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Efficacy of Multivitamin-Mineral Supplementation on Measures of Anxiety, Depression, Self-Esteem, Dysregulation, and Perceived Stress in Young Adults

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Efficacy of Multivitamin-Mineral Supplementation on Measures of Anxiety, Depression, Self-Esteem, Dysregulation, and Perceived Stress in Young Adults

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Abstract

Mental health in the United States is at an all-time low with 21% of adults 18+ suffering from depression or anxiety. When compared with other categories, emerging adults (18-25 years old) have the highest prevalence of mental health disorders at 30%. Young adults face an inordinate amount of stress given the COVID-19 pandemic, being in a unique developmental stage, experiencing new relationships, and transitioning from high school to their professional lives. Vitamins and minerals have roles in neurobiochemistry and have been investigated for effects on mental health with mixed results. Few studies factor in the unique emerging adult developmental stage or the potential influence of excessive body weight, which is associated with poor psychosocial measures. The purpose of this project is to investigate whether multivitamin-mineral (MVM) supplementation lowers measures of negative psychosocial functioning. To explore this, a randomized, placebo-controlled trial was done to compare the effects of MVM supplementation on mental health measures to those with no supplementation. One hundred and thirty-six young adults recruited by body mass index (BMI) completed the study after being randomly assigned to take a MVM supplement or placebo for 30 days. Participants completed the Beck Anxiety Inventory (BAI), the Center for Epidemiologic Studies Depression Scale (CES-D), the Single Item for Self-Esteem (SISE), the Abbreviated Dysregulation Inventory (ADI), and the Perceived Stress Scale (PSS) at baseline and again at the completion of the study. Data was analyzed using Independent Samples T-Test of change scores to determine if MVM supplementation improved psychological function in young adults compared with placebo, and whether the effect was more likely in those with overweight/obese BMI. Mean change score for the BAI (anxiety) was 5.42 (SD = 8.05) for the MVM group versus 2.05 (SD=6.79) for the placebo group, indicating that the MVM improved scores more so than

placebo ($P = 0.003$). MVM supplementation did not have an effect on measures of depression, dysregulation, self-esteem, or perceived stress. Likewise, there was no difference in response based on BMI. MVM supplementation may be a simple, practical, and cost-effective strategy to lower symptoms of anxiety in young adults.

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Introduction

Mental health issues like depression and anxiety are common in the United States with approximately 1 in 5 adults 18 and older suffering from an array of mental health problems [1]. These disorders lend to higher perceived stress, lower self-esteem, dysregulation, and an overall diminished quality of life [2]. Micronutrients are vitamins and minerals needed by all people in relatively small amounts, and are vital to normal development. They support the body in carrying out biological processes and contribute to overall well-being. Also, low biochemical levels of micronutrients are associated with poor cognitive function and mood [3]. This may be due to the various physical conditions and ailments that can develop without proper micronutrition which can drastically affect feelings of well-being. Even mild micronutrient deficiencies can result in a reduced feeling of well-being, overall fatigue, impaired memory, and reduced mood as the body does not have the building blocks for optimal functioning [4]. Aside from Vitamin D, the body cannot produce vitamins and minerals endogenously, so they must come from the diet. To support optimal health, many governments have developed recommended intakes of each micronutrient, but even with this guidance, many people are not meeting the minimum levels. The World Health Organization (WHO) estimates that over 2 billion people suffer from micronutrient deficiencies worldwide [5].

A group that is at risk of deficiency includes young adults (age 18-25), especially those that are overweight/obese [6]. Young adults are in a distinct developmental period referred to as emerging adulthood, however in research studies they are most often grouped with all adults despite being in a distinct developmental period and having very different challenges and lifestyles. Overweight/obesity adds an extra layer of complexity as this group is more likely to have a deficient micronutrient status [7].

The primary aim of the present study was to evaluate whether multivitamin-mineral (MVM) supplementation would improve symptoms of anxiety, depression, perceived stress, dysregulation, and low self-esteem in young adults. In addition, these measures were compared between normal weight and overweight/obese individuals to determine if weight had an effect on psychological outcomes.

Review of Literature

Mental Health in the United States

The United States is facing a national mental health crisis [8]. Twenty one percent of the US adult population, or 1 out of every 5 adults, live with a mental health disorder like depression or anxiety [1]. Symptoms of anxiety and depression and related challenges of low self-esteem, emotional dysregulation, and perceived stress are connected with higher productivity loss and more trouble in relationships [9,10]. Action should be taken to lower the strain of mental illness. Accessible, cost-effective solutions need to be proposed so that Americans can feel better and experience psychological well-being.

Micronutrients

Several vitamins and minerals are thought to contribute to psychological well-being. Some vitamins have been specifically identified for their contribution to brain and mental health. B-vitamins, which include Vitamin B12, B6, thiamin (B1), riboflavin (B2), niacin (B3), pantothenic acid (B5), biotin (B7), and folate (B9) are important in energy metabolism and a lack can slow energy and affect psychological measures [11]. A deficiency of these vitamins has been linked to neurotoxic levels of the amino acid homocysteine, the accumulation of which can

affect mood [12]. B-vitamins supplementation can decrease homocysteine levels, which has the potential to alleviate symptoms of depression and other mood related measures [13,14].

Vitamin C is another vitamin of interest, as moderate deficiencies can decrease dopamine levels, resulting in symptoms like depression, anxiety, fatigue, irritability, and mood changes [15]. Vitamin C and other antioxidant vitamins (A and E) can also offer protection against oxidative stress. Oxidative stress is caused when there are more free radicals than antioxidants in the body. Antioxidants have the ability to neutralize free radicals. When there are more free radicals than available antioxidants, brain functioning and neuronal signaling are negatively affected, creating pathways for depression and anxiety. Antioxidant supplementation can neutralize oxidative stress, thus having the potential to reduce levels of depression and anxiety [16].

