TEMPORAL ASSESSMENT OF BODY COMPOSITION CHANGES BEFORE, DURING AND AFTER RAMADAN: EFFECTS ON CELLULAR HEALTH AND BLOOD PRESSURE AMONG HEALTHY MALE SUBJECTS

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Department of Physiology



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By

Ilyas Abdul Masoud

A Dissertation Submitted in (Partial) Fulfilment of the Requirements for the Degree of Master of Science (Physiology) of

Muhimbili University of Health and Allied Sciences
October, 2024

CERTIFICATION

The undersigned certifies that they have read and here by recommend for acceptance by Muhimbili university of health and allied science a dissertation entitled; **"Temporal Assessment of Body Composition Changes Before, During and After Ramadan: Effects On Cellular Health and Blood Pressure Among Healthy Male Subjects",** in (partial) fulfilment of requirements for degree of Master of Science in Physiology of Muhimbili University of Health and Allied Sciences.

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Dr. Fredirick Mashili

(Supervisor)

_____

Date

_____

Dr. George Kiwango

(Co–Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

I, **Ilyas Masoud**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any university for similar or any other degree award.

Signature……..…… **Date** ……

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First and foremost, I offer my deepest gratitude to the Almighty GOD, whose grace has been my guiding light, providing me with the gift of life, daily sustenance, and the strength to bring this dissertation to fruition, ALHAMDULILLAH.

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Lastly, to my fellow residents, thank you for the camaraderie, the shared experiences, and the cherished moments during our training period.

DEDICATION

I dedicate this dissertation to my friend, lovely mother and confidant Aisha Saiwaad, everything I have and everything I am, is yours. For rich or poor, I want you to remember me like this.

ABSTRACT

Background: Ramadan fasting is a religious practice that involves abstaining from food and drink from dawn to sunset for a month. Millions of Muslims around the world observe this practice every year, but its effects on human physiology and health are not well understood. Previous studies have shown inconsistent and inconclusive results on the effects of Ramadan fasting on various physiological parameters, such as blood pressure, total body water, phase angle, and body fat percentage. Moreover, these studies have not considered the potential role of health behaviors, such as physical activity, and sleep patterns, in mediating or moderating the effects of fasting.

Objective: To evaluate the effects of Ramadan fasting and accompanying lifestyle changes on body composition, cellular health, and blood pressure in healthy males, and to determine if these physiological parameters are correlated and their state before, during and after Ramadan.

Materials and Methods: A quasi-experimental study was conducted on 26 healthy male Muslims aged 18-45. Participants were assessed a week before, the 3rd week of Ramadan, and 2 weeks after 30 days of Ramadan fasting. Blood pressure was assessed using a sphygmomanometer whereas fat free mass, total body water, phase angle, and body fat percentage were measured using bioelectrical impedance analyzer. Participants also provided demographic and health behaviors information via questionnaires. Statistical analysis was performed with STATA version 15, employing paired t-tests and Wilcoxon signed-rank tests to compare changes in body composition and blood pressure. Relationships between variables were examined using Pearson correlation coefficients. Significance was determined at $p < 0.05$ with a 95% confidence interval.

Results: Significant reductions were observed during Ramadan in waist circumference (81.76 cm to 80.72 cm; $p = 0.02$), hip circumference (96.84 cm to 95.57 cm; $p = 0.01$), and fat-free mass (59.55 kg to 58.11 kg; $p < 0.01$), while fat mass increased (9.20 kg to 10.37 kg; $p < 0.01$). Diastolic blood pressure showed moderate positive correlations with BMI, waist circumference, and total body water ($r = 0.45$, $p = 0.02$). After Ramadan, weight increased (68.45 kg to 69.25 kg; $p < 0.01$), along with fat-free mass percentage (85.96% to 88.04%; $p < 0.01$) and total body water (42.60 L to 44.56 L; $p < 0.01$). Phase angle improved

significantly post-Ramadan (7.12 to 7.53; $p < 0.01$). No significant changes were observed in blood pressure, BMI, or systolic blood pressure across the phases.

Conclusion: Ramadan fasting significantly impacts body composition and cellular health, with notable decreases in muscle mass and hydration during fasting. However, in healthy individuals, these changes tend to return to normal after the fasting period ends and are largely reversible, demonstrating the body's ability to recover in healthy individuals. Future studies should investigate whether the physiological flexibility observed in healthy individuals during Ramadan is maintained in individuals with underlying health conditions.

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LIST OF ABBREVIATION

BFP	Body Fat Percentage
BIA	Bioelectrical Impedance Analysis
BMI	Body Mass Index
BP	Blood Pressure
DBP	Diastolic Blood Pressure
ECW	Extracellular Water
ERC	Ethical Review Committee
ICW	Intracellular Water
MUHAS	Muhimbili University of Health and Allied Sciences
PA	Phase Angle
SBP	Systolic Blood Pressure
TBW	Total Body Water content

DEFINITION OF KEY TERMS

Ramadan fasting: Ramadan fasting is a religious practice that involves abstaining from food and drink from dawn to sunset for a month(1)

Blood pressure: Blood pressure is the force exerted by the blood against the walls of the blood vessels. It is measured by a sphygmomanometer in millimeters of mercury (mmHg) and expressed as two numbers: systolic blood pressure, which is the pressure when the heart contracts, and diastolic blood pressure, which is the pressure when the heart relaxes. According to the American Heart Association (AHA), normal blood pressure for adults (ages 20 and older) is less than 120/80 mmHg, whereas for adolescents the normal Systolic 112–128 mmHg, Diastolic 66–80 mmHg.

Hypertension (high blood pressure) is defined as having a systolic pressure of 130 mmHg or higher or a diastolic pressure of 80 mmHg or higher, most of the time.

However, it is important to note that recent guidelines have introduced new categories:

Elevated pressure: Systolic 120–129 mmHg and diastolic less than 80 mmHg.

Stage 1 hypertension: Systolic 130–139 mmHg or diastolic 80–89 mmHg.

Stage 2 hypertension: Systolic 140 mmHg or higher or diastolic 90 mmHg or higher.

Hypertensive crisis: Systolic higher than 180 mmHg and/or diastolic higher than 120 mmHg(2).

Total body water content: Total body water content is the amount of water in the body, which accounts for about 50-70% of the body weight. It is measured using bioelectrical impedance analysis. It is composed of two main compartments: intracellular water, which is the water inside the cells, and extracellular water, which is the water outside the cells(3).

Phase angle: Phase angle is a parameter derived from bioelectrical impedance analysis, which reflects the integrity and function of the cell membranes(4). It is calculated as the arc tangent of the ratio of the reactance and the resistance of the body. A higher phase angle indicates a higher cell membrane quality, and lower risk of mortality and morbidity, while a lower phase angle indicates a lower cell membrane quality and higher risk of mortality and morbidity(5).

Body fat percentage: Body fat percentage is the proportion of fat mass to total body mass. It is an indicator of body composition and health status, as excess body fat is associated with increased risk of chronic diseases, such as hypertension and diabetes.

For people aged 20 to 39, men should have 8% to 19%.

For people aged 40 to 59, men should have 11% to 21% body fat

For people aged 60 to 69, men should have 13% to 24% of body fat(6)

Waist Circumference: Waist circumference is the measurement taken around the narrowest part of the torso, typically just above the navel. It is a crucial indicator of abdominal fat, providing insights into central adiposity. Some changes in waist circumference during and after Ramadan may reflect shifts in fat distribution due to changes in eating patterns and physical activity during fasting(7).

Hip Circumference: Hip circumference measures the widest part of the buttocks. It is used in combination with waist circumference to assess the distribution of body fat, particularly through the waist-to-hip ratio. Changes in hip circumference can indicate alterations in overall body fat storage and distribution because of Ramadan fasting(8).

Fat-Free Mass (FFM): Fat-free mass refers to the total mass of the body minus all fat tissue. It includes muscle, bone, water, and other non-fat tissues. Changes in FFM to understand how muscle mass and hydration levels are affected during the fasting period and how they recover post-Ramadan, reflecting the body's adaptation to altered nutritional intake(9).

Body Mass Index (BMI): BMI is a measure of body fat based on a person's weight in relation to their height, calculated as weight (kg) divided by height squared (m^2). While BMI provides a general estimate of body composition, it does not distinguish between fat mass and lean mass. In this study, BMI is used as a general indicator of body size, but more specific measures like fat-free mass and body fat percentage offer a detailed understanding of the changes induced by Ramadan fasting(10).

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background Information

Abstaining from eating and drinking from dawn to dusk for an entire month, as practiced by millions of Muslims worldwide during the holy month of Ramadan, presents a unique opportunity to examine its effects on the body, mind, and spirit. This period of fasting has significant implications for physiological, psychological, and spiritual well-being(11). With the increasing prevalence of lifestyle-related diseases, the question of whether Ramadan causes improvement or deterioration in blood pressure and overall cellular health has become particularly intriguing. Ramadan fasting is a religious practice that is observed by Muslims during the ninth month of the Islamic lunar calendar. This religious fasting involves abstaining from food, drink, smoking, and sexual activity from dawn to sunset every day for the entire month(12). During Ramadan, the majority of Muslims eat two major meals- one before dawn (Suhr) and another immediately after the sunset (Iftar)(13).

Ramadan fasting differs from other types of intermittent fasting in several ways. It is obligatory for every adult Muslim who is sane, healthy, and not traveling, except for those with valid excuses such as illness, pregnancy, breastfeeding, menstruation, or old age(14). Other types intermittent fasting are optional and depend on the individual's choice and condition.

Ramadan has been shown to affect various physiological parameters, such as body composition, blood pressure due to a shift in feeding times, sleeping patterns and behavioral patterns such as physical activity(10). This religious fasting may lead to changes in body weight, body mass index, body fat percentage, and total body water, depending on the duration, timing, and intensity of fasting, as well as the feeding behavior and physical activity of the fasting individuals (15). Some studies have reported a significant decrease in body weight, body mass index, and body fat percentage, but no significant change in total body water, while others have reported no significant changes or even an increase in these parameters(16,17).

Previous studies have shown that Ramadan fasting may have a beneficial effect on blood pressure control, especially in hypertensive patients, by reducing the sympathetic nervous system activity. The calming effect from this spiritual practice is thought to be a reason for the improvements in lipid profile and endothelial function observed among hypertensive patients (18). These results could vary depending on the baseline blood pressure levels, the duration and timing of fasting and the hydration status, of the fasting individuals(19). More studies in different populations are needed to confirm the impact of Ramadan fasting on blood pressure and the mechanisms involved(7).

