

ABORDAGENS TEÓRICAS E PRÁTICAS EM PESQUISA

COORDENADORES

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RELAXING MASSAGE AND THE USE OF LAVENDER ESSENTIAL OIL IN PEOPLE LIVING WITH HIV:

A STUDY PROTOCOL

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ABSTRACT:

Introduction: Aging among people living with HIV (PLHIV) presents unique challenges, including comorbidities related to the infection, adverse effects of antiretroviral therapy (ART), and reduced quality of life. Integrative and complementary practices, such as relaxing massage and aromatherapy, have the potential to alleviate these effects and improve mental, immune, and metabolic health parameters. However, evidence on the effectiveness of these interventions in PLHIV remains scarce, highlighting the need for further research in this area. Objective: To detail the methodological steps to assess the effects of relaxing massage and aromatherapy in PLHIV over 50 years old on quality of life, self-perceived health, body image perception, anxiety, depression, cognitive function, and immunological and metabolic parameters. Method: This is a protocol of a randomized, blinded, parallel clinical trial based on CONSORT guidelines. The study will include participants grouped into three intervention groups and one control group, considering the time since HIV diagnosis and ART use. The intervention will consist of 12 weekly sessions of relaxing massage with lavender essential oil. Outcomes will be assessed before and after the intervention using validated questionnaires (sleep quality, anxiety, depression, among others) and laboratory tests (viral load, CD4+/CD8+ T lymphocytes, lipid profile, and blood glucose). Expected Results: The protocol aims to generate robust evidence on the benefits of complementary therapies in older PLHIV, addressing different clinical profiles. Conclusion: This protocol fills gaps in research on non-pharmacological interventions in PLHIV, contributing to clinical practices and future investigations.

Keywords: research protocol, HIV, relaxing massage, aromatherapy, quality of life, aging.

INTRODUCTION

Forty years after the discovery of Human Immunodeficiency Virus (HIV), significant advances in terms of medical care have been made, particularly with the development of the Antiretroviral Therapy (ART), which transform the infection from a fatal disease into a manageable chronic condition. These advancements have led to increased life expectancy for people living with HIV (PLHIV) [1,2,3]. Currently, the life expectancy of PLHIV is nearly equivalent to that of individuals without the infection [4], allowing for the observation of a growing population of PLHIV over 50 years old, many of whom have been diagnosed for several years [5,6,7].

Some researchers suggest that older, PLHIV may exhibit an accelerated aging process in comparison to older individuals without the infection, what can be explained by physiological changes induced by the infection of itself and by the long-term effects of ART, including immunosenescence, DNA damage, macromolecular damage, oxidative stress, inflammation, and metabolic alterations [8,9,10]. Overall, older PLHIV can be categorized into different subgroups: (1) individuals with long-term diagnoses who have lived with HIV and ART-related toxicity for many years; (2) individuals who acquired the virus later in life; and (3) those experiencing an inversion in the CD4/CD8 ratio [11,12,13].

In addition, side effects related to ART or the infection itself can lead to psychological complications such as anxiety, depression, and reduced quality of life [14,15], accelerating even more the aging process. Given these challenges, Integrative and Complementary Practices (ICPs), such as massage therapy and aromatherapy, have emerged as promising non-pharmacological strategies [16,17]. These interventions may help alleviate symptoms of anxiety, depression, and stress, consequently improving quality of life and self-perceived health in PLHIV [16,17]. However, despite their potential benefits,

evidence on the effectiveness of these interventions in PLHIV remains limited, with studies varying in methodological quality, sample size, and consistency of outcomes. This gap in the literature underscores the need for further high-quality research to better understand the impact of ICPs on aging, mental health, and overall well-being in this population, as explored in the following sections.

The clinical study aims to evaluate the effects of relaxing massage and aromatherapy on body image perception, anxiety, depression, cognitive function, and immunological and metabolic parameters in PLHIV over 50 years old. Additionally, the study seeks to determine whether these outcomes vary among different subgroups of older adults living with HIV. To achieve this, the study will detail the methodological steps to assess the effects of these interventions on quality of life, self-perceived health, anxiety, depression, cognitive function, and immunological and metabolic parameters, ensuring a comprehensive evaluation of their potential benefits in this population.

JUSTIFICATION AND HYPOTHESIS

There is a notable gap in research focusing on targeted interventions for aging PLHIV. Despite increased life expectancy, these individuals face significant challenges related to aging, such as comorbidities and polypharmacy. These factors can negatively impact their quality of life, mental health, and overall well-being.

