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Is hypnotherapy an effective treatment in smoking cessation in comparison to alternative methods?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not hypnotherapy is an effective treatment in smoking cessation in comparison to alternative methods?

Study Design: Systematic review of 3 English language primary studies, published between 2013-2014.

Data Sources: Three randomized controlled trials (RCTs) published on/after 2013 comparing the use of hypnotherapy to alternative methods in the treatment of smoking cessation. The other methods include nicotine replacement therapy, relaxation therapy and single versus group hypnotherapy and were obtained using the Cochrane Library and PubMed.

Outcomes Measured: The outcome of each study measured the effects of hypnotherapy by self-reported smoking abstinence and counting the number of cigarettes smoked per day at various follow up intervals.

Results: Dickson-Spillman and co-authors showed there was no significant difference in reported abstinence rates at the 2-week follow up ($p=0.13$) and the 6-month follow up ($p=0.73$). In addition to the 2 week follow up, there was no significant difference between the mean number of cigarettes smoked in the past 7 days when comparing hypnotherapy to relaxation therapy ($p=0.69$). Hasan and co-authors demonstrated patients receiving hypnotherapy versus nicotine replacement therapy were more likely to remain abstinent at 12 and 26 weeks post hospitalization, although there was no significant difference ($p=0.14$ and 0.06 , respectively). Riegel found at the end of treatment, group therapy reported a 48.2% quit rate whereas individual therapy reported a 37.9% quit rate with a 95% CI [0.61,3.80]. At the 3 month follow up, GT reported a 19.6% quit rate whereas IT reported a 13.8% quit rate with a 95% CI [0.44,5.30]. There were minimal to no adverse side effects reported in all three studies.

Conclusion: Hypnotherapy does appear to aid in smoking cessation; however, based on the findings in the three studies addressed in this review, there is not a statistically significant difference when using hypnotherapy to treat smoking cessation compared with alternative methods. The use of hypnosis to treat smoking cessation along with its treatment for other psychotherapies and addictions will likely be further explored in the future.

Key words: hypnotherapy, smoking cessation

INTRODUCTION

Cigarette smoking is the leading cause of preventable disease and death in the United States, attributing to 1 in 5 deaths annually.¹ It is estimated that 17.8% of U.S. adults aged 18 years or older currently smoke cigarettes.² Regardless of why people begin smoking tobacco, it is found that smokers have a greater risk of developing lung cancer, stroke and heart disease when compared to non-smokers.² Other illnesses that have direct associations with smoking tobacco include but are not limited to: Chronic Obstructive Pulmonary Disease (COPD), cancers of the larynx and mouth, esophageal cancer, pancreatic cancer, bladder cancer, cervical cancer, acute myeloid leukemia, colon cancer, asthma attacks and Crohn's disease. Those that partake are more at risk for cataracts, type 2 diabetes mellitus and rheumatoid arthritis. Interestingly enough, it can even have an effect on fertility and increase the risk for birth defects, miscarriages and stillbirths.²

Not only are the ill effects of smoking an expense to the individual monetarily and health wise, smoking is also a huge cost in medicine. In the U.S. the total economic cost of smoking is more than \$300 billion annually, which includes \$170 billion in direct medical care and \$156 billion in lost productivity due to its adverse effects.^{1,3} There is not an exact estimate of the number of health care visits each year currently available; however, "smoking contributes \$67 billion in expenditures for hospitals, \$21 billion in ambulatory care, \$10.6 billion in nursing home care, \$25.5 billion in prescription drugs, and \$8.2 billion in other services".¹

The proven risks associated with smoking tobacco clearly outweigh the benefits, which is why teaching non-smokers about abstinence and current smokers about cessation is of the utmost importance. Smoking cessation is the process of discontinuing tobacco use. After cessation has begun, some risks associated can be reduced shortly after. For example, 1 year after

cessation the risk of a myocardial infarction drops significantly and after 10 years, the risk for lung cancer drops by half.²

The process of smoking cessation can prove a challenge for patients and become frustrating after multiple attempts without success. The reason that is so incredibly difficult for some to refrain from smoking cigarettes after use is in part due to the chemicals contained in a cigarette. Tobacco contains a mixture of chemicals and additives including nicotine, an addictive chemical that aids in the process of dependence, tolerance and withdrawal symptoms. Nicotine was found to be the most addictive drug in the United States.⁴ Nicotine prevents the reuptake of acetylcholine ultimately increasing the amount in the central nervous system and skeletal muscle junctions. This in turn triggers a chemical reaction, which increases heart rate, alertness and reaction time. When inhaled and absorbed through the alveoli in the lungs, nicotine is directly associated with cardiovascular disease and causes a multitude of other disease processes. Simultaneously as this is occurring, dopamine and endorphins are released which are neurotransmitters that play a critical role in reward-motivated behavior and ultimately add to the pleasure associated with smoking.²

