FEASIBILITY OF A SHAM HYPNOSIS: EMPIRICAL DATA AND IMPLICATIONS FOR RANDOMIZED TRIALS OF HYPNOSIS

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ABSTRACT

Research on the efficacy of hypnosis has been limited due to the lack of a sham hypnosis comparison in randomized clinical trials. Researchers have relied on a variety of controls ranging from wait-lists to structured attention, resulting in a lack of blinding of participants and inconsistency among findings. The present study was designed to evaluate (a) whether white noise can be considered an 'inert' procedure and (b) the feasibility of a model of sham hypnosis that uses white noise presented within the hypnotic context. Seventy-five participants were randomized to one of three groups: hypnosis, sham (white noise presented in the context of hypnosis), or control (white noise in the absence of hypnotic context). Measures included participants' ratings of: (1) therapist professionalism; (2) consistency of the environment with hypnosis; (3) participants' perception that they received hypnosis; (4) the procedure as pleasant, relaxing, and beneficial; (5) the acceptability of the procedure; and (6) shifts in relaxation and expected benefit of hypnosis resulting from each procedure. No significant differences were observed among groups in ratings of professionalism. However, significant differences emerged with respect to the other measures when comparing participants who received sham hypnosis and those who received a hypnotic induction versus participants assigned to the white noise control, with effect sizes ranging from 0.17 to 0.85. Also, consistent with expectations, there were no significant differences between ratings of the sham hypnosis and the hypnosis procedure with respect to any of the remaining measures. Results support the feasibility of using white noise as an inert procedure that can serve as a credible sham hypnosis.

Key words: hypnosis, sham, placebo, hypnotherapy

Hypnosis has been applied to wide variety of medical and psychological problems such as pain (Olness et al., 1987; Zachariae & Bjerring, 1994; Jensen, 2009), headaches (Olness et al., 1987), vasomotor events (e.g. Elkins et al., 2008, 2010, 2011), gastroenterological disorders (Prior et al., 1990; Galovski & Blanchard, 1998; Miller & Whorwell, 2009), post-traumatic stress disorder (Vermetten & Christensen, 2010) and other anxiety disorders (Bryant, 2008), depression (Bryant, 2008; Alladin, 2009), alexithymia (Gay et al., 2008), and stress-induced immune dysregulation (Keicolt-Glaser et al., 2001).

However, evaluation of the efficacy of hypnosis has been limited due to the lack of a sham hypnosis (placebo) for comparison. There is currently no clearly identified and feasible sham hypnosis to use as a placebo for randomized clinical trials, which creates significant methodological limitations for the empirical validation of hypnotic interventions (Patterson & Jensen,

2003; Neumann, 2005). As a result, researchers have relied on a variety of controls, including attention or no-treatment, psychological interventions, or pill placebo (e.g. Spanos et al., 1988; Everett et al., 1993).

Further, a feasible sham hypnosis would be beneficial in conducting randomized research trials to be consistent with recent guidelines defining empirically supported treatments (APA, 1995; Chambless & Hollon, 1998). In accordance with foundational recommendations set forth by Division 12 of the American Psychological Association, Chambless and Hollon proposed that, to be considered a 'possibly efficacious treatment', a minimum of one study must demonstrate that the treatment's efficacy exceeds that of a placebo group or alternative treatment, or matches that of a treatment already recognized for its efficacy. If a treatment is to be considered 'efficacious', two studies must demonstrate its efficacy independently in separate research settings, and no empirically sound studies should demonstrate results to the contrary. To be considered 'efficacious and specific', the treatment must show superiority to another recognized treatment or placebo (either pill or psychological in a minimum of two independent research trials and settings).

Current clinical research reflects the need to empirically evaluate the efficacy of hypnosis according to these recommendations. Lynn (2000) noted, 'For hypnosis to achieve the coveted status of a well-established procedure in … treatment areas, only a few well-controlled studies are needed that … show that hypnotic interventions are superior to placebo control' (2000: 245). Accordingly, a feasible sham hypnosis should possess the following characteristics: (1) it would have to be believable; (2) it would have to be ineffective, a physically 'inert' procedure (i.e. Kirsch, 1985; Stewart-Williams & Podd, 2004); and (3), related to believability, a placebo would, ideally, appear to be 'identical'—or similar enough in appearance—to the treatment to produce relatively comparable expectancy effects (e.g. Kirsch, 2002).

