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A randomised trial of nutrient supplements to minimise psychological stress after a natural disaster

Bonnie J. Kaplan^{a,*}, Julia J. Rucklidge^b, Amy R. Romijn^b, Michael Dolph^a

^a Department of Paediatrics, Alberta Children's Hospital Research Institute, University of Calgary, Calgary, Canada

^b Department of Psychology, University of Canterbury, Christchurch, New Zealand

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ABSTRACT

After devastating flooding in southern Alberta in June 2013, we attempted to replicate a New Zealand randomised trial that showed that micronutrient (minerals, vitamins) consumption after the earthquakes of 2010–11 resulted in improved mental health. Residents of southern Alberta were invited to participate in a study on the potential benefit of nutrient supplements following a natural disaster. Fifty-six adults aged 23–66 were randomised to receive a single nutrient (vitamin D, $n=17$), a few-nutrients formula (B-Complex, $n=21$), or a broad-spectrum mineral/vitamin formula (BSMV, $n=18$). Self-reported changes in depression, anxiety and stress were monitored for six weeks. Although all groups showed substantial decreases on all measures, those consuming the B-Complex and the BSMV formulas showed significantly greater improvement in stress and anxiety compared with those consuming the single nutrient, with large effect sizes (Cohen's d range 0.76–1.08). There were no group differences between those consuming the B-Complex and BSMV. The use of nutrient formulas with multiple minerals and/or vitamins to minimise stress associated with natural disasters is now supported by three studies. Further research should be carried out to evaluate the potential population benefit that might accrue if such formulas were distributed as a post-disaster public health measure.

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1. Introduction

When natural disasters strike, one of the first daily functions to be impaired is the ability to obtain and prepare nutritious food. Hence, at a time when stress and anxiety are elevated, the nutrition needed to maximise mental health may be in short supply.

It is logical to consider that enhancing people's intake of minerals and vitamins (micronutrients) might be helpful for coping with natural disasters, as it has been known for centuries that a good diet can help optimise health. For example, micronutrients act as cofactors in neurotransmitter synthesis and metabolism, where they can be rate-limiting factors (Ames et al., 2002). There are at least seven randomised controlled trials (RCTs) of B-Complex and combined mineral/vitamin formulations in which improvements in depression, anxiety and stress have been demonstrated (Carroll et al., 2000; Harris et al., 2011; Kennedy et al., 2010; Lewis et al., 2013; Long and Benton, 2013a; Rucklidge et al., 2012; Schlebusch et al., 2000) although not all trials using broad-spectrum micronutrients have shown benefit for changing mood

and anxiety (Cockle et al., 2000; Haskell et al., 2008, 2010). However, all the negative trials were conducted on people who had no presenting psychological/psychiatric challenge. Further, a recent meta-analysis showed a small but meaningful effect of micronutrients on stress and anxiety but not mood (Long and Benton, 2013b).

The information most directly relevant to the context of natural disasters is the series of studies conducted in Christchurch, New Zealand after the earthquakes of 2010–11. When the 7.1 magnitude earthquake hit on September 4, 2010, the Mental Health and Nutrition Research Group at the University of Canterbury was in the midst of conducting a clinical trial of a broad-spectrum mineral/vitamin formula in adults with ADHD, but some individuals had completed the trial or not started the trial and therefore were not taking it on the day of the earthquake and the following weeks. Two weeks after the earthquake, those who were taking the formula at the time of the earthquake were significantly less anxious and stressed than those not taking it (Rucklidge and Blampied, 2011; Rucklidge et al., 2011). Subsequently, when the February 22, 2011 earthquake of 6.3 magnitude struck, this research group immediately implemented a randomised trial in the general population, comparing two doses of the same formula to a B-Complex formula (Rucklidge et al., 2012) previously shown to be efficacious for the treatment of stress and anxiety (Carroll et al., 2000;

* Correspondence to: University of Calgary, 3820–24 Avenue NW, Third Floor, Calgary, Canada AB T3B 2X9. Fax: +1 403 955 2772.

E-mail address: kaplan@ucalgary.ca (B.J. Kaplan).

Kennedy et al., 2010; Schlebusch et al., 2000). A nonrandomised group of adults from the community who did not take any micronutrients served as the control group. Those taking the nutrients showed significantly lower levels of Post-traumatic Stress Disorder (PTSD) symptoms after one month as compared with the controls, and those taking the higher dose of the broad-spectrum micronutrient formula reported greater improvement in mood and anxiety than those taking the B-Complex.

In June 2013 a combination of Rocky Mountain snowmelt plus heavy rain caused a devastating flood in southern Alberta, Canada. River flow rates more than tripled in a few hours and over 100,000 people were evacuated from their homes. As in New Zealand, a group at the local university had been studying the potential benefit of multinutrient treatment of stress and anxiety, so the flood provided an opportunity to try to replicate the New Zealand earthquake studies to determine the generalizability of those findings to natural disasters. The research design allowed us in addition to investigate whether a single nutrient (vitamin D) or broader spectrum of nutrients were comparable at reducing psychological symptoms. Three micronutrient formulas were evaluated for their impact on depression, anxiety and stress associated with the Alberta floods.

