

"Creating Harmonious Equilibrium: A Comprehensive Protocol To Assess Feasibility Of A SMET Yoga Module To Enhance Work-Life Balance Among Women Managers Via A Two-Armed Single Blind Randomized Controlled Trial"

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ABSTRACT

Background and objectives: The failure to achieve a balance between different life domains can have negative consequences on both physical health and psychological well-being. Imbalances in these domains can result in heightened stress levels, burnout, and other health problems (Borowiec, A. A., & Drygas, W. 2022)., with similar trends in the U.S. showing an annual burden of \$125 billion to \$190 billion due to psychological and physical health issues from Harvard Business Review (Eric Garton, 2017). Many modalities are used to maintain Work-Life Balance (WLB), and yoga is one of them. It may help manage a harmonious balance between the domains of work and personal life. Nevertheless, there isn't a predetermined module for work-life balance. The purpose of the current study is to evaluate the SMET yoga module's feasibility on work-life balance.

Material and methods: aimed seek for the proposed study to be carried out on the impact of SMET yoga on work-life balance (WLB). Work Interference with Personal Life (WIPL), Personal Life Interference with Work (PLIW) and Work Personal Life Enhancement (WPLE) and Stress. The feasibility testing of the module will be done with 120 women managers. In this study, we will use a single-blind randomized control trial to split the participants into two groups: one will receive SMET, and the other will serve as a control group.

Ethics & Dissemination: This research has received clearance from Bangalore's Swami Vivekananda Yoga Anusandhana Samsthana University's Institutional Ethics Committee (ID:RES/IEC-SVYASA/225/2022). We will ensure that every participant provides written informed consent before they are included in the study. Trial registration number: CTRI/2024/01/061355

Statistical analyses: The normality of the feasibility data will be checked, and suitable tests will be utilized to compare the two groups in order to estimate the differences between the SMET Yoga group and the control group prior to and subsequent to the test.

Expected outcomes: The outcome of this study is to explore and elucidate the impact of SMET yoga interventions, shedding light on their effectiveness in empowering women managers to navigate their professional and personal spheres with resilience and equilibrium. Lastly, the module's impact on WLB, cortisol, and perceived stress will be determined.

Keywords: Work-Life Balance, Stress, SMET, WIPL, PLIW, WPLE, PSS, Cortisol.

Introduction:

The concept of work-life balance (WLB) involves finding a harmonious equilibrium between one's professional life, which includes work responsibilities and career growth, and their personal life, which includes family, social activities, leisure pursuits, and personal development (Wepfer, A. G., et.al.,2018). Striking a balance between work and personal life requires effectively managing time and energy to promote overall well-being, satisfaction, and fulfilment. This involves minimizing conflict and stress in both areas. The balance between individual health, organizational productivity, and job satisfaction is of utmost importance (Greenhaus, J. H., Ziegert, J. C., & Allen, T. D. 2012).

The importance of work-life balance is highlighted by its connection to different aspects of employee well-being, such as mental health, job performance, and organizational commitment. Although achieving work-life balance (WLB) is crucial, it can be quite difficult, especially for women in managerial positions. These women often face distinct pressures when it comes to juggling their careers with family and personal obligations (Eagly & Carli, 2007). This particular group of people often experiences high levels of stress due to the challenges of juggling multiple responsibilities. This can result in burnout, which is characterized by feelings of emotional exhaustion, detachment from others, and a decrease in personal achievements (Maslach & Leiter, 2016). Not only does burnout have a negative impact on personal well-being, but it also has significant consequences for organizations, leading to reduced productivity and higher turnover rates (Halbesleben, 2010; Leiter & Maslach, 2016).

Yoga, stemming from ancient practices, has become a promising intervention for reducing stress and improving overall well-being. This practice combines physical postures, breath control, and meditation to enhance physical well-being and promote mental calmness (Jensen, P. S., et.al., 2012). A study conducted by Gothe et al. (2013) emphasizes the positive effects of yoga on reducing stress and boosting psychological resilience. This research suggests that yoga can be a valuable tool for improving work-life balance. Although there is extensive documentation on the benefits of yoga for managing stress, it is worth noting that there is a lack of standardized yoga modules that specifically focus on comprehensive work-life balance.

