

## Study Protocol

# Effect of Nature-based physical activity on post-traumatic growth among Healthcare providers with post-traumatic Stress: Protocol for a randomized controlled trial.

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## Abstract

**Background:** In the aftermath of trauma, post-traumatic growth is demarcated as a positive change and traumatic stress as a negative change, which further leads to PTSD. Previous studies have also indicated that both constructs can co-exist. Detailed descriptions of post-traumatic stress reactions are available in the literature, but the psychophysiological phenomenon of post-traumatic growth is still unclear. Studies have shown that the restorative effects of nature-based therapy have been accounted for a reduction in stress and increase positive affect. The purpose of designing this randomized control trial is to observe nature-based walk on post-traumatic growth and Psychophysiological alterations associated with it.

**Methodology:** This study is designed to examine recreational exposure to the natural environment for the promotion of post-traumatic growth among health care providers with traumatic stress. In addition, to assess whether post-traumatic growth is associated with psychophysiological alterations, i.e. Cortisol, C-Reactive Protein, Interleukin-6, Brain-Derived Neurotropic Factor and Heart Rate Variability. At baseline, the participant will be assessed with Trauma Symptom Checklist 40 to evaluate trauma intensity. Moreover, subjects who had developed PTG or did not have any trauma intensity will be excluded from the study. Blinded treatment will be provided to subjects meeting eligibility criteria and will be randomized into two groups sequentially as they agree to participate. The nature-based walk will be used as an intervention or experimental group vs the control (sit in nature). The study outcomes will be observed at baseline and 3-month follow-up.

**Discussion:** This trial will provide information on the effectiveness of nature-based walk therapy. Moreover, one of the more promising findings of this research will be essential information about trauma-related psychophysiological effects. This study will also evaluate both (experimental and control) groups that influence whether negative changes accompany positive changes in the aftermath of trauma or not.

**Trial registration:** The trial was registered with ClinicalTrials.gov (NCT04592770).

## Keywords

Natural Environments, Walking, Psychophysiology, Post-Traumatic Growth, Traumatic Stress



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## Introduction

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The World Health Organization estimated that by the year 2020, stress-related disorders would increase rapidly and be the second leading cause of psychological disabilities. This has led investigators to seek accessible and economic management to decrease the frequency with which the affected population is experiencing a negative effect due to stressful events.

In Pakistan, Health care providers are exposed to a range of critical job-related stressors. Persistent exposure to stressors may lead health care providers to cultivate traumatic stress<sup>1</sup>. A mounting number of research studies point out that to cope with trauma or traumatic stress might lead to post-traumatic growth<sup>2</sup>. Although post-traumatic growth is the positive psychological changes that are the results of struggling with challenging life circumstances or major life crises, and recently it has been linked to sports and nature-based walk or exercise<sup>2</sup>.

During the past decades, humankind has been drawn to nature to relax, recover, and find temporary independence from the stressors<sup>3</sup>. To relieve stress, avoidance from the civilized world, come into contact with nature are amongst the leading reported motives<sup>4</sup>. Healing effects of nature-based therapy have been making an allowance for reducing stress and increasing the positive effect<sup>5</sup>. Previous studies have shown for stressed individuals that nature can promote quicker and comprehensive restoration than man build atmospheres<sup>6</sup>. Research also indicates that nature-based therapy precipitates mental health benefits<sup>7</sup>. Although detailed descriptions of post-traumatic stress reactions concerning nature, walking, jogging, exercise, and psychotherapy etc., are available in the literature, the psychophysiological phenomenon of Post-traumatic growth is still unclear.

Previous three decades of experimental studies have shown positive evidence for the restorative effects of nature<sup>8</sup>. Concerning exercise, experimental studies based on psychological<sup>9</sup>, physiological<sup>10</sup>, and biochemical<sup>11</sup> levels shows that

nature-based exercise or green exercise is more advantageous than the similar workout in artificial built-up rooms<sup>9</sup>. A review by Gladwell et al. shows that the evidence linking beneficial physiological changes in response to nature exposure by walking in contrast to other surroundings is limited<sup>12</sup>. However, several health benefit studies of active and passive activities in nature contrasted with indoor, found that nature is connected with improved mental health and well-being<sup>13</sup>. Bowler et al. included studies in his review by using numerous physiological factors like heart rate variability, systolic and diastolic blood pressure, cortisol, etc., found not sufficient evidence in favour of the natural environment<sup>6</sup> (due to a lack of RCT).