Put together this growing body of evidence implies that, Ramadan fasting is a complex and multifaceted phenomenon that affects various physiological and psychological parameters in different ways(20) The literature on this topic is not consistent and conclusive, and there are several gaps and controversies that need to be addressed. More research is needed to understand the effects of Ramadan fasting on physiological changes and their implications for health and disease(21). This study aimed to investigate the effects of Ramadan fasting on blood pressure, total body water content, fat free mass, cellular health measured as phase angle, and body fat in healthy adults. Additionally, it sought to explore potential correlations between these parameters and lifestyle parameters, particularly evaluating whether changes in cellular health and blood pressure are related to alterations in body composition, physical activity and sleep.

1.2 Problem Statement

Ramadan fasting, a religious practice involving abstention from food and drink from dawn to sunset for a month, is observed annually by millions of Muslims worldwide(22). Despite its widespread observance, the effects of Ramadan fasting on human physiology and health remain insufficiently understood.

Ramadan fasting promotes mindful eating, **as** the shortened eating window encourages moderation and restraint. Some individuals experience reduced body fat during Ramadan, and the combination of fasting, prayer and reflection, may help them recalibrate their relationship with food(23). Fasting is also believed to trigger autophagy(24), a cellular process where damaged components are recycled, akin to a cellular cleanse. Ramadan also encompasses spiritual practices such as nightly prayers (Taraweeh), and Quran recitation, which may reduce stress and calm the cardiovascular system(24,25).

During Ramadan, fasting for at least 13 hours can lead to hypercortisolism, especially in the evening, depleting liver glycogen stores and initiating a shift from lipid synthesis to fat mobilization via fatty acid oxidation and ketones(26). These physiological changes, due to extended fasting periods may help in managing lifestyle-related disorders such as obesity and insulin resistance(27,28).

However, changes in feeding and sleep schedules during Ramadan can act as stressors and negatively impact the body(29). Additionally, the consumption of high caloric foods, in a limited window, common during Ramadan could contribute to adverse health effects(30). Traditionally, Iftar and Suhoor meals are high in calories, often featuring sugary, fried and fat-rich foods, which can complicate the potential benefits of fasting(31).

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Previous studies have reported conflicting results on how Ramadan fasting affects physiological parameters, such as blood pressure, total body water, cellular health (phase angle), and body fat percentage(32). Few studies have explored the role of health behaviors like physical activity, and sleep patterns, in mediating these effects. Furthermore, given that meals during Ramadan are often high in sugar and fat, more research is needed to understand how these factors collectively influence body composition and overall health(33).

To the best of our knowledge, no study has been done in Tanzania to assess the effects of fasting in Ramadan on physiological parameters while controlling for heath behaviors. Thus, a comprehensive investigation is required to examine the physiological changes associated with Ramadan fasting and their relationship with health behaviors and outcomes.

1.3 Rationale of the study

Despite the widespread practice of Ramadan fasting, its effects on human physiology and health remain poorly understood(34). Previous studies have investigated physiological parameters such as blood pressure, total body water, phase angle, and body fat percentage, but findings have been inconsistent and inconcusive. Some studies point to positive effects such as reduced blood pressure, increased total body water, improved cellular health, and lower body fat percentage(35). In contrast, other studies report negative outcomes or negligible changes(36).

These inconsistencies may be arise from differences in fasting duration, climate, seasonal influences, lifestyle choices, and individual characteristics. Furthermore, most studies have not adequately accounted for health behaviors, such as sedentary time, physical activity, and sleep patterns which significantly change during Ramadan due to altered eating and sleeping schedules.

Therefore, a systematic investigation is necessary to explore the physiological changes during Ramadan fasting and how they relate to health behaviors is necessary(2). Such an investigation could provide valuable insights into optimizing health benefits, minimize risks, and guiding evidence based recommendations for fasting individuals and healthcare professionals, particularly in the context of Dar es Salaam.

1.4 Research Questions

1. How does body composition change (body fat, body water and fat free mass) before, during and after Ramadan
2. How does systolic and diastolic blood pressure change before, during and after Ramadan
3. How does cellular health (measured by phase angle) change before, during and after Ramadan
1. Are there any relationships between specific changes in body composition and alterations in lifestyle factors (physical activity and sleep duration)
4. Are there any relationships between specific changes in body composition and changes in blood pressure, before, during and after Ramadan

1.5 Objectives

1.5.1 Main Objective

To evaluate body composition changes, including body fat, fat-free mass, and body water, and their impact on cellular health and blood pressure in healthy males before, during, and after Ramadan.

1.5.2 Specific Objectives

1. To determine changes in body fat, fat-free mass, and body water before, during, and after Ramadan among healthy males.
2. To assess alterations in systolic and diastolic blood pressure before during and after Ramadan
3. To assess alterations in cellular health, as measured by phase angle, before, during, and after Ramadan among the fasting individuals.
4. To determine specific relationship between changes in body composition (body fat, fat-free mass, and body water) and alterations in lifestyle factors (physical activity and sleep duration)
5. To determine the potential correlations between specific changes in body composition and variations in blood pressure levels before, during, and after Ramadan fasting.

1.6 Conceptual Framework

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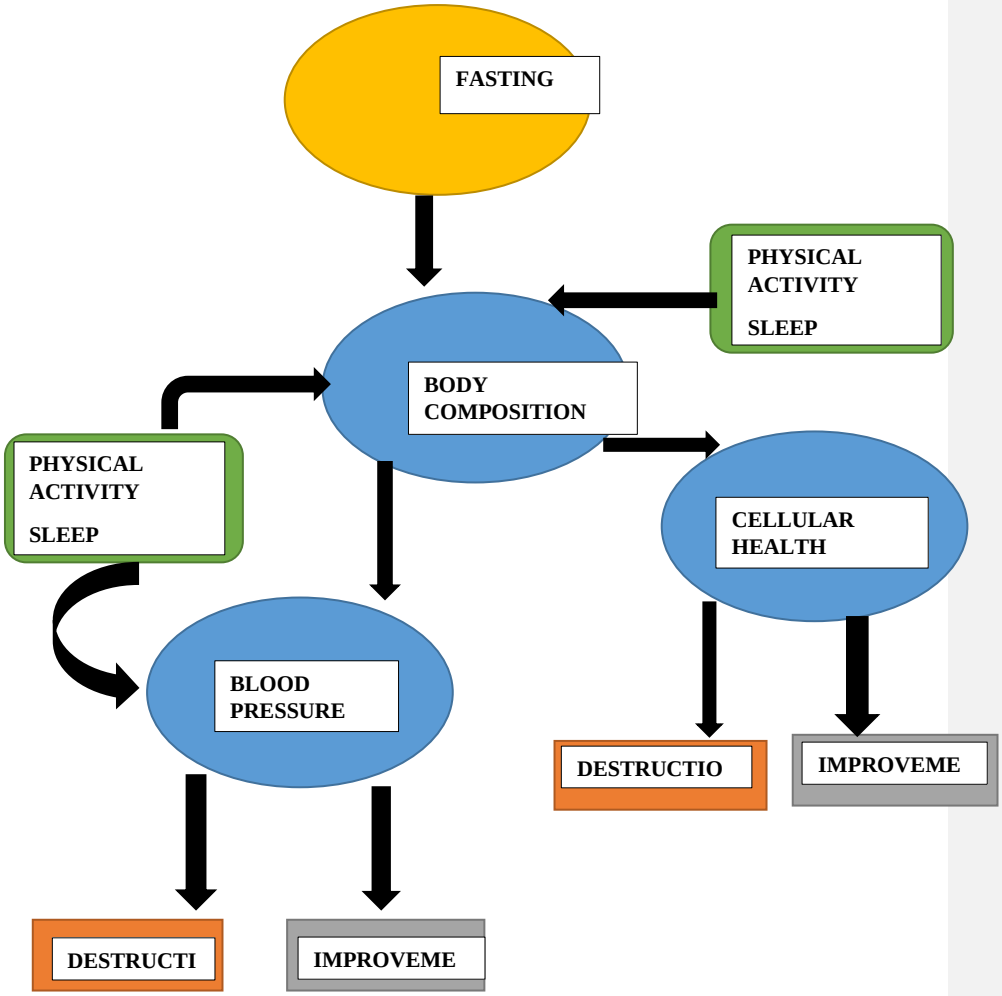


Figure 1: Conceptual framework

Description of the conceptual framework

Body composition may be influenced by fasting, sleep and physical activity.

We expect to see changes in body composition during fasting period.

Blood pressure levels may fluctuate during Ramadan due to changes in body composition and health behaviors (sleep and physical activity) during fasting period.

Cellular health may be influenced by fasting and body composition due to changes in body composition during fasting period.

Blood pressure and cellular health may deteriorate or improve as a result of fasting and body composition changes.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

Fasting is a practice that involves abstaining from food and drink for various periods and has been employed for both spiritual and health purposes across different cultures and religions. Intermittent fasting, a modern approach to fasting, is an interventional strategy that alternates between periods of eating and fasting. Unlike traditional diets that focus on reducing calories, intermittent fasting emphasizes the timing of food intake rather than its quantity or type. This method aims to optimize health by restoring cellular homeostasis, increasing antioxidant defenses, suppressing inflammation, promoting weight loss, and enhancing metabolic processes. Common forms of intermittent fasting include Time-Restricted Fasting (TRF), Alternate Day Fasting, and the Warrior Diet(27).

Religious fasting, such as the fasting observed during the holy month of Ramadan by Muslims, known as Sawm, represents a specific type of intermittent fasting. Ramadan fasting is distinct in that it combines spiritual purification, self-discipline, and devotion to God (Allah) with the practice of fasting. Unlike other forms of intermittent fasting(37), which may allow flexibility in choosing fasting and eating windows, Ramadan fasting adheres strictly to a dawn-to-dusk schedule, during which Muslims abstain completely from food, drink, smoking, and sexual activity(38).

The health impacts of Ramadan fasting are an area of growing interest and importance(23,24)(22). Investigating the effects of Ramadan fasting on body composition, such as fat mass, and on physiological parameters like blood pressure can provide valuable insights into its health implications. This understanding can help inform dietary recommendations and health management strategies for those observing Ramadan.

Studies on the health effects of intermittent fasting, including Ramadan fasting, have yielded mixed results. Some research indicates that intermittent fasting can improve body composition, reduce ectopic fat, and positively influence cardiometabolic factors compared to unrestricted eating(39). However, most studies have not found additional benefits beyond

these improvements, though some preliminary data suggest intermittent fasting might provide cardiometabolic benefits even in the absence of weight loss(40).