The SMET (Self-Management of Excessive Tension) yoga module is a unique and customized approach designed to help individuals dealing with work-life balance issues. This module combines traditional yoga practices with specific techniques for effectively managing work-related stress and personal tensions. Although it has great potential, it is crucial to thoroughly assess its effectiveness and practicality in real-world situations. This protocol presents a thorough approach to evaluate the potential of the SMET yoga module in enhancing work-life balance among women managers. The evaluation will be conducted through a two-armed single-blind randomized controlled trial (RCT). This study seeks to offer empirical evidence regarding the effectiveness of this yoga intervention in improving work-life balance and reducing burnout among a population that is especially susceptible to work-related stress. This module is being rigorously evaluated to contribute to the development of evidence-based practices that can support employees in achieving a more balanced and fulfilling work-life experience.

Background and Rationale:

The economic impact of burned-out employees is a significant concern, as highlighted in recent studies and a report by Eric Garton in the Harvard Business Review. These findings emphasize the need to address factors that contribute to burnout, such as work-life balance. There are several interventions available to promote work-life balance, including flexible work arrangements and mindfulness programs. However, yoga stands out due to its comprehensive approach, addressing physical, mental, and emotional well-being. Nevertheless, many yoga interventions fail to provide specific guidance on how to improve work-life balance. Considering the distinct obstacles encountered by women managers, who frequently balance numerous roles and responsibilities, there is a clear requirement for customized interventions to assist their work-life balance endeavors.

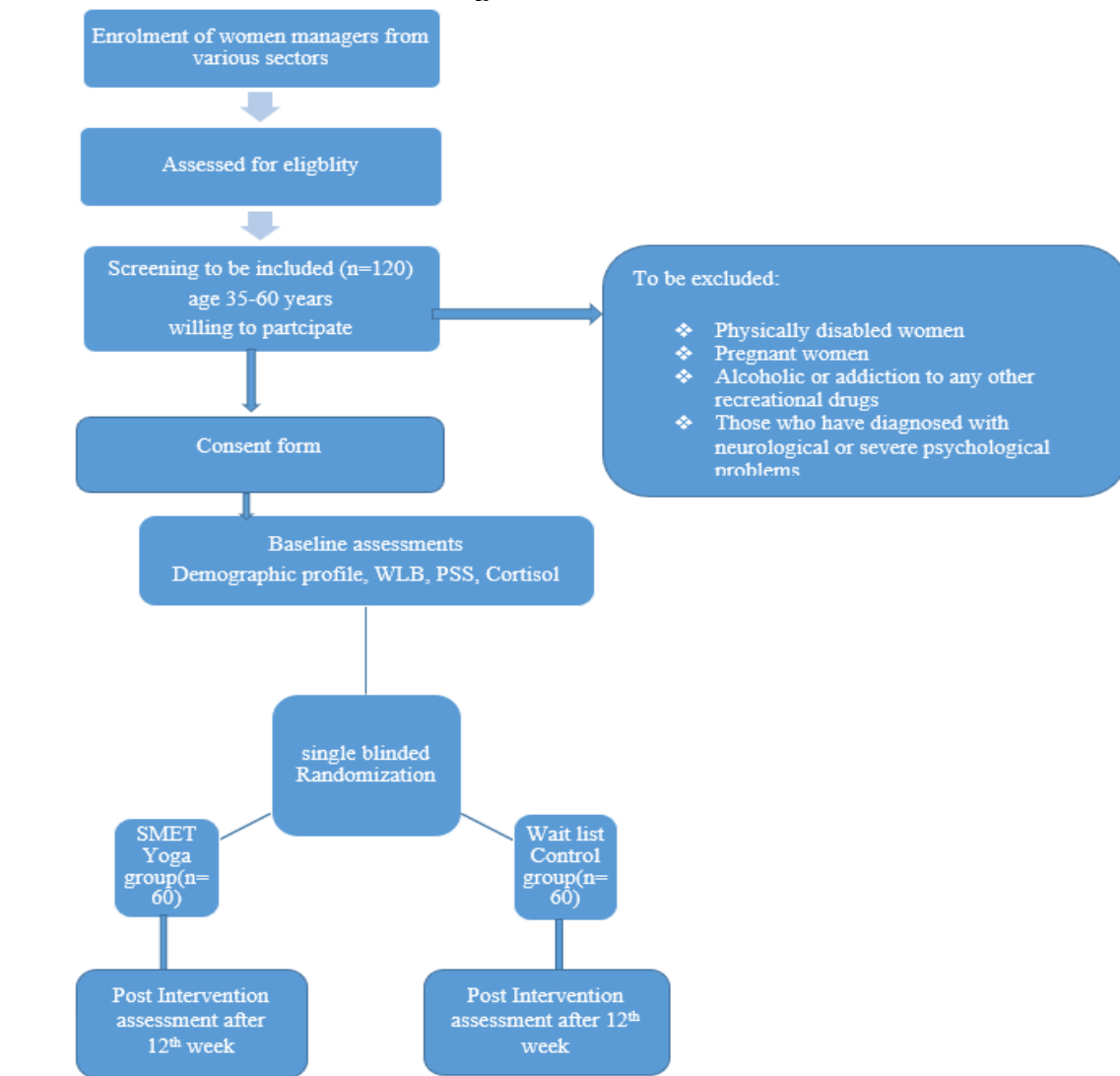
Materials and Methods:

Study design:

The upcoming study will be a two-armed randomized controlled trial with outcome assessors blinded. Its objective is to evaluate the impact of SMET yoga intervention on work-life balance among women managers in South India. The protocol has been drafted as per the framework of the guidelines established by the Consolidated Standards of Reporting Trials (CONSORT), the protocol has been drafted (Begg, C. et.al., 2006) (Fig.1). The intervention group will participate in the SMET yoga module, while the control group will continue their regular work until they receive the intervention after the study, forming a waitlist control group. Women managers from urban industrial sector would be invited through the respective Human Resource Department, in the Vishakhapatnam, Andhra Pradesh, South India. All individuals will receive comprehensive study information during the screening process to determine eligibility. Participation will be strictly limited to individuals who meet the eligibility criteria. The inclusion criteria for this study are as follows: individuals who

are between the ages of 35 and 60, women who hold managerial positions in various public and private sectors, individuals who express a willingness to participate in the trial, and individuals who do not have any plans to outing, they must remain in the local area during the intervention and testing period. Participants who have engaged in structured physical activity regimes or practiced Yoga within the past three months will not be eligible to participate. This policy also extends to individuals who have an accelerated pregnancy, those who have alcohol or recreational drug addiction, and individuals who have been diagnosed with neurological or severe psychological disorders. Individuals who express interest and meet the specified criteria will be obligated to furnish written informed consent. The subjects will be randomly assigned to either the SMET yoga intervention group or the waitlist control group as part of the process. The intervention will be administered for a period of 12 weeks.

Fig. 1 Trail Profile:



Randomization and blinding:

The process of randomization will be conducted utilizing a digital tool known as Calculator Soup. This task will be performed by an external statistician, who will allocate participants to either the intervention group or the control group in a 1:1 ratio. The randomization list shall be transferred into individual sealed envelopes. These envelopes will be opened by the research staff and distributed to participants subsequent to their baseline assessments. Randomization will be conducted by an external statistician, independent of the study implementation, in this research study, randomization and blinding were integral components of the experimental design aimed at minimizing bias and ensuring the validity of the findings. Additionally, a single-blind approach was implemented, participants are not aware of their group assignments, but the researchers are aware. This design helps reduce potential bias from participants' knowledge of whether they are in the control group or the experimental group. This prevented conscious or subconscious biases from influencing participant outcomes or data interpretation. Blinding was maintained throughout the study, including during

the randomization process, data collection, and statistical analysis, to minimize the risk of bias and enhance the credibility of the study results.