Previous years' studies on the PTG usually have used structured questionnaires, while no study has been conducted to observe the alterations in psychophysiological markers. According to the neurobiological findings, the stress and resilience model needs to put together to understand these factors as the underlying biology is the major contributing factor for triggering psychological risk and resilience factors<sup>14</sup>. Previous studies have evaluated the role and response of biological markers like brain-derived neurotrophic factor (BDNF), cortisol, cytokines such as interleukin-6 (IL-6), and C reactive protein (CRP) among traumatic stress subjects<sup>15-17</sup>. However, their role in association with post-traumatic growth is blurred.

There is mounting evidence from previous studies that subjects who have experienced stressful life events reap physical and psychological health benefits when they are engaged in exercise or nature-based therapy. To the best of our knowledge, this is the first Pakistani population-based study exploring the psychophysiological aspects and monitoring the effectiveness of the nature-based walk on post-traumatic growth.

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## Methodology

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### The objective of this trial

The purpose of designing this trial is to observe the effect of nature-based walk on post-traumatic growth and Psychophysiological changes associated with it.

### Study design

The study is a randomized controlled trial. Subjects will be randomized to receive the "walk-in nature" intervention (experimental group) or a control intervention "Sit in nature" (control group). Both groups will be assessed for study outcomes at baseline, after the 3-month intervention.

### Ethics

The study will be conducted in accordance with the declaration of Helsinki. Ethical approval for this study was obtained from the Pakistan medical association committee on ethics (No. 2020/ERC/8-12)

### Study registration

This study's protocol was registered at Clinical Trials.gov, registration number: NCT04592770 on October 19, 2020.

Available online:

<https://www.clinicaltrials.gov/ct2/show/NCT04592770>

### Participants

Subjects will be recruited from five significant hospitals based in Pakistan's largest city, i.e. Karachi. Subjects from diverse religions, ethnicities, and cultural backgrounds will be considered eligible for this study if they qualify for a pre-screening assessment. Subjects will be invited to participate in the study through announcements on the display board for each hospital staff. Written informed consent will be obtained from each study subject after providing detailed information regarding the study's objectives and its duration.

