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Efficacy of Multivitamin-Mineral Supplementation on Health-Related Quality of Life and Physical Activity in Young Adults

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Efficacy of Multivitamin-Mineral Supplementation on Health-Related Quality of Life and
Physical Activity in Young Adults

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science in Human Environmental Sciences

by

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Texas Christian University
Bachelor of Science in Strategic Communication, 2017

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Abstract

Micronutrients are essential for both physical and mental health. There is a correlation between poor health and mood and micronutrient deficiencies. Young adults age 18-24 are an at-risk, understudied population likely to benefit from multivitamin mineral supplementation. Multivitamin mineral supplementation is a potential way to bridge gaps in micronutrient levels, thus influencing health-related outcomes. Here, we provide the first attempt at influencing health-related quality of life and physical activity with a multivitamin mineral supplement in young adults. Using a supplement formulated without herbal extracts and caffeine, this double-blind study examined the efficacy of a daily multivitamin mineral supplement for 30 days on health-related quality of life and physical activity in young adults age 18-24 years. With obesity being a continued health concern and related to poor mental health, we also compared the effects in both healthy and excess body weight participants. While there were main group effects, there were no effects on health-related quality of life or physical activity when comparing between supplement and placebo group. While it is possible that supplementation may not have an influence on these outcomes, it is possible that low sample size or short study duration, among others, limited ability to more fully assess if there is an effect.

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Overview

Micronutrients are nutrients in the human diet that are required in very small amounts: the vitamins and minerals. All vitamins and minerals act as regulators and assist in all body processes to maintain life¹. Poor health and mood have been associated with micronutrient deficiencies². This poor psychosocial health, including depression, low self-esteem, peer victimization, and poor quality of life, correlates with excess weight³.

Obesity is a continued and growing health concern. The Centers for Disease Control and Prevention defines obesity as weight that is higher than what is considered as a healthy weight for a given height using Body Mass Index, BMI, to measure. BMI is a person's weight in kilograms divided by height in meters squared. Persons with a BMI of 18.5-24.9 are categorized as healthy or normal BMI. Overweight individuals are those with a BMI of 25.0 to 29.9 and obese individuals are those with a BMI of 30.0 or higher⁴. Nationwide, rates of obesity are high, and Arkansas ranks in the top 10 states for adolescent and adult obesity. Approximately 22 percent of adolescents and 35 percent of adults in Arkansas are obese. Arkansas also ranks in the top 10 for many obesity-related health outcomes including diabetes, hypertension, and mental distress⁵.

While there is a known correlation between poor health and micronutrient deficiencies, previous studies examining supplementation on mood have yielded mixed results. The mixed results are likely due to methodological reasons including varied contents of multivitamin supplements, absence of weight, and varied age ranges and developmental stages. There is also a gap in research on whether multivitamin-mineral supplementation improves health-related quality of life and engagement in physical activity due to improvement in mood.

Micronutrients

Biochemical processes in the brain affect mood. Minor deficiencies in micronutrients could negatively influence psychological parameters. These parameters, including aggression, antisocial behavior, inattention, and depression, all likely related to health-related quality of life, are likely to be the first to benefit from supplementation⁶. The known roles and nutritional biochemistry of various micronutrients provides explanations for these associations.

B vitamins including B6 (pyridoxine), folate, and B12 (cobalamin), play a considerable role in brain function and cognition⁷. They have many functions in the body, but most importantly they influence homocysteine levels throughout the body and assist in formation of certain neurotransmitters⁷. Homocysteine is a sulfur-containing amino acid which elevated plasma or serum levels were once considered a marker for impaired methylation cycle and are now implicated in human disease in its own right⁷. It is produced exclusively from the methylation cycle and is not available from dietary sources. Folate, vitamin B₁₂, and the active form of vitamin B₆ (pyridoxal phosphate) are required for methylation of homocysteine. The possible ways in which deficiencies of B₆, folate, and B₁₂ could impair brain function and increase mental health risk are multiple; however, most mechanisms are related to the associations with homocysteine⁷. There are reported associations between lowered B vitamins and/or elevated plasma homocysteine and cognitive decline. Also, lowered B₆, folate, and B₁₂ and elevated homocysteine have been associated with increased depression⁷.

B vitamins are required for the effective production of neurotransmitters serotonin, epinephrine, and dopamine⁷. Vitamin B₁₂ and folate influence serotonin activity. Serotonin is one of the most important neurotransmitters influencing mental health⁸. It relays signals between neurons, regulating their intensity. Low homocysteine is also needed for serotonin to function

explained through complex biochemical processes⁹. Epinephrine, more commonly known as adrenaline, has different functions on the body including increasing blood sugar levels, increasing heart rate, increasing contractility, and relaxation of smooth muscle in the airways to improve breathing. In similar ways to serotonin, homocysteine influences epinephrine production. Lastly, dopamine is a critical modulator of both learning and motivation¹⁰. B vitamins effect on homocysteine also modulates the production of dopamine⁷. Each of these neurotransmitters play a role in brain function, therefore, in mood. Each of these vitamins have the potential to influence mental health and deficiency of B vitamins can lead to decreased production of these neurotransmitters⁷.

Minerals such as zinc, magnesium, calcium, and selenium may similarly impact mood due to their influence on neurotransmitters¹. Zinc is required for many physiological processes such as cell proliferation and differentiation, nuclear acid metabolism, growth and development, and enzymatic activity regulation¹¹. Magnesium regulates a number of biochemical processes and influences the functioning of the majority of the organs. It also plays a vital modulatory role in brain biochemistry, influencing several neurotransmission pathways associated with the development of depression¹². Calcium is a universal messenger of extracellular signals and it regulates neurotransmitter synthesis and release¹³. Finally, selenium plays a role in brain function by providing antioxidant protection, having a relation to neurotransmission pathways, and neuron signaling¹⁴.

Lastly, oxidative stress may affect the brain in ways that contribute to mental health issues such as depression and anxiety. While oxygen is essential for aerobic life, excessive amounts of its free radical metabolic by-products are toxic, causing oxidative stress. Keeping oxygen levels as low as possible in the brain is needed to defend against oxidative stress¹⁵.

Minerals such as selenium, copper, manganese, and zinc act as cofactors for enzymes that prevent oxidative stress damage⁷. Enzymes that prevent damage from oxidation require these dietary minerals. Antioxidants are compounds that protect other compounds from damaging reactions involving oxygen by themselves reacting to oxygen. Antioxidants act as a defense to free radicals by inhibiting oxidation¹⁶. Oxidation is a potentially damaging effect of normal cell chemistry involving oxygen. Vitamins A, C, and E are known antioxidants and help protect against oxidative stress⁷. Vitamin A act as antioxidants by quenching free radicals. Vitamin C acts by becoming oxidized itself and stopping a chain reaction. Vitamin E, along with vitamin A, prevent lipid peroxidation which is critical for the preservation of cellular membranes⁷. Supplementing these micronutrients together via a multivitamin-mineral supplement may be an effective and easy way to influence mood and health.

Effects of Micronutrient Supplementation on Mood and Mental Health Measures

A number of randomized placebo-controlled studies have indicated that multivitamin mineral supplementation (MVMS) can enhance mood and cognition, and sense of well-being^{2,17}. Four of these placebo-controlled intervention studies used a supplement called Swisse Men's (or Women's) Ultivite to assess mood and overall well-being. This supplement contains nutrients found in typical over-the-counter supplements plus several herbal extracts. With acute exposure to the supplement, self-reported ratings of mood and mental stress improved¹⁸. Another study found that after 16 weeks of exposure to the supplement there were significant improvements in participants energy levels, mood, and sleep². One study found that the Swisse Ultivite supplement reduced depression, anxiety, and stress and improved alertness and general daily

functioning in older men¹⁸, while another found no significant effects on any chorionic mood measures¹⁹.

Six additional studies examined the effects of a variety of supplements, with no two studies using the same supplement. Three of the studies found significant improvements with micronutrient supplement on lowered violence and antisocial behavior in children ages 6-12 years old²⁰, improved depression and anxiety symptoms and quality of life in adults with depression²¹, as well as nursing home residents who showed improved symptoms of depression²². The other three studies reported weak to no effects on mood in children 8-14 years old²³, misbehavior in adolescents age 13-16²⁴, or aggressive behavior, impulsivity, and perceived stress in young adult men⁶.

Lastly, four additional studies used Berocca, a micronutrient supplement made by Bayer. Berocca contains B vitamins, vitamin C, calcium, magnesium, and zinc. After various lengths of intervention, each of the four studies found significant improvements in mood, stress, mental health and vigor, mental stamina, and alertness in males age 30-55^{25,26}, males age 18-42²⁷, and adults 18-65 years old²⁸.

While the results of these studies collectively suggest improvement in mood and mental health measures with micronutrient supplementation, the majority of the studies have significant limitations. These limitations are due to potentially influencing variables that were not factored into study designs. There are also additional outcomes warranting investigation that have thus far been overlooked. Below, the potentially influencing variables that should be addressed or accounted for in any future studies related to this topic will be discussed. These variables are supplement characteristics, obesity, and young adulthood. After that, health-related quality of

life, diet quality, and physical activity will then be discussed as potential outcomes of MVMS meriting examination.

Influence of Supplement Composition

Ingredients of a supplement determine its potential function. One of the major limiting variables previously overlooked is the ingredients used and amounts of supplements provided to participants. The supplements in the studies mentioned were not all the same and some included herbal extracts^{2,17-19}. Herbal extracts are widely known to play a role in different aspects of cognition. Multiple studies²⁹ have found that herbal extracts play a positive role in depression and anxiety, thus they have the potential to confound or mask results from the micronutrients being simultaneously supplemented.

Of the studies that used a typical MVMS, the dosage between studies was not the same. One study in particular tested a supplement with extremely high values of particular B vitamins²¹, while others used moderate amounts. It is difficult to adequately compare studies and results when the doses of micronutrients vary so widely. Therefore, future studies should consider using micronutrient compositions similar to those of previous studies with quality study designs.

