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The Integration of Heart-Centered Hypnotherapy and Targeted Medical Hypnosis in the Surgical/Emergency Medicine Milieu

Robert B. Speigel*

Abstract: Hypnosis and hypnotherapy, and specifically Heart-Centered Hypnotherapy are shown to be effective interventions for the mind-body treatment of physical, emotional, psychological and spiritual injury, disease, and symptoms[1]. Hundreds of highly trained mental health professionals practice as Certified Heart-Centered Hypnotherapists treating thousands of patients all around the world every day.

This paper reviews an impressive body of knowledge regarding Targeted Medical Hypnosis, and specifically digital audio delivered medical hypnosis, demonstrating its effectiveness in directly intervening with specific physiologic processes and modifying important physical responses during traditional medical intervention. The author differentiates the use of Heart-Centered Hypnotherapy and Targeted Medical Hypnosis in the treatment of mind-body injury and disease, and proposes a specific, convenient, efficient and low cost technology for the use of Targeted Medical Hypnosis interventions in the surgical/emergency medicine milieu.

A. Introduction

1. Overall

Heart-Centered Hypnotherapy (HCH) is a carefully crafted healing modality used by well trained and practiced mental health professionals in a safe one-on-one office environment or group therapy milieu. When used for specific mind-body conditions, HCH can be reinforced, supported, and augmented by specifically designed Targeted Medical Hypnosis (TMH) that may be delivered in a variety of forms, live or prerecorded. It is the purpose of the current discussion to differentiate Heart-Centered Hypnotherapy and Targeted Medical Hypnosis and present a specific model of TMH in the surgical/emergency medicine milieu.

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* 5100 S. Dawson St., Suite 200 Seattle, WA 98118 rob@speigeltherapy.com

2. Heart-Centered Hypnotherapy

Heart-Centered Hypnotherapy (HCH) has been shown to be an effective treatment modality for trauma related mind-body conditions, illnesses, and symptoms. The developers of this well-designed and tested treatment modality based their work on widely accepted knowledge of the human "fight or flight" response, and the proven relationship between untreated trauma and the predictable physiological reactions of the sympathetic and parasympathetic nervous system[2]. They postulate that without efficient and effective methods to discharge repressed energy from traumatic events and experiences, human beings develop physical, emotional, psychological, and spiritual symptoms and diseases.

Further specific study of HCH has shown that the therapeutic impact of Heart-Centered Hypnotherapy is an effective form of holistic treatment to aid in the healing of the mind, body, and soul of those who suffer with intractable Interstitial Cystitis[3].

The HCH treatment approach is used extensively by highly trained practitioners in an office or retreat environment (the Personal Transformation Intensive[tm]) and has been shown to be profoundly effective in helping in the treatment of many medical conditions. The author himself is an Advanced Certified Heart-Centered Hypnotherapist and further certified to teach the Personal Transformation Intensive. HCH is regularly used by its certified hypnotherapists to treat auto-immune related diseases, Irritable Bowel Syndrome, high blood pressure, addiction, pain, etc. Heart-Centered Hypnotherapy (HCH) is always used in conjunction with, and in addition to other allopathic and complimentary medical interventions.

HCH uses the following procedure as its mind/body intervention:

- Identifies the current symptom or disease as the starting point
- Induces hypnotic trance
- Regresses the patient to traumatic events in the patient's life that represent the unconsciously recorded mind/body source or origin of the symptom or disease
- Provides mind/body energetic release and healing hypnotic suggestions directed at the specific disease or symptom state

- Identifies the unconsciously recorded erroneous belief (belief) the patient formed at the source of the trauma or illness
- Identifies the unconsciously recorded behavioral decisions the patient formed at the source of the trauma or illness
- Actively reframes the early erroneous beliefs and decisions in the patient's conscious mind into conscious healthy beliefs and decisions

B. Background and significance of the use of targeted medical hypnosis technology in the surgery/emergency medical milieu

1. The link between targeted medical hypnosis and physiological functions:

A body of research exists showing significant evidence that TMH can effectively treat a variety of medical conditions. However, the research has failed to produce a tested and proven TMH device and protocol that can easily, efficiently, and cost-effectively be integrated into the patient care model. This paper is intended to provide research support for the testing and implementation of specifically designed TMH technology in the surgical and emergency medical trauma environments.