### Eligibility criteria

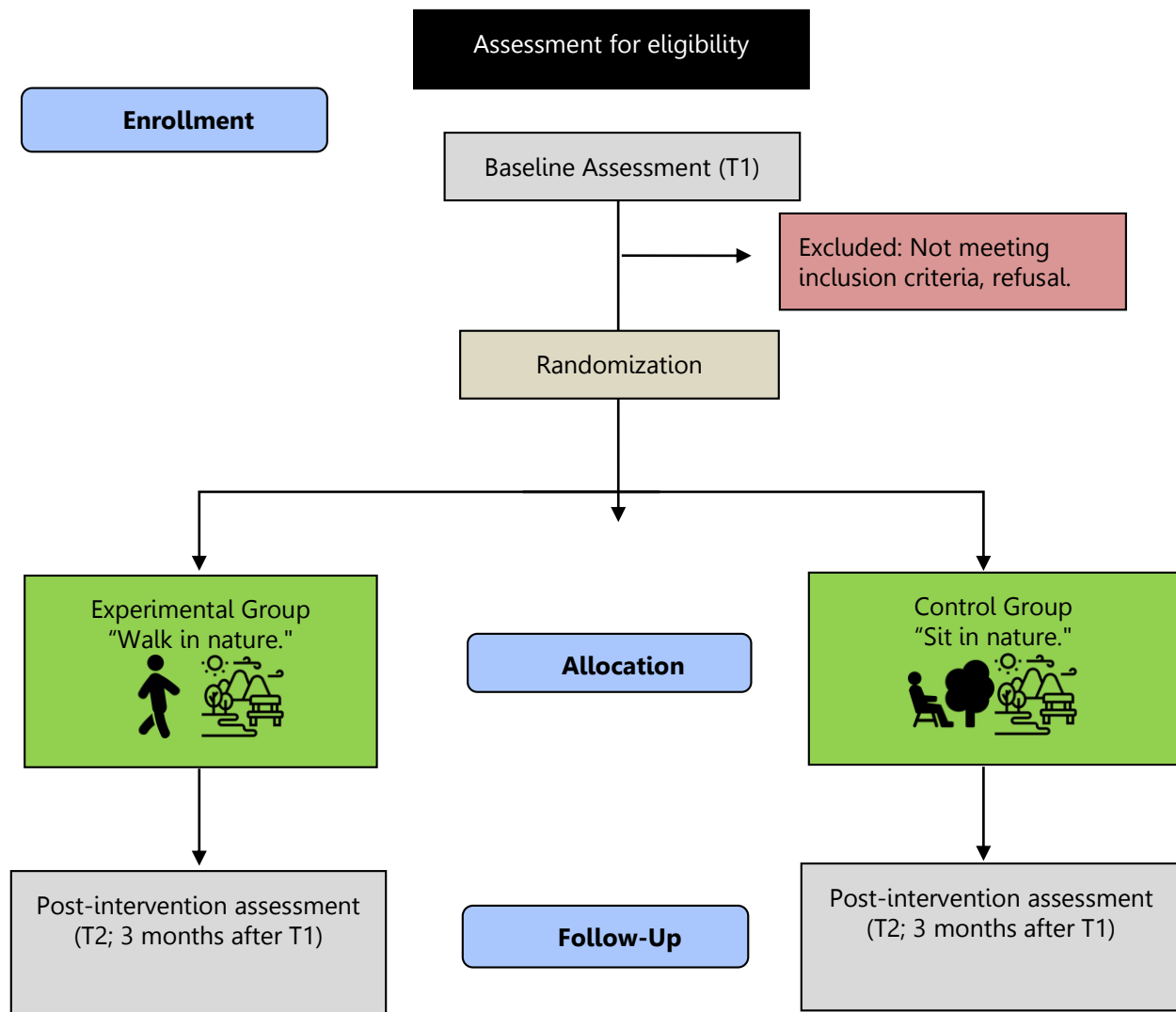
#### • Inclusion criteria

All subjects fulfilling the below-given criteria will be included:

1. Both genders, aged 16–50 years
2. Must be disease free (by their reports); there must be no evidence of any metastatic disease.
3. Fluent in written and spoken Urdu language (National Language of Pakistan).
4. Experienced any traumatic event in the last 12 months.
5. Informed written consent.
6. Being able to walk five times per week. (Participants will be asked to complete the Physical Activity Readiness Questionnaire)

#### • Exclusion criteria

1. Subjects who had received a planned psychological intervention for at least 6 months during the last 3 years implemented by a professional psychologist will be excluded.
2. Subjects with a recognized psychiatric disorder as per the Diagnostic and Statistical Manual of Mental Disorders and those subjects who had received Psychopharmacological drugs during the last 3 years.
3. Those subjects who had developed Post Traumatic Growth. (will be evaluated from Post Traumatic Growth Inventory)
4. Those subjects who do not have any trauma intensity. (will be evaluated from Trauma Symptom Checklist 40)
5. Subjects who are at high risk for physical injury during exercise.
6. Regular exercise in nature



**Figure 1: Flowchart of the study procedure**

### Interventions

- **The experimental intervention**

In this group, the nature walk will take place in a conserved and by far the Karachi city's largest recreational area. The safari park covers an area of 148 acres (0.60 km<sup>2</sup>); it has a zoo, geared with woodland, mountain viewing, safari tracks, and two natural lakes. The experiment will take place in the afternoon on a 5 km marked area. The stretching

exercise session duration will be 10 minutes, followed by 50 minutes walk session five times per week (total 12 weeks). Participants will be free to choose any walk intensity they liked.

