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Is Truehope's EMPowerplus Multivitamin Supplement Effective? A Critical Analysis of the Research

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Abstract

Truehope is a company that formulated EMPowerplus, a multivitamin and mineral supplement. The company states that the supplement is the most researched in the world with 34 publications. It claims that EMPowerplus is proven to be effective for a variety of mental health disorders. To ascertain whether such an extraordinary claim is accurate, I critically examined all the published journal articles pertaining to the supplement. Overall, I found that the overwhelming majority of the studies had significant flaws and were too weak and poorly done to substantiate Truehope's claim about the supplement's effectiveness. It is concluded that the people of Truehope are engaging in pseudoscience and should modify their statements about their products to be more honest and accurate. It is hoped that through this paper consumers will learn to cherish the scientific method and strive to apply it by thinking critically when they come across products with extraordinary claims, in order to distinguish items that are evidence-based from those that are not, and to avoid being potentially scammed.

Keywords: Truehope, EMPowerplus, EMP advanced, supplement

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Is Truehope's EMPowerplus Multivitamin Supplement Effective? A Critical Analysis of the Research

Truehope is a company that formulates and sells nutritional supplements. It is best known for its first and top-selling supplement, EMPowerplus, also known as EMP Advanced and EMPowerplus Advanced (Truehope Nutritional Support Ltd. [Truehope], n.d.), which is a blend of 36 vitamins, minerals, amino acids, and antioxidants. Generally, it is marketed to provide benefits to everyone (including children), but it is particularly promoted for improving mental wellbeing. What makes this supplement unique is the company's claim on its website, that it is the most scientifically researched micronutrient product in the world (Truehope, 2021).

This paper aims to evaluate the published literature on EMPowerplus to unearth the extent of its efficacy. It commences with Truehope's claim for its flagship supplement, followed by positive aspects about the research on EMPowerplus with an elaboration on peer review, randomization, placebo control, and double-blind procedures. Thereafter, the limitations of the research are discussed. Included in this section is a discussion on testimonials and the placebo effect, the argument that most of the publications on the supplement lack conclusive evidence for its efficacy, and a discourse on the function of pilot studies, case studies, and confounding variables. Next, to uphold impartiality, two randomized controlled trials (RCTs) conducted on EMPowerplus are analyzed for their strengths and weaknesses, respectively. Stemming from this analysis, the scientific role of replication is examined. It is argued from these RCTs—in consideration with the other publications—that Truehope should limit the claim of EMPowerplus' efficacy to attention deficit hyperactivity disorder (ADHD). A final limitation addressed is the lack of FDA evaluation.

According to the Truehope website, there are 35 published papers investigating the effects of EMPowerplus (Truehope, 2021). Truehope uses these articles as evidence that EMPowerplus is effective for a variety of psychological and neurological conditions, including depression, anxiety, obsessive-compulsive disorder (OCD), ADHD, bipolar disorder, stress, autism, and psychosis.

After reviewing the literature on EMPowerplus, some positive aspects of the research were found. All 35 articles are peer-reviewed, which strengthens the research by reducing the possibility for authors to skew the results with their personal beliefs and biases (Hale, 2018). Furthermore, four of the studies are RCTs, two of which are placebo-controlled and double-blind.

Randomization of the participants to the groups being compared is the best way to ensure they are as identical as possible (Hall, 2012) so that effects observed on the dependent variable can be attributed to the independent variable and not to another variability between the groups. Having one of the groups take a placebo (e.g., sugar pill) helps control for the placebo effect, which is the tendency to feel better after taking any treatment, even if it does not contain any therapeutic agent (Stanovich, 2013). Moreover, in a double-blind trial, neither the participants nor the experimenters know which group the participants are placed in. This double-blind procedure further decreases biases, such as experimenter bias, which is when experimenters' intentional or unintentional expectations about participants influence the results (Cozby & Rawn, 2016). These features of peer-review and traditional clinical testing (i.e., RCTs, placebo control, and double-blind) are considered high standards for the scientific investigation of a therapeutic compound.

Another positive feature of the publications, mentioned on Truehope's website, is that the research comes from 49 independent researchers at 15 universities around the world. The company also asserts that it never funded any of the research. Such research, done independent of any ties to the maker of the product being tested, rationally encourages impartiality.

