

# An open-label pilot test for evaluating the efficacy and safety of BodyDetox24

## Background

BodyDetox24 is a product composed and designed to purify the body by detoxification. It is composed of selected herbs and nutrients, whose active ingredients are extracted by a special extraction procedure that provides high activity. Contrary to other detoxifying products which are said to act within weeks, BodyDetox24 acts in a very short time, i.e. within 24 hours. Although the action might seem drastic, the product has been tested in toxicological tests and documented to cause no harm to healthy people.

## Study design

Healthy volunteers were invited to participate in this pilot test by advertisements in a local newspaper and the test was performed at and supervised by a local out patient clinic in Sandefjord, Norway. The test aimed at investigating changes (if any) in blood chemistry parameters and the personal experience of participants by notations in a form for self-evaluation.

*Inclusion criteria:* Healthy, not seriously ill volunteers

*Exclusion criteria* Pregnancy or lactating, gall stone problems, taking vital medicines. (Taking vital medicines was defined as using medicines which had to be taken at regular intervals and where the intake could not be delayed for 4 hours).

Due to the action of BodyDetox24 it is suitable to use the product in non-working days, i.e. during week-ends or holidays. Before entering the test (a couple of days before a week-end, generally on a Wednesday, Thursday or Friday) participants had blood samples drawn for a standard clinical laboratory analysis at day 0. At the same time they were given a self-evaluation form to be filled in before and after using BodyDetox24. After having fulfilled a 24 hour course of BodyDetox24 during the week-end participants returned to the local clinic for a second blood sample within 3 days, i.e. no more than a week was to pass from start to finish of the test.

The self-evaluation form consisted of 4 parameters, which participants should estimate on a 5-step scale before and after taking BodyDetox24. The scale was numbered from 0 (No) to 4 (Very much) for the parameters Energy, Sleep, and General well-being. For the parameter Tiredness the 5-step scale was reversed.

## Results – Clinical laboratory analysis

41 healthy volunteers, 18 males and 23 females, entered and completed the test. An additional group of 15 healthy volunteers participated in the self-evaluation section of the study, so that results from this part of the study are based on a total of 56 included participants.

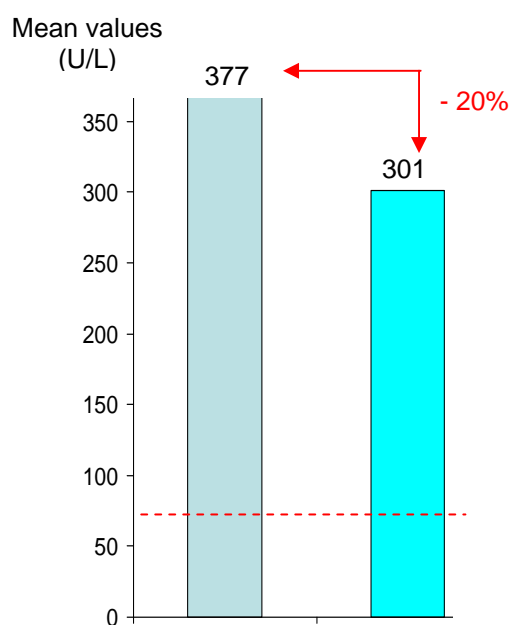
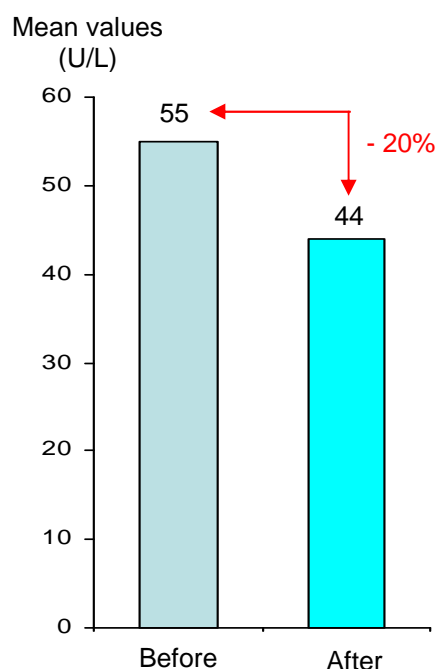
From the standard clinical laboratory analyses the following parameters were judged to be relevant in relation to BodyDetox24:

Parameter	Indication of	Laboratory reference value
Gamma-glutamyl transferase, $\gamma$ -GT) Alanine Aminotransferase (ALAT)	Liver status	< 75 U/L < 45 U/L
Creatinine	Kidney status	45 – 90 U/L
Potassium (K <sup>+</sup> ) Sodium (Na <sup>+</sup> )	Electrolyte status	3,6 – 5,0 $\mu$ mol/L 137 – 145 $\mu$ mol/L
Lactate dehydrogenase, (LD) Magnesium (Mg <sup>+2</sup> )	Safety	< 205 U/L 0,71 – 0,94 $\mu$ mol/L

### Gamma-glutamyl transferase, $\gamma$ -GT

An increase in  $\gamma$ -GT is seen in liver damage, often (but not exclusively) in connection with use of alcohol or drugs.

	Mean value before treatment	Mean value after treatment	Reference value
The whole group	55 U/L	44 U/L	< 75 U/L
Participants with values above the reference before or after the test	377 U/L	301 U/L	< 75 U/L



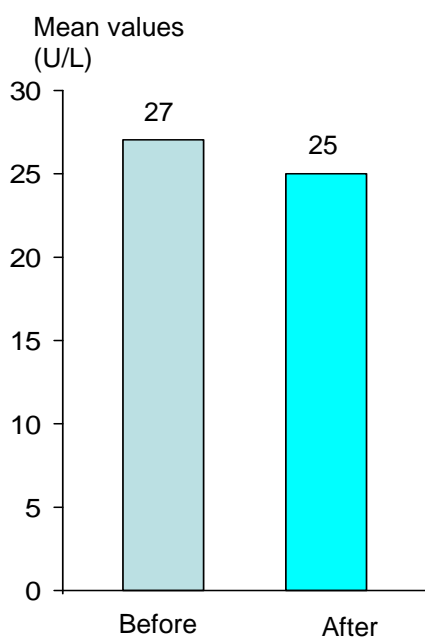
Mean values for the whole study group were below the reference and reduced by 20 %

A small group of participants had mean values above the reference. They were reduced by 20 % but not below the reference.

## Alanine Aminotransferase, ALAT

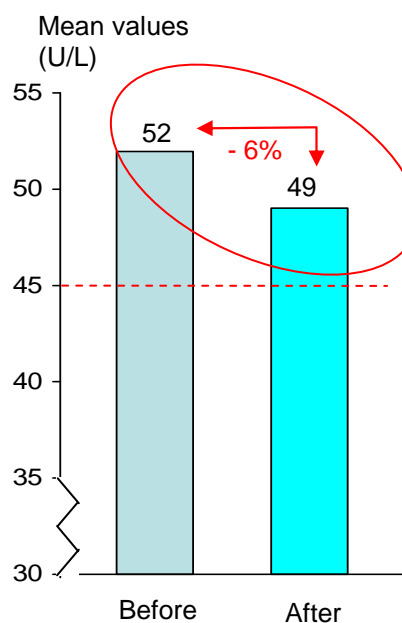
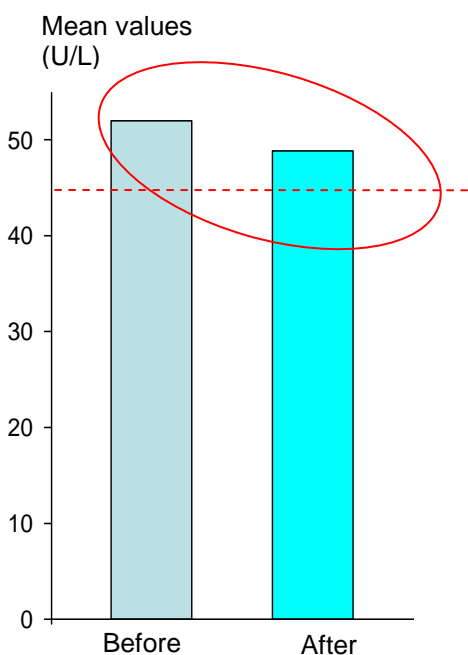
s-ALAT is a marker of liver function. Increased values are seen at liver damage, e.g. at alcohol consumption. No particular change in mean values was recorded in the healthy study group, who all were below reference value.

