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Combinatorial Nutraceutical Supplement Pill (CNSP) stimulates naïve adult telomerase positive stem cells *In-Situ to* reverse signs and symptoms in multiple human health concerns

Henry E Young [1, 2, *]

[1] *Dragonfly Foundation for Research and Development, Macon, GA 31210 USA.*
[2] *Henry E Young PhD Regeneration Technologies, Macon, GA 31210 USA.*

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Abstract

Previous IRB-approved studies demonstrated that a rare population of endogenous adult telomerase positive stem cells (aTPSCs), isolated and activated ex vivo, displayed a 100% safety record for reinfusion and an 86% efficacy at reversing signs and symptoms in 97 individuals in 18 disease states. Recent studies demonstrated that these rare aTPSCs could also be activated in vivo by ingestion of a combinatorial nutraceutical supplement pill (CNSP). With IRB permission, CNSP was originally developed for an individual too fragile to undergo the fresh isolate aTPSC technologies. Without any other medical intervention, ingestion of CNSP for 12 months raised his ejection fraction from <10% to about 50%. Based on the results from his study (n=1) [100% safe and 100% efficacious], we received IRB permission to expand the number of clinical trials to determine the effectiveness of using CNSP for other health concerns. Herein, are the preliminary results from 40 people in 28 health concerns utilizing CNSP only and CNSP with other treatment modalities, to affect a better quality of life. Participants were assessed in phase-0, open access, open ended clinical trials, for 1-4+ years. Participants in all 28 clinical trials demonstrated 100% safety and 100% efficacy at reversing signs and symptoms in their respective health concerns, giving them an apparent better quality of life.

Keywords: Adult; Telomerase; Stem Cells; Chronic Diseases

1. Introduction

Embryonic stem cells (ESCs), induced pluripotent stem cells (iPSCs), and mesenchymal stem cells (MSCs) have been proposed as the “go to” stem cells for regenerative medicine. Unfortunately, their results in clinical trials have shown less than stellar results. When ESCs and iPSCs are implanted in their naïve state they form teratomas. The ESCs and iPSCs need to be pre-incubated to defined cell types before implantation, thus negating teratoma formation, but also negating their inherent plasticity for completely repairing tissues. While implantation of MSCs has shown to be 100% safe, their efficacy is 1-5% for reversing signs and symptoms in various disease applications [1-30].

A very rare population of endogenous telomerase positive stem cells (aTPSCs) was discovered in 1975 and extensively examined for their capabilities for forming 69 separate cell types within 15 species of adult animals, including humans, Figure 1 [31-33].

