

A study to investigate the effectiveness of combining technology, prescription diet, lifestyle changes and biometric monitoring to achieve optimum weight loss and body image

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Abstract

Obesity is a problem of epidemic proportions and despite public health measures, is actually getting worse. Being overweight or obese has significant implications on health and wellbeing and treating complications costs the NHS huge resources. Although there is evidence for dietary interventions and exercise, this study investigates a holistic approach combining diet, exercise, motivational support and non-surgical body treatments and its impact on body weight and other measurements. At the end of a 4 month period, 10 patients lost an average weight of 12.9kg and 15.2cm on waist sizes as well as improvements in blood pressure, cholesterol and mental wellbeing. Further research is planned to look at continuing the program beyond 4 months and also looking at a maintenance program to maintain weight loss.

Introduction

England, along with the rest of the UK, has an unenviable position as one of the world leaders in excess weight. We have one of the highest rates of obesity in Europe and one of the highest in the developed world¹. In England, most people are overweight or obese. This includes 61.3% of adults and 30% of children aged between 2 and 15. People who are overweight have a higher risk of getting type 2 diabetes, heart disease and certain cancers. Excess weight can also make it more difficult for people to find and keep work, and it can affect self-esteem and mental health. Health problems associated with being overweight or obese cost the NHS more than £5 billion every year².

Despite this, there is little help available on the NHS. A meta-analysis looking at the long-term efficacy of anti-obesity drugs showed less than a 5kg weight loss over a period of 1-4 years³. It is for this reason people are turning more increasingly to the private sector. Weight loss is a thriving industry with over £1bn spent on diet products in the UK alone last year⁴. Similarly, global equipment sales for body contouring devices have seen a rapid increase. Technology is more advanced and treatments are now more effective, more affordable, more available and with less downtime for the average consumer.

However, devices do have their limitations and this study aims to determine the benefit of a holistic approach combining medical technology (3D-lipo device with cryolipolysis, cavitation, radio-frequency and vacuum rolling) with a lifestyle program incorporating diet, exercise and wellbeing.

Study participants

Patients were recruited on a voluntary basis, after completing a medical history questionnaire and assessment. Exclusions to participation included pregnancy and lactation, patients under the age of 18 years, pacemaker or metal implants, eating disorders, immunosuppression, milk intolerance and uncontrolled medical conditions.

A total of ten patients were recruited with an average age of 37.7 years (range from 25 to 45 years) and an average starting Body Mass Index (BMI) of 35.8 (range from 30.2 to 44.1) which is in the severely obese category. Nine patients completed the 4 month trial with one patient withdrawing from the study at 3 months due to a change in life circumstances and depression. After the 4 month period, patients were asked if they would like to continue for a further 2 months extension period of which 5 patients remained on the study. There were no financial incentives for participation and no cost to the patient.

Study protocol

All patients were given an overview of the study and the time commitment involved. A consent form and confidentiality agreement was signed by each patient. At the initial consultation, biometric measurements were taken (Tanita Segmental Body Composition Scales), Health and Wellbeing scores (The Warwick-Edinburgh Mental Well-Being Scale), urine testing, blood testing (Full blood count, renal function, liver function, thyroid function, glycosylated haemoglobin, cholesterol and HDL), blood pressure and hip, waist and chest measurements. Standardised photographs were taken at the start of the trial and at 4 weekly intervals and also upon completion of the study.

Dietary advice was given throughout the program and patients were provided with recipes, snacks and meal suggestions. Each patient had an allowance of protein, greens, starchy carbohydrates and a dressing calculated using a unique point based system developed specifically for the study. The principles of the diet component consisted of a milkshake at 7am, a snack at 10am, a soup sachet at 1pm, a milkshake at 4pm and a meal at 7pm. If required as part of the program, a further snack was allowed at 10pm. The soups and milkshakes were provided to the patients and contained a special formulation that was developed specifically for the study and to encourage weight loss and to provide essential vitamins and nutrients. The essence of the diet was to maintain a healthy, balanced blood glucose level throughout the day without any peaks or troughs, by doing this; patients did not feel hungry or have cravings throughout the day and did not complain of lack of energy or feeling low. Although specific timings were recommended, there was flexibility to suit different lifestyles although it was advised to try and have something to eat or drink every 3 hours. During holiday periods when patients were not preparing their own food, they were encouraged to continue on the soups and milkshakes and given additional advice on foods to try and avoid. After the initial 2 weeks, patients were allowed to have a cheat meal once a week where there were no restrictions.

