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

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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;

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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.

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