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Research report

An evaluation of the cognitive and mood effects of an energy shot over a 6 h period in volunteers. A randomized, double-blind, placebo controlled, cross-over study **



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ARTICLE INFO

Article history: Received 10 December 2012 Received in revised form 3 April 2013 Accepted 6 April 2013 Available online 12 April 2013

Keywords: Energy shot CDR System Power of attention Continuity of attention Alertness Working memory

ABSTRACT

Energy drinks are widely available mostly containing glucose, and several have been demonstrated to improve alertness and cognitive function; these effects generally being identified 30–60 min after administration. The present study assessed whether an energy shot without carbohydrates would affect major aspects of cognitive function and also mood in volunteers over a 6 h time period. This randomized, double-blind, placebo-controlled, crossover study compared the acute effects of the energy shot with a matching placebo in 94 healthy volunteers. Cognitive function was assessed with a widely used set of automated tests of attention and memory. Mood was assessed with the Bond-Lader, Beck Anxiety Index, Beck Depression Index, Chalder Fatigue Scales (CFS), and the POMS. The volunteers were requested to limit their sleep to between 3 and 6 h the night before each testing day. Compared to the placebo, the energy shot significantly improved 6 validated composite cognitive function measures from the CDR System as well as self-rated alertness; the benefits on 4 of the cognitive measures still remaining at 6 h. The overall effect sizes of the performance improvements were in the small to medium range and thus notable in this field. In conclusion, an energy shot can significantly improve important aspects of cognitive function for up to 6 h compared to placebo in partially sleep-deprived healthy volunteers.

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Introduction

Energy drinks are widely available and are taken by consumers with the expectation that they will improve alertness and attention. They commonly contain caffeine, B-vitamins, taurine and sugars, in addition to other ingredients depending upon the specific brand (Higgins, Tuttle, & Higgins, 2010). Other energy products have also been developed containing similar ingredients, examples include energy shots and energy gum. Feelings of "low energy" or fatigue can be caused by working too many hours, sleeping too few hours, or the stress in coping with the demands of daily life (Lieberman, 2007). For the public, the definition of energy is complex but has been condensed to "the mental will to engage in an activity" (Geiger, 2004). As such, mental energy is acknowledged to be recognised by the public as essential for accomplishing daily

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activities and for the quality of life and health (Cook & Davis, 2006). The scientific community has traditionally defined energy in terms of physical work or energy output. More recently, efforts have been made to quantify 'mental energy'. A workshop held by the International Life Sciences Institute (ILSI) in 2004 proposed in a model of mental energy comprised of three primary dimensions: cognition, mood, and motivation defined as "the ability to perform mental tasks, the intensity of feelings of energy/fatigue, and the motivation to accomplish mental and physical tasks" (Page S5; O'Connor, 2006). Lieberman (2007) proposed standardised methods for assessing mental energy, concluding that "cognitive tests that assess vigilance, ability to sustain attention, and choice reaction time are optimal for assessment of mental energy" (page 229); while for self-ratings "particular moods, such as vigor and fatigue, are closely identified with mental energy, as measured by the POMS and other questionnaires" (page 232).

Caffeine is the most common ingredient in energy products. It is a well-established natural stimulant, known as a constituent of coffee, tea, some soft drinks and chocolate. Caffeine has been described as the most widely consumed behaviourally active food/drug in the

^{*} Acknowledgement: The study was sponsored by Emord and Associates, Clifton, VA. USA.

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world (Lieberman, 2001). The amount of caffeine in a 5-oz cup of coffee ranges from 40 to 150 mg depending upon how it is made. The amount of caffeine in a cup of tea is lower, from 9 to 50 mg. Cola beverages commonly contain 36–71 mg in a 12-oz serving.

There is a large body of scientific data on the effects of caffeine on cognitive function and mood (Smith, 2011); numerous studies have reported that caffeine, in amounts present in one or more cups of coffee, improves a range of tests of attention and vigilance. Also, when individuals are sleep deprived, caffeine has beneficial effects on mood and attentional performance. There is a bell shaped dose–response effect with caffeine, with increased stimulation up to 500 mg, while with higher doses the benefits start to deteriorate (Lieberman, 2007; Smith, 2011). Caffeine is rapidly absorbed from the digestive tract and distributed to all tissues, including the brain. The peak plasma concentration is achieved 30 min after oral intake and the plasma half-life has been reported to vary from 3 to 10 h depending upon the individual (Higgins et al., 2010).

