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Efficacy Of Multicomponent Positive Psychology Group Intervention Through Randomized Controlled Trial: Study Protocol

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ABSTRACT

Introduction. The Doctor of Philosophy (PhD) degree is the zenith of academic achievement and the most prestigious of the doctoral programs, however there is a growing concern about the mental health issues among this graduating population. In the past decade Western research has presented a bleak depiction of mental health status of the trainee graduates with alarming titles in their editorials, which has lead both, academics and policy makers to implement several interventional strategies. Whereas mental health status of doctoral students from developing countries has not been addressed adequately and attempts to design interventional programs for this segment of population are quite limited. Therefore aim of this trial study is to establish the efficacy of an indigenously designed intervention Lets Flourish Together for PhD scholars based upon positive psychology techniques to promote well-being and enhance flourishment.

Methods and Analysis. The intervention comprises of eight components based on positive psychology techniques, to be delivered over a period of 8-weeks. 154 PhD scholars will be recruited from six universities of Pakistan showing moderate levels of psychological distress assessed during screening process (t0) through DASS-21, in a two-armed randomized controlled trial. Other assessments will take place at (t1) before the start of the

intervention, (t2) a week after the intervention and (t3) following a month. The primary outcome measure of the study is DASS-21, whereas secondary outcomes are flourishment (Positive Psychotherapy Inventory), motivation (Motivation for PhD Studies), perceived social support (Multidimensional Scale of Perceived Social Support), time management skills (Time Management Questionnaire), extent of task delaying (Procrastination Scale), personality traits (Ten Item Personality Inventory), sleep quality (Jenkins Sleep Scale) and physical activity (Six-point Physical Activity Scale). Analysis of data will be based on intention-to-treat principles.

Ethics and Dissemination. This trial has been approved by the Institutional Review Board of the Foundation University School of Science and Technology (FURC/IRB/Spring-2022/29). Results will be published in peer-reviewed journals and presented in conferences.

Trial Registration. The trial is registered at the WHO Primary Trial Registry Platform through Chinese Clinical Trial Registry; ChiCTR2200063701, dated: 9-15-2022. This is protocol version 1, in case of any important protocol modification, trial registry will be updated.

Keywords: Mental Health, Positive Psychology, Flourishing, Intervention, Efficacy, Randomized Controlled Trials.

Strengths and Limitations of this Study

- To our knowledge, this is the first full-scale randomized controlled trial study intending to deliver flourishment training intervention among doctoral students in Pakistan.
- The contents of the designed training are based on need assessment and suggestions from higher academics.
- Results of trainees' acceptance will help gain further insights into the intervention program and to broaden its utility.
- As a limiting factor, the study will not be able to determine specific component responsible for change.

Introduction

PhD degree is recognized with high prestige and respect worldwide. Degree holders are expected to be highly knowledgeable, skillful and copiously efficient members of society.

However these doctors, during their studies experience every thick and thin of hitches and difficulties. PhD scholars represent a mix populous because most of these student have work contracts, doctoral grants or any other work agreement to earn a living along with social and family bindings.[1] The years spent as PhD student are undoubtedly transitional, promoting independence for more professional growth from a dependent role of a student. This brings many uncertainties and hardships but within these upheavals, the future well-being of these aspirant academics evolves[2], therefore understanding the well-being of these working students is of immense importance[3].

Literature from Western countries indicate "mental health crisis" among the graduate students representing high prevalence rate of psychological distress. In a comprehensive survey with clinically validated scales it was shown that graduating trainees are at six times higher risk of experiencing anxiety and depression with reference to general population with a percentage of 39 and 41 respectively[4], other studies indicate prevalence ranging from 36.30%[5] to 55.9%[1]. A study from Belgium by Levecque et al. [6] revealed that more than half (51.1%) of doctoral students met criteria for psychological distress, whereas recent UK-based mental health survey[7] reported 70.9% and 74.2% clinically relevant symptoms of depression and anxiety, prompting advocacy for strategies to help restore and promote well-being of this group.