In the present study, we examined the feasibility of white noise presented in the context of hypnosis. We aimed to evaluate (1) whether white noise can be considered an 'inert' procedure and (2) the credibility of a model of sham hypnosis that uses white noise as a potential form of 'hypnosis' when presented within the hypnotic context. We chose white noise because no empirical evidence exists that white noise possesses hypnotic components or creates effects equivalent to those demonstrated by the administration of hypnotic suggestions. We hypothesized that within the proper context, white noise, called 'experimental hypnosis', could be presented as an effective sham hypnosis condition.

METHOD

PARTICIPANTS

Participants were 75 undergraduate volunteers drawn from a large private Texas university. Participants were required to be at least 18 years of age. Further, individuals who reported prior experience with clinical hypnosis were excluded from the study. Prior to recruitment of participants or initiation of the study, we attained approval from the university's Institutional Review Board.

MEASURES

Procedural rating. Because this was a feasibility study, and no measures have been developed to evaluate the characteristics of sham hypnosis, we designed a set of questions to evaluate the sham. In each of the groups, participants were asked the following questions after the administration of their procedure:

1. Did your therapist interact with you in a professional manner?
2. Was the environment consistent with a hypnosis session?
3. Were you provided with a hypnosis session?
4. Was your experience pleasant?
5. Was your experience relaxing?
6. Did you benefit from today's session?
7. If yes, in what way(s) did you benefit?
8. If no, why not?

In addition, subjects were asked to rate on a 0 to 5 Likert scale the degree to which they agreed with the following statements:

1. The therapist acted in a professional manner.
2. The environment was conducive to a hypnotic experience.
3. I was provided with a quality hypnosis session.
4. My experience was pleasant.
5. My experience was relaxing.
6. I benefitted from today's session.

The scale used the following anchors: (1) strongly disagree; (2) disagree; (3) neither agree nor disagree; (4) agree; and (5) strongly agree.

Shifts in benefit expectancy. To evaluate shifts in participants' expectancy that hypnosis can help people relax, participants were also asked to rate the question: 'Based upon your experience, to what degree do you believe hypnosis can help people relax?' using a visual analogue scale (VAS) entitled 'Benefit Expectancy' both before and after their session.

Shifts in relaxation. To evaluate participants' shifts in relaxation, they were asked, 'Right now, how relaxed do you feel?' using a VAS entitled 'Relaxation Index' anchored with 'Not at all relaxed' and 'As relaxed as I could possibly feel' before and after their session.

Acceptability of procedures. The Treatment Acceptability Questionnaire (Hunsley, 1992) was used as an indirect measure of the believability of the sham procedure. The questionnaire is a six-question semantic differential scale that measures the degree to which individuals find a proposed treatment to be (1) acceptable, (2) ethical, (3) effective, and (4) likely to have negative side effects. The measure also evaluates the degree to which participants find the researcher or therapist providing their procedure to be knowledgeable and trustworthy, thus providing an indirect evaluation of the believability of procedures—in particular, the sham procedure. The questionnaire demonstrates good internal consistency, Chronbach's α ranges from 0.74 to 0.81, and test-retest reliability, $r = 0.78$ (Hunsley, 1992).

SETTING

In accordance with the work of Wickless and Kirsch (1989) and Kirsch et al. (1999), we manipulated the environment with environmental cues to create 'experiential expectancy' (Wickless & Kirsch, 1989). The study was conducted in a professional working laboratory in a comfortable setting similar to a medical office. Participants were greeted by a graduate or undergraduate research assistant or an administrative professional and were allowed to wait in a comfortable and professional waiting area until their session. Participants were led to the research room by a research assistant or the primary researcher, and those randomized to the sham or hypnosis groups entered through a door upon which hung a professional sign that read 'Session in Progress'. Adapted from Wickless and Kirsch (1989), the sham and hypnosis procedures were conducted in a quiet, dimly lit office, and participants were seated in a comfortable recliner. Credentials conveying the researcher's expertise in hypnosis were hung on the wall, and bookshelves in the room were lined with clearly marked books on hypnosis. The researcher and any research assistants dressed in business casual clothing and wore professional lab coats embroidered with 'Baylor Mind-Body Medicine Laboratory'. Persons randomized to the white noise only condition were administered their procedure in a room that was free from cues associated with a hypnotic context.