Minerals such as selenium, zinc, calcium, and magnesium have been tied to improving psychological states. Selenium has been shown to improve symptoms of depression and anxiety [13]. Zinc is an important mineral in immunity and wound healing, the lack of which has been connected to depression [17]. Magnesium is an essential mineral in nerve transmission and neuromuscular conduction. Data strongly supports its use in alleviating symptoms of depression and emerging data suggests it may have a protective effect on anxiety [18].

Because nutrients do not function in isolation, it is important to consider the benefits of a multivitamin-mineral supplement rather than just an isolated vitamin or mineral. Those with a deficiency in one vitamin or mineral are likely deficient in others as well and could benefit from a well-rounded supplement.

Micronutrient Supplementation and Effects on Anxiety and Depression

Several randomized placebo-controlled trials have shown promising results in MVM supplements and their effects on anxiety. In a 28-day study with 80 men who were given either a MVM supplement or placebo, there was a reduction in symptoms of anxiety [17]. In another study with 300 men and women aged 20-50, significant improvements in anxiety were evident after 30 days of treatment [19]. In a meta-analysis, 2 out of 4 studies showed decreased anxiety measures in subjects who took MVM supplements. When pooling all the participants across the studies, the summated effect showed an improvement in subclinical measures of anxiety [13]. In another study of 65 men and women (45-64 years old) following a gluten-free dietary pattern, those with higher scores of anxiety and depression at baseline had lower scores after 6 months of MVM supplementation [20].

Similar positive results were seen in studies focusing on depression outcomes. In a study of 60 people receiving either a MVM supplement or placebo for 12 weeks, there was a reduction in depressed/dejected mood [21]. Another study of 114 healthy college students reported that, after 6 months of MVM supplementation, they responded with reduced symptoms of depression [11]. However, the placebo group also reported reduced symptoms as well, likely attributed to response expectancy.

While there is evidence of improvement in depression and anxiety by taking MVM supplements, there are also studies that show no effect. An 8-week trial with 50 women aged 25-45 showed no improvement in psychological state after a MVM treatment [22]. A meta-analysis of 3 trials focusing on MVM supplementation and depression reported no effect when pooling the data together [13]. In another meta-analysis of 9 different studies on depression outcomes, none showed any benefit [23]. In a systematic review on anxiety outcomes, 6 out of 10 studies

showed no benefits. Of the positive studies, two showed an overall reduction in anxiety, while one showed positive results in a subgroup of participants with poor anxiety status at baseline and another only showed positive results in males [23].

Micronutrient Supplementation and Effects on Perceived Stress, Dysregulation, and Self-Esteem

Perhaps the most promising benefit from MVM supplementation is its effect on perceived stress. A number of studies have shown decreased stress ratings following a period of supplementation with multivitamin-minerals. In a 28-day study of 80 men, there was a reduction in perceived stress [17]. A 33-day study of 215 men aged 30-55 also reported improvement in perceived stress scores [24]. In a trial with older men aged 50-69, participants lowered their stress after 8 weeks of receiving supplementation [25]. In a trial with 173 younger men with a mean age of 20.9 years old, perceived stress was lowered after 12 weeks on a MVM supplement [26]. A study of 59 18–65-year-olds showed an improvement in symptoms of perceived stress after 12 weeks [27]. Another longer study with 108 people ranging in ages from 30-70 showed a reduction in perceived stress after 6 months. Interestingly, the placebo group also showed a reduction in perceived stress, demonstrating the influence of the placebo effect [28].

While the literature suggests regular multivitamin-mineral supplementation has positive effects on reducing perceived stress, it is worth noting that not all studies showed benefits. In a systematic review, 4 out of 10 studies did not show any decrease in perceived stress after supplementation [23]. In a meta-analysis, 3 of 8 studies also did not report a reduction in stress [13]. Heterogeneity across studies including different MVM formulations, populations, and methodologies can contribute to the differing results.

To my knowledge, there are no published studies of MVM supplementation and its effect on dysregulation or self-esteem. However, dysregulation and low self-esteem are closely tied to anxiety and depression, which have been studied [2]. Dysregulation refers to the poor ability to manage emotional responses. In dysregulated people, emotions are overly intense in comparison to the situation that triggered them. The result is impulsive, out of control behavior. Self-esteem is the judgement that individuals make about their own self-worth. Low self-esteem is a precursor to depression in young adults and is a risk factor for depressive symptoms throughout all stages of adult life [29]. Because even small micronutrient deficiencies can alter brain biochemistry, mood changes can result from unbalanced diets. It stands to reason that balancing biochemical levels in the brain can regulate mood, emotions, and improve self-esteem.

Limitations to Existing Research

Although there is some evidence suggesting micronutrient supplementation may be a means to decrease risk of anxiety, depression, dysregulation, low self-esteem, and perceived stress, there are key limitations in how most of the studies were designed. These limitations include not factoring in the unique developmental stage of emerging adulthood, the potential influencing effect of excess body weight, and the use of supplements that contain constituents other than vitamins and minerals. Those in the developmental stage of emerging adulthood and/or having excess body weight may be at higher risk for symptoms of psychological issues as discussed in detail below. The use of a supplement that includes non-nutrient constituents as a study treatment hinders the ability to study the effects specific to vitamins and minerals as also discussed in detail below.

