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Outcome Monitoring Summary: New York Rescue Workers Project

Over 900 women and men completed sauna detoxification services at the New York Rescue Workers Detoxification project since its inception in 2002 to address exposures sustained during the September 11 attack and collapse of the World Trade Center. Clients come from many walks of life including employment by the NY Fire Department, NY Police Department, Local Union 78 for asbestos work, Department of Sanitation, local businesses, schools, or health services. Yet others were local residents or volunteers at Ground Zero.

This report summarizes results for 475 randomly selected individuals who volunteered to provide extensive medical data both at enrollment and again on completion of the regimen for outcome monitoring purposes. In this way, paired data could be analyzed for change.

In addition to extensive medical examinations that include blood chemistry panels (as indicators of organ function), staff routinely collect data to assess the program's goals of improved quality of life, improved health, and reduction in symptom severity.

What improvements are seen in their quality of life and concern for health?

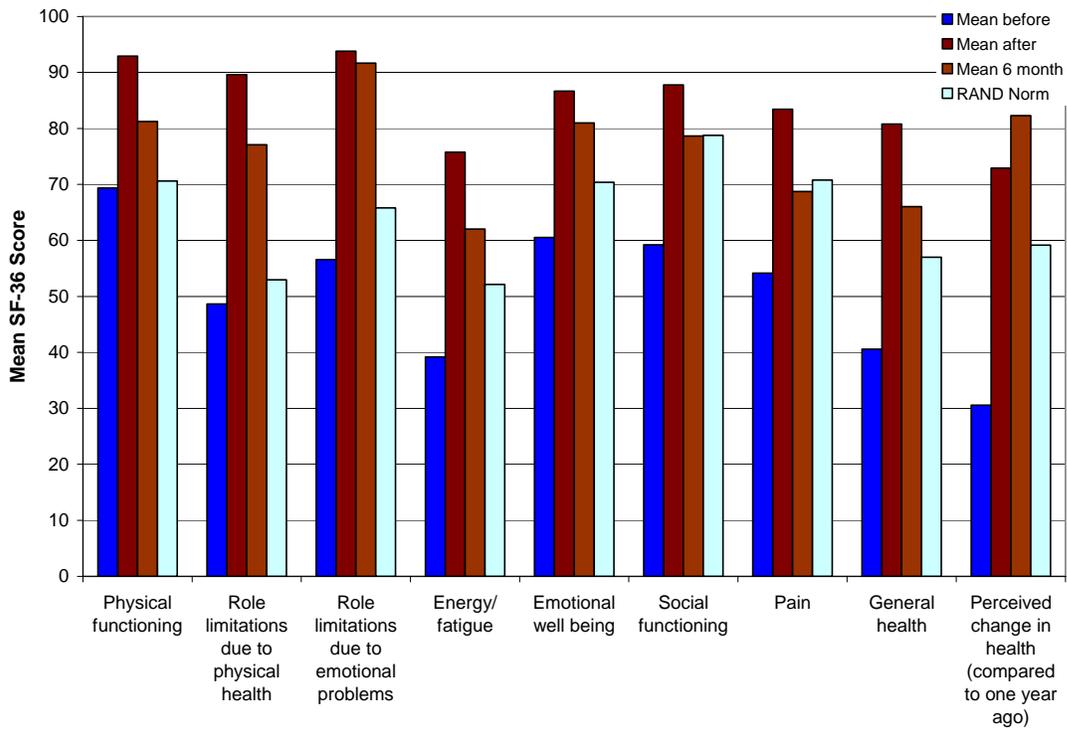
The RAND SF-36 taps eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, general mental health, social functioning, energy/fatigue, and general health perceptions. It also includes a single item that provides an indication of perceived change in health. RAND has published "healthy population" scores for comparison.

Implemented during the last few years of conducting the project, 188 clients have completed before and after surveys with a random 25 clients contacted and asked to complete surveys at six months after completing the sauna regimen.

For each category, New York Rescue Worker clients were at or below scores obtained from a general population in all health categories. On completion of the detoxification regimen, clients had scores significantly above their pre-treatment scores and significantly above the norms for all categories. Even at six months after completion, client scores remained well above their pre-program levels.

