-sectional survey evaluating alexithymia and TRF among PLWHA receiving ART. Data from this sample has been used in two previous studies regarding the prevalence and associated factors of alexithymia among PLWHA and the reliability and validity testing of the Chinese version of the HIV treatment fatigue scale,^{12,13} however, the influencing factors of PLWHA have not yet been reported. The survey respondents were PLWHA treated at infectious disease outpatient clinics of two hospitals (the fourth affiliated hospital of Harbin Medical University and Harbin Infectious Disease Hospital) in the northeastern region of China. The inclusion criteria were as follows: (1) diagnosed with HIV/AIDS; (2) aged 18 years or older; (3) currently receiving ART; and (4) able to read and write in Chinese. Data were collected using a structured questionnaire survey conducted between January and December 2019. All eligible participants were informed of the study's principles of voluntary participation and confidentiality. Identity numbers were used to protect participants' privacy. After obtaining the patient's consent through a signed informed consent form, specially trained personnel conducted face-to-face surveys.

Ethical Approval and Participation Consent

The study was approved by the Ethics Review Committee of the Harbin Center for Disease Control and Prevention. A total of 1115 patients completed the survey. Respondents who did not fully answer or complete more than half of the questionnaire were excluded, leaving 717 (64.3%) samples for the final analysis.

Measures

The dependent variable in this study was TRF among PLWHA, which was assessed using the Treatment Regimen Fatigue Scale (TRFS). The TRFS is a well-validated self-report instrument comprising of 22 items across 2 subscales: cynicism (15 items) and self-efficacy (7 items). Each item was scored from -3 (strongly disagree) to 3 (strongly agree), with a global TRFS score ranging from -66 to 66 and the scores for cynicism and self-efficacy ranging from -45 to 45 and -21 to 21, respectively. To simplify calculations, we shifted the total scale score by adding 66 points, changing the range to 0 to 132. Respondents were classified into two groups based on the median adjusted TRFS score: non-fatigue (<57) and fatigue (≥57). The reliability of the TRFS was confirmed with a Cronbach's alpha of 0.866.

Determinants of TRF

The Patient Health Questionnaire-9 (PHQ-9) was used to assess depression. The PHQ-9 comprises nine items (eg, “Feeling low, depressed, and hopeless”) rated on a four-point Likert scale ranging from 0 (not at all) to 3 (nearly every day), with a total score ranging from 0 to 27. A total score ≥ 10 indicated depression. The Chinese version of the PHQ-9 is a reliable and valid tool for screening depression,^{14–16} with a Cronbach’s alpha of 0.849 in this study.

Sociodemographic data were collected for each participant, including gender, age, location, educational background, marital status, and income level. Clinical characteristics included treatment duration, CD4+cell count, viral load, side effects of ART, and the presence of other chronic diseases. Additional psychosocial variables potentially affecting TRF were also included, such as depression, having an intimate confidant, life satisfaction, and whether they have received psychological counseling from health care professionals.

Statistical Analysis

Descriptive statistics were analyzed using frequencies and percentages, with TRFS scores presented as Mean \pm Standard Deviation. Chi-square tests were performed to assess statistical significance of independent variables, with those having p -values < 0.10 included in the final logistic models. Two multivariate logistic regression models were constructed to assess the effect of the inclusion of different variables in the models. Model I was adjusted for clinical characteristics and psychosocial factors. Model II was adjusted for the factors in Model I along with sociodemographic characteristics. Odds ratios (OR) and 95% confidence intervals (CI) were calculated. Statistical analyses were performed using SPSS version 23.0, with the significance level set at a $p < 0.05$.

Results

The demographics of the 717 participants are summarized in Table 1. Most respondents were men (96.8%), unmarried (81%), had an undergraduate or higher education level (40.4%), reported a monthly household income of 3000 to 5000 yuan (47.3%), and lived in urban areas (78.5%). The unadjusted self-reported mean global TRFS score was -15.59 ± 22.90 , with a range of -66 to 25 .

Univariate analysis results indicate statistically significant differences by group for educational background, living area, monthly income, years of treatment, presence of other chronic diseases, depression, psychological counseling, having an intimate confidant, and life satisfaction (Table 2).

The results of the multivariable logistic regression analysis are presented in Table 3. In Model 1, we found that depression (OR=3.317, 95% CI=2.325–4.733), presence of other chronic diseases (OR=2.193, 95% CI=1.353–3.555), and longer treatment duration (OR=1.493, 95% CI=1.048–2.127) were important risk factors for TRF; while having an intimate confidant (OR=0.459, 95% CI=0.318–0.663), and life satisfaction (OR=0.510, 95% CI=0.340–0.765) were protective factors for TRF. In Model 2, longer treatment duration (OR=1.767, 95% CI=1.203–2.594), other chronic diseases (OR=1.786, 95% CI=1.057–3.019), and depression (OR=3.177, 95% CI=2.180–4.629), remained risk factors for TRF when accounting for the sociodemographic factors (location, educational background, household monthly income). Having an intimate confidant (OR=0.514, 95% CI=0.347–0.760), life satisfaction (OR=0.564, 95% CI=0.365–0.870), living in urban area (OR=0.491, 95% CI=0.295–0.817), and having an undergraduate or higher education level (OR = 0.568, 95% CI=0.335–0.965) were protective factors for TRF.