Influence of Emerging Adulthood. Young adulthood (age 18-25) is a unique and often overlooked developmental period. It is a transitionary period bridging life as a teenager to one of independence, making major life decisions, and beginning their professional careers [30]. Their life stage and experience present specific challenges on both their physical and emotional health. Young adults must learn to manage finances, with limited life and work experience. If in college, they manage frequent deadlines, pressures of testing and making good grades, while balancing a social life. This time of life is characterized by change and exploration of possible life directions [30]. Rates of anxiety and depression among young adults have always been higher than other age categories, but they have skyrocketed during the Covid-19 pandemic [2]. Adding to regular hardships are the added side effects of the pandemic: loneliness, job insecurity, social distancing, cancelled events, and changing regulations. Data from a June 2020 CDC survey reported that 63% of young adults identify with an anxiety or depressive disorder. On top of that, a staggering 1 in 4 admitted to seriously considering suicide in the past 30 days [2]. Compared with other age groups, young adults have the highest levels of perceived stress [8]. On average, young adults rate their stress in the last month as 6.1 out of 10, compared with other groups who rate it as 5.6/10 (24–41-years old), 5.2/10 (42–55-years old), 4/10 (56–74-years old), and 3.3/10 (ages 75+). With a large proportion of young adults being college students, almost all of them (87%) report education as a significant source of stress. Moreover, 82% feel stressed and uncertain about what the year will look like, and 67% feel that planning for their future is impossible. Depression is affecting large majorities of young adults with about 7 in 10 reporting they feel restless, find it hard to think properly or concentrate, feel lonely, or miserable and unhappy.

Given such heavy pressures and mood disturbances, young adults need added resources to cope. They are known for eating rushed meals, having sporadic eating patterns, and

unhealthy food choices [4]. Excess alcohol and/or caffeine consumption can take the place of nutrient dense food and also decrease micronutrient absorption [31]. Financial and time restraints can prevent access to healthy, well-balanced meals. High stress, anxiety, and depression can trigger high-sugar/high-fat cravings with little to no nutritive value [32]. These feelings combined with societal pressure to be thin breed eating disorders like anorexia and bulimia, which are common in this age group [33].

Influence on Overweight/Obesity. Overweight is defined by the World Health Organization as having a body mass index (BMI) between 25-30 kg/m^2 and obese as over 30 kg/m^2. The prevalence of overweight/obesity in America is growing rapidly. In 1962, 13.4% of the adult population in the United States was obese with 31.5% being overweight. Contrast that with the latest numbers in 2018, 42.5% of American adults were obese with 73.6% being overweight [34]. Aside from increased mortality, obesity increases the risk for diseases like diabetes, cardiovascular disease, hypertension, and sleep apnea. There are also many psychological effects. Overweight/obesity is associated with higher rates and risks of developing anxiety and depression [35,36]. People with higher BMIs more often battle social stigmatization, body image issues, and related self-esteem issues. In many cases obese people struggle with binge eating that contributes to excess psychological stress [37].

Whether or not the micronutrient deficiencies contribute to the obesity or the obesity causes the deficiencies is under debate [38]. Overweight/obese persons may be deficient in vitamins/minerals because of their diet, which is typically low in fruits and vegetables [39]. Deficiencies can also be caused by a change in the way micronutrients are metabolized and stored in adipose tissue [7]. Several studies show that the concentrations of serum antioxidants

are inversely related to BMI; as BMI increases, antioxidant levels decrease. This could be the result of the body spending more antioxidants to combat the higher oxidative stress found in overweight/obese individuals [6]. A lack of B-vitamins can cause a buildup of homocysteine, which has been linked to depression [12]. B-vitamins can improve symptoms of depression and perceived stress by lowering homocysteine levels [13]. Homocysteine levels have been shown to be significantly elevated in obese subjects [40]. Besides potential B-vitamin deficiencies, overweight/obese people are at higher risk for many micronutrient deficiencies in comparison with those of normal weight [41].

Influence of Supplement Composition. A third major limitation in comparing studies of MVM supplementation is the differing composition of supplements. Many studies included supplements that contained caffeine or herbal extracts, which have the potential to confound the results. For example, caffeine is a well-known stimulant. St John's wort is a popular herbal remedy in several European countries with some evidence of efficacy for improving mild to moderate depression [42]. At least 110 additional medicinal plants are under investigation for anti-depressive effects [43]. Many MVM supplements studied for effects on psychological measures included herbal/medicinal plant extracts along with the vitamins and minerals, making it less clear whether any potential effect was from the herb or the micronutrient combination. Also, different supplements with varying amounts of vitamins and minerals were used across studies, thus making it difficult to generalize the results. Of note, J. Harris et al. said the current formulation of the Berocca supplement is "the most widely studied multivitamin/mineral to date, with the evidence suggesting beneficial effects on cognitive performance and potential increase in physical energy levels" [3]. However, this particular supplement was only used in a handful of

studies. Questions to ask when considering which supplement to use may include: What are the active ingredients in the supplement? What is the optimal dose? Does baseline micronutrient status contribute to the efficacy of the supplementation? Do different individuals need different formulations?

Summary and Objectives

Micronutrients are vital to both physical and mental health. MVM supplements can cover gaps in diet and nutrition to prevent deficiencies and ensure adequate health. There is ample evidence supporting high B-vitamin MVM supplementation improving measures of perceived stress. There is some evidence to support MVM supplementation to lessen symptoms of depression and anxiety. The mixed results may be due to differences in the experimental protocols, including different tests to measure outcomes, supplements with varying formulations, and different length and timing of supplementation. There is no published data on MVM supplementation and dysregulation or self-esteem, despite their close connection to anxiety and depression.

While several studies discuss the benefits of MVM supplementation on mood measures, most include a broader age range than 18-25. This younger group may be at higher risk for micronutrient deficiencies and due to their higher levels of stress, anxiety, depression, and psychological distress, may benefit more from supplementation. They are also at an opportune time to enact behavioral changes to increase life-long health and vitality. A subgroup at even more nutritional risk within the category of young adults are those who are overweight/obese. MVM supplementation is a low-cost intervention and may be a simple way to bridge micronutrient deficiencies and improve negative mood markers.

To address the above limitations, the current study proposes to address young adults aged 18-25. Young adults are at a stage of life where they have the ability to make choices and create habits that will affect them lifelong. We will use a MVM supplement without added caffeine or herbal extracts that is modeled after the Bayer produced, Berroca supplement, which has had positive results in several studies [17,24,44]. It is formulated with higher B vitamins, vitamin C, calcium, magnesium, and zinc. We will determine treatment effects over 30 days based on what has been done in other studies with positive results [17,19,24]. We will assess the efficacy of this supplement on measures of depression, anxiety, perceived stress, dysregulation, and low self-esteem in young adults. We will also compare whether there is a difference in effects between those with normal BMI and those with overweight/obese BMI. We hypothesize that, after 30 days on the MVM supplement, mood measures will be improved and the effect will be greater in overweight/obese participants.