To date, no studies have examined the differential effects of massage therapy and aromatherapy among different subgroups of older PLHIV—distinguishing between those who have aged with HIV and those who acquired the infection later in life. The hypothesis of this study is that relaxing massage combined with aromatherapy will

positively influence mental health, self-perception, and physiological parameters in PLHIV, with potential variations in outcomes depending on the clinical profile of each subgroup.

OBJECTIVE

This manuscript presents the study protocol for the planned clinical trial. It details the methodology, intervention strategies, and analytical approaches that will be used to investigate the effects of relaxing massage and essential oil use on sleep quality, self-perceived health, self-esteem, quality of life, body image perception, anxiety, depression, cognitive function, medication adherence, and immunological and metabolic parameters in PLHIV over 50 years old with distinct clinical profiles.

The development of this protocol is crucial, as it provides a structured and reproducible framework for conducting the clinical trial. By establishing clear methodological guidelines, this protocol ensures the rigor and reliability of the study, ultimately contributing to the scientific understanding of complementary therapies for aging PLHIV.

METHOD

This study protocol will be applied in a future parallel clinical trial, in which participants will be assigned to different groups and compared through statistical analysis. The trial will be blinded, meaning the researcher administering the intervention will not be aware of each participant's group allocation.

The study aims to evaluate the effects of relaxing massage with essential oils on various health outcomes in PLHIV undergoing ART. The experimental design will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized studies.

The protocol of this randomized clinical trial is registered on ClinicalTrials.gov under the identification number NCT06731491. This study also follows the SPIRIT Checklist for Trials to ensure rigorous protocol reporting.

STUDY LOCATION

Participants will be recruited at the Special Unit for the Treatment of Infectious Diseases of the Hospital das Clínicas, Ribeirão Preto Medical School, University of São Paulo, Brazil (UETDI/HC-FMRP/USP). The intervention, involving relaxing massage with essential oils, will take place at the Laboratory of Kinanthropometry and Human Performance (LaCiDH) of the School of Physical Education and Sport of Ribeirão Preto, University of São Paulo (EEFERP/USP).

ETHICAL ASPECTS

The project was approved by the Ethics and Research Committee of EEFERP under the CAAE number 78708524.5.0000.5659. It complies with the guidelines for research involving human subjects as stated in Resolution CNS 466/12 of the Brazilian National Health Council and will follow the Declaration of Helsinki [18]. Participants will be informed about the study's objectives and methods, with an emphasis on their right to withdraw from the research at any time.

STUDY PARTICIPANTS

Participants will be invited to join the study while waiting for their medical appointment at UETDI/HC-FMRP/USP or via phone call if they meet the inclusion criteria previously verified in their medical records. The researcher will present study details, explaining the objectives, risks, procedures, and benefits. If the volunteer agrees to participate, a convenient date and time will be scheduled for them to visit the intervention site and undergo an initial assessment. The researcher and the participant will sign the Informed Consent Form, with one copy retained by the participant and another by the researcher.

ELIGIBILITY CRITERIA

Participants must meet the following inclusion criteria:

- Both sexes;
- Age ≥ 50 years;
- Diagnosed with HIV at age ≥ 18 years;
- HIV diagnosis for more than six months;
- ART use for more than six months;
- Clinically stable, with an undetectable viral load (< 40 copies per ml of blood);
- Not undergoing treatment for opportunistic diseases or cancer;
- No rare metabolic disorders;

- No physical signs of cachexia;
- No musculoskeletal disorders that impair the ability to perform physical exercises;
- Medical clearance for physical exercises;
- No use of ergogenic products that could alter body composition, energy metabolism, or immune response;
- Not pregnant;
- Not breastfeeding;
- No prosthetic limbs;
- No amputated body parts;
- Not engaged in a regular physical exercise program in the past six months.

Participants' data will be excluded if:

- They withdraw from the study;
- They fail to complete all study stages, including at least 80% attendance in the relaxing massage sessions with essential oils.
- Participant Grouping

Participants will be assigned to three intervention groups and one control group:

- G1 (Chronic HIV group) = PLHIV aged ≥ 50 years, diagnosed with HIV for ≥ 10 years, undergoing ART, and without a recorded CD4/CD8 ratio < 1 .