	Mean value before treatment	Mean value after treatment	Reference value
The whole group	27 U/L	25 U/L	< 45 U/L
Participants with values above the reference before or after the test	52 U/L	49 U/L	< 45 U/L



Mean ALAT values for the whole group was below the reference value (< 45 U/L) before as well as after using BodyDetox24.

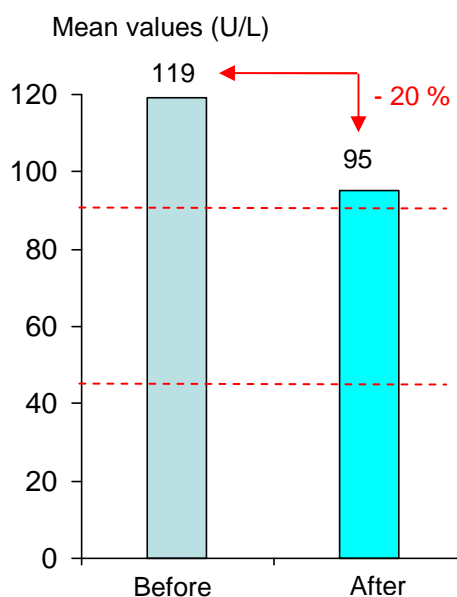
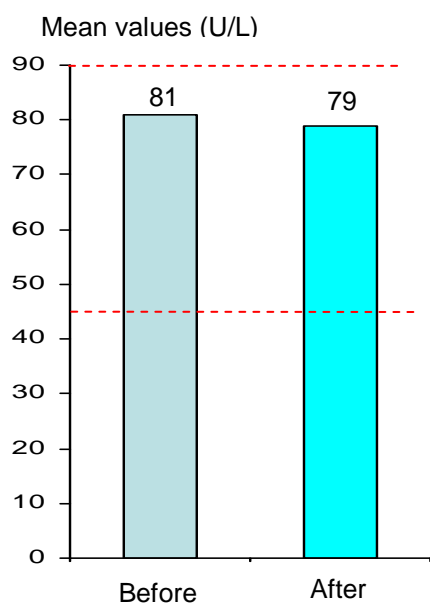
A small number of participants had initial ALAT values above the reference value. Mean values for this group were reduced by 6%. (Figure is shown in detail to the right).



## Creatinine

Creatinine in serum is increased in disturbed kidney function. An increase in s-creatinine for an individual indicates a decreasing kidney function and – inversely – a reduced s-creatinine value for an individual indicates a better kidney function.

	Mean value before treatment	Mean value after treatment	Reference value
The whole group	119 U/L	95 U/L	45 – 90 U/L