Methods

Recruitment/Participants

A total of 136 young adults were recruited from a mid-south public university via flyers on campus, postings in a campus newsletter, and through classroom announcements. To be eligible, participants had to be 18-25 years old, going to school or working part-time; and have no diagnosis of malabsorption or related gastrointestinal diagnoses, nor diagnosis of impaired liver or renal function, nor any mental health diagnoses. They also had to agree to abstain from other supplements during the study. All current supplementation was required to be suspended a week prior to starting the study until after the study was completed. Potential participants were screened on the phone by the study staff who followed scripted prompts to determine eligibility.

Those who qualified were confirmed by learning the details about the study and completing the informed consent process. Once confirmed, the study staff collected information on age, BMI, health indicators, and nutritional status. A total of 136 people were randomized via a random sequence generator and completed the study. This study was approved by the University of Arkansas Institutional Review Board for human subject research (Approval #1709073942).

Randomization and Study Design

For this double-blinded study, participants were randomized using a random sequence generator into two groups. The treatment group took two multivitamin-mineral supplements daily for 30 days. The control group also took two capsules that were placebos with the exact size, texture, and look of the multivitamins. The participants were assessed at the beginning and end of the experiment (Day 0 and Day 30 respectively) via self-administered online questionnaires. The MVM supplement was made specifically for the study by a Collier Compounding Pharmacy, a local compounding pharmacy. The composition of the multivitamin-mineral supplement was matched to the composition of Berroca tablets because the most promising results published in the literature were studies that used this product [3]. They also did not contain herbal extracts or caffeine which could have had their own effects on the endpoints measured. The composition of the MVM supplement is detailed 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

Participants were given a week's worth of supplements and then reported back to the study office each week to return unused pills and receive pills for the upcoming week. Compensation was also given during this check-in for each week completed. Compliance was determined by measuring the unused pills that were returned to the office. Reminders were sent out before pill pick up, to start supplementation, and to complete surveys. Subjects who completed the entire study received $100 distributed incrementally throughout the 30 days as a way to motivate continued compliance.

Questionnaires

Participants filled out an online survey at baseline and Day 30 of the study. The survey was a combination of the following six randomly presented validated assessments that were compiled as a single Qualtrics survey to measure psychological functioning. The Beck Anxiety Inventory (BAI) is a 21-item survey that measures symptoms of anxiety on a Likert scale. A score between 0-7 indicates minimal anxiety, 8-15 mild, 16-25 moderate, and 26-63 severe anxiety. [45]. The Center for Epidemiologic Studies Depression Scale (CES-D) is a 20-item self-

reported measure of characteristic attitudes and symptoms of depression developed by the National Institute of Mental Health. Scores over 16 indicate depression with higher scores indicating more depression symptomology [46]. The Single Item for Self Esteem (SISE) is a single item question that asks participants to rate their self-esteem on a Likert scale. It is a validated test shown to be as reliable as the Rosenberg Self-Esteem Scale [47]. The Abbreviated Dysregulation Inventory (ADI) is a shortened version of the more complete Psychological Dysregulation Inventory. It is a 30-item survey that assesses emotional, cognitive, and behavioral dysregulation [48]. The Perceived Stress Scale (PSS) is the most widely used instrument for measuring the perception of stress with only 10 questions [49]. Subjects were reminded via text and email to complete the assessments within 3 hours of taking the supplement.

Body Mass Index (BMI)

Each subject was weighed and measured by trained study staff to get an accurate BMI on day 0 and day 30. Participants were asked to remove their shoes and anything heavy to obtain the most accurate measurements. Height was measured in centimeters using a stadiometer and converted to meters to be calculated. Weight was taken in kilometers by a portable scale. BMI was then computed online with a BMI calculator [50]. Subject's BMI placed them in a normal weight or overweight/obese group. After all data was collected, a two tailed independent samples t-test was performed on the change scores for each mood measure to test the hypothesis that those with overweight/obese BMIs would see a greater improvement in psychological functioning with MVM supplementation.

Statistical Analyses

First, descriptive statistics were conducted on the full sample. Dependent variables included anxiety, depression, perceived stress, dysregulation, and self-esteem. Higher scores indicated higher anxiety, depression, perceived stress, dysregulation, and lower self-esteem. Next, a change score was calculated for each of the dependent variables by taking the 30-day scores and subtracting them from corresponding baseline scores. An independent t-test was run to detect both main effects as well as interaction effects between the control and intervention group. Further analysis was conducted using change scores and an independent two-tailed t-test for both normal and overweight/obese BMI groups. Because the hypothesis was based on change in only one direction, the two tailed p-value was divided in half and the new p-value <0.05 was considered significant. Levene's test for equality of variances was run on all variables to determine if equal variances could be assumed or not. Effect size was measured by Cohen's d to see the relationship between the variables with $d=0.8$ representing a large effect size, $d=0.5$ a medium effect size, and $d=0.2$ a small effect size. Analyses were conducted using SPSS, v. 27 [51].

Results

Participant Characteristics

The study had a total of 154 participants at baseline. After accounting for non-compliance and dropouts, 136 participants were included for data analysis. Of the 136 participants, 63 received placebo and 73 received the MVM supplement (Table 2). The majority of participants were students, living in an urban area, and employed part-time. The study was made up of 108 females (47 received placebo and 61 received the supplement) and 28 males (16 received

placebo and 12 received the supplement). Student status was similar between groups with the exception of the placebo group having more juniors and the supplement group having more seniors. There was no significant difference between groups in regards to BMI, age, geographic living location, and employment status.

Table 2. Participant characteristics and p-values for comparison of characteristics between placebo and MVM groups.