Although the research evidence suggests that psychosocial factors can directly influence both physiologic function and health outcomes[4], mainstream medicine is experiencing difficulty moving beyond the biomedical model. One research group reported a literature review that was undertaken to examine the efficacy of mind-body interventions including relaxation, (cognitive) behavioral therapies, meditation, imagery, biofeedback, and hypnosis for several common clinical conditions. They conducted an electronic search of MEDLINE, PsycLIT, and the Cochrane Library databases, and a manual search of the reference sections of relevant articles for related clinical trials. Studies examining mind-body interventions for psychological disorders were excluded, as were studies examining more body-based therapies, such as yoga and tai chi chuan. Data extracted from relevant systematic reviews, meta-analyses, and randomized controlled trials showed considerable evidence of the efficacy for several mind-body therapies in the

treatment of coronary artery disease (e.g., cardiac rehabilitation), headaches, insomnia, incontinence, chronic low back pain, disease and treatment-related symptoms of cancer, and improving post surgical outcomes. Their report suggested that additional research is required to clarify the relative efficacy of different mind-body therapies, and factors that might predict more or less successful outcomes, and mechanisms of action[5].

A closer review of the literature clearly demonstrates that mental processes and physiological functions are "joined at the hip" and include the mind's ability to effect autonomic, endocrine and immune functions[6,7]. The following selected studies supporting mind-body interaction and the positive effects of hypnosis in the surgical milieu impressively focus the science demanding further proof of method and integration of mind based therapies into medical practice.

2. Evidence that targeted medical hypnosis improves surgery/emergency results:

Of the variety of methods of mind-body interventions tested, medical hypnosis has shown great promise in a number of functional medical applications including pre-surgical mental preparation and stress reduction, reducing intra-operative blood loss, reducing hospital stay, pain reduction and accelerated bone and wound healing[8,9,10,11]. Medical hypnosis has been used to augment coronary bypass surgery, severe burn treatment, and emergency medicine[12,13,14].

The use of medical hypnosis with surgical patients has received significant attention since trance anesthesia was introduced in the early 1800's. John Elliotson, a revered Professor of Practical Medicine at University College, London, and his protégé, James Esdaile, a medical officer for the British East India Company, each reported a large number of surgeries performed painlessly with the mesmeric trance as the only anesthetic agent. While Esdaile's results noted the simple fact that his patients referred their family and friends to his service, he also had data of a harder kind. At a time when surgical mortality was about 40%, Esdaile's death rate was reduced to only about 5% - an objective outcome that he plausibly attributed to the successful relief of pain and surgical trauma with mesmerism[15].

When chemical anesthesia was introduced in the middle of the 19th century, hypnosis for surgical relief fell into disuse. Chemical anesthesia was simple and complete, while hypnosis was more difficult to administer and did not guarantee complete unconsciousness. In addition, as scientific method became the standard for acceptable medical intervention and evidence-based medicine has become the current standard of care, hypnosis did not receive much research attention until recently.

In 2002, Montgomery, et al conducted meta-analyses of research examining the state of the art of the use of hypnosis with surgical patients[16]. They examined published controlled studies (n= 20) that used hypnosis with surgical patients to determine: 1) overall, whether hypnosis has a significant beneficial impact, 2) whether there are outcomes for which hypnosis is relatively more effective, and 3) whether the method of hypnotic induction (live versus audiotape) affects hypnosis efficacy. Their results revealed a significant effect size (D=1.20), indicating that surgical patients in hypnosis treatment groups had better outcomes than 89% of patients in control groups. No significant differences were found between clinical outcome categories or between methods of the induction of hypnosis including audio delivered hypnosis.

The data gathered are supported by previously published meta-analyses on hypnotic analgesia generally[17] as well as socio-cognitive views of hypnosis[18] and experimental studies[19]. The beneficial effects were apparent in each of the clinical outcome categories chosen for analysis: negative affect, pain, pain medication, physiological indicators, recovery, and treatment time. Both self report and objectively assessed end points were influenced. The authors found no evidence to support the position that the findings were dependent on the method of the hypnosis administration or study design. They go on to report that given that hypnosis is a non-pharmacologic intervention by nature, the present finding of a significant positive physiological effect is potentially important. Future randomized clinical trials should attempt to determine if there are classes of physiological variables for which hypnosis has an impact, and classes of variables for which hypnosis does not. The author's discussion addressed some of the limitations of their findings including the limited number of studies comparing taped versus live hypnosis,

and that the finding of no difference may be due to the small sample size. They further discussed how other possibly confounding variables may have influenced the study's conclusions. Overall, the results of their study support the position that hypnosis is an effective adjunctive procedure for a wide variety of surgical patients.