* Corresponding author: Henry E Young

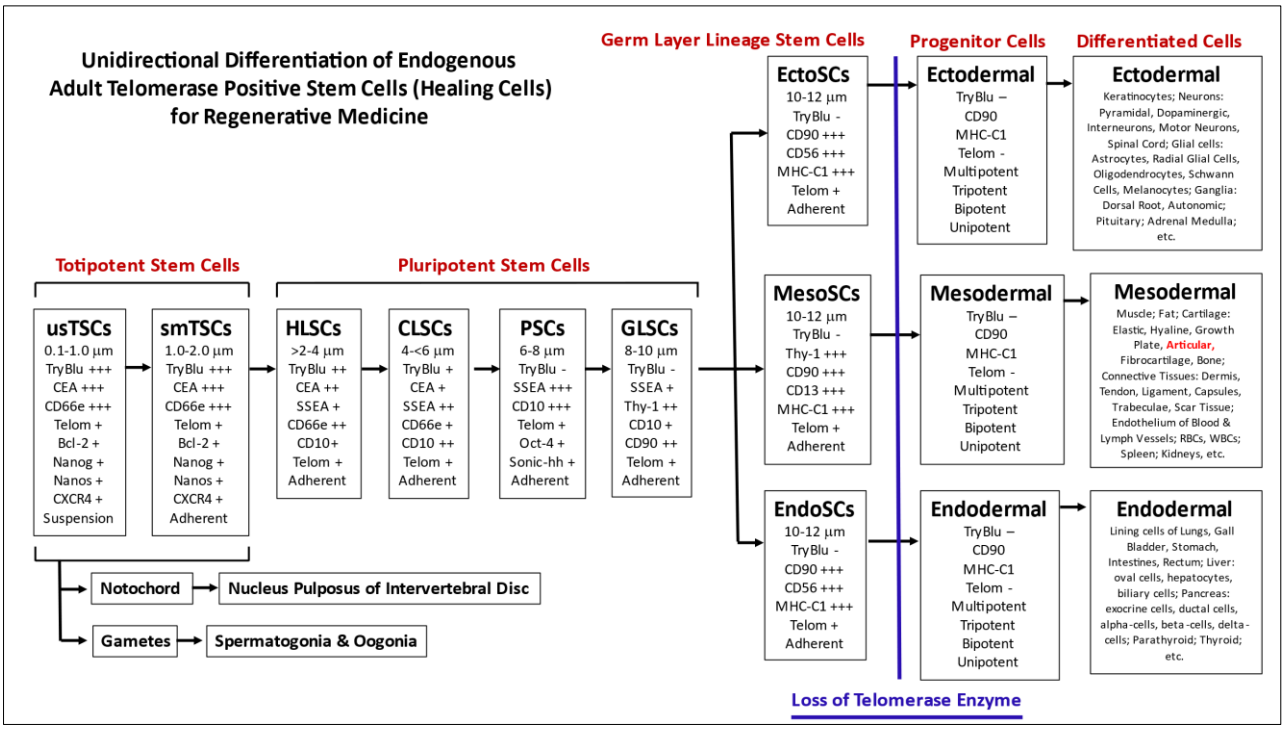

Figure 1 Summary of differentiation potentials of aTPSCs with respect to subcategories, size, Trypan blue staining, cell surface markers, expressed genes, growth in culture, and differentiation potential [32]. *Reprinted with permission from Young HE. Fresh Isolate Adult Telomerase Positive Stem Cells: An addition to Embryonic Stem Cells (ESCs), Induced Pluripotent Stem Cells (iPSCs), and/or Mesenchymal Stem Cells (MSCs) for Regenerative Medicine. GSC Advanced Research and Reviews. 2023; 16(1):066-081*

The patented fresh isolate aTPSC technologies further explained the FDA-mandated minimally invasive techniques to isolate, activate ex vivo, and reinfuse activated telomerase positive stem cells in particular locations for various disease treatments [34]. In an IRB-approved study, utilizing aTPSC fresh isolate technologies with 97 participants across 18 chronic diseases or health concerns demonstrated that the isolated, ex vivo activated, and reinfused aTPSCs were 100% safe to use with an averaged efficacy of 86% for reversing signs and symptoms in their respective diseases [32-52]. These results suggested that fresh isolate aTPSC technologies could be useful as an additional stem cell source for regenerative medicine [32-34].

One individual that was denied entrance into the fresh isolate aTPSC technology trials had been treated for diagnosed leukemia with multiple chemotherapeutic drugs that severely damaged his heart. One week following surgery for a 5-way CABG (coronary arterial bypass grafting) and 15 drug eluting stent procedures, he suffered a massive myocardial infarction. He left the hospital with less than 10% ejection fraction, could not walk ten steps without passing out, and his name was placed on the national registry for heart transplants by his cardiologist. Due to his reduced ejection fraction, he was deemed too fragile to permanently remove oxygen-carrying blood for the fresh isolate aTPSC cardiac therapy [53].

A combinatorial nutraceutical supplement pill (CNSP) was designed to activate the aTPSCs in situ, without the aTPSCs ever having to leave the body for activation and then reinfusion [54]. CNSP combined the proliferation agent and mobilization agent used for the fresh isolate aTPSC technologies with other biological agents discovered during factor testing with the aTPSCs [32,34]. CNSP was designed to stimulate symmetrical cell division in the maternal aTPSCs to produce equivalent maternal stem cells and daughter stem cells. To stimulate the mobilization of the resultant daughter cells from their connective tissue niches and into the blood stream. To increase circulation to all tissues and organs throughout the body. To activate in situ the aTPSC homing receptors for damaged tissues. To activate in situ aTPSC receptors for tissue resident inductive exosomes to direct localized tissue repair. To support a strong innate immune system, which is key critical for healing without scar tissue formation. And to prevent tissue overgrowth [34]. Results from the initial cardiac myopathy study showed that CNSP was 100% safe to ingest and over a 12-month period raised his ejection fraction to approximately 50% [53].