2. Methods

At study entry (baseline) questionnaires assessed (a) exposure to the flood, (b) overall impact of the flood on physical and emotional health, (c) diet quality, and (d) depression, anxiety and stress. Those who qualified for the study were randomly allocated to one of three treatment groups (single nutrient, B-Complex, and broad-spectrum mineral/vitamin (BSMV)). Vitamin D was selected as the single nutrient comparator because of some prior evidence based on a meta-analysis of its benefit (albeit small) for people with depressive symptoms (Kjaergaard et al., 2012; Shaffer et al., 2014) as well as the generally heightened public awareness about vitamin D's contributions to health. The factorial design allocated people in equal numbers across groups. Group assignment was based on computer-generated block randomisation (block=5), and concealed in envelopes opened at time of randomisation. Treatment effects over six weeks were evaluated from questionnaire responses; compliance and side effects were also monitored. This study was approved by the Conjoint Health Research Ethics Board of the University of Calgary (REB13-0550) and the University of Canterbury Human Ethics Committee, and was prospectively registered with the Australia New Zealand Clinical Trial Registry (ANZCTR 12613001051730).

2.1. Participants

From late 2013 to mid-2014, adults in southern Alberta were invited via social media to participate in a study on the potential benefit of nutrient supplements following a natural disaster. Interested individuals were directed to a website to answer screening questions. Eligible individuals were invited to an intake interview. An assistant prepared the concealed randomisation assignment prior to intake interviews; interviewers who enrolled participants opened the next sequential envelope to determine group assignment. Those not meeting criteria were directed to local resources for mental health care.

Participants had to be > 18 years, whose homes were damaged by the flood. They had to have at least one score above the cut-offs of the Depression, Anxiety and Stress Scale (DASS) (Lovibond and Lovibond, 1995b), as follows: > 10 (for depression), > 7 (for anxiety) or > 14 (for stress). They also had to be free of psychiatric medications for at least four weeks. Candidates were excluded if they reported a neurological disorder involving the central nervous system (CNS) (e.g., epilepsy), known allergies to the nutrients, pregnancy or breastfeeding, untreated or unstable thyroid disease, known abnormality of mineral metabolism (e.g., Wilson's disease), substance dependence within the previous month, currently taking any other multivitamin/mineral, or currently taking any other medication with primarily CNS activity. Recruitment was terminated one year post-flood, although the goal of 30 participants per group was not met.

2.2. Intervention

Those who met the inclusion criteria were randomised to one of three groups. Randomisation occurred at the intake interview, after eligibility was confirmed and the consent form was signed. All intervention formulas are Health Canada-approved and have Natural Product Numbers (NPNs). Ingredients are in Table 1.

Table 1
Ingredient list of daily dose of vitamin D, B-Complex, and Broad Spectrum Mineral/Vitamin formula.

	Vitamin D, consumed in 1 pill/day	B-Complex, consumed in 1 capsule/day	Broad Spectrum, ^a consumed in 4 capsules/day
Vitamin A (mcg)			384.0
Vitamin B6 (mg)		20.0	8.0
Vitamin B12 (mcg)		500.0	200.0
Vitamin C (mg)			133.2
Vitamin D (IU)	1000		320.0
Vitamin E (mg)			53.6
Thiamine (mg)		50.0	4.0
Riboflavin (mg)		20.0	3.2
Folate (mcg)		400.0	320.0
D-pantothenic acid (mg)		50.0	4.8
Intrinsic factor (mg)		20.0	
Biotin (mcg)		300.0	240.0
Niacin (mg)		50.0	20.0
Chromium (mcg)			138.8
Copper (mg)			1.6
Iodine (mcg)			45.2
Iron (mg)			3.2
Calcium (mg)			293.2
Magnesium (mg)			133.2
Manganese (mg)			2.0
Molybdenum (mcg)			32.0
Phosphorous (mg)			186.8
Potassium (mg)			53.2
Selenium (mcg)			45.2
Zinc (mg)			10.8

^a And a proprietary blend of phenylalanine, L-methionine, citrus bioflavonoids, germanium sesquioxide, nickel, vanadium, grape seed, L-glutamine, inositol, choline bitartrate and ginkgo biloba.

2.2.1. Vitamin D, consumed in one pill/day

This vitamin is of key importance for oxidative stress at the cellular level, and for immunity, inflammation, and muscle function (Larson-Meyer, 2013). With respect to mental health, the role of vitamin D is gaining increasing support. For instance, Maddock et al. recently reported an association between low vitamin D status and vulnerability to depression (Maddock et al., 2013). Although the use of vitamin D alone to effectively manage serious mental disorders has not been supported scientifically, there are some impressive examples of treatment benefits in individual case studies (Humble, 2010). For the current study, vitamin D (1000 IU) produced by Douglas Laboratories was used (NPN 80009658). This vitamin D is in medium-sized white pressed tablets.

2.2.2. B-Complex, consumed as one capsule/day

As mentioned, improvements in depression, anxiety and stress in response to supplementation with B vitamins have been demonstrated in several RCTs. A formula produced by Douglas Laboratories was used, B-Complex with Metafolin™ (NPN 80021762). This B-Complex is in large transparent gelatin capsules.