One study shows promise for the use of hypnosis with child patients in the surgical and emergency medicine arena. The study by French authors included fifty children from 2 to 11 years of age who were randomized into two groups: group H received hypnosis as premedication; group M were given normal doses of a benzodiazepine orally 30 min before surgery. Preoperative anxiety was evaluated using the Modified Yale Preoperative Anxiety Scale (mYPAS) score when arriving in the department (T1), when entering the operating room (T2), and when fitting the facemask (T3). Postoperative behavioral disorders were evaluated using the Posthospitalization Behavioral Questionnaire (PHBQ) at days 1, 7 and 14.

The two groups showed no significant difference preoperatively with the PHBQ: (M) 21 (17–25) vs (H) 20 (8–25) and mYPAS score: (M) 28 (23–75) vs (H) 23 (23–78). The number of anxious children was less during induction of anesthesia in the hypnosis group (T3: 39% vs 68%) ($P < 0.05$). Postoperatively, hypnosis reduced the frequency of behavior disorders approximately by half on day 1 (30% vs 62%) and day 7 (26% vs 59%).

The authors concluded that hypnosis seems effective as premedication in children scheduled for surgery. It alleviates preoperative anxiety, especially during induction of anesthesia and reduces behavioral disorders during the first postoperative week.[20]

Another remarkable study on the efficacy of hypnosis in the surgical melieu assessed the effects of perioperative hypnosis on reducing the length of hospitalization and alter the need for postoperative analgesics in patients undergoing the Nuss procedure, a difficult and invasive procedure to correct pectus excavatum. This condition is a common congenital deformity of the anterior wall of the chest in which several ribs and the sternum grow abnormally. It produces a caved-in or sunken

appearance of the chest, and commonly affects school age children.

Ten consecutive patients (age range, 12–18 years) underwent the Nuss procedure with the same operative technique. For pain management they were divided into two sequential groups: the 5 patients in the non-hypnosis group were managed with an epidural catheter, and analgesia was supplemented with intravenous or oral narcotics as requested. The second group of 5 patients was prepared by teaching them self-hypnosis for postoperative pain management in one or two brief sessions. Postoperative self-hypnosis was prescribed and encouraged. These patients were allowed patient controlled analgesia and were supplemented with intravenous or oral narcotics as requested.

The patients in the hypnosis group spent an average of 2.8 days in the hospital compared with 4.6 days in the non-hypnosis group ($p<0.01$). There was also a trend toward less narcotic use. Postoperative discomfort was better controlled with oral analgesics in the hypnosis group. There were no adverse effects from the hypnosis.

The authors concluded that in their small study, perioperative hypnosis was associated with a reduced hospital stay in patients undergoing the Nuss procedure for pectus excavatum[21].

Other research supports the efficacy of hypnosis in the surgical arena and reflects the lack of difference in live versus taped hypnosis. One important study examined how emotional factors influence recovery, blood loss and blood pressure in maxillofacial surgery patients where the surgery was performed under general anesthesia. Patients in group 1 were administered a hypnosis tape containing preoperative therapeutic suggestions, patients in group 2 were administered hypnosis tapes containing pre- and perioperative suggestions, and patients in group 3 were administered a hypnosis tape containing perioperative suggestions only. The patients who received taped suggestions were compared to a group of matched control patients. Patients in group 1 exhibited a 30% reduction in blood loss, a 26% reduction in blood loss was shown in group 2, and group 3 showed a 9% reduction in blood loss. Lower blood pressure was

found in the groups that received pre- and perioperative suggestions only[22].

