

# A New Swallowable Intra-gastric Balloon for Weight Loss Not Needing Endoscopy: Early Experience in Combination with a VLCKD

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**Introduction:** Weight loss with intra-gastric balloons tends to taper later in therapy. Very low calorie ketogenic diets (VLCKD) may be useful later in balloon therapy.

**Aim:** To evaluate the efficacy and safety of a new swallowable intra-gastric balloon that does not require endoscopy or anesthesia in combination with a VLCKD in the final month of therapy.

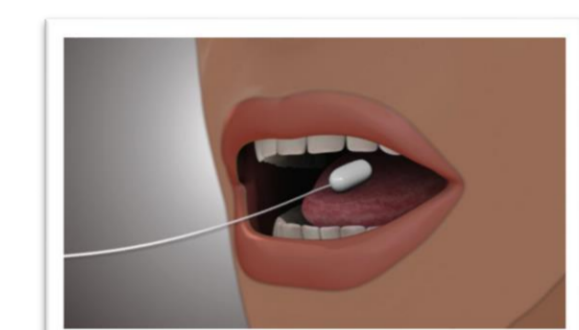
**Methods:** This was a prospective, non-randomized study in 38 obese individuals (BMI 30-45 kg/m<sup>2</sup>) treated with the Elipse Balloon. The balloon remains in the stomach for 4 months after which it spontaneously opens, empties, and is excreted. Follow-up was performed every 2 weeks. In the last 4 weeks, a ketogenic diet (~700 kcal/day) was introduced to enhance weight loss.



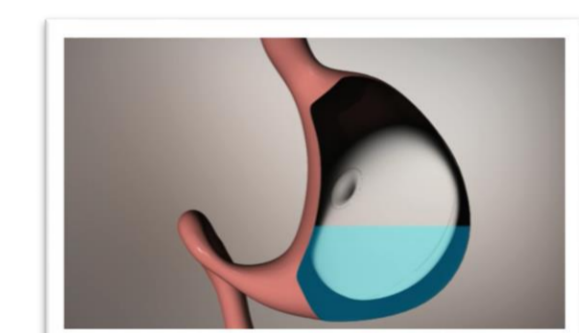
## The Elipse® Balloon



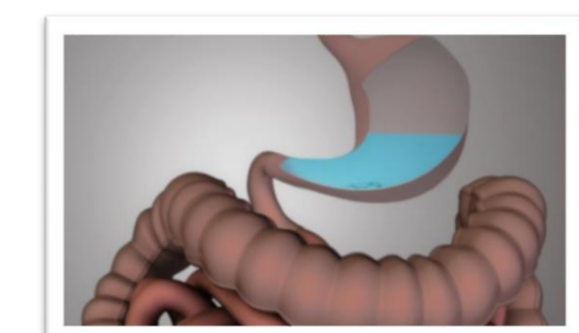
The Elipse Balloon is swallowed and filled through a thin catheter.