- **The control intervention**

Subjects will undergo 12 weeks of nature therapy that includes exposure to natural landscapes. The duration of the sessions will be 60 minutes, five times per week. The subjects will be asked to sit and

relax in the evening in the same recreational area, which is used for the experimental group.

### Recruitment & Assessment Procedures

- Enrollment: Those subjects who had experienced any traumatic event in the last 12 months will be enrolled.
- Assessment of eligibility: Subject meeting eligibility criteria will be included in the study.
- Baseline assessment (T1): All the variables, i.e. Post-traumatic growth inventory (PTGI), Trauma symptom checklist-40 (TSC-40), Traumatic stress scale (TSS), C-Reactive protein (CRP), Brain-derived neurotrophic factor (BDNF), Interleukin-6 (IL-6), Cortisol and Heart rate variability (HRV) will be measured at baseline.
- Randomization: Subjects based on eligibility criteria will be randomly allocated to the experimental or control group sequentially as they agree to participate.
- Allocation: A booklet with detailed instructions will be provided to the study subjects according to the groups allocated.
- Follow-up assessment (T2): After 3 months, all the variables measured at the baseline phase (T1) will be measured again.
- Statistical Analysis: Pre & post-analysis will be conducted in this phase.

### Outcome Measures

Alongside demographic questions (including age, gender, weight, height, ethnicity, etc.), we have carefully selected measurement instruments:

- **Psychological Measures**
  - a. Post-Traumatic Growth Inventory (PTGI)
  - b. Trauma Symptom Checklist (TSC-40)
- **Physiological Measures**
  - a. Cortisol
  - b. Brain-derived neurotrophic factor (BDNF)
  - c. C - Reactive Protein (CRP)
  - d. Interleukin-6 (IL-6)

(Cortisol, BDNF, CRP and IL-6 will be determined using an enzyme-linked immunosorbent assay (ELISA); all kits will be used following the manufacturer's instructions.)

### e. Heart Rate Variability

### Sample Size

A sample size of 246 was calculated with at least 123 subjects that will be placed in both groups for statistically significant variation of PTG to be observed among experimental versus control groups. It was calculated according to a meta-analysis on PTG, where an estimated effect size of 0.36 (equally with both Hedges' g and Cohen's d) with a two-sided test using G power 3.1.3., alpha 0.05 and a power of 0.80.

### Randomization

Subjects based on eligibility criteria will be randomly allocated to the experimental or control group in the 1:1 ratio. Computer-generated random numbers will be used for randomization. After taking the subject's necessary information, a unique code will be provided to each included subject by the study center. The code will be mentioned in each form of each subject.

### Statistical Analysis

The data will be analyzed using  $2 \times 2$  mixed factorial design analysis of variance (ANOVA) to calculate whether there is a significant change in PTG among the intervention and control group subjects. After the intervention, if a higher ratio of PTG will be observed in the experimental group, the interventional impact of the five factors of PTG will be examined with further analysis. Sequentially for each secondary outcome, additional ANOVAs will be used to investigate differences between groups at 3 months and baseline. Adjusted ANOVA will be performed, keeping socio-demographic and other variables as co-variants to determine whether the socio-demographic and other characters could result in alterations in effect between the two groups.

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## Discussion

A randomized controlled trial conducted by Gunnthora Olafsdottir et al. shows under low or high chronic stress, the psychophysiological outcomes of walking indicate buffering HPA axis activation. Moreover, effective cardiac-vagal activation was seen while viewing nature scenes in stress conditions<sup>18</sup>. In another study that compared scenes from human-made environment vs nature scenes, it was found that higher cardiac-vagal activity was seen in the course of recovery in the nature-scene viewing situation. Even though various studies are favourable, it gives the impression that the current evidence is often restricted<sup>10,19</sup>.

A study conducted by Jessie L. Bennett et al. documented significant findings proposing that sports and recreation programs can be used to decrease post-traumatic stress symptoms<sup>2</sup>. However, the current study extends to observe the effect of nature-based walk on post-traumatic growth and Psychophysiological alterations associated with it.

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## Conflicts of Interest

None.

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