PROCEDURE

Participants were randomized to one of three groups: (1) White Noise (WN); (2) Hypnosis in the Context of Hypnosis (H+C); or (3) White Noise in the Context of Hypnosis (WN+C). A researcher or research assistant presented participants with basic information about the study and provided informed consent. During the informed consent process, participants were told that they were participating in psychological research investigating a model for the conduct of randomized clinical trials of hypnosis. Additionally, they were provided with information regarding the types of questions they would be answering as part of their participation in the research, as well as the general order of procedures. They were told they would be randomized to one of three groups and that, depending on their randomization group, they might or might not receive hypnosis during the first part of the session.

After completing the informed consent form, all participants were asked to complete a demographic questionnaire, 'Benefit Expectancy' and 'Relaxation Index' visual analogue scales. Participants randomized to the hypnosis and sham conditions were then given some initial, brief introductory material about hypnosis to read. Following administration of White Noise, Hypnosis in the Context of Hypnosis, or the sham, participants were administered the Procedural Rating Form by a separate researcher. Additionally, participants were again asked to complete the VAS 'Benefit Expectancy' and 'Relaxation Index' scales. They were also asked to complete the Treatment Acceptability Questionnaire. All participants were offered debriefing and, if necessary, provided with a referral and contact information for professional mental health consultation.

GROUP 1: WHITE NOISE (WN)

Twenty-five subjects were administered approximately 20 minutes of white noise without any hypnotic context. Subjects in the white noise condition were told that they were not rand-

omized to receive hypnosis during the first part of their session, but would instead be listening to approximately 20 minutes of white noise.

GROUP 2: HYPNOSIS IN THE CONTEXT OF HYPNOSIS (H+C)

Twenty-five subjects were administered hypnosis in the context of hypnosis as described above. Participants received the following introduction after the initial instructions:

Thank you for participating in our hypnosis study. Because we want to make sure everyone receives an identical, standardized hypnosis session, your hypnosis session has been pre-recorded and will be administered via an audio CD. However, during your session, I will be sitting in the chair in the corner of the room to ensure that your procedure is completely standardized and there are no technical problems that might interrupt your session [the therapist indicates the corner of the room where a chair has been set in a place that is generally out of the direct view of the participant]. You have been selected to participate in an experimental hypnotic relaxation procedure. Recent technological advances such as fMRIs [functional magnetic resonance imaging] have allowed researchers to see that hypnosis produces unique patterns of activation in certain areas of the brain. We are very excited about preliminary data from the development of this hypnosis procedure, and we have found that we can produce patterns of brain activation congruent to those seen in current research. Hypnosis is a procedure that involves focusing your attention and allowing your mind and body to relax. Your unconscious mind can receive hypnosis directly through this process. We are very much interested in your hypnotic experience. During your session, pay attention to your experiences so that you can report them to the research assistant at the end of your trial. If you are ready, I will start your hypnosis CD so that your session may begin.

Following this introduction by the research assistant, participants in the hypnotic treatment condition were played a CD with an initial statement followed by a standard induction and suggestions for relaxation. The introduction on the hypnosis CD was as follows:

This is a recording that you may use to experience hypnosis for relaxation. Hypnosis is a process of focusing your attention and allowing your mind and body to relax. Through this process, your unconscious mind can receive the effects of hypnosis. Because of the effects of hypnosis, it is important that, when you use this recording, you remain comfortably seated, setting other things temporarily aside so that you may fully experience the effects of hypnosis. You should not listen to music or engage in driving or other activities during hypnosis, and you should only use this recording when you can allow yourself to become completely absorbed in hypnosis and the hypnotic experience. Different people experience different things. Whatever you experience will be right for you, as you allow whatever happens to happen, and pay attention to your hypnotic experience so that you may report your experiences to the researcher at the end of your session. In a few moments, this introduction will end, you will hear a pause, and your hypnosis session will begin. You may now close your eyes and allow yourself to experience hypnosis.