	Placebo (N=63)	MVM (N=73)	P-value of differences between groups
Gender			0.103
Females	47 (74.6%)	61 (83.6%)	
Males	16 (25.4%)	12 (16.4%)	
BMI			0.363
Normal (18.5-24.9)	33	35	
Overweight/obese (≥25)	30	38	
Age (Average ± SD)	20.89 ± 1.87	20.47 ± 1.68	
Student Status			0.436
Non-Student	2 (3.2%)	1 (1.4%)	
Freshman	8 (12.7%)	10 (13.7%)	
Sophomore	13 (20.6%)	19 (26%)	
Junior	18 (28.6%)	9 (12.3%)	
Senior	13 (20.6%)	25 (34.2%)	
Grad Student	9 (14.3%)	8 (11%)	
Geographic living location			0.140
Rural	5 (7.9%)	10 (13.7%)	
Urban	58 (92.1%)	63 (86.3%)	
Level of Education Completed			0.050
Some high school	0 (0%)	1 (1.4%)	
High school	10 (15.9%)	17 (23.3%)	
Some college	37 (58.7%)	44 (60.3%)	
Associate degree	4 (6.3%)	1 (1.4%)	
Bachelor's degree	11 (17.5%)	10 (13.7%)	
Post-graduate degree	1 (1.6%)	0 (0%)	
Employment Status			0.417
Unemployed	20 (31.7%)	23 (31.5%)	
Part-time	39 (61.9%)	44 (60.3%)	
Full-time	4 (6.3%)	6 (8.2%)	

Change in Psychological Variables

Changes in psychological functioning were analyzed by treatment (placebo or supplement) x time (baseline, post-treatment). Descriptive statistics are presented on mood measures at baseline and 30 days in Table 3. Levene's test for equality of variances passed on all mood measures except for dysregulation so equal variances were not assumed with the ADI change score. This gave a higher p-value for dysregulation. Analyses using an alpha level of 0.05 revealed statistically significant pre-post effects on measures of anxiety, indicating that MVM supplementation reduced anxiety with moderate effect ($t(134) = -2.82$, $p=0.003$, $d=-0.485$). Dysregulation measures also improved with a statistically significant change score, but in favor of the placebo ($t(103)=1.76$, $p=0.041$, $d=0.31$). When comparing change scores for the subcomponents of dysregulation (emotional, cognitive, and behavioral) there was a statistically significant difference for cognitive dysregulation, but in favor of the placebo. There was no improvement in perceived stress ($t(134)=-0.034$, $p=0.49$, $d=-0.006$). There was also no difference between treatment and placebo groups on measures of depression ($t(134)=1.58$, $p=0.058$, $d=0.27$) or self-esteem ($t(134)=0.38$, $p=0.35$, $d=0.065$).

Table 3: Mean (+/- SD) scores of placebo and MVM for psychological measures at baseline and 30 days with change scores and p-value for comparison of change scores between placebo and MVM groups.

Assessment	Group	Sample size (N)	Baseline mean (SD)	Day 30 mean (SD)	Change score mean (SD)	P-value of the change score
Beck Anxiety Inventory	MVM	73	29.78 (8.05)	24.36 (4.87)	5.42 (7.10)	P=0.003
	Placebo	63	27.76 (0.77)	25.71 (0.77)	2.05 (6.79)	
Abbreviated Dysregulation Inventory	MVM	73	63.07 (7.28)	60.07 (6.77)	3.00 (6.16)	P=0.041
	Placebo	63	61.87 (8.42)	56.40 (10.02)	5.48 (9.59)	
Center for Epidemiologic Studies Depression Scale	MVM	73	18.62 (3.35)	16.90 (3.56)	1.73 (3.35)	P=0.058
	Placebo	63	19.05 (3.07)	16.37 (3.83)	2.68 (3.70)	
Single Item for Self-Esteem	MVM	73	2.22 (0.80)	2.05 (0.80)	0.16 (0.58)	P=0.35
	Placebo	63	2.25 (0.90)	2.05 (0.87)	0.21 (0.72)	
Perceived Stress Scale	MVM	73	20.90 (5.14)	20.07 (5.86)	0.84 (7.06)	P=0.49
	Placebo	63	21.19 (5.60)	20.40 (4.62)	0.79 (7.14)	

Effect of BMI

We also determined whether MVM supplementation had a greater effect on measures of psychological functioning in those with excess weight. There was a statistically significant difference in change scores between the placebo and MVM group for depression, however it was in favor of the placebo group ($t(134)=1.99$, $p=0.025$, $d=0.341$). No statistically significant effect was found for dysregulation ($t(134)=0.17$, $p=0.433$, $d=0.029$), perceived stress ($t(134)=-0.47$, $p=0.319$, $d=-0.081$), self-esteem ($t(134)=-0.66$, $p=0.255$, $d=-0.114$), or anxiety ($t(134)=-0.66$, $p=0.256$, $d=-0.113$).

Table 4: Mean (+/- SD) scores of normal and overweight BMI for psychological measures at baseline and 30 days with change scores and p-values for comparisons of change scores between overweight and normal BMI groups.

