PILOT INVESTIGATION OF A VIRTUAL GASTRIC BAND HYPNOTHERAPY INTERVENTION

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Abstract: This 24-week-long pilot investigation of 30 men and women with a BMI > 27 kg/m² aimed to determine whether virtual gastric band (VGB) hypnotherapy has an effect on weight loss in overweight adults, compared to relaxation hypnotherapy and a self-directed diet. Levels of weight loss and gain ranged from −17 kg to +4.7 kg in the VGB hypnotherapy group and −9.3 kg to +7.8 kg in the relaxation group. There was no significant difference between VGB hypnotherapy as a main effect on weight loss, ($\chi^2 = 0.67, p = .41, df = 1$) and there was no evidence of differential weight loss over time, ($\chi^2 = 4.2, p = .64, df = 6$). Therefore, the authors conclude that there was no significant difference between VGB hypnotherapy and the relaxation hypnotherapy.

Obesity prevalence has reached epidemic proportions. In England, just over a quarter of adults (26%) were obese in 2010, and by 2030 it is estimated that 41–48% of men and 35–43% of women will have a body mass
Obesity increases morbidity and mortality, thus reducing quality of life and productivity (Jebb, Kopelman, & Butland, 2007). Consequently, reducing the incidence and development of obesity are major public health concerns (Nishida, Uauy, Kumanyika, & Shetty, 2004; Jebb et al., 2007). The National Institute for Health and Care Excellence (NICE) clinical guidelines for obesity have recently been reviewed, and it is estimated that the mean percentage weight loss from participating in a lifestyle weight-management program is somewhat lower than the originally stated 5%, with an average of around 3% of baseline weight. The Programme Development Group have stated that even losing this relatively small amount of weight is likely to lead to health benefits (particularly if the weight loss is maintained for many years) (Centre for Public Health Excellence at NICE [UK] & National Collaborating Centre for Primary Care [UK], 2006; National Institute for Health and Care Excellence, 2014).

Hypnotherapy is becoming more accepted as a complementary therapy for certain conditions such as irritable bowel syndrome (National Collaborating Centre for Nursing and Supportive Care [UK], 2008). In a meta-analysis of 18 studies (six of which related to obesity), Kirsch, Montgomery, and Sapirstein (1995) concluded that the addition of hypnosis substantially enhanced treatment outcomes. They also stated that the effect of adding hypnosis to the protocol was the most pronounced for treatments of obesity at long-term follow-up, indicating that those who had received hypnosis tended to continue to lose weight after the treatment ended (Kirsch et al., 1995).

Cochrane and Friesen (1986) compared weight loss among 60 overweight women who were randomized into three groups: hypnosis treatment utilizing audiotapes, hypnosis treatment without audiotapes, and a control group. The study found that weight loss after 1 month and again after 6 months was similar in both treatment groups but did not occur in the control group, thus indicating that, in this study, hypnosis was an effective treatment for weight loss (Cochrane & Friesen, 1986).

More recently, a study was conducted by Stradling, Roberts, Wilson, and Lovelock (1998) that looked at the use of hypnotherapy as an adjunct to dietary advice in producing weight loss. Sixty obese patients were enrolled into either a stress-reduction hypnotherapy, energy-intake-reduction hypnotherapy, or a dietary-advice group. Those receiving hypnotherapy attended two sessions, a month apart, which last 30 minutes. All participants had their weight monitored regularly for 18 months. This study showed a statistically significant result in favor of hypnotherapy; however, they did not utilize a control group, and the weight loss after 18 months was clinically insignificant.

Clinical hypnosis is a procedure in which a therapist suggests that a client experiences changes in sensation, perception, thought, and
behavior with some therapists believing that hypnotic inductions produce an altered state of consciousness (Kirsch et al., 1995). Mott and Roberts (1979) stated that, although there is evidence that hypnosis may have a role in weight loss treatment, well-designed research studies are needed to establish the extent of its usefulness. Stewart (2005) stated that studies looking at hypnotherapy as a single treatment for weight loss are limited and have shown varied levels of success.

