

## **Amyotrophic Lateral Sclerosis and Frontotemporal** Degeneration

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# ALSUntangled 42: Elysium health's "basis"

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#### **RESEARCH ARTICLE**

### ALSUntangled 42: Elysium health's "basis"

THE ALSUNTANGLED GROU

ALSUntangled reviews alternative and off-label treatments (AOTs) for people with ALS (PALS). Here we evaluate 'Basis' therapy for ALS in response to 148 requests (1). As with all our previous reviews, this article will focus on the specific possibility that Basis might slow, stop, or reverse ALS progression. Reviews on potential symptomatic benefits (such as improved pain or energy levels) are outside the scope of our program.

#### Overview: what is basis?

Basis is the first and currently only product being sold by Elysium Health (2). Each capsule of this oral dietary supplement contains two main ingredients, nicotinamide riboside (125 mg) and pterostilbene (25 mg). It is advertised to 'promote well-being at the cellular level' (3). Elysium's website specifically states it 'is not intended to diagnose, treat, cure or prevent any disease, and is intended for healthy adults' (2).

#### Mechanism(s)

One of the ingredients in Basis, nicotinamide riboside, is a precursor to nicotinamide adenine dinucleotide (NAD+). Elysium's website reports that treatment with Basis at their recommended dose (two capsules daily) increased whole blood NAD+levels in healthy human volunteers by 40%(3); these results have not yet been published in a peer-reviewed journal. NAD+is a coenzyme involved in intracellular bioenergetics and signaling, affecting metabolism and homeostasis (4). It is also a cofactor for other enzymes, including sirtuins which can regulate histone acetylation, patterns of gene expression, and responses to oxidative stress (4). The other ingredient in Basis, pterostilbene, is a naturally occurring antioxidant found in blueberries which might also activate sirtuins (5)Mitochondrial energy production (6), histone acetylation and patterns of gene expression (7) are all abnormal in PALS, and there is evidence of increased oxidative stress (8). However, it is not yet clear that any of these abnormal pathways actually drives progression in ALS. Human trials of agents that affect these pathways have generally been disappointing (9). ALSUntangled assigns а 'Mechanism' grade of 'D' (Table 1).

#### Pre-clinical data

A separate method for increasing NAD + decreased mutant SOD1 astrocyte-induced motor neuron death in a cell culture model of ALS (10). Other methods for activating sirtuins have had generally favorable effects across different ALS cell and animal models (11). However, we found no studies specifically using Basis in any pre-clinical models of ALS. Thus, ALSUntangled assigns a TOE 'Pre-Clinical' grade of 'U' (Table 1).

#### Cases

Through an internet search, we located one patient whose blog suggested he took a Basis-like regimen and experienced an ALS reversal (12). He kindly sent us his records. We confirmed that this 33-yearsold male did have a history, exam and EMG consistent with limb-onset ALS. He became progressively weaker over three years. He took a large number of unproven treatments including nicotinamide and Reservatrol (which is similar to pterostilbene (13)) and then experienced a 4-point improvement in his ALSFRS-R score that has now

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Table 1. Table of Evidence	e (TOE) Gr	ades for Basis ir	ı ALS.
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	Grade	Explanation
Mechanism	D	Acts on at least one biological mechanism (increased NAD+) but it is not clear that this mechanism is relevant in ALS
Pre-clinical	U	There are no pre-clinical data on Basis in ALS models
Cases	U	We found no PALS taking Basis
Trials	U	There have been no trials of Basis in ALS
Risks	С	Elysium Health's small, brief duration trial showed no serious adverse events in healthy volunteers; we do not know what percentage experienced non-serious adverse events and we found no safety data at all in PALS

been sustained for 16 months. While this degree of ALS improvement is unusual (14), there are multiple possible explanations for it including a mimic syndrome. We contacted a representative from Elysium Health to inquire about any PALS taking their specific product. They stated that they were aware of PALS taking Basis, but did not have feedback to share. No PatientsLikeMe participants have reported taking Basis for ALS (15). Google search identified no PALS specifically reporting use of Basis. ALSUntangled thus assigns a 'Cases' grade of U (Table 1).

#### Trials

We found no trials of Basis in PALS. Thus, ALSUntangled assigns a 'Trials' grade of U (Table 1).

#### Safety, cost, and dosing of basis

Elysium's website reports there were no serious adverse events in healthy participants taking either taking two (n=40) or four (n=40) capsules or a placebo (n = 40) daily during an eight-week trial (16). The website does not go into details about any non-serious adverse events. We emailed Elysium asking about non-serious adverse events and were told these did occur, but the only one 'possibly related to Basis was mild diarrhea and only at the high dose' (17). We do not know what percentage of Basis treated participants experienced this or any other non-serious adverse event. These data support an ALSUntangled 'Risks' grade of at least C (Table 1). It should be noted, however, that these safety data were gathered in a small sample over a short duration, and have not yet been published in a peer reviewed journal. Also, there are no safety data in PALS.

The cost of Basis is \$1 per capsule, and Elysium recommends a dose of two capsules daily. This recommended dose is not based on knowledge of a clinically meaningful degree of NAD+levels, but rather 'through feedback and anecdotal evidence' (17). We were unable to find any data that would allow determination of a clinically meaningful increase in NAD+levels.

#### Conclusions

Basis has mechanisms of action that could theoretically be useful in treating ALS. It appeared reasonably safe in a small, short duration study of healthy volunteers and it is fairly inexpensive. However, we found no data in preclinical ALS models, no case reports, and no trials in PALS. Based on this lack of data, ALSUntangled cannot currently recommend use of Basis to slow, stop, or reverse the progression of ALS.

#### **Disclosures statement**

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