Research Protocol:

Spatiotemporal gait parameters of healthy and stroke patients during overground, self-paced treadmill, and body-weight supported treadmill walking.

Submitted to:

Institutional Review Board

BUET, Dhaka-1000, Bangladesh.

Principal Investigator

Dr. Muhammad Tarik Arafat, PhD

Professor, Department of Biomedical Engineering

BUET, Dhaka, Bangladesh.

Co-Principal Investigator:

Dr. Mohammad Moniruzzaman

Associate professor
Department of Physical Medicine and Rehabilitation, Dhaka Medical College Hospital (DMCH), Dhaka-1205, Bangladesh.

Date of Submission: 20/08/2024

List of Documents

1. **Annexure – A:**
    a. Filled-up Ethical Clearance Application Form.
    b. Signature of Principal Investigator (s) & Co-investigator (s) with details address.

2. **Annexure – B:**
    Abstract for BME Ethical Review Committee (BMEERC)

3. **Annexure – C:**
    BMRC format for Submission of the Proposal for Ethical Approval

4. **Annexure – D:**
    Informed consent form (English) from participants or the parent / legal guardian

5. **Annexure – E:** Budget

ANNEXURE - A

Application for Ethical Clearance

Title of the study: Spatiotemporal gait parameters of healthy and stroke patients during overground, self-paced treadmill, and body-weight supported treadmill walking.

Principal Investigator:

Dr. Muhammad Tarik Arafat, Professor

Department of Biomedical Engineering (BME), BUET, Dhaka - 1000, Bangladesh.

Co-Principal Investigator(s):

Dr. Mohammad Moniruzzaman

Department of Physical Medicine and Rehabilitation, Dhaka Medical College Hospital (DMCH), Dhaka-1205, Bangladesh.

Place of the Study/Institution(s): Biomechanics and biofluid lab, Department of Biomedical Engineering (BME), BUET, Dhaka - 1000, Bangladesh.

Type of Study: Comparative study.

Duration of Study: 6 months

Total Cost: 30,000 Tk.

Funding Agency: N/A.

Circle the appropriate answer to each of the following

(If not Applicable write NA)

1. Source of Population:

(a) Ill Participant (Yes) No

(b) Non Ill Participant (Yes) No

(c) Minors or persons under guardianship Yes (No)

2. Does the study involve?

(a) Physical risks To the subjects (Yes) No

(b) Social Risks Yes (No)

(c) Psychological Risks to subjects Yes (No)

(d) Discomfort to Subjects (Yes) No

(e) Invasion of the body Yes (No)

(f) Invasion of Privacy Yes (No)

(g) Disclosure of Information damaging to Subject or others Yes (No)

3. Does the study involve?

(a) Use of records, (Hospital, medical, Death, birth or other) (Yes) No

(b) Use of fetal tissue Or abortus Yes (No)

(c) Use of organ or Body fluids Yes (No)

4. Are subjects clearly informed about?

(a) Nature and purposes of study (Yes) No

(b) Procedures to be followed including alternatives used (Yes) No

(c) Physical risks (Yes) No

(d) Private questions N/A

(e) Invasion of the Body N/A

(f) Benefits to be Derived (Yes) No

(g) Right to refuse to participate or to withdraw from study (Yes) No

(h) Confidential handling of data (Yes) No

(i) Compensation where there are risks or loss of working time or privacy is involved in any particular procedure N/A

5. Will signed consent form/verbal consent be required?

(a) From Subjects (Yes) No

(b) From parent or guardian (if subjects are minors) N/A

6. Will precautions be taken to protect anonymity of subjects (Yes) No

Note: If the final instrument / questionnaire is not completed prior to review, the following information should be included in the abstract.

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific question to be asked in the sensitive areas.
3. An indication as to whom the questionnaire will be presented to the committee for review.

We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects or any changes of the Methodology before making any such changes.

Signature

Dr. Muhammad Tarik Arafat
Professor, Department of Biomedical Engineering (BME)
Bangladesh University of Engineering and Technology (BUET)
Dhaka - 1000, Bangladesh.