Despite these positive aspects of the research, there are many methodological concerns and a paucity of evidence to support the claims about the efficacy of this supplement. For instance, there is a page on Truehope's website dedicated to testimonials from consumers on which many people swear by the efficacy of EMPowerplus in relieving and curing their psychological and physical conditions, which range from schizophrenia and mood disorders to spastic quadriplegia and migraines (Truehope, 2021). These results sound impressive. However, as convincing as testimonials seem, Stanovich (2013) argues that they are inadequate as evidence for the efficacy of a given treatment. A major limitation of testimonials is that the relief people notice may be due to the placebo effect. Placebo effects are so powerful that merely suggesting to people that they are given a treatment can be sufficient to make them feel better (Stanovich, 2013). In fact, Taylor and colleagues (2017) state that "any medical procedure, ranging from drugs to surgery to psychotherapy, can have a placebo effect."

Moreover, excluding the RCTs, all the publications—31, to be precise—are not qualified to provide satisfactory evidence that EMPowerplus is effective (see Table 1 for details and citations of the publications). The overarching weakness of these publications is that other than the controlled trials, none of them are true experiments, as they do not have a control group for

comparison. Therefore, they cannot demonstrate conclusive evidence that EMPowerplus causes the effects observed. Even the controlled trials provide weak evidence for causation, for they are not double-blind, placebo-controlled, or randomized.

These 31 publications have various limitations that prevent them from providing strong evidence for EMPowerplus' efficacy. A pilot study, for example, is conducted to see if a proper trial is feasible with the designs or variables being pursued (Leon et al., 2011). The data resulting from a pilot study cannot establish a causal relationship because one, it is not a hypothesis testing study, so efficacy and effectiveness are not assessed; and two, the sample size is typically small (Leon et al., 2011). Moreover, case studies are primarily valuable in the early stages of research, in developing hypotheses to be further tested (Loftus & Guyer, 2002). Due to their limitations, case studies cannot test hypotheses. For instance, they do not include a comparison group to rule out alternative explanations, and there are few controls for biases such as researchers reporting only that which confirms their assumptions (Loftus & Guyer, 2002). Consequently, case studies and pilot studies provide good incentives to continue testing EMPowerplus, but they do not offer evidence that it is effective for a given condition. Most, if not all, of the 31 studies warrant future RCTs.

It is important to note that no person is precisely the same as another. For instance, humans have unique biological differences which interact with other factors, such as diet (Hall, 2012). Therefore, various confounding variables can emerge in studies (Hall, 2012). These variables make clinical trials on humans especially challenging in determining the exact cause of an effect, all the more reason to develop the best design possible. A way to eliminate confounding variables—and thus increase the validity of a study—is through random assignment (Cozby & Rawn, 2016).

Since there is insufficient space to specify the limitations of all 35 publications, the focus will be on the ones that are closest to a well-designed scientific trial, the RCTs. As mentioned, two of the RTCs lack blinds and placebo controls (Kaplan, Rucklidge, et al., 2015; Rucklidge et al., 2012). This in itself poses serious issues, such as the possibility of placebo effects and experimenter bias. Hence, despite being true experiments, they are poorly designed.

The two double-blind placebo-controlled RCTs (Rucklidge et al., 2018; Rucklidge et al., 2014) appear well-designed. In Rucklidge and colleagues (2014), the participants were adults with ADHD. The sample size was 80, which the authors determined—after a pilot study—was

adequate for this experiment to detect a statistically significant effect. The effect sizes ranged around the medium level, varying from .46 to .67, which means the improvements that occurred for the micronutrient group compared to placebo were meaningful (Gravetter & Wallnau, 2014).

Nonetheless, there are notable limitations of Rucklidge and colleagues (2014). The authors primarily relied on clinical interviews and self-reports and noted the need for more objective measures such as functional magnetic resonance imaging. The findings must be interpreted with caution due to some inconsistencies across raters (self, observers, and clinicians). The researchers also mentioned that the generalizability of the improvements is limited. For example, the results may not generalize to those on medication, as most participants were not on medications. From nine nutrients analyzed through blood tests, only three showed significant increases in the micronutrient group at the study's end compared to baseline levels: vitamin D, B12, and folate. The authors did not address the implications of these specific nutrients and the stagnancy of the others analyzed. Perhaps one may improve ADHD symptoms just by taking those 3 vitamins rather than the blend of 36 ingredients EMPowerplus contains (Grohol, 2015). Due to these problems, and especially since no double-blind RCT was done on the supplement before this study, the findings are preliminary and not conclusive evidence.