Virtual Gastric Band hypnotherapy trains the mind and body to accept less food by making the brain believe the stomach is smaller than it is. It originated as a publicized but nonevidence-based intervention. Hypnotherapists Martin and Marion Shirran are believed to be first who pioneered the technique, and they registered the trademark for the Gastric Mind Band in North America and Europe (Shirran, Shirran, & Graham, 2010).

The aim of this study was to assess weight loss in overweight individuals using VGB group hypnotherapy in comparison to group relaxation hypnotherapy combined with a self-directed diet in another group.

**Method**

*Subjects*

Thirty participants were recruited by advertisement in the University of Hull common areas. Both male and female volunteers with a body mass index of more than 27 kg/m$^2$ were included. Volunteers who were on any previous weight-loss program, had experience with hypnotherapy, had any coexisting medical problems, had a history of eating disorders, had excessive use of alcohol or any recreational drugs, were pregnant or had any recent acute illness were excluded.

*Techniques*

Participants were asked to attend a group hypnotherapy session (either VGB hypnotherapy or relaxation hypnotherapy) lasting 1 hour, every week for a 4-week period. Participants were then given a 4-week break before they returned at Week 8 for a further 1-hour refresher hypnotherapy session. Participants were also asked to attend at Weeks 16 and 24 to be weighed at the HONEI clinical trials unit by registered dieticians. No further hypnotherapy was provided after Week 8. See Figure 1 for details of the trial schedule. All of the hypnotherapy group sessions for both the VGB hypnotherapy group and the relaxation group were carried out by the same hypnotherapist who holds a Practitioner Diploma in Clinical Hypnotherapy and is registered with the General Hypnotherapy Standards Council. All sessions were held in the seminar room at the Sports Centre of the University of Hull.
Figure 1. Trial schedule. Gives an outline of the number of visits each participant attended and the therapy they received.

**Virtual Gastric Band Hypnotherapy**

The VGB hypnotherapy program included a number of mind-management techniques designed to form a new set of eating habits. The program was developed by our hypnotherapist using a mixture of both traditional hypnotherapy (such as that described by James Braid; Upshaw, 2006) and Ericksonian hypnotherapy (Zeig & Rennick, 1991).
The VGB hypnotherapy used “imaginary surgery” to persuade participants that the surgery has taken place (McRae et al., 2004). Before the hypnosis began, participants were given some guidelines to follow consciously, including eating three times a day, being aware of the food consumed, being aware of the signs of becoming “full,” and aiming to increase exercise for 30 minutes each day. In addition to attending the VGB hypnotherapy group sessions, participants were given a self-hypnosis recording to listen to every day to reinforce the suggestions that were made in the group sessions. This recording included a number of mind-management techniques designed to form a new set of eating habits. A description of the characteristics of the virtual gastric band hypnotherapy and the hypnotic induction procedure used to produce the VGB can been viewed in Appendix 1.

Relaxation Hypnotherapy
The relaxation hypnotherapy consists of participants being guided into hypnosis and given mental imagery and suggestions of relaxation, calmness, and peace. No suggestions regarding behavior, habits, or outcomes were used. This group also received a self-hypnosis recording to listen to every day; however, this focused more on relaxation and mental imagery and gave no suggestions regarding behavior or habits. The relaxation group was also provided with the British Heart Foundation’s “So You Want to Lose Weight for Good” booklet (British Heart Foundation, 2009). This booklet is a 36-page document designed to aid self-directed weight loss and is provided free of charge by the registered charity the British Heart Foundation. The participants were provided with the booklet to take away and aid their self-directed weight loss; no active weight-loss intervention was provided. The relaxation hypnotherapy group regime followed an identical timeline to the VGB hypnotherapy group. The relaxation hypnotherapy was added to the study design so that subjects received the same amount of health care professional input, given that it is recognized that response to any therapy can be influenced by the amount of time spent with the participant (Cameron, 1996). However, there was a concern that the dropout rate would be potentially too great in the relaxation group, so the British Health Foundation self-administered intervention was given as an “active” intervention.