Assessment	BMI Group	Sample size (N)	Baseline mean (SD)	Day 30 mean (SD)	Change score mean (SD)	P-value of the change score
Beck Anxiety Inventory	Overweight	68	28.74 (8.00)	25.28 (5.47)	3.46 (7.80)	P=0.256
	Normal	68	28.96 (6.48)	24.69 (5.56)	4.26 (6.45)	
Abbreviated Dysregulation Inventory	Overweight	68	62.90 (7.60)	58.63 (8.55)	4.26 (8.59)	P=0.433
	Normal	68	62.13 (8.07)	58.10 (8.70)	4.03 (7.42)	
Center for Epidemiologic Studies Depression Scale	Overweight	68	18.88 (3.30)	16.12 (3.64)	2.76 (3.50)	P=0.025
	Normal	68	18.75 (3.15)	17.18 (3.67)	1.57 (3.50)	
Single Item for Self-Esteem	Overweight	68	2.07 (0.76)	1.93 (0.68)	0.15 (0.63)	P=0.255
	Normal	68	2.40 (0.90)	2.18 (0.95)	0.22 (0.67)	
Perceived Stress Scale	Overweight	68	20.88 (4.90)	20.35 (5.75)	0.53 (7.17)	P=0.319
	Normal	68	21.19 (5.78)	20.09 (4.86)	1.10 (7.01)	

Discussion

Anxiety

Taking a MVM supplement for 30 days decreased anxiety in young adults in this study. Previous studies on multivitamin-mineral supplementation and anxiety showed mixed results with some studies reporting an effect [13,17,20] and others showing no difference [21,23]. Part of the discrepancy in results may be due to heterogeneity between studies. For one, studies used different formulations of multivitamins and minerals in their supplements. Our study used a formulation that contained high B-vitamins that has been shown to have greater effect [13]. Sample sizes and target populations also varied widely from 50 older men [25] to 216 women aged 25-50 [14]. No other study focused solely on young adults ages 18-25. Another reason for the mixed results could be the difference in instruments used to measure anxiety. Out of 8 studies, ours is the only one that used the Beck Anxiety Inventory (BAI) [13]. Other inventories used included the Hospital Anxiety and Depression Scale (HADS), the Hamilton Anxiety Rating Scale (HAM-A), the Depression Anxiety Stress Scale (DASS), the General Health Questionnaire-28 (GHQ-28), and the Visual Analog Scale (VAS). The BAI's focus on somatic symptomology allows it to better differentiate anxiety from depression. The other scales directly (HADS) [52] or indirectly (HAM-A) [53] measure both anxiety and depression. Other scales also additionally measure perceived stress (DASS) [54], insomnia, and social dysfunction (GHQ-28) [55]. Another commonly used survey was the VAS, which measures subjective mood at the present moment and not retroactively like the other Likert scales [25]. This method of testing would primarily reveal acute effects of supplementation. However, studies with check-in protocols that require an overnight fast and abstinence from MVM supplementation when testing

would not benefit from the multivitamin-mineral's acute effects [21] and that may be reflected with the VAS.

Another key difference in our study is the number of females compared with the number of males in prior research on anxiety and MVM supplementation. A large majority of previous studies were conducted with male study participants [17,24,25,44] and our research had a large percentage of females. Women tend to have overall more anxiety than males [56], thus MVM supplementation could have a greater effect on them.

Differing methodology can potentially explain some of the negative results in other studies. In one study of 216 females, both the MVM and placebo groups showed an increase in anxiety after 62 days [14]. However, this study was primarily measuring cognitive function and assessing anxiety was secondary. Participants went to a lab for several hours to perform memory tasks, take mood surveys, and get their blood drawn. Wanting to perform well on tests they had previously taken and in an anxiety-provoking environment could explain the increase in anxiety, especially since it was shown in both groups. In another study of 60 men and women with a mean age of 42.2 years old (SD 10.1 years), there was no difference in anxiety between groups after 90 days of MVM supplementation. Besides having an overall small sample size, this study also used two different MVM pills- one was a sustained release pill to allow for slower absorption and the other was regular [21]. The inclusion of a sustained release pill could limit the acute effect subjects may have felt when testing, thus altering the results. The population was also very different- focusing primarily on people employed full-time who deal with chronic, work stress.

Dysregulation and Self-Esteem

MVM supplementation also resulted in lowered levels of dysregulation in young adults for both treatment and placebo groups. However, the placebo group had a lower score than the MVM, indicating that the MVM did not perform better than the placebo. The Abbreviated Dysregulation Inventory was used to measure 3 categories of dysregulation: emotional, cognitive, and behavioral. In a study that investigated gender differences in cognitive, behavioral, and affective dysregulation with 551 participants aged 12-19, male participants presented higher scores in behavioral dysregulation than girls [57]. Because our study contained a large majority of females, dysregulation results may have been skewed more than if a traditional measure of dysregulation was used. Most available instruments to measure dysregulation only focus on the emotional aspect of dysregulation. Another explanation for the results includes the possibility that multivitamin-minerals do not have an effect on dysregulation. In a comparative study on emotional dysregulation between 50 older adults (aged 60-80) and young adults (aged 18-30), the older adults showed less emotion dysregulation suggesting an improved ability with age to cope with emotions [58]. It is possible that young adults need time and life experience to develop healthy self-regulation and it's not something that can be influenced biologically.

There was no difference in regards to self-esteem in young adults. Self-esteem scoring is subjective and can easily change depending on mood. We hypothesized an effect from MVM supplementation as the acute effects from supplementation have been shown to improve mood, which could raise self-esteem ratings. A possible reason for our results could be the single-item test used to measure self-esteem. While proven to be valid, it also has lower test-retest reliability than multi-item measures of global self-esteem like the Rosenberg Self-Esteem scale. The SISE

is more susceptible to extremity and agreement bias because it only has one positively keyed item [59].

Although our study did not connect MVM supplementation with higher self-esteem, it is still an area worth pursuing. Low self-esteem levels are linked with depression, suicidal ideation, loneliness, peer rejection, poor academic performance, and life dissatisfaction [60]. Exploration of supplement timing, length of treatment, and supplement formulation are appropriate subjects for further research.

Perceived Stress and Depression

The lack of a difference between placebo and multivitamin groups on measures of perceived stress did not align with previous research that showed a strong relationship. Several methodological differences between the current study and the majority of previous studies provide some reasons for the discrepancy in results. As mentioned with anxiety measures, the majority of the previous research was done on men, while our study included 79% women. This combined with the unique area of focus on young adults may also contribute to the differing results. Women respond differently to stress than men and are more likely to experience stress in the form of physical symptoms [61]. Moreover, young adults are the most likely group to suffer with stress [2]. Our study contained one of the most stressed cohorts in America. Another major methodological difference is that most of the prior research used supplements containing added herbal extracts. Popular choices were ginkgo biloba and green tea [19,62]. Gingko biloba is a plant extract that has been shown in multiple studies to lower rates of oxidative stress, which contribute to many conditions like depression and anxiety [63]. Oxidative stress has been linked to higher rates of perceived stress [64]. Green tea is made from Camellia sinensis leaves and has

properties that can modulate EEG oscillatory brain activity, which is associated with relaxation and perception of stress [65]. These additions may contribute to the improvements in perceived stress more than vitamins and minerals on their own. Our study intentionally excluded herbal extracts and caffeine to better isolate the potential effects of the vitamins and minerals.