The hypothesis to be tested was "**CNSP can be used to activate aTPSCs *in-situ* to reverse signs and symptoms in multiple health concerns**". We believe CNSP is an alternate technology, besides the fresh isolate aTPSC technologies, to use aTPSCs for regenerative medicine.

2. Material and methods

In an IRB-approved protocol for an open access, opened ended, everyone gets treated phase-0 clinical trial, forty people were treated with CNSP only or CNSP in combination with one or more multiple treatment modalities. Participants were instructed to ingest CNSP daily, using a ramp up procedure to achieve their optimum healing dose of CNSP. They started with one capsule of CNSP per day for the first week; then two capsules per day for the second week; then three capsules per day for the third week; and so on and so forth until optimum healing dose was achieved. Optimum healing dose was based on weight of the individual. Optimum healing dose is defined as one capsule of CNSP per 25 pounds body weight. For example, for a 150-pound person an optimum healing dose equated to six CNSP capsules per day. CNSP can be taken any time of day, with or without food.

No Informed Consent dos and don'ts were imposed on the CNSP participants, as were imposed on those in the IRB-approved clinical trials for the fresh isolate aTPSCs technologies [55]. While some participants in the CNSP trials entered before Covid lockdowns, there was a bolus of 20 people that enter the trial at the beginning of Covid lockdowns (2019-2022). Most of those individuals are still in the long-term portion of their trials. The participants were requested to keep a weekly journal comparing signs and symptoms pre-CNSP ingestion to current signs and symptoms after beginning CNSP ingestion.

3. Results and discussion

Table 1 Results from IRB-Approved Clinical Study Protocols for aTPSC Therapy with CNSP

1	Degenerative Disc Disease, Back Pain, Scoliosis	1	None	Individual presented with back pain and 35^{o} from midline scoliosis secondary to degenerative disc disease. Treated with fresh isolates, chiropractic manipulations, and CN-SP – complete resolution of symptoms.	100%
2	Lupus-Induced Glaucoma	1	None	CN-SP + surgery to reduce internal eye pressures from 30+ bilateral to normal: right eye 10 and left eye 12, CN-SP maintaining eye pressures, 4+ years and counting	100%
3	Back Pain	1	None	Fresh Isolates + Chiropractic manipulations + CNSP resulted in reduced pain	100%
4	Degenerative Disc Disease	1	None	Fresh Isolates + Chiropractic manipulations + CNSP resulted in restoration of articular cartilage at facet joints; restoration of topography of intervertebral discs; allow restoration of movement	100%
5	Induced Scoliosis	1	None	Fresh isolates + chiropractic manipulations + CNSP resulted in restoration of 10^{o} from midline to vertical alignment of vertebral column	100%
6	Systemic Lupus Erythematosus (SLE)	1	None	Fresh isolates + CNSP maintaining stasis – 24+ months and counting	100%
7	Idiopathic Pulmonary Fibrosis (IPF)	1	None	Fresh isolates + CNSP maintaining FEV1 at ~70%, with O2 saturation at 99-100%, 24+ months and counting	100%
8	Cardiomyopathy	1	None	Maintaining cardiac output at ~70% with S/D of 106/50 with HR of 60, 24+ months and counting	100%
9	Vision	20	None	Increased color acuity, colors are brighter and sharper	100%
10	Brain Fog	20	None	Decreased brain fog	100%
11	Cognition	20	None	Increased cognition	100%
12	Energy Level	20	None	Increased energy levels	100%