Influence of Obesity

The obesity epidemic presents many challenges to health and chronic disease prevention across the lifespan. Many public health efforts are aimed at reducing obesity rates nationwide. The prevalence of obesity among U.S. adults is almost 40 percent, affecting nearly 93.3 million adults³⁰. In Arkansas, obesity affects around 698,000 adults⁵. National trends suggest that excess

weight in pediatric populations persists into adulthood³¹. These rates are troubling given that excess weight is associated with a variety of poor physical and mental health outcomes. Physical health outcomes associated with obesity include diabetes, cardiovascular disease, sleep apnea, and cancer³². Psychologically, excess weight is associated with higher rates of depression, low self-esteem, peer victimization and poor quality of life³. Each of these qualities potentially relate back to diet and micronutrient status.

Overweight or obese individuals are more likely to have low serum levels of various micronutrients than their normal weight counterparts³³. These individuals typically consume adequate total energy, so low micronutrient levels may result from inadequate nutrient intake in the diet. Aspects of being overweight or obese have also been shown to alter the absorption, distribution, metabolism, and/or excretion of micronutrients³³. Thus, multivitamin-mineral supplementation may be of particular potential benefit to overweight and obese individuals. Despite the known relationship between obesity and mental health, the previous studies related to MVMS and mood neglected to factor in weight as a variable. Future studies should therefore consider weight and BMI as variables of interest.

Influence of Young Adulthood

Another limitation of the previously mentioned studies is that different developmental stages were not factored in. There is a noticeable broad age range across studies^{19,21,25-28}. However, adulthood is broken down into distinct developmental periods, each presenting with unique health challenges including changes in psychological, emotional, and physical development³⁴. Young adulthood represents a unique developmental time in the lifespan. Young adults are those ages 18 to 24. The process of becoming an adult is more gradual and varied

today than in the past. Developmentally, this age group is leaving home and developing independence in decision-making³⁵. Adult responsibilities, such as financial independence and residential and employment stability are still in flux at this stage. This is also a critical time for identity development. As young adults move out of the home and begin exploring new behaviors, they make choices which shape them into the person they want to become. Young adults make choices that have the potential to impact lifelong behavioral patterns. Compared to adolescents, young adults have worse health in multiple areas and many high-risk behaviors peak during this time. For example, rates of obesity, depression and suicide, and alcohol use are all greater during this time compared to adolescents³⁶. Overall, the transition from adolescence to adulthood is marked with risk of excess weight gain. As obesity increases in this time period, so do the comorbid psychological and physical impairments.

Also, age and life-stage have previously been demonstrated to alter nutrient absorption³⁷. Recommended nutrient intakes also change throughout the lifespan. Young adults are an overlooked and understudied high-risk group. Young adults have some of the unhealthiest eating habits compared to other age groups³⁸. Having a low diet quality indicates lower intakes of healthier items from core food groups such as fruits, vegetables, whole grains, and other key nutrients, and higher intakes of energy-dense, nutrient poor foods such as processed food and sugary beverages³⁸. Low diet quality thereby potentially leads to inadequate micronutrient intakes. While college students are typically used as a convenience sample to generalize to populations of adults, few studies have focused solely on the health and well-being of this age group. With this, young adults should not be grouped with all adults over the age of 18 years, but rather warrant scientific focus on their age group and developmental stage, especially in relation to diet and mood.

Health-Related Quality of Life as an Outcome

Increasingly, health care providers are recognizing that measures of disease alone are insufficient in defining health status. Quality of life has become a complementary health status measure. It is a broad multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life³⁹. Health-related quality of life (HRQOL) has evolved to encompass aspects of overall quality of life that can be clearly shown to affect health. The CDC has defined HRQOL as an individual's or group's perceived physical and mental health over time⁴⁰. They created four highly validated HRQOL items, the first focusing on self-perceived health. The second and third items relate to recent physical and mental health symptoms and are considered mutually exclusive and are worded as such. The fourth item is conceptualized as a global measure of disability that incorporates both physical and mental health. The CDC HRQOL questionnaire is as follows:

1. In general, how would you rate your health?
2. Now thinking about your physical health, for how many days during the past 30 days was your physical health not good?
3. Now thinking about your mental health, for how many days during the past 30 days was your mental health not good?
4. During the past 30 days, on how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, recreation?

While some studies have explored the relationship between micronutrients and overall quality of life, only one has focused on micronutrients and HRQOL. This recent study found a negative impact of vitamin D deficiency on HRQOL when exploring the extent to which

micronutrient deficiencies affect children's HRQOL, using vitamin D deficiency as a case study⁴¹. With the current gap in literature and an effective HRQOL tool available, there is an opportunity to explore the relationship between micronutrient status and health-related quality of life. Careful considerations in study design that were overlooked in the previously mentioned MVMS studies should also be considered including weight, age, and exercise.

Physical Activity as an Outcome

Macronutrients including proteins, carbohydrates, and fat provide sources of energy needed to fuel the body and provide structure to perform work. Micronutrients enable the use of macronutrients for all physiological process. Vitamins and minerals are key regulators of health and function which includes work performance⁴². Previous studies have explored if MVMS can enhance health and sports performance,⁴³ but not if MVMS use or micronutrient status can influence frequency of exercise. Micronutrient deficiencies may play a role in frequency of physical activity.

There is a growing body of literature that recognizes the positive effects of physical activity on mood⁴⁴. Exercise can improve anxiety, stress, depression, and psychological functions. Contrarily, studies show consistent negative associations between mental health and sedentary behavior, or physical inactivity⁴⁵. While there are known positive effects of physical activity, a large proportion of those with mood and/or anxiety disorders do not exercise regularly⁴⁶. Indicated barriers to physical activity include physical conditions, time constraints, and lack of will power/self-discipline, most of which relate back mood. Studies suggest that one of the main reasons people take multivitamins is to increase both physical and mental energy⁴⁷. Since physical activity and inactivity correlate with aspects of mental health, MVMS could result in more physical activity by which enhancing mood and mental health indicators.

Summary and Objectives

Micronutrients are essential to health and well-being, both physical and mental. Several micronutrients are involved with biochemical processes in the brain. MVMS is a potential way to bridge gaps in micronutrient intake, thus potentially influencing other health-related outcomes. While there are many previous studies related to MVMS and mood/mental health measures, there are key considerations in study design that were overlooked and need to be factored into future related studies. When looking at effects of micronutrient supplementation on the brain, care should be taken to choose a supplement that excludes herbal extracts and caffeine due to their potential to alter brain function. Further, having excess weight or being a young adult may uniquely contribute to risk of alterations in mood and mental health, and thus may contribute greater response to interventions. Lastly, there is reason to suspect that MVMS may favorably influence overall health-related quality of life and engagement in physical activity.

Using a supplement patterned after the Berocca studies that is void of herbal extracts and caffeine, we will examine the efficacy of daily MVMS use on health-related quality of life and physical activity in young adults (18 – 24 years old). Moreover, we will compare whether effects are greater in those with excess body weight. We hypothesize that supplementation over a 30-day period will improve these measures, and more so in overweight/obese young adults.

Methods

Recruitment/Participants

Participants were recruited from a mid-south public university via campus flyers, postings in a digital campus news source, and through classroom announcements. Initial eligibility was determined by a scripted phone call by study staff. Inclusion criteria were 18 to 24 years old; healthy or overweight/obese BMI; going to school or working part time; ability to swallow pills; no malabsorption; no gastrointestinal diagnosis, impaired liver/renal function; no iron deficiency anemia; not taking prescriptions for a mental health diagnosis; and willing to abstain from taking other drugs and herbal supplements for the duration of the study. Final eligibility was confirmed during the informed consent process, which included training and familiarization of participants with the study protocol. Demographic information was collected, and baseline assessments completed immediately after participants completed the informed consent process. The demographic and baseline assessments included age, BMI, health indicators, and nutritional status. A total of 137 men and women aged 18-24 years were randomized and completed this controlled trial. Of the participants, 72 were of healthy BMI (18.5-24.9) and 65 were overweight/obese BMI (25+). This study was approved by the University of Arkansas Institutional Review Board for human subject research (Approval #1709073942).

Randomization and Study Design

Participants were randomized to receive either a placebo or a multivitamin mineral supplement in identical pill form. Study participants were divided by chance into separate pill groups. Groups were randomized using a random sequence generator. Participants took two pills

every morning for 30 days. Participants were required to come to the study office every week to return all unused pills, pick up a week’s supply of their designated pill, and to collect compensation as applicable. Compliance was assessed weekly via pill counting. Participants had two assessment days on Day 0 and Day 30. On these days they completed self-administered online questionnaires. The amounts of micronutrients in the multivitamin mineral supplement were similar to the Berocca® supplement and are listed in Table 1.

Table 1. Composition of MVM Supplement

Vitamin/Mineral	Amount in Supplement	RDA	%RDA
B1 = Thiamin	15 mg	1.1 – 1.2 mg	1364
B2 = Riboflavin	15 mg	1.1 – 1.3 mg	1364
B3 = Nicotinamide	50 mg	14 – 16 mg	357
B5 = Pantothenic Acid	23 mg	5 mg	460
B6	10 mg	1.3 mg	769
B12	10 µg	2.4 µg	416
C	500 mg	75 – 90 µg	667
H = Biotin	150 µg	30 µg	500
Folic Acid	400 µg	400 µg	100
Calcium	100 mg	1,000 mg	10
Magnesium	100 mg	310 – 400 mg	32
Zinc	10 mg	8 – 11 mg	125

Questionnaires

Participants completed self-administered online assessments at baseline and at the end of the 30-day study protocol. Questionnaires assessed health indicators, including health-related quality of life, exercise, and nutrient intake for diet quality. Assessments were a compilation of validated and accepted instruments presented randomly through a Qualtrics survey. The CDC’s Health Related Quality of Life-14 Measure (HRQOL) was used to assess multiple dimensions related to physical, emotional, and social functioning. HRQOL increasingly has been acknowledged as a valid health indicator and measures physical functioning, psychological well-

being, social and role functioning and health perceptions⁴⁰. The International Physical Activity Questionnaire (IPAQ) is the most widely used physical activity questionnaire⁴⁸. It is a 4-item measure of health-related physical activity. Subjects were reminded to complete the assessments via text and email. Participants received a total of \$100 in cash for completing the study. Compensation was distributed incrementally as participants progressed through though the study to further encourage completion of the study.

