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Mental Health among People Living with HIV: Protocol for a Randomized Controlled Trial

[1,2]Najwa Afiqa Roshaizad, [1]Firdaus Mukhtar, [1]Normala Ibrahim, [1]Sindhu Nair Mohan, [2]Nasrudin Subhi

[1]Psychiatry Department, Faculty of Medicine and Health Science, Universiti Putra Malaysia,

[2]Centre for Research in Psychology and Human Well-Being, Faculty of Social Sciences and Humanities, Universiti Kebangsaan Malaysia

Corresponding Author Email : najwaafiqa@ukm.edu.my

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Abstract

Background: A few studies have reported that mental health among People Living with HIV positive (PLHIV) is an important matter to be discussed. Therefore, there is evidence to support further research into exploration of mental health especially psychological intervention. This study will examine whether a psychological intervention (Cognitive Behaviour Therapy) could reduce depression, anxiety, and negative automatic thought in PLHIV.

Methods: This proposed research study will adopt a cross-sectional and single-blind randomized controlled trial (RCT) design, conducted in two phases. In phase 1, participants will answer questionnaire that cover demographic, anxiety, depression, automatic thought, emotion regulation, stigma, adherence, and social support. Participants with high score in anxiety and depression automatically offered to be phase 2 participants, which is Randomized Controlled Trial (RCT). Anxiety, depression, and automatic thought score will be obtained before, immediately after and at 1-month follow-up after completing CBT.

Discussion: This study aims to evaluate the effectiveness of a Cognitive Behavioral Therapy (CBT) program in reducing anxiety, depression, and negative automatic thoughts among people living with HIV (PLHIV). Additionally, it will examine the prevalence of anxiety and depression as well as the relationships between these variables. If the intervention proves effective, it could serve as a valuable mental health strategy and an alternative treatment option for PLHIV in Malaysia.

Keywords: PLHIV, Mental Health, Rct, Study Protocol, Depression, Anxiety, Psychological Intervention.

Introduction

Background

The first case of Human Immunodeficiency Virus (HIV) in Malaysia was detected in 1986. As of 2023, approximately 85,000 people are living with HIV (PLHIV) in the country, with the majority aged between 20 and 39 years (UNAIDS, 2023). Although there has been a decline in

the number of new HIV cases, HIV and AIDS remain leading causes of death worldwide. In Malaysia, the states with the highest prevalence of HIV cases are Selangor (31%), the Federal Territory of Kuala Lumpur (12%), and Penang (10%) (Ministry of Health Malaysia [MOH], 2023). Initially, the primary key populations affected were injection drug users (IDU), followed by female sex workers and transgender individuals. However, recent trends indicate an increase in HIV cases among men who have sex with men (MSM), accompanied by a rise in sexually transmitted infections (STIs) such as syphilis, gonorrhoea, and herpes zoster (MOH, 2023).

Information on HIV testing, prevention, and treatment is now more accessible. Both government and private healthcare facilities in Malaysia offer voluntary testing and treatment services for PLHIV, who retain the right to decline these services (MOH, 2023). Highly Active Antiretroviral Therapy (HAART), introduced in Malaysia in 1997, enables PLHIV to lead near-normal lives by suppressing the virus to undetectable and untransmittable levels (U=U) (SciELO, 2016). While HAART is not a cure and requires lifelong adherence, starting treatment immediately after diagnosis, along with social support from family and friends, is crucial for its success (MOH, 2023).

PLHIV face challenges such as HIV testing, treatment adherence, and side effects. Stigma and discrimination further hinder treatment efforts, leading to mental health issues like anxiety and depression. Factors contributing to these mental health problems include diagnosis disclosure, low social support, unemployment, medication management, and opportunistic infections (MOH, 2023). Addressing these challenges requires a comprehensive approach that integrates medical treatment with psychological and social support to enhance the quality of life for PLHIV.

Additionally, recent studies have highlighted the prevalence of inadequate HIV knowledge among the Malaysian general population, which contributes to ongoing transmission and stigma (Adnan et al., 2024). Mental health issues, including depression and anxiety, are prevalent among PLHIV in Malaysia, often exacerbated by societal stigma and discrimination (Armoon et al., 2022). These factors underscore the importance of comprehensive education and mental health support in HIV management strategies.

