JWS JOURNAL OF WORLD SCIENCE

JOURNAL OF WORLD SCIENCE
https://jws.rivierapublishing.id/index.php/jws
Volume 4 No. 11 November 2025

P-ISSN: 2828-8726
E-ISSN: 2828-9307

From Vitality to Security: Stem Cells and Testosterone Supporting Health and National Defense with the Vinski Protocol

Deby Susanti Pada Vinski[1] , Natasha Cinta Vinski[2] , Svetlana Trofimova[3] , Andi Kurniawan Nugroho[4] , Prihati Pujowaskito[5]
Celltech Stem Cell Centre Laboratory and Banking, Indonesia[1]
Universitas Hasanuddin, Indonesia[2]
Institute of Bioregulation and Gerontology, Russia[3]
Universitas Semarang, Indonesia[4]
Universitas Pertahanan Indonesia, Indonesia[5]
Email: drdeby@eradunia.com[1] , natashacintavinski@gmail.com[2] , dr.s.trofimova@gmail.com[3] , andikn@usm.ac.id[4] , pujowaskito@yahoo.com[5]

ABSTRACT
The vitality and health of a nation's citizens, particularly those serving in emergency and defense forces, are critical components of national security. Regenerative and hormonal medicine represents an innovative frontier in performance medicine with potential applications for enhancing human resilience and operational readiness. This Phase 1 clinical trial evaluates the safety and preliminary efficacy of the Vinski Protocol, a novel therapeutic approach combining umbilical cord-derived mesenchymal stem cells (UC-MSCs) with testosterone optimization therapy. Twenty-five healthy men aged 25–45 years received three intravenous infusions of UC-MSCs alongside weekly testosterone cypionate injections over 12 weeks. Primary outcomes assessed safety through adverse event monitoring and clinical laboratory profiles, while secondary outcomes measured changes in serum testosterone levels, VO2 max, body composition, inflammatory markers (C-reactive protein [CRP] and interleukin 6 [IL-6]), and subjective vitality assessments. The protocol demonstrated excellent tolerability with no serious adverse events; only 12% of participants reported mild, transient fatigue. Statistically significant improvements were observed in testosterone levels (+215 ng/dL, $p < 0.01$), lean body mass (+2.1 kg, $p < 0.05$), VO2 max (+11.8%, $p < 0.05$), and reductions in CRP and IL-6 levels ($p < 0.05$). Participants also reported enhanced energy and mental clarity. These findings provide preliminary evidence supporting the feasibility and potential efficacy of the Vinski Protocol as an integrated regenerative-hormonal approach to optimizing individual vitality and health resilience, with implications for performance medicine in high-demand occupational settings.
Keywords: hormonal medicine, mesenchymal stem cells, national defense, regenerative medicine, testosterone therapy, umbilical cord stem cells, Vinski protocol

INTRODUCTION

Global health challenges increasingly threaten the operational readiness and long-term well-being of individuals in high-demand occupations, particularly those serving in defense, emergency response, and security sectors. According to the World Health Organization (2023), occupational stress and physical demands contribute to accelerated biological aging and increased susceptibility to chronic diseases among first responders and military personnel. Data from the U.S. Department of Defense indicate that nearly 40% of active-duty service members experience suboptimal physical fitness markers, including reduced aerobic capacity and elevated inflammatory biomarkers, which compromise mission effectiveness (Smith et al., 2022). These declining health metrics pose substantial risks not only to individual performance but also to national security infrastructure, as the effectiveness of defense and emergency systems depends fundamentally on the physiological and cognitive resilience of personnel.

Performance medicine has emerged as a critical field focused on optimizing human physical, cognitive, and immunological capacity beyond the treatment of disease (Nindl et al., 2015; Pedersen, 2019; Schmidt et al., 2023). This discipline seeks to enhance baseline function through evidence-based interventions that target multiple physiological systems simultaneously (Johnson & Williams, 2021). Recent advances in regenerative medicine, particularly mesenchymal stem cell (*MSC*) therapy, have demonstrated promise in tissue repair, immune modulation, and functional recovery across diverse clinical contexts (Maldonado et al., 2023). Concurrently, testosterone optimization therapy has been established as an effective intervention for enhancing muscle mass, aerobic capacity, and cognitive performance in individuals with suboptimal hormone levels (Basaria et al., 2010).

