Disasters, policies and micronutrients: the intersect among ethics, evidence and effective action

Neville M Blampied, Roger T Mulder, M Usman Afzali, Oindrila Bhattacharya, Meredith F Blampied, Julia J Rucklidge

We will address health system policy issues relating to the ethical approval process for health research and dissemination as well as the willingness of the health system to incorporate information from published health research into clinical practice. This submission is based on recent direct experiences with the health system response to disasters and the ethical approval process. It is an expression of our responsibility, as university academics, to be 'critic and conscience of society' imposed by the Education Act (1989). Our experience demonstrated a disconnect between research and practice and between the needs of researchers to do prompt research and the laborious processes of ethics committee review.

Some history: in September 2010 one of us was conducting an ethically approved, randomised placebo-controlled trial (RCT) of a micronutrient treatment for adults with a diagnosis of attention-deficit/hyperactivity disorder (ADHD). At the time of the 7.1 Darfield (NZ) earthquake, 33 participants had been comprehensively assessed but only some were receiving active treatment when the earthquake struck. This established a natural experiment examining the way in which consumption of the nutritional supplement might impact the participants' response to the stress of a natural disaster. Consistent with prior research demonstrating efficacy of nutritional supplements on the stress response,[1–4] those taking the micronutrients were found to have statistically and clinically significantly reduced levels of depression, anxiety and stress one and two weeks post-earthquake, relative to the untreated group.[5] Approval for this extension to the research protocol was given immediately post-earthquake by the University of Canterbury Human Ethics Committee (UCHEC).

After the 22 February 22 2011 aftershock which killed 185 people and wrecked much of Christchurch City (NZ), the research team performed an RCT comparing several kinds and dose levels of nutritional supplementation (including micronutrients) to treatment-as-usual (TAU) with adult members of the Christchurch community as participants. The results of this study and its subsequent follow-up[6,7] confirmed the substantial benefits for psychological stress and distress resulting from taking micronutrients compared with TAU. In addition, rates of probable post-traumatic stress disorder (PTSD) dropped from 65 to 19% with a one-month micronutrient intervention compared with no change in the TAU group (whose PTSD risk remained ~48%). A further study demonstrated substantial benefits of micronutrient consumption for children with earthquake-exacerbated anxiety.[8] The benefits of micronutrients for survivors of a natural disaster were also subsequently replicated in an RCT that compared micronutrients with vitamin D following disastrous floods in Southern Alberta, Canada, in 2013.[9]

All the cited research was ethically approved, trial registered and conducted using rigorous research designs. The data were comprehensively analysed by appropriate analytic methods and published in peer-reviewed, international journals. Therefore, we argue that there is considerable scientific evidence that micronutrient treatment is an empirically supported therapy for survivors of highly stressful

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events, including disasters, according to the Chambless and Hollon criteria,[10] specifically via support from at least two independently conducted, methodologically sound trials, and that the intervention reduces the risk of developing long-term PTSD symptoms.

On 15 March 2019, a gunman entered two Mosques in Christchurch, killed 51 people and injured 49. This catastrophe exposed a large number of people (both those directly surviving the attack and those in the wider community) to severe distress and increased their likelihood of PTSD, with PTSD incidence likely to range from 30–60% of those exposed and to potentially persist for up to two years post-event for up to one-third of those affected.[11]

In the immediate aftermath of the shootings, the authors felt individually and collectively that we faced a scientific and ethical dilemma. How best to use the knowledge we had gained from previous research in Christchurch and elsewhere to help the survivors of this latest catastrophe? Some of us contacted various responsible authorities to draw their attention to the benefits of supplying micronutrients to those affected. Those contacted included the Minister of Health, members of the Canterbury District Health Board (CDHB), general practice (GP) advisors at Pegasus Health (representing medical practitioners in general practice), local politicians and Members of Parliament, the Prime Minister's Chief Science Advisor, plus others. However, none of those contacted saw the use of a nutritional intervention as a priority, or they considered it too difficult to implement at the time.