Exercise was agreed using the F.I.T.T. principle (Frequency, Intensity, Time and Type) and concentrated on different domains (aerobic exercise, resistance training, functionality and mobility and flexibility). Physical activity was measured and assessed using the Borg scale which subjectively gauges the perceived exertion with each exercise. The Borg scale ranges from 6 (no exertion at all) to 20 (maximum exertion). Exercise was discussed more and encouraged greater as patients remained on the study. As participants were successfully losing weight, they found that they had more energy and were more capable of doing exercise. Exercise was tailored to the individual using a specific workbook and ranged from exercises as simple as getting out of a chair without using the arms to assist to intense gym sessions with a personal trainer.

Treatments occurred on a weekly basis using the 3D-lipo device and consisted of a combination of cryolipolysis, cavitation, radiofrequency and vacuum rolling. Although cryolipolysis was used at the start of the trial, the majority of treatments consisted of cavitation. Vacuum rolling was used at the end of each treatment session. Each treatment lasted approximately 45 minutes and the area to be treated and the technology used was at the discretion of the clinician on an individual basis. During the duration of the program, the average number of treatments received by each patient was 17.1.

Each patient had a unique treatment plan based on their own targets, their Basal Metabolic Rate (BMR) and exercise capabilities.

(1) Weekly visits

The patient attended on a weekly basis for a 3D-lipo treatment. Biometric measurements (which includes weight and BMR) and urine testing occurred at each visit. During the treatment, further motivational, dietary and exercise advice was given and further reinforcement of the program. If targets were not being met, the patient was given the option to see the clinician to re-assess before the monthly visit. If any medical problems were identified, they were referred back to the clinician for further assessment and suitability to remain on the program. During the course of the study, no-one was excluded on medical grounds.

(2) Monthly visits

Patients were seen by the clinician on a monthly basis to review targets and adjust diet according to the points system. Blood pressure was recorded at each visit and photographs taken. Medical assessments were conducted and any concerns discussed. Exercise and diet was reviewed and further targets set.

During the 4 months, all patients received active treatment with an initial 2 weeks detox at the start. The detox phase included all elements of the program but with additional restrictions on diet and drinks; this included no alcohol, no carbonated drinks, avoiding tea and coffee and no cheat nights.

It is well publicised that even successful weight loss strategies do not seem to be very effective long term and a systematic review found that only 15% of patients had a successful outcome over time (median 5 years)⁵. It is intended when patients have completed their treatment and achieved their target weight, they will be given the option to enter a maintenance phase. This will include monthly visits with the clinician as outlined above, adherence to the diet program and exercise regime but without any additional body treatment.

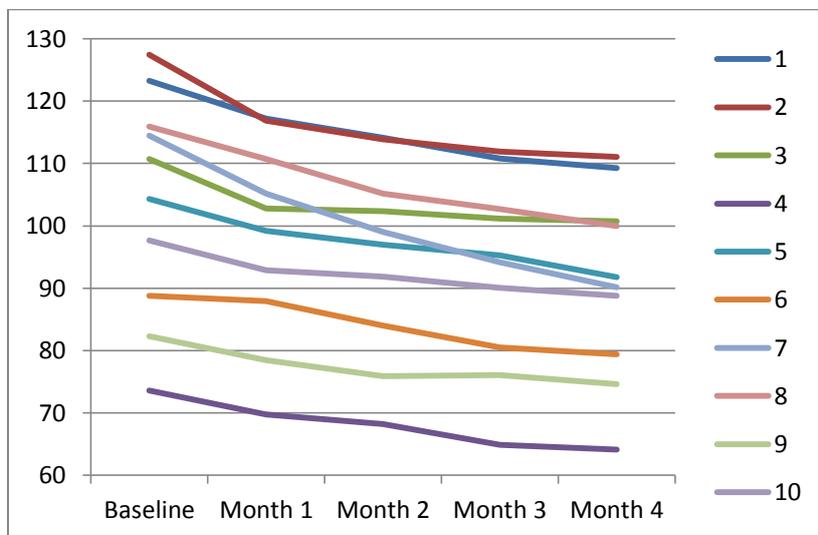
Results

(1) Weight loss

The average weight loss achieved during the study was 12.9kg (range from 7.7kg to 24.3kg), although as individual weights were so different at the start of the program, weight loss is best to be described as percentage weight loss from baseline. The average percentage weight loss was 12.2% (range 9.0% to 21.2%). The average BMI at the start was 35.8 (range from 30.2 to 44.1) and at the end of the 4 month study was 31.2 (range from 26.5 to 38.7).