This statement was followed by a recorded standard induction and suggestions for relaxation. The entire session lasted approximately 20 minutes. After the administration of hypnosis and alerting, the researcher asked the subjects to describe their experience of hypnosis.

GROUP 3: PLACEBO CONDITION: WHITE NOISE IN THE CONTEXT OF HYPNOSIS (WN+C)

Twenty-five subjects were administered approximately 20 minutes of white noise in the same context as the hypnosis group. They were also given the same instructions and introductory information as the hypnosis group, with the following exceptions: (1) participants were told that the experimental hypnotic relaxation procedure utilized white noise; and (2) they were told that effects of the 'hypnosis' were produced by subtly altering the frequencies in white noise.

RESULTS

DEMOGRAPHIC VARIABLES: DESCRIPTIVE STATISTICS

Data from the main sample were evaluated for outliers though the use of box plots. It was determined that observations of four of the participants deviated 2.5 or more standard deviations from the mean of one or more variables of interest. Data from these cases were deleted and four additional subjects were run for a final sample of 75 participants.

Table 1. Demographic factors of study participants. All values are expressed as a percentage of the specified population.

Variable	N	%
Gender		
Female	62	83
Male	13	17
Race		
Asian	7	9
African-American	7	9
Hispanic	9	12
Middle Eastern	1	1
Caucasian	48	64
Classification		
Freshman	39	52
Sophomore	14	19
Junior	16	21
Senior	6	8

The final sample was comprised of 75 undergraduate volunteers. Table 1 provides the frequencies and percentages associated with gender, race, and grade classification. Analysis of

demographic variables did not indicate significant differences between groups in the areas of gender, $\chi^2(4) = 3.503$, $p = 0.477$, $\phi_C = 0.153$, race, $\chi^2(8) = 4.611$, $p = 0.798$, $\phi_C = 0.175$, or year in school $\chi^2(6) = 6.875$, $p = 0.333$, $\phi_C = 0.214$.

EVALUATION OF WHITE NOISE AS AN INERT PROCEDURE: PERCEPTION OF BENEFIT

In order to evaluate the inertness of the white noise, we assessed the relation between group assignment and participants' perception of benefit through dichotomous and Likert-scale ratings. Group assignment, the independent variable, was determined by randomization into hypnosis, sham hypnosis (the placebo condition), or white noise in the absence of hypnotic context. The dependent variable was participants' perception of benefit from the procedure they received. We expected that subjects who received a hypnotic induction (H+C) and those randomized to the sham condition (WN+C) would demonstrate significant differences from those who received white noise without hypnotic context (WN) in dichotomous and Likert-scale ratings of perceived benefit from the condition to which they were randomized. We also anticipated that there would be no significant difference between subjects' perception of the procedure as beneficial in the sham and hypnosis conditions. Participants' dichotomous ratings of perception of benefit indicated that those randomized to the hypnosis condition (100%) or placebo condition (92%) were significantly more likely to rate the procedure as beneficial than those randomized to white noise in the absence of hypnotic context (16%), $\chi^2(2) = 50.54$, $p < 0.001$, $\phi_C = 0.821$.

Likert ratings of participants' perception of benefit also indicated that subjects assigned to the hypnosis or sham groups rated the procedures as significantly more beneficial than those randomized to white noise without hypnotic context, $F(2, 72) = 66.34$, $p < 0.001$, $\eta_p^2 = 0.648$. To evaluate pair-wise differences among means, follow-up tests were conducted. Levene's Test of Equality of Error Variances indicated equal variances between means could not be assumed; thus, the Games-Howell procedure was utilized for pair-wise comparisons. As anticipated, results indicated a significant difference between the means of the hypnosis group and the white noise group, $p < 0.001$, as well as the sham and white noise group, $p < 0.001$. However, no significant difference was found between means of the hypnosis and sham groups, $p = 0.165$.