In an expanded study by the same authors published in a second journal a larger cohort examined whether a combination of preoperative hypnotherapy and perioperative suggestions could reduce stress experienced by patients undergoing maxillofacial surgery under general anesthesia. The results were presented for an enlarged group of 90 surgery-matched experimental and control subjects (mean ages 23.9 and 22.6 yrs, respectively), as well as for a subsample of 38 age- and surgery-matched experimental (mean age 19.1 yrs) and control (mean age 19.7 yrs) subjects. Starting 2 weeks before surgery, the experimental subjects were asked to listen daily to an 18 minute hypnosis tape, which was also played during the operation. Blood loss, edema, and rate of recovery were recorded. A questionnaire addressing cooperation with the tape, and the subjects' opinion regarding the intervention was administered 8 weeks post-operatively. The results showed that postsurgical edema and pyrexia were reduced in both hypnosis groups and that the consumption of pharmaceutical anti-anxiety agents was significantly reduced in the subsample group[23].

These findings are easily generalized to patients receiving emergency medical care resulting from accident and other physical trauma.

In another study, the authors investigated whether playing a taped cognitive-behavioral message during and immediately following bariatric surgery will improve performance of a postoperative regimen designed to enhance recovery. They conducted a double-blinded placebo-controlled study consisting of 27 morbidly obese bariatric surgical patients randomly assigned to listen to either a blank (Controls) or a positive therapeutic message audiotape (Tape). A Postoperative Regimen Checklist (PRC) quantified different parts of the postoperative recovery regimen. The resulting data showed that patients in the Tape group, compared to the Controls: 1) achieved better scores at most PRC assessment points ($p < 0.05$), 2) required less encouragement to perform tasks ($p < 0.05$), and 3) were discharged from the hospital a mean of 1.6 days earlier. The authors concluded that a taped cognitive-behavioral message, played to patients repetitively during and immediately following

bariatric surgery, is effective in enhancing postoperative compliance and reducing in-patient length of stay.[24]

Some of the most impressive findings were produced in a clinical study published in 2003 that sought to test whether hypnotic intervention could be used to augment not only functional recovery, but also structural healing. The study compared the relative efficacy of hypnotic intervention, supportive attention, and usual care only on early post-surgical wound healing. Eighteen healthy women presenting for medically recommended reduction mammaplasty at an ambulatory surgery practice underwent the same surgical protocol and postoperative care following preoperative randomization *(n* = 6 each) to one of the three treatment groups: usual care, 8 adjunctive supportive attention sessions, or 8 adjunctive hypnosis sessions targeting accelerated wound healing.

The primary endpoints were objective, observational measures of incision healing made at 1 and 7 weeks postoperatively by medical staff blind to the participants' group assignments. Data included clinical exams and digitized photographs that were scored using a wound assessment inventory (WAI). Secondary outcome measures included the participants' subjectively rated pain, perceived incision healing (VAS Scales), and baseline and post-surgical functional health status (SF-36).

Analysis of variance showed the hypnosis group's wound healing to be significantly greater than the other two groups', $p<.001$, through 7 postoperative weeks; standard care controls showed the smallest degree of healing. In addition, at both the 1 and 7- week post-surgical observation intervals, one-way analyses showed the hypnosis group to be significantly more healed than the usual care controls, $p<0.02$. The mean scores of the subjective assessments of postoperative pain, incision healing and functional recovery trended similarly. The results of this study also hold promise for the use of hypnosis in emergency trauma care[7].

C. Rationale for the application of the technology

1. Introduction and background

Surgery is stressful – both surgical patients and surgical medical personnel will attest to that fact. So are emergency medical situations in the field, whether they are in the general population, or in the military theater. While the medical/emergency staff is under the stress of performing their duties along with the stress of their own daily lives, and the patient's families or comrades are under the stress of supporting their loved one while dealing with their own feelings about the patient's condition, the patient's stress is multiplied. The patient must endure the anticipatory anxiety of their medical condition and the potential outcome of their surgery along with the added physical insult of the surgical event itself. The emergency medical patient must deal with their immediate shock and injuries, the noise and chaos of the emergency situation and the activities of the first responders, while the first responders must deal with the stress of the emergent medical needs of the patient.

Studies have been completed that help us understand where, when, and how stress influences the surgical or emergency process, but not how it might be ameliorated. One study reports that simply trying to recover from cardiac surgery in the ICU results in significant post-traumatic stress with long term negative results. The patients in the study were evaluated for traumatic memories from post-operative treatment (defined as the subjective recollection of pain, respiratory distress, anxiety/panic, and nightmares in the cardiovascular intensive care unit), symptoms of chronic stress, including those of post-traumatic stress disorder, and health related quality of life (HRQL) pre-operatively (at baseline) and at 6 months after cardiac surgery. A state of chronic stress was defined as the development of post-traumatic stress disorder at 6 months after surgery.