Date: 20/08/2024

Name of Co-investigator (S) **Signature**

*** Include all the Investigator, Co-Investigators.**

ANNEXURE - B

ABSTRACT FOR

BME Ethical Review Committee (BMEERC)

The Ethical Review Committee will not consider any application which does not include a specific abstract/summary for the committee. The abstract should summarize the study's purpose, the methods, and procedures to be used by addressing each of the following items. If an item is not applicable, please note accordingly:

1. Describe the requirements in respect of the population and explain the rationale for using the population of special groups such as children, Incompetent person, or groups whose ability to give voluntary informed consent is questionable.
   Response: The primary aim of the study is to evaluate the differences in variability in spatiotemporal gait parameters of stroke patients during overground, self-paced treadmill, and body-weight supported treadmill walking. Stroke, while more common in older adults, can affect people of all ages. As a result, our study participants range in age from 18 to 75 years, allowing us to better understand the impact of stroke across a larger age range. Children under the age of 18 and individuals who are unable to provide voluntary informed consent will be given consent from a parent or legally authorized guardian. Furthermore, consent will be obtained from children who are old enough to understand the study, ensuring that they are willing to participate. Pregnant women are not allowed to participate in the study due to safety concerns. The specific inclusion criteria are listed below:
   Post-stroke patients who are able to walk and aged between 18 to 75 (not pregnant).

2. Describe and assess any potential risks - physical, psychological, social, legal or other and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they cannot be used.
   Response: The primary aim of the study is to compare the variability in spatiotemporal gait parameters of stroke patients across overground, self-paced treadmill, and body-weight supported treadmill walking, and to identify which walking technique yields the most consistent and beneficial gait metrics, indicating a more stable and effective recovery. If the post-stroke subject is afraid of falling, an overhead harness will be used to ensure their safety during data collection.
   The use of the body weight support structure (BWSS), which is designed to help participants with balance issues, carries minimal physical risk. The structure can support up to 5 tons and has been tested on healthy adults weighing an average of 80 kg for up to 4 minutes. The overhead harness is intended to provide comfort by evenly distributing pressure across the lumbar and thoracic regions, and it includes a thigh belt for added safety. There may be some psychological discomfort due to unfamiliarity with the

equipment or the testing environment. There are no anticipated social or legal risks in this study.

3. Describe procedures for protecting against or minimizing potential risks and assessment of their likely effectiveness.
   Response: The study is designed to minimize potential risks through careful planning and implementation of safety measures. The primary risk mitigation strategy involves using a body weight support structure during data collection for stroke subjects. This structure can support up to 5 tons and has been tested for safety and comfort. It includes an overhead harness to provide support during walking. During the data collection process, participants will be continuously monitored by the study investigators. Any signs of physical discomfort, fatigue, or deterioration in condition will result in the immediate termination of the experimental trial. Participants unable to walk with the overhead harness or express discomfort will not be subjected to the experiment.

4. Include a description of the methods for safeguarding confidentiality or protecting anonymity.
   Response: The study will implement strict protocols to safeguard the confidentiality and anonymity of participants. All collected data will be accessible only to authorized study personnel. Personal identifying information will be removed from the data after the study is completed. Each participant will be assigned a unique code, and only coded data will be used in the analysis and reporting of study results.

5. When there are potential risks to the subject, or the privacy of the individual may be involved, the investigator is required to obtain a signed informed consent from the participant. For minors, informed consent must be obtained from the authorized legal guardian or parent of the subject. Describe consent procedures to be followed, including how and where informed consent will be obtained.
   (a) If signed consent will not be obtained, explain why this requirement should be waived and provide an alternative procedure such as a verbal consent.

   Response: Informed consent will be obtained.

   (b) If information is to be withheld from a subject, justify this course of action.

   Response: No information will be withheld from the subject.

   (c) If there is a potential risk to the subject or privacy of the individual or loss of work time is involved in any particular procedure, include a statement in the consent form stating whether any compensation will be available.

   Response: Not applicable since there is a minimal risk of privacy and loss of work time.

6. If the study involves an interview, describe where and in what context the interview will take place. State approximate length of time required for the interview.

   Response: The study will not require an interview.

7. Assess the potential benefit to be gained by the individual subject as well as the benefits which may accrue to society in general because of the work. Indicate how the benefits may outweigh the risks.