Discussion

TRF can affect adherence to long-term therapy and impact disease outcomes among PLWHA.⁵ Measuring TRF may help identify PLWHA requiring additional support and at risk of treatment failure. Unfortunately, TRF among PLWHA remains understudied.¹⁷ This study aimed to measure the levels of TRF and identify influencing factors among PLWHA in China.

The mean global score of TRF was -15.59 (SD=22.90), which was higher than the scores reported in studies conducted in the United States (-41.2 ± 21.08) and Ethiopia (-42.82 ± 17.4).^{9,17} Such discrepancies may stem from cultural differences in stigma and attitudes toward HIV/AIDS. A previous study showed that people reported a high level

Table 1 Participant Characteristics and Coding (n = 717)

Variables	Coding	n (%)	Mean±SD	Missing Values n (%)
Gender			—	0 (0)
Male	1	694 (96.8)		
female	0	23 (3.2)		
Age			—	7 (1.0)
0~25	1	56 (7.8)		
26~35	2	297 (41.4)		
36~45	3	258 (36.0)		
>45	4	99 (13.8)		
Marital status			—	43 (6.0)
Married	1	93 (13.0)		
Unmarried	0	581 (81.0)		
Education background			—	14 (2.0)
Junior high school or below	1	137 (19.1)		
High school/secondary school	2	276 (38.5)		
Undergraduate or above	3	290 (40.4)		
Monthly income			—	3 (0.4)
3000 yuan or below	1	192 (26.8)		
3000 to 5000 yuan	2	339 (47.3)		
5000 yuan or above	3	183 (25.5)		
Living area			—	0 (0)
Urban area	1	563 (78.5)		
Rural area	0	154 (21.5)		
Treatment duration			—	14 (2.0)
>3 years	1	315 (54.1)		
≤3 years	0	388 (43.9)		
CD4+cell count (cells/ μL)			—	10 (1.4)
<200	1	35 (4.9)		
200–499	2	195 (27.2)		
≥500	3	477 (66.5)		
Viral load (copies/mL)			—	14 (2.0)
≥50	1	629 (87.7)		
<50	0	74 (10.3)		
Side effect of ART			—	1 (0.1)
Yes	1	62 (8.6)		
No	0	654 (91.2)		
Presence of other chronic diseases			—	5 (0.7)
Yes	1	141 (19.7)		
No	0	571 (79.6)		
Depression			—	25 (3.5)
Yes (>9)	1	337 (47.0)		
No (≤9)	0	355 (49.5)		
Psychological counseling			—	15 (2.1)
Yes	1	344(48.0)		
No	0	358(49.4)		
Intimate confidant			—	12 (1.7)
Yes	1	367 (51.2)		
No	0	338 (47.1)		
Life satisfaction			—	12 (1.7)
Yes	1	196 (27.3)		
No	0	509 (71.0)		

(Continued)

Table 1 (Continued).

Variables	Coding	n (%)	Mean±SD	Missing Values n (%)
TRF (cut-off score of 57)			—	0 (0)
Yes	1	368 (51.3)		
No	0	349 (48.7)		
Global score of TRFS	—	—	-15.59±22.90	—
Cynicism	—	—	-9.31±19.68	—
Self-efficacy	—	—	6.28±9.87	—

Table 2 Self-Reported of TRF According to the Characteristics of PLWHAs (n=717)