2.2 Variations in Body Composition

Studies consistently report alterations in body composition during Ramadan. While some individuals experience weight loss and reduced body fat, others may maintain or even gain weight. A study done on 23 subjects to investigate the effect of Ramadan fasting on body fat percentage showed that Ramadan fasting had a positive effect on their body fat as it decreased gradually from the first week towards the fifth week(35). This was not in congruent with another study whose aim was to measure anatomical, physiological and cognitive function of healthy individuals practicing fasting during Ramadan as it leads to fat free mass reductions and cognitive functions(41). The duration and intensity of fasting, dietary habits, and individual variability contribute to these variations

2.3 Blood Pressure Alterations

Monitoring blood pressure during fasting is crucial for identifying potential risks. One study evaluated the impact of Ramadan fasting on blood pressure levels in patients with hypertension. It reviewed 10 studies that compared blood pressure measurements before, during, and after Ramadan in hypertensive patients who fasted or did not fast. Blood pressure responses during Ramadan are diverse. Some individuals exhibit lower blood pressure, while others remain unchanged. Factors such as hydration status, meal timing, and overall health play a role. The article concluded that Ramadan fasting may have a beneficial effect on blood pressure control, but the results are inconsistent and more high-quality studies are needed to confirm this finding(42).

2.4 Cellular Health and Phase Angle

One study examined the effect of Ramadan fasting on cellular health, as measured by phase angle, a bioelectrical impedance parameter that reflects the integrity and quality of cell membranes. It measured phase angle in 30 healthy adults before, during, and after Ramadan. Ramadan fasting may influence phase angle values due to shifts in hydration, nutrient intake, and metabolic adaptations. This study finds that Ramadan fasting increased phase angle

significantly, indicating an improvement in cellular health and function. Although the study included a moderate sample size, larger studies are needed for validation and the results remain inconclusive(9)

2.5 Associations between Body Composition and Cellular Health

Some studies suggest that as individuals shed excess body fat, their cellular health may improve. Reduced fat mass could lead to less inflammation, better insulin sensitivity, and enhanced mitochondrial function. The month of Ramadan, with its daily fasting from dawn to sunset, offers a unique natural experiment. Observers alter their eating patterns, potentially impacting body composition and cellular health. Limited evidence suggests that improvements in body composition (e.g., reduced body fat) may correlate with favorable changes in cellular health(43). However, more rigorous studies are needed to establish causality by considering factors like sex, age and genetics(33)

2.6 Associations between Body Composition and Blood Pressure

While some studies suggest links between weight loss and blood pressure reduction, individual responses vary. Factors such as sodium intake, physical activity, and genetic predisposition contribute to this complex relationship. One article investigated the effect of body composition and the characteristic of metabolic syndrome in apparently healthy Muslims, especially in hot environments. It measured 44 students in college and showed no significant changes in body composition before and after Ramadan, but there was a slight but significant elevation in SBP during and after Ramadan(36).

CHAPTER THREE

3.0 MATERIAL AND METHODOLOGY

3.1 Study Design

This is a quasi-experimental study design involving data collection of body anthropometric measures, body composition and blood pressure repeatedly at different time periods (a week before Ramadan, end of week 2 (day 15 to day 20) during Ramadan and two weeks after 30 days of Ramadan fasting).

3.2 Study setting and study area

The study was conducted in Dar es salaam, Tanzania. It is one of the fastest growing cities globally making it relevant for urban health research. The city has a large and diverse Muslim population, who observe Ramadan fasting every year, and who may have different physical activity and sleep habits during the Ramadan. The city also has various environmental and climatic factors, such as high temperature and humidity that may affect the physiological parameters of the participants, such as blood pressure, body water, phase angle, and body fat (44).

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3.3 Study Population

Healthy male Muslims aged 18 to 45 years who live in Dar es Salaam and intend to fast during Ramadan. Targeting males, within a narrow age range was sought to minimize bias that can be introduced by sex and age variation.

3.4 Inclusion and exclusion criteria

3.4.1 Inclusion criteria

1. Being a healthy adult male aged 18 to 45 years
2. Being willing to participate in the study and have signed the informed consent
3. Intending to fast throughout the month of Ramadan

3.4.2 Exclusion criteria

1. Having any chronic or acute medical condition
2. Taking any medication that may affect the physiological parameters
3. Having any dietary or physical activity restrictions
4. Age above 45 years

3.5 Sample Size

The sample size was calculated based on the primary outcome of blood pressure (SBP).

The study recruited 29 participants based on the suggested beneficial effects of Ramadan fasting on blood pressure independent of changes in weight, total body water, and fat mass and supported recommendations for some governmental guidelines that described Ramadan fasting as a safe religious practice with respect to blood pressure.

In order to calculate the appropriate sample size for this study, we used the effect size derived from the London's Ramadan Study (LORANS)(42), which investigated the effect of Ramadan fasting on blood pressure. The effect size (Cohen's d) for the change in systolic blood pressure was 0.78, indicating a large effect. Therefore, a small sample size is acceptable to be statistically significant.

The sample size calculation was based on a repeated measures design, taking measurements at three time-points from a single group**:**

$$\mathbf{n = \frac{2 * (Z_{\alpha/2} + Z_{\beta})^2 * \sigma^2}{\Delta^2}}$$

We assumed a significance level (α) of 0.05 and a power (1 - β) of 80%, resulting in Z-scores of 1.96 and 0.84, respectively. The standard deviation of systolic blood pressure was 9.4 mmHg. Therefore, the minimum detectable difference (Δ) between pre- and post-Ramadan SBP means was calculated as the product of the effect size and the standard deviation, which resulted in a value of 7.3 mmHg.

Plugging these values into the sample size formula, we obtained the following result:

$$n = \frac{2 * (1.96 + 0.84)^2 * 9.4^2}{(7.3)^2}$$

$$n \approx 25.7$$

Considering that a fractional participant is not possible, we rounded up the value to the nearest whole number, which resulted in a required sample size of 26 participants. Adjusting for the expected attrition rate, we targeted to enroll 29 participants.

3.6 Sampling technique

The study employed non-probability sampling, specifically convenience sampling. Participants for this study were recruited from several mosques in Dar es salaam, Tanzania. The selection of mosques followed a purposive sampling approach, aiming to include a variety of mosques across different districts of the city (Kinondoni, Ilala, Ubungo and Temeke) to ensure diversity in the participant pool. Mosques with large congregations and those located in different areas of the city were chosen to maximize participant reach. At least three participants were recruited from each district.

3.7 Variables

3.7.1 Dependent variables

- Phase angle, total body water content, blood pressure, BMI, body fat percentage, fat-free mass, anthropometric measures (body weight, height, waist and hip circumference).

3.7.2 Independent variables

- Ramadan fasting status (fasting(during) and non-fasting periods (before and after))

Primary outcome measures

1. Blood pressure
2. Cellular health (Phase angle)

3.8 Data Collection

3.8.1 Quantitative component:

The structured questionnaire was used to collect demographic information and self-reported health behaviors data (physical activity, sleep duration, smoking and alcohol use) and physiological measurements were taken to assess anthropometric measurements, blood

pressure (DBP and SBP), body composition (BFP, FFM TBW and PA) before, during and after Ramadan fasting.

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3.8.2 Screening and Recruitment

Mosque leaders were approached in person, explaining the objectives and benefits of the study, along with assurances of confidentiality and respect for religious practices. Once mosque leaders granted permission, they facilitated the recruitment process by announcing the study after prayers and allowing me to engage with interested congregants. After announcements were made by mosque leaders. I stationed myself outside the mosque to provide additional information about the study to potential participants. Information pamphlets were also distributed, detailing the study objectives, procedures, and inclusion criteria. Participants interested in the study were encouraged to come forward voluntarily. They were screened on-site to determine eligibility based on inclusion criteria: male, healthy, aged 18-45, Muslim, and intending to fast for the full duration of Ramadan.

Eligible participants underwent an initial health assessment, including measurements of blood pressure, body composition, and demographic information collection. Potential participants with abnormal findings, such as high blood pressure or medical conditions that could compromise their health during the fasting period, were informed of their results and referred to appropriate healthcare services for further evaluation. These individuals were not included in the study to ensure their safety. Participants who did not meet the inclusion criteria (e.g., those with pre-existing health conditions, abnormal blood pressure readings, or those not fasting for the full duration) were politely informed that they could not participate in the study. They were provided with an explanation for exclusion and were advised to seek medical follow-up if any abnormal findings were detected during the initial screening. In these cases, participants were also thanked for their willingness to participate, and they were reassured that their privacy would be maintained.

Informed consent was obtained from those who agreed to participate after being provided with detailed information about the experiment, its objectives, procedures, potential risks, and benefits. Following informed consent, participants underwent a baseline assessment (section below) and were enrolled in the study. This baseline assessment served as the

starting point for tracking their progress throughout the fasting period and non-fasting periods.

3.8.3 Baseline Assessment

- Baseline questions: Participants were asked to provide demographic information and required to fill in the questionnaire that requires information about their health behaviors
- Anthropometric Measurements: Measurements of height, weight, and waist circumference were taken using standardized techniques and calibrated equipments. Body mass index (BMI) was calculated by dividing weight in kilograms by height in meters squared (kg/m2). These measurements helped evaluate the participants' initial body composition and monitor changes throughout the experiment.
- Blood pressure: Blood pressure was measured using a sphygmomanometer, an electronic blood pressure monitor. Participant were asked to sit quietly for 5 minutes before the measurement and to avoid talking, smoking, or drinking caffeine for at least 30 minutes before the measurement. The measurement was repeated twice and the average was recorded.
- Body composition: Participants body composition was measured using bio impedance analysis (BIA). Participants were asked to remove shoes, socks, and any metal objects from body and to lie down on a mat. Electrodes were attached to hands and feet and a small electric current was passed through their body. The measurement took a few minutes and participants did not feel any pain but may have felt some discomfort.
- Physical Activity Assessment: Participants were asked to provide information about their current physical activity levels, including the intensity, duration, and frequency of activities performed. Physical activity was categorized as low, moderate and vigorous depending on the number of minutes performed per week and the intensity accordingly using a standard Likert scale
- Sleep quality assessment: To assess sleep quality over the past 30 days, participants completed a self-report questionnaire evaluating sleep onset, duration, continuity, and morning refreshment, selecting from three categories: less than 6 hours, 6-7 hours, and more than 7 hours. To determine changes in sleep patterns during

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Ramadan fasting, participants indicated whether their sleep had changed, and if so, described the nature of these changes: less sleep at night due to prayers and meals, more naps during the day, difficulty falling asleep or waking up frequently, feeling less refreshed in the morning, or other specified changes.

- However, sleep quality and physical activity was assessed across all the time points (before, during and after Ramadan)

3.9 Data Analysis

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Quantitative Data Analysis: Data was entered and cleaned on Microsoft excel and then analyzed using STATA software version 15. Descriptive statistics were calculated to summarize the demographic and lifestyle characteristics of the 26 healthy adult male participants. This included percentages and frequencies for variables such as age, smoking habits, alcohol consumption, sedentary behavior, and overall health ratings.

Before conducting further statistical analyses, normality tests were performed on the continuous variables to determine if they were normally distributed. The Shapiro-Wilk test was employed for this purpose. If the p-value of the Shapiro-Wilk test was greater than 0.05, the data was considered normally distributed. If the p-value was less than 0.05, the data was not normally distributed, indicating the need for non-parametric tests.