Broadly speaking mental health problems can be reduced by traditional psychotherapeutic approaches that aim to cure illness, whereas Positive Psychology approaches help prevent mental health issues and promote wellness[8]. Application of positive psychology interventions in academic arena has shown significant elevations in well-being and reduction in mental health issues but an ample body of research is still required for higher academic institutions to adopt these approaches as regular part of their curricula.[9]

Positive Psychology Interventions

Positive psychology essentially aims to enhance the amount of 'Flourishing' across the globe[8,10]. Many randomized controlled trial (RCT) studies' meta-analytical reviews have been conducted to prove the effectiveness of positive psychology interventions (PPIs) so far. Weiss et al.[11] analyzed 27 studies and demonstrated a small effect size of (d=.44) for an increase in psychological well-being,

whereas another meta-analysis of 37 studies from Western countries by Hendriks et al.[12] reported moderate to large effect sizes in elevating subjective well-being (d=.66), psychological well-being (d=.99), and significant effect sizes in decreasing anxiety (d=1.7), stress (d=.76) and depression (d=.67). Meta-analysis from non-Western countries including clinical and nonclinical samples also revealed promising results in the application of Multicomponent PPIs, indicating significant effects in raising subjective (d=.86) and psychological well-being (d=.64) and reducing depression (d=.78) and anxiety (d=1.24)[13].

Koydemir et al.,[14] analyzed sixty-eight RC studies, having a nonclinical sample of 16,085 adults, though the effect sizes were small with an overall effect of 0.23 and when subjective and psychological well-being were taken together Cohen's d was found to be 0.43, but the analysis revealed many interesting facts regarding efficacy of PPIs. Interventions that had more components and were longer (> 4 weeks) and focused on both aspects of well-being were more effective. Young adults had stronger short-term effects whereas adults had long-term effects and interventions that were applied face-to-face not via any assistance of technology were capable of producing slightly better effect sizes. Systematic review from 25 meta-analyses, 42 review papers, and high-quality RCTs of PPIs intended to engender well-being revealed small to moderate effect size for well-being (subjective & psychological), small to medium-sized positive effect on anxiety and depression and moderate effect size for stress reduction in WEIRD (Western, Educated, Industrial, Rich, and Democratic) countries, suggesting such researches in the non-WEIRD countries[15].

In bulk of these studies, only few have been conducted with doctoral student population using PPIs ranging from single to multicomponent[1,9,16,17,18,19] and among these studies, fewer have shown significant effects in decreasing distress symptoms and increasing well-being. More over all of these researches have been conducted in developed countries, the scarcity of information from low and middle income countries (LAMICs) still remains void.[13]

Randomized Controlled Trials (RCTs) are appraised as the 'Gold Standard' in clinical research, [20] but are usually not conducted in LAMICs due to high cost and complexity. Analysis of 625 articles from Indian Journal of Positive Psychology, having researches from Asian countries including India, had only 2 RCT

studies with low quality of research.[13] Meta-analysis of MPPI programs of many non-Western studies has shown the effect sizes to be higher than that of Western studies but the difference is mainly attributed to overall lower quality of non-Western studies,[13] while some researchers suggest that PPIs constitute a good cultural fit with non-Western population because Western culture is often described as independent, whereas Eastern culture is characterized as interdependent.[21-23]

Pakistan is an Asian lower-middle income[24] country where the number of PhDs multiply each year but no empirical data exists explaining the indigenous, need based, solution oriented intervention application for these learners. The current research therefore intends to conduct a good quality RCT study with PhD scholars in three cities of Pakistan to establish the efficacy of indigenously designed Intervention Program with an expected profound output in augmenting flourishment and reducing psychological distress.

METHODS

Study Design

This is a parallel, two-arm RCT study for investigating the efficacy of Multicomponent Positive Psychology Intervention to enhance Flourishment among PhD scholars. Experimental group will receive the 8-week intervention 'Lets Flourish Together' (termed as LFT) and the Control group (No Intervention Group-NIG) will receive no intervention. Assessment of primary and secondary outcomes will continue for a period of 3 months. Valuations will take place at screening level (t0) by the lead researcher, whereas the Data Handling Team (DH-Team) will carry baseline assessment (t1) after recruitment and before start of the intervention, post-treatment assessment (t2) one week after the completion of the intervention and follow-up assessments (t3) one month after the post-treatment (see figure 1).