Intervention:

Participants who are randomly assigned to the yoga group will get a SMET yoga module. It is a well validated specialized yoga module designed to alleviate stress and enhance overall well-being of executives by Dr. H. R. Nagendra of S-VYASA University in Bengaluru, SMET integrates a series of yoga postures, breathing exercises, and relaxation techniques aimed at reducing physical and mental tension. This module promotes the harmonization of body and mind, enabling individuals to manage stress more effectively (Meenakshy, K. B., 2014). It was demonstrated that the SMET module contributed to an increase in positive affectivity, which in turn improved quality of life, and reduced occupational stress for employees (Vasu, J et.al., 2022). The SMET Yoga Module: Self-Management of Excessive Tension is a yoga-based program for managing stress. It is an all-encompassing yoga module that includes theory sessions on stress awareness, resilience, coping Counselling, and Discourses, as well as practice sessions like Cyclic Meditation (CM) that include Asana, Relaxation techniques, and Meditation. The researcher will instruct the module with the participants through virtual classes at their own place in the morning and evening, in groups. The classes will be held five days a week, each lasting sixty minutes.

Waitlist Control Group:

We opted for a waitlist design for the inactive control group because we felt it was a more responsible alternative to continuing to provide the care that the inactive control group. They will be instructed to proceed with their regular day without engaging in any planned physical activity as they are being enlisted. After the 12-week trial ends, these individuals will continue to receive the same SMET yoga as the intervention group.

Outcome Measures:

Effectiveness will be assessed based on recruitment and retention rates, adherence to the intervention protocol, and participant satisfaction. Secondary outcomes include changes in cortisol levels (Kirschbaum, C., & Hellhammer, D. H.1994) and perceived stress (Cohen et al., 1983).., assessed with the help of the questionnaire. By elucidating the impact of SMET yoga interventions on WLB, cortisol levels, and perceived stress, the study seeks to empower women managers to navigate their professional and personal spheres with resilience and equilibrium. The findings may inform the development of evidence-based interventions to promote WLB and mitigate stress-related health risks among this demographic.

Assessments:

Standard Protocol Items have been used to report the enrollment, intervention, and assessment schedule. Prior to randomization, the baseline evaluation will be carried out. Each participant will be asked to fill out a basic demographic questionnaire that includes their age, date of birth, occupation, income, and level of education. We will also take anthropometric measurements such as weight, height, and body mass index. According to research by Kerr, W. C., Greenfield et.al. (2009), Drinking five or more drinks on one or multiple occasions within the preceding year is considered as a sign of risky drinking. To better capture employees' perspectives on WLB, a scale with 19 items was initially created by Fisher-McAuley et al. (2003) and later reduced to a 15-item version.

Work Life Balance (WLB) is measured on a 15-item scale that includes three constructs: work interference with personal life (WIPL), work personal life enhancement (WPLE), and work personal life interference with work (PLIW). It is a five-point Likert scale (strongly disagree to strongly agree) and has adequate internal consistency and Cronbach's alpha was >0.80 in a study (Dolly Dolai 2015), where all the three subscales were found to have high reliability with Cronbach's alpha was >0.70 in many studies (Lee, 2012). For cortisol test 5ml saliva collected in a sterile screw capped container before brushing teeth from the respondents and subjects are instructed to avoid stress, exercise, eating and drinking 30 minutes prior to sample collection. This method of collecting samples is called ECLIA. The collected salivary cortisol has measured by $\mu\text{g/l}$.

Statistical Analysis:

SMET recruitment targets 98 individuals, estimated using g power software with a moderate effect size of $f = 0.25$ and 80% power ($\alpha = 0.05$), recommended for work-life balance (H. L. C. Ong & S. Jeyaraj 2014). After power analysis, 98 people were sampled. Attrition later will add 22%, therefore 120 women managers will be recruited for intervention and wait list control groups. The baseline characteristics of the participants will be summarized using the mean and standard deviation (SD) or the median and interquartile range (IQR) for continuous variables. For categorical variables, the frequency and percentage will be used. The primary outcome analyses will adhere to the intention-to-treat principle. Baseline and 12-week results will be included. All analyses will use IBM SPSS V.26 and R (V.76). A statistical threshold of $\alpha = 0.05$ will be used.