To analyze changes in physical activity and sleep duration before, during, and after Ramadan, descriptive statistics and repeated measures ANOVA were used. The repeated measures ANOVA assessed the mean differences across the three time points (before, during and after Ramadan).

Repeated measures ANOVA was also employed to analyze changes in body composition parameters across the three time points (before, during, and after Ramadan). The parameters analyzed included phase angle, blood pressure (DBP and SBP), fat-free mass (FFM), body fat percentage, and total body water (TBW). Post-hoc tests with Bonferroni correction were used to identify specific time points with significant differences. Significant fluctuations were identified and reported with p-values indicating statistical significance ($p<0.01$).

Pearson correlation coefficients were calculated to explore relationships between lifestyle factors (physical activity and sleep) and body composition parameters during Ramadan.

Additionally, Pearson correlation coefficients were calculated between physical activity, body composition parameters and blood pressure were analyzed. Statistical significance was set at $p < 0.05$ with a 95% confidence interval.

3.10 Ethical Consideration

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The study adhered to the principles outlined in the Helsinki Declaration to ensure the ethical conduct of medical research. This included prioritizing the safety and well-being of participants, ensuring that the health benefits of the study outweighed any potential risks, and upholding principles of justice.

Participation in this study did not involve any significant risks. The procedures, including the administration of questionnaires and body composition measurements, were non-invasive and posed no serious health threats. Participants might have experienced minor discomfort or inconvenience during the measurement procedures.

Although there were no direct benefits to participants, the data collected from this study could contribute to the advancement of scientific knowledge and potentially benefit individuals fasting during Ramadan in the future. Moreover, participants had the opportunity to contribute to the improvement of healthcare practices and scientific research.

An informed consent form was provided to each participant, who had the freedom to join the study voluntarily and the right to withdraw at any time without any consequences. This ensured that participants retained all their rights throughout the study.

Confidentiality was strictly maintained. Participant information was accessible only to the researcher, and questionnaires were anonymized by using numerical identifiers instead of real names. The results of the study were shared with participants upon its conclusion.

Ethical clearance was obtained from the institutional review board of MUHAS. Additionally, permission to conduct the study within the physiology laboratory was secured from the head of the Department of Physiology

3.11 Dissemination Plan

Following data analysis and study completion, study results will be written up for publication in a scientific journal article. Additionally, results will be packaged into PowerPoint Presentations for dissemination to relevant parties including MUHAS and other stakeholders such as the Ministry of Health.

CHAPTER FOUR

4.0 RESULTS

4.1 Demographic and lifestyle characteristics of study participants (n=26)

A total of 26 healthy adult males were included in the study. Participants had a mean age of 28 ± 6.59 years, with majority (n=13; 50.2%). A majority of participant spent seven or more hours sedentary daily (n=15; 57.7%). When asked about their overall health and well-being, the majority of participants rated their health as good (n=12; 46.2%). As shown in table 1.

Table 1: Demographic and lifestyle characteristics (n=26)

Characteristic	n (%)
Age group	
19-24	9 (34.6)
25-34	13 (50.2)
35-44	5(18.4)
Sedentary behavior	
3-6 hours	11(42.3)
7+	15 (57.7)
Overall health and well-being	
Excellent	4 (15.4)
Good	12 (46.2)
Fair	10 (38.4)

Changes in physical activity and sleep duration among participant during study duration

Concerning sleep duration, before Ramadan, most participants (n=13; 43%) slept 6-7 hours, with fewer sleeping more than 7 hours (n=9; 30%). During Ramadan, more participants slept over 7 hours (n=13; 43%), while those sleeping 6-7 hours decreasing to (n=9; 30%). After Ramadan, still a majority (n=12; 40%) slept over 7 hours ($p>0.05$). As shown in figure 2

In-terms of physical activity, most participants (n=12; 40%) reported vigorous activity before Ramadan. Whereas during Ramadhan, the majority (n=18; 60%) of participant were observed to have low physical activity. Post-Ramadan, a shift to vigorous activity among participant (n=16; 53%) was observed ($p<0.05$). As show Figure 3.

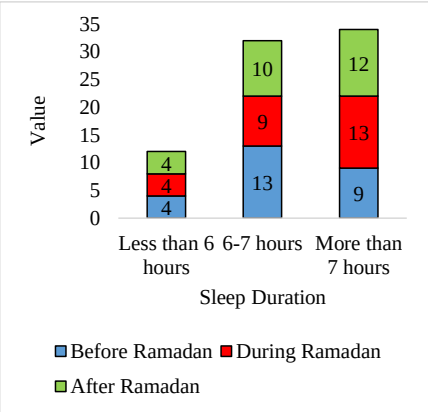


Figure 2: Change in Sleep duration before, during, and after Ramadan among 26 participants

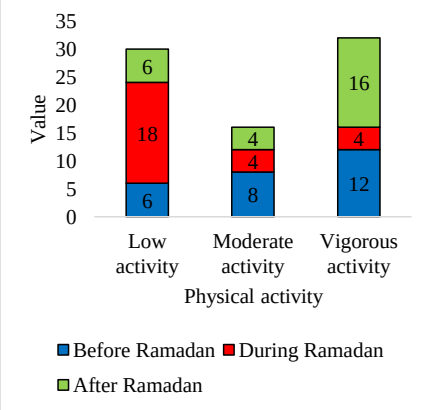


Figure 3: Change in Physical activity levels before, during and after Ramadan (n=26)

4.2 Change in body composition (Percentage body fat, fat-free mass and total body water) over time (n=26)

In terms of fat-free mass (FFM), there was a decrease from 59.55 kg before Ramadan to 58.11 kg during Ramadan ($p<0.01$), but it increased to 60.24 kg post-Ramadan ($p<0.01$) (Figure 6).

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The body fat percentage increased from 12.2% before Ramadan to 14.0% during Ramadan ($p<0.01$), followed by a decrease to 12.0% post-Ramadan ($p<0.01$) (Figure 5). Post Ramadan, total body water (TBW) showed a significant increase from 42.60 liters during Ramadan to 44.56 liters two weeks post-Ramadan ($p<0.01$) (Figure 7).

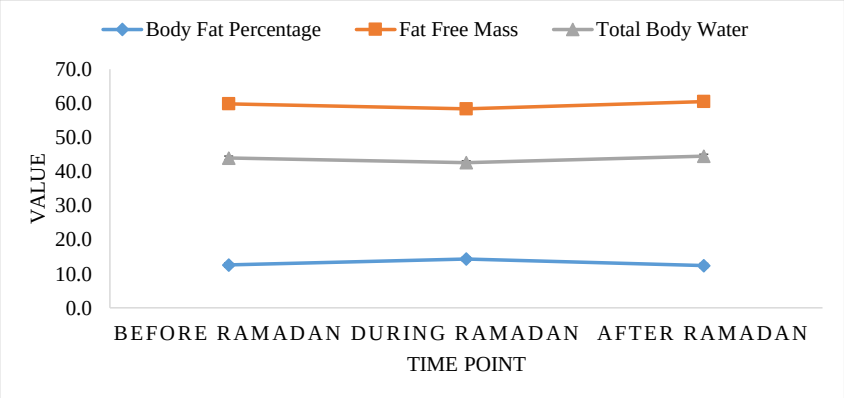


Figure 4: Body composition trends before, during and two weeks after Ramadan)

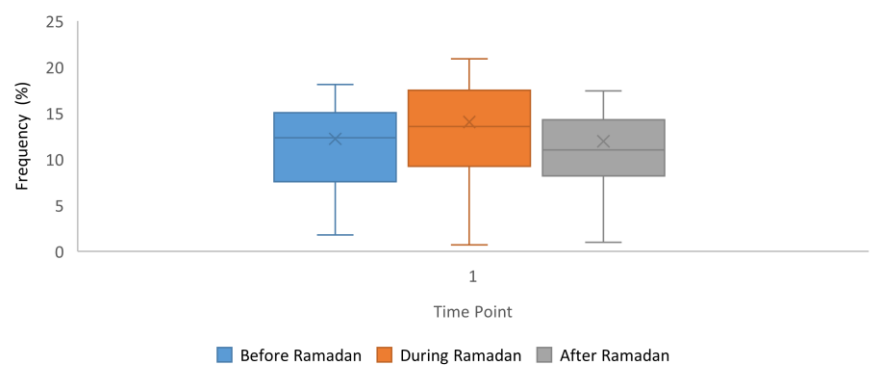


Figure 5: Distribution of body fat percentage before, during and two weeks after Ramadan

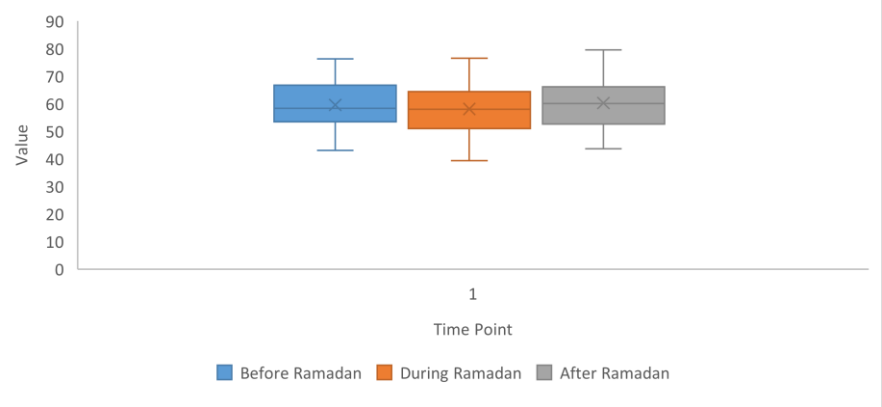


Figure 6: Distribution of fat free mass before, during and two weeks after Ramadan

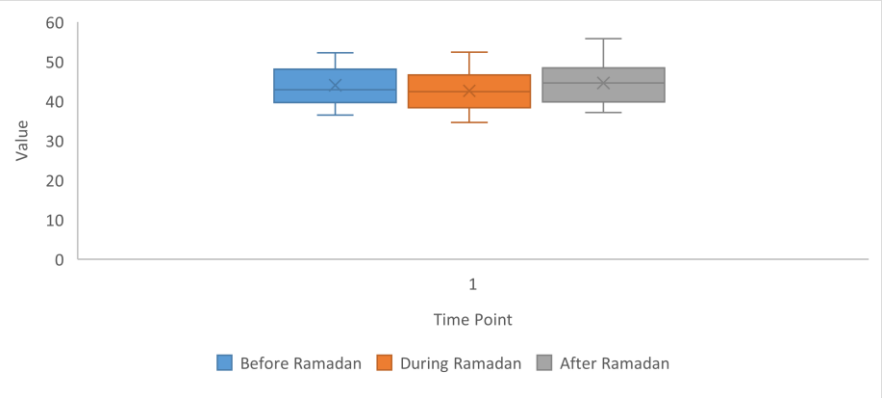


Figure 7: Distribution of total body water before, during and two weeks after Ramadan

Alterations in systolic and diastolic pressure over time

Blood pressure showed minor changes. Systolic blood pressure (SBP) slightly decreased from 118.34 mmHg before Ramadan to 117 mmHg during Ramadan, though this change was not statistically significant (p=0.45) (Figure 9). Diastolic blood pressure (DBP) slightly increased from 73.92 mmHg before Ramadan to 76.03 mmHg during Ramadan (p=0.15), and continuing decreasing post Ramadhan decreasing to 74.80 mmHg (p=0.35 (Figure 10).