Variables	Category	TRF		P
		Yes (n=368)	No (n=349)	
Gender	Male	359 (97.6)	335 (96.0)	0.234
	Female	9 (2.4)	14 (4.0)	
Age	0~25	29 (7.9)	27 (7.7)	0.052
	26~35	135 (36.7)	162 (46.4)	
	36~45	144 (39.1)	114 (32.7)	
	>45	57 (15.5)	42 (12.0)	
Marital status	Married	44 (11.9)	49 (14.0)	0.369
	Unmarried	304 (82.6)	277 (79.4)	
Education background	Junior high school or below	86 (23.4)	51 (14.6)	0.000
	High school/secondary school	164 (44.6)	112 (32.1)	
	Undergraduate or above	112 (30.4)	178 (51.0)	
Monthly income	3000 yuan or below	98 (26.6)	94 (26.9)	0.011
	3000 to 5000 yuan	191 (51.9)	148 (42.4)	
	5000 yuan or above	78 (21.2)	105 (30.1)	
Living area	Urban area	250 (67.9)	313 (89.7)	0.000
	Rural area	118 (32.1)	36 (10.3)	
Treatment duration	>3 years	180 (48.9)	135 (38.7)	0.005
	≤3 years	180 (48.9)	208 (59.6)	
CD4+cell count (cells/ μL)	<200	20 (5.4)	15 (4.3)	0.308
	200~499	92 (25.0)	103 (29.5)	
	≥500	253 (68.8)	224 (64.2)	
Viral load (copies/mL)	≥50	318 (86.4)	311 (89.1)	0.095
	<50	45 (12.2)	29 (8.3)	
Side effect of ART	Yes	28 (7.6)	34 (9.7)	0.304
	No	340 (92.4)	314 (89.9)	
Presence of other chronic diseases	Yes	102 (27.7)	39 (11.2)	0.000
	No	262 (71.2)	309 (88.5)	
Depression	Yes (>9)	231 (62.8)	106 (30.4)	0.000
	No (≤9)	120 (32.6)	235 (67.3)	
Psychological counseling	Yes	151 (41.0)	193 (55.3)	0.000
	No	210 (57.1)	148 (42.4)	
Intimate confidant	Yes	140 (38.0)	227 (65.0)	0.000
	No	223 (60.6)	115 (33.0)	
Life satisfaction	Yes	59 (16.0)	137 (39.3)	0.000
	No	304 (82.6)	205 (58.7)	

Note: Bold represents $p < 0.10$ and the variables will be ultimately included in the multiple factor logistic regression.

Table 3 Logistic Regression Analysis of Factors Associated With TRF

Variables	Model 1		Model 2	
	OR	95% CI	OR	95% CI
Treatment duration (>3 years=1)	1.493*	1.048–2.127	1.767**	1.203–2.594
Viral load (≥ 50 copies/mL=1)	0.927	0.519–1.657	0.945	0.507–1.760
Presence of other chronic diseases (yes=1)	2.193**	1.353–3.555	1.786*	1.057–3.019
Depression (yes=1)	3.317***	2.325–4.733	3.177***	2.180–4.629
Psychological counseling (yes=1)	0.826	0.568–1.202	0.814	0.551–1.205
Intimate confidant (yes=1)	0.459***	0.318–0.663	0.514**	0.347–0.760
Life satisfaction (yes=1)	0.510**	0.340–0.765	0.564*	0.365–0.870
Living area (Urban=1)			0.491**	0.295–0.817
Education background				
Junior school or below (reference)				
High school/secondary school			0.954	0.571–1.592
Undergraduate or above			0.568*	0.335–0.965
Monthly income				
3000 yuan or below (reference)				
3000 to 5000 yuan			1.387	0.889–2.165
5000 yuan or above			1.184	0.701–2.001
Age				
0~25 (reference)				
26~35			0.938	0.457–1.928
36~45			1.395	0.668–2.913
>45			1.648	0.705–3.853

Notes: *P < 0.05; **P < 0.01; ***P < 0.001. Model 1: unadjusted; Model: adjusted for living area, education, monthly income and age.

of HIV stigma in countries with a low HIV prevalence.¹⁸ Although HIV/AIDS prevalence is relatively low in China, the high mean TRF score underscores the need for increased attention in this country.

Psychosocial factors have been associated with treatment compliance, and this study suggests that they can also affect TRF. In China, PLWHA may experience HIV stigma, such as stereotyping, social exclusion, and low social support, which are linked to poor mental health outcomes, such as depression.^{19,20} Our study found that depression was the most significant risk factor for TRF in PLWHA (OR=3.317), which is consistent with the previous findings of Claborne et al.⁹ In addition, the requirement for lifelong HIV medications created feelings of isolation for PLWHA, potentially leading to depression and further exacerbating TRF. In a previous study, depression negatively impacted patients' motivation to continue therapy.⁶

This study found that life satisfaction reduces the likelihood of reporting TRF among PLWHA. However, only about a quarter of the participants (27.3%) reported being satisfied with their lives. Previous studies indicate that people satisfied with their lives report fewer missed medication days.²⁰ Life satisfaction likely correlates with optimism; patients' life satisfaction levels may be adversely affected by the high level of stigma associated with AIDS in China, which worsens TRF.²¹

Emotional support from others is crucial to the psychological resilience of PLWHA.²² This study identified having an intimate confidant as a protective factor for TRF. Previous studies have found that social psychological support improves medication adherence, addresses feelings of isolation, and alleviates emotional pain.^{23,24} Having an intimate confidant with whom PLWHA can discuss various issues, even if they cannot "solve" the problem, is likely to provide significant therapeutic value for PLWHA, as it helps them feel psychologically well and motivated to comply with treatment.²⁵ These results indicate that in addition to disease care, there is a need for psychosocial support throughout the HIV care process to address the multiple needs of PLWHA.²⁶ Addressing shame and isolation is especially pertinent, and coping with psychosocial health issues should be an integral part of future HIV care.