The Institutional Review Board (IRB) of the Foundation University Islamabad (FUSST) has approved the design and procedures of this study (FURC/IRB/Spring-2022/29). The study protocol is in accordance with the commendations of Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Checklist for clinical trial protocols[25] and will be presented according the Consolidated Standards of Reporting

Trials for Social and Psychological Interventions (CONSORT-SPI) 2018 guidelines for RCTs.[26]

Participants' Eligibility Criteria and Screening

After giving inform consent, PhD scholars will fill the primary outcome measure for screening purpose. Eligibility criteria are: (1) at least one year of PhD enrollment, (2) age between 26-60 years, (3) presence of psychiatric symptoms reflected by DASS-21;[27] scoring between 10-20 (mild to moderate) on depression subscale, and/or between 8-19 (mild to severe) on anxiety subscale, and/or between 15-33 (mild to severe) on stress subscale. Exclusion criteria are: (1) having less than one year of enrolment in PhD, (2) intending to or have availed semester leave, (3) scores on DASS-21 lie in severe/extremely severe category on depression subscale, and/or extremely severe on anxiety and/or stress subscale.

Randomization, Treatment Allocation and Blinding

DH-Team will centrally conduct stratified (by institution) randomization through computer (MS-Excel) generated lists for each participating institution with a random sequence allocation ratio of 1:1 (i.e., participants will either be allocated to experimental or controlled condition with reference to computer generated numbers). The DH-Team comprising of three MS students, not otherwise involved in the trial and blinded towards all further procedures, will process data, however blinding on the part of participants will not be possible.