Statistical Analysis

First, descriptive statistics were conducted on the full sample. Next, a split-plot analysis of variance (ANOVA) was conducted to detect both main effects as well as interaction effects between the control group (placebo pill) and the intervention group (MVMS) at time 1 (baseline) and time 2 (follow up day 30). Dependent variables included four health-related quality of life (HRQOL) variables which include the number of physical unhealthy days, number of mentally unhealthy days, the number of physically and mentally unhealthy days (combined), and the number of days where health was a limited factor (all coded 0 to 30). Physical activity was also used as a continuous dependent variable. Next, further analyses were conducted by BMI group by conducting the same split-plot ANOVA using the normal weight sample, and the overweight sample, respectively. Analyses were conducted using SPSS, v26⁴⁹ 49.

Results

Participant Characteristics

The study had a total of 154 participants at baseline. After excluding dropouts and those with compliance issues, 137 participants were included for data analysis. Of the 137 participants, 67 received placebo and 70 received the supplement (Table 2). The majority of participants were undergraduate or graduate students, living in an urban area, with some college completed, and employed part-time. The study consisted of 107 females (49 received placebo and 58 received the supplement) and 34 males (18 received placebo and 12 received the supplement). Student status was similar between the two groups with the exception of the supplement group having more seniors than the placebo group. The majority of participants in both groups lived in urban geographic locations.

Table 2. Participant Characteristics

	<u>Placebo</u> (N=67)	<u>MVMS</u> (N=70)
Females	49 (73.1%)	58 (82.9%)
Males	18 (26.9%)	12 (17.1%)
BMI		
Normal (18.5-24.9)	35 (52.2%)	37 (52.9%)
Overweight/obese (≥ 25)	32 (47.8%)	33 (47.1%)
Age (Average \pm SD)	21 yrs \pm 1.76	20 yrs \pm 1.79
Student Status		
Non-Student	2 (3.0%)	3 (4.3%)
Freshman	10 (14.9%)	9 (12.9%)
Sophomore	18 (26.7%)	15 (21.4%)
Junior	15 (22.4%)	11 (15.7%)
Senior	12 (17.9%)	25 (35.7%)
Grad Student	10 (14.9%)	7 (10%)
Geographic living location		
Rural	6 (9.0%)	11 (15.7%)
Urban	61 (91.0%)	59 (84.3%)
Level of Education Completed		
Some high school	-	1 (1.4%)
High school	9 (13.4%)	17 (24.3%)
Some college	42 (62.7%)	38 (54.3%)
Associate degree	2 (3.0%)	4 (5.71%)
Bachelor's degree	12 (17.9%)	10 (14.3%)
Post-graduate degree	2 (3.0%)	-
Employment Status		
Unemployed	21 (31.3%)	20 (28.6%)
Part-time	40 (59.7%)	46 (65.7%)
Full-time	6 (9.0%)	4 (5.7%)

HRQOL

When examining the results of the split-plot ANOVA, two key results will be investigated. First, “main effects” are overall trends of all participants, regardless of whether or not each individual was in the control or intervention group (i.e., a standard repeated measures ANOVA) to determine if there was an overall change between baseline and time 2. Next,

“interaction effects” were investigated in order to determine if there were differences between individuals when partitioned into their respective control or intervention groups. In other words, a significant interaction term of less than .05 would determine if group membership in the intervention group had a statistically significant difference when compared to individuals in the control group.

Main effects and interaction effects will be investigated in three different contexts. The first is using all individuals (main effects) and their control or intervention group (interaction effects). The second is looking at main and interaction effects using only those in the healthy BMI group, and the third is using only those in the unhealthy BMI group.

Physically Unhealthy Days. The results of split-plot ANOVA interaction for each HRQOL variable, excluding BMI, are presented in Figure 1. Though both groups showed descriptive decreases in the number of unhealthy days (the control group had a net decrease of .75 days while the intervention group had a net decrease of .43), no main effects were detected ($F= 1.187$, $p= .278$, $R^2= .01$; that is, regardless of the intervention). With respect to differences by group (control versus intervention), no interaction effects were present ($F= .090$, $p= .765$, $R^2= .001$), indicating no effects as a result of the intervention.

Regarding BMI, for the healthy weight group, both the control group and intervention group decreased in the number of physically unhealthy days (net decreases of .94 and 1.94 days, respectively), yet this was only a trend for an overall decrease (main effects: $F= 2.930$, $p= .09$, $R^2= .04$). The interaction was also not statistically significant ($F= .144$, $p= .519$, $R^2= .002$). For the overweight group, the control group had a net decrease of .56 days, while the intervention group had an increase of .62 days. No main effects ($F= .001$, $p= .973$, $R^2< .001$) or interactions ($F= .519$, $p= .706$, $R^2= .002$) were detected.

Mental Unhealthy Days. Mental Unhealthy Days is also represented in Figure 1. Similar to Physically Unhealthy Days, there was no interaction effect by group ($F=.029$, $p=.866$, $R^2<.001$). However, there were statistically significant main effects detected ($F=26.235$, $p=.000$, $R^2=.168$), regardless of intervention.

When factoring in BMI for mental unhealthy days, all participants showed statistically significant improvement (main effects: $F=12.579$, $p=.001$, $R^2=.164$ and $F=13.345$, $p=.001$, $R^2=.173$, respectively). Both the control and intervention group for the healthy BMI saw no interaction effects were detected ($F=.002$, $p=.969$, $R^2=.000$). Similarly, the overweight BMI group saw no interaction effects between the control and intervention groups ($F=.067$, $p=.796$, $R^2=.001$).

Physical and Mental Unhealthy Days Combined. The results of split-plot ANOVA interaction for number of physically and mental unhealthy days combined are shown in Figure 1. Both groups showed descriptive decreases in the number of combined days (the control group had a net decrease of 2.69 days while the intervention group had a net decrease of 2.21), and statistically significant main effects were detected ($F= 14.895$, $p=.000$, $R^2= .103$; that is, regardless of the intervention). With respect to differences by group (control versus intervention), no interaction effect was present ($F= .018$, $p= .893$, $R^2= .000$), indicating no effects as a result of the intervention.

For physical and mental unhealthy days combined, all participants showed significant improvement with significant main effects ($F=11.529$, $p=.001$, $R^2=.153$ for the healthy weight and $F=5.627$, $p=.021$, $R^2=.081$ for the overweight group). However, no effects were detected for either healthy BMI ($F=1.246$, $p=.268$, $R^2=.019$) or overweight BMI ($F=.328$, $p=.569$, $R^2=.005$) in regard to interaction between control and intervention.

Health Limitation Days. Lastly, also presented in Figure 1 are the results of split-plot ANOVA interaction for number of health limitation days. Both placebo and MVMS groups showed descriptive decreases in the number of combined days (the control group had a net decrease of .95 days while the intervention group had a net decrease of 2.21) and statistically significant main effects were detected ($F= 14.7756$ $p=.000$, $R^2=.101$; that is, regardless of the intervention). With respect to differences by group (control versus intervention), no interaction effects were present ($F= 2.317$, $p= .130$, $R^2= .017$), indicating no effects as a result of the intervention.

Regarding BMI for health limitation days, for the healthy BMI group, main effects were detected ($F=15.884$, $p=.000$, $R^2=.199$), however, no statistical significance was found between the control and intervention groups ($F=1.596$, $p=.211$, $R^2=.024$). The overweight BMI group showed no main or interaction effects present ($F=3.609$, $p=.062$, $R^2=.053$ and $F=.950$, $p=.333$, $R^2=.014$, respectively) also indicating no effects as a result of the intervention.

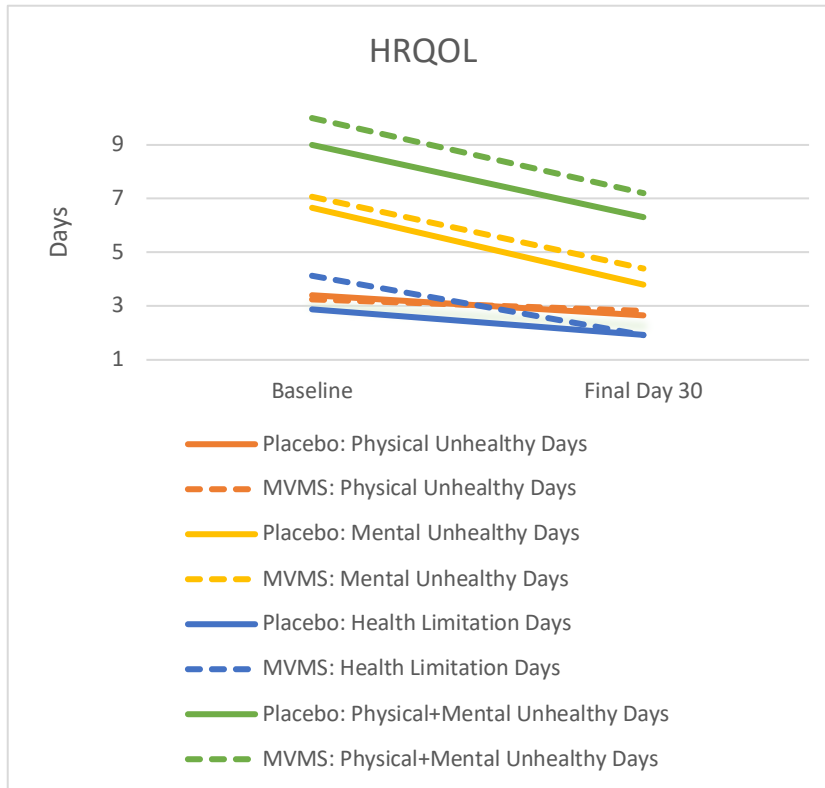


Figure 1. HRQOL Split-Plot ANOVA Interactions

Physical Activity

The results of split-plot ANOVA interaction for physical activity are shown in Figure 2. There was no difference in physical activity between the placebo and MVMS after the 30-day study ($F=.803$, $p=.372$, $R^2=.006$). There also were no main effects detected for physical activity ($F=1.562$, $p=.214$, $R^2=.012$).