Out of 148 patients, twenty-seven (18.2%) had post-traumatic stress disorder at 6 months after cardiac surgery. Of those, only seven (4.8%) had evidence of pre-existing post-traumatic stress disorder before undergoing cardiac surgery. Patients with new post-traumatic stress disorder at 6 months after cardiac surgery (20 new iatrogenic PTSD patients) had a significantly higher number of traumatic memories from

postoperative treatment in the cardiovascular intensive care unit ($p = .01$)[25].

In another study, laboratory analyses found that psychological stress is associated with slower healing of small superficial wounds. Researchers investigated the relationship between psychological stress and wound repair in patients following routine surgery. Forty-seven adults with an inguinal hernia were given a standardized questionnaire assessing psychological stress and worry about the operation before undergoing open incision repair. Wound fluid was collected from 36 participants over the first 20-hour postoperative period. Wound healing was assessed by standardized laboratory tests. Other outcome measures included patient self-reports of recovery. The results showed that psychological stress impairs the inflammatory response and matrix degradation processes in the wound immediately following surgery. The authors concluded that the results suggest that in clinical practice, interventions to reduce the patient's psychological stress level may improve wound repair and recovery following surgery[26].

2. Significance of the Activlink Hypnotek Targeted Medical Hypnosis Technology

It is the intent of this discussion to present the rationale for, and the potential efficacy and efficiency of the Targeted Active Medical Suggestion Device™ (TAMS™) and the Targeted Active Post-hypnotic Signaling Device™ (TAPS™) in the treatment of emergency medical patients and general surgery patients. Future research of this technology is proposed with the primary endpoints being objective, observational measures of incision and wound healing made at specific intervals post operatively by medical staff blind to the participant's study group assignments. Data will include clinical exams and digitized photographs scored using a validated wound assessment inventory (WAI) developed specifically for surgical wound assessment[2]. Secondary endpoints would include the patients' subjectively rated pain, perceived healing, and baseline and post surgical functional health status assessed by the SF-36® Health Survey.

The author holds certain method patents for medical hypnosis technology and designs for new technology

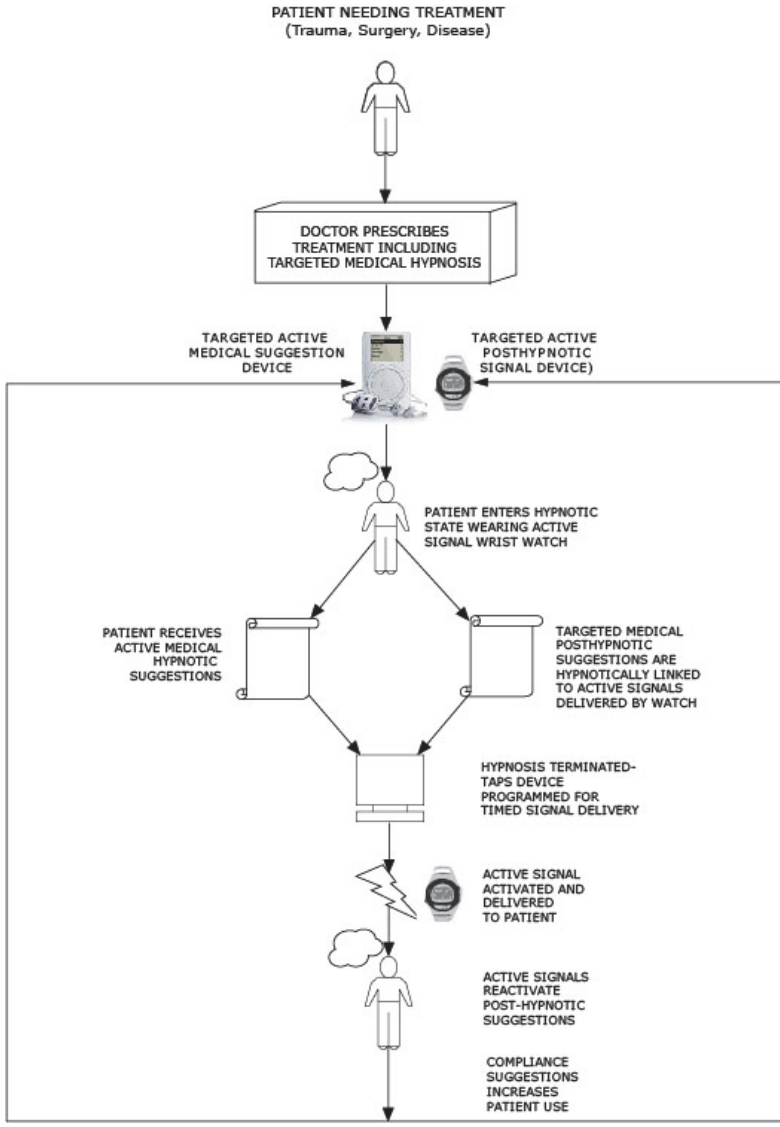
representing future iterations of TMH delivery systems. The primary patent is U.S. Patent Number 5,425,699 entitled *"Method of Modifying Human Behavior Using Signal Triggered Post-Hypnotic Suggestion"*. Under its current patent, the technology consists of a wrist-worn signaling device capable of delivering audible, visual and tactile post-hypnotic suggestion signals. The wrist device is paired with a personal CD player with high quality noise suppressing headphones, and a pre-recorded audio CD containing multiple medical hypnosis programs.