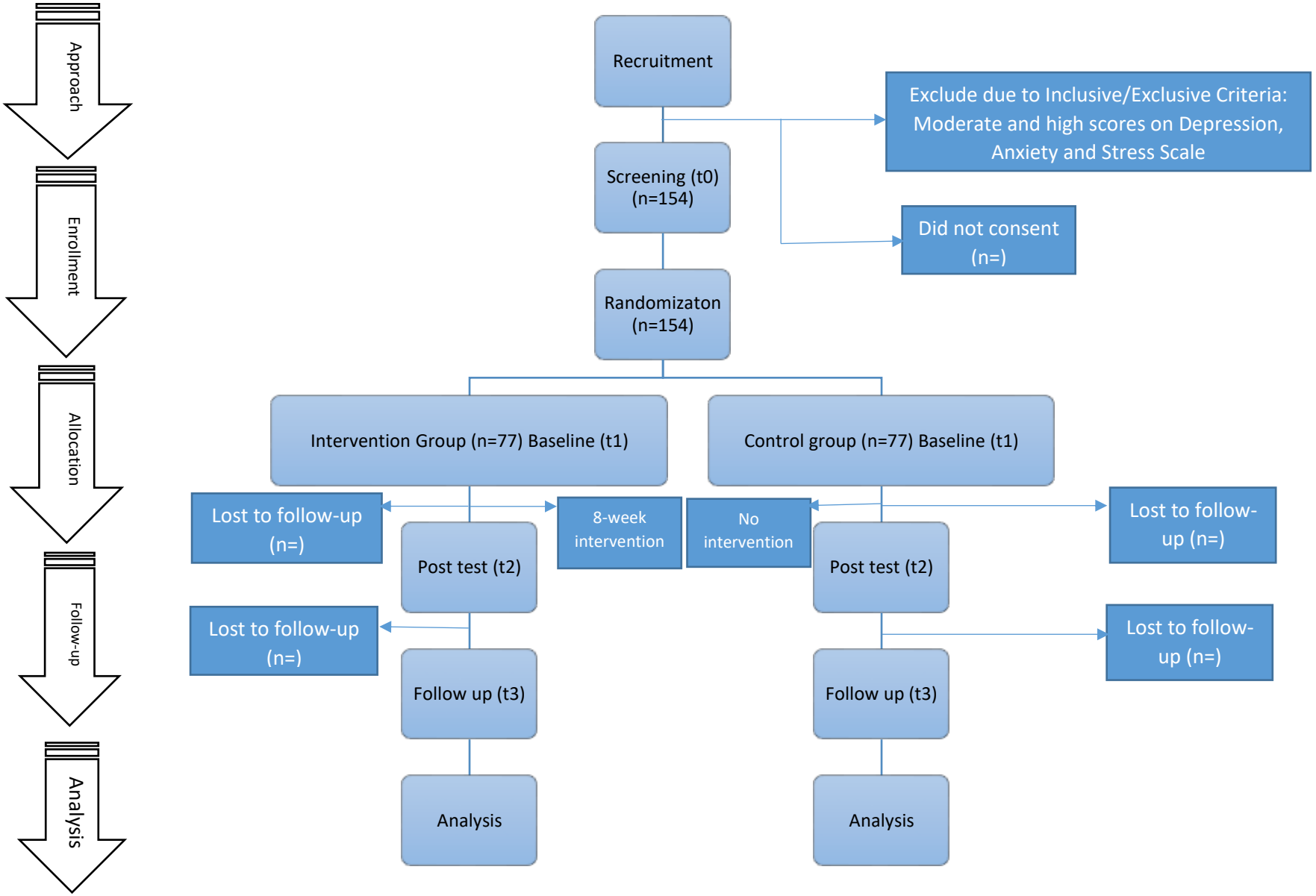
Recruitment

Recruitment had been delated somewhat because of political unrest in the country, therefore it was initiated from mid-January, 2023 and will continue until targeted sample size will be achieved. Recruitment plan encompass a robust, comprehensive online and offline recruitment approach. After permission from administration of universities, flyers are distributed amongst PhD students, PhD supervisors are requested to share the flyer with their PhD students via email, WhatsApp groups and Facebook page of universities. PhD students who show their interest are sent screening tool kit through email and WhatsApp. Screening data is being collected by lead researcher and handed over to DH-Team for data processing.

Study Procedures

After screening (t0) and randomization, the DH-Team will contact participants allocated to intervention group (LFT) via email to complete secondary (baseline-t1) outcome measures and share training details, while the control group (NIG) will be asked to complete secondary outcome measures, no further information will be shared at this point. The LFT will receive 8-week training comprising of four sessions delivered fortnightly of MPPI termed as “Lets Flourish Together”. Each training session will comprise of 8 to 10 participants and will be held at the respective university of the participants. One week after completion of the training program, participants of both groups (LFT & NIG) will be asked to complete questionnaires for post-assessment (t2) and after one month for follow-up (t3), each time offering them a chance to win a free voucher at restaurant (M) amongst their group.

Figure 1. Design and study plan. Source: CONSORT-SPI 2018



Intervention: Adjustment for PhD Scholars

The intervention is primarily based on PERMA theory of well-being[10] by Seligman, however we have adapted the flourishment training program "Lets Flourish Together" for PhD scholars from multiple resources aiming to enhance flourishment and reduce psychosocial and academic distress during the doctoral studies. Useful suggestions were drawn from analysis of qualitative data from PhD scholars and PhD supervisors for raising well-being and enhancing flourishment and tailored content from "Positive Psychology Foundations" online course[28] by Chris and Miriam. The "REVAMP" intervention for medical doctors designed by Jordyn[29] and the CARE program[30] designed by Rebecca et al. for French PhD students have also been consulted. The contents and the mode of treatment delivery are adjusted according to the needs of our target group. Researcher plans to have two-hour session fortnightly, with 8-10 participants per group within the premises of each selected institution, for 8 weeks. The session sequence will be psycho-education, group discussion followed by in-session exercises and explanation of home assignment (requiring 10-15 min) that help in developing the habit of practicing positive psychology techniques in everyday life. Each session will end with a summary, followed by questions to broach any uncertainty.

This year in spring, a formative user evaluation of "Lets Flourish Together" was conducted to ensure that the intervention is understandable, acceptable and relevant to our target group. A group of five PhD scholars were given the manual to read and practice selected exercises and rate them from 1(not at all useful) to 5(extremely useful) in order to show relevance and suitability, their suggestion were appreciated and incorporated. An outline of the intervention contents is given in Table 1.