There are numerous treatment options that play a critical role in smoking cessation. Currently used methods for treatment are but not limited to quitting abruptly without assistance which is also known as “cold turkey”, nicotine replacement therapies (patch, gum, lozenge, inhaler, nasal spray), prescription dosed nicotine replacement therapy, anti-depressant medications (Varenicline tartrate, Bupropion SR), laser therapy, acupuncture, hypnotherapy, counseling and support groups.² A combination of these modalities may be used such as therapy with medication or two or more therapies together. However, as with all types of therapies and medications, each method will work differently depending upon the individual patient.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not “Is hypnotherapy an effective treatment in smoking cessation in comparison to alternative methods?”

METHODS

The criteria used for the selection of the 3 studies included both men and women over the age of 18 currently using inhaled tobacco. The intervention being reviewed in this study included hypnotherapy sessions. In one study, hypnotherapy was compared to nicotine replacement therapy. In another RCT, hypnotherapy was compared to group relaxation therapy. Lastly, hypnotherapy was compared between group and single sessions. The outcomes measured in the 3 studies included the incidence of self-reported smoking cessation and counting the number of cigarettes smoked per day. The types of studies included are 3 randomized controlled trials (RCTs); one is a free choice study and another a cluster randomized, parallel-group, controlled trial.

Key words used to search the articles included “hypnotherapy” and “smoking cessation”. All articles were originally published in peer-reviewed journals in the English language. Data was searched and collected by the author using articles in PubMed and the Cochrane library from 2013-2014. Articles were selected based on relevance to the clinical question and if they included patient oriented evidence that matters (POEMS). Inclusion criteria consisted of studies that were RCTs or clinical trials published after 2012, additional criteria in Table 1. Exclusion criteria included patients under 18 years old. The statistics of this study used to evaluate patient outcomes included p values, RBI, NBI, CI, and NNT. The demographics and characteristics of the included studies are displayed in table 1.

Table 1 - Demographics & Characteristics of included studies (Table 1)

Study	Type	#Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Dickson-Spillmann ⁵ (2013)	Cluster -RCT	223	18 years and older	-Consuming greater than or equal to 5 cigarettes/day -Willing to quit -Not using cessation aids at the time	-Acute alcohol or substance abuse -Signs of psychotic symptoms noticed by therapist at start of session	37	Hypnotherapy vs. Relaxation therapy
Hasan ⁶ (2014)	RCT	122	18-75 years old	-Current smokers admitted with a cardiac or pulmonary illness	-Patients admitted with a terminal illness -Pregnant -History of substance abuse or a major psychiatric d/o -If they could not be followed after discharge due to cognitive or language barriers -Those that have received hypnotherapy or NRT in the past 6 months	42	Hypnotherapy vs. Nicotine Replacement Therapy
Riegel ⁷ (2013)	RCT; free choice study	85	23 – 68 years old	-Smoking history of at least 2 years - Daily consumption of at least 10 cigarettes/day	-Under 23 years old	8	Group vs. Individual hypnotherapy

OUTCOMES MEASURED

All of the outcomes measured were POEMS related to the treatment of smoking cessation. In the study by Dickson- Spillmann and co-authors, the outcomes measured were by counting the number of cigarettes. This was accomplished by counting the number of cigarettes smoked per day at a 2-week follow up and at a 6-month follow up.⁵

In the study by Hansan, Zagarins and co-authors the outcomes were measured by self reported smoking abstinence. This was recorded at a 12 week and 26 week post- hospitalizations follow up.⁶

In the study by Riegel the outcomes were measured using a symptom checklist – 90-revised (SCL – 90 R), creative imagination scale (CIS) and questionnaire on changes in experience and behavior called Veranderungsfragebogen des Erlebens end Verhaltens (VEV). This was recorded with quit rates at the end of treatment and again at a 3 month follow up with a tolerance interval of 2 weeks.⁷

RESULTS

Three studies compared the use of hypnotherapy to treat smoking cessation in adults age 18 years and older currently smoking inhaled tobacco. One study was a randomized controlled trial⁶, one was a cluster randomized, parallel-group, controlled trial⁵ and one was a randomized controlled trial: a free choice study.⁷