Protocol
Participants attended a screening visit at the University of Hull and, once informed consent was gained, they were randomized to receive either VGB hypnotherapy or relaxation hypnotherapy. Randomization was undertaken using an online generator (GraphPad Software, 2012), a 1:1 treatment allocation was used, and the block size was not revealed.
The initial assessment was undertaken at the HONEI clinical trials unit by dieticians registered with the Health Care and Professions Council. A health questionnaire was administered, and height and weight measurements were obtained at screening after informed consent. The health questionnaire included questions asking the patient if they had diabetes, asthma, stroke, heart attack, epilepsy, kidney problems, depression, mental illness, skin condition, or any other health condition not listed above. Weight was taken on SECA 799 stand-on scales and measured without shoes, and participants were asked to wear similar clothing at each visit. Participants were told which day to attend for their group hypnotherapy sessions, but the type of hypnotherapy they would receive was not revealed until their first hypnotherapy session.

Recruitment took place between January and February 2012 with the intervention commencing in March 2012 and ending in September 2012. Ethical permission was obtained from Hull York Medical School, the University of Hull, where the study was undertaken. The study was undertaken in accordance with the Declaration of Helsinki.

**Statistical Analysis**

Based on an expected 3 kg weight difference (SD = 3.5 kg) between the two hypnotherapy interventions, a sample size of 12 participants was required. This calculation assumed 80% power with a two-sided alpha error of 5%. To account for a dropout rate of 10%, we recruited 15 participants per arm. Dropout was assumed to be nondifferential between arms.

The primary outcome measure (weight in kg) was analyzed using mixed-effects linear regression (Verbeke & Molenbergs, 2000). We fitted a full two-way factorial model of weight on treatment and time (Fitzmaurice, Laird, & Ware, 2011). Time of measurement was measured unevenly (baseline, 2, 3, 4, 8, 16, and 24 weeks). Probability plots were used to check for normality of residuals. A nominal level of 5% significance (two-tailed) was assumed. The Stata statistical computer package was used to analyze the data (StataCorp, 2013).

**Results**

**Descriptive Statistics**

All enrolled participants met the inclusion criteria specified for the trial (N = 30). The study consisted of 28 women and 2 men. The mean age (SD) for the VGB hypnotherapy group was 38.46 (13.97) years and 43.20 (13.71) years for the relaxation hypnotherapy
group. The mean body mass index (BMI) for both groups was in the obese range $\geq 30$ kg/m$^2$ (World Health Organization, 1995) with a mean (SD) of 34.15 kg/m$^2$ (5.87) for the VGB hypnotherapy group and 37.30 kg/m$^2$ (6.28) for the relaxation hypnotherapy group. The mean (SD) baseline weight for the participants was 93.56 kg (20.18) for the VGB hypnotherapy group and 98.42 kg (18.01) for the relaxation hypnotherapy group. There was quite a large range in the starting BMIs of participants in both groups. The VGB hypnotherapy group ranged from 28.03–49.94 kg/m$^2$ and the relaxation hypnotherapy group ranged from 28.58–48.11 kg/m$^2$, which shows a large variance in both groups.

Attendance Rate

Of the 30 participants enrolled, 25 completed the trial (VGB hypnotherapy group $n=12$, relaxation hypnotherapy group $n=13$); No reasons were given by the participants ($n=3$) that withdrew from the VGB hypnotherapy group. In the relaxation hypnotherapy group, 1 participant withdrew due to time commitments and the other patient failed to attend their first appointment. Twenty percent ($n=3$) of the VGB hypnotherapy group did not attend the last two follow-up sessions (Visits 6 and 7), which could be attributed to the fact that no hypnotherapy was administered in the last two sessions; the participants were only weighed by the dieticians. This did not occur in the relaxation hypnotherapy group, and all 13 participants left in the trial by Week 24 attended at least one of the final two visits. If no weight was recorded for the participant, the value was left blank for statistical testing.

Comparison of Virtual Gastric Band Versus Relaxation Hypnotherapy for Effects on Weight Loss

Absolute weights at the start of the trial ranged from 68.3–141.8 kg for the VGB hypnotherapy group and 71.8–129.4 kg for the relaxation hypnotherapy group. Levels of weight loss and weight gain ranged from $-17$–$+4.7$ kg in the VGB hypnotherapy group and $-9.3$–$+7.8$ kg in the relaxation hypnotherapy group. Table 1 shows that there was no significant difference between treatment as a main effect and weight loss, ($X^2 = 0.67, p = .41$, $df = 1$), and that there was no evidence of differential weight loss over time, ($X^2 = 4.2, p = .64$, $df = 6$). Figure 2 shows the individual patient data of weight over time.