- G2 (Non-chronic HIV group) = PLHIV aged ≥ 50 years, diagnosed with HIV for < 10 years, undergoing ART, and without a recorded CD4/CD8 ratio < 1 .
- G3 (Nadir CD4 group) = PLHIV aged ≥ 50 years, undergoing ART, and with a recorded CD4/CD8 ratio < 1 .
- Control Group (CG) = PLHIV aged ≥ 50 years, undergoing ART, and without a recorded CD4/CD8 ratio < 1 . The CG will be advised to maintain their routine activities for 12 weeks.

The sample size calculation was performed for an analysis of variance (ANOVA) with four independent groups, considering a significance level of 5% ($\alpha = 0.05$), statistical power of 80% ($1 - \beta = 0.80$), and a large effect size ($f = 0.8$), as defined by Cohen (1988) [19]. The formula used was: $n = 2 \times (k - 1) \times (f^2 + 1) / F_{crit}(v1, v2)$ where k is the number of groups ($k = 4$), f is the effect size, and $F_{crit}(v1, v2)$ represents the critical value of the F distribution with degrees of freedom between ($v1 = k - 1$) and within ($v2 = N - k$) the groups. The parameters used were based on the study by Reyhler *et al.* (2017) [20], which evaluated the effect of massage on anxiety and quality of life in people living with HIV. Considering an expected dropout rate of 20%, the final sample size was adjusted to 26 participants per group, totaling 104 participants.

DATA COLLECTION PROCEDURES

Data collection will involve gathering information from study participants, including anamnesis, questionnaires assessing sleep quality, self-perceived health, self-esteem, quality of life, body image perception, anxiety, depression, cognitive function, and medication adherence. These data will be collected by the researcher. Routine laboratory tests—assessing immunological and metabolic parameters—will be conducted by laboratory technicians at HC-FMRP/USP.

MEDICAL HISTORY

The medical history will be conducted through the application of a questionnaire developed by the researcher as an initial stage of data collection. It includes questions related to personal characterization, such as demographic aspects, self-reported skin color, education level, marital status, number of household members, family income, social vulnerability, polypharmacy, delirium, history of falls, incontinence, and the presence of symptoms or clinical conditions detailed in the inclusion and exclusion criteria. Additionally, information regarding exercise history, type of work, injuries, surgeries, family history of diseases, time since HIV diagnosis (in months), duration of ART use (in months), previously administered therapies, use of other medications, smoking, drug and alcohol use, co-infection with the Hepatitis C virus, history of stroke, chronic obstructive pulmonary disease, cardiovascular disease, and COVID-19 diagnosis (including presence of sequelae) will be collected.

SLEEP QUALITY

Sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI), a questionnaire validated for use in Brazil. The PSQI retrospectively measures sleep quality over the past month using self-report/recall. It consists of 19 individual items assessing seven sleep quality components: (1) sleep duration; (2) sleep disturbances; (3) sleep latency; (4) daytime dysfunction due to sleepiness; (5) sleep efficiency; (6) overall sleep quality; and (7) use of sleep medications [21]. These seven component scores (ranging from 0 to 3) are summed to produce a global score between 0 and 21, with higher scores indicating poorer sleep quality (Buysse *et al.*, 1989).

A global PSQI score of ≤ 5 indicates good sleep quality, while a score > 5 suggests poor sleep quality [19]. The PSQI has demonstrated good psychometric performance in Brazil [22, 23].

SELF-ESTEEM

Self-esteem will be assessed using the Rosenberg Self-Esteem Scale (1965) [23], validated in Brazil by Sbicigo *et al.* (2010) [24]. The scale consists of 10 statements, with 6 addressing positive self-image and self-worth and 4 referring to negative self-image or self-deprecation. Responses follow a Likert format with three options: “agree,” “neither agree nor disagree,” and “disagree.” Higher scores on the scale indicate higher levels of self-esteem.

QUALITY OF LIFE AND SELF-PERCEIVED HEALTH

To assess self-perceived health, two questions from the WHOQOL-HIV-Bref will be used. This instrument was developed by the World Health Organization (2003) [25] to assess the quality of life of people living with HIV and was validated in Brazil by Pedroso *et al.* (2012) [26]. It consists of 31 questions assessing six domains (Physical, Psychological, Level of Independence, Social Relationships, Environment, and Spirituality) and the overall quality of life and health perception. Responses follow a Likert scale with five options, ranging from 1 to 5. Scores range from 4 to 20, with higher scores indicating better quality of life [26,27].