Dickson-Spillman and co-authors conducted a study containing 223 smokers that were 18 years or older. During recruitment, they noticed the pattern of “clusters” of individuals that shared similar features (such as work colleagues) therefore this trial falls under a cluster-randomized, parallel group, controlled trial. Participants needed to be consuming greater than or equal to 5 cigarettes per day, willing to quit and not using any type of cessation aid at the time. Participants were excluded from the study for alcohol and/or substance abuse, and signs of

psychotic symptoms noticed by a therapist at the start of sessions. There was no upper limit on age. After viewing advertisements, participants were mailed information about the interventions, cost, associated risks and how randomization worked. The therapy sessions consisted of three parts: a psycho-educational part (40 minutes), the actual intervention (40 minutes), and a debriefing about which intervention was given (20 minutes). The 37 participants that withdrew were considered “continuing smokers”. At the 2-week follow up, there was no significant difference in reported abstinence rates when comparing hypnotherapy to relaxation therapy (p=0.13). In addition, there was no significant difference between the mean number of cigarettes smoked in the past 7 days when comparing both interventions (p = 0.69). At the 6-month follow up, the intervention was not significant on self-reported 30-day nicotine abstinence (p= 0.73). The NNT was calculated to be -2.1% (see Table 2), so this negative number means for every 2 participants who were treated with a single session of group hypnotherapy there was one fewer incidence of smoking cessation than in the group of participants in the single group relaxation therapy. There were no adverse events found. ⁵

Table 2. Analysis of Outcomes and Numbers Needed to Treat.

Dickson(2013)	Patients	CER	EER	RBI	ABI	NNT
	223	17.8%	14.7%	-0.17%	-3.1%	-2.1%

Hasan and co-authors studied 164 current smokers between the ages of 18 and 75 years old admitted with a pulmonary or cardiac illness. Participants were excluded if they had a history of substance abuse, psychiatric illness, terminal illness, pregnant, unable to follow up due to a behavioral or language barrier and/or if they have received NRT or hypnotherapy within the last 6 months. Participants were randomized to 1 of 3 treatments: hypnotherapy, NRT or a combination or the two. Hypnotherapy consisted of one, ninety-minute session, 1-2 weeks post-

hospitalization by a certified hypnotist and tobacco treatment specialist. Those in the NRT group received a free one-month supply of patches with the dose based on the amount and time they smoked prior to hospitalization. Of the initial sample size, 42 participants declined treatment and were included in a separate “self quit” group. Patients receiving hypnotherapy were more likely to remain abstinent at 12 and 26 weeks post hospitalization compared to those receiving NRT. Although there is no significant difference ($p= 0.14$), 43.9% of patients receiving hypnotherapy remained abstinent compared with 28.2% receiving NRT at 12 weeks. At 26 weeks, smoking abstinence rates were 36.6% with hypnotherapy and 18% with NRT, showing no significant difference ($p= 0.06$). NNT was calculated to be 6, which is moderately small for this study (see table 3). This study reports no adverse effects of the interventions found. ⁶

Table 3. Analysis of Outcomes and Numbers Needed to Treat.

Hasan(2013)	Patients	CER	EER	RBI	ABI	NNT
	164	18%	36.6%	103%	18.6%	5.37%

Riegel studied 93 smokers between the ages of 23 and 68 years old. Inclusion criteria included at least a 2-year smoking history with use of at least 10 cigarettes per day. In this free choice study, patients were given the option of individual versus group hypnotherapy sessions. Eight patients declined consent and were excluded from this study, leaving a total of 85 patients in the final sample. Individual treatment (IT) consisted of 29 people and 3 sessions of therapy whereas group treatment (GT) consisted of 56 people that participated in 4 sessions; each session was 90 minutes long. At the end of treatment, GT reported a 48.2% quit rate whereas IT reported a 37.9% quit rate with a 95% CI [0.61,3.80]. At the 3 month follow up, GT reported a 19.6% quit rate whereas IT reported a 13.8% quit rate with a 95% CI [0.44,5.30]. NNT was calculated to be 10, which is very small for this study (see table 4). Drop out rates were 23.5% during treatment

and 34.1% missing at follow-up, which was due to stress, illness, unsatisfactory treatment and abstinence before treatment began; they were counted for as smokers. The data collected suggests the majority of subjects did not feel side effects of the treatment. ⁷

Table 4. Analysis of Outcomes and Numbers Needed to Treat.