2.2.3. Broad-Spectrum Mineral/Vitamin formula (BSMV), consumed as four capsules/day

The Truehope formulas have been shown to improve mood and anxiety symptoms in a variety of studies (cf. Rucklidge and Kaplan, 2013). Although these formulas exist in several variations, only one had an NPN at the time of this study: Truehope EMP™ by Truehope Nutritional Support, Ltd. (NPN 80000383). This formula is in large transparent gelatin capsules.

2.3. Outcome measures

Outcome measures were completed online by participants, at baseline and then every two weeks for the duration of the trial.

2.3.1. Primary outcomes (determined a priori)

- The Depression Anxiety and Stress Scale (DASS (Lovibond and Lovibond, 1995b)) was administered at the Intake Interview and used as a baseline score.

Its 42 items assess current symptom severity and scores can range from zero to 126. The participants were asked to rate each item on the scale as it applied to them over the previous week, ranging from did not apply to me at all (0) to applied to me very much, or most of the time (3). Examples of items include: "I felt I had nothing to look forward to" (depression), "I felt I was close to panic" (anxiety), and "I found it difficult to tolerate interruptions to what I was doing" (stress). Higher scores reflect greater impairment. Scores below 10 (for depression), 7 (for anxiety) and 14 (for stress) are considered to be within the normal to mild range. There is evidence of the validity of the DASS for use in both clinical and community settings (Antony et al., 1998; Brown et al., 1997), the measure has high internal consistency (Cronbach's alpha scores of > 0.7) and there are significant correlations between DASS scores and other measures including the Beck Anxiety and Beck Depression Scales (correlation coefficients, r , ranged from 0.58 to 0.78 (Lovibond and Lovibond, 1995a)) and the Positive and Negative Affect Scale ($r=0.69$ (Henry and Crawford, 2005)). More recently, the DASS was determined to show a sensitivity of 79.1% and a specificity of 77.0% although the scale did not distinguish between those experiencing only depression or only anxiety (Tran et al., 2013).

- Modified Clinical Global Impressions (CGI-I (Spearing et al., 1997)) was used only at the end of the 6 weeks of intervention to ask participants to rate how much they thought their mood, anxiety, stress, energy, and sleep had changed since they started the trial, using a scale from 1 (very much improved) to 7 (very much worse). This scale is widely used for clinical trials and was adapted, by changing the wording of the questions from third person to second person, so that participants could rate their own impressions of change since there was no further contact with the researchers after informed consent was provided.

2.3.2. Secondary outcomes

- Impact of Events Scale—Revised (IES-R; (Weiss and Marmar, 1997)) is a 22-item measure that has been widely used in different cultures following exposure to various traumatic events including hurricanes (Dougall et al., 1999; Ironson et al., 1997) and earthquakes (Asukai et al., 2002; Wang et al., 2010). The three factor structure of the IES-R subscales (intrusion (8 items), avoidance (8 items) and hyperarousal (6 items)) correspond with the core diagnostic criteria in the DSM-IV for PTSD.

2.3.3. Other measures

- Traumatic Exposure Severity Scale (TESS (Elal and Slade, 2005)) was adapted for the flood experience. Its 24 items assess Resource Loss (e.g., Did you need

food and water aid after the flood?), Damage to Home and Goods (e.g., Did you have to relocate because your house became structurally unsafe to live in?), Personal Harm (e.g., Were you physically injured in the flood?), Concern for Significant Others (e.g., Were any members of your family or your loved ones physically injured in the flood?) and Exposure to the Grotesque (e.g., Did you see dead bodies or body parts in the period following the flood?). The scale assesses both occurrences (range 0–24) and distress if any of the occurrences were endorsed [how distressing was this for you from 1 (not at all) to 5 (extremely)]; range 0–120].

- Diet quality questionnaire. The diet quality items were adapted from descriptions of a healthy eater developed by Baker et al. (2003). They defined a healthy eater as someone who eats in a balanced way, eats three meals a day, does not eat too much junk food, eats moderate amounts, and stops eating when full. These descriptions were adapted and validated by Kuijer and Boyce (2012). Participants were asked to indicate from 1 (< once a week) to 5 (daily) how often over the previous 2 weeks they ate breakfast, ate a balanced meal, ate even when full, ate lots of fruits and vegetables, and ate fast foods or snack foods such as potato chips or candy bars. Three items are reverse scored. They were also asked about average daily servings of fruit and vegetables [from 1 (< one serving) to 5 (4 or more servings)], and to indicate from 1 (not very healthy) to 7 (very healthy) how healthy they thought their diet was. Total scores ranged from 9 to 47, with a higher score indicative of a healthier diet. In the validation study, Kuijer and Boyce (2012) showed that the questions were correlated highly with a 2-week diary report of those behaviors (correlations varied from 0.49 to 0.93). Moreover, the retrospective recall was found to be a fairly accurate estimate of the eating behaviors as reported during the diary period. The summing of the items has been used successfully in other studies such that a higher score on the summed scale indicates healthier eating behaviors (Cronbach's alpha 0.67 (Kuijer and Boyce, 2014)). This questionnaire was completed at baseline and 6 weeks.
- Alcohol, caffeine, cigarettes and illicit drugs. Every two weeks during the trial, participants were asked to record the amount of alcohol, caffeinated beverages (coffee, tea, coke, etc.), cigarettes, and illicit drugs consumed over the previous two-week period. Responses were standardized according to approximate amount of caffeine in different types of drinks (e.g., green tea was coded as 0.5 cups, but energy drinks were coded as 2 cups) and alcohol consumption was converted to an estimate of number of standard drinks consumed.
- Sleep quality. Participants were asked to complete five items of the Pittsburgh Insomnia Rating Scale assessing sleep quality (Moul et al., 2002). Questions ask about how much they were bothered by getting to sleep, waking in the night, waking too early, not getting enough sleep and not having refreshing sleep. They were asked to rate each question from 0 (not at all bothered) to 3 (severely bothered). The responses to the five items were summed for a total score ranging from 0 to 15.