Thus, the first of our 'critic and conscience' observations concerns the difficulty of getting a health system, even one with extensive, recent experience of disaster, to incorporate into post-disaster clinical practice new scientific evidence about treatments that are potentially beneficial to survivors and their wider community. A change in practice seems to be particularly difficult when it involves community rather than hospital-based treatment and when it involves psychological rather than physical injuries.

Thus, in light of the lack of official response to our evidence, we faced a continuing dilemma: What then should we do—another research study, or should we actively translate our scientific knowledge into clinical action? We chose the latter course, raised some money from donors to purchase supplies of micronutrients, and made these available to any self-identified members of the Christchurch Muslim community who sought treatment. We were fortunate that one member of our team is a member of this community and able to act as liaison and consultant in this clinical work. We monitored the psychological wellbeing and response to treatment of recipients, as is usual practice, via an online questionnaire.

In contrast to the research studies, but consistent with clinical practice, those receiving treatment were not randomised to treatment conditions, there was no control condition, there were no selection or exclusion criteria imposed (we advised participants concurrently taking other treatments, including medication, to discuss their micronutrient consumption with their therapist/prescriber) and we did not prescribe either the dose taken nor the duration of treatment. The manufacturer's recommended dose is three capsules twice a day, but some people took more, some less. We did, however, ensure that all participants gave full informed consent to treatment (and subsequent use of the data to assist with securing more funding), including information about possible side-effects of micronutrients, and other treatment options.

We did, after initiating this clinical work, consider if it might be extended into a research study. Preliminary approaches to both the UCHEC and to the Health and Disability Ethics Committee (HDEC) suggested to us that (a) these committees might well decline any application, and (b) that it was very likely to take many months to get a decision. Complicating ethical decision-making is that the micronutrient formulation is sometimes regarded as a medicine due to a possible therapeutic benefit for mental health symptoms. This therefore might require additional approval from other official Ministry of Health committees (such as the Standing Committee of Therapeutic Trials). Also, more ethical review steps have been instigated over the last few years, including external peer review, the development of a protocol, and more extensive community consultation, that make for a lengthier review process. Consequently, in our view, by the time that

any ethical approval for a research project was obtained (if it was), the opportunity to maximally help the community would have reduced substantially.

This leads to our second 'critic and conscience' observation: if intervention research is to be done into the aftermath of disasters, ethics committees need to establish some process for rapid approval of research protocols. We were fortunate that we were able to obtain rapid approval for our initial post-earthquake study. We can only speculate as to why the indications were that this would not happen in the current circumstances given the similarity in measures and intervention across the research studies over time: this was not a new treatment that the ethics committees had not been presented with before. We believe that this matter—clear policies about and the capacity to make rapid decisions about research in the immediate aftermath of a disaster—needs urgent attention.

The ethical debate then shifted to address the question "Could we publish our clinical observations?" A prolonged and arduous exchange with HDEC established (by 4 September 2019) that the committee considered that the clinical work we had done was within the scope of HDEC review and *should have received HDEC approval prior to commencement* because it was not considered to be part of standard care (whatever that might be). Nevertheless, HDEC advised that *this decision does not prohibit publication*. After another three months of further exchanges with UCHEC, they ruled similarly (25 November 2019). As a final 'critic and conscience' observation, we note that this is both a good outcome (in that it does not suppress potentially useful information freely provided by affected people in the expectation that it could be used to help others) and a potentially useful precedent. We further note that we do not for a moment suggest that the various individuals involved in making these two decisions were not doing anything other than striving to reach a correct, ethical decision. Nevertheless, the months it took for decisions to be reached and communicated meant that the clinical information we gathered could not be effectively shared in a more timely way with those who might have been able to implement the knowledge we had gained, to the benefit of the affected community. It also highlights that there is no obvious route for dissemination of information gathered through clinical practice in circumstances such as these.