   Response: The study offers potential benefits to individual subjects and society, which outweigh the minimal risks associated with participation. After conducting the experiment, each participant will receive a gait analysis report. Especially, in the case of post-stroke patients, the gait impairment can be evaluated by this report. Again, In Bangladesh, there is a scarcity of gait analysis facilities. Moreover, the study could serve as a foundation for further research in gait analysis within Bangladesh that may inform and enhance therapeutic practices, leading to better treatment and rehabilitation strategies for post-stroke patients. In the long run, the establishment of gait analysis research can have a significant public health impact, improving the quality of care for individuals with gait abnormalities. The potential risks associated with the study are minimal and include minor physical discomfort or fatigue during the gait analysis.

8. In case of an experimental drugs, provide information about its status of registration for open sale in Bangladesh and in other developed countries.

   Response: N/A.

9. For experimental 'new' drugs* which are not registered in Bangladesh provide full information about the toxicity studies carried out in animals or human volunteers. Published papers on this regard shall be annexed.

   Response: N/A.

10. If placebo is to be used justify its uses and why the study cannot be done without its use.
    Response: N/A.
11. If an experimental 'new' drug* is to be used give a statement regarding its sponsorship and the conditions for such sponsorship.

    Response: N/A.

12. State if the activity requires the use of records (hospital, medical, birth, death or other), organs, tissues, body fluids, the fetus or the abortus.

    Response: Yes. The study will require the use of medical records, including stroke type, the duration since the stroke occurred, paretic side by stroke, hospital admission and release dates etc.

ANNEXURE - C

Project Title: Spatiotemporal gait parameters of healthy and stroke patients during overground, self-paced treadmill, and body-weight supported treadmill walking.

Summary:

This study aims to collect and analyze spatiotemporal data from stroke patients using an in-house gait analysis setup. Each walking modality-overground, self-paced treadmill, and body-weight supported treadmill provides distinct advantages and challenges. Overground walking simulates natural conditions but lacks mechanical support; self-paced treadmill walking provides a controlled environment with adjustable speed; and body-weight supported treadmill walking reduces lower extremity pressure and the risk of falling. A locally made body weight support structure (BWSS) is used for fall prevention in hemiparetic patients during data collection. The BWSS includes: Hand winch system with locking mechanism, Double pulley system, An overhead harness, and A 10 ft Stainless steel wire (loading capacity=5 ton). For Overground, data collection is done using two force plates positioned in the middle of a linear pathway, an 8-camera video monitoring system, and AcqKnowledge software is used for data analysis. Data collection from the self-paced treadmill and body-weight supported treadmill also occur through the video monitoring system. Data collection will adhere to standard protocols to ensure safety and accuracy. Participants will walk along the pathway, and gait data will be recorded using the force plates and video system. By analyzing gait parameters such as step length, stride length, cadence, gait speed, and the duration of stance and swing phases, the study aims to identify which modality offers the most consistent and stable gait patterns, indicating improved motor control and coordination.

Introduction:

Stroke is the leading cause of disability worldwide, affecting the lives of millions of people. One of the most debilitating effects of stroke is impaired gait, which impairs mobility and independence [1]. It is especially prevalent in low- and middle-income countries such as Bangladesh. Stroke is the third leading cause of death from non-communicable diseases in Bangladesh, putting a significant burden on both individuals and the healthcare system. Stroke prevalence in Bangladesh is around 11.39 per thousand people, with higher rates in rural areas and among elderly males [2]. Gait abnormalities are experienced by about 80% of stroke survivors, and they can significantly impair their daily activities and overall quality of life [3]. The significant number of disability-adjusted life years (485 per 10,000 people) lost due to stroke severely impacts the nation's economy [4]. Despite the high occurrence of disability due to stroke in Bangladesh, there are significant limitations in analyzing the gait characteristics of stroke patients. Gait rehabilitation uses a variety of walking modalities, such as body weight supported treadmill walking, self-paced treadmill walking, and overground walking. Every modality has particular benefits and drawbacks. The most natural kind of gait training is provided by walking on terrain that closely resembles actual walking conditions. However, because of the unpredictable nature of the environment and the lack of

mechanical support, it can be challenging for stroke patients [5]. Self-paced treadmill walking provides a controlled environment in which the patient's speed can be adjusted based on their abilities, allowing for a consistent walking rhythm and feedback [6]. This modality is useful for strengthening gait patterns and increasing endurance. However, body weight supported treadmill walking allows the patient to partially offload their weight, which lessens the pressure on their lower extremities and improves safety by lowering the chance of falls [7]. Variability in gait parameters such as step length, stride length, cadence, gait speed, and the duration of the stance and swing phases is an important aspect of gait analysis. High variability in gait frequently indicates instability and inefficiency, which are undesirable outcomes in rehabilitation. Lower variability, on the other hand, indicates more consistent and stable gait patterns, implying improved motor control and coordination.