Table 1. Modules and content of the intervention "Lets Flourish Together"

Modules	Content
1. Introduction and Positive Emotions	Well to participants, trainer's introduction. Introduction to Positive Psychology Cultivating positive emotions Gratitude practices Savoring practices
2. Engagement	'Flow' for researchers

	Using signature strengths Over use of strengths
3. Resilience	Dimensions of resilience Resilience toolkit SSRI Optimism and ABCDE of resilience
4. Relationships	Nurturing relationships Gottman's risk and protective factors Developing relationship with family, friends, self and supervisor
5. Meaning	Living with purpose Best possible self Spirituality
6. Mindfulness	Spiritual happiness How mindfulness is helpful Practicing mindfulness
7. Achievement	SMART goal setting 9-things successful people do differently Time management skills
8. Physical body	Somatopsychic well-being The four count breath Hunt the good stuff from the course

Control Group

Participants in the control group will be contacted by email to complete the baseline assessment (t1) and after 4 weeks they will be contacted again via email to greet and inquire about any change in contact information, no other information will be shared. After 8 weeks of the baseline valuations, participants will be asked again to fill in the assessments (t2) and return within a week time and a month later again for a follow-up assessment (t3).

Training Facilitation and Intervention Manual

The training will be facilitated by lead researcher (HA) and supported by (TF) MS degree holder in Psychology after having two days training of the core contents. Two intervention manuals (trainer & trainee manuals) are developed to assure standardized implementation of the intervention. The trainer manual includes detailed explanation of every module; introduction of each flourishment component, core theoretical concepts and detailed instructions of in-session exercises and home assignments with examples. The trainee manual includes brief introduction of concepts presented during each session, instructions for carrying

out in-session and home assignments along with worksheets for performing the exercises. The manual has been developed to guarantee a standardized intervention process.

Study Measures

A brief overview of all outcome measures and different assessment time points are presented in Table 2. To gauge the academic and psychosocial issues encountered by PhD scholars different scales based upon brevity and availability in English language are being used.

Table 2. Intended questionnaires and measurement points

Questionnaire	Measurement	Screening (t0)	Pre-test (t1)	Post-test (t2)	Follow-up (t3)
DASS-21	Symptoms of depression, anxiety, stress	✓		✓	✓
PPTI	Flourishment		✓	✓	✓
M. PhD	Motivation for PhD studies		✓	✓	✓
MSPSS	Multidimensional Scale of Perceived Social Support		✓	✓	✓
TMQ	Personal time management assessment		✓	✓	✓
PS	Procrastination Scale		✓	✓	✓
TIPI	Ten Item Personality Inventory		✓	✓	✓
JSEQ	Jenkins Sleep Evaluation Questionnaire		✓	✓	✓
Six-point scale	Physical activity levels		✓	✓	✓
BD	Brief demographic	✓		✓	✓
DD	Detailed demographic		✓		

Primary Outcome Measure

Depression, Anxiety and Stress Scale-21 (DASS-21)

The Depression, Anxiety and Stress Scale 21-item (DASS-21) is used to assess the extent of psychiatric symptoms that affect mental well-being. Participants rate the frequency of their feelings in the last month on a 4-point Likert scale ranging from 0 (never) to 3 (almost always). Scores of depression, anxiety and stress subscales are calculated by summing up the scores of the relevant items. The cut-off scores of conventional severity labels are given in the DASS-21 manual.[27] Reliability of each scale is Cronbach alpha of .87 for depression, .79 for anxiety, and .83 for the stress and the overall scale has excellent construct validity.[32]

Secondary Outcomes Measures

Positive Psychotherapy Inventory (PPTI)

Flourishment (subjective & psychological well-being), based on PERMA theory of well-being is measured with 25-item Positive Psychotherapy Inventory[31] (PPTI). It uses 5-point Likert; 5 (very much like me) to 1 (not at all like me) with an overall score range from 25 to 125, the higher the score the more flourishing the individual is. Subscales of PPTI Positive emotions, Engagement, Relationships, Meaning, and Accomplishment have shown satisfactory internal consistency with Cronbach's alphas reliability .77, .81, .84, .71, .77 respectively and have demonstrated good construct validity.[31]