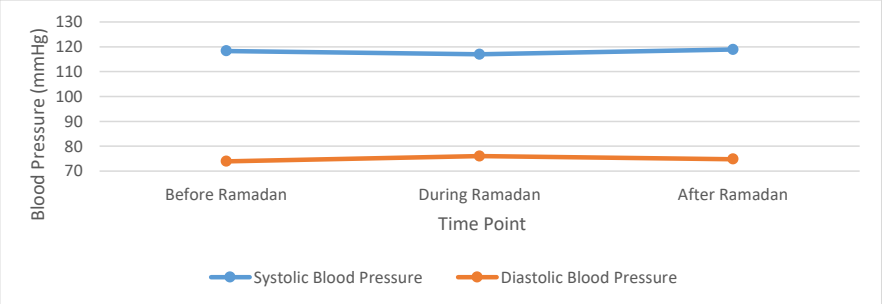


Figure 8: Systolic and diastolic blood pressure trends over time (Before, during and two weeks after Ramadan)

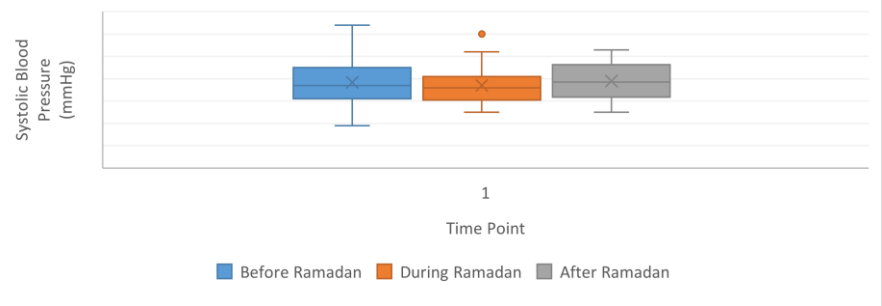


Figure 9: Distribution of systolic blood pressure before, during and two weeks after Ramadan

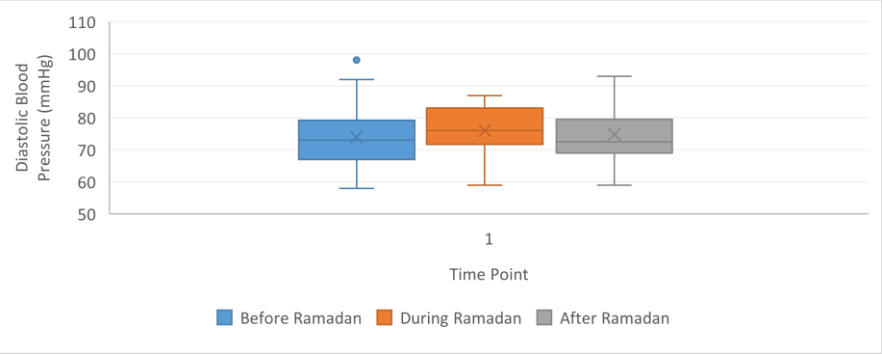


Figure 10: Distribution of diastolic blood pressure before, during and two weeks after Ramadan

Changes in cellular health as measured by phase angle over time (n=26)

During Ramadan, phase angle, indicating cellular health, declined from 7.45 to 7.12 ($p<0.01$) compared to before Ramadan. Meanwhile cellular health as measured by phase angle improved from 7.12 to 7.53 ($p<0.01$) post Ramadan as compared to during Ramadan

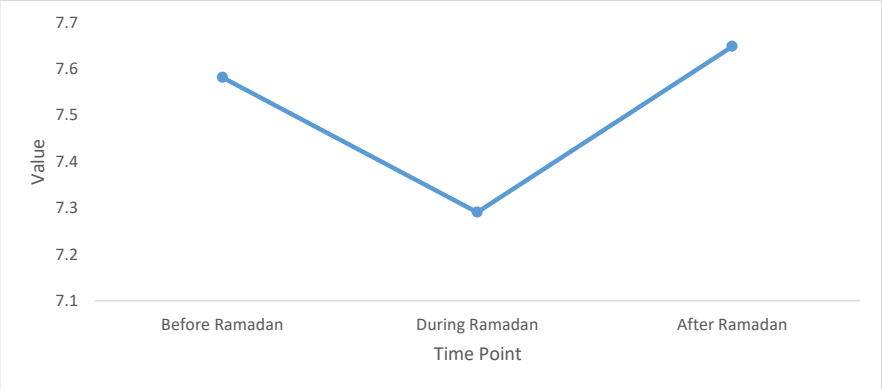


Figure 11: Cellular health trends over time (Before, during and two weeks after Ramadan)

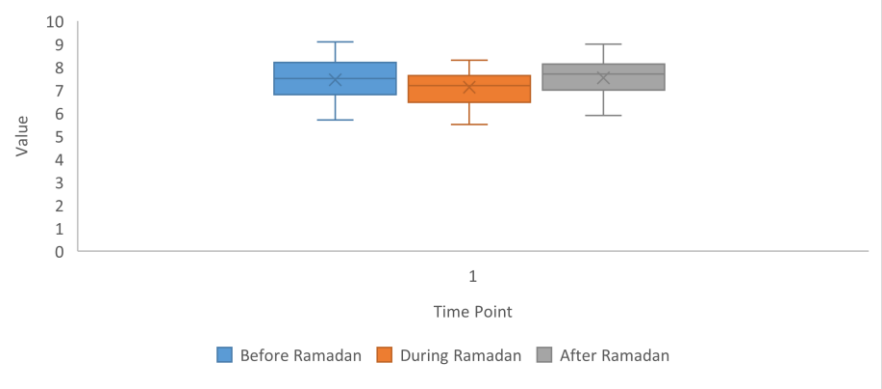


Figure 12: Distribution of phase angle before, during and two weeks after Ramadan

Correlations between Body Composition and Alteration in Lifestyle factors (Physical activity and Sleep) During Ramadan in Healthy Male Subjects (n=26)

The study explored the correlations between specific lifestyle factors (physical activity and sleep) and various body composition parameters during Ramadan. Throughout the fasting period, physical activity and sleep duration showed generally weak and non-significant correlations with most body composition parameters. However, there was a moderate negative correlation between physical activity and percentage body fat ($r = -0.5$, $p = 0.0080$). In addition, sleep showed no significant correlations with all body composition parameters.

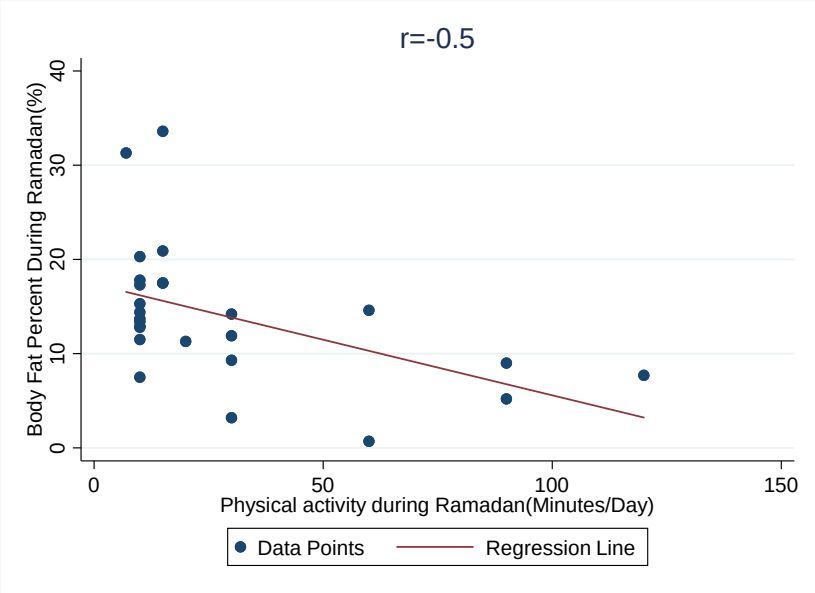


Figure 13: Correlations between Percentage body fat and Physical activity During Ramadan in Healthy Male Subjects (n=26)

Correlations between Body Composition and Blood Pressure Before, During and After Ramadan (n=26)

The study explored the correlations between various body composition parameters including BMI, waist circumference, hip circumference, total body water (TBW), fat mass, and fat-free mass (FFM) and blood pressure parameters during the different phases of Ramadan.

Before Ramadan, DBP consistently showed moderate positive correlations with BMI, waist circumference, hip circumference, and TBW before, during, and after Ramadan. Specifically, after Ramadan, DBP correlated moderately with BMI (r = 0.4525, p = 0.02), reflecting the influence of body composition on vascular resistance

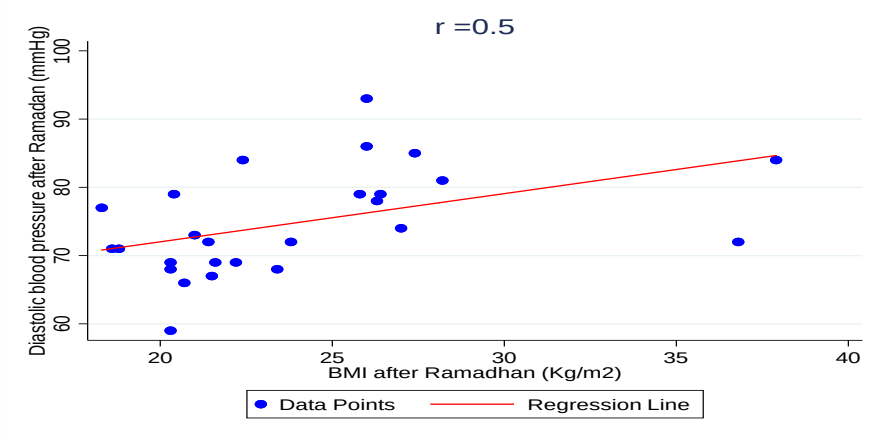


Figure 14: Correlation between Diastolic Blood Pressure and BMI after Ramadan

CHAPTER FIVE

5.0 DISCUSSION

This study examined the physiological changes in body composition, blood pressure, and cellular health among 26 healthy adult males before, during, and two weeks after Ramadan fasting. The findings indicate that the fasting period significantly and negatively impacts body composition and cellular health but not blood pressure, with body composition and cellular health returning to normal, two weeks after Ramadan

Compared to the period just before Ramadan, we found significant reductions in waist and hip circumferences during the fasting period suggesting a decrease in overall body size(8,35). Despite this, body fat percentage increased, indicating a shift towards higher fat storage. This increase in body fat can be attributed to the altered eating schedule and disrupted circadian rhythm(29,45). During Ramadan, intake of high calorie meals is often concentrated in the evening (iftar at 1830hrs) and pre-dawn hours (0430hrs). Given that these are predominantly inactive hours, the consumption of energy-dense foods during this period could create a negative energy balance, leading to fat storage(39,46,47).