Objectives:

In this study, we aim to evaluate the gait differences among three different waking modalities with respect to spatiotemporal gait parameters. This will be achieved through a comparative analysis of spatiotemporal data between those groups. To ensure the safety of the subjects, the data collection protocols will be strictly followed, incorporating already tested procedures that have shown no probable risk. The BWSS has been tested with healthy individuals and is manufactured using widely available components in Bangladesh. The objectives of the study are as follows:

- **Study objectives:** To evaluate the variations in spatiotemporal gait parameters of three different waking modalities and analyze and determine which walking technique provides the most reliable gait metrics, suggesting a more stable and possibly advantageous recovery outcome.

- **Study Hypothesis:** We hypothesize that body weight supported treadmill walking will exhibit the least variability in spatiotemporal gait parameters compared to overground walking and self-paced treadmill walking. This suggests that BWST provides a more controlled environment, promoting more consistent and reliable gait patterns, which may translate to a more stable and potentially advantageous recovery outcome for individuals with stroke.

Rationale:

Stroke is a leading cause of disability worldwide, significantly impairing mobility and increasing the risk of falls. In Bangladesh, stroke is not only a major health concern due to its high prevalence and mortality rate but also has a substantial economic impact, with a large number of disability-adjusted life years lost. Despite the high incidence of stroke and the resultant gait impairments, there is a significant gap in the availability of gait analysis in Bangladesh. Most existing studies in

the region rely on traditional, observational methods that often provide inaccurate data and focus primarily on spatiotemporal parameters, neglecting crucial biomechanical insights.

Gait analysis, which measures characteristics such as stride length, step time, and swing time (spatiotemporal parameters), is critical for evaluating gait quality and monitoring rehabilitation progress. Overground walking analysis is widely regarded as the gold standard [8]. However, environmental factors such as uneven surfaces, obstacles, and a fear of falling can cause data variability [9]. Treadmill walking provides a controlled environment and facilitates data collection, but the question remains: which environment yields the most reliable and informative data for post-stroke gait assessment and rehabilitation planning?

This study fills this knowledge gap by investigating the variability of spatiotemporal gait parameters across three walking environments:

- Overground walking: Represents real-world walking but can be influenced by environmental factors, as previously stated.
- Self-paced treadmill walking provides a controlled environment, but may not fully challenge balance and coordination, potentially yielding less informative data on these aspects of gait.
- Body weight supported treadmill walking (BWST): Provides partial support, potentially promoting more consistent gait patterns due to lower balance demands, which may be beneficial for initial gait training.

Understanding the variability of gait parameters across these environments is important for several reasons. Identifying the environment that produces the most consistent and reliable gait data enables researchers and clinicians to select the best assessment method for post-stroke patients. This can result in more accurate assessments of gait impairments and progress during rehabilitation. Therapists can tailor gait training programs to specific environments based on rehabilitation objectives and individual needs. For example, because of its supportive nature, BWST may be a useful tool for initial training, whereas overground walking practice becomes more critical as balance and coordination improve. Additionally, it will provide a reliable and safe method for gait analysis that can be widely adopted in Bangladeshi healthcare setting and lay the groundwork for future research and clinical applications in gait analysis and rehabilitation for stroke patients in Bangladesh. Ultimately, this study seeks to improve the assessment and management of gait impairments in stroke patients, contributing to better rehabilitation outcomes and enhancing the quality of life for affected individuals.

Methodology:

Study design

Comparative study.

Patient Selection

Inclusion criteria:

- Participants must be between 18 to 75 years old.
- More than 1- month post stroke patient.
- Participants must be able to walk with or without assistance.
- Patients including both the male and female.
- Participants must be able to provide informed consent to participate in the study.

Exclusion Criteria:

- Severe cognitive or communicative disorders.
- Significant joint malposition.
- Psychological, cognitive dysfunction, and any other neuromuscular problem.
- Pregnant women will be excluded to avoid any potential risks to the mother and fetus.
- Unstable cardiovascular disease like congenital heart disease, deep vein thrombosis, coronary heart disease, previous history of heart attack or heart failure.