The TAPS™ device can consist of existing and reliable vibrating wrist or pocket devices capable of delivering active auditory, visual and tactile signals and stimulation to the user. The devices are fully programmable to deliver the proper signals for both the training and delivery modes. Therefore, specific active post-hypnotic signals can be delivered to the patient on a predetermined schedule. The signals consist of a visual cue, and auditory cue, and/or a tactile cue. Hypnotic suggestions regarding compliance are included in the hypnosis text.

The TAPS™ devices can also be paired with a MP3 player with vibration as a TAMS™ device capable of holding and delivering a variety of pre-recorded medical hypnosis protocols and potentially delivering the TAPS signals. Besides the medical hypnosis programs, the device will deliver medical instructions, information on the technical use of the devices, and information for product support. The targeted active medical suggestion programs will consist of classical hypnosis, suggestion, and post-hypnotic suggestions taking the user through the following sequence:

1. Visualized relaxation training
2. A general induction sequence
3. Introduction of hypnotic anchors (stimuli of specific physical states connected to specified signals)
4. Placing of targeted medical hypnotic suggestions
5. Anchoring of the TAPS™ signals
6. Linking suggestions and post-hypnotic suggestions directly to the TAPS™ signals
7. Placing of the compliance triggers

The following figure represents the overall treatment protocol incorporating the technology into standard of practice:



Instructions for the entire regimen along with the hypnosis suggestions are accomplished as the user listens to the audio program. The entire treatment effect is accomplished automatically and without conscious thought or remembering. The patient need do no more than listen to the TAMS™ track each day or as often as they desire, and wear the TAPS™ watch.

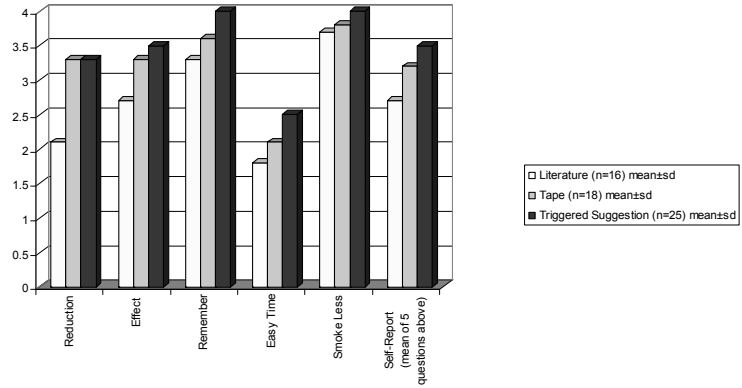
The watch signals automatically repeat themselves on a programmed basis. Superior treatment effect, as well as superior compliance was demonstrated in NIH sponsored phase I and phase II smoking cessation studies that took place between 1996 and 2001[27]. These features are automatically maintained by nature of the hypnosis suggestions and the suggestion cues provided by the device.