Additionally, the altered eating schedule that occur in Ramadan could interfere with the normal sleep-wake-cycle, consequently disrupting the circadian rhythm. This disruption can contribute to obesity through several fat-storing mechanisms(48,49). Elevated levels of hormones cortisol, ghrelin and leptin, along with decreased levels of melatonin, have all been implicated in circadian-related fat gain in both humans and animals(48,49). Many studies have demonstrated that cortisol levels rise during the nighttime when there is sleep deprivation or disruption, as it happens in Ramadan(50,51). Elevated cortisol levels are also known to trigger muscle loss(52,53), which may explain the decreased fat-free mass observed during Ramadan in our study. Furthermore, the relatively high-calorie meals commonly consumed during this religious practice may compete with protein intake, further contributing to the overall decrease in fat-free mass observed.

Conversely, total body water decreased during Ramadan, along with reduction in fat-free mass and an increase in total body fat. Although reduced water intake during Ramadan could contribute to decreased total body water, the overall reduction observed is primarily due to changes in cellular water-holding capacity (54). Physiologically, muscle cells (part of the fat-free mass) hold more water than fat cells, explaining the concurrent decrease in total body water and fat-free mass (55). Consequently, overall cellular health, measured as BIA-phase angle, showed a significant decline during Ramadan, indicating a reduction in cell membrane integrity, cellular mass, quality of lean tissue and overall cellular health. Healthy cells are characterized by high membrane integrity and water-holding capacity, which together are reflected as a high phase angle in BIA measurements (54).

Despite drop in phase angle during Ramadan, the phase angle increased significantly two weeks after the fasting period. At a cellular level, this transient drop in phase angle (which also reflect cell density) may also indicate increased cellular turnover and autophagy, where the body clears damaged cells, organelles and proteins and recycles cellular components as an adaptive response to fasting(24). Indeed, the significant improvement post-Ramadan suggests a recovery and enhancement of cellular health when regular eating patterns resumed(29). The presence of antioxidants and phytonutrients, one among a few key nutrients for recovery found in fruits and veggies help mitigate oxidative damage brought about by fasting to cellular structures(13). One typical justification for this, are foods such as fruits and vegetables, which are rarely if any, included in the two meals of iftar and suhoor(23). These are commonly reintroduced in greater quantities post-Ramadan. Together, these nutrients whose intake was restricted mid Ramadan, support the increase in phase angle by improving membrane stability and cellular health.

Interestingly, despite the deleterious changes observed during Ramadan, blood pressure parameters remained relatively stable throughout the study, with only minor and non-significant changes observed. Systolic blood pressure slightly decreased during Ramadan, while diastolic blood pressure increased slightly. Previous studies conducted during Ramadan have shown that Ramadan fasting in hypertensive patients can lead to a significant decrease in overall blood pressure, (35). Similarly, in our study, we observed a slight, albeit not significant, decrease in systolic blood pressure during Ramadan. This suggests that in healthy individuals, the perturbations in body composition that accompany Ramadan fasting

do not necessarily impact negatively, the systolic blood pressure. Except for a significant positive correlation between DBP and BMI that was observed two weeks after Ramadan, blood pressure parameters showed no correlation with body composition parameters.

Several studies have examined the effect of Ramadan fasting on blood pressure. A study involving 85 participants (aged 29 to 61) from five mosques in London reported interesting findings. After adjusting for variables such as age and gender, they observed an average reduction of 7.29 mmHg in systolic blood pressure and 3.42 mmHg in diastolic blood pressure in the days immediately following Ramadan (28). The results held true for healthy people, as well as those with high blood pressure(2) and diabetes(38,56,57). The mental and emotional benefits of Ramadan, including spiritual practices such as prayers and recitation of the Quran, likely contributed to the stable blood pressure observed, as participants reported experiencing profound calmness and increased peace of mind. Overall, the psychological impact of spirituality accompanying Ramadan fasting induces a calming effect through various mechanisms (21), which may help maintain stable cardiometabolic parameters despite some physiological perturbations. Further research is needed to clarify the interaction between physiological and psychological pathways during Ramadan.

Post-Ramadan, a significant increase in BMI, WC and HC was observed along with an increase in body fat, reflecting a resumption to normal eating patterns. All subjects in our cohort reported to have resumed to their normal daily routine including normal eating and sleeping patterns. Fat-free mass increased significantly also due to resumption to normal feeding and sleeping patterns. Cellular health as reflected by an increase in phase angle improved significantly along with an increase in total body water. Additionally, reported mean physical activity time significantly increased as people were resuming to normal routines. This further explain the improvements in body composition and overall cellular health observed two weeks after Ramadan.

As people were resuming to normal routines, a significant improvement in reported physical activity but not sleeping time was observed. Given that most participants were taking more day-time naps during Ramadan to compensate for the time they remained awake for iftar and suhoor, sleeping time did not change significantly before, during and after Ramadan. Regular physical activity boosts the overall energy expenditure causing a negative energy

balance which favor fat use(58,59). In deed our findings revealed a moderate negative correlation between physical activity and body fat percentage ($r = -0.5$, $p = 0.0080$). This indicates that increased physical activity is associated with a reduction in body fat(11), supporting the idea that maintaining physical activity during fasting can help mitigate fat accumulation.

Furthermore, regular use of muscles that occur during physical activity contribute to an increasing muscle mass which in turn improves the overall metabolism cellular water holding capacity(58,59). These physiological changes seem to have contributed to the overall improvements in body composition and cellular health (Measures as a decrease in body fat and increases in fat-free mass, total body water and phase angle) observed two weeks after Ramadan fasting. Overall, this implies that in healthy males, the perturbations in body composition and cellular health that occur during Ramadan fasting are not permanent, they revert back to normal two weeks after the period of fasting.

5.1 Study Limitations

Despite providing important physiological and psychological insights in relation to Ramadan fasting and health, findings from this study should consider the following limitations

1. Specific population: The exclusive focus on healthy adult males means the findings may not be applicable to females or individuals with underlying health conditions. Furthermore, the study's context, including cultural practices and geographic location, may influence the results, limiting the applicability to other populations with different fasting practices or environmental conditions.
2. Short-Term Focus: The study examines changes only during one Ramadan period and the subsequent two weeks, which may not capture long-term or cumulative effects of repeated annual fasting.
3. Self-Reported Data: Reliance on self-reported sleep and physical activity time may introduce bias or inaccuracies, affecting the reliability of the findings.
4. Discussion based on specific dietary assumptions: While the timing, quantity, and quality of meals consumed during Ramadan are generally uniform, variations can occur. This study did not consider these variations, and the discussion and conclusion related to diet are based on general assumptions. It is important to note that the

discussion is not focused specifically on the details of dietary intake, but rather on Ramadan fasting in general.

5.2 Strength of the study

Despite the above limitations, this study has the following strength

1. Objective measurements of physiological parameters and comprehensive Analysis: The study provides a thorough examination of multiple physiological parameters, including body composition, blood pressure, and cellular health, offering a detailed understanding of the effects of Ramadan fasting.
2. Controlled Variables and temporal assessment in a quasi-situation: By focusing on healthy adult males and adjusting for age and **sex**, the study minimizes confounding factors, allowing for a more accurate assessment of the fasting impacts. Additionally, the inclusion of measurements before, during, and after Ramadan allows for a clear observation of the temporal changes and recovery patterns associated with real life fasting.
3. Use of holistic approach and advanced techniques: The study utilizes bioelectrical impedance analysis (BIA) to measure phase angle, providing insights into cellular health and integrity, which adds a novel dimension to understanding the impacts of fasting. By considering both physiological and psychological aspects, the study acknowledges the complex interplay between mind and body, providing a more comprehensive view of health during Ramadan.
4. Measurement error was minimized by using standardized measurement protocols and calibrated equipment such as bioelectrical impedance analysis and blood pressure monitors. Additionally, conducting repeated measurements and averaging the results helped reduce random error

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

In conclusion, this study demonstrates significant but reversible perturbations in body composition and cellular health among healthy males during Ramadan fasting. These changes are attributed to the intake of energy-dense foods within a short eating window, coupled with changes in sleep patterns and reduced physical activity, typical during Ramadan. Despite these physiological disturbances, blood pressure remained stable, likely due to the calming effects of spiritual practices during Ramadan. These findings highlight the need for further research to explore the interaction between psychological and physiological mechanisms, the long-term effects of repeated annual fasting, and whether similar physiological plasticity occurs in individuals with diseases. Additionally, it is important to investigate these effects in females to provide a comprehensive understanding of the health impacts of Ramadan fasting.

6.2 Recommendation

Based on the study's findings, it is recommended that individuals observing Ramadan maintain balanced nutrition, regular physical activity, and adequate hydration to mitigate the physiological impacts of fasting.

To counteract increased fat storage and muscle mass loss, consuming nutrient-dense foods, particularly during iftar and suhoor, is essential. Including protein-rich foods can help preserve muscle mass, while incorporating fruits and vegetables can enhance cellular health and hydration.

Maintaining moderate physical activity levels during Ramadan can help reduce body fat percentage, reduces risks of cardiovascular events and metabolic events such as obesity and support overall health. Post-Ramadan, continuing regular exercise and balanced dietary habits will aid in stabilizing body composition and improving cellular health.

More investigations need be conducted to explore the effect of Ramadan fasting on different population like women, teenagers and old aged individuals as well as people with special conditions, such as hypertensive, obese or diabetic patients.

Put together, another study with a larger sample size is required to ensure the generalization of results to the population as this study's participants were mostly lean individuals.

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APPENDICES

Appendix I: Informed consent form – English version

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

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Ext: 1016
Direct Line: +255-22-2152489
Telefax: +255-22-2152489
E-mail: drp@muhas.ac.tz

Participant identity number ……

My Name is Ilyas Masoud, a postgraduate student in the Department of Physiology at Muhimbili University of Health and Allied Sciences (MUHAS). I am conducting a research study on temporal assessment of body composition changes before, during and after Ramadan: particularly evaluating its effects on cellular health and blood pressure among healthy male subjects. This research will last for 2 months.