Data collection procedure:

Participants will be selected based on pre-determined inclusion criteria to ensure they fit for the study. Data will be collected through face-to-face interview using a pretested semi-structured questionnaire and informed verbal consent will be taken prior to interview. All the participants demographic information (age, weight, height, etc.) will be collected. Participants evaluated by Berg Balance test and Time Up & Go (TUG) test questionnaire form. All participant names have been properly defined to make sure confidentiality. After that the participants will be instructed to walk in their natural and comfortable manner. All participants will undergo a familiarization trial to get comfortable with the experimental setup and procedures. Then, participants will perform linear walking during two consecutive trials. Then take 2 minutes rest for treadmill walking after that again take 2 minutes rest for BWSTW. Data will be collected using a force plate and an 8-camera video monitoring system on all three walking modalities. The collected spatiotemporal data will be analyzed by statistical methods to identify differences among those modalities. Specific focus will be on key spatiotemporal parameters such as step length, stride length, cadence, gait speed, and the duration of the stance and swing phases use as important aspects of gait analysis

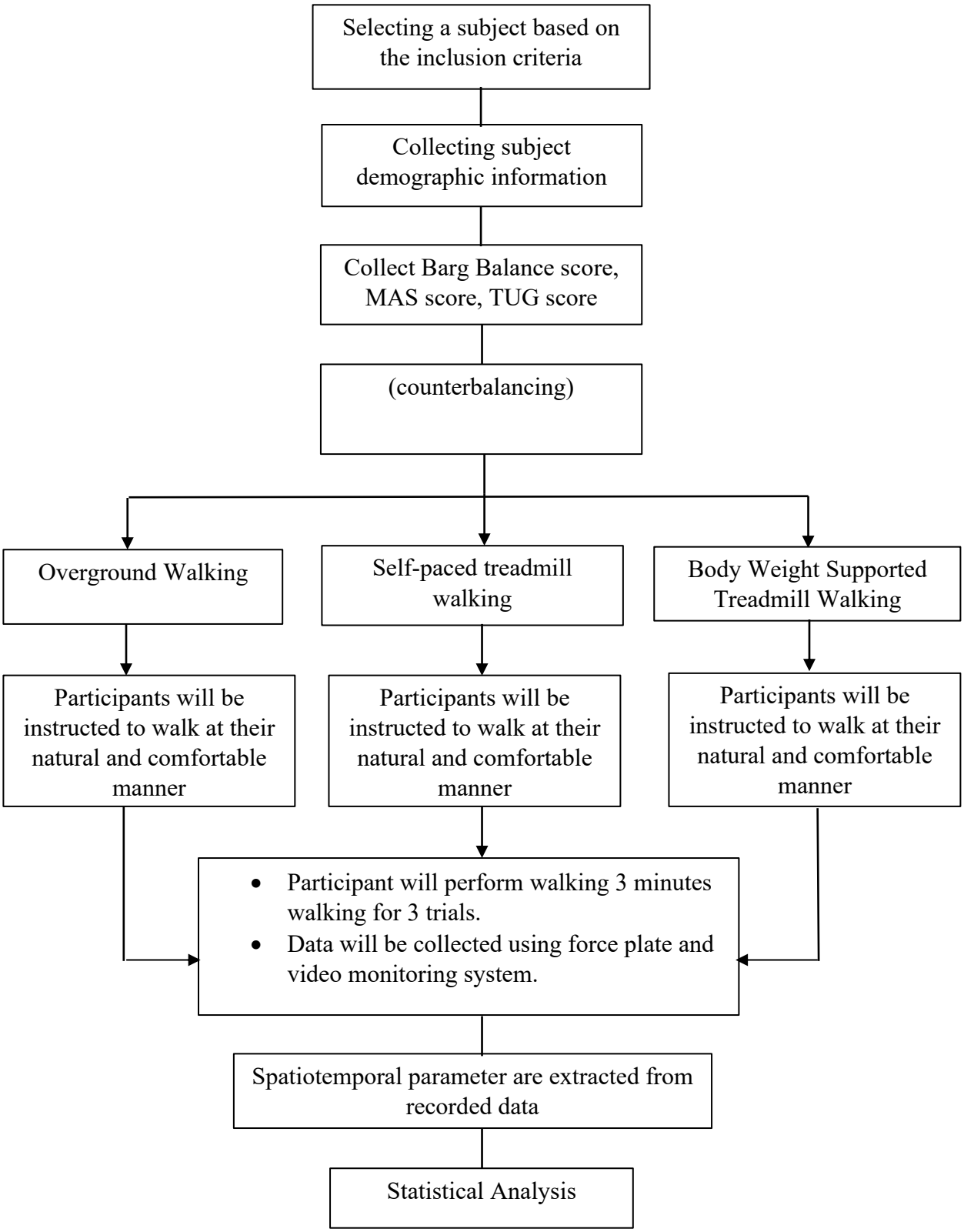

Figure: Flow chart of study plan

Phase-3-Extended Study ():