Discussion

In line with recommendations for pilot studies, statistical testing was kept to a minimum (Lancaster, Dodd, & Williamson, 2004). The results
Table 1
*A Mixed-Effects Linear Regression Model: Effects Are Calculated as Differences from the Reference Groups*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Effect (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VGB</td>
<td>4.8 (18.5, 8.51)</td>
<td>.41</td>
</tr>
<tr>
<td>Time (weeks)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>−0.2 (−2.2, 1.3)</td>
<td>.63</td>
</tr>
<tr>
<td>3</td>
<td>−0.7 (−2.4, 0.9)</td>
<td>.39</td>
</tr>
<tr>
<td>4</td>
<td>−1.4 (−3.3, 0.4)</td>
<td>.12</td>
</tr>
<tr>
<td>8</td>
<td>−0.8 (−2.6, 1.0)</td>
<td>.38</td>
</tr>
<tr>
<td>16</td>
<td>−0.8 (−2.7, 0.9)</td>
<td>.34</td>
</tr>
<tr>
<td>24</td>
<td>−0.1 (−1.8, 1.6)</td>
<td>.88</td>
</tr>
<tr>
<td>Interaction of treatment and time</td>
<td></td>
<td>.64</td>
</tr>
<tr>
<td>VGB × 2 weeks</td>
<td>−0.6 (−3.1, 1.8)</td>
<td>.61</td>
</tr>
<tr>
<td>VGB × 3 weeks</td>
<td>−0.8 (−3.3, 1.7)</td>
<td>.52</td>
</tr>
<tr>
<td>VGB × 4 weeks</td>
<td>−0.2 (−2.8, 2.3)</td>
<td>.87</td>
</tr>
<tr>
<td>VGB × 8 weeks</td>
<td>−0.5 (−3.0, 2.0)</td>
<td>.67</td>
</tr>
<tr>
<td>VGB × 16 weeks</td>
<td>−1.0 (−3.8, 1.6)</td>
<td>.43</td>
</tr>
<tr>
<td>VGB × 24 weeks</td>
<td>−2.4 (−5.0, 0.1)</td>
<td>.06</td>
</tr>
<tr>
<td>Constant</td>
<td>98.4 (88.7, 108.0)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Random effects</th>
<th>Estimate (95% CI)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>312.4 (181.1, 538.2)</td>
<td></td>
</tr>
<tr>
<td>Variance (residual)</td>
<td>4.8 (3.7, 6.2)</td>
<td></td>
</tr>
</tbody>
</table>

of this study showed a slight trend towards a greater weight loss for participants receiving VGB hypnotherapy in comparison to relaxation hypnotherapy. However, these results were not statistically significant after 24 weeks. Perhaps if the trial had run longer than 24 weeks, if the hypnotherapy continued longer than 4 weeks, or if there had been a larger sample size, there would have been a statistical difference in the weight loss between the groups.

The trend towards nonattendance for Visits 6 and 7 did not occur in the relaxation hypnotherapy group. This could be attributed to the complementary virtual gastric band therapy treatment that was offered to the relaxation hypnotherapy group as an incentive for completing the trial. No incentive was offered to the VGB hypnotherapy group. According to the power calculations completed before the start of the trial, we required a minimum of 12 participants per group to complete the study. This was achieved, as mentioned above.

The NICE clinical guidelines (Centre for Public Health Excellence at NICE [UK] & National Collaborating Centre for Primary Care [UK], 2006) for obesity suggest that a weight loss of 5% of total body weight over a 6-month period can be beneficial in terms of reducing risk of
diabetes and reducing hypertension. These guidelines have recently been under review and suggest that a weight loss as small as 3% can lead to health benefits, especially if this weight loss is maintained long term (NICE, 2014). Two participants in the VGB hypnotherapy group achieved a weight loss of more than 5% compared to only 1 in the relaxation hypnotherapy group. Interestingly, 3 people in the VGB group and 4 people in the relaxation hypnotherapy group achieved a weight loss of over 3%. It must be noted that the largest weight loss was achieved by a participant in the VGB group who lost 17 kg over the 6-month trial period, which equates to 11.9% of their body weight.