*Change in Medical Outcomes with Detoxification
 (RAND SF-36 Item Health Survey)
 before/after n=188; 6-month n=25*

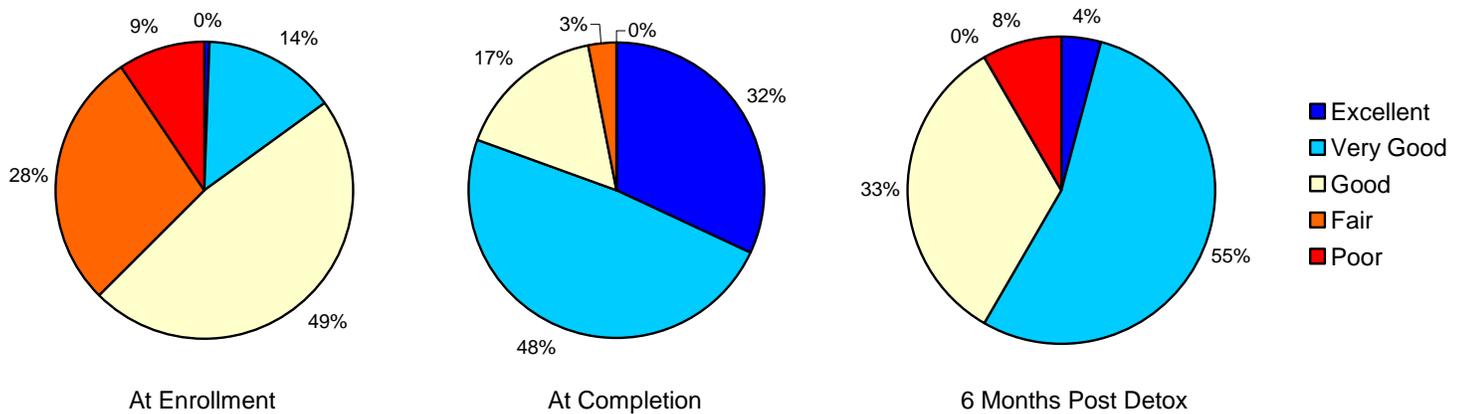
p < 0.001 when comparing before/after scores for all health categories



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At enrollment, only 14 percent stated their current health was very good and none stated they were in excellent health. Additionally, 86 percent of these participants reported their health was poor, fair or good when they enrolled in the program. At completion 80 percent stated their health was very good or excellent and six months later 59 percent of clients still maintained this level of good health with an additional 33 percent of clients reporting good health.

Improvement in Self-Reported Perception of Health
n=475



On average it takes 33 days, seven days a week, to complete this regimen. Participants who are employed maintain their work schedules during this period.

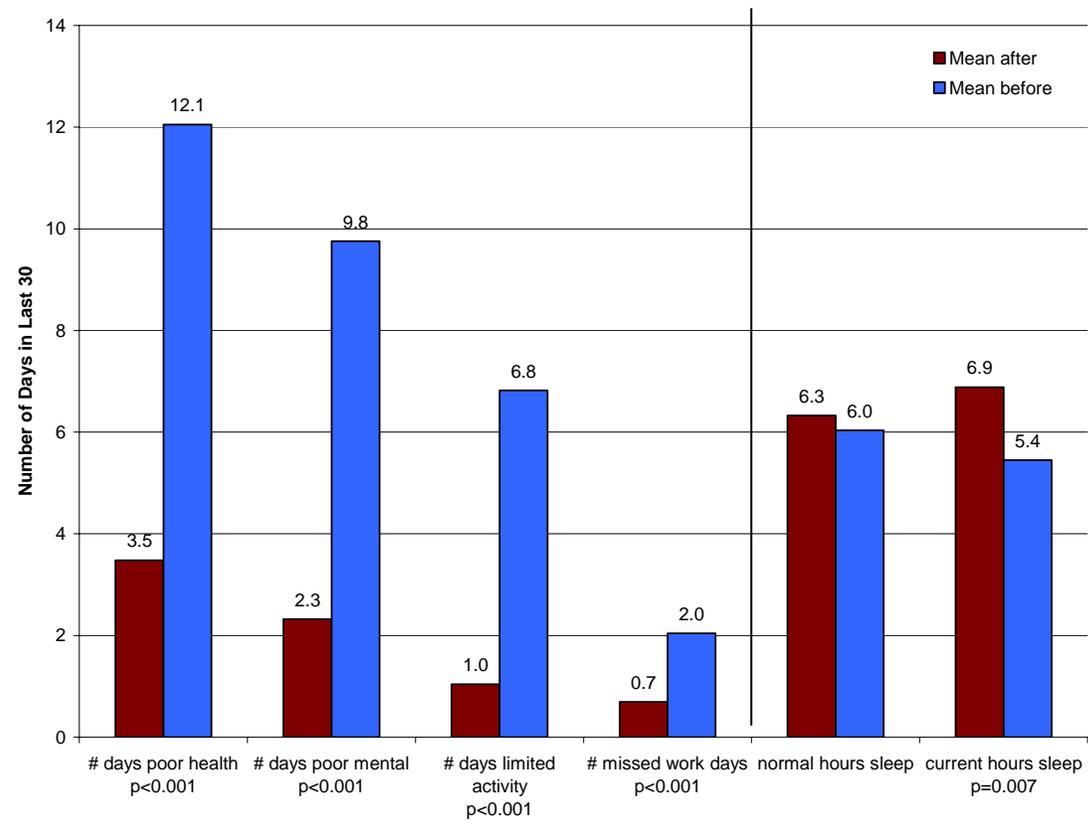
Participants report averaging 2.0 days of missed work during the 30 day period prior to starting their detoxification program. They also averaged 12.1 days of poor health including 6.8 days when their health situation caused them to limit their activities.