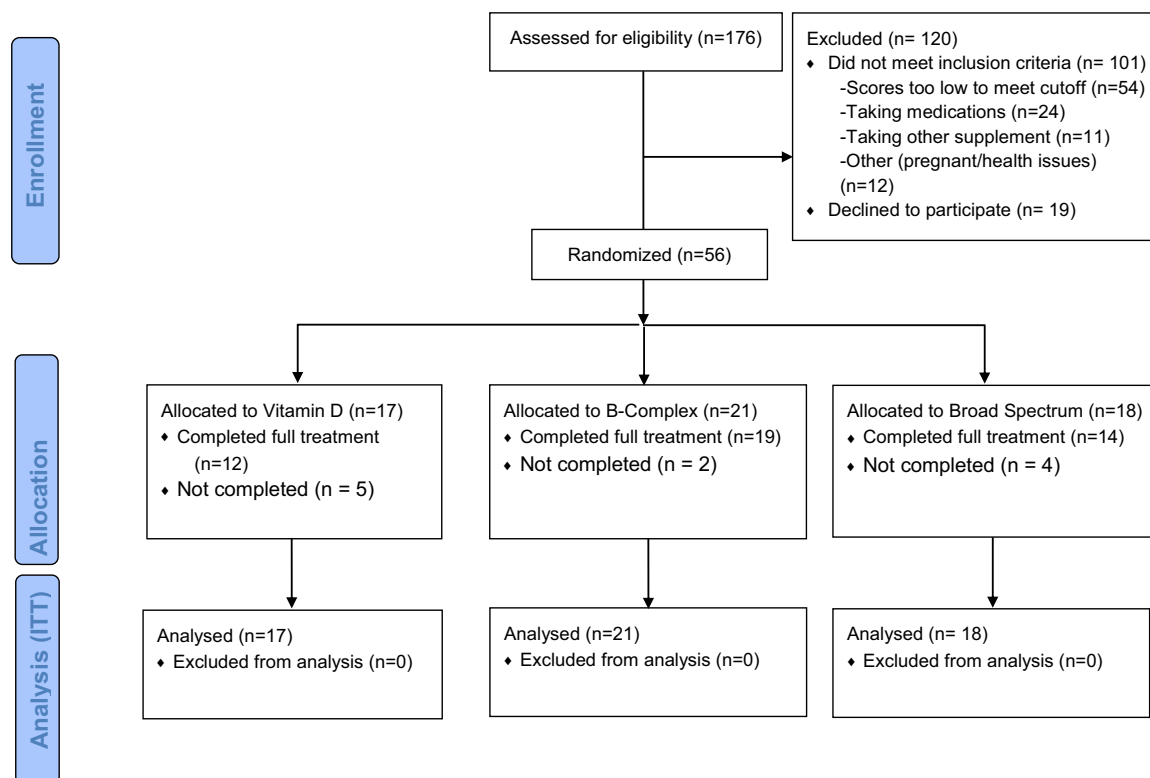


Fig. 1. CONSORT flow diagram.

Table 2
Baseline characteristics of study participants.

