This is an Accepted Manuscript of an article published by Taylor & Francis in International journal of clinical and experimental hypnosis on 2 September 2017, available online:

http://wwww.tandfonline.com10.1080/00207144.2016.1209037

Full title - Pilot Investigation of a Virtual Gastric Band Hypnotherapy Intervention

Shortened title - Virtual Gastric Band Hypnotherapy for Weight loss.

Stephanie Allen[1], Sarah Goodwin[1], Liz Wells[1], Claire Whitham[1], Huw Jones[1], Alan Rigby[1] Thozhukat Sathyapalan[1, 4] Marie Reid[1,3], Stephen Atkin[1,2,4]

[1] Hull York Medical School/HONEI, University of Hull, 11 Salmon Grove, Hull, HU6 7SX.

[2] Weill Cornell Medical College Qatar, Qatar Foundation, Education City, PO Box 24144, Doha, Qatar.

[3] Department of Psychology, University of Hull, Hull, HU6 7RX

[4]Michael White Diabetes Centre, Hull Royal Infirmary, 220-236 Anlaby Road, Hull, HU3 2RW

Correspondence to: Stephanie Allen, HONEI, 11 Salmon Grove, Hull, HU6 7SX, PH: 01482 305 208, Fax: 01482 305 206, Stephanie.Allen@hull.ac.uk

Contributors: Claire Whitham & Marie Reid designed the trial. Claire Whitham & Sarah Goodwin wrote the initial protocol. Claire Whitham & Sarah Goodwin co-ordinated the study, screened and randomised the participants and collected the data. Liz Wells, Alan Rigby and Huw Jones analysed the data and carried out statistical tests. Liz Wells and Stephanie Allen drafted the manuscript with contribution from Marie Reid, Stephen Atkin and Thozhukat Sathyapalan. All authors read and approved the final manuscript.

Keywords: Hypnotherapy, obesity, weight loss, gastric band.

Ethical Approval: The Hull York Medical School, University of Hull (1011) granted ethical approval on 16th January 2012

Funding: There was no external funding for this study. It was funded by departmental funds.

Conflict of interest: All authors declare no relationships or activities that would appear to have influenced the submitted work. There are no conflicts of interest to declare.

Abstract

This was a pilot investigation of 30 men and women with a BMI > 27kg/m^2 over a 24 week period. It 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 -17kg to +4.7kg in the VGB hypnotherapy group and -9.3kg to +7.8kg in the relaxation group. There was no significant difference between VGB hypnotherapy as a main effect on weight loss (Chi^2=0.67, p=0.41, df=1) and there was no evidence of differential weight loss over time (Chi^2=4.2, p=0.64, df=6). Therefore, this study concludes that there was no significant difference between VGB hypnotherapy and the relaxation hypnotherapy.

120 words

Introduction

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 index of 30 kg/m^2 or above (Swift, Choi et al. 2013). Obesity increases morbidity and mortality, thus reducing quality of life and productivity (Jebb, Kopelman et al. 2007). Consequently, reducing the incidence and development of obesity are major public health concerns (Nishida, Uauy et al. 2004; Jebb, Kopelman 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 programme 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) (NICE 2006; NICE 2014).

Hypnotherapy is becoming more accepted as a complementary therapy for certain conditions such as irritable bowel syndrome (NICE 2008). In a meta-analysis of 18 studies (6 of which related to obesity), Kirsch et al (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, Montgomery et al. 1995).

Cochrane and Friesen (1986) compared weight loss amongst 60 overweight women who were randomised into three groups: hypnosis treatment utilising audiotapes, hypnosis treatment without audiotapes and a control group. This 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 and Friesen 1986).

More recently a study was conducted by Stradling et al (1998) which looked at the use of hypnotherapy as an adjunct to dietary advice in producing weight loss. 60 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 favour of hypnotherapy, however they did not utilise a control group and the weight loss after 18 months was clinically insignificant (Stradling, Roberts et al. 1998).