On completion of their detoxification regimen, participants missed less than a day of work during the previous 30 day period, a period of time when they were participating in the detoxification regimen. Their health and emotional state are vastly improved and they average one day of limited activities.

Finally, many clients state they cannot sleep well. Although what they consider their normal hours of sleep does not change much, their actual sleep patterns vastly improve from 5.4 hours per night to nearly 7 hours.

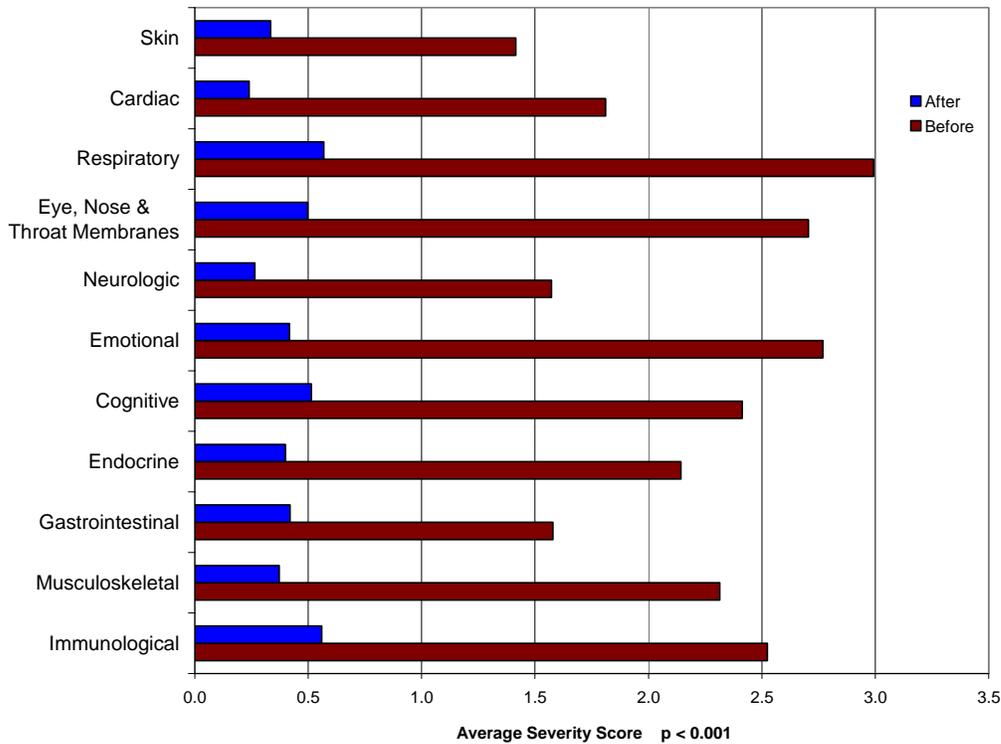
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Improvement in Missed Work Days, Days of Limited Activity, and Sleep Patterns n=475



Participants are asked about 58 different symptoms that provide information on eleven key body systems where symptoms are commonly associated with chemical exposures. Clients report remarkable reductions in the severity of each of these categories.