Patient	Baseline	Month 1	Month 2	Month 3	Month 4	Loss (Kg)	Loss (%)
1	123.3	117.2	114.1	110.8	109.3	14.0	11.4%
2	127.4	116.9	113.9	111.9	111.1	16.3	12.8%
3	110.7	102.8	102.4	101.2	100.7	10.0	9.0%
4	73.6	69.8	68.2	64.9	64.1	9.5	12.9%
5	104.3	99.2	97.0	95.3	91.8	12.5	12.0%
6	88.8	87.9	84.0	80.5	79.4	9.4	10.6%
7	114.5	105.2	99.0	94.2	90.2	24.3	21.2%

8	115.9	110.7	105.2	102.7	100.0	15.9	13.7%
9	82.3	78.5	75.9	76.1	74.6	7.7	9.4%
10	97.7	92.9	91.9	90.1	88.8	8.9	9.1%
AVERAGE	103.9	98.1	95.2	92.8	91.0	12.9	12.2%



(2) Body measurements

Hip, waist and chest measurements also showed significant improvement with an average reduction in hip size of 12.5cm (range from 6.5cm to 22.5cm), waist size of 15.2cm (range from 7.5cm to 26.5cm) and chest size of 7.3cm (range from 1cm to 13.5cm). All measurements were taken using a specific body measuring tape measure and by the same person to ensure consistency. Self-reported improvement in body image was high.

(3) Blood pressure

An average improvement of systolic blood pressure of 13.4mmHg (range from -2mmHg to 34mmHg) and diastolic blood pressure of 7.8mmHg (range from -2mmHg to 27mmHg) was observed during the study period. Blood pressure was recorded by the clinician using a standard aneroid sphygmomanometer. At the start of the study, one patient was known to be hypertensive and on medication with an initial blood pressure of 129/86mmHg and final blood pressure of 115/82mmHg.

(4) Blood tests

Full blood count, renal function, liver function and thyroid function remained stable throughout the study period. The average total cholesterol at the start of the study was 5.7mmol/L and had improved by an average of 1.1mmol/L upon completion of the 4 month trial. There was very little change observed in glycosylated haemoglobin levels with the HbA1c falling by 0.1%.

(5) Urine tests

Urine dipstick testing was conducted on a weekly basis with the aim to detect ketosis. During the study period, there was only a single episode of a ketone positive dipstick recording and this was during a viral illness and vomiting that the patient has been experiencing at the time.

(6) Wellbeing self-assessment

Patients completed a WEMWBS⁶ (The Warwick-Edinburgh Mental Well-being Scale) to measure mental wellbeing at the start and end of the clinical study. The WEMWBS is a well-recognised peer reviewed tool. All but one patient showed improvements in their scores and an average improvement of 15.6% (range from -2.9% to 37.1%) was recorded. The majority of patients had scores of between 40-59 at the outset which lies in the average range and by completion, most patients were in the above average mental wellbeing range.

(7) Photographs

Picture 1: Before and after pictures, patient 4



Picture 2: Before and after pictures, patient 7



Conclusion

All patients that completed the trial showed significant weight loss and improvements in body measurements with favourable outcomes in blood pressure and cholesterol measurements. No adverse events were reported throughout the study and only one patient withdrew from the trial (although this was not felt to be related to participation in the program). Feedback was very positive and this has been reflected in improvements in mental wellbeing scores.

Discussion

The results from this small study prove extremely promising and the results from offering a combination approach using technology, diet, exercise and motivational support seem greater than any of the individual components. In fact, a review of the literature looking at the evidence of non-surgical treatment states "They do not serve as a significant method for weight loss, and as such, realistic expectations should be set with patients."⁷

It will be interesting to see if further weight loss is obtained by continuing the study for a further 2 months and the study has been extended to 5 patients who wished to continue on the program and had not yet achieved their target weight. After completing 6 months, patients will also be given the option to remain on a maintenance program involving continuing diet, exercise and motivational support and a monthly review assessment. Hopefully this will demonstrate sustained weight loss.

Finally, this has only been a small study including 10 patients and it is hoped when the program is rolled out nationally, much more robust data will be available to confirm the findings of this trial.

Disclaimer: Dr Martyn King and Sharon King RN, NIP have a commercial interest in the 3D lipolite medical weight loss program which combines technology, diet and exercise.

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