D. Previous results of Activlink research

The Activlink technology was thoroughly tested in two NIH sponsored studies conducted between 1996 and 2000. The studies involved over 950 subjects and examined the use of similar TAMS and TAPS technology for the treatment of nicotine addiction. Statistically significant results showed equal performance for the hypnosis technology when compared to medical treatment.

Phase 1 Study Results:

In the phase I trial, 107 women (41 pregnant and 66 non-pregnant) tested two forms of post-hypnotic suggestions to reduce or quit smoking: traditional post-hypnotic suggestions, and post hypnotic suggestions linked to "triggers" later delivered by a wrist worn electronic triggering device. Subjects in these two groups received audio hypnosis tapes and results were compared to a control group that received stop-smoking literature. The cessation rates of subjects receiving post-hypnotic suggestions anchored to a common internal cue—the urge to smoke—were compared to cessation rates of subjects receiving post-hypnotic suggestions linked to additional external triggers—random visual and auditory signals delivered by a programmed wristwatch. The latter cue, termed "triggered-suggestion" at the time, was intended to automatically provoke, or "trigger", the post-hypnotic suggestion producing more favorable results. Due to the tight restrictions on eligibility (only a sample of pregnant and non-pregnant female smokers could participate), the time limitations (a 6-month SBIR grant), and the large sample size required (156 subjects), the study was unable to recruit the full complement of subjects. In spite of the limitations, the triggered-suggestion test group showed superior self-reported results and had the highest retention rate.



Approximately half of the literature and tape groups provided final, self-report questionnaires along with about two-thirds of the triggered suggestion group. The triggered suggestion group had a better outcome on the self-report than the other two groups combined, with a mean of 3.5 for five questions compared to 3.0 for the other two groups combined (3.2 for the tape alone and 2.7 for the literature group), yielding p=0.02 (Table 2). As shown in the table, the triggered suggestion method received the highest participant rating on four out of the five questions and on the overall mean.

Of particular note, the triggered suggestion group and its reminder device had the highest rating on the third, "I remembered", question. It also had the most significant difference from the combined other groups on this question. Using post hoc tests to compare the three groups (Tukey's method), the triggered suggestion group was significantly better than the literature group on the first question ("The intervention I used caused a significant reduction in my smoking behavior", p = 0.006) on the third question ("Most days I remembered what I was supposed to do to quit smoking." p = 0.03) and on the overall mean (p = 0.005). The tape-only group was significantly better than the literature group on the first question ("The intervention I used caused a significant reduction in my smoking." p = 0.01).

Table 2 – Self-Report on Smoking Reduction and Experience with Cessation Method					
Questionnaire	Literature (n=16) mean±sd	Tape (n=18) mean±sd	Triggered Suggestion (n=25) mean±sd	3-Group p-value	2-Group p-value*
Reduction	2.1±1.2	3.3±1.0	3.3±1.1	0.004	0.09
Effect	2.7±1.5	3.3±1.4	3.5±1.2	0.2	0.2
Remember	3.3±1.0	3.6±0.8	4.0±0.6	0.03	0.01
Easy Time	1.8±1.0	2.1±1.0	2.5±0.9	0.8	0.04
Smoke Less	3.7±1.1	3.8±1.3	4.0±0.9	0.7	0.4
Self-Report (mean of 5 questions above)	2.7±0.7	3.2±0.7	3.5±0.7	0.007	0.02

*Comparison of triggered suggestion to the combination of literature and tape groups.

Note: Scores are means on the following scale:

1.0 = Least favorable response to treatment

3.0 = Neutral

5.0 = Most favorable response treatment

The results of this phase I trial were sufficiently promising that a two-year phase II study was approved.

Phase II Study Results

During Phase II, 799 moderate to heavy cigarette smokers were recruited and randomly assigned to one of three experimental groups; the Triggered-Suggestion Device (TSD), the Nicotrol nicotine replacement patch (Nicotrol), or the SmokEnders Quit Kit (SE). In this way, the TSD was tested against a pharmacological intervention (Nicotrol) and another behavioral intervention (SE). Subjects were followed at three, six, and twelve months intervals with a self-report questionnaire, and all quits were confirmed with a measure of carbon monoxide in expired air at the twelve month follow-up. The primary endpoints in the study were smoking cessation, smoking reduction and satisfaction with treatment method.