Characteristic	Vitamin D	B-Complex	BSMV	p-value*
Number of participants	17 30%	21 38%	18 32%	–
Age (Mean, SD)	46.0 (12.8)	48.0 (16.2)	43.9 (10.5)	0.644
Female	14 (82%)	18 (86%)	17 (94%)	0.531
Household Income				
< \$20,000	2 (12%)	0 (0%)	2 (11%)	0.310
\$20,000–39,000	2 (12%)	6 (29%)	1 (6%)	–
\$40,000–69,000	6 (35%)	5 (24%)	6 (33%)	–
\$70,000–99,000	5 (29%)	4 (19%)	3 (17%)	–
> \$100,000	2 (12%)	6 (29%)	6 (33%)	–
Education				
Less than high school	1 (6%)	0 (0%)	1 (6%)	0.830
Completed high school	2 (12%)	6 (29%)	4 (22%)	–
Completed trade school	5 (29%)	5 (24%)	6 (33%)	–
Completed undergrad degree	6 (35%)	8 (38%)	6 (33%)	–
Completed graduate degree	3 (18%)	2 (10%)	1 (6%)	–
Ethnic origin				
Caucasian	16 (94%)	19 (91%)	18 (100%)	0.455
Black	1 (6%)	0 (0%)	0 (0%)	–
Chinese	0 (0%)	1 (5%)	0 (0%)	–
First Nations	0 (0%)	1 (5%)	0 (0%)	–
History of mental illness	4 (24%)	7 (33%)	1 (6%)	0.105
Smoker	2 (12%)	5 (24%)	5 (28%)	0.486
TESS Occurrence (Mean, SD) ^a	8.8 (2.7)	7.8 (3.1)	6.9 (3.5)	0.233
TESS Distress (Mean, SD) ^a	26.7 (14.1)	34.3 (16.6)	29.1 (15.7)	0.339
Diet quality (Mean, SD) ^b	31.5 (5.3)	31.5 (7.3)	30.6 (5.5)	0.881
Cannabis user	1 (6%)	0 (0%)	1 (6%)	0.536
Alcohol abuse ^c	0 (0%)	3 (14%)	3 (17%)	0.225
Caffeine use (Mean, SD) ^d	24.4 (26.7)	15.5 (18.7)	28.9 (25.2)	0.287

BSMV = Broad Spectrum Mineral/Vitamin formula.

^a TESS = Traumatic Exposure Severity Scale, scores range from 0 to 24 for occurrences and 0–120 for distress.

^b Scores range from 9 to 47.

^c Determined by Canadian Centre on Substance Abuse guidelines and defined as no more than two drinks a day, 10 per week for women, and three drinks a day, 15 per week for men.

^d Caffeine assessed as number of caffeinated drinks (coffee, red bull, tea, coke, etc.) consumed over the two weeks prior to baseline.

* p-Values are from chi square and ANOVA tests.

- Adverse events. Participants were asked about common side effects associated with taking medications (e.g., headaches, rash, and nausea).

2.4. Statistical analyses

The two primary outcome measures were defined *a priori* (DASS and CGI-I). Paired sample *t*-tests were used to assess change from baseline to end-of-treatment for each group. The changes from baseline to the end-of-treatment were compared between randomised groups using ANCOVA, with baseline level as the covariate. Change measures (CGI-I ratings) assessed at the end of treatment were compared using one-way ANOVA. Categorical outcomes were compared between groups using Chi-square tests with odds ratios and 95% confidence intervals. Adverse event rates were compared between treatment groups using Fisher's exact tests. All analyses on primary and secondary measures were undertaken on an intention-to-treat (ITT) basis except for the CGI-I ratings as there were no baseline ratings to carry forward. For those participants not completing the trial, data from their final assessment were used (which may have been baseline). All tests were two-tailed, and *p*-values less than 0.05 were considered statistically significant. Cohen's *d* (with confidence intervals) was used as a measure of effect sizes, with 0.2 being small, 0.5 being medium and 0.8 being large.

3. Results

The sample consisted of 56 participants, 17 assigned to vitamin

D, 21 to B-Complex and 18 to BSMV (see Fig. 1 for the CONSORT diagram and Table 2 for demographic information). Baseline comparisons between groups showed no significant differences for any demographic characteristics.

There were no differences in treatment-emergent adverse events across groups (data not shown). Five people from the vitamin D group, 2 from the B-Complex group, and 4 from the BSMV group dropped out at some point prior to the sixth week of the trial. The reasons for dropout varied widely, from a cancer diagnosis to being too busy with flood recovery projects, with no apparent trends between treatment groups. Overall, compliance in taking the nutrients was high for all three treatment groups, with the vitamin D, B-Complex, and BSMV groups reporting 93%, 94%, and 93% compliance, respectively.

3.1. Baseline comparisons

There were no significant group differences in DASS, IES-R or TESS scores at baseline. The DASS was also assessed at the screening stage: screening and baseline scores did not differ, indicating that the passage of time during the two weeks prior to the trial had little effect (data not shown).

3.2. Primary outcomes

All groups changed significantly from pre- to post-treatment except on DASS Anxiety where the vitamin D group did not show a significant change across time. ANCOVA tests controlling for baseline scores compared the DASS change over time between groups (Table 3), where significant differences for DASS Anxiety ($F(2, 52)=5.41$, $p < 0.01$), DASS Stress ($F(2, 52)=3.81$, $p < 0.05$), and DASS Total ($F(2, 52)=4.33$, $p < 0.05$) were observed. Post-hoc analysis of the change scores revealed that the B-Complex and BSMV groups improved significantly more than the vitamin D group, with no significant differences observed between B-Complex and BSMV. Overall, large effect sizes were observed on both the Anxiety and Stress subscales of the DASS and DASS Total between the vitamin D group and the B-Complex group (Anxiety, $d=0.89$; Stress, $d=0.76$; DASS Total, $d=0.81$), and between the vitamin D group and the BSMV group (Anxiety, $d=1.08$; Stress, $d=0.88$; DASS Total, $d=0.94$), indicating that the treatment effect on both the B-Complex and BSMV groups was greater than the effect of the treatment on the vitamin D group. The negligible effect sizes between the B-Complex group and the BSMV group show that the treatments were equally effective for these two groups. Fig. 2 illustrates the differential effect of the treatments across the three groups on one of the primary outcome variables, the DASS stress subscale.