Despite substantial progress in each therapeutic domain independently, limited research has explored the potential synergistic effects of combining regenerative and hormonal interventions (Clemmensen et al., 2019; Muzzio et al., 2021). Previous studies examining *MSC* therapy have primarily focused on disease-specific applications such as cardiovascular recovery (Clavellina et al., 2023), autoimmune disorders (Jasim et al., 2022), and musculoskeletal injuries (Copp et al., 2023). Similarly, testosterone replacement research has concentrated on hypogonadal populations rather than optimization in healthy individuals seeking enhanced performance (Li et al., 2023). The absence of integrated approaches represents a significant gap in performance medicine, particularly for populations requiring sustained high-level function under physiological stress.

The phenomenon of interest in this study is the potential for synergistic enhancement of human vitality through combined regenerative and hormonal therapy. Preliminary evidence suggests that *MSCs* and testosterone may act through complementary mechanisms: *MSCs* facilitate tissue repair and immune homeostasis through paracrine signaling (Kou et al., 2022), while testosterone drives anabolic processes that enhance muscle protein synthesis and metabolic efficiency (Pittenger et al., 2019). The convergence of these pathways may create a favorable systemic environment for optimizing multiple dimensions of human performance simultaneously. However, no prior clinical trials have systematically evaluated the safety, feasibility, or efficacy of this integrated approach in healthy individuals.

The urgency of this research is underscored by growing recognition that traditional approaches to maintaining workforce readiness in defense and emergency sectors are insufficient. As global threats evolve and operational demands intensify, there is an imperative to develop evidence-based interventions that can enhance resilience, accelerate recovery, and sustain peak performance in high-stress environments. The current study addresses this critical need by investigating whether combined regenerative-hormonal therapy can safely and effectively optimize physiological function in healthy adults, thereby establishing a foundation for future applications in occupational and defense settings.

This research introduces novel contributions to the scientific literature in several ways. First, it represents the first clinical trial to systematically evaluate the combined administration of *UC-MSCs* and testosterone optimization therapy in healthy individuals. Second, it employs a comprehensive assessment framework measuring hormonal, metabolic, inflammatory, and functional outcomes to capture the multisystemic effects of the intervention. Third, it provides preliminary safety data essential for advancing this therapeutic approach toward larger-scale clinical translation.

The primary objectives of this study are: (1) to evaluate the safety and tolerability of the *Vinski Protocol* through comprehensive adverse event monitoring and laboratory assessments; (2) to examine preliminary efficacy by measuring changes in serum testosterone levels, body composition, aerobic capacity, and inflammatory biomarkers; and (3) to assess subjective changes in vitality, energy, and cognitive function. The theoretical benefits of this research include advancing understanding of regenerative-hormonal synergy in human performance optimization. Practical benefits encompass establishing an evidence-based protocol that may be adapted for use in defense, emergency response, and other high-demand occupational contexts where enhanced resilience and sustained performance are strategically important. By integrating cellular regeneration with hormonal optimization, this research offers a paradigm-shifting approach to human performance medicine with potential applications extending beyond individual health to organizational and national security objectives.

METHOD

This investigation was conducted as a single-center, open-label Phase 1 clinical trial. The study protocol received approval from the institutional review board, and all procedures adhered to the Declaration of Helsinki and Good Clinical Practice guidelines. Written informed consent was obtained from all participants prior to enrollment.

Twenty-five healthy male participants aged 25-45 years were recruited. Inclusion criteria specified body mass index between 18-27 kg/m², absence of chronic medical conditions, and no use of anabolic or immunosuppressive agents within the preceding 12 months. Exclusion criteria included autoimmune disorders, history of malignancy, and serious cardiac events within the past year.

UC-MSCs were isolated from umbilical cord tissue obtained from screened, consenting donors following cesarean delivery. Cells were processed through enzymatic digestion under Good Manufacturing Practice conditions and underwent quality control testing for viability, sterility, and endotoxin levels prior to administration.

Participants received three intravenous infusions of 50 million viable UC-MSCs at baseline, Week 4, and Week 8. Each infusion was administered over 30 minutes via peripheral venous catheter with 24-hour post-infusion monitoring. Concurrently, participants received weekly intramuscular injections of 100 mg testosterone cypionate, with dose adjustments every two weeks to achieve target serum levels of 600-900 ng/dL.

Safety was assessed through adverse event documentation and laboratory monitoring (complete blood count, hepatic and renal function, prostate-specific antigen, lipid profiles) at baseline and every four weeks. Efficacy outcomes included serum testosterone (measured via LC-MS/MS), body composition (dual-energy X-ray absorptiometry), VO2 max (cardiopulmonary exercise testing), inflammatory markers (CRP and IL-6), and subjective wellbeing (SF-36 and PROMIS fatigue scales).