BMI did not affect the results of physical activity. There were no statistically significant results for the healthy BMI group main effects ($F=1.424$, $p=.237$, $R^2=.022$) or between the control and intervention groups ($F=.805$, $p=.373$, $R^2=.012$). As for the overweight BMI group, no results were detected for main effects ($F=.370$, $p=.545$, $R^2=.006$) or interaction effects ($F=.161$, $p=.690$, $R^2=.003$).

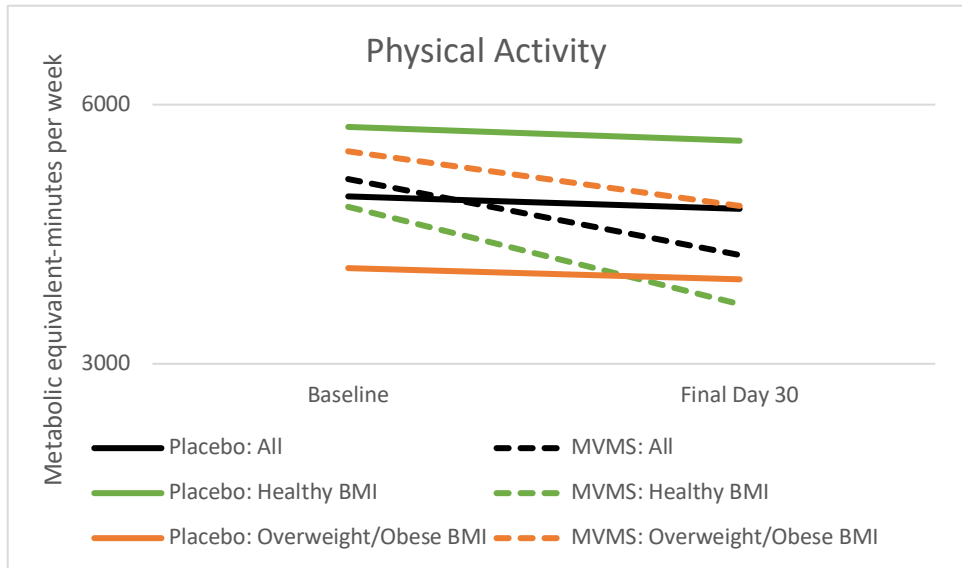


Figure 2. Physical Activity Split-Plot ANOVA Interactions

Discussion

Overall, there was greater improvement in the MVMS group than the placebo group numerically, but the differences did not reach statistical significance. There were no statistically significant differences between the placebo and MVMS groups for any of the variables; however, there were instances of statistical significance regarding main effects, regardless of the intervention. When factoring in BMI, results for outputs were similar to overall results suggesting that weight and/or BMI is not a factor for HRQOL or physical activity being influenced by MVMS.

The lack of statistical significance between placebo and MVMS groups could be due to a variety of reasons, one main reason being small sample size. While the study had a large sample size to begin with, the number of participants with adequate or complete data was lower. A small sample size could result in lower power and a greater chance of a Type II error. Our sample size potentially was not powered high enough. This issue of sample size also relates to participant compliance. Compliance issues with participants were multiple and resulted in some participants

not being included in data analyses; this could have further decreased the ability to accurately assess the effects of the MVMS.

To our knowledge, this was the first attempt using a MVMS to potentially influence HRQOL. The most relevant previous study only looked at deficiency of a single micronutrient, not the influence of a multivitamin mineral supplement. Assessing participants' micronutrient status could have determined if a supplement was needed. Moreover, those lacking initially in micronutrients could have been those that we saw improvements in. It could be that MVMS does influence HRQOL if micronutrient levels are low enough to begin with. Having diet quality as a variable could have been useful in determining this information. Diet quality is a term that is often used in nutritional epidemiology to evaluate the population's dietary habits and the efficacy of dietary interventions⁵⁰. Different diet quality methods have proved to be useful indicators of micronutrient content in the diet⁵¹. MVMS are used to supplement and improve diet quality. However, adequate nutrient intake can usually be achieved through a well-balanced diet and supplementation may not confer additional health benefits⁵². Diet quality can often be poorly defined and hard to measure. However, one approach has been developed and frequently used in the literature to define diet quality and that is the Healthy Eating Index (HEI). Nearly 300 publications have used HEI to evaluate food intake and diet quality⁵³. Developed by the USDA Food and Nutrition Service, HEI is used to assess how well a set of foods aligns with key recommendations of the Dietary Guidelines for Americans. The Dietary Guidelines for Americans (DGA) is designed for nutrition and health professionals to help individuals consume a healthful and nutritionally adequate diet.

Alternatively, or in addition to diet quality, biochemical levels of micronutrients would be useful in determining if the supplement provided benefit. A blood draw at baseline and day 30

for biochemical assessment of thiamin and riboflavin [spectrophotometric functional assays using red blood cells⁵⁴, vitamin B6 (plasma pyridoxal-5-phosphate by High Performance Liquid Chromatography (HPLC)⁵⁵, vitamin B12 (plasma by ELISA kit), vitamin C (plasma ascorbic acid by commercial ELISA kit), folate (serum by commercial ELISA kit), vitamin D (serum 25-hydroxy-vitamin D by HPLC⁵⁶), and iron status (whole blood hemoglobin spectrophotometrically⁵⁷, zinc protoporphyrin by hematofluorometer, plasma ferritin by commercial ELISA kit). Although not supplemented, assessment of vitamin D and iron status should be taken due to their known role in cognition that are independent of the supplemented micronutrients. Biochemical assessment of niacin, pantothenic acid, and biotin are lacking consensus on the appropriate analytical method. Magnesium and zinc are not mentioned here for biochemical assessment because plasma magnesium levels can remain normal during deficiency, and zinc levels only drop in extreme deficiency.

Time could also play a role in the findings from this study. While most variables were not different between the two groups, the study did find slight results. MVMS could potentially take longer than 30 days to influence HRQOL and physical activity. Similarly, age could influence the findings. We chose to focus on young adults for a variety of reasons; however, a MVMS may not influence young adults as expected.

The lack of finding a difference between the two groups could also be due to a placebo effect, placebo effect being the participants' belief in the treatment producing results that cannot be attributed to the placebo itself⁵⁸. The act of taking a daily pill and the knowledge of what the study was looking at could have made the participants think their health was improving and narrowed the difference at the Day 30 assessment. Alternatively, there may be no true effect from the MVMS.

There was no difference in physical activity between the two groups. This could be due to the way the questionnaire was worded. Participants were to enter how many hours of different exercise was performed, followed by how many minutes of exercise was performed. There were multiple instances that participants entered very different or drastic answers for the two questions. For instance, one participant entered that they performed 300 hours of exercise. Because of these inconsistencies, the outliers were left blank. This affected the person's overall physical activity score as well as the overall data for the group.

Strengths and Limitations

This study has numerous strengths mostly relating to study design. The close consideration in developmental period and detailed inclusion criteria were strong choices which enhanced the quality of the study. Also strengthening our study was the supplement used because it contained only vitamins and minerals and excluded herbal extracts and caffeine. The study also used high quality methods to measure study endpoints; all questionnaires used were previously validated and are widely accepted.

Nonetheless, this study was not without its limitations. While the questionnaires used were all of high quality, they were all self-reported measures. The only measure not self-reported was BMI. Another limitation was participant compliance. The study team had measures in place to encourage compliance, but participants could have forgotten to take pills but still reported that they did. A blood or urine sample collected at baseline and day 30 may have helped accurately assess compliance with pill intake. Another limitation is the small sample size with limited generalizability, particularly with such small numbers of males participating, which may have

limited power. However, being the first study to our knowledge to assess MVMS on HRQOL measures and physical activity, it was difficult to determine the target sample size.

Conclusion

MVMS did not influence HRQOL measures or physical activity over a 30-day study period. However, these measures were influenced, regardless of intervention, perhaps due to a placebo effect. Whether methodological effects or placebo effect were at play, these findings lend themselves to future studies. A multivitamin mineral supplement could still be beneficial to young adults of both healthy and overweight/obese BMI. The quality of this study was high due to study design and justification. Although no effect from the supplement was observed, future research should examine this topic further. Since this study was the first of its kind, there could be methodological differences that lead to a truer assessment of the relationship. Future studies of the effects of MVMS on HRQOL measures and physical activity should include assessment of serum nutrient levels and diet quality. Also, assessment of supplementation for longer than 30 days with a larger sample size is warranted.

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Appendices

Appendix A

Study Recruitment Flyer



RESEARCH PARTICIPANTS NEEDED FOR VITAMIN STUDY!

You may be eligible to participate in a research study about Multivitamin/Mineral Supplementation!

Eligibility Requirements:

- Aged 18 - 24
- Must be going to school or working at least part-time

What does this study involve?

- A screening questionnaire to determine eligibility to participate
- Taking an oral supplement once daily for 30 days
- Completing an online assessment on five different days throughout the month

COMPENSATION IS \$100! All queries are confidential.

For more information, please contact Sarah Ann Pendergraft: sapender@uark.edu

Appendix B

Participant Screening Script and Questionnaire

Hello, my name is ___ and I am a research assistant with the Multivitamin-Mineral Supplementation study at the University of Arkansas. Is now a good time to talk and give you some information about the study? (If yes, say thank you and continue on. If no, then ask if there is a better time to call back).

Thank you very much for your interest in our study. First, I would like to tell you a little about the study and if you are interested then ask you a few questions to determine if you are eligible to participate.

This research study is looking at the effects of multivitamin-mineral supplementation on mood and overall well-being. Participants in this study will be asked to take a daily multivitamin supplement or placebo for 30 days and complete online questionnaires asking about mood, physical health and diet, and weight-related health. Your participation would last approximately 32 days and you would be compensated \$100 for participating.