Another difference in results may be due to the inventories used to measure perceived stress. In a study of working adults, one of the primary measures of perceived stress was the Occupational Stress Inventory-Revised (OSI-R) [21]. It specifically measures work-related functioning and stress. Our population was primarily college students, who experience stress, but perhaps in a different way.

Many of the studies showing improvement of perceived stress after MVM treatment include biochemical analysis at pre and post testing to measure compliance and stress biomarkers [17,27,28]. In a study of 80 men mostly students, aged 18-42, levels of perceived stress decreased significantly in the group who received MVM supplementation. The study incorporated resting blood samples to measure zinc status in participants. Zinc levels increased in the treatment group, while perceived stress levels decreased, confirming compliance [17]. Another study with positive results for perceived stress collected blood and saliva samples in 59 people aged 18-65. The saliva collected was used to measure cortisol levels and the blood labs detected over and underconsumption of the supplement [27]. By collecting biological samples from participants, researchers were able to confirm that protocol was followed.

The literature shows mixed results on whether or not MVM supplementation has an effect on depression. Like with studies on supplementation and perceived stress, depression studies also often used multivitamin-mineral supplements that also contained herbal extracts like ginseng or guarana [11,21,25]. Ginseng is a root of plants in the genus Panax. It has the ability to

regulate hormonal changes on the hypothalamic-pituitary-adrenal axis. It also has been proven to suppress the occurrence of psychological diseases like depression and anxiety [66]. Guarana is made from the seeds of the guarana plant and is known for its high caffeine content [67]. Caffeine has been linked with increased well-being, improvement in mood, and a reduction in symptoms of depression [68].

There also is some question of timing as it relates to when mood is measured relative to intake of the supplement. In a study of MVM supplementation on measures of mood, Pipingas et al. instructed subjects not to take the supplement before going to the center for each study visit so that chronic effects of the MVM supplementation could be studied. There was no apparent impact on any mood measures, including perceived stress and depression [62]. However, as a sub-part of their study, they sent home participants with weekly mobile at-home mood assessments and were instructed to take their surveys on multiple occasions after having taken their daily supplement. This allowed them to more closely study the acute effects the supplement had on the participants. Results from these assessments showed that current mood during testing can affect responses. Many of the questions on the surveys asked participants to reflect on their mood in the last week to answer the questions. However, current mood can alter responses and not reflect an accurate portrayal of the prior week. The short-term effects of multivitamin mineral supplements have the potential to improve mental health status as is shown in a study by Schlebusch et al. with several patients who reported feeling better for a few hours after taking one [69]. In our study, participants were instructed to take their one at-home final survey within 3 hours of taking their supplement. Taking the supplement within 3 hours of testing would assure that the acute effects of the MVM could reflect in the survey. However, since this was not

monitored, compliance could not be confirmed, making it difficult to know if the supplement had an effect during testing.

Effect of BMI

Daily MVM supplementation improved ratings of depression at Day 30 for both the treatment and control group in those with an overweight/obese BMI compared with normal BMI. The difference between MVM and placebo groups in mean change score was statistically significant, but it was the placebo group that had the greatest improvement. Hence, MVM was not better than the placebo in lowering depression scores in people with an overweight/obese BMI. No other psychological measures were significantly different between the normal weight and overweight/obese groups. Perhaps the study length or sample size was not long enough to adequately raise micronutrient levels enough to make a difference.

Strengths

This double blinded, randomized control trial had many strengths. Validated, widely accepted instruments were used to measure psychological parameters that influence mood. The study incorporated a wash out period of a week for all participants to stop taking supplements to minimize any carryover effects of habitual practices into the study period. The target study population of young adults is a distinct age group not often studied, but very often struggling with mental health issues [2,30]. This age category is often grouped together with other adults in research, despite being in a very different life and developmental stage. This study focused only on 18–25-year-olds. It also encouraged compliance and participation through weekly check-ins

in person, email reminders, texts, and compensation that was given in stages to promote completion of study protocols.

The supplement itself was modeled on a promising commercial multivitamin-mineral product that has shown positive results in several studies [3]. It did not contain added herbal extracts or caffeine in an effort to isolate the effects of just the vitamins and minerals.

And lastly, this study approach took into account the potential impact that excess body weight may have in response to MVM supplementation. This enabled exploration of whether those with excess weight, as defined by having a BMI in the overweight or obese category, are more likely to respond better than those of normal weight to supplementation in improving measures of psychological functioning. The need for investigation of the potential modifying effect of BMI is warranted given that those with excess weight are at higher risk of poorer psychological functioning and mood as well as higher risk for micronutrient deficiencies.

Limitations

Several important limitations of our study should be noted. Females were overrepresented in the study with 108 of the 136 or 79%, participants being women. Men and women differ with their psychological response to stressful events, with women often experiencing greater rates of depression, anxiety, and stress [61]. With only 12 study participants taking the MVM supplement being male, the results may not be generalizable. The majority of participants were also college students, which excludes young adults not in college. College students experience stresses that are different than young adults who only work or live at home with their parents. Recruiting in places other than on a college campus could improve generalizability.