The aim of this phase of study is to compare the Spatiotemporal parameter among different waking modalities. The standard protocols will be followed while conducting experiment, in the Department of Biomedical Engineering (BME), BUET. The various aspect of this final and most important component of the study are described below:

Sample Size calculation: In this comparative study, the gait velocity in between different waking modalities is considered as the primary parameters. The following formula may use for calculating the sample size for each group of the trial:

Sample size, $N = \frac{2.\sigma^2\left(Z_{1-\beta}+Z_{1-\alpha/2}\right)^2}{d^2(k-1)}$ ……*(i)*

Where,

N = Required sample size

d = Difference in means of two group (effect size)

σ = SD

k = is the number of groups being compared.

$Z_{1-\beta}$ = It is the desired power

$Z_{1-\alpha/2}$ = Critical value and a standard value for the corresponding level of confidence. (At 95% CI it is 1.96)

To estimate the sample size, we considered the mean difference of the velocity of the post stroke patient to be at least 0.17 with a standard deviation of 0.3. We estimated that 24 individuals would be needed to satisfy the comparative studies between three groups, based on the statistical power of 80%, at a two-sided alpha level of 0.05. The statistical formula (i) used for the comparative test [10]. Considering dropouts and left-against-medical advice (LAMA) cases, sample size $N = 25$ will be considered. Thus, a total of 25 subjects will be considered for the equal allocation of this study. The different aspects of the study are summarized in Table I.

Table 1: Summary of the comparative study between healthy and post stroke individuals

Aspect of the study	Description
Study Type	Comparative
Design	Comparative study
No of subjects	25
Objective	Evaluate the variations in spatiotemporal gait parameters of those waking modalities.
Study Population	Inclusion Criteria for post-stroke patients:

	• Participants must be between 18 to 75 years old. • More than 1- month post stroke. • Participants must be able to walk with or without assistance. • Patients including both the male and female. • Participants must be able to provide informed consent to participate in the study. Exclusion Criteria for post-stroke patients: • Severe cognitive or communicative disorders. • Significant joint malposition. • Psychological, cognitive dysfunction, and any other neuromuscular problem. • Pregnant women will be excluded to avoid any potential risks to the mother and fetus. • Unstable cardiovascular disease
Procedure	Post stroke group: • Giving instruction • Randomly assigning patients to all the modalities • Data collection through force plate and video cameras • Extracted spatiotemporal parameters from recorded data
Outcomes	Primary Outcome: • Gait velocity Secondary Outcome: • Step length • Stride length • Cadence • Stance and swing phases duration • Single and double support time • Ground reaction force
Data Collection	Data collected before trial: • Patient clinical condition • Time after stroke and before data collection • Duration of therapy/rehabilitation Data collected during walking: • Force plate data • Video monitoring data
Data analysis	• Comparative test between the primary outcome of three group • Wilcoxon sign rank test & a paired sample t test • Interclass correlation coefficient between those group • Mean difference and standard deviation between those group

References

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[2] A. T. M. H. H. K. D. M. Md Badrul Alam Mondal, "Prevalence and risk factors of stroke in Bangladesh: A nationwide," *eNeurologicalSci,* vol. 28, no. 100414, 2022.

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[10] S. K. e. a. Sharma, "How to calculate sample size for observational and experimental nursing research studies," *National Journal of Physiology, Pharmacy and Pharmacology,* vol. 10, no. 1, pp. 1-8, 2020.

ANNEXURE - D

INFORMED CONSENT FORM (ENGLISH)

Project Title: Spatiotemporal gait parameters of healthy and stroke patients during overground, self-paced treadmill, and body-weight supported treadmill walking.

Principal Investigator:

Dr. Muhammad Tarik Arafat, Professor
Department of Biomedical Engineering (BME), BUET, Dhaka - 1000, Bangladesh.