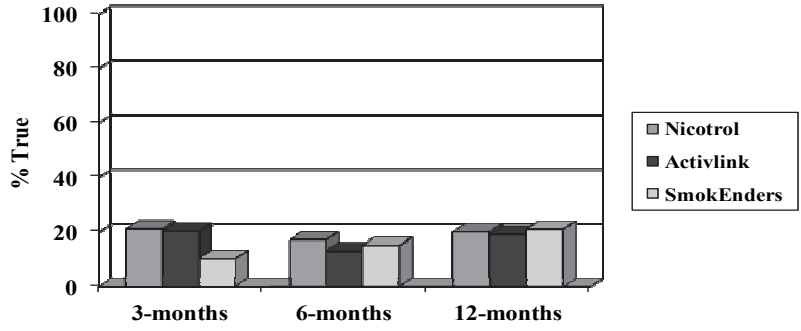
Overall, the results show that all treatment groups provided value to both male and female smokers for smoking cessation. While the highest quit and reduction rates were found in the Nicotrol group, the TSD group exhibited a solid clinical performance that compared well with the nicotine patch in several important regards. The TSD group was able to achieve a

sustained quit rate that matched the Nicotrol group at the one-year follow-up (19% versus 20% respectively) and consistently outperformed SE when all attempts at quitting were evaluated. As a method of smoking reduction, the TSD was able to produce higher rates of reduction than the SE treatment and equivalent rates of reduction when compared to the Nicotrol patch. Throughout the data, there is evidence of the Nicotrol and the TSD groups performing more similarly than and, in many cases, superior to the SE treatment. The value of an interactive reminding device for smoking cessation was supported in this study and the TSD may offer an innovative treatment option for this psychologically complex and ultimately dangerous behavioral choice. The following chart and graph show some of the detailed results of the study:

Characteristic	Triggered Suggestion	Nicotrol	SmokeEnders
Number of subjects	266	265	268
Age (Mean [SE])	40 [9]	39 [9]	39 [10]
Gender (% Females)	39	38	48
Education # Years, (Means [SE])	13 [1]	13 [2]	13 [2]
Married/Partner (% Yes)	63	71	70
Ethnicity (% Caucasian)	91	90	91
Start Smoking Age, (Mean [SE])	16 [4]	16 [4]	16 [5]
Cigarettes/Day #, (Mean [SE])	23 [9]	24 [9]	23 [9]
% Tried to Quit	89	88	86
% Retention			
3 month	78	78	75
6 month	77	77	73
12 month	73	72	70

On the basis of overall quits at the 3-month, 6 month and 12 month endpoints, the Triggered Suggestion hypnosis method (denoted in this graph by the product name, “Activlink”) performed equally to the validated medical product (Nicotrol) at each test point.

Statement: "I quit smoking and have not started again."



E. Conclusion

Heart-Centered Hypnotherapy is the method of choice in the treatment of unresolved trauma resulting in mind-body, emotional, psychological, and spiritual dysfunction and symptoms. Its use is limited in scope to in-office or in-retreat live treatment venues. Targeted Medical Hypnosis is the treatment of choice in immediate and emergent mind-body events and diseases treated in the surgical/emergency medical milieu, and for pain and healing amelioration. It can be administered by a live hypnotherapist present in the surgical chamber or emergency situation using a general hypnosis protocol of relaxation training and trance induction (whether the patient is conscious or not), anchoring of resources (family resources, safety, trust of medical care providers, spiritual anchoring, etc), placement of correct mind/body healing suggestions, placement of post hypnotic recovery and pain management suggestions, anchoring of the post-hypnotic suggestions, and count up out of trance (if the patient is conscious).

Targeted Medical Hypnosis can also be administered easily and portably and with equal effectiveness to live administration using recorded hypnosis protocols and audio-playback technology anchored with electronic signaling. The promising results of the author's previous studies of Targeted Medical Hypnosis technology for smoking cessation, paired with the

supportive literature citations regarding the use of TMH to affect positive therapeutic physiologic changes, creates a compelling case for the further testing and use of the proposed technology in the surgical/emergency medical milieu.

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