Change In Symptom Severity With Detoxification
n = 440



Each category assesses 4-5 specific symptoms. Answers range from 0 indicating no symptoms of that type to 10 indicating that the described symptom is severe.

Change in Intelligence Quotient:

Mean intelligence quotient scores for these clients increased from 112.2 to 116.4, a change that was statistically significant for this group (p < 0.001). Clients receive a different test version at each administration time.

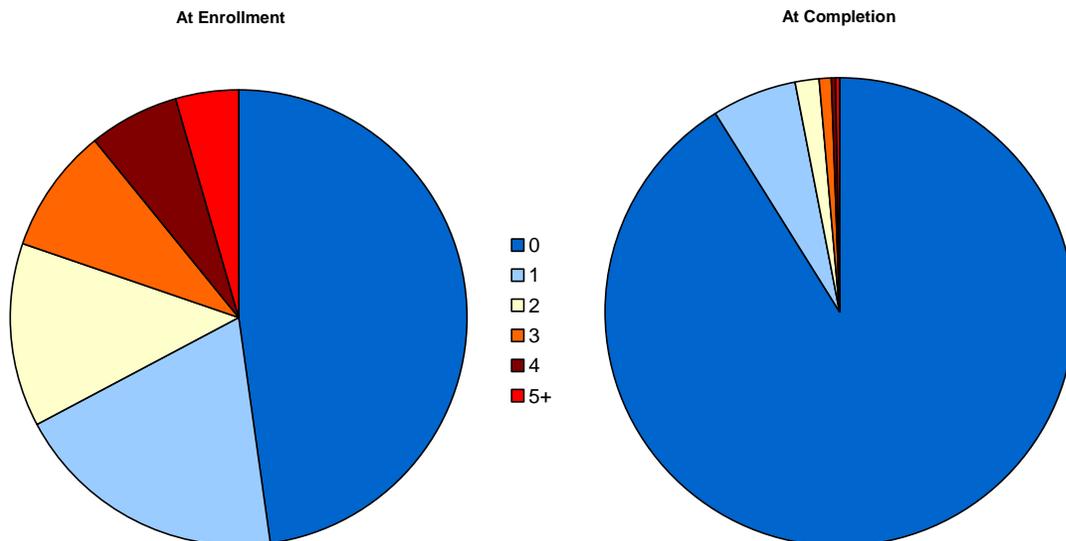
Need for medication:

Over half of these clients are being prescribed a variety of medications in attempt to reduce symptoms. The most commonly-prescribed are medications aimed at opening the airway including Albuterol (a non-steroid drug), Advair (a steroid drug), and Pulmicort (an inhaled steroid), often prescribed in combinations along with Nexium (for Gastroesophageal reflux disease - GERD), Prednisone (a steroid-based, general anti-inflammatory drug), and Ambien (for short-term treatment of insomnia). A number of clients are also taking various thyroid and other hormone-related medications.

While these medications have been demonstrated to be valuable tools for physicians, most are intended for short-term use. Clinical trials have not evaluated their use over the course of several years, or their use in the combinations that are common among rescue workers.

Many of these medications are associated with high incidences of upper and lower respiratory, gastrointestinal, nervous system and mood, and musculoskeletal adverse events, side-effect profiles that make the use of these drugs undesirable for longer than the absolutely necessary periods—particularly in a chemically exposed population.

Number of Medications Taken to Abate Symptoms
n=475



Most clients are concerned about the number of medications they are taking. As symptoms abate during the program, many medications can be reduced with physician supervision. Upon completion of detoxification, 96.5 percent of the participants in the funded group were completely free of the need for any medications.

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Blood chemistry tests and organ function:

Results are obtained for a panel of standard laboratory blood chemistry tests including complete blood cell count (CBC – tests for a variety of anemias), comprehensive metabolic panel (status of the kidneys, liver, electrolyte and acid/base balance, blood sugar and blood proteins), thyroid panel (hormones that regulate metabolism and energy balance) and blood lipid panel.

The majority of test results are within the normal range for a healthy person. However, several key tests indicate substantial health improvements as follows.