13	Fatigue/Tiredness	20	None	Less Fatigue and tiredness	100%
14	Generalized Aches & Pains	20	None	Gone, systemic pain free	100%
15	Depression	20	None	Decreased depression	100%
16	Outlook on Life	20	None	Better outlook on life	100%
17	Weight Loss	2	None	Weight loss, 30 lbs. in female and 15 lbs. in male – 6 months post CNSP ingestion	100%
18	T12 Paraplegic, loss of both motor and sensory functions below waist	1	None	Regained sensory input from waist to top of knees; can move thighs, both flexion (quadriceps) and extension (hamstrings) – 6 months after starting CNSP, maintaining 12+ months after starting CNSP	100%
19	Hip Pain	1	None	No more hip pain one week after starting CNSP, continues pain free – 24+ months on CNSP	100%
20	Power Lifter	1	None	Damaged wrist and knee joints were injected with autologous aTPSCs, followed by ingestion of CNSP for 12+months. There was a decrease in times between obtaining power lifting best PRs (Personal Records).	100%
21	Post Myocardial Infarction	1	None	<10% cardiac output after MI, could not walk ten steps without passing out, placed on national heart registry for transplant. Within 6 months on CNSP, cardiac output raised to 35%. +6 more months, cardiac output >45%. Playing 9-holes golf weather permitting.	100%
22	Open heart surgery to replace mitral valve	1	None	Maintaining stasis after heart surgery – 9+ years	100%
23	Shingles	1	None	Reduced pain, itching, burning sensations. On a pain scale of 0 to 10; subjective pain is 2/10, most days. When under stress pain increases to 4/10.	100%
24	Squamous Cell Carcinoma	1	None	100% healing of wound with minimal scarring, created by removal of cancer	100%
25	Injured Shoulder / Rotator Cuff	1	None	Healing of the labrum around the head of the humerus, reduced pain to about 5% and increased function to 90%	100%
26	Rheumatoid Arthritis	1	None	Reduced pain, increased ambulation	100%
27	Hair color, Wrinkles, Crepe Skin	3	None	Otherwise, healthy 72-year-old female concerned about gray hair, face wrinkles, and crepe skin. Ingesting CNSP for 12+ months. Hair returning to original hair color (dark brown), ~~and~~ facial topography losing wrinkles, and body losing crepe skin.	100%
28	Severe Crippling Depression	1	None	82-year-old female had lost her husband after 60 years marriage. Seven years later she fell and broke her humerus just below shoulder joint. Initial shoulder joint replacement failed and a second shoulder joint replacement was installed. One year later she broke her arm mid humerus. This was repaired and she was sent to a rehabilitation facility, where she received less than adequate care. She was removed to her home, where she stated "Life is not worth living. I want to be with 'husband', I want to die". She was started on one capsule of CNSP. Two years later she has a better outlook on life. She is currently a spry, ornery, 92-year-old without filters.	100%

Totals 40 Safe Average Efficacy = 100%

Embryonic stem cells (ESCs), induced pluripotent stem cells (iPSCs), and mesenchymal stem cells (MSCs) are the current stem cell forerunners for use in regenerative medicine. If ESCs and/or iPSCs are implanted in their native telomerase positive naïve state, they will form teratomas (a conglomerate of cancerous tissues). To prevent this from happening the ESCs and iPSCS need to pre-differentiated to form telomerase negative cell-specific progenitor cells and/or

differentiated cells. At this point they lose their inherent plasticity in their naïve state, e.g., the ability to proliferate indefinitely and the ability to form any somatic cell of the body [4-13]. Autologous MSCs have demonstrated a safety record of 100% for implantation into adults, but for conditions other than the generation of white fat, hyaline cartilage, and/or endochondral bone, their efficacy for reducing signs and symptoms in various diseases has been 1-5% at best [1-3, 7, 14-30].

In previous studies, aTPSCs isolated and activated *ex vivo* were introduced as a potential fourth category of stem cells for regenerative medicine [32]. Their averaged IRB-approved clinical trial results demonstrated a 100% safety record and an efficacy of 86% at reducing signs and symptoms in 97 adults with 18 various health conditions [35-52]. While most individuals with co-morbidities can withstand the permanent removal of up to 420cc's of blood, other individuals are too fragile to withstand the aTPSC procedures [53].