Treatment duration was a significant predictor of TRF.⁹ Individuals undergoing long-term treatment are prone to TRF, possibly due to diminishing motivation and commitment compared to the period immediately following diagnosis.⁶ Even for proactive patients, maintaining a commitment to long-term treatment can be very difficult, because they may lack a sense of achievement, especially during asymptomatic periods.⁹ Over time, they may feel emotionally fatigued, cynical, and therefore, disconnected from the advice of healthcare providers.²⁷ The critical role of social support in improving ART and other medication adherence is well-documented in the literature, and similar approaches could be used to address the unique challenges posed by ART fatigue.⁹

In addition, multimorbidity is prevalent among PLWHA using ART.^{28,29} As individuals with HIV age, their risk of comorbidities and multimorbidity increases. Compared to patients with a single disease, those with comorbidities face the dual burden of multiple health issues and experience significantly greater nursing challenges.³⁰ People with HIV and chronic non-communicable diseases believe that chronic diseases are more difficult to manage than HIV.²⁸ Early research findings suggest that the treatment burden for HIV-infected individuals may further increase due to comorbidities, putting PLWHA at risk for suboptimal chronic disease management.^{31,32} Multidisciplinary and collaborative care is essential to mitigate the complex societal and structural challenges exacerbating the risk for these chronic health conditions.

In this study, urban PLWHA were less likely to report TRF compared to rural PLWHA. One possible explanation is the accessibility of healthcare services and drugs in rural areas, which necessitates that residents travel significant distances for HIV-related care. For decades, China has been a dual-structure society, with distinct characteristics for PLWHA in urban and rural areas.^{33,34} In China, PLWHA must regularly visit designated hospitals in cities for examination and to receive free medication,³⁵ making urban living more convenient in terms of time and travel. This difference in geographical accessibility is a common phenomenon observed in research conducted in China.³⁶ A previous study also showed that China's HIV stigma level in rural areas was higher than that in urban areas.³⁷ These results indicate that future responses to TRF must involve the implementation of separate interventions for urban and rural areas. Specifically, addressing TRF may be pertinent for PLWHA who are socially and economically vulnerable, especially in rural areas.

Finally, higher educational attainment (university education or higher) was identified as a protective factor for TRF. Education enhances understanding of the disease and its treatment. Higher education levels are often associated with greater health literacy, which correlates with adherence to ART.³⁸

Limitations

This study has some limitations. First, the data collected were self-reported, introducing the possibility of social desirability and recall bias. Second, the cross-sectional nature of the study prevents the identification of causal relationships between variables. Third, this study used data from Heilongjiang province in northeast China. Given the diverse epidemic characteristics of HIV across regions in China, along with potential ethnic and cultural differences. The findings may not be generalizable to other provinces. Despite these limitations, this study suggests that TRF may vary according to social context. Hence, as the government seeks to provide comprehensive HIV/AIDS care in diverse localities, the high levels of TRF must be addressed. TRF contributes to treatment non-compliance, adversely affecting the quality of life and physical well-being of PLWHA. For patients on long-term therapy, TRF can arise from multiple sources, and patients must recognize that physical or psychosocial factors may contribute to TRF.

Conclusion

The prevalence of TRF among PLWHA in China is relatively high and is influenced by multiple factors including psychosocial, clinical, and demographic characteristics. Therefore, strengthening social support for PLWHA is imperative. Medical institutions and stakeholders working on HIV must enhance mental health screening and provide treatment for depression among PLWHA. Furthermore, scientific education efforts must be strengthened, with a focus on providing drug guidance for patients with comorbid chronic non-communicable diseases and improving access to nearby HIV-related medical services. This study's findings highlight the need to develop multilevel interventions to reduce TRF, addressing the complex needs of PLWHA and mitigating the adverse impact of TRF on HIV treatment outcomes. Further longitudinal research is needed to explore the factors influencing TRF and to strengthen and expand upon the current findings.

Abbreviations

ART, Antiretroviral therapy; HIV/AIDS, Human immunodeficiency virus/Acquired immunodeficiency syndrome; PLWHA, People living with HIV/AIDS; PHQ-9, Patient Health Questionnaire-9; SD, Standard Deviation; TRF, Treatment Regimen Fatigue.

Data Sharing Statement

Due to the research involves sensitive populations, the data in this study cannot be shared.

Ethics Approval and Consent to Participate

This study has been performed in accordance with the Declaration of Helsinki. All eligible participants signed an informed consent before participating in the study. And ethics approval was obtained from the ethics review committee of the Harbin Center for Disease Control and Prevention.

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Disclosure

The authors report no conflicts of interest in this work.

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