Paired t-tests compared baseline and Week 12 outcomes, with statistical significance set at $p < 0.05$. Data are presented as mean ± standard deviation.

In parallel with UC-MSC infusion, participants were initiated on testosterone cypionate injections at a dose of 100 mg per week. This dose was titrated every two weeks to achieve serum testosterone concentrations within the mid-physiological range (600–900 ng/dL). The rationale for testosterone optimization was to enhance anabolic balance, energy, and cognitive performance while avoiding supraphysiologic exposure. Prior clinical experience illustrates that negative cardiovascular and hematologic consequences are most frequently linked to overdose on testosterone, which makes it desirable to monitor and adjust individual doses (Basaria et al., 2010). The injectable cypionate was selected because it has consistent pharmacokinetics and is used clinically every day.

Safety monitoring involved comprehensive laboratory testing at baseline and every four weeks during the trial. Parameters monitored included complete blood count, liver enzymes, renal function, prostate-specific antigen (PSA), and fasting lipid profiles. They were chosen to monitor systemic organ function and hormone-specific risk. Monitoring also followed precedent in regenerative medicine trials, where hepatic and renal safety have consistently been an issue (Margiana et al., 2022). Moreover, serum testosterone levels were quantified by liquid chromatography–tandem mass spectrometry (LC-MS/MS) to present accurate hormonal measurements. Monitoring biomarker validity is at the core of measuring efficacy and safety in early-phase trials, especially in the integration of regenerative and endocrine therapies.

An impartial clinical monitor who was not part of the study team monitored laboratory values and adverse events at regular time intervals. Mild side effects such as infusion-related fatigue or flushing were observed and evaluated for causality. An unusual or severe reaction would have required a hold on protocol for safety assessment. Such conservative monitoring is consistent with standard measures in the MSC clinical literature, where immune-mediated reactions are a theoretical but highly infrequently observed risk (Uccelli et al., 2007). Analogously, testosterone trials have had to include cardiovascular or prostate outcome monitoring, underlining the need for close longitudinal follow-up.

The Vinski Protocol was conceived as a Multiple & Precision Strategy, designed to target regenerative and endocrine properties of human function through individually tailor-made & orchestra intervention.

Individually tailor-made means that the treatment for one patient is not necessarily the same as for another patient. Each protocol is designed according to the patient's unique biological profile, health condition, and therapeutic needs, ensuring personalized precision in regenerative and hormonal therapy.

Orchestra intervention describes stem cell treatment combined with hormone therapy as a continuous and harmonized process—similar to orchestration—within the human body. If one part of the body is repaired or treated, other supporting parts must also remain synchronized and healthy to achieve true systemic balance and resilience.

Furthermore, the Vinski Protocol is structured with a Multi-Discipline Approach & Precision Strategy, which integrates the expertise of various specialists and professionals. This ensures that every imbalance within the body is addressed comprehensively, aligning regenerative medicine and hormone optimization into a coordinated plan. By combining multiple expert perspectives with precision-based tailoring, the protocol provides a holistic intervention that restores equilibrium and maximizes systemic health.

MSCs have been shown to exhibit regenerative and immunomodulatory activity, intervening in the secretion of trophic factors, control of inflammatory cascades, and facilitating tissue repair (Uccelli et al., 2007). Later clinical trials underscore their potential in autoimmune settings, where they dampen systemic inflammation and restore homeostasis to otherwise treatment-resistant disease (Jasim et al., 2022). Concurrently, testosterone replacement has demonstrated robust anabolic effects, such as enhanced muscle strength, lean body mass, and cognitive function. However, the risks of adverse cardiovascular and hematologic effects should be observed closely and dosing adjusted (Basaria et al., 2010). Combined, they provide a complementary therapy—cellular-level regeneration with hormonal optimization.

The regenerative component of the protocol acts on umbilical cord-derived MSCs, which constitute a reproducible, ethically sound source of multipotent stromal cells. Their therapeutic use is potentially beneficial in more than one organ system. In cardiovascular diseases, MSCs have been found to contribute to improved myocardial recovery and vascular remodeling after acute ischemia (Clavellina et al., 2023). Musculoskeletal repair has also been aided, with findings indicating enhanced cartilage stability and decreased inflammation in degenerative joint disease (Copp et al., 2023). Neurologically, UC-MSCs have also been found to be beneficial in ischemic stroke models, where their pro-angiogenic and anti-apoptotic factors facilitate the recovery and repair of neural tissue (Guo et al., 2021). Their immunosuppressive factors also make them promising agents in autoimmune diseases such as rheumatoid arthritis (Lv et al., 2021). In addition, during hepatic regeneration, MSC therapy was associated with increased hepatocyte proliferation and improved biochemical function, testifying to their systemic regenerative potential (Zhang et al., 2021).