Another limitation is the lack of biochemical measurements, such as urine or blood to measure compliance or mood-related biomarkers. Compliance was measured by participants returning to the study office with unused pills and study staff recording the number of pills not used. Subjects could have forgotten to take pills or taken extra on one day, but report that they had followed the protocol as instructed and not bring the unused pills to the study office. Also, there was no way to know if subjects were taking other supplements during the study. If there had been a fasted blood draw at baseline and 30 days, we could have known their status for several micronutrients at baseline and then compared that with their Day 30 status to help in assessing compliance. Knowing baseline status would also provide objective data to identify whether a participant already had normal levels of micronutrients prior to starting the study protocol and thus were less likely to respond to supplementation. We would also be able to see measurements like high blood sugar or caffeine, which would have the potential to skew the results irrespective of the MVM supplements. In addition, biomarkers like homocysteine and stress hormones could have been measured as indicators of physiological response to stress.

Surveys were also taken online, unsupervised. Not having anyone watching them, participants may have rushed or half-heartedly filled out their survey. Another limitation could be the requirement that all participants stop any supplementations they were taking during and one week prior to the study. If participants were taking a supplement with potential benefits to mood like Vitamin D, omega-3 fatty acids, or herbs, removal of the supplement could increase negative psychological symptomology over time [70,71]. Finally, there is the question of whether 30 days is long enough for MVM supplementation to have an impact. It may be too short for the emergence of further treatment-related effects.

Conclusion

MVM supplementation over 30 days decreased symptoms of anxiety young adults. It lowered ratings of dysregulation, but more for the placebo group than the treatment group. It also lowered depression ratings in overweight/obese subjects, but again with lower scores in the placebo group. Our findings, if replicated, could have useful implications for young adults. MVM supplements are a simple, cost-effective way to assure proper micronutrient status in a population that is often deficient [33] and at higher risk for anxiety, depression, and other psychological impairments [2,8]. Multivitamin-minerals can work quicker and with less effort than traditional stress management methods.

Future research should include a larger sample size, but still include recruitment by BMI. Possible inclusion criteria could recruit only participants who had not taken supplements of any kind over the 6 months to assure no carryover into the study. A longer study of 3 months or more with both acute and chronic dosing regimens could also help differentiate treatment effects. Designing the survey in which items get switched to require more participant attention would minimize the potential of indiscriminate completion of the survey, particularly with subsequent administration of the survey. Adding a biological component would provide biomarkers to measure stress levels and give the ability to see micronutrient status. Finally, a focus on less psychological measures would allow for a shorter survey that could be taken across multiple time points. This could provide more consistent data to offset having an exceptionally good or bad mood on test day, which could skew results.

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Appendices

Appendix A

Study Recruitment Flyer

UNIVERSITY OF ARKANSAS

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 you 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: _____

Appendix D

Participant Instruction Booklet

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 *before* 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**	
• 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)	○	○	○	○
Wake up in the middle of the night or early morning (3)	○	○	○	○
Have to get up to use the bathroom (4)	○	○	○	○
Cannot breathe comfortably (5)	○	○	○	○
Cough or snore loudly (6)	○	○	○	○
Feel too cold (7)	○	○	○	○
Feel too hot (8)	○	○	○	○
Have bad dreams (9)	○	○	○	○
Have pain (10)	○	○	○	○
Other reason (11)	○	○	○	○

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)	○	○	○	○
Feeling hot (2)	○	○	○	○
Wobbliness in legs (3)	○	○	○	○
Unable to Relax (4)	○	○	○	○
Fear of worst happening (5)	○	○	○	○
Dizzy or lightheaded (6)	○	○	○	○
Heart pounding/racing (7)	○	○	○	○
Unsteady (8)	○	○	○	○
Terrified or afraid (9)	○	○	○	○
Nervous (10)	○	○	○	○
Feeling of choking (11)	○	○	○	○

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

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)	○	○	○	○
I had trouble keeping my mind on what I was doing. (2)	○	○	○	○
I felt depressed. (3)	○	○	○	○
I felt that everything I did was an effort. (4)	○	○	○	○
I felt hopeful about the future. (5)	○	○	○	○
I felt fearful. (6)	○	○	○	○
My sleep was restless. (7)	○	○	○	○
I was happy. (8)	○	○	○	○
I felt lonely. (9)	○	○	○	○
I could not "get going." (10)	○	○	○	○

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)	○	○	○	○
I put my plans into action. (2)	○	○	○	○
I think about the future consequences of my actions. (3)	○	○	○	○
Once I have a goal I make a plan to reach it. (4)	○	○	○	○
As soon as I see things are not working, I do something about it. (5)	○	○	○	○
I consider what will happen before I make a plan. (6)	○	○	○	○
I think about my mistakes to make sure they don't happen again. (7)	○	○	○	○
I spend time thinking about how to reach my goals. (8)	○	○	○	○
Failure at a task or in school makes me work harder. (9)	○	○	○	○
I stick to a task until it is finished. (10)	○	○	○	○

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)	○	○	○	○
I lose sleep because I worry. (2)	○	○	○	○
When I am angry I lose control over my actions. (3)	○	○	○	○
I get so frustrated that I often feel like a "bomb ready to explode." (4)	○	○	○	○
I "fly off the handle" for no good reason. (5)	○	○	○	○
There are days when I'm "on edge" all the time. (6)	○	○	○	○
I easily become emotionally upset when I am tired. (7)	○	○	○	○
Often I am afraid I will lose control of my feelings. (8)	○	○	○	○
I slam doors when I am mad. (9)	○	○	○	○
My mood goes up and down without reason. (10)	○	○	○	○

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

Number of days ()

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

Number of days ()

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

Number of days ()

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)	○	○	○	○	○	○
Have you thought that your thighs, hips or bottom are too large for the rest of you? (2)	○	○	○	○	○	○
Have you felt so bad about your shape that you have cried? (3)	○	○	○	○	○	○
Have you avoided running because your flesh might wobble? (4)	○	○	○	○	○	○
Has being with thin people made you feel self-conscious about your shape? (5)	○	○	○	○	○	○
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) _____

Appendix F

IRB Approval Letter

UNIVERSITY OF ARKANSAS

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

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