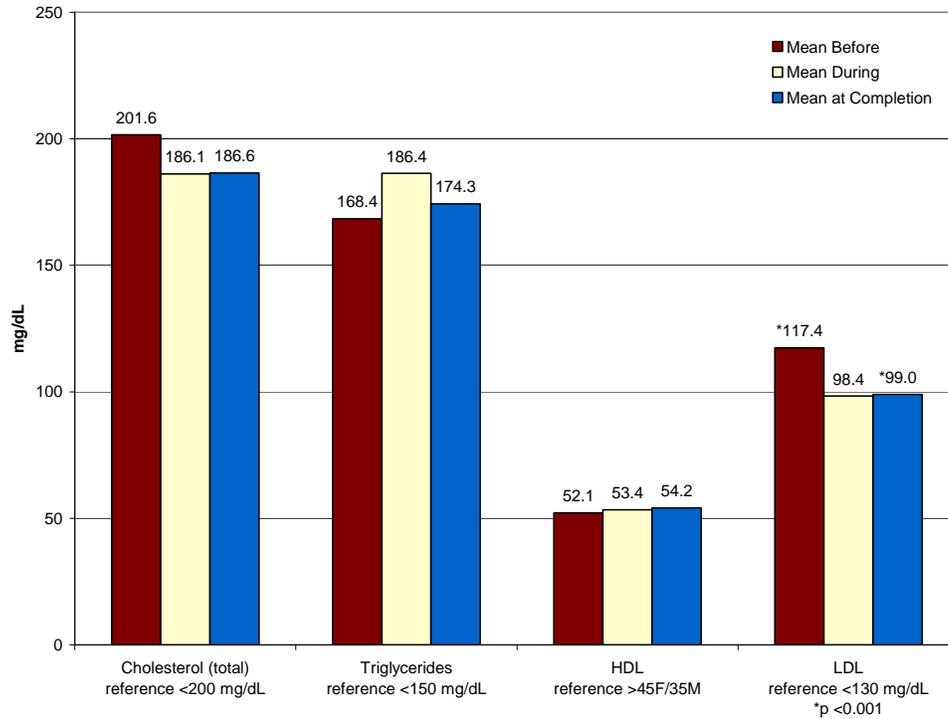
Blood Lipid Profile:

Components of the detoxification regimen, particularly niacin as well as exercise, stimulate release of fatty acids and triglycerides from tissues into the blood thereby mobilizing fat stored toxins. This is reflected in a temporary increase in blood triglycerides in program participants that begins to return to starting levels by completion of the program. It is important to note that evidence assigning risks to elevated triglyceride levels are not that compelling. Cardiac and other health risks are associated more strongly with elevated low density lipoprotein (LDL) and lowered high density lipoprotein (HDL). Both total cholesterol levels and LDL improve markedly during the detoxification regimen.

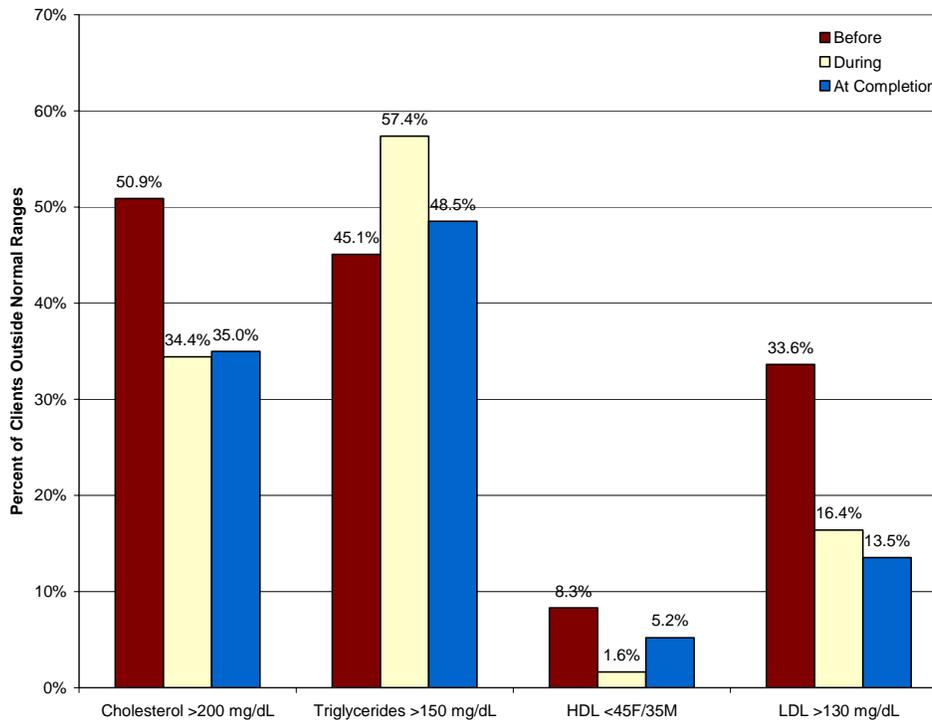
There is emerging evidence that exposure to chemicals may increase low density lipoprotein (LDL) and total cholesterol. Of those clients with elevated cholesterol and LDL levels at enrollment, many return to more ideal levels during the detoxification regimen. Of those who remain above the reference levels, most have moved toward reference values.