The endocrine component utilizes testosterone replacement to reinstate mid-physiological serum levels. The approach hinges on levels ranging between 600 and 900 ng/dL that are optimal for stable anabolic balance without attendant risks of supraphysiologic exposure (Li et al., 2023). Promoting hormonal homeostasis is not only essential in brain and muscle activity but may also have direct interaction with regenerative therapy. Given that the heterogeneity of MSC populations affects treatment outcomes, the systemic hormonal environment may have a determining effect on efficacy.

Synergy between this double-barrel attack may be best defined in terms of common pathways of systemic repair. MSC-extracellular vesicles transport growth factors and microRNAs that regulate inflammation, induce angiogenesis, and trigger cellular repair at sites distant from where they were released (Kou et al., 2022). On the other hand, metabolic controllers such as adipokines intersect with MSC activity, indicating that endocrine equilibrium influences the therapeutic impacts of stem cells (Pham et al., 2023). By uniting regenerative and hormonal therapy, the Vinski Protocol seeks to capitalize on these intersecting processes, providing a system that combines cellular rehabilitation and anabolic maximization.

RESULTS AND DISCUSSION

Baseline Participant Data

The twenty-five male participants were 33.4 ± 5.7 years old on average. Baseline clinical and biochemical variables were within normal values, and no patient dropped out or was lost to follow-up. Such high retention demonstrates good tolerability and participation throughout the intervention phase. Compared to historical cohorts of testosterone replacement therapy (TRT), the initial level of testosterone for this cohort of 452 ± 87 ng/dL was similar to the groups designated as low-to-mid physiological and suggests the prominence of optimization over correction of hypogonadism disease (Basaria et al., 2010).

Safety Outcomes

No serious adverse events were noted during the 12-week intervention. Mild and transient adverse effects, including flushing and fatigue, were noted by three subjects (12%) following UC-MSC infusion. They were spontaneous and did not require clinical attention. There were no changes in liver enzymes, renal function, complete blood count, or PSA levels. Absence of hepatotoxicity and nephrotoxicity concurs with the broad MSC clinical literature, wherein low immunogenicity and immunomodulatory potential have consistently suggested safe profiles (Uccelli et al., 2007). Similarly, low levels of clinically significant adverse events concur with current systematic reviews of MSC therapy, even in immunologically high-risk settings such as graft-versus-host disease (Kadri et al., 2023).

Efficacy Outcomes

The efficacy results are summarized in Table 1.

Table 1. Efficacy Outcomes

Parameter	Baseline	Week 12	% Change	*p*-value
Serum Testosterone (ng/dL)	452 ± 87	667 ± 102	+47.5%	<0.01

VO_2 max (mL/kg/min)	42.3 ± 4.5	47.3 ± 5.0	+11.8%	<0.05
Lean Body Mass (kg)	61.2 ± 4.1	63.3 ± 4.0	+3.4%	<0.05
CRP (mg/L)	2.4 ± 1.1	1.2 ± 0.6	–50%	<0.05
IL-6 (pg/mL)	4.5 ± 1.2	2.7 ± 0.9	–40%	<0.05

Serum Testosterone

Serum testosterone rose impressively from baseline to Week 12 (+215 ng/dL, $p < 0.01$) to the mid-physiological target level. This approach is consistent with earlier TRT trials where titrated dosing has been noted to maximize anabolic markers without supraphysiological levels (Basaria et al., 2010).

Lean Body Mass

Lean body mass also increased by 2.1 kg (+3.4%, $p < 0.05$), measured via dual energy X-ray absorptiometry (DEXA). These results are also substantiated by evidence from the literature, which suggests that MSCs play a role in musculoskeletal healing, cartilage stabilization, and muscle repair (Copp et al., 2023). More recent meta-analyses of the use of MSC in regenerative medicine also note their role in musculoskeletal resilience and overall tissue support, substantiating these results (Maldonado et al., 2023).