Are you still interested? (*If they are not interested in participating: Thank you for your time and interest in the study.*)

If yes: Great! We are happy to hear you are interested in participating. We have a few screening questions that we would like to ask to determine your eligibility in the study. These questions ask your basic information and if you have any health-related diagnoses that could possibly impair the effectiveness of the multivitamin supplementation. Do I have your permission to ask these questions?

Note to research assistants: Please go through the entire screening questionnaire even if they are disqualified half way through.

Screening Questionnaire

1. What is your name?
2. What is your phone number and email address?
3. What is your preferred method of contact?
4. What is your height?
5. What is your current weight?
6. BMI?
7. Are you between 18 and 24 years old?

Yes

No

8. Are you pregnant or planning to become pregnant? (If male, skip this question)
 Yes No N/A
9. Are you going to school or working at least part-time?
 Yes No
10. Have you ever been diagnosed with malabsorption, or any related gastrointestinal diagnoses for example, Chron's disease or inflammatory bowel syndrome?
 Yes No
11. Have you ever received a diagnosis related to impaired liver or renal function?
 Yes No
12. Do you have iron deficiency anemia?
 Yes No
13. Have you ever been diagnosed with a mental health disorder, for example, general anxiety, depression, bipolar disorder or an eating disorder?
 Yes No
14. Are you currently taking any prescription medications for a mental health diagnosis?
 Yes No
15. Are you willing to abstain from taking any other supplements during the study and abstain from taking any drugs, including marijuana?
 Yes No
16. Are you extremely uncomfortable or unable to swallow pills?
 Yes No

NOTE: People responding *YES* to questions 7, 9, 10, 11, 12, 13, and 15 or a *NO* to question 14 are not eligible for the study.

For those not eligible to participate (answering yes to any of the above disqualifies the person from participating): I am sorry to inform you that unfortunately you are not eligible to participate in the Multivitamin-Mineral Supplementation study. Thank you very much for your interest in participating.

For those eligible to participate: You are eligible to participate in our study! Next, we would like for you to come to our study laboratory so that we can obtain your informed consent, explain the study instructions, and get some further background information from you. Our study laboratory is located on the 2nd floor of the Home Economic building in office 205D on the University of Arkansas campus. When would be a good time for you to come in? (Schedule a date and time).

We appreciate your interest in the multivitamin-mineral supplementation study and we look forward to meeting you on (date) and (time). If you have any questions or trouble locating our lab, please do not hesitate to contact me at _____.

Appendix C

Participant Informed Consent Form

Multivitamin-Mineral Supplementation & Mood Study Consent to Participate in a Research Study

Principal Researcher: Jennifer Becnel, PhD & Sabrina Trudo, PhD, RD

INVITATION TO PARTICIPATE

You are invited to participate in a research study investigating the effects of multivitamin-mineral supplementation on your health. You are being asked to participate in this study because you are between the ages of 18 and 24 years old, going to school or working at least part-time, and have no gastrointestinal or mental health diagnoses. Please take time to review the following form, ask questions, and decide whether you wish to participate or not.

WHAT YOU SHOULD KNOW ABOUT THE RESEARCH STUDY

Who are the Principal Researchers?

This study is being conducted by Jennifer Becnel, PhD and Sabrina Trudo, PhD, RD of the School of Human Environmental Sciences at the University of Arkansas. Dr. Becnel can be reached by phone at 479-575-2358 or by email at becnel@uark.edu. Dr. Trudo can be reached by phone at 479-575-4863 or by email at trudo@uark.edu.

What is the purpose of this research study?

Poor health and mood have been associated with micronutrient deficiencies. The purpose of this study is to examine the effects of multivitamin-mineral supplementation on mood, health, and weight-related satisfaction in young adults.

Who will participate in this study?

This study will include 140 young adult men and women. To participate, you must be the ages of 18-24, going to school or working at least part-time, have no malabsorption or related gastrointestinal diagnosis, no mental health diagnosis, and not taking prescription medications. You must be willing to take only the provided multivitamin-mineral supplement for 30 days.

What am I being asked to do?

During your first visit to the study laboratory, study staff will explain the study and address any questions or concerns you may have. If you agree to participate, study staff will take your height and weight and outline a detailed schedule for your participation in the study. You will also fill out a short questionnaire asking basic questions about yourself. At this time, we ask that you discontinue use of dietary/herbal supplements (including all vitamins and teas).

Participation in this study will last 31 days. You will be randomly assigned to take two pills daily for a month of either a multivitamin-mineral supplement or placebo (not containing any vitamins or minerals). You will not know if you are assigned to take the multivitamin-mineral supplement or the placebo. During the 31 days, you will be asked to visit the study laboratory weekly (every 7 days) to pick up the multivitamin-mineral supplements or placebo. The multivitamin-mineral supplement or placebo is to be taken every morning at approximately the same time. Additionally, you are asked to complete two online questionnaires on five assessment days: Day 1, Day 3, Day 4, Day 15, and Day 30. The first online questionnaire will ask questions about psychological functioning, health, and weight-related satisfaction. The second online questionnaire will ask about your dietary intake in the previous 24 hours. The questionnaires should take approximately one hour to complete, total. On the last day of the study, you will be asked to return to the study laboratory to have your height and weight taken again. Below is an outline of the study schedule.

Study Schedule

- Day 0: Return to the study laboratory to pick up the supplements/placebo. You will be given 7 days' worth of the supplement/placebo.
- Day 1: Begin taking the supplement/placebo in the morning and complete the online assessments within 3 hours of taking the supplement/placebo.
- Day 3: Complete the online assessments within 3 hours of taking the supplement/placebo.
- Day 4: Complete online assessment *before* taking the supplement/placebo.
- Day 7: Return to the study laboratory for another week's supply of the supplement/placebo.
- Day 14: Return to the study laboratory for another week's supply of the supplement/placebo.
- Day 15: Complete the online assessments within 3 hours of taking the supplement/placebo.
- Day 21: Return to the study laboratory for another week's supply of the supplement/placebo.
- Day 30: Complete the online assessments within 3 hours of taking the supplement/placebo.
- Day 31: Return to the study laboratory to finish out the study and have your height and weight taken.

What are the possible risks or discomforts?

You may feel uncomfortable answering some of the questions in the online questionnaire. If you feel any discomfort, you can omit an answer to a question or terminate your involvement in the study. You will not be penalized for omitting answers or terminating the questionnaires early. There may be discomfort from swallowing the supplement/placebo pills if you are not accustomed to swallowing pills. If you find that you cannot tolerate swallowing pills, you do not have to complete the study. The amounts of the vitamins and minerals in the supplement are similar to supplements that are available for purchase at stores.

What are the possible benefits of this study?

There are no benefits to participating in the study.

Will I receive compensation for my time and inconvenience if I choose to participate in this study?

You will receive a total of \$100 in cash for completing the study, distributed as each assessment day is completed. Compensation is received for each day the online questionnaires are completed. Amounts increase for each questionnaire day (Day 1 = \$10, Day 3 = \$15, Day 4 = \$20, Day 15 = \$25, Day 31 = \$30). To minimize the number of times you need to visit the laboratory, compensation will be dispersed on Day 7, Day 21, and Day 31.

Will I have to pay for anything?

There will be no cost associated with your participation in this study.

What are the options if I do not want to be in the study?

If you do not want to be in this study, you may refuse to participate. Also, you may refuse to participate at any time during the study. Your standing and relationship with the University of Arkansas will not be affected in any way if you refuse to participate or drop out of the study.

How will my confidentiality be protected?

All information will be kept confidential to the extent allowed by applicable State and Federal law. Participants in this study will be assigned an ID number to ensure confidentiality. A master list linking participant's names to ID numbers and all participant data will be kept on a secure server that only the study staff will have access to.

Will I know the results of the study?

At the conclusion of the study you will have the right to request feedback about the results. You may contact the Principal Researcher, Jennifer Becnel at becnel@uark.edu or 479.575.2358. You will receive a copy of this form for your files.

What do I do if I have questions about the research study?

You have the right to contact the Principal Researcher as listed below for any concerns that you may have.

Jennifer Becnel, PhD
Assistant Professor of Human Development and Family Sciences
Human Environmental Sciences
HOEC 118
1 University of Arkansas
Fayetteville, AR 72701
479.575.2358
Becnel@uark.edu

Sabrina Trudo, PhD, RD
Associate Professor of Nutrition
21st Century Endowed Chair in Human Environmental Sciences
HOEC 118
1 University of Arkansas
Fayetteville, AR 72701
Tel: 479.575.4863
trudo@uark.edu

You may also contact the University of Arkansas Research Compliance office listed below if you have questions about your rights as a participant, or to discuss any concerns about, or problems with the research.

Ro Windwalker, CIP
Institutional Review Board Coordinator
Research Compliance
University of Arkansas
109 MLKG Building
Fayetteville, AR 72701-1201
479-575-2208
irb@uark.edu

STATEMENT OF CONSENT

I have read the above statement and have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I understand the purpose of the study as well as the potential benefits and risks that are involved. I understand that participation is voluntary. I understand that no rights have been waived by signing the consent form. I have been given a copy of the consent form.

Name of Participant: _____

Signature of Participant: _____

Signature of Investigator: _____

Date: _____

Multivitamin-Mineral Supplementation & Mood Study

Participant Instruction Booklet

For questions about any part of the study, please contact your study coordinator.

Study Coordinator: Sharon Chang

Laboratory: HOEC 205D

Research Coordinator: _____

Coordinator Phone Number: _____

Emergencies—Dr. Becnel

(480) 276-2955

Email

Yc031@uark.edu



Please stop taking all medications and dietary/herbal supplements (including all vitamins and teas) beginning one week before the study period.

Stop on: _____

Purpose of the Study

The primary purpose of this study is to examine the effects of a multivitamin-mineral supplement (MVM) on psychological functioning, health, and weight-related satisfaction among young adult college students.

Study Procedures and Time Commitment

This is a research study looking at the effects of Multivitamin-Mineral Supplementation on mood and overall well-being. The total timeline for the project is two years, during which we will conduct a randomized controlled trial at the University of Arkansas, Fayetteville. However, you are required to participate in the study only for 31-days.