The second double-blind RCT (Rucklidge et al., 2018) had a larger sample (n = 93). Larger sample sizes in studies generally produce data that more accurately represent the true population value (Cozby & Rawn, 2016). The participants were aged 7–12 and had ADHD. All of them received standardized ADHD assessments on a variety of measures. Also, the researchers reported success in blinding, so guessing which treatment they were taking was no better than chance. This decreases the possibility of expectancy effects. The micronutrient group demonstrated improvement on certain core ADHD symptoms (primarily related to inattention) and on secondary symptoms associated with ADHD, including aggression and emotional regulation.

Notwithstanding, there are noteworthy weaknesses in this study. The major issue is that direct benefit on core ADHD symptoms was small, and these findings varied across raters (clinicians, parents, and teachers). Additionally, there were no improvements on core ADHD symptoms related to hyperactivity-impulsivity. Because the participants were medication-free children, the results might not generalize to children taking medication for ADHD. These

limitations echo the researchers' conclusion that future research and replication are needed to confirm the outcomes of this study, rendering it preliminary.

Rucklidge and colleagues (2018) state that their study partially replicated the other double-blind RCT (i.e., Rucklidge et al., 2014). While they may be correct by using the term "partially," the formula used in the two studies was not identical. EMPowerplus was used in the adult ADHD study, while a micronutrient supplement called Daily Essential Nutrients (DEN) was used in the other study. The former contains 36 ingredients (Rucklidge et al., 2014), and the latter is similar but consists of different amounts and contains four more ingredients, including lithium (Rucklidge et al., 2018). DEN was manufactured by one of the co-founders of Truehope, David Hardy, who left Truehope in 2013 and formed his own company called Hardy Nutritionals.

Attempting to replicate a study by using another formula, even if the ingredients are slightly dissimilar, does not appear to comply with the scientific method. What if it was one or more of the components in DEN, which are not found in EMPowerplus, that had the significant effect? Adding just one active ingredient can affect the outcome of a trial. Hence, the beneficial effects in both studies may not be from the same source, so they cannot be said to replicate each other. It is quite hard to ascertain which ingredient had what effect, if any, especially when factoring in all the alternative explanations, such as biases. The difficulty in pinpointing exactly which part of a multicomponent treatment causes an effect is one reason why scientists typically test one variable at a time (Hall, 2012).

Regardless of different supplements being used, another important problem applicable to both Rucklidge and colleagues (2014) and Rucklidge and colleagues (2018) is that the disorder involved is ADHD. This is only one out of the many aforementioned disorders that Truehope claims its product is proven to benefit. A more honest and carefully worded claim is that the research suggests EMPowerplus *may* help a subset of people with ADHD.

As a final consideration, while Truehope declares the supplement's proven ability to help with mental disorders, the common Food and Drug Administration (FDA) disclaimer, that the product is not meant to treat, cure, or prevent any disease, appears at the bottom of its website (Truehope, 2021). If the company believes EMPowerplus truly works, why does it not have the product evaluated by the FDA after all these years?

In light of the contradictions and flaws in the research associated with the most studied multivitamin in the world (allegedly), Truehope should stop making causal claims, which can

lead to the deception of desperate consumers searching for relief. To avoid engaging in pseudoscience, it would befit the company to accurately modify its claims or acquire more conclusive evidence regarding EMPowerplus' efficacy.

Tables

Table 1

List of 31 Publications with Citations

Number and Type of Publication	Citation
Ten case studies	Frazier et al., 2009; Gurevich & Robinson, 2016; Harrison et al., 2013; Kaplan et al., 2002; Kaplan et al., 2017; Kaplan et al., 2016; Rodway et al., 2012; Rucklidge, 2009; Rucklidge, 2013; Rucklidge & Harrison, 2010
Two case series	Kaplan et al., 2001; Kaplan et al., 2004
Six pilot studies	Frazier et al., 2012; Frazier et al., 2013; Kaplan, Hilbert, et al., 2015; Mehl-Madrona & Mainguy, 2017; Rucklidge, Johnstone, et al., 2011; Rucklidge, Taylor, et al., 2011
Three controlled trials	Mehl-Madrona et al., 2010; Rucklidge & Blampied, 2011; Rucklidge, Johnstone, et al., 2011
Two single case experiments	Gordon et al., 2015; Sole et al., 2017
Two non-experimental follow ups	Rucklidge et al., 2014; Rucklidge et al., 2017
Two quasi-experiments with one-group designs	Gately & Kaplan, 2009; Rucklidge et al., 2010
Systematic review about safety	Simpson et al., 2011
Non-experimental data analysis of a previous study	Rucklidge et al., 2013
Two commentaries	Popper, 2001; Simmons, 2003

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