VO2 Max

VO2 max aerobic capacity augmented by 11.8% ($p < 0.05$). These enhancements are consistent with those reported in cardiovascular MSC research, where infusion has been related to enhanced myocardial recovery and vascular remodeling (Clavellina et al., 2023). The preclinical stroke model also indicates the capacity of MSCs to restore vascular repair and functional restoration, lending construct validity to the systemic changes in oxygen consumption and endurance (Guo et al., 2021).

Inflammatory Markers

Inflammatory markers were also significantly decreased, with C-reactive protein (CRP) decreasing by 50% and interleukin 6 (IL-6) by 40% ($p < 0.05$). These findings agree with evidence on MSC immunomodulatory effects, which inhibit the production of pro-inflammatory cytokines and re-establish systemic homeostasis in autoimmune diseases (Li et al., 2021). Clinical trials in autoimmune disease patient cohorts have produced similar reductions in inflammatory mediators (Jasim et al., 2022). Furthermore, MSC-derived extracellular vesicles are also well-established as being the primary effectors of paracrine repair, anti-inflammatory response, and systemic modulation (Kou et al., 2022).

Subjective Well-Being

Subjects showed significant improvement in subjective energy, cognitive clarity, and mood, as measured by SF-36 and PROMIS fatigue scores. These findings are consistent with integrated reviews of MSC therapies, which attributed systemic regeneration and enhanced vigor along with organ-specific effects (Mei et al., 2024). Additionally, translational models require performance medicine to enhance resilience in occupational and high-demand environments, consistent with the broader applicability of MSC-based therapies in sustaining human performance (Zhidu et al., 2024).

Discussion

Interpretation of Findings

These Phase 1 clinical trial findings demonstrate that the Vinski Protocol, which employs TRT and UC-MSCs, is safe and effective in augmenting measures of vitality, physical resistance, and overall health. The enhancements in several domains—hormonal balance, lean body mass, aerobic capability, regulation of inflammation, and subjective well-being—demonstrate that the double-therapy intervention affects multiple mechanisms. The synergy is explained by the convergence of anabolic and regenerative processes. MSCs were able to initiate tissue repair through paracrine trophic factor release, immune response modulation, and induction of cellular regeneration (Caplan, 2017). The addition of MSCs into damaged microenvironments with paracrine signal secretion offers a regenerative scaffold for other systemic processes to build upon. On the other hand, testosterone rises through anabolic mechanisms, increasing protein production, red blood cell mass, and neuromuscular efficiency (Pittenger et al., 2019). The combination of MSC therapy with TRT creates an environment in which anabolic signals are offset by a favorable cellular and immunological milieu, synergizing the effects of each treatment when administered independently.

One of the most prominent results of this trial was the dramatic lowering of pro-inflammatory mediators such as CRP and IL-6, which closely parallels the reported immunomodulatory literature on MSCs. The latter exert their action by downregulating the production of pro-inflammatory cytokines and inducing anti-inflammatory mediators, correcting systemic balance in immune dysregulation diseases (Uccelli et al., 2007). Current clinical trials have proven the feasibility of MSC therapy in autoimmune diseases, whereby it suppresses disease activity while enhancing homeostasis (Jasim et al., 2022). The decreases noted in otherwise healthy men indicate that MSCs can enhance immune responsiveness to its peak even beyond frank pathology. This finding implies that this approach may be beneficial for highly stressed individuals, such as soldiers or emergency medical workers, who are continually exposed to physiological stressors that disrupt inflammatory homeostasis.

Comparison with Literature

When compared with other areas of MSC use, the outcomes of this study align with varied outcomes in more than one organ system. In cardiology, UC-MSCs have been found to facilitate myocardial recovery and vascular remodeling after ischemic incidents, which is indicative of their ability to re-establish tissue perfusion and function under stress (Clavellina et al., 2023). The increase in VO2 max is consistent with this finding and indicates that MSC-induced vascular remodeling also applies in healthy subjects under performance-protocol conditions.

Musculoskeletal gains were also observed in this trial, as evidenced by a statistically significant gain in lean body mass. Previous research has established that MSC therapy can enhance cartilage stability, decrease degenerative inflammation, and enable musculoskeletal injury recovery (Copp et al., 2023). These processes also supplement the anabolic effect of testosterone, thus resulting in synergistic enhancement of muscle mass and structural integrity. In the same manner, reviews of MSC application in regenerative medicine have identified their ability to maintain musculoskeletal resilience, which is important for individuals with physically demanding jobs (Maldonado et al., 2023). Neurological analogy was also observed. In models of ischemic stroke, MSCs have induced neurogenesis and angiogenesis, facilitating the repair of neural circuits (Guo et al., 2021). Although this trial did not directly measure neurological damage, patients reported enhanced cognitive clarity and mental vigor, which can be partially attributed to the paracrine actions of MSCs on the central nervous system. These self-reporting metrics may indicate MSC-mediated neuroprotection and the capacity of testosterone to maintain cognitive function.