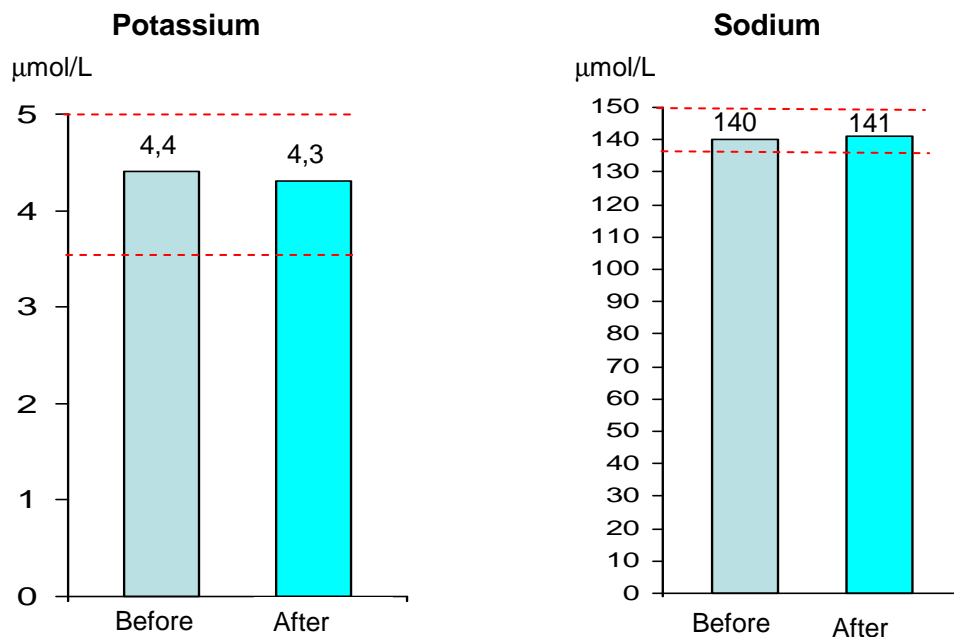


Mean s-creatinine values for the group were normal before and after BodyDetox24

Mean s-creatinine values for a group of participants with elevated creatinine values were reduced by 20 % after BodyDetox24 treatment. The significance of this is not known, but it might indicate an improved kidney function.

## Electrolytes Potassium (K<sup>+</sup>) and Sodium (Na<sup>+2</sup>)

	Mean value before treatment	Mean value after treatment	Reference value
Potassium	4,4 µmol/L	4,3 µmol/L	3,6-5,0 µmol/L
Sodium	140 µmol/L	141 µmol/L	137-145 µmol/L



No changes were seen in mean serum potassium and mean sodium values, indicating that using BodyDetox24 will not cause electrolytic disturbances. The results indicate that BodyDetox24 is safe to use.

### Magnesium (Mg<sup>+2</sup>)

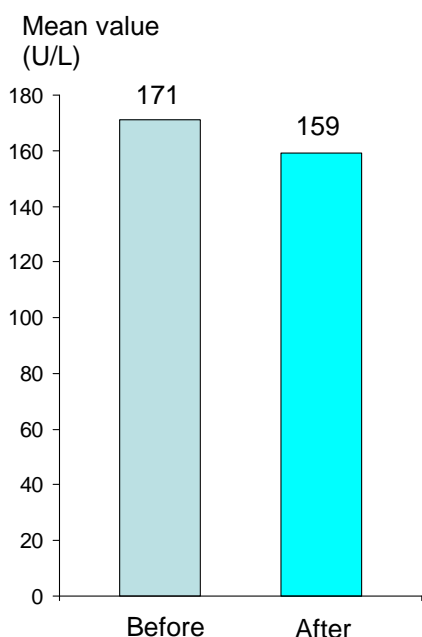
	Mean value before treatment	Mean value after treatment	Reference value
Magnesium	0,87 μmol/L	0,86 μmol/L	0,71-0,94 μmol/L

The main ingredient that empties the colon is Epsom salt (magnesium sulfate). This salt is not absorbed by the body, but it passes through the gut carrying water and waste products with it (osmotic laxative). The result confirms that BodyDetox24 is safe to use

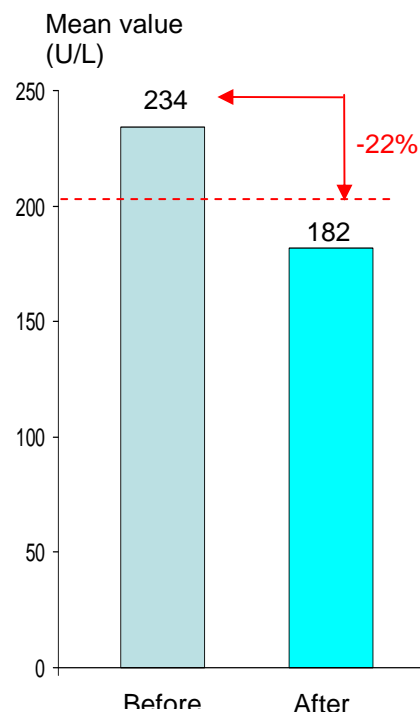
### Lactate dehydrogenase (LD)

Serum-LD is a non-specific marker of cell damage. Increased values in serum might be a sign of damaged red blood cells, heart- or skeleton cells or liver cells.