You may qualify for the study if you are/have:

- 18 – 24 years old;
- Going to school or working at least part-time;
- No diagnosis of malabsorption or related gastrointestinal diagnoses (e.g., Crohn’s disease, inflammatory bowel disease);
- No diagnosis related to impaired liver or renal function;
- No mental health diagnosis (e.g., general anxiety disorder, depression, bipolar-related diagnoses);
- Not taking prescription medications for mental health diagnoses;
- And willing to not take any other supplements during the study.

After the screening interview over the phone, if you qualify, you will be asked to come to the study laboratory to have your height and weight taken, fill out a one-time demographic questionnaire, and be given the study instructions and activities. At this time, we will randomly assign you to either the MVM supplement or placebo group. The following week, you will return to the study laboratory to receive a week’s supply of the supplement or placebo pills and will be instructed to take two pills at approximately the same time every morning. You will return to the study laboratory once a week for another week’s supply of the supplement or placebo pills and to return any pills that you did not take during the previous week.

You will also be asked to complete the following two questionnaires on each of the five assessment days: Consent Day, Day 3, Day 4, Day 15, and Day 31. They are,

1. **Questionnaire- I:** A self-administered online questionnaire to assess your psychosocial functioning, health indicators, and weight related satisfaction. It is a set of questionnaires that will be presented in a random order each time through Qualtrics software.

2. **Questionnaire- II:** A self-administered online questionnaire, ASA24[®], to assess your dietary intake in the previous 24 hours. ASA24[®] is completed separately using a website and confidential login from the National Cancer Institute.

You will be instructed to complete the questionnaires within three hours after taking the supplement or placebo on Day--3, Day 15, and Day 31. However, on Day 4 you will be required to complete the questionnaires **before** taking the supplement. Links to the questionnaires will be provided to you and you will be reminded to complete the questionnaires via text, email, or phone calls.

Coming to HOEC

The Home Economics (HOEC) building is located on the University of Arkansas, Fayetteville campus. The study office is located on the 3rd floor of HOEC in 205D.

Supplement

The Multivitamin-Mineral Supplement that we are using in this study was formulated to contain selective nutrients such as B vitamins, vitamin C, calcium, magnesium, and zinc and no additional compounds such as herbals. The composition of MVM supplement is given in the table below. We will randomly assign you either to an MVM supplement group or a placebo group. You will be asked to take two pills at a time each day. For research purposes, we will make both the supplement and placebo pills look exactly the same and you will not know whether you are taking MVM pills or placebo pills.

Supplement packets can be picked up from the study laboratory every Tuesday. Please bring back the empty supplement packs from the week prior when you pick up the new pack for the next week.

Vitamin/Mineral	Amount in Supplement	RDA	%RDA
B1 = Thiamin	15 mg	1.1 – 1.2 mg	1364
B2 = Riboflavin	15 mg	1.1 – 1.3 mg	1364
B3 = Nicotinamide	50 mg	14 – 16 mg	357
B5 = Pantothenic Acid	23 mg	5 mg	460
B6	10 mg	1.3 mg	769
B12	10 µg	2.4 µg	416
C	500 mg	75 – 90 µg	667
H = Biotin	150 µg	30 µg	500
Folic Acid	400 µg	400 µg	100
Calcium	100 mg	1,000 mg	10
Magnesium	100 mg	310 – 400 mg	32
Zinc	10 mg	8 – 11 mg	125

Questionnaires

You will be asked to complete questionnaire-I and questionnaire-II on each of the five assessment days. In addition, you will be asked to complete one time questionnaires on demographics and alcohol consumption at the start of the study.

Demographics:

A demographic questionnaire will ask about age, gender/sex, year and full or part time in college, socioeconomic status and work status, geographic location (urban vs. rural), food insecurity, Greek life engagement, general eating behaviors, and sleep behaviors.

Alcohol Use:

Participants will complete 6 questions from National Institute on Alcohol Abuse and Alcoholism (NIAAA) on frequency of drinking and binge drinking behaviors.

Questionnaire-I:

Questionnaire-I is a compilation of several mini questionnaires to assess psychological functioning, weight related functioning and health measures.

1). Psychological Functioning Measures:

BAI (Beck Anxiety Inventory): The BAI evaluates physiological and cognitive symptoms of anxiety.

Center for Epidemiologic Studies Depression Scale (CES-D): The CES-D is a brief assessment measuring attitudes and symptoms of depression.

Self-Esteem: A single item measures self-esteem or your feelings about yourself.

ADI (Abbreviated Dysregulation Inventory): The ADI evaluates ability to control thoughts, feelings, and behavior.

PSS (Perceived Stress Scale): The PSS assesses feelings and thoughts related to stress and coping.

2). Weight-Related Functioning Measures:

IWQOL-Lite (Impact of Weight on Quality of Life-Lite): The IWQOL-Lite assesses the impact of obesity on quality of life in areas of physical functioning, self-esteem, public distress, and work.

BSQ (Body Shape Questionnaire): The BSQ measures individuals' self-perception of their body shape and body satisfaction/dissatisfaction.

3). Health Measures:

HRQOL (CDC Health Related Quality of Life-14 Measure): The HRQOL is a measure developed by the Centers for Disease Control to assess health related to physical, emotional, and social functioning.

IPAQ (International Physical Activity Questionnaire): The IPAQ measures health-related physical activity.

Questionnaire-II:

ASA24[®] (Automated Self-Administered 24-Hour Dietary Assessment Tool): The ASA24[®] was developed by the National Cancer Institute and assesses what was eaten over the previous 24-hour period.

Detailed Schedule of Study Activities

Day	Date	Instructions	Complete
Consent		Agree to participate in study; measurements taken; complete questionnaires	Questionnaire I Questionnaire II
Day 0		Pick up supplements from study lab	
Day 1		Begin taking the supplement in the morning	
Day 3		Complete the online questionnaires within 3 hours of taking the supplement	Questionnaire I Questionnaire II
Day 4		Complete the online questionnaires <i>before</i> taking the supplement	Questionnaire I Questionnaire II
Day 7		Return to the study lab for another week's supply of the supplement & return any unused supplements	
Day 14		Return to the study lab for another week's supply of the supplement & return any unused supplements	
Day 15		Complete the online questionnaires within 3 hours of taking the supplement	Questionnaire I Questionnaire II
Day 21		Return to the study lab for another week's supply of the supplement & return any unused supplements	
Day 30		Complete the online questionnaires within 3 hours of taking the supplement	Questionnaire I Questionnaire II
Day 31		Return to the study lab to finish out the study & return any unused supplements	
<ul style="list-style-type: none"> • Take 2 pills at a time every day throughout the study period • Avoid herbal supplements, herbal teas and other vitamin-mineral supplements during the study period 			

Things to Avoid During the Study

You will be asked not to take any other vitamin, mineral and herbal supplements and teas as well as herbal teas during the study. You should let us know if a medication is started for a mental or physical health-related diagnosis any time during the study.

Compensation

Thank you for your interest in participating in the Multivitamin-Mineral Supplementation & Mood Study. You will receive a total of \$100 in cash as a stipend to compensate you for your

time, effort, and inconvenience related to completing the study. This stipend will be distributed incrementally as assessments are completed. Cash is received for each day the online questionnaires are completed. Amounts increase for each questionnaire day (Day 1 = \$10, Day 3 = \$15, Day 4 = \$20, Day 15 = \$25, Day 31 = \$30). Stipends can be picked up from the study laboratory on Day 7, Day 21, and Day 31.

Questions and Contact Information

If you have any questions at any time, you can contact the study coordinator, Ryan Grant at 479-575-7538. The researchers conducting this study are Jen Becnel, PhD and Sabrina Trudo, PhD, RD. If you have any questions for them, you can contact Dr. Becnel at 479-575-2358 and Dr. Trudo at 479-575-4863. If you have any questions or concerns about your rights as a research participant, then you are encouraged to contact Ro Windwalker at 479-575-2208.

Services Available for Discomfort Experienced during the Questionnaire

The online questionnaires that you are asked to take ask questions regarding depression, anxiety, and how you feel about yourself. If you experience any discomfort while answering these questions, please do not hesitate to contact Counseling and Psychological Services (CAPS) here on campus at 479.575.5276.

Appendix E

Demographic Baseline Questionnaire.

This is the complete questionnaire participants took at baseline. A slightly modified version was completed on the final day of participation which excluded the following blocks: demographics, parent education, food insecurity, sleep, alcohol, and eating behavior.

MVM Demographics

Q19 Welcome to the Multivitamin-Mineral Supplementation study!

This study is investigating multivitamin-mineral supplementation and mood. We would appreciate you taking about 15 minutes to complete the following survey. Be assured that all answers you provide will be kept in the strictest confidentiality. Any personal information obtained is for linking participants across surveys and will not be shared. Please click the red arrow button to begin.

Q21 What is your first and last name?

Q3 What is your age in years?

Skip To: End of Survey If Condition: What is your age in years? Is Greater Than 25. Skip To: End of Survey.

Skip To: End of Survey If Condition: What is your age in years? Is Less Than 18. Skip To: End of Survey.

Q5 What is your gender?

- Male (1)
- Female (2)
- Other (3)

Q9 Are you a full-time or part-time student?

- Full-time (1)
- Part-time (2)
- Not a student (3)

Skip To: Q11 If Are you a full-time or part-time student? = Not a student

Q7 What year are you in college?

- Freshman (1)
- Sophomore (2)
- Junior (3)
- Senior (4)
- Graduate Student (5)
- Not a college student (6)

Q11 What is your highest level of education completed?

- Some high school (1)
- High school (2)
- Some college (3)
- Associate's degree (4)
- Bachelor's degree (5)
- Post graduate degree (6)

Q13 What is your employment status?

- Full-time (1)
- Part-time (2)
- Unemployed (3)

Q15 What is your geographic living location?

- Urban (1)
- Rural (2)

Q17 Are you currently or were you ever involved in Greek life?

Yes (1)

No (2)

Q12 What is the highest level of education your mother completed?

8th grade or less (1)

Some high school (2)

High school degree (3)

Completed vocational/technical training (4)

Some college (5)

College degree (bachelor's) (6)

Some graduate school (7)

Completed master's or doctoral degree (8)

Q14 What is the highest level of education your father completed?