The autoimmune literature offers further fronts of overlap. MSC therapy has been successful in curbing systemic inflammation among patients with autoimmune diseases, such as systemic lupus erythematosus (Li et al., 2021). Decreases have been observed in graft-versus-host disease, and MSC therapy has been an effective immunosuppressant (Kadri et al., 2023). The observed declines in CRP and IL-6 in the current trial echo these findings, suggesting that MSC treatment may retune immune function not only in obvious conditions of disease but also in otherwise healthy individuals who intend to enhance performance resiliency.

In liver conditions, MSC therapy has also been proven to stimulate hepatocyte proliferation and biochemical improvement in patients with chronic liver disease (Zhang et al., 2021). Despite the lack of proper attention to liver outcomes in this project, the stability of normal liver enzymes among the participants implies that UC-MSCs are non-hepatotoxic, reaffirming the safety of repeated administration.

One of the central characteristics of nuance is the heterogeneity of MSC populations, which could shape therapeutic effectiveness. As described in recent reviews, MSCs differ among donors, tissue of origin, and culture conditions, resulting in differences in potency and immunomodulatory profiles (Li et al., 2023). This heterogeneity highlights the need for uniformly prepared preparation protocols and careful donor screening, as conducted in this trial, to optimize safety and efficacy.

Mechanistic Insights

Mechanistically, the advantage noted in the current study is attributable to MSC paracrine activity. Extracellular vesicles secreted by MSCs, such as exosomes, contain growth factors, cytokines, and microRNAs that modulate immune processes, promote angiogenesis, and trigger tissue repair (Kou et al., 2022). These vesicles transport their cargo to distant locations, which accounts for the systemic effects noted despite intravenous MSC administration. Modulation of inflammation, with increased tissue repair, offers a mechanistic rationale for improvements in VO2 max, lean body mass, and inflammatory markers.

The interaction between MSC function and metabolic signals supports this mechanistic rationale. Adipokines—or peptides secreted from metabolically active adipose tissue—have been known to modulate MSC differentiation and potency. Obesity-associated dysregulated adipokine signaling, for instance, has been found to suppress MSC therapeutic activity (Pham et al., 2023). Inclusion of testosterone therapy, which affects metabolic pathways independently, may provide the Vinski Protocol with an even more beneficial systemic environment for MSC function. This concept offers a plausible rationale for the observed enhancement of performance and metabolic markers.

Relevance for Defense and National Security

The application of these results extends beyond individual-level health optimization to defense and national security. Military forces, search and rescue personnel, and elite athletes are repeatedly subjected to physical, psychological, and immunological stress. Optimization of recovery function, endurance, and resilience is thus a strategic imperative. These results indicate that the Vinski Protocol can be used as a model for performance medicine intended to optimize readiness in these populations.

The existing literature on occupational health and anti-aging justifies this explanation. Regenerative medicine literature reviews of MSC therapy highlight its potential for maintaining tissue resilience and preventing age-related deterioration (Maldonado et al., 2023). Likewise, clinical evaluations of system rejuvenation identify gains in vitality, immunity, and physical function (Mei et al., 2024). Translational implications also highlight how interventions combining performance medicine might be implemented to enhance resilience in occupational and defense environments, thus meeting national security needs (Zhidu et al., 2024). Combining cellular repair and hormonal optimization, the Vinski Protocol represents a new bio-medical strategy for ensuring functional health in individuals entrusted with national defense.

Limitations

Despite these promising findings, several limitations must be considered. The limited sample size (n = 25) diminishes the generalizability of the results and magnifies the risk of type II error for less extreme outcomes. Further, the open-label design of the trial lacks the strength of randomized placebo-controlled trials. Hence, expectancy effects are a concern, especially in subjective measures such as reported energy and clarity of mind (Margiana et al., 2022). The follow-up period was only 12 weeks, limiting the capacity to evaluate long-term safety, durability of effect, or late adverse effects. These limitations are consistent with those of global MSC translational research, whereby small initial trials dominate the literature, and study design heterogeneity complicates evidence synthesis (Jovic et al., 2022). The problems of reproducibility and regulation persist, and the importance of scaling upcoming trials with adequate power and sound methodology has been highlighted.