There were a number of limitations in the study design. The participants in this study received group hypnotherapy rather than one-on-one individualized treatment with the hypnotherapist. Wadden and Flaxman (1981) suggest that individual sessions allow the therapist to be maximally responsive to a patient’s treatment needs while at the same time adhering to a standard protocol. Group treatment, however, may possibly provide a greater social support for the dieter. During the design of this trial, the possibility of future prescription of this procedure by health care providers was considered, and it was decided that group sessions would be the most cost-effective method. During the group hypnotherapy sessions there was no interaction between participants; therefore, there was limited benefit of a group setting for the

Figure 2. Line graph of weight over time of individual patient data.
individual. This may have prevented full participation in the session and reduced the effectiveness of the intervention.

Another limitation is that this study did not measure hypnotizability. In a study by Anderson (1985), it was found that the degree of hypnotizability could influence the amount of weight lost in a hypnotherapeutic obesity-treatment program. They found that people who are highly hypnotizable lost significantly more weight than the medium or low hypnotizable participants.

In a study conducted by Bolocofsky, Spinler, and Coulthard-Morris (1985), it was found that the use of hypnosis as an adjunct to behavioral treatment of obesity resulted in not only a significant weight reduction during the program but also a continued weight loss after the therapist’s contract was terminated. These results support the use of a combined hypnobehavioral approach, which employs hypnosis as a part of a total treatment regimen. One main limitation to our study design is that self-directed weight-loss information was only offered to the relaxation hypnotherapy group and not the VGB hypnotherapy group. This was done as an incentive to reduce the dropout rate of the relaxation group. Ideally, this would have been offered to both groups as a combination therapy.

Bolocofsky et al. (1985) asked participants to pay a $20 deposit that was refunded at the completion of the program and Wadden and Flaxman (1981) requested a $15 deposit to help with the motivation of participants. In private practice, participants have to pay for treatment, which may indicate that the individual is at the point where they are actively seeking change and, when taking into consideration the expectation factor, are more likely to succeed than a person receiving it free of charge (Stanton, 1976). This may be a contributing factor as to why the results in our study were not as conclusive as previous studies in the field of hypnosis and weight loss.

Although it was not possible to blind participants to this intervention, advertisement for this trial could have been improved. The advert highlighted the active treatment and there was disappointment on allocation to the relaxation hypnotherapy group. There is some thought that for a highly credible control group, participants must have the same expectation and motivation (Kazdin, 1979), and, during the design of this trial, this was not considered.

In conclusion, there was no significant difference between the effectiveness of VGB hypnotherapy and the relaxation hypnotherapy group. This may be due to the fact that we used group hypnotherapy as opposed to one-on-one treatment or that the treatment was given in isolation of dietary advice rather than in combination with it. There is definitely scope for larger trials to be conducted that address the limitations we experienced during this study, but the data we collected here do not support the theory that VGB hypnotherapy aids in weight loss.
**Acknowledgments**

Contributors Claire Whitham and Marie Reid designed the trial. Claire Whitham and Sarah Goodwin wrote the initial protocol. Claire Whitham and Sarah Goodwin coordinated the study, screened and randomized the participants and collected the data. Liz Wells, Alan Rigby, and Huw Jones analyzed the data and carried out statistical tests. Liz Wells and Stephanie Allen drafted the article with contributions from Marie Reid, Stephen Atkin, and Thozhukat Sathyapalan. All authors read and approved the final article. Ethical Approval was obtained from The Hull York Medical School, University of Hull (1011) January 16, 2012.