Risk evaluation:

The screening of all candidates who are eligible as part of an assessment of potential risks is carried out by research assistants who have received training. Participants who have health issues that could potentially prevent them from participating will be eliminated from consideration as a result of this screening. In order to ensure that continuous monitoring is carried out and to provide the participants with the opportunity to provide feedback, the trainer will hold regular monthly meetings with the participants. For the purpose of guaranteeing safety and mitigating any potential harm that may occur, this will be of great assistance.

Administration of data:

Data management refers to the supervision of a research project by a monitor, who is accountable for monitoring the advancement of the study and guaranteeing the safeguarding of the participants' rights and well-being. The researcher will have sole responsibility for overseeing the code, security, and storage of data. Moreover, the researcher will verify the precision of data values by reprocessing them.

Discussion:

The study's robust design, incorporating randomization and blinding, aims to minimize biases and ensure the validity of the findings. By focusing on women managers, the research addresses a critical and often overlooked demographic in workplace wellness studies. The SMET Yoga module's holistic approach to stress management is particularly relevant, as it encompasses physical, mental, and emotional health, offering a potential multifaceted solution to the complex issue of work-life balance for women in high-stress, high-responsibility roles.

If the trial demonstrates that the SMET Yoga module is effective, the implications could be substantial for organizational policies and wellness programs. Effective work-life balance interventions could lead to improved job satisfaction, reduced burnout, and enhanced productivity among women managers. Organizations could adopt the SMET Yoga module as part of their wellness initiatives, providing targeted support that addresses the specific needs of female managerial staff. Additionally, this study could contribute to the broader field of occupational health, offering evidence-based strategies for stress reduction and improved work-life balance that can be adapted across various sectors.

Despite the rigorous design, several limitations must be acknowledged. The feasibility study's sample size may restrict the generalizability of the findings to a wider population. Self-reported measures, although using validated instruments, may introduce response bias. Furthermore, maintaining the single-blind design could present practical challenges, potentially affecting participant adherence and engagement with the intervention. These limitations highlight the need for careful interpretation of the results and suggest areas for further research.

Conclusion

In summary, this protocol establishes a solid foundation for evaluating the feasibility and potential impact of the SMET Yoga module on enhancing work-life balance among women managers. The anticipated findings could provide valuable insights into developing targeted interventions that promote well-being and productivity in high-stress occupational settings, particularly for women in managerial roles who face unique work-life balance challenges.

Confidentiality:

Upon inclusion, every participant will be allocated a distinct identification number. The participant proforma will be utilized to code and store data, which will later be implemented in Microsoft Excel. Only the principal investigator and co-investigator will have access to the collected data. The codes used to randomly assign participants to trials will also be kept confidential.

Availability of data and materials:

The data sets generated and/or analyzed for the study on work-life balance are not relevant to the data sharing policy as the article specifically focusses on a study protocol. Upon completion of the study, the de-identified data utilized to derive these conclusions will be included as an appendix in a peer-reviewed journal as an appendix. As a result, we believe that the data sharing statement will be relevant to the proposal study's final manuscript.

Declarations:

Securing approval from the ethics committee and acquiring consent to participate: The research will be conducted in strict adherence to the protocol and regulations set forth by the ethical committee of the institution. The research project has been granted approval to proceed by the Institutional Ethics Committee of Swami Vivekananda Yoga Anusandhana Samsthana University in Bangalore (RES/IECSVYASA/225/2022). Additionally, the information on the experiment can be found in the Clinical Trials Registry of India (CTRI/2024/01/076340). The researcher is going to make sure that each participant gives their written

informed permission. It is required to obtain confirmation from the ethics committee before making any changes to the existing research protocol that are related to the safety of patients or the possible benefits of the research. It is planned that these modifications will be included in future publications of this study.

Conflict of interest:

The authors do not have any competing interests.

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