Future Directions

Future studies should address the identified constraints through randomized controlled trials in more heterogeneous, larger populations, including both sexes and wider age ranges. Longer follow-up durations should be incorporated in trials to assess the long-term stability of benefits and identify late-appearing adverse effects. MSC procurement, culture conditions, and dosing must remain standardized to provide reproducibility and comparability between trials (Li et al., 2023). In conjunction with methodological advancement, mechanistic studies should examine the function of extracellular vesicles as therapeutic agents and the effects of systemic metabolic state on MSC efficacy. They include adipokine, sex hormone, and regenerative therapy interaction studies in defining the mechanisms by which endocrine modulation enhances stem cell activity.

From a translational viewpoint, the next steps should include testing the protocol in defense and emergency settings to determine whether it can enhance readiness, decrease recovery time, and inhibit long-term stress-related health deterioration (Pham et al., 2023). Large-scale translation should involve open regulatory routes, such as standardized safety monitoring and ethical assessment. MSC therapy analyses highlight that these paradigms are required to bridge successful Phase 1 outcomes into scalable clinical interventions (Mei et al., 2024; Zhidu et al., 2024). Such activities will also need to incorporate cost-effectiveness assessments and feasibility assessments, enabling interventions to be delivered at scale within defense and emergency health systems. The findings support the potential for research to discover new applications in these two areas. Through the integration of scientific excellence with strategic health agendas, the Vinski Protocol may transition from clinical innovation into national resilience architecture.

CONCLUSION

This Phase 1 clinical trial demonstrates that the Vinski Protocol—combining umbilical cord-derived mesenchymal stem cells (*UC-MSCs*) with testosterone optimization therapy—is safe, well-tolerated, and effective in enhancing vitality, physical performance, and immunological resilience in healthy adult men, with significant improvements in hormonal balance, lean body mass, aerobic capacity, inflammatory markers, and subjective well-being through synergistic mechanisms. The "orchestra intervention" approach tailors these therapies for synchronized systemic benefits, addressing primary objectives on safety and efficacy while holding implications for defense and emergency sectors critical to national security. For future research, randomized controlled trials with larger, diverse populations, longer follow-ups, mechanistic studies on *MSC*-derived extracellular vesicles and hormonal interactions, optimized dosing, and real-world evaluations in high-stress operational settings are recommended to enable scalable translation.

REFERENCES

Caplan, A. I. (2017). Mesenchymal stem cells: Time to change the name! *STEM CELLS Translational Medicine, 6*(6), 1445–1451. https://doi.org/10.1002/sctm.17-0051

Clavellina, D., Balkan, W., & Hare, J. M. (2023). Stem cell therapy for acute myocardial infarction: Mesenchymal stem cells and induced pluripotent stem cells. *Expert Opinion on Biological Therapy, 23*(10), 951–967. https://doi.org/10.1080/14712598.2023.2245329

Clemmensen, C., Finan, B., Müller, T. D., DiMarchi, R. D., Tschöp, M. H., & Hofmann, S. M. (2019). Emerging hormonal-based combination pharmacotherapies for the treatment of metabolic diseases. *Nature Reviews Endocrinology*.

Copp, G., Robb, K. P., & Viswanathan, S. (2023). Culture-expanded mesenchymal stromal cell therapy: Does it work in knee osteoarthritis? A pathway to clinical success. *Cellular and Molecular Immunology, 20*, 626–650. https://doi.org/10.1038/s41423-023-01020-1

Guo, Y., Peng, Y., Zeng, H., & Chen, G. (2021). Progress in mesenchymal stem cell therapy for ischemic stroke. *Stem Cells International, 2021*, Article 9923566. https://doi.org/10.1155/2021/9923566

Jasim, S. A., Yumashev, A. V., Abdelbasset, W. K., Margiana, R., Markov, A., Suksatan, W., Pineda, B., Thangavelu, L., & Ahmadi, S. H. (2022). Shining the light on clinical application of mesenchymal stem cell therapy in autoimmune diseases. *Stem Cell Research & Therapy, 13*(1), Article 101. https://doi.org/10.1186/s13287-022-02782-7

Jovic, D., Yu, Y., Wang, D., Wang, K., Li, H., Xu, F., Liu, C., Liu, J., & Luo, Y. (2022). A brief overview of global trends in MSC-based cell therapy. *Stem Cell Reviews and Reports, 18*(5), 1525–1545. https://doi.org/10.1007/s12015-022-10369-1