Findings from LR

Individuals living with HIV (PLHIV) frequently encounter significant mental health challenges, including elevated rates of depression, anxiety, and experiences of stigma. These psychological burdens can adversely affect their quality of life and hinder adherence to antiretroviral therapy (ART), which is crucial for effective HIV management (Betancur et al. 2017; Cook et al. 2002).

Psychosocial interventions have demonstrated effectiveness in addressing these mental health concerns among PLHIV. A systematic review and meta-analysis encompassing 62 studies revealed that such interventions yield a modest yet positive impact on mental health outcomes, notably reducing symptoms of depression and anxiety (Patel et al, 2021; Kroenke etal. 2001). The success of these interventions is often linked to the quality of the therapeutic relationship and the duration of treatment, with longer engagements typically producing more substantial benefits (Reuda et al. 2016; McGowan et al.2018).

Cognitive Behavioral Therapy (CBT), a structured form of psychotherapy, has been particularly beneficial for PLHIV experiencing depression and anxiety. CBT assists individuals in identifying and modifying negative thought patterns and behaviors, thereby alleviating psychological distress. Research indicates that CBT not only reduces depressive symptoms but also enhances ART adherence, leading to improved health outcomes (Nakimuli-Mpungu et al. 2020; Hossenian et al. 2011). Moreover, brief CBT interventions have shown promise in mitigating internalized stigma and bolstering social support among PLHIV. A randomized controlled trial demonstrated that brief CBT significantly decreased levels of depression and stigma while improving treatment adherence and quality of life (Scott-Heldon et al. 2013; Onu et al. 2016).

Integrating mental health services with HIV care is essential for a holistic approach to treatment. The World Health Organization emphasizes the importance of such integration, highlighting that addressing mental health not only improves psychological well-being but also enhances ART adherence and retention in care (WHO, 2022). In summary, addressing the mental health needs of PLHIV through interventions like CBT is vital for improving both psychological well-being and physical health outcomes. Tailoring these interventions to individual needs and ensuring their integration into comprehensive HIV care can significantly enhance the quality of life for those affected.

Justification

Research in Malaysia and worldwide are focusing more on pharmacological aspect of treatment for PLHIV. However, there are many psychological issues that need to be addressed together with HAART treatment. Mental health problems were proved as one of the barriers to treatment adherence among PLHIV and can affect prevention to viral replication. Anxiety, depression are common problems among PLHIV, in addition to self-stigma, discrimination and low social support. All these conditions will lead to poor progress for 90-90-90 target set by UNAIDS and WHO.

Psychological intervention is an alternative way in helping PLHIV to cope with mental health problems effectively and improve their quality of life. All these interventions will help them with managing emotions, dealing with chronic disease, and adjustment period. Other than that, it can assist them in making decisions, coping skills, and relapse prevention.

Cognitive Behavioral Therapy (CBT) has been proven to be an effective method for helping people living with HIV (PLHIV) reduce symptoms of depression and anxiety. It works by assisting patients in identifying negative automatic thoughts and managing their fear-driven thought patterns. In Malaysia, there is limited research utilizing CBT as an intervention for PLHIV, particularly in group settings. Therefore, this study aims to address this gap by providing insights into the effectiveness of CBT as a psychological intervention for PLHIV in Malaysia.

Research Aim & Objectives

General objectives **:** To investigate anxiety, depression, automatic thought, emotion regulation, self-stigma, adherence, social support and effect of psychological intervention on mental health among people living with HIV (PLHIV).

Specific objectives:
a. To identify the prevalence of anxiety and depression among PLHIV.
b. To investigate the relationship between sociodemographic factors with anxiety and depression among PLHIV
c. To investigate the relationship between negative automatic thought, emotion regulation self-stigma, adherence, and social support with anxiety and depression among PLHIV.
d. To determine the level of depression, anxiety, automatic thought before and after the psychological intervention.

Research Question
a. What is the prevalence of anxiety and depression among PLHIV?
b. What is the relationship between sociodemographic factors with anxiety and depression among PLHIV?
c. What is the relationship between negative automatic thought, emotion regulation self-stigma, adherence, and social support with anxiety and depression among PLHIV?
d. What is the level of depression, anxiety, automatic thought before and after the psychological intervention?

Hypothesis
a. There will be high prevalence of anxiety and depression among PLHIV.
b. There will be a significant relationship between sociodemographic factors with anxiety and depression among PLHIV.
c. There will be a significant relationship between negative automatic thought, emotion regulation self-stigma, adherence, and social support with anxiety and depression among PLHIV.
d. There will be a significant reduction in levels of depression, anxiety, automatic thought before and after the psychological intervention.