	Mean value before treatment	Mean value after treatment	Reference value
The whole group	171 U/L	159 U/L	< 205 U/L
Participants with values above the reference before or after the test	234 U/L	182 U/L	< 205 U/L



Mean serum-LD values for the whole group were below the reference value and further reduced (< 205 U/L).



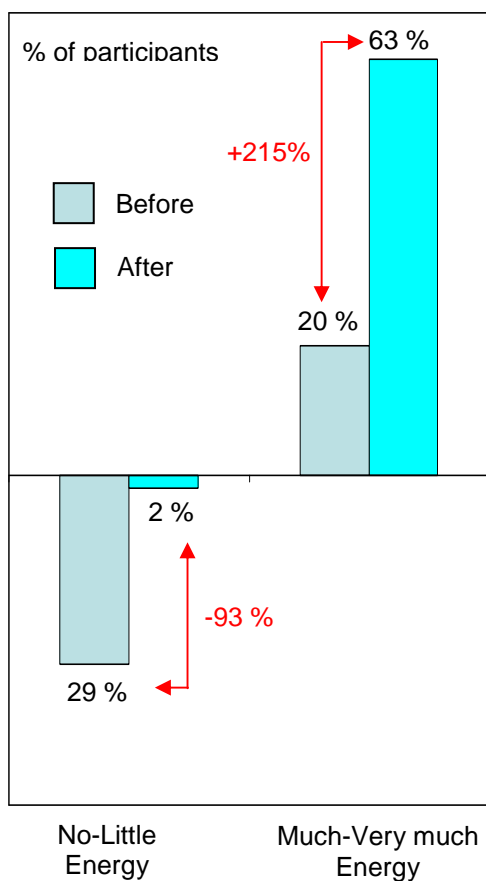
Five participants had s-LD valued above the reference before using BodyDetox24. The mean of their values was afterwards reduced by 22 % to normal.

### Results – Self-evaluation

A total of 56 volunteers participated and filled in a self-evaluation form, noting their personal experiences before and after using BodyDetox24 on a 5-step scale regarding changes – if any – in Energy, Tiredness, Sleep, and General well-being. The scale was numbered from 0 (No) to 4 (Very much) for the parameters Energy, Sleep, and Well-being. For Tiredness the 5-step scale was reversed.

#### Energy

	Before		After	
	Number participants	Percent	Number participants	Percent
No energy (0)	0	} 28,6%	0	} 1,9 %
Little energy (1)	16		1	
Medium energy (2)	29	} 19,6 %	19	} 63 %
Much energy (3)	10		30	
Very much energy (4)	1		4	
Total number	56		54	

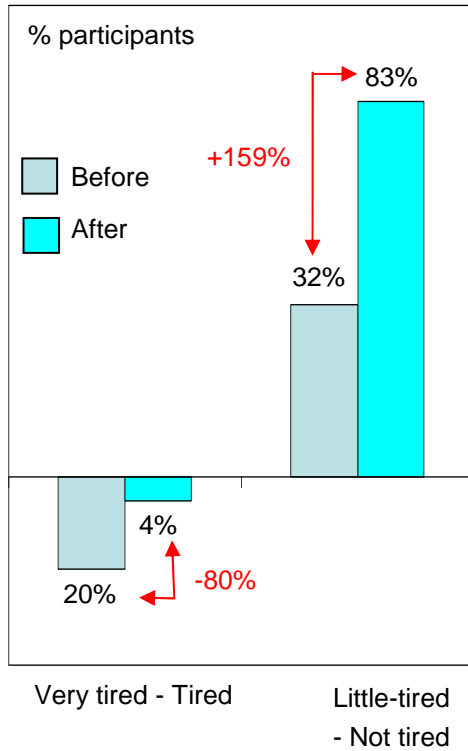


29% of the participants felt no or little energy before taking the BodyDetox24 treatment. This group dropped to 2% - a reduction with 93%

The 20% of the study group, which initially felt energetic (much or very much energy) rose to 63% - an increase by 215%.