Purpose of the study

The purpose of this study is to temporally assess body composition changes before, during and after Ramadan: particularly evaluating its effects on cellular health and blood pressure among healthy male subjects.

How to participate in the study

You will be screened for eligibility and then prepared for data collection. Some measurements will also be taken from you in the beginning, during follow up period and at the end of the study such as blood pressure, body composition (BFP, phase angle and TBW), weight, height, waist circumference and hip circumference.

Confidentiality and privacy

Information obtained from participants in this study will be confidential, only members of the research team will be aware of them. Privacy will also be maintained while taking some measurements like anthropometric measurements, body composition and blood pressure. This information will be collected in a controlled environment one participant at a time.

Cost.

You are not required to pay any cost during follow up period. Information and measurement will be taken during follow up periods as your routine follow up.

Voluntary participation and the right to withdraw from the study

Your participation is voluntary and you have the right to withdraw from participating in this study at any time. Whatever your decision may be, it will have no effect in any way to your rights to care and treatment.

Risks

There are little to no risks associated with participating in this study. The procedures involved, including the questionnaire and body composition measurements, are non-invasive and pose no serious health risks. However, you may experience minor discomfort or inconvenience during the measurement procedures

Benefits

While there may not be direct benefits to participants, the information gathered from this study may contribute to scientific knowledge and benefit individuals fasting during Ramadan in the future. Additionally, participating in research allows you to contribute to the advancement of science and the improvement of healthcare practices.

Investigator's Statement

I, the investigator have educated the research participant on the purpose and applications of this study.

Signature……Date……

If you have questions during the course of the study, you may contact the following;

Ilyas Masoud
Principal investigator
Muhimbili University of Health and Allied Sciences (MUHAS)
Department of Physiology
P.O.Box 65001 Dar es Salaam
Mobile phone; 0777 33 22 55

Dr Fredirick Mashili
Supervisor
Department of Physiology
Muhimbili University of Health and Allied Sciences
P.O.Box 65001, Dar es Salaam
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Office of the director of research and publication (DRPI)
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Participant's Statement

I am willingly to participate in this study investigating the temporal assessment of body composition changes before, during and after Ramadan: effects on cellular health and blood pressure among healthy male subjects

I do this with a full understanding of the purposes of the study and the procedure involved, which include filling out a study questionnaire, and measuring blood pressure and body composition, all of which have been explained to me by Ilyas Masoud.

Signature/fingerprint of Participant…….

Signature of witness……Date……

Appendix II: Informed consent form- Kiswahili

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

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E-mail: drp@muhas.ac.tz

Namba ya utambulisho ya mshiriki ……

Mimi Ilyas Masoud, mwanafunzi wa shahada ya uzamili katika chuo kikuu cha afya na sayansi shirikishi kitengo cha sayansi ya fiziolojia. Ninafanya utafiti juu ya ukadiriaji wa muda wa mabadiliko ya muundo wa mwili kabla, wakati na baada ya ramadhani: athari kwenye afya ya selulari na shinikizo la damu kati ya watu wazima wanaume wenye afya. Utafiti huu utadumu kwa kipindi cha miezi miwili.

Dhumuni la utafiti

Dhumuni la utafiti huu ni ukadiriaji wa muda wa mabadiliko ya muundo wa mwili kabla, wakati na baada ya ramadhani: athari kwenye afya ya selulari na shinikizo la damu kati ya watu wazima wanaume wenye afya.

Jinsi ya kushiriki katika utafiti.

Uchunguzi wa awali utafanyika kuangalia wenye vigezo vya kushiriki na kujibu maswali kadhaa yanayohusiana na mwenendo wako wa kimaisha. Utapimwa baadhi ya vipimo kama muundo wa mwili, shinikizo la damu, urefu na uzito mwanzoni mwa utafiti, wakati wa ufuatiliwaji na mwishoni mwa utafiti.

Usuri na faragha.

Taarifa zitakazochukuliwa kutoka kwa washiriki wa utafiti huu zitakuwa ni siri ya waendesha utafiti tu. Utahakikishiwa faragha pia wakati wa kuchukuliwa vipimo na kila mshiriki atachukuliwa vipimo peke yake.

Gharama

Hakuna gharama yeyote utakayotozwa kwa kushirirki katika utafiti huu.

Uhiyari wa kushiriki na haki ya kujitoa katika utafiti.

Ushiriki wako katoka utafiti huu ni hiyari na una haki ya kujitoa katika utafiti wakati wowote. Vyovyote uamuzi wako utakavyokuwa hautaathiri mwenendo wako wa kimaisha

Hathari

Hakuna athari yeyote ya kuchukuliwa vipimo mbalimbali wakati wa utafiti.

Faida

Utapata faida za kujua hali yako ya kiafya ya. Matokeo ya utafiti huu yatachangia katika kuboresha utoaji wa huduma za afya kwa watu wote wenye nia ya kufunga .

Tamko la mwendesha utafiti

Mimi mwendesha utafiti huu nimewafundisha washiriki wa utafiti huu dhumuni na matumizi ya utafiti huu.

Sahihi ……. Tarehe …….

Kama una swali lolote wakati wa uendeshaji wa utafifti huu wasiliana na wafuatao;

Ilyas Masoud
Mtafiti mkuu
Chou kikuu cha afya na sayansi shirikishi Muhimbili.
Idara ya sayansi ya fiziolojia
S.L.P 65001 Dar es Salaam
SIMU; 0765 510 801

Dk Fredirick Mashili
Msimamizi wa mwendesha utafiti mkuu
Chou kikuu cha afya na sayansi shirikishi Muhimbili.
Idara ya sayansi ya fiziolojia
S.L.P 65001 Dar es Salaam
SIMU; 0752 255 949
Ofisi ya mkurugenzi utafiti na machapisho
Chuo kikuu cha afya na sayansi shirikishi Muhimbili
S.L.P 65001 Dar es Salaam

SIMU: +255-22-2150302/6
Barua pepe: drp@muhas.ac.tz

Tamko la mshiriki.

Kwa idhini yangu mwenyewe bila kushurutishwa, ninakubali kushuriki katika utafuti huu kuhusu ukadiriaji wa muda wa mabadiliko ya muundo wa mwili kabla, wakati na baada ya ramadhani: athari kwenye afya ya selulari na shinikizo la damu kati ya watu wazima wanaume wenye afya.

Nafanya hivi nikiwa na uelewa kamili wa dhumuni la utafiti huu na hatua zake zote ikiwa ni pamoja na kutoa taarifa sahihi nitakazoulizwa na kuchukuliwa vipimo ikiwemo shinikizo la damu na muundo wa mwili kama ambavyo nimeelekezwa na Ilyas Masoud

Sahihi/dole gumba la mshiriki…….

Sahihi ya shahidi…….

Tarehe …….

Appendix III: Questionnaire- English version

TEMPORAL ASSESSMENT OF BODY COMPOSITION CHANGES BEFORE, DURING AND AFTER RAMADAN: EFFECTS ON CELLULAR HEALTH AND BLOOD PRESSURE AMONG HEALTHY MALE SUBJECTS.

Participant identity number ……

Section 1: Demographic Information

Please provide the following information about yourself:

- Age (years):
- Sex (male/female):
- Education level (primary/secondary/higher education):
- Occupation (self-employed/employed/unemployed):
- Marital status (single/married):

Section 2: Health Behaviors

Please answer the following questions about your health behaviors before and during Ramadan:

- Water intake: How many glasses of water do you drink on a usual day? One glass of water is equivalent to 250 ml or 8 oz. Please choose the option that best describes your intake:
    1. None
    2. 1-3 glasses/day
    3. 4-6 glasses/day
    4. 7 or more glasses/day

- Caffeine intake: How many cups of caffeinated beverages do you drink on a usual day? Caffeinated beverages include coffee, tea, energy drinks, cola, etc. Please choose the option that best describes your intake:

    1. None
    2. 1-2 cups/day
    3. 3-4 cups/day
    4. 5 or more cups/day

- Smoking habits: Do you smoke any tobacco products, such as cigarettes, cigars, pipes, etc.? Please choose the option that best describes your smoking habits:
    1. No, I do not smoke
    2. Yes
- Alcohol habits: Do you drink any alcoholic beverages, such as beer, wine, spirits, etc.? Please choose the option that best describes your alcohol habits:
    1. No, I do not drink
    2. Yes,
- Physical activity: How much time and how often do you spend doing physical activity in a usual week? Physical activity includes any activity that makes you breathe harder and your heart beat faster, such as walking, jogging, cycling, swimming, sports, etc. Please answer the following questions:
    - How many days per week do you do any physical activity?
    - On those days, how much time do you spend doing physical activity (in minutes)?
    - How would you rate the intensity of your physical activity on a scale of 1 to 10, where 1 is very light and 10 is very hard?
- Sedentary behaviour: How much time do you spend sitting on a usual weekday and weekend day? Sitting time includes any time spent sitting at work, school, home, or during transportation, such as driving, taking the bus, etc. Please answer the following questions:
    1. 3-6 hours
    2. More than 7 hours
- Sleep Quality in the Past 30 Days: How would you rate your sleep quality in the past 30 days? Sleeping duration includes how well you fall asleep, how long you sleep, how often you wake up, and how refreshed you feel in the morning. Please choose the option that best describes your sleep quality:
    1. Less than 6 hours
    2. 6-7 hours
    3. More than 7 hours

- Sleep Pattern: Has your sleep pattern changed during Ramadan fasting?
    1. Yes
    2. No
- If Yes, Please Explain How Your Sleep Pattern Has Changed:
    1. Less sleep at night due to prayers and meals
    2. More naps during the day
    3. Difficulty falling asleep or waking up frequently
    4. Feeling less refreshed in the morning
    5. Other (please specify): _____
- Overall health and well-being: How do you rate your overall health and well-being in the past 30 days? Health and well-being include your physical, mental, emotional, and social aspects of your life. Please choose the option that best describes your overall health and well-being:
    1. Poor
    2. Fair
    3. Good
    4. Very good
    5. Excellent

Section 3: Physiological Measurements

Measurements of physiological parameters before, during and after Ramadan will be taken by trained staff using standardized equipment and procedures. Please follow the instructions given by the staff and cooperate with them.

		Before Ramadan	Mid Ramadan	Post Ramadan
weight (kg)				
height (m)				
BMI (kg/m2)				
Waist circumference (m)				
Hip circumference (m)				
Blood pressure (mmHg)	SBP			

	DBP			
TBW (L)	ECW			
	ICW			
Body fat mass (kg)				
Fat free mass (kg)				
Phase angle (^{0})				
Body fat percentage (%)				
Fat free mass percentage (%)				

Section 4: Additional Comments

Please use this space to provide any additional comments or feedback about the study or the questionnaire.