Methods
Study design
This study consist of two phases :
Phase 1 : A cross-sectional study (n=221) using questionnaires that measure anxiety, depression, automatic thought, emotion regulation, self-stigma, adherence and social support. Research instruments that will be used in this study is Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), Automatic Thought Questionnaire (ATQ), Emotion Regulation Inventory (ER), HIV Self-stigma Survey (HSS), Medication Adherence Report Scale (MARS), and Multidimensional Scale of Perceived Social Support (MSPSS).

Phase 2 : In Phase 2 of the data collection, a randomized controlled trial (RCT) adhering to the CONSORT guidelines will be conducted. Participants identified with high scores during Phase 1 will be invited to participate in this phase of the research. They will be randomly assigned to one of two groups: an intervention group and a control group. The target recruitment is 40 participants for each group. The intervention group will undergo four sessions of group-based Cognitive Behavioral Therapy (CBT), while the control group will receive treatment as usual.
Measurements will be conducted at three time points: pre-treatment, post-treatment, and one-month follow-up. The instruments utilized in this phase include the Beck Anxiety

Inventory (BAI), Beck Depression Inventory (BDI), and the Automatic Thought Questionnaire (ATQ). This comprehensive approach will allow for the assessment of treatment effectiveness over time.

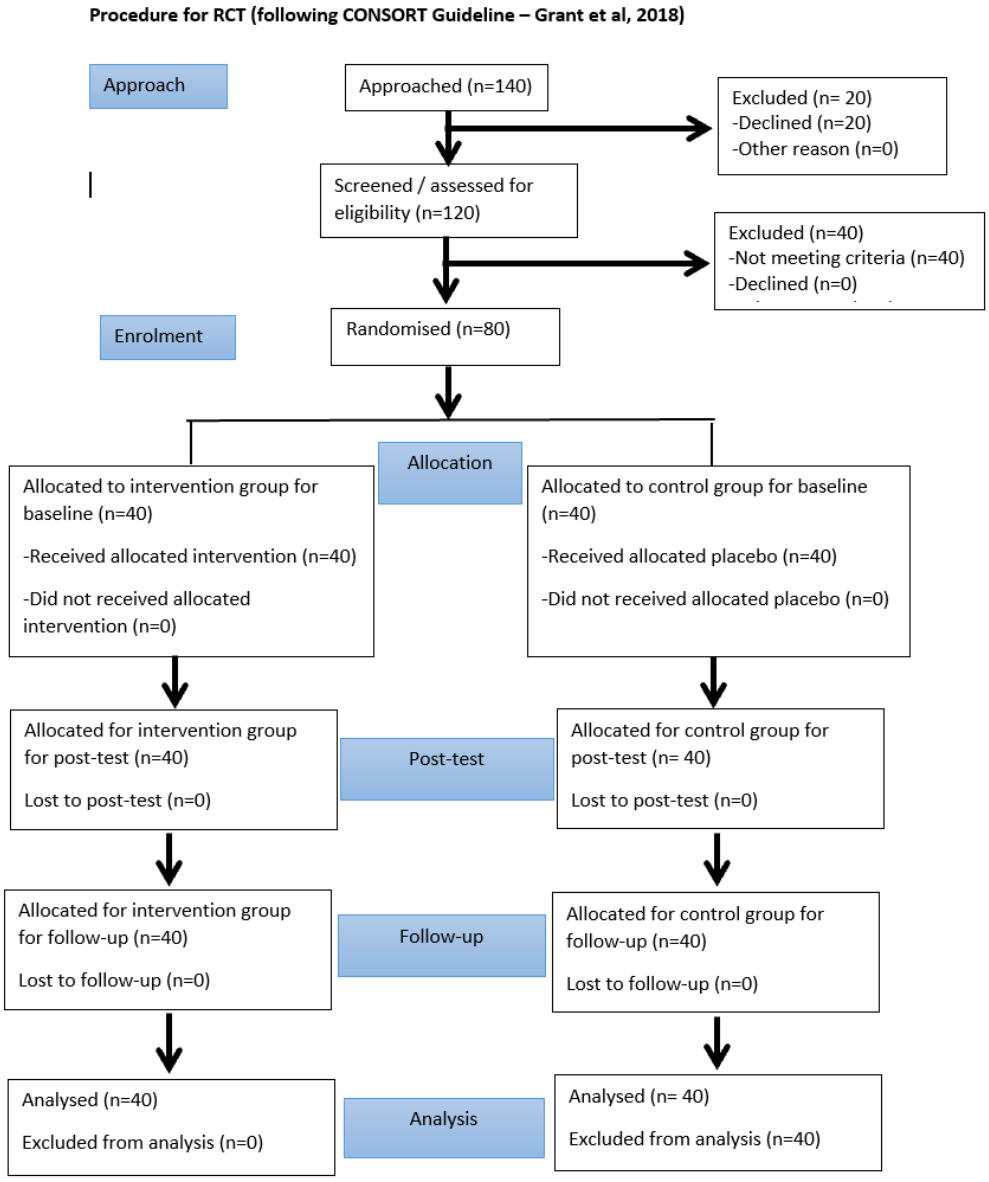

Figure 1 : Consolidated standards of reporting trials diagram

Study Site and Participants

All participants will be recruited from organizations that provide services for people living with HIV (PLHIV), including both government-linked entities and non-governmental organizations (NGOs). The researchers have sought permission from Majlis Agama Islam Selangor (MAIS) and the Agensi Antidadah Kebangsaan (AADK) to conduct data collection at shelter homes under their jurisdiction. Sample size estimation for phase 1 is 221 and 80 for phase 2 (40 intervention and 40 control). The researcher will approach selected shelter homes and NGOs to provide an explanation of the study, along with an official letter and informed consent forms. Several meetings will be conducted prior to the start of the data collection process to ensure understanding and cooperation.

To be eligible for the study, participants must meet the following criteria:

1. Be diagnosed as HIV-positive.
2. Be aged between 18 and 60 years.
3. Be able to understand and provide written or verbal informed consent.
4. Be able to communicate in Malay, English, or both.
5. Not have any conditions that could interfere with their ability to participate, such as severe mental disorders or cognitive impairments.

For Phase 2, additional eligibility criteria include:

- Scoring moderate to high on the Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), and Automatic Thought Questionnaire (ATQ).