8th grade or less (1)

Some high school (2)

High school degree (3)

Completed vocational/technical training (4)

Some college (5)

College degree (bachelor's) (6)

Some graduate school (7)

Completed master's or doctoral degree (8)

Q16 In the last 12 months, the food that I/we bought just didn't last, and I/we didn't have money to get more.

- Often True (1)
- Sometimes True (2)
- Never True (3)
- Don't Know (4)

Q18 In the last 12 months, I/We couldn't afford to eat balanced meals.

- Often True (1)
- Sometimes True (2)
- Never True (3)
- Don't know (4)

Q22 In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money for food?

- Yes (1)
- No (2)
- Don't know (3)

Q20 In the last 12 months, were you ever hungry but didn't eat because there wasn't enough money for food?

- Yes (1)
- No (2)
- Don't know (3)

Q21 In the last 12 months, did you or other adults in your household ever cut the size of your meals or skip meals because there wasn't enough money for food?

- Yes (1)
- No (2)
- Don't know (3)

Skip To: End of Block If in the last 12 months, did you or other adults in your household ever cut the size of your meals... = No

Skip To: End of Block If in the last 12 months, did you or other adults in your household ever cut the size of your meals... = Don't know

Q23 How often in the last 12 months did you or other adults in your household ever cut the size of your meals or skip meals because there wasn't enough money for food?

- Almost every month (1)
- Some months but not every month (2)
- Only 1 or 2 months (3)
- Don't know (4)

Q61 During the past month when have you usually gone to bed?

Q62 During the past month how long (in minutes) has it taken you to fall asleep each night?

▼ 5 minutes (2) ... 60 minutes or more (13)

Q63 During the past month, what time have you usually gotten up in the morning?

Q64 The following questions relate to your usual sleep habits during the past month only. Please indicate the most accurate reply for the majority of days and night in the past month.

How many hours of actual sleep did you get at night? (1)

How many hours were you in bed? (2)

Q65

During the past month, how often have you had trouble sleeping because you:

	Not during the past month (1)	Less than once a week (2)	Once or twice a week (3)	Three or more times a week (4)
Cannot get to sleep within 30 minutes (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wake up in the middle of the night or early morning (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have to get up to use the bathroom (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cannot breathe comfortably (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cough or snore loudly (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feel too cold (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feel too hot (8)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have bad dreams (9)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have pain (10)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other reason (11)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q66 During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?

- Not during the past month (1)
- Less than once a week (2)
- Once or twice a week (3)
- Three or more times a week (4)

Q67 During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

- Not during the past month (1)
- Less than once a week (2)
- Once or twice a week (3)
- Three or more times a week (4)

Q68 During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?

- Not during the past month (1)
- Less than once a week (2)
- Once or twice a week (3)
- Three or more times a week (4)

Q69 During the past month, how would you rate your sleep quality overall?

- Very good (1)
- Fairly good (2)
- Fairly bad (3)
- Very bad (4)

Q20 During the last 12 months, how often did you usually have any kind of drink containing alcohol? **By a drink we mean half an ounce of absolute alcohol (e.g. a 12oz can or glass of beer or cooler, a 5oz glass of wine, or a drink containing 1 shot of liquor).** Choose only one.

- Every day (1)
- 5 to 6 times a week (2)
- 3 to 4 times a week (3)
- Twice a week (4)
- Once a week (5)
- 2 to 3 times a month (6)
- Once a month (7)
- 3 to 11 times in the past year (8)
- 1 or 2 times in the past year (9)
- I did not drink any alcohol in the past year, but I did drink in the past (10)
- I have never drank any alcohol in my life (11)

*Skip To: Q22 If During the last 12 months, how often did you usually have any kind of drink containing alcohol? B...
= I did not drink any alcohol in the past year, but I did drink in the past*

*Skip To: Q24 If During the last 12 months, how often did you usually have any kind of drink containing alcohol? B...
= I have never drank any alcohol in my life*

Q26 During the last 12 months, how many alcoholic drinks did you have on a typical day when you drank alcohol?

- 25 or more drinks (1)
- 19 to 24 drinks (2)
- 16 to 18 drinks (3)
- 12 to 15 drinks (4)
- 9 to 11 drinks (5)
- 7 to 8 drinks (6)
- 5 to 6 drinks (7)
- 3 to 4 drinks (8)
- 2 drinks (9)
- 1 drink (10)

Q28 During the last 12 months, what is the largest number of drinks containing alcohol that you drank within a 24-hour period?

- 36 drinks or more (1)
- 24 to 35 drinks (2)
- 18 to 23 drinks (3)
- 12 to 17 drinks (4)
- 8 to 11 drinks (5)
- 5 to 7 drinks (6)
- 4 drinks (7)
- 3 drinks (8)

2 drinks (9)

1 drink (10)

Q30 During the last 12 months, how often did you drink this largest number of drinks? Choose only one.

Every day (1)

5 to 6 times a week (2)

3 to 4 times a week (3)

Twice a week (4)

Once a week (5)

2 to 3 times a month (6)

Once a month (7)

3 to 11 times in the past year (8)

1 or 2 times in the past year (9)

Q32 During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks containing any kind of alcohol within a two-hour period? (That would be the

equivalent of at least 5 (4) 12oz cans or bottles of beer, 5 (4) 5oz glasses of wine, 5 (4) drinks each containing once shot of liquor or spirits.) Choose only one response.

- Every day (1)
- 5 to 6 days a week (2)
- 3 to 4 days a week (3)
- Two days a week (4)
- One day a week (5)
- 2 to 3 days a month (6)
- One day a month (7)
- 3 to 11 days in the past year (8)
- 1 or 2 days in the past year (9)

Skip To: End of Block If During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks... = Every day

Skip To: End of Block If During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks... = 5 to 6 days a week

Skip To: End of Block If During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks... = 3 to 4 days a week

Skip To: End of Block If During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks... = Two days a week

Skip To: End of Block If During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks... = One day a week

Skip To: End of Block If During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks... = 2 to 3 days a month

Skip To: End of Block If During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks... = One day a month

Skip To: End of Block If During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks... = 3 to 11 days in the past year

Skip To: End of Block If During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks... = 1 or 2 days in the past year

Q24 So you have never had a drink containing alcohol in your entire life.

- Correct, I have never drank (1)
- No, I did drink (2)

Skip To: Q22 If So you have never had a drink containing alcohol in your entire life. = No, I did drink

Skip To: End of Block If So you have never had a drink containing alcohol in your entire life. = Correct, I have never drank

Q22 During your lifetime, what is the maximum number of drinks containing alcohol that you drank within a 24-hour period?

- 36 drinks or more (1)
- 24 to 35 drinks (2)
- 18 to 23 drinks (3)
- 12 to 17 drinks (4)
- 8 to 11 drinks (5)
- 5 to 7 drinks (6)
- 4 drinks (7)
- 3 drinks (8)
- 2 drinks (9)
- 1 drink (10)

Q29 During the past 6 months, have you had times when you eat continuously during the day or parts of the day without planning what and how much you would eat?

- Yes (1)
- No (2)

Skip To: Q27 If During the past 6 months, have you had times when you eat continuously during the day or parts of... = Yes

Q27 Did you experience a loss of control, that is, you felt like you could not control your eating?

Yes (1)

No (2)

Q39 In the past 3 months, have you had any episodes of binge eating?

Yes (1)

Maybe (2)

No (3)

Q38 During the past 3 months, how often did you keep eating a meal even though you were not hungry anymore?

Never (1)

Rarely (one per month or less) (2)

Occasionally (once per week) (3)

Most of the time (multiple times per week) (4)

Q31 In the past 3 months, how often did you keep eating a meal even though you felt full?

Never (1)

Rarely (once per month or less) (2)

Occasionally (once per week or more) (3)

Most of the time (multiple times per week) (4)

Q33 During the past 3 months, how much of your daily food intake did you consume after suppertime?

0 (none) (1)

1-25% (up to a quarter) (2)

26-50% (about half) (3)

51-75% (more than half) (4)

76-100% (almost all) (5)

Q35 During the past 3 months, how often did you get up (at least once) in the middle of the night other than [having] to use the bathroom?

- Never (1)
- Less than once a week (2)
- About once a week (3)
- More than once a week (4)
- Every night (5)

Q37 During the past 3 months, how often would you have a snack in the middle of the night?

- Never (1)
- Sometimes (2)
- About half the time (3)
- Usually (4)
- Always (5)

Q41 Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past week, including today.

Not at all (1) Mildly, but it didn't bother me much (2) Moderately- it wasn't pleasant at times (3) Severely- it bothered me a lot (4)

Numbness or Tingling (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling hot (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wobbliness in legs (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Unable to Relax (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fear of worst happening (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dizzy or lightheaded (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Heart pounding/racing (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Unsteady (8)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Terrified or afraid (9)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nervous (10)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling of choking (11)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Hands trembling (12)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Shaky/unsteady (13)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fear of losing control (14)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulty in breathing (15)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fear of dying (16)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Scared (17)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Indigestion (18)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Faint/lightheaded (19)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Face flushed (20)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hot/cold sweats (21)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q43 Below is a list of ways you might have felt or behaved. Please indicate how often you have felt this way during the last week.

	Rarely or none of the time (less than 1 day) (1)	Some or a little of the time (1-2 days) (2)	Occasionally or a moderate amount of time (3-4 days) (3)	All of the time (5-7 days) (4)
I was bothered by things that usually don't bother me. (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I had trouble keeping my mind on what I was doing. (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt depressed. (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt that everything I did was an effort. (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt hopeful about the future. (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt fearful. (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My sleep was restless. (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I was happy. (8)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt lonely. (9)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I could not "get going." (10)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q45 I have high self-esteem

- Strongly Agree (1)
- Agree (2)
- Neutral (3)
- Disagree (4)
- Strongly disagree (5)

Q47 Below is a series of statements. Indicate how often they are true of you by choosing the option that best describes you.