EVALUATION OF THE CREDIBILITY OF THE SHAM

To evaluate the credibility of the sham, we used dichotomous and Likert-scale ratings to examine the relation between group assignment and participants' ratings of (1) the therapist's professionalism, (2) evaluation of the environment as consistent with a hypnosis session, (3) perception they received hypnosis, (4) evaluation of the procedure they received as pleasant, and (5) evaluation of the procedure as relaxing. We anticipated that participants who received the sham and those who received a hypnotic induction would demonstrate significant differences from those who received white noise without hypnotic context in both dichotomous and Likert-scale ratings of the above dependent variables. Additionally, we anticipated that participants randomized to the hypnosis or sham conditions would not significantly differ in dichotomous or Likert-scale procedural ratings.

Analysis of dichotomous ratings indicated that participants randomized to hypnosis or the sham were significantly more likely than those randomized to white noise in the absence of

hypnotic context to (1) rate the environment as consistent with a hypnosis session, (2) report that they had received hypnosis, (3) rate the procedure they received as pleasant, and (4) rate their experience as relaxing. However, when dichotomous ratings were utilized to rate the therapist's professionalism, no significant difference was found between groups. Results of these analyses are summarized in Table 2.

Table 2. Analyses of dichotomous procedural ratings

	Beneficial	Professional therapist	Environment	Receipt of hypnosis	Pleasant	Relaxing
X^2 (2)	50.54	4.110	70.59	75.00	45.98	41.04
p	< 0.001	0.128	< 0.001	< 0.001	< 0.001	< 0.001
Φ_C	0.821	0.234	0.970	1.00	0.788	0.750

To evaluate the relation between group assignment and participants' Likert-scale ratings of each of the above dependent variables, we conducted one-way analyses of variance. When omnibus tests were significant, pair-wise differences among means were evaluated through follow-up tests. Levene's Test of Equality of Error Variances was utilized to indicate whether equal variances among means could be assumed. The Games-Howell procedure was utilized for pair-wise comparisons when the assumption of homogeneity of variances was not met. However, when Levene's test indicated equal variances among means could be assumed, Tukey's HSD (Honestly Significant Difference) test was utilized for pair-wise comparisons. Means and standard deviations of Likert-scale procedural ratings are shown in Table 3. Results of the ANOVA (Analysis of Variance) analyses can be seen in Table 4.

Table 3. Means and standard deviations of Likert scale procedural ratings

	Beneficial	Professional therapist	Environment	Receipt of hypnosis	Pleasant	Relaxing
Hypnosis						
Mean	4.60	4.92	4.60	4.68	4.76	4.80
Standard deviation	0.500	0.277	0.500	0.476	0.436	0.408
Sham						
Mean	4.24	4.84	4.48	4.56	4.56	4.60
Standard deviation	0.831	0.374	0.510	0.651	0.651	0.577
White noise						
Mean	2.08	4.04	1.88	1.52	2.48	2.52
Standard deviation	1.077	0.889	0.600	0.714	1.122	1.229

Table 4. Results of ANOVA analyses of Likert scale procedural ratings

	Beneficial	Professional therapist	Environment	Quality hypnosis	Pleasant	Relaxing
F	66.34	17.65	203.63	207.35	63.82	59.48
P	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
η_p^2	0.648	0.329	0.850	0.852	0.639	0.623
Pairwise comparisons						
p H & WN	< 0.001*	< 0.001*	< 0.001**	< 0.001**	< 0.001*	< 0.001*
p (WN+C) & WN	< 0.001*	0.001*	< 0.001**	< 0.001**	< 0.001*	< 0.001*
p H & (WN+C)	0.165 (NS)*	0.668 (NS)*	0.712 (NS)**	0.775 (NS)**	0.416 (NS)*	0.343 (NS)*

* Games-Howell utilized for pair-wise comparisons.
** Tukey's HSD used for pair-wise comparisons.