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Pilotstudie einer virtuellen Gastric Band Hypnotherapie Intervention

Stephanie Greetham, Sarah Goodwin, Liz Wells, Claire Whitham, Huw Jones, Alan Rigby, Thozhukat Sathyapalan, Marie Reid, und Stephen Atkin


Stephanie Reigel

Enquête pilote sur une gastroplastie virtuelle hypnothérapeutique

Stephanie Greetham, Sarah Goodwin, Liz Wells, Claire Whitham, Huw Jones, Alan Rigby, Thozhukat Sathyapalan, Marie Reid et Stephen Atkin

Résumé: Cette étude pilote d’une durée de vingt-quatre semaines effectuée auprès de 30 hommes et femmes ayant un IMC > 27 visait à déterminer si l’hypnothérapie associée à un anneau gastrique virtuel (AGV) a un effet sur la perte de poids chez des adultes obèses, comparativement à l’hypnothérapie de relaxation et à un régime autogéré. Les pertes et gain de poids ont varié de −17 kg à + 4,7 kg au sein du groupe auquel on a administré une hypnothérapie associée à un AGV, et de −9,3 kg à + 7,8 kg au sein du groupe ayant pratiqué la relaxation. On n’a relevé aucune différence significative entre l’hypnothérapie associée à un AGV comme effet principal sur la perte de poids, $X^2 = 0,67, p = 0,41, df = 1$, ni de signe de perte de poids différentielle au fil du temps, $X^2 = 4,2, p = 0,64, df = 6$. Les auteurs en concluent par conséquent qu’il n’y a aucun différence significative entre l’hypnothérapie associée à un AGV et l’hypnothérapie à l’aide de la relaxation.

Johanne Reynault
C. Tr. (STIBC)

Investigación piloto de una intervención hipnoterapéutica de banda gástrica virtual

Stephanie Greetham, Sarah Goodwin, Liz Wells, Claire Whitham, Huw Jones, Alan Rigby, Thozhukat Sathyapalan, Marie Reid, y Stephen Atkin

Resumen: Esta investigación piloto de 24 semanas con 30 hombres y mujeres con un IMC > 27kg/m2 tuvo como propósito determinar si la hipnoterapia de banda gástrica virtual (VGB por sus siglas en Inglés) tiene algún efecto
en la reducción de peso en adultos con sobrepeso, comparada con una hipnoterapia de relajación y una dieta auto-dirigida. Los niveles de pérdida de peso oscilaron entre $-17$kg hasta $+4.7$kg en el grupo de hipnoterapia VGB y $-9.3$kg a $+7.8$kg en el grupo de relajación. No se encontraron diferencias significativas entre la hipnoterapia VGB como efecto principal en la pérdida de peso, $X^2 = 0.67, p = .41, df = 1$, y no se encontró evidencia de un diferencial de peso a lo largo del tiempo, $X^2 = 4.2, p = .64, df = 6$. Por lo tanto, los autores concluyen que no hubo diferencias significativas entre el grupo de hipnoterapia VGB y la hipnoterapia de relajación.

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APPENDIX 1: CHARACTERISTICS OF THE VIRTUAL GASTRIC BAND HYPNOTHERAPY

Session 1 (Week 1)

- Imagining a gastric band operation.
- Suggestions for eating smaller amounts, drinking water, stopping eating as soon as they feel comfortable.
- Metaphors for no longer using their body as a rubbish bin.
- Future orientation of seeing themselves slimmer, fitter, healthier.
- Reinforcement of suggestions for new eating habits.

Session 2 (Week 2)

- Goal setting.
- Further metaphors for listening to the instinctual signals from the stomach and responding to these.
- Recognizing the different parts of ourselves, that is, the part that wants to overeat and the part that wants to be slimmer, choosing which part to whom to listen.
- Aversion therapy for specific food types if they have an issue, that is, chocolate (using an imaginary fat bucket, what the fat looks and smells like).
- Future Projection, seeing themselves slimmer.
- Further suggestion therapy, smaller amounts, etc.

Session 3 (Week 3)

- Further consideration of possible future outcomes.
- The cinema technique and making choices seeing themselves on a screen, slimmer and healthier, imagining jumping into the screen, and feeling all the feelings that they will have when they reach their goal (associating feelings of confidence, health, etc.).
• Releasing things that have held them back in the past, that is, comfort eating.
• Further suggestion therapy for smaller amounts.

Session 4 (Week 4)

• Reinforcement of all the above sessions.

Session 5 (Week 8)

• Refresher session.