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*Change In Blood Lipid Profiles With Detoxification
n = 475*



Change in Percent of Clients with Blood Lipid Profiles Outside the Reference Range



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Thyroid function:

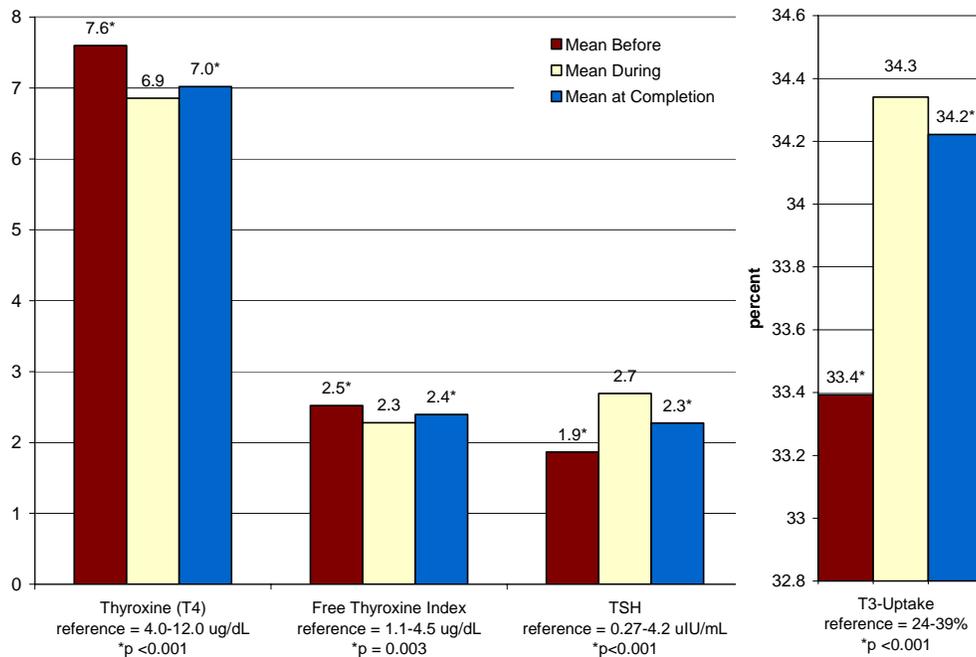
Hormones regulate the activity of most of the vital organs in the body. Pollutants, especially PCBs and heavy metals, disrupt endocrine function, particularly the thyroid and adrenal glands.

Thyroid hormones regulate metabolism and energy balance, as well as growth, development and activity of the nervous system. They also stimulate carbohydrate and fat breakdown and increase protein synthesis. Effects associated with abnormal thyroid function include mood disorders, especially depression and anxiety, low energy, weight change, reproductive and skin problems, and altered cholesterol levels.

There is also emerging evidence that contaminants disrupt the hormone function of white fat – an organ producing hormones that regulate energy level, inflammation, and cravings. Very recent understanding of fat-secreted hormones shows a direct regulatory effect on pituitary and thyroid hormones. This may be a key link explaining the relationship between fat-stored toxins and altered thyroid function.

Average levels of thyroid-related hormones are shown below. Although mean values are not outside the norms, approximately 25 percent of participants had abnormal thyroid hormones at the start of treatment. All of these showed improvement by treatment end. Statistical significance was calculated based on pairs of before/after samples.