### Tiredness

	Before		After	
	Number participants	Percent	Number participants	Percent
Very tired (0)	1	19,6%	0	3,7%
Tired (1)	10		2	
Medium tired (2)	27	32,1%	7	83,3%
Little tired (3)	16		37	
Not tired (4)	2		8	
Total number	56		54	



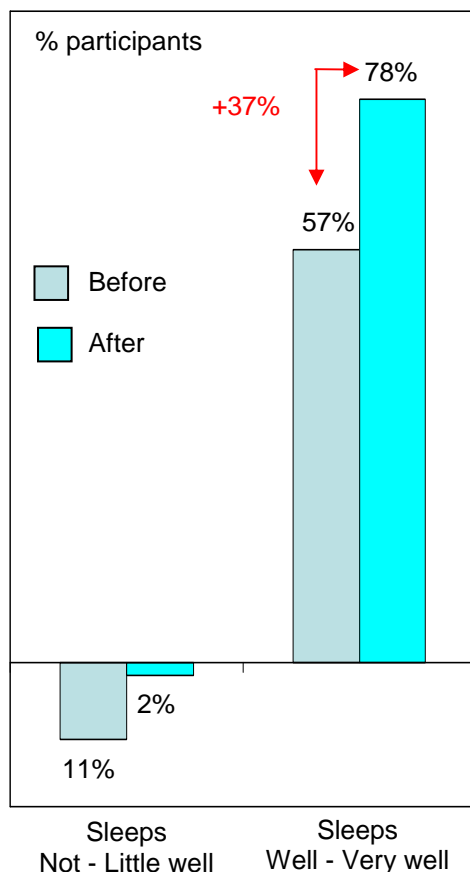
Before taking BodyDetox24 treatment 20% of the volunteers felt very tired or tired. This group was reduced by 80% after treatment.

32% of the participants felt little or not tired before using BodyDetox24. This group increased by 159% to 83% after taking BodyDetox24.

### Sleep

	Before		After	
	Number participants	Percent	Number participants	Percent
Sleeps not well (0)	0	10,7%	0	1,9%
Sleeps little well (1)	6		1	
Sleeps rather well (2)	18	32,1%	11	20,3%
Sleeps well (3)	23	57,1%	24	77,8%
Sleeps very well (4)	9		18	
Total number	56		54	





A minority (11%) the participants slept not well or just a little well before taking BodyDetox24. This group declined further after BodyDetox24.

The group that slept well or very well before taking BodyDetox24 (57%) increased with 37% up to 78%

## Well-being

The parameter "General well-being" was in the final analysis judged to be too unspecific and meaningless, and was therefore not taken into consideration for evaluation.

## Conclusion

This pilot study was performed on healthy volunteers. Mean values for biochemical blood parameters were therefore within normal (below or within reference values).

Single liver values (s-ALAT, s-γ-GT) outside normal values were improved but not normalized. This could be interpreted as using BodyDetox24 might have a positive effect on the liver.

Mean kidney function values (s-creatinine) were normal for the whole group before and after using BodyDetox24. For a small group of participants the mean value was slightly elevated before using BodyDetox24. This mean value was reduced by 20% but not normalized. The significance of reducing a mean serum creatinine value for a group of individuals is not known, but it might be interpreted as an improved kidney function in this sub-population.

No changes in serum electrolytes (potassium, sodium) or magnesium indicates that BodyDetox24 does not cause electrolyte disturbances. Specifically, the normal value for magnesium indicates that the magnesium salt used as an osmotic laxative (Epsom salt, magnesium sulphate) is not absorbed.

Mean values of the non-specific marker of cell damage, lactate dehydrogenase (s-LD), were also within normal range before and after BodyDetox24. Elevated mean values before using BodyDetox24 recorded for a minor group of participants were reduced by 22% to normal, which might be interpreted as an indication of a slight cell repair.

Basically, this small open-label pilot test confirms that BodyDetox24 is safe to use, as indicated by the toxicological data and previous experiences with BodyDetox24. The product functions without causing any harm as indicated by blood analyses. Furthermore, after using BodyDetox24 a majority of the volunteers felt more energetic, less tired and slept better.