Overall, our experience as clinicians and researchers was that our health and ethics systems are not set up to deal with the implementation nor the evaluation of nonstandard but evidence-based treatments given within both a clinical and research context under post-disaster conditions. The (informal) message we heard repeatedly was that there was no problem with providing any treatment, as long as we didn't want to evaluate its efficacy! We suspect, however, that the public would be keen for processes to be in place so that any interventions are routinely evaluated for efficacy such that adjustments can be made based on evidence and not politics or industry influence. We urge the leaders of our health system to listen to and be prepared to translate scientific evidence from disaster research into practice, and ethics committees to facilitate rather than obstruct future post-disaster research.

Competing interests:
Nil.

Author information:
Neville M Blampied, School of Psychology, Speech and Hearing, University of Canterbury, Christchurch; Roger T Mulder, Department of Psychological Medicine, University of Otago, Christchurch; M Usman Afzali, School of Psychology, Speech and Hearing, University of Canterbury, Christchurch; Oindrila Bhattacharya, School of Psychology, Speech and Hearing, University of Canterbury, Christchurch; Meredith F Blampied, School of Psychology, Speech and Hearing, University of Canterbury, Christchurch; Julia J Rucklidge, School of Psychology, Speech and Hearing, University of Canterbury, Christchurch.

Corresponding author:
Prof Neville Blampied, School of Psychology, Speech and Hearing, University of Canterbury, Private Bag 4800, Christchurch.
neville.blampied@canterbury.ac.nz

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REFERENCES:

1. Schlebusch L, Bosch BA, Polglase G, Kleinschmidt I, et al. A double-blind, placebo-controlled, double-centre study of the effects of an oral multivitamin-mineral combination on stress. S Afr Med J. 2000; 90:1216–23.
2. Stough C, Scholey A, Lloyd J, Spong J, et al. The effect of 90 day administration of a high dose vitamin B-complex on work stress. Human Psychopharmacology. 2011; 26:470–6.
3. Long SJ, Benton D. Effects of vitamin and mineral supplementation on stress, mild psychiatric symptoms, and mood in nonclinical samples: A meta-analysis. Psychosom Med. 2013; 75:144–53.
4. Young LM, Pipingas A, White DJ, Gauci S, et al. A Systematic Review and Meta-Analysis of B Vitamin Supplementation on Depressive Symptoms, Anxiety, and Stress: Effects on Healthy and 'At-Risk' Individuals. Nutrients. 2019; 11:2232.
5. Rucklidge JJ, Blampied NM. Post earthquake functioning in adults with Attention-Deficit/Hyperactivity Disorder: Positive effects of micronutrients on resilience. NZ J Psychol. 2011; 40:51–7.
6. Rucklidge JJ, Andridge R, Gorman B, Blampied NM, et al. Shaken but unstirred? Effects of micronutrients on stress and trauma after an earthquake: RCT evidence comparing formulas and doses. Human Psychopharmacology: Clinical and Experimental. 2012; 27:440–54.
7. Rucklidge JJ, Blampied N, Gorman B, Gordon H, et al. Psychological functioning one year after a brief intervention using micronutrients to treat stress and anxiety related to the 2011 Christchurch earthquakes: A naturalistic follow-up. Human Psychopharmacology: Clinical and Experimental. 2014; 29:230–43.
8. Sole EJ, Rucklidge JJ, Blampied NM. Anxiety and Stress in Children Following an Earthquake: Clinically Beneficial Effects of Treatment with Micronutrients. Journal of Child and Family Studies. 2017:1–10.
9. Kaplan BJ, Rucklidge JJ, Romijn AR, Dolph M. A randomized trial of nutrient supplements to minimize psychological stress after a natural disaster. Psychiatry Res. 2015; 228:373–9.
10. Chambless DL, Hollon SD. Defining empirically supported therapies. J Consult Clin Psychol. 1998; 66:7–18.
11. Galea S, Nandi A, Vlahov D. The epidemiology of post-traumatic stress disorder after disasters. Epidemiol Rev. 2005; 27:78–91.