BODY IMAGE PERCEPTION

Body image perception will be assessed using the silhouette rating scale by Stunkard *et al.* (1983) [28], adapted and validated for Brazil by Scagliusi *et al.* (2006) [29]. Participants will be presented with a series of silhouettes assigned specific values and asked to identify the one that most closely resembles their current body perception and their ideal body image. The perceived body size and shape will then be compared to the ideal body image by subtracting the ideal silhouette score from the current score. The resulting discrepancy score ranges from -8 to 8, indicating the level of body image dissatisfaction, with a score of zero representing satisfaction and any nonzero score indicating dissatisfaction [30, 31].

ANXIETY AND DEPRESSION

Anxiety and depression will be assessed using the Hospital Anxiety and Depression Scale (HADS) by Zigmond and Snaith (1982) [32], which was validated in Brazil in 1995 by Botega *et al.* [33]. The scale consists of 14 questions, with seven assessing anxiety (HADS-A) and seven assessing depression (HADS-D). Each subscale is scored from 0 to 21, with a cutoff score of ≥ 9 indicating the presence of anxiety or depression.

COGNITIVE FUNCTION

Cognitive function will be evaluated using the Mini-Mental State Examination (MMSE), a cognitive screening questionnaire

assessing temporal and spatial orientation, memory, attention, naming, comprehension, and motor praxis [34], validated in Brazil [35]. The questionnaire consists of two sections: the first assesses orientation, attention, and memory, totaling 21 points, while the second evaluates naming ability, command following, free writing of a sentence, and copying a drawing, totaling 9 points. The cutoff scores are 13 points for illiterate individuals, 18 points for those with low to medium education, and 26 points for individuals with high education levels.

ADHERENCE TO MEDICATION THERAPY

The “Cuestionario para la Evaluación de la Adhesión al Tratamiento Antiretroviral” (CEAT-VIH) by Remor (2002) [36], validated in Brazil [37], will be used to assess adherence to medication therapy. It is a self-administered instrument consisting of 20 questions. The total score ranges from 17 to 89, with higher scores indicating greater medication adherence.

IMMUNOLOGICAL AND METABOLIC PARAMETERS

To assess the clinical stability of PLHIV, viral load levels and CD4+ and CD8+ T lymphocyte counts will be measured. To analyze the metabolic parameters associated with cardiovascular risk, serum levels of glucose, HDL-c, LDL-c, total cholesterol, and triglycerides will be measured and evaluated. These analyses are conducted at the Viral Load Laboratory – Serology Sector of HC-FMRP/USP. The analyses of fasting plasma glucose, insulin resistance, HDL-c, LDL-c,

total cholesterol, and triglycerides will be performed using the enzymatic method with the Wiener Lab® Kit.

For immune response assessments, viral load levels will be considered detectable when HIV RNA is > 40 copies mL^{-1} . Viral load will be determined using the Real Time Abbott method, with the Siemens - Versant® HIV-1 RNA 3.0 kit and the DNA Analyzer System 340® device. CD4+ and CD8+ T lymphocyte counts (cells/mm^3) will be performed by Flow Cytometry, using the Multitest® kit and the Facs Calibur® cytometer (Becton Dickinson – San Jose, CA). It is essential to highlight that these tests will be routinely collected during the outpatient follow-up of participants at the UETDI of HC-FMRP/USP.

A maximum period of three months (before or after) from the physical evaluation date will be considered acceptable for lipid and glucose tests. This period is deemed appropriate for assessing the participant's current metabolic state. If the participant does not have tests within the specified period, a new blood collection will be proposed within this timeframe. For viral load levels and CD4+ T lymphocyte counts, six months (before or after) from the initial and final evaluations will be acceptable.

Immunological and metabolic parameters will be assessed in both pre- and post-intervention periods at the UETDI of HC-FMRP/USP.

RELAXING MASSAGE PROTOCOL WITH ESSENTIAL OILS

Twelve sessions of hand relaxing massage with essential oils will be performed once a week, lasting 30 minutes, on the posterior trunk region. The duration, frequency, and massage areas follow

previous studies involving PLHIV [38]. The participant will be positioned in the prone position, with the trunk area uncovered for the intervention. The pressure of the relaxing massage will be of moderate intensity, corresponding to a sphygmomanometer cuff pressure between 50 and 80 mmHg [39].

The massage will be conducted by two professionals experienced in applying the necessary pressure to stimulate relaxation. Grape seed oil will be used as the carrier oil, as it is a universal carrier for essential oils, has moisturizing properties, and is hypoallergenic, allowing for broader use, including on sensitive skin [40]. Lavender essential oil will be used at a 2% concentration, equivalent to 50 drops of essential oil per 100 mL of carrier oil.