Motivation for PhD Studies Scale (M. PhD)

To gauge motivation we will use "Motivation for PhD" scale, based on the self-determination theory.[33] The scale comprises of 15 items with each 3 items measuring five types of self-determination continuum; intrinsic, integrated, identified, introjected and external, with Cronbach's alphas reliability values .73, .81, .65, .61, and .76 respectively. The scale also shows good convergent and discriminant validity.[34]

Multidimensional Scale of Perceived Social Support (MSPSS)

To assess social support multidimensional scale of perceived social support by Zimet et al.[35] will be used. The scale has 12 items, 4 items for each of 3 subscales relating to family, friends and significant others, Cronbach's alpha reliability of the subscales are .87, .86, .86 respectively and of total scale is .89, with an adequate validity.[36]

Time Management Questionnaire (TMQ)

Time management questionnaire developed by Wayne State University[37] will be used to measure time management skills of PhD scholars. The scale has 25 items, scored on 3-point Likert scale, where '2' is for always and '0' is for never, with a total score ranging from 50 to 0, where high score indicate better time management skills.

Procrastination Scale (PS)

Procrastination scale developed by Lay[38] consists of 20-items, and is used to assess participants' extent of delaying tasks. Items are rated as extremely uncharacteristic=1, to extremely characteristic=5, with score range 20-100. Reverse coded items are 3,4,6,8,11,13,14,15,18,20. The reliability coefficient ranges from .89 to .94.

Ten Item Personality Inventory (TIPI)

The Ten Item Personality Inventory is a brief measure, with one item representing each pole of the five dimensions namely Extraversion, Agreeableness, Conscientiousness, Emotional Stability, and Openness to Experience. Each of the ten items are rated on a 7-point scale ranging from 1 (disagree strongly) to 7 (agree strongly). The TIPI takes about a minute to complete and shows sufficient content validity and .72 test-retest reliability.[39]

Jenkins Sleep Scale (JSS)

The JSS is an efficient, brief instrument designed to evaluate frequency and intensity of sleep problems, over the past month on a Likert-type scale where 0 means “not at all”, while 5 means “22-31 days”. High scores indicate more acute sleep difficulties. It takes about 2 minutes to administer and possesses internal consistency ranging from .63 to .79.[40]

Six-Point Physical Activity Scale (PAS)

The Six-Point Scale devised by Hirvensalo et al.[41] will be used to measure the level of physical activity and its intensity among participants. The scale scores physical activity from 1 to 6 with many rubrics referring to necessary mobility to perspiring and depth of breathing. The scale can be used to categorize physical activity into three levels: low, moderate, and high. Low, if scores are 1 or 2, moderate if scores are 3 or 4 and high if scores range to 5 or 6. The scale has fair to good concurrent validity.[42]

Demographic Data

A brief demographic data will be obtained at the time of screening for communication purpose, and at the post and follow-up

assessment for identification, however at the time of baseline assessment, a detailed demographic data will be obtained.

Data Management, Privacy and Ethics

Data will be handled confidentially by DH-Team, consisting of three MS students at Foundation University Islamabad. Institutions and participants will be assigned IDs and codes to conceal their identification. After analysis the lead researcher will keep the data in a coded file for any future query by participants and for research purpose. Anonymized results will be presented in national/ international conferences and published in peer-review journals.

Participants in this study will not be inflicted with any risk. Nevertheless, temporary changes may occur in mood during participation in the in-session exercises or home assignments, for which participants will be informed at the beginning of every session to reflect upon their positive and/or any negative or uncomfortable feelings associated with practice of positive psychology techniques. The trainer will guide and support in case of any required assistance.

Statistical Methods

Power Calculation

G*Power (http://gpower.hhu.de/) is used to calculate the sample size, with the ability of detecting at least a moderate effect size (d = 0.50) on the primary outcome measure between the experimental group (LFT) in comparison with control group (NIG). For a two-tailed independent t-test with 80% power and .05 alpha, 64 participants are required for each group (N=128). Considering a drop-out rate of 20% at most, a total of 154 PhD scholars will be recruited for protocol analysis.