That was the case for a particular individual whose ejection fraction following a massive myocardial infarction was less than 10% (#21). The individual had been treated for diagnosed leukemia with multiple chemotherapeutic drugs that severely damaged his heart. One week following surgery for a 5-way CABG (coronary arterial bypass grafting) procedure, including 15 drug eluting stents to revascularize his heart, he suffered a massive myocardial infarction. He left the hospital with less than 10% ejection fraction, could not walk ten steps without passing out, and his name was placed on the national registry for heart transplants by his cardiologist. Due to his reduced ejection fraction, he was deemed too fragile to permanently remove oxygen-carrying blood for the fresh isolate aTPSC cardiac therapy [53].

For that individual, with IRB-approval, CNSP was devised to mimic the results from the fresh isolate aTPSC technologies, but without the connective tissue-resident aTPSCs being isolated and activated ex vivo, rather the aTPSCs activated in vivo. CNSP combined the proliferation agent and mobilization agent used for the fresh isolate aTPSC technologies with other biological agents discovered during factor testing with the aTPSCs [54]. CNSP was designed to stimulate symmetrical cell division in the maternal aTPSCs to produce equivalent maternal stem cells and daughter stem cells, using the proliferation agent. To stimulate the mobilization of the resultant daughter aTPSCs from the connective tissues and into the blood stream, the mobilization, GC, agent was used. Additional agents were added to Increase circulation to all tissues and organs throughout the body. To activate the aTPSC homing receptors in situ for damaged tissues. To activate aTPSC receptors in situ for tissue resident inductive exosomes to direct localized tissue repair. To support a strong innate immune system, key critical for healing without scar tissue formation. And to prevent tissue overgrowth [54].

During the first six months of CNSP ingestion his ejection fraction rose from less than 10% to 35%, an increase of >25%, and his name was removed from the transplant registry. Another six months ingestion of CNSP caused an additional increase in ejection fraction to ~50% [53,54]. His results suggested that CNSP could mimic results seen with the fresh isolate aTPSC technologies [47], but at a slower steady rate [53].

Based on his results, the IRB was petitioned to allow expansion of the number of health concerns that CNSP might potentially affect. As shown in Table 1, the CNSP clinical trial was expanded to 28 health conditions with 40 participants in the trial, some for as long as 3-4+ years. The ongoing results from these trials demonstrated some interesting aspects. It was noted that some conditions required only CNSP intervention to affect a positive response for reversing signs and symptoms of particular health concerns, Table 1. #s 8,9-19, and 21-28. Other health concerns required two interventions (fresh isolate aTPSC technologies followed by long term ingestion of CNSP), Table 1. #s: 2,6,7, and 20. And still other health concerns required three interventions to affect a positive response, e.g., fresh isolate aTPSC technologies, CNSP, and chiropractic manipulations, Table 1. #s: 1,3,4, and 5.

Of particular note was the reports from 20 participants that entered the trials during the Covid lockdowns (2019-2023). These individuals reported some rather interesting side effects, not adverse, just interesting. The side effects reported during their first month of CNSP ingestion included increased color acuity, decreased brain fog, increased cognition, less fatigue and tiredness, more energy, systemic pain reduction, decreased depression, and a better outlook on life (Table 1, #'s: 9-16). The remaining individuals in their respective trials either reported a reversal of their signs and symptoms, or alterations in their physiology that impacted their perceived health conditions.

Table 1. #28, is a good example of single intervention with CNSP. An 82-year-old female had lost her husband after 60 years marriage. Seven years later she fell and broke her left humerus just below her shoulder joint. Initial shoulder joint replacement failed and a second shoulder joint replacement was installed. One year later she broke her left arm at the mid humerus region. This was repaired and she was sent to a rehabilitation facility, where she received less than adequate care. She was removed to her home, where she stated "Life is not worth living. I want to be with my 'husband',

I want to die". She started ingesting one capsule of CNSP per day. Two years later, living in her own home with a live-in caregiver, she has a better outlook on life. She is currently a spry, ornery, 92-year-old without filters.