Appendix IV: Questionnaire- Kiswahili version

UKADIRIAJI WA MUDA WA MABADILIKO YA MUUNDO WA MWILI KABLA, WAKATI NA BAADA YA RAMADHANI: ATHARI KWENYE AFYA YA SELULARI NA SHINIKIZO LA DAMU KATI YA WATU WAZIMA WANAUME WENYE AFYA

Namba ya utambulisho ya mshiriki…….

Sehemu 1: Taarifa za Kidemografia

Tafadhali jaza taarifa zifuatazo kuhusu wewe mwenyewe:

• Umri (miaka):

• Elimu (msingi/sekondari/chuo kikuu):

• Kazi (amejiajiri/mwenye kazi/hana kazi):

• Hali ya ndoa (barobaro/ameoa):

• Idadi ya watoto (ikiwapo wapo):

Sehemu 2: Tabia za Afya

Tafadhali jibu maswali yafuatayo kuhusu tabia zako za afya kabla na wakati wa Mwezi wa Ramadhani:

• Unywaji wa maji: Unakunywa vikombe vingapi vya maji kwa siku ya kawaida? Kikombe kimoja cha maji ni sawa na 250 ml au 8 oz. Tafadhali chagua chaguo linaloelezea unywaji wako vyema:

1. Hakuna
2. 1-3 vikombe/siku
3. 4-6 vikombe/siku
4. 7 au zaidi ya vikombe/siku

• Unywaji wa kafeini: Unakunywa vikombe vingapi vya vinywaji vyenye kafeini kwa siku ya kawaida? Vinywaji vyenye kafeini ni pamoja na kahawa, chai, vinywaji vya nishati, cola, nk. Tafadhali chagua chaguo linaloelezea unywaji wako vyema:

1. Hakuna
2. 1-2 vikombe/siku
3. 3-4 vikombe/siku

4. 5 au zaidi ya vikombe/siku

• Tabia za kuvuta sigara: Je, unavuta bidhaa yoyote ya tumbaku, kama vile sigara, sigara za kienyeji, mipepesi, nk.? Tafadhali chagua chaguo linaloelezea tabia yako ya kuvuta sigara:

1. Hapana, sivuti
2. Ndio,

• Tabia za kunywa pombe: Je, unakunywa vinywaji vyovyote vya pombe, kama vile bia, divai, vileo, nk.? Tafadhali chagua chaguo linaloelezea tabia yako ya kunywa pombe:

1. Hapana, sijawahi kunywa
2. Ndio,

• Shughuli za kimwili: Unatumia muda gani na mara ngapi unafanya shughuli za kimwili kwa wiki ya kawaida? Shughuli za kimwili ni pamoja na shughuli yoyote ambayo inakufanya upumue kwa bidii na moyo wako kupiga kwa kasi, kama vile kutembea, kukimbia, baiskeli, kuogelea, michezo, nk. Tafadhali jibu maswali yafuatayo:

- o Unafanya shughuli za kimwili siku ngapi kwa wiki?
- o Siku hizo, unatumia muda gani kufanya shughuli za kimwili (kwa dakika)?
- o Ungeipa kipimo gani cha nguvu shughuli zako za kimwili kwenye kiwango cha 1 hadi 10, ambapo 1 ni mwanga sana na 10 ni ngumu sana?

• Muda wa kukaa: Unatumia muda gani kukaa kwenye siku ya kawaida ya wiki na siku ya wikendi? Muda wa kukaa ni pamoja na wakati wowote uliotumika kukaa kazini, shuleni, nyumbani, au wakati wa usafiri, kama vile kuendesha gari, kuchukua basi, nk. Tafadhali jibu maswali yafuatayo:

1. Saa 3 mpaka 6
2. Zaidi ya saa 7

• Ubora wa Usingizi katika Siku 30 Zilizopita: Unawezaje kupima ubora wa usingizi wako katika siku 30 zilizopita? Muda wa kulala unajumuisha jinsi unavyolala vizuri, muda unaolala, mara ngapi unaamka, na jinsi unavyohisi umepumzika asubuhi. Tafadhali chagua chaguo linaloelezea vyema ubora wa usingizi wako:

1. Chini ya saa 6
2. Saa 6-7
3. Zaidi ya saa 7

• Mpangilio wa Usingizi: Je, mpangilio wako wa usingizi umebadilika wakati wa kufunga mwezi wa Ramadhani?

1. Ndio
2. Hapana

• Ikiwa Ndio, Tafadhali Eleza Jinsi Mpangilio Wako wa Usingizi Umebadilika:

1. Kulala kidogo usiku kutokana na maombi na milo
2. Kulala zaidi mchana
3. Ugumu wa kulala au kuamka mara kwa mara
4. Kuhisi umepumzika kidogo asubuhi
5. Mengine (tafadhali eleza): _____

• Afya na ustawi kwa ujumla: Unaelezeaje afya yako na ustawi wako kwa ujumla katika siku 30 zilizopita? Afya na ustawi ni pamoja na vipengele vyako vya kimwili, kisaikolojia, kihisia, na kijamii katika maisha yako. Tafadhali chagua chaguo linaloelezea afya yako na ustawi wako kwa ujumla:

1. Mbaya
2. Haki
3. Nzuri
4. Nzuri sana
5. Kamilifu

Sehemu 3: Vipimo vya Fiziolojia

Vipimo vya fiziolojia kabla, katikati na baada ya Mwezi wa Ramadhani vitachukuliwa na wafanyakazi waliofundishwa kwa kutumia vifaa na taratibu zilizopangwa. Tafadhali fuata maagizo yaliyotolewa na wafanyakazi na ushirikiane nao

		Kabla ya Ramadhan	Katikati ya Ramadhan	Baada ya Ramadhan
Uzito (kg)				
Urefu (m)				
BMI (kg/m2)				
Upana wa Kiuno (m)				
Upana wa Nyonga (m)				
Shinikizo la damu (mmHg)	SBP			

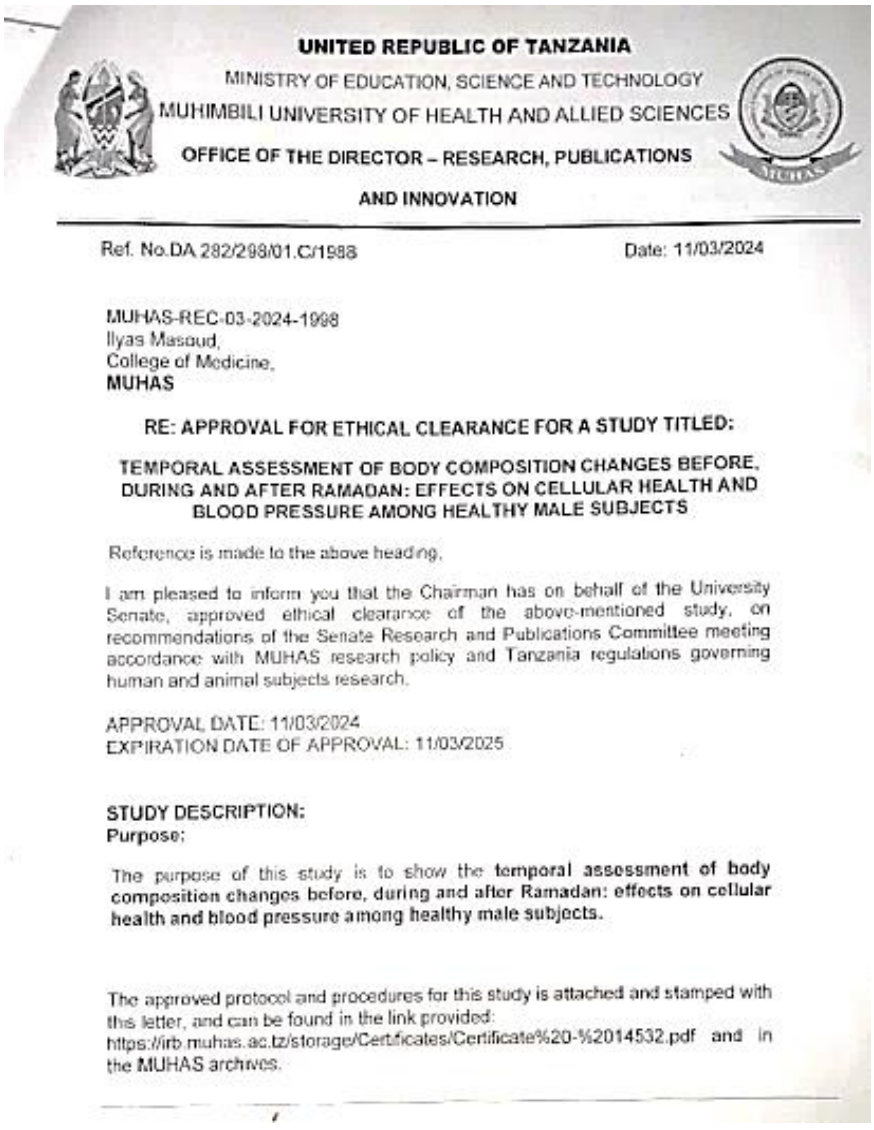
	DBP			
Maji ya Mwili Yote (L)	ECW			
	ICW			
Mafuta ya Mwili (kg)				
Mwili Bila Mafuta (kg)				
Mlalo wa Fizikia				
Asilimia ya Mafuta ya Mwili (%)				
Asilimia ya Mwili Bila Mafuta (%)				

Sehemu 4: Maoni Mengine

Tafadhali tumia nafasi hii kutoa maoni au mrejesho zaidi kuhusu utafiti au maswali haya

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Appendix V: Approval for ethical clearance



UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA 282/298/01.C/1988 Date: 11/03/2024

MUHAS-REC-03-2024-1988
Ilyas Masoud,
College of Medicine,
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED:

TEMPORAL ASSESSMENT OF BODY COMPOSITION CHANGES BEFORE, DURING AND AFTER RAMADAN: EFFECTS ON CELLULAR HEALTH AND BLOOD PRESSURE AMONG HEALTHY MALE SUBJECTS

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 11/03/2024
EXPIRATION DATE OF APPROVAL: 11/03/2025

STUDY DESCRIPTION:
Purpose:

The purpose of this study is to show the **temporal assessment of body composition changes before, during and after Ramadan: effects on cellular health and blood pressure among healthy male subjects.**

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014532.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain Data Transfer Agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain Material Transfer Agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country.
8. Apply for and obtain permission to publish the results from National Institute for Medical Research. The application should be before submitting to a publisher and not concurrently through the email publications@nimr.or.tz.
9. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research, Publications & Innovations
Box 65001

Dr. Nahya Salim Masoud,
Chairperson, MUHAS Research and Ethics Committee