Change In Thyroid Profiles With Detoxification
n = 475

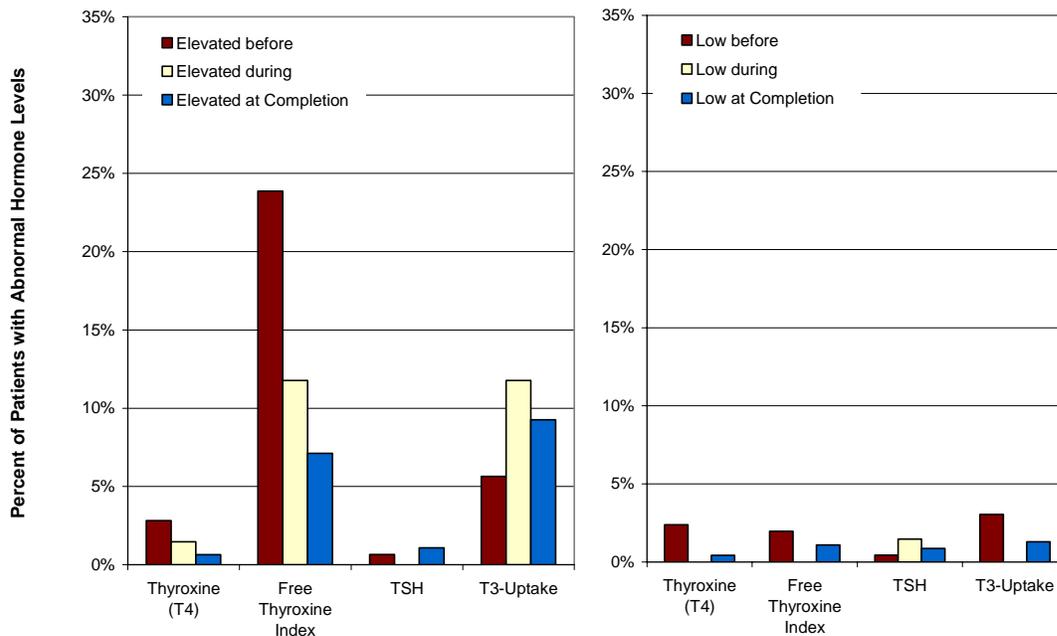


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The patterns seen in clients outside the normal range present an interesting picture. The elevated Free Thyroxine and T3 levels seen in a quarter of the clients indicate an overactive thyroid that is not caused by overactive pituitary function as indicated by relatively normal TSH levels. Most of the thyroid hormone circulating in the blood is bound to transport proteins and is measured as Thyroxine. When thyroid hormone is bound, it is not biologically active. Only a very small fraction of the circulating hormone is free (unbound) and is biologically active.

Thyroid hormone regulates essential functions in every cell of the body including regulating basal metabolic rate and the rate of oxygen use; protein, fat, and carbohydrate metabolism; and vitamin metabolism. Further, thyroid hormones act on specific organs and body systems including glucose metabolism and release of cholesterol by the liver, increased stomach secretion of digestive juices, nervous system health, various reproductive functions including conception and milk production, and it promotes skin health by regulating hydration and exocrine secretions.

Decrease in Percent of Clients with Thyroid-related Hormones Outside the Reference Range



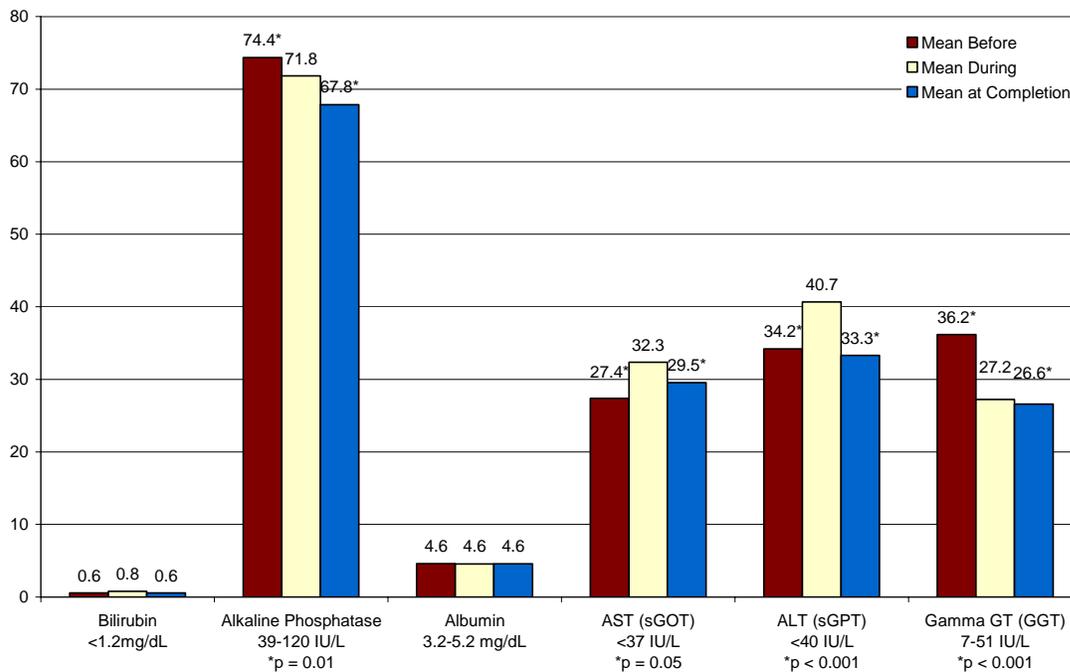
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Safety of the detoxification regimen:

One study of 103 individuals (Schnare et al 1982) notes that the detoxification regimen is well tolerated with only minor complications. A second safety study (Tsyb et al 1998) reviewed the medical status of individuals who had completed detoxification to address exposures sustained during the Chernobyl catastrophe and determined that there were no adverse effects associated with the regimen. This regimen has since been safely delivered to tens of thousands of individuals with a variety of exposures.

To monitor the safety of this regimen, every client completes daily reports and is monitored for water intake, electrolyte intake, blood pressure and cardiac rate daily by trained staff. Additionally, liver function is monitored as a component of the blood chemistry testing. Although two liver enzymes increase somewhat during the detoxification regimen—likely reflecting increased liver detoxification activity—the overall liver profiles remain within the normal ranges for most clients with an overall picture of good liver health.

Liver Function Remains Healthy During Detoxification
n = 475



To analyze the safety of this regimen specifically with respect to those exposed during the attack and collapse of the World Trade Center, the Research Director FASE reviewed the daily report forms of 100 sequential medical folders.

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In contrast with the severe and often debilitating symptoms seen prior to enrollment, clients begin to feel remarkably better and more energetic in a matter of days. All but one client (who spent only one day on the program) remarked on their reduction in symptoms and return to health.

Of the 100 enrolled clients, the completion rate was 84 percent with an average program length of 33 days (range is 19 – 74 days). The average length of time on the program for those who did not complete was 25 days (range is 1 – 54 days). Medical reasons for discontinuation and adverse events are summarized below however the main reason for discontinuation was a conflict with work or family schedules (10 percent).

All clients experienced mild events that they often related to earlier lifetime incidents or specific exposures including 9-11. These cleared with continued participation on the program including; mild flu-like symptoms (87 percent), gastrointestinal discomfort or nausea (42 percent), muscle or joint aches (40 percent), nasal congestion (35 percent), sleeplessness (33 percent), emotions (31 percent), fatigue (24 percent), and headache (21 percent).

Many clients (38 percent) had a black or colored discharge in their sweat, some at multiple times in the program; different colors at different times were common.

Fifteen clients had moderate adverse events as these required them to miss program days; sleeplessness (10 percent), fever (4 percent) and headache (1 percent). All of these resolved and the individuals completed their program.

Although a staff physician is available at the request of the client, only 13 clients needed to see the doctor. Of these, five visits were about issues unrelated to the regimen, including a sprained ankle from playing softball – this client noted his returned energy and enthusiasm.

Six individuals did not complete the regimen due to medical events and requested a medical consult. Three clients did not comply with sleep or diet recommendations (avoid fatty foods, caffeine) given them during their orientation. One person had serious muscle cramps prior to enrolling in the regimen and was unable to complete the program. One person developed a hernia from moving furniture, took time off to address the hernia and has not resumed the program. One person who was unhappy with her post 9-11 obesity, became interested in weight loss and has simply not made time for her final treatment examinations.

In summary, although there are a number of common, transient discomforts associated with the regimen, this review demonstrated that adverse events are rare and not of a serious nature. Clients are well prepared for the discomforts that do occur and continue through them to achieve the full results of program completion.