Clinical hypnosis is a procedure in which a therapist suggests that a client experience changes in sensation, perception, thought and behaviour, with some therapists believing that hypnotic inductions produce an altered state of consciousness (Kirsch, Montgomery 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 (Mott and Roberts 1979). Stewart (2005) stated that studies looking at hypnotherapy as a single treatment for weight loss are limited and have shown varied levels of success (Stewart 2005).

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 publicised but non-evidence based intervention. Hypnotherapists, Martin and Marion Shirran, are believed to be first that pioneered the technique and they registered the trade mark for the Gastric Mind Band in North America and Europe (Shirran 2010).

The aim of the 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.

Methods

Subjects

30 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 programme, hypnotherapy, had any co-existing medical problems, a history of eating disorders, excessive use of alcohol or any recreational drugs, pregnancy and 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 in week 8 for a further 1 hour refresher hypnotherapy session. Participants were also asked to attend at week 16 and 24 to be weighed at the HONEI clinical trials unit (11 Salmon Grove, University of Hull, HU6 7SX) 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 relaxation group were carried out by the same hypnotherapist who holds a Practioner 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, University of Hull.

Virtual Gastric Band Hypnotherapy

The VGB hypnotherapy programme included a number of mind management techniques designed to form a new set of eating habits. The programme 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 and Rennick 1991). The VGB hypnotherapy used 'imaginary surgery' to persuade participants that the surgery has taken place (McRae, Cherin et al. 2004). Before the hypnosis began, participants were given some guidelines to follow consciously, including eating 3 times/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 behaviour/habits or outcomes were used. This group also received a self-hypnosis recording to listen to every day; however this focussed more on relaxation and mental imagery and gave no suggestions regarding behaviour/habits. The relaxation group were also provided with the British Heart Foundation 'So you want to lose weight for good' booklet. 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 healthcare professional input, given that it is recognised 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 randomised to receive either VGB hypnotherapy or relaxation hypnotherapy. Randomisation was undertaken using an online generator (GraphPad Software), 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 (11 Salmon Grove, University of Hull, HU6 7SX) by dieticians registered with The Health Care and Professions Council. A health questionnaire, 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 was 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 3kg 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 drop-out rate of 10%, we recruited 15 participants per arm. Drop-out was assumed to be non-differential between arms.

The primary outcome measure (weight in kg) was analysed using mixed-effects linear regression (Verbeke 2000). We fitted a full 2-way factorial model of weight on treatment and time (Fitzmaurice 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 (2-tailed) was assumed. The Stata statistical computer package was used to analyse the data.

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 BMI for both groups was in the obese range $\geq$ 30 kg/m^2 (WHO 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 BMI's of participants in both groups. The VGB hypnotherapy group ranged from 28.03 to 49.94 kg/m^2 and the relaxation hypnotherapy group ranged from 28.58 to 48.11 kg/m^2 which show 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 one participant withdrew due to time commitments and the other patient failed to attend their first appointment. 20% (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, as all 13 participants left in the trial by week 24 attended at least one of the final 2 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 kg to +4.7 kg in the VGB hypnotherapy group and -9.3kg to +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 (Chi^2=0.67, p=0.41, df=1) and that there was no evidence of differential weight loss over time (Chi^2=4.2, p=0.64, 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 et al. 2004). The results of this study showed a slight trend towards a greater weight loss for participant's 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, or 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 non-attendance 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 (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 (NICE 2006). 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 one 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 17kg 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 individualised 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 (Wadden and Flaxman 1981). 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 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 hypnotisability. In a study conducted by Anderson et al (1985) it was found that the degree of hypnotisability can 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 (Andersen 1985).

In a study conducted by Bolocofsky (1985) it was found that the use of hypnosis as an adjunct to behavioural 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 (Bolocofsky, Spinler et al. 1985). These results support the use of a combined hypno-behavioural 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 (1985) asked participants to pay a $20 deposit which was refunded at the completion of the program (Bolocofsky, Spinler et al. 1985) and Wadden and Flaxman (1981) requested a $15 deposit to help with the motivation of participants (Wadden and Flaxman 1981) . 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 does not support the theory that VGB hypnotherapy aids in weight loss.

Acknowledgements:

The study was funded by the HONEI project at the University of Hull. All authors declare no relationships or activities that would appear to have influenced the submitted work.

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