1. The Elipse Balloon is swallowed



2. Filled to 550mL



3. Remains in the stomach for 4 months

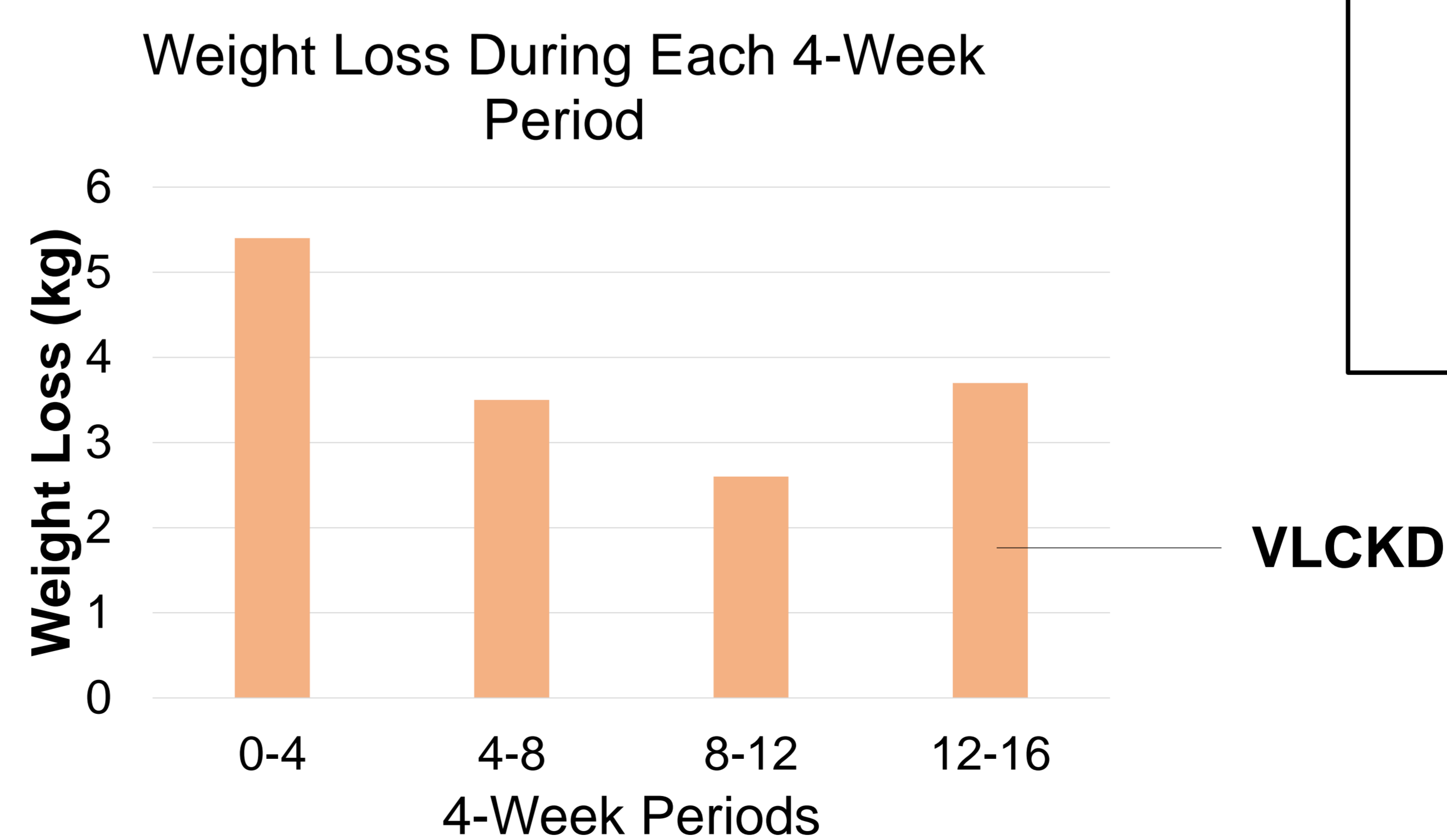
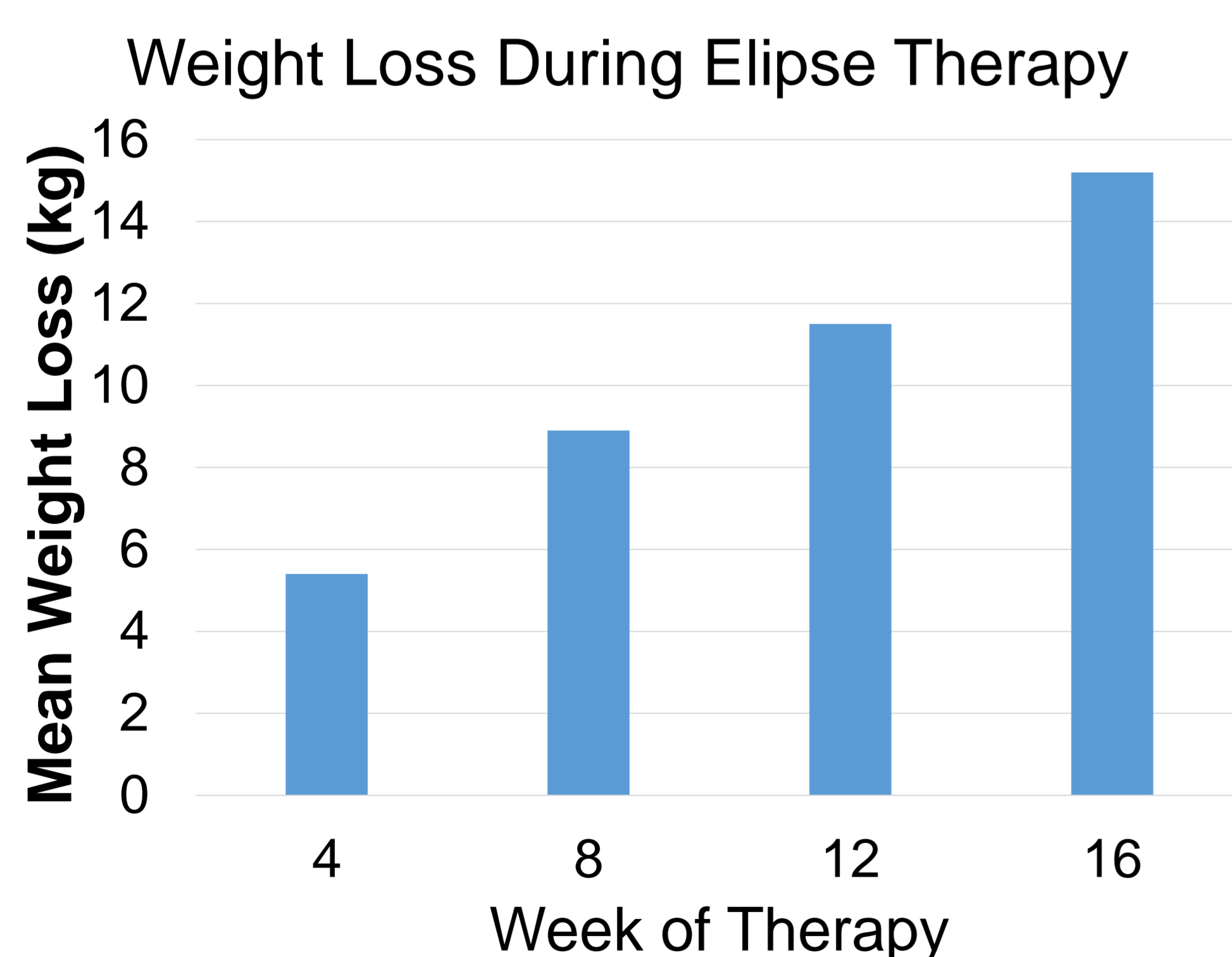


4. Spontaneously empties and is excreted in the stool

## Results

	Baseline Characteristics
<i>n</i>	38
Age (yrs)	46.4 ± 10.6
Gender	28M / 10F
Weight (kg)	109.7 ± 21.9
BMI (kg/m <sup>2</sup> )	38.6 ± 6.7

- All balloons swallowed, filled, excreted successfully
- No serious adverse events
- In the VLCKD period, a mean weight loss of 3.7kg was observed, similar to that observed between Weeks 4-8.



**Conclusion:** The Elipse Balloon appears to be a safe and effective weight loss method. Furthermore, the introduction of a VLCKD improves weight loss. The procedureless nature of the Elipse Balloon may make it amenable to a larger population of obese patients not responding to diet treatment and a variety of clinicians (e.g. nutritionists, dietitians, and internists) who currently do not have access to endoscopic or surgical weight loss devices.