Riegel (2013)	Patients	CER	EER	RBI	ABI	NNT
	85	37.9%	48.2%	27%	10.3%	9.7%

DISCUSSION

Smoking cessation is a common problem many patients and practitioners are faced with. It poses a challenge to stop a routine once formed as a habit, especially while withdrawal symptoms can occur, such as: weight gain, cravings, feeling irritable and having trouble thinking. ^{8,9} There are various methods for cessation such as nicotine replacement therapy and prescription medications, however one study estimated that 22% of smokers relapsed within 3 months. ¹⁰ Data has demonstrated that over 42% of all adults that use cigarettes on a daily basis stopped smoking for one day or more in 2012 because they were trying to quit. ¹

Hypnotherapy is an alternative method used in smoking cessation that does appear to aid in abstinence ^{5,6,7}. This method of psychotherapy gives the patient an opportunity to change certain behaviors by using guided relaxation, increased concentration and focused attention allowing the therapist to work on specific tasks while blocking out distractions simultaneously. It is important to note while in this trance like state the patient has full control over their mind and body. ¹¹

Hypnosis has also been implemented in other settings which includes but is not limited to: treating specific phobias, pain management, anxiety, headaches, pre-operation settings, depression, asthma, eating disorders and utilized in labor and delivery. The risks associated with this therapy include creating false memories unintentionally created by the therapist, which is

why hypnosis remains controversial for treating dissociative disorders. Other side effects include: drowsiness, headache, anxiety and/or stress, however none of these adverse side effects were reported in the three studies being analyzed.^{5,6,7,11}

One problem with the proposed treatment is insurance coverage. Due to the fact that hypnosis is considered an alternative medicine intervention currently undergoing experimentation and investigation, many insurance companies will not cover the therapy. Insurance companies such as Aetna indicate that there is inadequate evidence of peer-reviewed medical literature for the effectiveness of hypnosis.¹² It is likely due to the unknown benefit of the therapy that insurance companies won't cover the cost and maintenance thereafter, making this an expense to the patient and risk they have to be willing to take.

There are limitations that exist when collecting evidence regarding hypnosis used in the treatment of smoking cessation. All 3 studies shared some similar limitations restricting their efficacy. Due to the nature of the studies, it was impossible to keep the participants blinded with an intervention of hypnotherapy. This could have led to a motivational incentive to remain abstinent for those receiving the therapy intervention. Also, there was no control group in all three studies giving no definitive baseline for comparison. In addition, each of the studies had a relatively small sample size, which poses difficulty in applying these results to a larger sample of demographics.^{5,6,7} Furthermore, each study should remain ongoing to demonstrate whether continued abstinence is obtained. Additional studies warrant a larger sample size and ongoing follow-ups for an extended period of time to collaborate statistics on the extended effects of hypnotherapy.

There were also specific limitations to the study by Dickson-Spillman and co-authors. The inclusion criteria did not include a specific time frame needed for patients to use cigarettes

to qualify for the study. Participants joined in “clusters” of social networks and work-place colleagues, allowing motivation to become negatively or positively affected by those around them. Also, there was a drop out rate of 37 participants that were considered “continued smokers” which could have skewed the results. ⁵

The Hasan and co-authors study was conducted post-hospitalization allowing pulmonary and cardiac illness to dictate the population size and whether patients were able to follow up. Roughly 1/3 of patients withdrew from the study and were placed in a “self quit” group, decreasing the initial sample size and skewing results of the study. This was the only study in this review to have placed the use of nicotine replacement therapy or hypnotherapy in the past 6 months in their exclusion criteria, allowing researchers to visualize the benefits of the therapy without intervening influences. ⁶

In the Riegel study, it demonstrates the issue with an initial small sample size and applying the data to the rest of the population. Also, with the exception of age there were no exclusion criteria for the population making it difficult to generalize the results to similar patient demographics. ⁷

CONCLUSION

Hypnotherapy does appear to aid in smoking cessation; however, based on the findings in the three studies addressed in this review, there is not a statistically significant difference when using hypnotherapy to treat smoking cessation compared with alternative methods ^{5,6,7}. Studying tobacco smokers is difficult for both the participant and the researcher due to the high rate of relapse in this population, ability to keep participants blinded, sample size and associated co-morbidities among this population. ^{1,5,6,7}

Future research studies should consider placing patients in a controlled setting. For example, an inpatient treatment center would limit the external stressors for relapse during trials.

A comparison of abstinence rates between those in the treatment center versus those in a home environment pre-treatment and post-treatment would be useful. This would be similar to how other substance abuse is treated in partial hospitalization and inpatient centers, especially if there are multiple substance abuse diagnoses occurring at the same time. Research could also demonstrate craving scales and checklists while in the treatment center. In future studies stricter inclusion criteria should be set for the amount and time of consumption of cigarettes and the willingness of the participant to quit. Exclusion criteria should include co-morbidities posing threat to the study and withdrawal rates. Further studies are also needed to aim for FDA and insurance approval. The use of hypnosis to treat smoking cessation along with its treatment for other psychotherapies and addictions will likely be further explored in the future.

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