Never true (1)

Occasionally true (2)

Mostly true (3)

Always true (4)

I have difficulty remaining seated at school or at home during dinner. (1)

I get very fidgety after a few minutes if I am supposed to sit still. (2)

I have difficulty keeping attention on tasks. (3)

I get into arguments when people disagree with me. (4)

Little things or distractions throw me off. (5)

I can't seem to stop moving. (6)

Most of the time I don't pay attention to what I am doing. (7)

I get bored easily. (8)

I am easily distracted. (9)

I spend money without thinking about it first. (10)

Q49 Below is a series of statements. Indicate how often they are true of you by choosing the option that best describes you.

	Never true (1)	Occasionally true (2)	Mostly true (3)	Always true (4)
I develop a plan for all my important goals. (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I put my plans into action. (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think about the future consequences of my actions. (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Once I have a goal I make a plan to reach it. (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
As soon as I see things are not working, I do something about it. (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I consider what will happen before I make a plan. (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think about my mistakes to make sure they don't happen again. (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I spend time thinking about how to reach my goals. (8)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Failure at a task or in school makes me work harder. (9)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I stick to a task until it is finished. (10)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q51 Below is a series of statements. Indicate how often they are true of you by choosing the option that best describes you.

	Never True (1)	Occasionally True (2)	Mostly True (3)	Always True (4)
I have trouble controlling my temper. (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I lose sleep because I worry. (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
When I am angry I lose control over my actions. (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I get so frustrated that I often feel like a "bomb ready to explode." (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I "fly off the handle" for no good reason. (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There are days when I'm "on edge" all the time. (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I easily become emotionally upset when I am tired. (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Often I am afraid I will lose control of my feelings. (8)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I slam doors when I am mad. (9)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My mood goes up and down without reason. (10)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q52 The questions in this scale ask you about your feelings and thoughts during the last week. In each case, you will be asked to indicate how often you felt or thought a certain way.

Never (1)

Almost Never (2)

Sometimes (3)

Fairly Often (4)

Very Often (5)

How often have you been upset because of something that happened unexpectedly? (1)

How often have you felt that you were unable to control the important things in your life? (2)

How often have you felt nervous and "stressed"? (3)

How often have you felt confident about your ability to handle your personal problems? (4)

How often have you felt that things were going your way? (5)

How often have you found that you could not cope with all the things that you had to do? (6)

How often have you been able to control irritations in your life? (7)

How often have you felt that you were on top of things? (8)

How often have you been angered because of things that were outside of your control? (9)

How often have you felt difficulties were piling up so high that you could not overcome them? (10)

Q54 Would you say that in general your health is

- Excellent (1)
- Very good (2)
- Good (3)
- Fair (4)
- Poor (5)
- Don't know/Not sure (6)

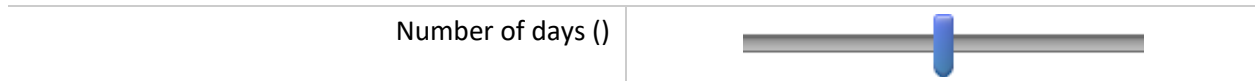
Q56 Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?

0 3 6 9 12 15 18 21 24 27 30



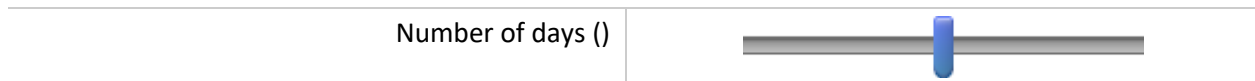
Q58 Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?

0 3 6 9 12 15 18 21 24 27 30



Q60 During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?

0 3 6 9 12 15 18 21 24 27 30



Q62 Are you LIMITED in any way in any activities because of any impairment or health problem?

- Yes (1)
- No (2)
- Don't know/Not sure (3)

*Skip To: End of Block If Are you LIMITED in any way in any activities because of any impairment or health problem?
= No*

Q64 For HOW LONG have your activities been limited because of your major impairment or health problem?

- Days (1)
- Weeks (2)
- Months (3)
- Years (4)
- Don't know/not sure (5)

Q66 Because of any impairment or health problem, do you need the help of other persons with your PERSONAL CARE needs, such as eating, bathing, dressing, or getting around the house?

- Yes (1)
- No (2)
- Don't know/not sure (3)

Q68 Because of any impairment or health problem, do you need the help of other persons in handling your ROUTINE needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes?

- Yes (1)
- No (2)
- Don't know/not sure (3)

Q70 Over the last week, how true are the following statements:

Never true (1) Rarely true (2) Occasionally true (3) Often true (4) Always true (5)

Because of my weight, I have trouble picking up objects. (1)

Because of my weight, I have trouble tying my shoes. (2)

Because of my weight, I have difficulty getting up from chairs. (3)

Because of my weight, I have trouble using stairs. (4)

Because of my weight, I have difficulty putting on or taking off my clothing. (5)

Because of my weight, I have trouble with mobility. (6)

Because of my weight, I have trouble crossing my legs. (7)

I feel short of
breath with
only mild
exertion. (8)

I am troubled
by painful or
stiff joints. (9)

My ankles and
lower legs are
swollen at the
end of the day.
(10)

I am worried
about my
health. (11)

Q72 Over the last week, how true are the following statements:

Never true (1)

Rarely true (2)

Occasionally true (3)

Often true (4)

Always true (5)

Because of my weight, I am self-conscious. (1)

Because of my weight, my self-esteem is not what it could be. (2)

Because of my weight, I feel unsure of myself. (3)

Because of my weight, I don't like myself. (4)

Because of my weight, I am afraid of being rejected. (5)

Because of my weight, I avoid looking in mirrors or seeing myself in photographs. (6)

Because of my weight, I am embarrassed to be seen in public places. (7)

Because of my weight, I do not enjoy sexual activity. (8)

Because of my weight, I have little or no sexual desire. (9)

Because of my weight, I have difficulty with sexual performance. (10)

Because of my weight, I avoid sexual encounters whenever possible. (11)

Q74 Over the last week, how true are the following statements:

Never true (1) Rarely true (2) Occasionally true (3) Usually true (4) Always true (5)

Because of my weight, I worry about fitting into seats in public places (e.g., theaters, restaurants, cars, airplanes). (1)

Because of my weight, I worry about fitting through aisles or turnstiles. (2)

Because of my weight, I worry about finding chairs that are strong enough to hold my weight. (3)

Because of my weight, I experience ridicule, teasing, or unwanted attention. (4)

Because of my weight, I experience discrimination by others. (5)

Because of my weight, I have trouble getting things accomplished or meeting my responsibilities. (6)

Because of my weight, I am less productive than I could be. (7)

Because of my weight, I don't receive appropriate raises, promotions, or recognition at work. (8)

Because of my weight, I am afraid to go on job interviews (9)

Q76 Over the past **FOUR WEEKS:**

	Never (1)	Rarely (2)	Sometimes (3)	Often (4)	Very Often (5)	Always (6)
Has feeling bored made you worry or agonize about your shape? (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have you thought that your thighs, hips or bottom are too large for the rest of you? (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have you felt so bad about your shape that you have cried? (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have you avoided running because your flesh might wobble? (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Has being with thin people made you feel self-conscious about your shape? (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Have you worried about your thighs spreading out when sitting down? (6)

Has eating sweets, cakes, or other high calorie food made you feel fat? (7)

Has worry about your shape made you feel you ought to exercise? (8)

Q78 During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?

▼ 0 (1) ... 7 (8)

Q80 How much time did you usually spend doing vigorous physical activities on one of those days?

Hours per day (1) _____

Minutes per day (2) _____

Q82 During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

▼ 0 (1) ... 7 (8)

Q84 How much time did you usually spend doing moderate physical activities on one of those days?

Hours per day (1) _____

Minutes per day (2) _____

Q86 During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

▼ 0 (1) ... 7 (8)

Q88 How much time did you usually spend walking on one of those days?

Hours per day (1) _____

Minutes per day (2) _____

Q90 During the last 7 days, how much time did you spend sitting on a week day?

Hours per day (1) _____

Minutes per day (2) _____

IRB Approval Letter



To: Jennifer Nicole Becnel
HOEC 210

From: Douglas James Adams, Chair
IRB Committee

Date: 04/24/2018

Action: **Expedited Approval**

Action Date: 04/24/2018

Protocol #: 1709073942

Study Title: Effects of Multivitamin-Mineral Supplementation on Psychological and Physical Health in Young Adults with Excess Weight and of Healthy Weight

Expiration Date: 04/10/2019

Last Approval Date:

The above-referenced protocol has been approved following expedited review by the IRB Committee that oversees research with human subjects.

If the research involves collaboration with another institution then the research cannot commence until the Committee receives written notification of approval from the collaborating institution's IRB.

It is the Principal Investigator's responsibility to obtain review and continued approval before the expiration date.

Protocols are approved for a maximum period of one year. You may not continue any research activity beyond the expiration date without Committee approval. Please submit continuation requests early enough to allow sufficient time for review. Failure to receive approval for continuation before the expiration date will result in the automatic suspension of the approval of this protocol. Information collected following suspension is unapproved research and cannot be reported or published as research data. If you do not wish continued approval, please notify the Committee of the study closure.

Adverse Events: Any serious or unexpected adverse event must be reported to the IRB Committee within 48 hours. All other adverse events should be reported within 10 working days.

Amendments: If you wish to change any aspect of this study, such as the procedures, the consent forms, study personnel, or number of participants, please submit an amendment to the IRB. All changes must be approved by the IRB Committee before they can be initiated.

You must maintain a research file for at least 3 years after completion of the study. This file should include all correspondence with the IRB Committee, original signed consent forms, and study data.

cc: Sabrina Trudo, Investigator
Ryan W Grant, Key Personnel
Natalie Miller, Key Personnel
Taylor Michelle Peabody, Key Personnel
Ya-Hsuan Chang, Key Personnel

To Whom It May Concern:

Sarah Ann Pendergraft completed the necessary training to work on Protocol# 1709073942R001, Effects of Multivitamin-Mineral Supplementation on Psychological and Physical Health in Young Adults with Excess Weight and of Healthy Weight.

Sincerely,
Jennifer Becnel, PhD
Primary Investigator