SHIFTS IN EXPECTED BENEFIT OF HYPNOSIS AND RATINGS OF RELAXATION

As an additional measure of the sham's credibility, we also examined the relation between group assignment and participants' (1) pre- and post-session shifts in expected benefit of hypnosis and (2) pre- and post-session shifts in ratings of relaxation. We hypothesized that subjects randomized to hypnosis (H+C) or sham hypnosis (WN+C) would demonstrate significant differences from those randomized to receive white noise in the absence of hypnotic context (WN) in both pre- and post-session shifts in expected benefit of hypnosis and in pre- and post-session shifts in their ratings of relaxation. To evaluate the relation between the independent variable (group assignment) and the dependent variables (pre- and post-session shifts in expected benefit of hypnosis and ratings of relaxation), we first conducted an ANOVA to determine significant differences between groups. Depending on the outcome of the Levene Test of Error Variances, the Games-Howell procedure or Tukey's HSD test was utilized to examine pair-wise comparisons. Means and standard deviations of these variables are shown in Table 5. Results of ANOVA analyses are summarized in Table 6.

EVALUATION OF ACCEPTABILITY OF PROCEDURES

We further evaluated the credibility of the sham by examining the relation between group assignment and participants' scores on the Treatment Acceptability Questionnaire. We anticipated that participants randomized to hypnosis (H+C) or placebo (WN+C) conditions would demonstrate significant differences from those randomized to receive white noise in the absence of hypnotic context (WN) in each item measured by the Treatment Acceptability Questionnaire as well as total treatment acceptability scores. To evaluate the relation between the group assignment and each of the dependent variables, we first calculated an omnibus F

Table 5. Means and standard deviations of VAS shifts in expected benefit and relaxation ratings

	Pre-post shifts in expected benefit of hypnosis	Pre-post shifts in ratings of relaxation
Hypnosis		
Mean	22.16	25.00
Standard deviation	15.715	15.028
Sham		
Mean	19.12	25.52
Standard deviation	21.890	31.229
White noise		
Mean	-3.44	2.48
Standard deviation	20.736	25.092

Table 6. Results of ANOVA analyses of VAS shifts in expected benefit and relaxation

	Pre-post shifts in expected benefit of hypnosis	Pre-post shifts in ratings of relaxation
F (2,72)	12.69	7.09
P	< 0.001	0.002
η_p^2	0.623	0.165
Pairwise comparisons		
p H & WN	< 0.001*	0.005**
p (WN+C) & WN	0.001*	0.004**
p H & (WN+C)	0.840 (NS)*	0.997 (NS)**

* Games-Howell utilized for pair-wise comparisons.
** Tukey's HSD used for pair-wise comparisons.

to determine significant differences between groups. The Games-Howell procedure or Tukey's HSD test was then utilized to examine pair-wise differences among group means depending upon the results of Levene's Test of Equality of Error Variances. Means and standard deviations are shown in Table 7. Results of the ANOVA analyses are summarized in Table 8.

Table 7. Means and standard deviations of Treatment Acceptability Questionnaire

	Acceptable	Ethical	Effective	Negative side effects	Knowledgeable	Trustworthy	Total
Hypnosis							
Mean	6.08	6.56	5.96	2.04	6.80	6.84	34.17
Standard deviation	0.759	0.651	0.841	1.083	0.408	0.374	2.334
Sham							
Mean	5.80	6.64	5.72	2.04	6.80	6.72	33.72
Standard deviation	1.155	0.569	1.100	1.457	0.500	0.678	2.894
White noise							
Mean	2.80	4.88	2.76	2.52	5.08	5.56	23.60
Standard deviation	1.414	1.481	1.234	1.503	1.498	1.227	4.444

Table 8. Results of ANOVA analyses of Treatment Acceptability Questionnaire

	Acceptable	Ethical	Effective	Negative side effects	Knowledgeable	Trustworthy	Total
F	63.42	25.197	69.25	1.021	27.81	17.79	78.59
P	< 0.001	< 0.001	< 0.001	0.365 (NS)	< 0.001	< 0.001	< 0.001
η_p^2	0.638	0.412	0.658	0.028	0.436	0.331	0.589
Pairwise comparisons							
p H & WN	< 0.001*	< 0.001*	< 0.001**		< 0.001*	< 0.001*	< 0.001*
p WN+C & WN	0.001*	<.001*	< 0.001**		< 0.001*	< 0.001*	0.001*
p H & WN+C	0.573 (NS)*	0.889 (NS)*	0.709 (NS)**		1.00 (NS)*	0.721 (NS)*	0.823 (NS)*

* Games-Howell utilized for pair-wise comparisons.