Most studies of caffeine and energy drinks which have detected improvements in cognitive function and alertness have identified these effects over the 60 or so minutes following ingestion (e.g. Adan & Serra-Grabulosa, 2010; Alford, Cox, & Wescott, 2001; Brunyé, Mahoney, & Lieberman, 2012; Einöther, Martens, Rycroft, & DeBruin, 2010; Haskell, Kennedy, Milne, Wesnes, & Scholey, 2008; Haskell, Kennedy, Wesnes, Milne, & Scholey, 2007; Haskell, Kennedy, Wesnes, & Scholey, 2005; Howard & Marczinski, 2010; Scholey & Kennedy, 2004; Smith, 2011; Smith, Sutherland, & Christopher, 2005). Some studies have studied out to longer periods of up to 2 h, and the enhancing effects of the products tested have either began to fade or passed by the end of this period (e.g. Fine, Kobrick, Lieberman, et al., 1994; Reyner & Horne, 2002; Smit, Cotton, Hughes, & Rogers, 2004). Longer term evaluation is very rare, though one study did measure the effects of guarana 75 mg up to 6 h, finding evidence of a benefit at 6 h on a measure of attention (Kennedy, Haskell, Wesnes, & Scholey, 2004).

The energy shot to be studied is marketed under the trade name 5-h Energy[®]. It is a dietary supplement that contains caffeine, taurine and glucuronolactone, as well as several B-vitamins. It does not contain sucrose or glucose, as it is sweetened with sucralose (Splenda). This clinical study was designed to evaluate the effects of the product compared to placebo on major aspects of cognitive function, alertness and mood in volunteers that were fatigued due to partial sleep deprivation (3-6 h sleep the night before). The study also examined whether or not the product would have an effect on blood glucose levels. The primary hypothesis was that the product would produce a sustained effect upon cognitive function and alertness over a 6 h period. The CDR System was selected as the instrument to assess cognitive function in this study. It has been used to study a wide range of cognition enhancers in volunteer and patient populations (e.g. Wesnes, 2005); including of direct relevance to the present study energy drinks (Scholey & Kennedy, 2004), caffeine (Haskell et al., 2005, 2008) and guarana (Haskell et al., 2007; Kennedy et al., 2004).

Materials and methods

Participants

Healthy volunteers between the ages of 18 and 55, BMI \geqslant 18 and \leqslant 30 (normal weight to overweight, but not obese) were recruited for the study. The subjects were phone-screened prior to scheduling the preliminary screening visit. Women of child-bearing potential had to agree to use appropriate birth control methods during the study. Subjects were excluded if they had any chronic or acute diseases, smoked cigarettes, had any dietary restrictions or had a fast-

ing plasma glucose level >120 mg/dl, or a non-fasting plasma glucose level >140 mg/dl. Those who used any drugs which could affect memory or mental performance (e.g. cholinergic agents, NMDA inhibitors) were also excluded. Those who were taking dietary supplements that might affect memory or mental performance (Ginkgo biloba, ginseng, choline, taurine, Huperzine A, Acetyl-L-carnitine, dimethylaminoethanol, lecithin, phosphatidylcholine, phosphatidylserine or DHEA) were also excluded unless they agreed to a 4-week wash-out period before the beginning of the study.

Investigational products

The sponsor of the study provided the two investigational study products: the energy shot and a matching placebo which was identical in size, appearance and taste. The ingredients are listed in Table 1. The placebo was sugar and caffeine-free with small amounts of flavour ingredients added to simulate the flavour of the supplement. The amount of study product and placebo was approximately 2 oz (60 mL) for each. The formulation of the placebo was created by an independent consultant hired by the sponsor who was unconnected with the conduct of the study. This consultant was on site at the bottling facility to ensure that the bottling, labelling, packing and shipping of all study materials was carried out according to strict standards, and that no tampering with or mishandling of the test products took place.

Study design

This was a prospective, randomized, double-blind, placebo-controlled, two-way crossover study comparing the energy shot and placebo. Blinding was ensured with the use of identical bottles, outer packaging, labelling and colour for the investigation products. Independent review board (ethics committee) approval was obtained prior to the initiation of any study procedures (Copernicus Group IRB, Cary, NC, USA). The study was designed and managed by the Medicus Research LLC Contract Research Organization (Northridge, CA, USA) and was run at the Staywell Research clinical research site also located in Northridge, CA. Subjects were members of the public recruited from a database of volunteers and also by advertisements. All subject visits were performed in the same clinic location which is temperature controlled 24 h a day by an independent HVAC system and using an interior conference room which was not exposed to street noise.

Table 1Investigational products.

ES	Placebo
B-vitamins • Vitamin B6 - 40 mg • Niacin (Vitamin B3) - 30 mg • Vitamin B12 - 500 mcg • Folic acid (Vitamin B9) 400 mcg Energy blend - 1870 mg • Taurine • Glucuronolactone (glucuronic acid) • Malic acid • N-acetyl-1-tyrosine • 1-phenylalanine • Caffeine 157 mg • Citicoline Other ingredients • Water • Flavours • Sucralose (Splenda) • Potassium sorbate • Sodium benzoate	Water Berry flavour Sucralose (Splenda) Citric acid Potassium sorbate Sodium benzoate

http://www.forbes.com/sites/clareoconnor/2012/02/08/whats-in-a-bottle-of-5-henergy/

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