Statistical Analysis

All statistical analysis will be executed according to intent-to-treat (ITT) principle for comparing participants. For investigating the baseline differences between the study groups, independent t tests and chi-square statistics x^2 will be used and for determining the internal consistency of the constructs, Cronbach's alpha will be used. Results of non-significant differences of socio-demographic data between the two groups at the baseline assessment will help

explain success of randomization. To examine the efficacy of the intervention, all participants who have been randomized will be subjected to ITT analysis.

Expectation Maximization[43] (EM) method will used for imputation of missing data on continuous measures of t1, t2 and t3. The EM method substitutes the missing data through maximum likelihood estimation by using the observed data through the process of iteration. . The participants who will complete at least 75% of the intervention will be defined as completers and will be subjected to ITT (completers-only) analysis.

Repeated measure ANOVA in 2 (groups) x 3 (time) design will be performed to observe the significant variations between LFT and NIG groups with primary outcomes depression, anxiety and stress (DASS-21) and all the secondary outcome variables. To calculate substantial difference with-in groups, pooled standard deviation will be divided by the difference obtained from subtracting mean post-test or follow-up scores from the mean baseline scores. To determine between-group effects, pooled standard deviation will be divided by the difference from the scores of post-test and follow-up assessments of experimental group and that of control group. The knowledge of these effect sizes[44] (Cohen's d) will help to gain insight about the magnitude of significant difference obtained by the treatment applied.

Discussion

To the best of our understanding, the current study will serve the first to explore the efficacy of a Flourishment Training Program for PhD students of Pakistan to promote their mental health and well-being. In the present article, we have highlighted the intervention development process and have identified several valuable resources for adaptations and adoption of positive psychology exercises for promoting PhD students' mental health. The study will be conducted in at least six higher education institutions from three cities of Pakistan.

Given the practicality of the proposed study, it has many distinctive strengths. First, the core contents of the indigenously tailored training is based upon the need and suggestions of the higher academia identified through qualitative research and previous literature. Besides the relevance and necessity of the program, the methodical quality stands out as another strength,

especially with reference to developing countries where conducting RCTs is still sparse in research. This protocol study attempts to investigate the usefulness and mechanism of action of theory-and-research based MPPI as a face-to-face intervention through a two-parallel arm controlled trial, with ITT analysis application of to avoid selection bias and possibility of intervention to reflect an overestimated effect. Third, the intervention is highly standardized in application and conducting procedures through the use of trainer and trainee manuals. Forth, our study is expected to broaden the existing knowledge of positive psychology techniques as it focuses on well-being and flourishment instead of mental illness and uses multi-components instead of single component. Another strength of our study concerns the recruitment strategy by employing broad online and offline strategies in different universities of three cities of Pakistan, we will be able to cater a wider range of potential participants helpful in establishing efficacy of the newly designed intervention.

Despite several strengths, there could be some probable constrains related to the study that need to be taken into consideration. First, our results may not be generalized to the entire PhD population as our sample will be collected from only three cities of the country. However, using stratified (by institutions) randomization procedures, will help in equal distribution of certain characteristics within each group and therefore, there will be no harm to the internal validity of the study. Secondly, the study will not be capable to specify that which pertinent factor of the intervention would have led to possible effects in the results. This limitation warrants the need of future research. Third, drop out from assessment (incomplete data) and non-adherence to the intervention may occur causing attrition of sample that can bias the results. Reasons for attrition could be related to participants' characteristics (e.g. busy schedule or lack of motivated for longer period) or intervention characteristics (e.g. components not much pertinent or lengthy). However, we presume to have higher adherence rates compared with online interventions, as this intervention is face-to-face and interactive[45] involving every participant to provide input and gain benefit from training.

Taken together, our findings will contribute to a new arena of MPPIs for enhancing well-being and flourishing among highly imperative segment of our population for mental health

promotion. If proven effective, results of the study will be valuable in terms of policy making for universities offering PhD studies, supervisors working with PhD students and officials of Higher Education Commission to fuel evidence-based policies for universities to address mental health concerns.

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Contributors: PI designed the intervention, drafted the manuscript and Dr. Sadaf Ahsan has reviewed each step and approved the manuscript for publication.

Competing interests: All authors have no competing interests.

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