Location:

Biomechanics and biofluid lab, Department of Biomedical Engineering (BME), BUET, Dhaka - 1000, Bangladesh.

Interviewer details:

The interview will be conducted by study investigators at the lab.

Purpose of the Study:

The purpose of this study is to compare the variability of spatiotemporal gait parameters in stroke patients across three different walking modes: overground walking, self-paced treadmill walking, and body-weight supported treadmill walking. By collecting and analyzing detailed gait data from stroke patients using these methods, the study hopes to determine which walking technique provides the most reliable and consistent gait metrics, indicating improved motor control and coordination. Lower variability in these parameters indicates a more stable and favorable recovery outcome. The findings will include evidence-based recommendations for optimizing gait rehabilitation programs, as well as information for healthcare professionals about the benefits and limitations of each walking modality. Finally, the study aims to improve rehabilitation strategies and recovery outcomes for stroke patients.

Types of participation of the study respondents:

If you agree to participate in this study, you will be required to provide information on your demographics and medical history.

Duration of study:

The study will be performed for one hour.

Procedures of the study:

The procedure of this study involves the following steps:

1. Demographic (including age, weight, height) and clinical information will be collected from you.
2. You will be instructed to walk as naturally as possible by looking at the opposite wall.
3. A randomized trial will be conducted to acclimate you to the experimental setup.
4. When the investigator will instruct you, you need to start walking. Your gait data will be collected using two force plates and an 8-camera video monitoring system on all three waking modalities.
5. You need to complete at least three walking trials.
6. Your GRF data and video footage will be examined to ensure accurate foot contact with the force plates.
7. If your collected data are distorted by noise or any other things, the investigator will ask you to walk again.
8. If you have any discomfort wearing body harness, or feel any kind of fatigue during walking you should immediately let the study investigators know.

Potential benefits:

The study offers significant potential benefits for both for you and society as a whole. Individually, you will receive your gait analysis report which will help the doctors to understand your gait impairments. The use of a BWSS ensures your safety during data collection.

Risks, hazards and discomforts:

The study is designed to be as safe as possible. Wearing the harness at 1st time may cause discomfort for you. Since you're are a stroke patient, you may experience anxiety during the gait analysis due to the unfamiliar equipment. Additionally, you may feel fatigue or exhaustion from the walking trials

Reimbursements:

You will not be reimbursed for any medical expenses. However, if any health hazard occurs due to the participation in this study, adequate steps will be taken by the study investigators. Again, if you are unable to afford the travel expenses while attending the study session, the reimbursement will be offered to cover the expense. This reimbursement will be provided at the conclusion of your participation.

Confidentiality:

The confidentiality of about your information will be rigorously maintained throughout the study. Personal identifying information will be collected from you initially for contact but will be removed from the dataset after data collection to ensure anonymity. You will be assigned a unique identification code, which will be used in all data analysis and reporting.

Rights to withdraw from participation:

Participation in this study is voluntary and you may withdraw from the study for any reason at any time. You will not be penalized in any way for declining to take part in or withdrawing from the study. If you decide to withdraw, the gait data collection procedure will be discontinued.

I am consciously and voluntarily participating in the above research study entitled "**Spatiotemporal gait parameters of healthy and stroke patients during overground, self-paced treadmill, and body-weight supported treadmill walking.**". I understand that I will not be given any financial benefit for my participation. The doctors assured me that participating in this study would not harm me physically or mentally and that at any time I would be able to voluntarily withdraw from the study and my treatment would have no effect on it. All my information will be kept confidential.

[Photographing / Video recording]

Photographing/video recording of a participant will be used to visualize experimental setups for the purposes including publication, grant application and public relations. Private information such as the participant's name will not be made available.

Do you agree with Photographing / Video recording during the experiment?

Yes **No**

During any part of the experiment, whenever participants feel discomforts beyond tolerance, trials can be stopped.

Name of participant:	Signature/Thumb print of the participant:

Name of the witness:	Signature of the witness:
Name of the interviewer:	Signature of the interviewer:

[*please note: Where the participant/s are aged under 18, separate parental consent is required; where the participant/s are unable to answer for themselves due to disability, parental or guardian consent may be required.]

INFORMED CONSENT FORM

(English Version)

Spatiotemporal gait parameters of healthy and stroke patients during overground, self-paced treadmill, and body-weight supported treadmill walking.