- Being a participant from Phase 1.

Procedures and Study Assessment

Phase 1: Cross sectional study: A simple random sampling method will be employed for participant recruitment in this phase. The researcher will use a sampling frame consisting of the respondents' names and randomize the selection process using Microsoft Excel. Before distributing the questionnaire, respondents will be provided with written informed consent, and the researcher will explain all necessary details about the study, including its purpose, potential risks, and benefits. Respondents will also be informed about their rights, including the voluntary nature of their participation, confidentiality, and privacy protections. They will be given sufficient time to complete the surveys honestly.

Data collection for this phase will be paper-based, with respondents encouraged to ask questions if they encounter any difficulties understanding the items. After all surveys are completed, the researcher will review the responses for completeness and accuracy before entering the data into the Statistical Package for the Social Sciences (SPSS) software, version 29, for analysis. Data collection will be conducted face-to-face to ensure clarity and support throughout the process.

Phase 2: Intervention study: The research procedure for the randomized controlled trial (RCT) will adhere to the CONSORT guidelines (Grant et al., 2018), involving multiple stages: approach, enrolment, allocation, follow-up, and analysis. Participants meeting the eligibility criteria will receive written informed consent, and the researcher will explain the study details, including its objectives, risks, and benefits. Respondents will also be informed of their rights, voluntary participation, and privacy protections before agreeing to take part.

This study will follow a single-blind (subject-masked) RCT design. Participants will be randomly assigned to either the intervention or control group using a random allocation technique. This method ensures unbiased group assignment by chance, minimizing potential confounding factors. Randomization will be conducted using consecutively numbered, sealed, opaque envelopes containing pre-generated random numbers for group allocation, a procedure developed by the researcher. Given the multisite nature of the study, participants will be recruited from multiple shelter homes.

Intervention Program: The psychological intervention is based on Cognitive Behavioral Therapy (CBT) and is tailored to the study objectives, population characteristics, environment, and logistical constraints. The intervention group will participate in a structured four-session

CBT program, with one session conducted weekly, each lasting 1.5 hours. The 40 participants will be divided into four smaller groups, ensuring an optimal group size of 8–12 participants per session.