The relaxing massage protocol will follow Swedish massage techniques, as outlined in Table 1, beginning with movements from the lumbar region to the neck and returning to the lumbar area.

Table 1 - Relaxing Massage Protocol – Movements, Repetitions, and Duration

Massage Movements	Repetitions	Duration
Superficial gliding from the lumbar region to the neck, returning to the lumbar	8 times	1 minute
Deep gliding from the lumbar region to the neck, returning to the lumbar	10 times	2 minutes
Friction from the lumbar region to the neck, returning to the lumbar	12 times	1 minute
Deep gliding alternating hands on the sides of the back, moving from the lumbar region to the trapezius muscles and back	3 times	2 minutes
Rolling from the lumbar region to the neck, returning to the lumbar	15 times	2 minutes
Gliding from the neck to the shoulders in an “S” shape down to the lumbar region	6 times	1 minute
Compression on the trapezius muscle	10 times per side	1 minute

Massage Movements	Repetitions	Duration
Compression around the spine in circular motions from the cervical to the lumbar region	3 times	1 minute
Deep gliding alternating hands on the sides of the back, moving from the lumbar region to the trapezius muscles and back	3 times	2 minutes
Gliding with fingers in a saddle shape around the spine, from the lumbar to the cervical region	5 times	30 seconds
Kneading from the lumbar region to the trapezius muscles and back	4 times	5 minutes
Gliding from the lumbar region to the trapezius muscle	5 times	1 minute
Kneading on the trapezius muscles	25 times per side	1 minute
Gliding with the forearm in an "S" shape from the lumbar region to the neck diagonally	6 times	1 minute
Tapotement from the lumbar region to the neck, returning to the lumbar region	4 times	40 seconds
Deep gliding from the lumbar region to the neck, returning to the lumbar region	10 times	2 minutes
Superficial gliding from the lumbar region to the neck, returning to the lumbar region	5 times	1 minute

STATISTICAL ANALYSIS

The independent variable considered is relaxation massage with the use of essential oils, and the primary outcome variables will include sleep quality, self-perceived health, self-esteem, quality of life, body image perception, anxiety, depression, cognitive function, adherence to medication therapy, and immunological and metabolic parameters.

An initial exploratory analysis will be conducted to assess the distribution behavior of the data. If the data present a normal distribution, a descriptive analysis, including central tendency measures, standard deviation (SD), and confidence interval (CI), of the outcome variables at different periods (pre- and post-intervention) will be performed. If the data do not follow a normal distribution, the description of the outcome variables will be based on the median, minimum and maximum values, and interquartile range (25th and 75th percentiles).

If the data are normally distributed, a paired t-test will be used to identify differences between the pre- and post-intervention periods for the intervention and control groups. Subsequently, a one-way ANOVA will be used to verify differences between the intervention and control groups in the pre- and post-intervention periods. If the data do not follow a normal distribution, the Mann-Whitney U test for dependent samples will be used to identify differences between the pre- and post-intervention periods for the intervention and control groups. Subsequently, the Wilcoxon test for independent samples will be used to verify differences between the intervention and control groups in the pre- and post-intervention periods.

The effect size (η^2) of relaxation massage with essential oils on the outcome variables will be calculated. Analyses will be conducted using SPSS 23.0 software, assuming a predefined statistical significance level ($\alpha = 0.05$).

EXPECTED RESULTS

The hypothesis is that massage therapy with aromatherapy will promote significant improvements in health-related parameters for PLHIV. Additionally, we expect that the responses related to these

complementary therapies will show a magnitude corresponding to the particularities of each intervention group.

CONCLUSION

The consequences related to aging and prolonged exposure to ART in PLHIV have been shown to increase the risks of developing chronic diseases, reducing quality of life, and increasing factors related to stress, anxiety, depression, and biological aging. As these factors develop, these risks may accumulate, posing a significant health concern, impacting quality of life, and increasing the risk of mortality in this population.

Therefore, complementary therapies may help improve metabolic and functional aspects, body composition, and quality of life, contributing to the reduction or maintenance of risks associated with prolonged ARV exposure, aging, and quality of life. Thus, this rigorous protocol on the relationship between massage therapy and aromatherapy with health-related aspects, quality of life, and the different profiles of PLHIV will provide valuable data. These findings will offer insights that can be applied to clinical practice and scientific research regarding the use of complementary therapies for different profiles of PLHIV.

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