Kadri, N., Amu, S., Iacobaeus, E., Boberg, E., & Le Blanc, K. (2023). Current perspectives on mesenchymal stromal cell therapy for graft versus host disease. *Cellular & Molecular Immunology, 20*(6), 613–625. https://doi.org/10.1038/s41423-023-01022-z

Kou, M., Huang, L., Yang, J., Chiang, Z., Chen, S., Liu, J., Guo, L., Zhang, X., Zhou, X., Xu, X., Yan, X., Wang, Y., Zhang, J., Xu, A., Tse, H., & Lian, Q. (2022). Mesenchymal stem cell-derived extracellular vesicles for immunomodulation and regeneration: A next generation therapeutic tool? *Cell Death & Disease, 13*(7), Article 580. https://doi.org/10.1038/s41419-022-05034-x

Maldonado, V., Patel, N., Smith, E., Barnes, C. L., Gustafson, M. P., Rao, R. R., & Samsonraj, R. M. (2023). Clinical utility of mesenchymal stem/stromal cells in regenerative medicine and cellular therapy. *Journal of Biological Engineering, 17*(1), Article 44. https://doi.org/10.1186/s13036-023-00361-9

Margiana, R., Markov, A., Zekiy, A. O., Hamza, M. U., Al-Dabbagh, K. A., Al-Zubaidi, S. H., Hameed, N. M., Ahmad, I., Sivaraman, R., Kzar, H. H., Al-Gazally, M. E., Mustafa, Y. F., & Siahmansouri, H. (2022). Clinical application of mesenchymal stem cell in regenerative medicine: A narrative review. *Stem Cell Research & Therapy, 13*(1), Article 366. https://doi.org/10.1186/s13287-022-03054-0

Mei, R., Wan, Z., Yang, C., Shen, X., Wang, R., Zhang, H., Yang, R., Li, J., Song, Y., & Su, H. (2024). Advances and clinical challenges of mesenchymal stem cell therapy. *Frontiers in Immunology, 15*, Article 1421854. https://doi.org/10.3389/fimmu.2024.1421854

Muzzio, N., Moya, S., & Romero, G. (2021). Multifunctional scaffolds and synergistic strategies in tissue engineering and regenerative medicine. *Pharmaceutics*.

Nindl, B., Jaffin, D. P., Dretsch, M., Cheuvront, S., Wesensten, N., Kent, M. L., Grunberg, N., Pierce, J., Barry, E. S., Scott, J. M., Young, A. J., O'Connor, F., & Deuster, P. (2015). Human performance optimization metrics: Consensus findings, gaps, and recommendations for future research. *Journal of Strength and Conditioning Research*.

Pedersen, B. (2019). The physiology of optimizing health with a focus on exercise as medicine. *Annual Review of Physiology*.

Pham, D.-V., Nguyen, T.-K., & Park, P.-H. (2023). Adipokines at the crossroads of obesity and mesenchymal stem cell therapy. *Experimental & Molecular Medicine, 55*(2), 313–324. https://doi.org/10.1038/s12276-023-00940-2

Pittenger, M. F., Discher, D. E., Péault, B. M., Phinney, D. G., Hare, J. M., & Caplan, A. I. (2019). Mesenchymal stem cell perspective: Cell biology to clinical progress. *NPJ Regenerative Medicine, 4*(1), Article 22. https://doi.org/10.1038/s41536-019-0083-6

Schmidt, M. A., Jones, J. A., & Mason, C. E. (2023). Optimizing human performance in extreme environments through precision medicine: From spaceflight to high-performance operations on Earth. *Cambridge Prisms: Precision Medicine*.

Zhang, L., Ma, X.-J.-N., Fei, Y.-Y., Han, H.-T., Xu, J., Cheng, L., & Li, X. (2021). Stem cell therapy in liver regeneration: Focus on mesenchymal stem cells and induced pluripotent stem cells. *Pharmacology & Therapeutics, 232*, Article 108004. https://doi.org/10.1016/j.pharmthera.2021.108004

Zhidu, S., Ying, T., Rui, J., & Chao, Z. (2024). Translational potential of mesenchymal stem cells in regenerative therapies for human diseases: Challenges and opportunities. *Stem Cell Research & Therapy, 15*(1), Article 266. https://doi.org/10.1186/s13287-024-03885-z