Session Overview

1. *Session 1: Ice-breaking and Psychoeducation*
   - Introduction to HIV and its psychological impact, including the relationship between situations, automatic thoughts, behaviors, and emotions.
   - Information on HIV, its side effects, mental health, and related variables is shared to build understanding and awareness.
2. *Session 2: Cognitive Skills Development*
   - Focus on identifying and challenging negative automatic thoughts.
   - Participants learn how to re-evaluate these thoughts based on evidence rather than interpretation, developing healthier cognitive patterns.
3. *Session 3: Behavioral Interventions*
   - Participants are encouraged to adopt lifestyle changes and engage in activities that reduce anxiety and mitigate negative automatic thoughts.
   - Strategies for maximizing positive activities are discussed and practiced.
4. *Session 4: Relapse Prevention and Termination*
   - Emphasis on preventing relapse, relaxation techniques, and problem-solving skills.
   - Participants engage in reflective activities and finalize their intervention journey.

Each session will begin with a detailed explanation of its purpose, content, and steps. The sessions will utilize interactive methods such as role-playing, drawing, games, and group discussions to enhance engagement and learning. The effectiveness of the intervention will be assessed using measures for anxiety, depression, and negative automatic thoughts. These assessments will be administered at three time points: pre-intervention, post-intervention, and one-month follow-up. All data will be entered into the Statistical Package for the Social Sciences (SPSS) software, version 29, for analysis. This process ensures a robust evaluation of the intervention's impact on the participants' mental health outcomes.

Planned Data Analysis

Table below shows planned statistical analysis for aims in current research

Aim	**Statistical Analyses**
To investigate the prevalence of anxiety and depression among PLHIV	Descriptive analysis (mean, SD, frequency, prevalence)
To investigate the relationship between sociodemographic factors with depression and anxiety among PLHIV	Pearson Correlation
To investigate the relationship between negative automatic thought, emotion regulation, self-stigma, adherence, and social support with anxiety and depression among PLHIV	Pearson Correlation
To determine the level of anxiety, depression, negative automatic thought, stigma before and after the psychological intervention	Repeated measure ANOVA

All analyses will be using SPPSS version 29.

Ethical Consideration

This study was approved by Jawatankuasa Etika Universiti Putra Malaysia (JKEUPM) on 19th May 2021 (Approval number : JKEUPM-2021-158).

Respondents' right and welfare: Participation in this study is entirely voluntary, and respondents have the right to withdraw at any point without providing a reason. They will be fully informed about the study's characteristics and aims and treated with dignity throughout the process. Respondents are encouraged to ask questions if they do not understand any aspect of the research. Their well-being will be prioritized in all aspects, including physical, emotional, and psychological need.

Informed consent: Written and oral informed consent will be obtained before data collection, with a thorough explanation of all relevant information, rights, and ethical components. Respondents must carefully review and fully understand the consent form before agreeing to participate, ensuring they can provide consent both physically and mentally.

Privacy and Data Storage: To protect privacy, respondents will not be identified by their real names, reducing stigma and preventing information leakage. Their identities will be used solely for research purposes, and they will be informed if their information might be shared with another party. All collected data will be securely stored and accessible only to the researcher.

Token: All participants in this study will be given token of appreciation (daily necessities) upon completing data collection and intervention process.

Results

Overview

A scoping review was conducted to inform this research study, with a specific focus on people living with HIV (PLHIV). The measures and intervention manuals have been finalized, ensuring a robust framework for the study. The data collection phase is scheduled for completion in 2024.

Integration of Data

Findings from Phases 1 and 2 will enhance our understanding of mental health among people living with HIV (PLHIV) and provide valuable insights for designing future interventions tailored to their needs. Analyzing data collected from both phases will result in combined outcomes that enable the formulation of well-informed and acceptable conclusions.

Discussion

Principal Findings

The previously conducted scoping review revealed a high and concerning prevalence of mental health symptoms among people living with HIV (PLHIV). Furthermore, Cognitive Behavioral Therapy (CBT) has been shown to effectively alleviate symptoms of depression and anxiety in PLHIV, thereby enhancing their quality of life. These findings provide strong justification for conducting this research, focusing on exploring and investigating psychological interventions tailored to the needs of PLHIV.

Conclusions

The key findings from both phases of this research project will offer comprehensive insights into depression, anxiety, self-stigma, emotion regulation, treatment adherence, and social support among PLHIV. These findings will benefit PLHIV and helping professionals alike, contributing to strategies that enhance their quality of life.

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