CGI-I results for change in mood, anxiety, stress, sleep, and energy are shown in Table 4. Group differences were observed only for CGI stress ($F(2, 42)=3.680$, $p < 0.05$), with post-hoc analysis revealing that the B-Complex and BSMV groups did not differ from each other but both reported greater improvements in stress ($p < 0.05$) compared with the vitamin D group, with large effect sizes ($d=0.79$ and 1.09 respectively). Responders are typically classified dichotomously as those who identify themselves as “much” to “very much” improved: 2 (17%) of those in the vitamin D group, 8 (42%) of those in the B-Complex group and 8 (57%) of those in the BSMV group were classified as responders on the CGI stress scale, with post-hoc analyses revealing that significantly more people were classified as responders in the BSMV group compared with the vitamin D group ($\chi^2 (n=26)=4.473$, $p < 0.05$; odds ratio = 6.7 (95%CI = 1.047–42.431)).

3.3. Secondary outcomes

There were significant changes for all the groups on the IES-R

Table 3
DASS and IES-R outcomes.^a

Outcome	Treatment	Baseline	Change, baseline to 6 weeks	Percent change	<i>p</i> for within group change (paired sample <i>t</i> -test)	<i>p</i> for time by treatment interaction ^b	Post-hoc analyses ^c	Vit D vs. B-Complex (effect size ^d (95% CI))	Vit D vs. BSMV (effect size ^d (95% CI))	B-Complex vs. BSMV (effect size ^d (95% CI))
Primary outcome		Mean (SD)	Mean (SD)							
DASS depression	Vitamin D	11.8 (7.3)	-2.8 (3.8)	-24%	0.008	0.135	–	0.58 (–0.06 to 1.24)	0.64 (–0.04 to 1.32)	0.05 (–0.58 to 0.68)
	B-Complex BSMV	13.0 (8.5) 14.3 (8.2)	-6.7 (6.8) -7.6 (8.8)	-52% -53%	< 0.001 0.002					
DASS anxiety	Vitamin D	11.8 (7.0)	-2.4 (5.6)	-20%	0.104	0.007	B-Complex, BSMV > Vitamin D	0.89 (0.22–1.57)	1.08 (0.37–1.79)	0.18 (–0.44 to 0.81)
	B-Complex BSMV	8.4 (6.2) 8.7 (7.2)	-5.1 (4.9) -6.1 (7.5)	-61% -70%	< 0.001 0.003					
DASS stress	Vitamin D	21.1 (6.6)	-5.6 (9.5)	-27%	0.026	0.029	B-Complex, BSMV > Vitamin D	0.76 (0.10–1.43)	0.88 (0.19–1.58)	0.12 (–0.51 to 0.74)
	B-Complex BSMV	18.6 (8.7) 20.0 (9.9)	-10.1 (7.5) -11.7 (10.1)	-54% -59%	< 0.001 < 0.001					
DASS total	Vitamin D	44.7 (17.1)	-10.8 (16.7)	-24%	0.017	0.018	B-Complex, BSMV > Vitamin D	0.81 (0.14 to 1.48)	0.94 (0.24 to 1.64)	0.13 (–0.50 to 0.76)
	B-Complex BSMV	40.0 (21.2) 43.0 (21.5)	-21.8 (17.1) -25.4 (23.8)	-55% -59%	< 0.001 < 0.001					
Secondary outcome										
IES-R avoid	Vitamin D	1.5 (0.6)	-0.5 (0.8)	-33%	0.036	0.607	–	0.36 (–0.27 to 0.99)	0.30 (–0.37 to 0.96)	0.06 (–0.56 to 0.70)
	B-Complex BSMV	1.2 (0.7) 1.2 (0.7)	-0.5 (0.5) -0.4 (0.6)	-42% -33%	< 0.001 0.016					
IES-R intrusion	Vitamin D	1.8 (0.7)	-0.4 (0.8)	-22%	0.041	0.278	–	0.45 (–0.19 to 1.11)	0.48 (–0.19 to 1.15)	0.03 (–0.60 to 0.66)
	B-Complex BSMV	1.7 (0.7) 1.4 (0.7)	-0.7 (0.6) -0.6 (0.6)	-41% -43%	< 0.001 0.001					
IES-R arousal	Vitamin D	1.7 (0.5)	-0.4 (0.9)	-24%	0.072	0.132	–	0.39 (–0.24 to 1.04)	0.50 (–0.17 to 1.18)	0.11 (–0.52 to 0.74)
	B-Complex BSMV	1.4 (0.8) 1.3 (0.6)	-0.6 (0.8) -0.6 (0.7)	-43% -46%	0.001 0.001					
IES-R total	Vitamin D	36.3 (9.8)	-9.7 (16.3)	-27%	0.026	0.323	–	0.50 (–0.15 to 1.15)	0.40 (–0.26 to 1.07)	0.09 (–0.53 to 0.73)
	B-Complex BSMV	31.6 (14.1) 28.2 (12.0)	-13.6 (10.9) -11.4 (11.6)	-43% -40%	< 0.001 0.001					