Another single intervention with ingestion of CNSP demonstrated an alteration in their resultant physiology that impacted their perceived health concern. For example, an overweight female (Table 1, #17) began taking CNSP to repair her damaged and painful knees, so she could resume jogging. While taking CNSP she noted a decrease in pain, increased energy, and a 30-pound weight loss. This occurred all within the first six months of CNSP ingestion. With loss of 30 pounds, her knees became relatively pain free and she is jogging daily. Her results suggested that if one area was "repaired", in her case a 30 lb. weight loss, it would have positive ramifications on other areas of the body, allowing her to jog relatively pain free.

Table 2 Number of People Seeking Interventions for Health Concerns in USA and Worldwide

Health condition	**#S in United States**	**#s Worldwide**
Degenerative Scoliosis	6-9 million	416 million
Induced Scoliosis	6-9 million	416 million
Lupus-Induced Glaucoma	3 million	76 million
Back Pain	266 million	619 million
Degenerative Disc Disease	52 million by age 65	403 million
Celiac Disease	3 million	112 million
IBS, Crohn's	45 million	1.2 billion
Systemic Lupus Erythematosus (SLE)	1.5 million	3.41 million
Neurodegenerative diseases	7 million	3.4 billion
Pulmonary Diseases	42 million	65 million
Cardiomyopathy	82.6 million	523.2 million
Vision Loss	200,000	43 million
Brain Fog	99.9 million	600 million
Cognition Impairment	16 million	1.5 billion
Energy Level	3.3 million	24 million
Fatigue/Tiredness	3.3 million	24 million
Chronic Pain	68.7 million	1.5 billion
Depression	21 million	304 million
Weight Loss	5.9 million	2.5 billion
Paraplegic	131 million	15.4 million
Quadriplegia	4 million	15 million
Hip Pain	300,000/year	4.5 million/year
Post Myocardial Infarction	7.9 million	30.4 million
Injured Shoulder / Rotator Cuff	4 million	2 billion
Osteoarthritis	63 million	595 million
Rheumatoid Arthritis	1.5 million	18 million
Hair color, wrinkles, crepe skin	80 million	103 million

In other instances, it was noted that someone might need two interventions to affect a positive response. For example, a female power lifter (Table 1, #20) was given poor coaching advice early on in her career that resulted in damage to both her wrists and knees. Autologous aTPSCs were injected into her wrists and knees and then followed up with CNSP ingestion. For the past 12 months+ her times between personal best "PRs" (performance records) has been decreasing, compared to post autologous aTPSC intervention, but before ingestion of CNSP.

It was also noted that multiple treatment interventions in some instances were necessary to affect a positive response. This was the case for two individuals with scoliosis, one at 35 degrees from midline (#1) and the other at slightly greater than 10 degrees from midline (#5). Their conditions necessitated multiple treatment modalities, e.g., multiple facet injections of ex vivo activated aTPSCs, continuous ingestions of CNSP, and chiropractic manipulations to bring their respective vertebral columns back to zero degrees from midline.

The results from the fresh isolate aTPSC technologies and CNSP clinical trials suggest that one or more interventions might be necessary to invoke a positive response with respect to reversal of signs and symptoms with respect to various health concerns, whether those concerns are chronic or terminal diseases, psychological manifestations, orthopedic concerns, or cosmetic concerns. The numbers are staggering for the individuals in the USA and worldwide seeking medical and/or pharmacological interventions for their diagnosed and/or perceived health concerns (Table 2).

4. Conclusion

CNSP appears to be one of several potential interventions used to treat individuals with perceived health concerns. The ongoing results from these clinical trials demonstrate that it was 100% safe to ingest CNSP and the resultant efficacy from CNSP only, CNSP with fresh isolate aTPSC technologies, and CNSP with fresh isolate aTPSC technologies and chiropractic manipulations for reversing signs and symptoms was 100% with no apparent adverse side effects. These results suggest that both the ex vivo activated fresh isolate aTPSCs technologies and the CNSP in vivo activated aTPSCs are an addition to ESCs, iPSCs, and mesenchymal stem cells for regenerative medicine

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of informed consent

DFRD is actively recruiting individuals for phase-0, open access, open-ended pro-bono, clinical trials, using CNSP in addition to regular treatment regimens. Informed consent was obtained from all individual participants included in the study.

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