** Tukey's HSD used for pair-wise comparisons.

DISCUSSION

The present study examined the feasibility of using white noise presented in the context of hypnosis as a sham condition. The primary aims of the study were (1) to evaluate whether white noise can be considered an 'inert' procedure and (2) to evaluate the credibility of a

model of sham hypnosis that uses white noise as a potential form of 'hypnosis' when presented within the hypnotic context. We randomized participants to one of three groups: hypnosis, sham (white noise presented in the context of hypnosis), or control (white noise presented in the absence of hypnotic context). Results indicated that participants perceived each of the three conditions as presented in a professional manner.

Participants who received the sham hypnosis and those who received a hypnotic induction demonstrated significant differences from those assigned to the white noise control in all other dichotomous and Likert-scale ratings of variables of interest which included ratings of: (a) therapist's professionalism; (b) the consistency of the environment with hypnosis; (c) participants' perception that they received hypnosis; (d) participants' evaluation of the procedure as pleasant, relaxing, and beneficial; (e) the acceptability of the procedure; and (f) shifts in relaxation and expected benefit of hypnosis resulting from each procedure. Additionally, we found no significant differences between ratings of the sham and hypnosis procedure with respect to any of the measured domains. Thus, our results support the feasibility of using white noise as an inert procedure that, given the proper environmental context, can serve as a credible sham hypnosis condition.

The current study was the first to examine white noise as a means to create a credible sham hypnosis condition. It may be that other 'inert interventions' could also be adapted within a similar model of providing a sham condition in the context of hypnosis. However, further research will be needed to determine this possibility. Also, the present study was conducted with undergraduate participants and additional research will be needed to fully establish generalizability to other populations. Additionally, participants were self-selected to participate in an experiment designed to evaluate 'experimental hypnosis procedures'. Thus, it is possible that participants' responses to procedures were influenced by their perception of the purpose of the experiment or preconceived expectations of their experience. Also, the hypnotic context may involve many factors that influence placebo effects, such as researcher warmth, environmental comfort, and contextual cues in the environment, and these factors warrant attention.

The use of a sham procedure in clinical trials of hypnosis can also contribute to evaluating theoretical understandings of hypnosis as it relates to patient-oriented applications. The present study is consistent with theoretical formulations that propose that contextual and expectancy factors contribute to response to clinical hypnosis interventions (Kirsch 1991, 1994). It is not so much whether these factors are relevant, but to what degree they are the 'active ingredients' in the benefit from hypnosis in clinical settings. Lynn and Rhue (1991) have proposed an 'integrative model' of hypnosis that considers situational, interpersonal, and intrapersonal variables in response to hypnotic interventions. If hypnosis is more than a placebo intervention, then it is likely that multiple components contribute to benefits from clinical hypnosis. However, the exact role of these multiple factors in clinical hypnosis research is unknown. The use of a sham hypnosis condition in clinical trials may provide greater understanding of these factors as components such as expectancy, therapist–patient rapport, and individual differences in hypnotizability may be controlled and their contribution to responsiveness determined.

Also, notably, the present study relied entirely upon participants' subjective report rather than behavioural indices or physiological indicators of response to hypnosis. Thus, results depended upon the accuracy of participants' subjective report. It is possible that the development of a sham procedure and utilization of behavioural and/or physiological indicators of

response to hypnosis, in addition to subjective report, could clarify the long- standing theoretical debates regarding the source of hypnotic effects.

Therefore, it is important that future research utilizing the sham include behavioural and/or physiological indices of hypnosis in addition to subjective participant report. Additionally, future research that integrates the sham hypnotic procedure within clinical trials may provide additional refinements to the methodology. Moreover, research that includes a credible sham hypnosis condition may further identify the role of placebo effects in clinical interventions and assist in deconstructing effective components of hypnosis. The creation of a feasible sham hypnosis may help fill current methodological gaps in the literature, allow for greater unification and standardization of methodological procedures, reduce confounding factors among controls, thus allowing for clearer delineation of the effects of hypnosis, and enable hypnosis research to achieve the 'gold standard' in empirical investigation: the randomized, placebo-controlled clinical trial.

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