^a Using ITT protocol. Vitamin D (*n*=17), B-Complex (*n*=21), BSMV (*n*=18) DASS=Depression Anxiety and Stress Scale; IES-R=Impact of Event Scale; BSMV=Broad Spectrum Mineral/Vitamin formula

^b ANCOVA comparing changes from baseline to 6 weeks across the three treatment groups, controlling for baseline score

^c B-Complex, BSMV > Vitamin D indicates that B-Complex and BSMV had a greater change than Vitamin D

^d effect size as Cohen's *d*: mean difference between the estimated marginal means/ $\sqrt{\text{mean squared error corrected for unequal group sizes}}$

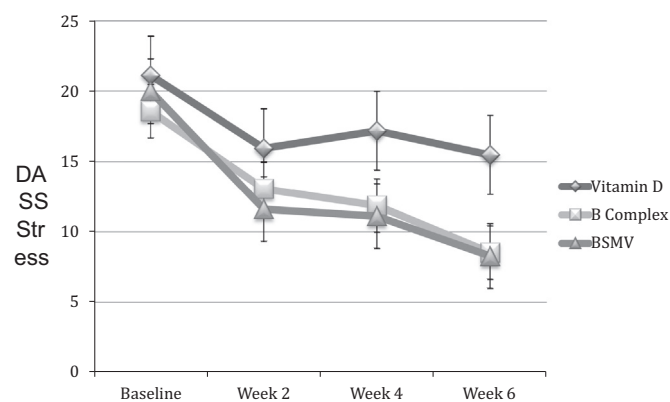


Fig. 2. Change in DASS Stress from baseline to week 6. BSMV=Broad Spectrum Mineral Vitamin.

except for vitamin D on the arousal subscale (Table 3). There were no group differences across time on the IES-R.

3.4. Other variables

Additional analyses were performed on changes in diet quality

and behavior throughout the study. There were no significant changes reported for cannabis, alcohol, tobacco (smoking) or caffeine consumption from baseline to week 6 for any of the groups and no differences between groups. There were no group differences at end of treatment in reported changes in exercise over the trial. Self-reported diet quality improved over the 6 weeks in all groups, but there were no differences between groups either at baseline or end of treatment. Additionally, improved sleep quality was observed from baseline to week 6 only for the BSMV group ($t(1, 12)=4.214, p < 0.001$), but there were no group differences in sleep quality at the end of the trial.

4. Discussion

This trial found that people consuming the B-Complex or the BSMV formulas showed significantly greater reduction in stress and anxiety compared with those consuming only vitamin D. Based on the primary and secondary outcome measures, the groups consuming the B-Complex or the BSMV formulas showed significant changes on all variables from beginning to end of treatment. The vitamin D group showed significant changes on all variables except the Anxiety subscale of the DASS and the Arousal subscale of the IES-R. Significant group differences were observed showing greater change in self-reported Anxiety and Stress for

Table 4
Change in mood, sleep, anxiety, stress, and energy at week 6, by treatment group from the CGI-I scale.^a

Characteristic	Vitamin D (n=12) M (SD)	B-Complex (n=19) M (SD)	BSMV (n=14) M (SD)	p for treatment comparison ^b	Post-hoc analyses ^c	Vit D vs. B-complex (effect size ^d (95% CI))	Vit D vs. BSMV (effect size ^d (95% CI))	B-complex vs. BSMV (effect size ^d (95% CI))
CGI-I change in:								
Mood	3.0 (1.0)	2.5 (1.0)	3.0 (1.4)	0.370	–	0.37 (–0.37 to 1.10)	0 (–0.78 to 0.78)	0.36 (–0.35 to 1.08)
Anxiety	3.1 (0.9)	2.7 (1.0)	2.7 (0.6)	0.467	–	0.42 (–0.32 to 1.16)	0.46 (–0.33 to 1.26)	0.04 (–0.68 to 0.74)
Stress	3.4 (1.1)	2.7 (0.9)	2.5 (0.7)	0.034	B-Complex, BSMV > Vitamin D	0.79 (0.03 to 1.54)	1.09 (0.24 to 1.93)	0.29 (–0.43 to 1.01)
Energy	3.3 (1.2)	3.2 (0.9)	2.9 (0.9)	0.584	–	0.03 (–0.70 to 0.76)	0.49 (–0.31 to 1.29)	0.46 (–0.26 to 1.18)
Sleep	3.4 (1.1)	3.4 (0.8)	3.2 (0.6)	0.807	–	0.03 (–0.70 to 0.76)	0.23 (–0.56 to 1.01)	0.19 (–0.52 to 0.91)

BSMV, Broad Spectrum Mineral/Vitamin formula.

^a Data are means and standard deviations (SD) from the CGI only from people who completed the week 6 survey.

^b Results from ANOVA model.