I am giving consent to take part in the above-mentioned research study of Department of Biomedical Engineering, BUET. The nature of the research has been explained to me.

I am ensuring that,

I am taking part in this study voluntarily ……. Yes ☐ No ☐

I am voluntarily giving my time to the research ……. Yes ☐ No ☐

I am giving my permission to let the researchers
of BME, BUET to keep the consent form as rec …… Yes ☐ No ☐

and I have been allowed to ask questions about this study and my participation in it. I understand that all my personal information will be kept confidential, and no part of this information that might reveal my identity will be published. I also understand that I can refuse to take part in this study any time I want, and I will not be accounted for any questioning or harm for my refusal.

Name of Participant …… Sign of Participant …….

Name of Investigator …….. Sign of Investigator ……

Date.....

[*please note: If the participants are unable to answer for themselves due to disability, guardian consent may be required.]

Case Report Form

Project Title: Spatiotemporal gait parameters of healthy and stroke patients during overground, self-paced treadmill, and body-weight supported treadmill walking.

Participant Information					
1.	Patient's name			Age	
2.	Patient ID			Gender	☐ Male ☐ Female
3.	Address			Contact no.	
4.	Height (cm)		5. Weight (kg)	Date of Stroke	
6.	Type of Stroke	☐ Ischemic ☐ Hemorrhagic		7. BMI	
8.	Affected Side	☐ Right ☐ Left			

Medical History				
9.	Hypertension	☐ Yes ☐ No	10.Diabetes Mellitus	☐ Yes ☐ No
11.	Heart Disease	☐ Yes ☐ No	12. Previous Strokes	☐ Yes ☐ No
13.	Peripheral Artery Disease	☐ Yes ☐ No	14. Chronic Kidney Disease	☐ Yes ☐ No
15.	Smoking	☐ Yes ☐ No	16. Alcohol Use	☐ Yes ☐ No
17.	BP	18.Heart Rate		Number of Previous Strokes

Gait Analysis Information					
19.	Date of Gait Analysis		20. Time Since Stroke (months)		
21.	Balance Test (Berg Balance Scale)	Score: _____/56	22. Muscle Strength (MRC Scale)	Right Leg: _____/5 Left Leg: _____/5	
23.	Spasticity (Modified Ashworth Scale)	Right Leg: _____/4 Left Leg: _____/4			

Gait Analysis Parameters				
24.	Walking Speed (m/s)		25. Cadence (steps/min)	_____

26.	Stride Length (cm)	Right Leg: _____ Left Leg: _____	27. Step Length (cm)	Right Leg: _____ Left Leg: _____
28.	Gait Cycle Duration (s)	_____		
29.	Stance Phase (% of gait cycle)	Right Leg: _____ Left Leg: _____	30. Swing Phase (% of gait cycle)	Right Leg: _____ Left Leg: _____
31.	Double Support Time (s)	_____	32. Single Support Time (s)	_____
33.	Vertical GRF (N)	Paretic Leg: _____ Non- paretic Leg: _____	34. Anteroposterior GRF(N)	Paretic Leg: _____ Non- paretic Leg: _____
35.	Mediolateral GRF(N)	Paretic Leg: _____ non-paretic Leg: _____		

Observational Gait Analysis & Functional Outcome Measures				
36.	Initial Contact	☐ Heel ☐ Flat Foot ☐ Toe		
37.	Midstance	☐ Normal ☐ Hyperextension ☐ Flexed Knee		
38.	Toe-off	☐ Normal ☐ Delayed ☐ Early		
39.	Symmetry	☐ Symmetrical ☐ Asymmetrical		
40.	Assistive Devices Used	☐ None ☐ Cane ☐ Walker ☐ Other: _____		
41.	Timed Up and Go (TUG) Test (seconds)		42. 10-Meter Walk Test (seconds)	

Completed by:

Name of Investigator	Signature	Date

Annexure – E

Budget

The total budget for the proposed study is Tk. 30,000/-. The budget of the project is provided below:

No	Description	Unit	Unit Cost (BDT)	Qty.	Cost (BDT)
1	Reimbursement -Travel Cost of participants	L.S.	1000	25	25,000
2	Miscellaneous Expenses	L.S.	4000	1	4000
3	Contingency (5%)	L.S	1000	1	1000
Total Cost					30,000

Grand Total: Tk. 30,000/-