^c A lower score is indicative of greater improvement on this scale (which ranges from 1 very much improved to 7 very much worse with 4 indicative of no change); hence, B-Complex, BSMV > Vitamin D means that the B-Complex and BSMV groups reported greater improvement compared with the Vitamin D group

^d Cohen's *d* calculated as difference between two groups/pooled standard deviation.

both the BSMV and B-Complex groups as compared with the vitamin D group. Effect sizes between these groups were large, and there were no differences between the BSMV group and the B-Complex group. Group differences could not be better accounted for by changes in alcohol, cigarette and caffeine consumption, exercise, diet, or sleep.

This replication of the NZ earthquake studies (Rucklidge et al., 2011, 2012; Rucklidge and Blampied, 2011) suggests the possibility that micronutrients could be useful for the reduction and prevention of mental health problems following natural disasters and that a greater spectrum of nutrients is more effective than one nutrient alone. Although the measure of dietary quality employed in this study was a general one, and did not assess actual nutrient intake, the results are consistent with what would be expected: that nutrient intake in people displaced from their homes would decrease from the crisis but would increase over time as they returned to their normal life patterns. The demonstration that more powerful effects on psychological functioning can be achieved with a greater number of nutrients challenges the typical approach of giving only one nutrient to effect symptom change (Rucklidge et al., 2013). The findings reported here are also consistent with other studies showing that nutrient treatment with B-Complex or broad-spectrum formulas has a positive impact on mental health (Kaplan et al., 2007; Rucklidge and Kaplan, 2013).

Though this was a replication, the issue of PTSD could not be addressed, as the IES-R scores at baseline were much lower than those obtained in the earthquake study with many fewer having probable PTSD at baseline. The experience of earthquakes and floods are not the same. As with most floods, the one studied here was a single event, followed by an outpouring of civic assistance. In contrast, the NZ earthquakes lasted for over a year, with participants experiencing 1–2 significant aftershocks every day through the trial (source: www.geonet.co.nz).

This study's main limitation was the difficulty in recruiting, which resulted in a small sample size. One cause of that difficulty was that the civic support provided by the government included mental health treatment that usually resulted in medication, an exclusion criterion for this study. On the other hand, the sample size meant that only large effects between groups could be detected. The large effect sizes observed when compared to the single nutrient formula highlights the potential value of consuming either a B-Complex or broader micronutrient formula for improving public health following an environmental catastrophe. The fact that both of these formulas provide many B vitamins adds to the evidence showing the value of B vitamins in managing stress.

The BSMV formulation has three non-nutrient, botanical components: ginkgo biloba, citrus bioflavonoids, and grape seed. They

are present because the manufacturer believes they can benefit general brain health, but their quantities are so tiny relative to those used elsewhere both clinically and in research that it is unlikely they would have a significant impact on mental health on their own. For instance, one study of ginkgo biloba's effect on anxiety used doses 10–20 times higher than the dose in the BSMV formulation (Woelk et al., 2007); we are unaware of studies on the effects of citrus bioflavonoids or grape seed for mental health, although doses suggested clinically for these botanicals are much higher than the doses contained in the BSMV.

The results need to be interpreted bearing in mind the lack of placebo (the use of which would have been unethical) and the lack of blinding. Taking four capsules may induce a more powerful placebo effect than taking one, although the B-Complex was only one capsule and did induce the same changes as taking four. Generalizability is limited by our recruitment method through social media, meaning that we may not have reached those people who did not have access to the internet either due to lower socioeconomic status or through greater displacement after the flood. Another study limitation was that our measure of food intake could not capture the intake of specific nutrients. Analysis of nutrients from food diaries could be considered in future research if participants are able to provide additional information, but this can be a challenge in a post-disaster crisis setting. Such additional data could inform whether the dietary intake of the participants after the flood was inadequate or whether the nutritional requirements of the body following the flood increased to respond to the additional stress. The latter hypothesis would be consistent with the triage theory proposed by McCann and Ames (2009) that states that when the “availability of a micronutrient is inadequate, nature ensures that micro-nutrient-dependent functions required for short-term survival are protected at the expense of functions whose lack has only longer-term consequences” page 889. In other words, nutrients are triaged to the fight-flight response, and in so doing, optimal brain function may be compromised, leading to the expression of psychological symptoms.

Natural disasters pose a significant public health challenge. Additional nutrients provide the body and brain with what is needed to cope with chronic stress at a time when nutrient intake is compromised, given how metabolically demanding the stress response can be if sustained over time (McCann and Ames, 2009). Micronutrient supplements have consistently been shown to benefit mental health, and they would be a cheap and easy intervention to add to all crisis teams (Ames et al., 2002). Further international research on this intervention is suggested.

Author contributions

BJK directed the study, interpreted results, and wrote the first draft of the manuscript; JJR directed the analysis and interpretation of the results; AR established all data collection procedures to be parallel to the study being replicated, and interpreted the results; MD coordinated the study, supervised the interviewers, and managed the data entry and analyses. All authors edited the final version of the manuscript.

Conflict of interest

No author has any conflict of interest or financial relationship to report.

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