

# WHAT PARTICIPANTS SAY ABOUT DIETING TO ACHIEVE DIABETES REMISSION

The Counterbalance and DiRECT trials showed that very-low-energy and low-energy diets can lead to remission of Type 2 diabetes. But what is it like being on one of these trials? A new study explores the barriers and facilitators to success in a situation where calorie intake is severely restricted. The findings could be used to optimise the outcomes of future diabetes remission studies

**W**eight loss achieved through a very-low-energy diet (VLED) can normalise blood glucose levels in people with Type 2 diabetes. Moreover, a review of the evidence shows that VLEDs are associated with greater weight loss than low-energy diets, minimal interventions or standard care at three and six months. Although VLEDs may seem challenging, attrition rates are actually similar to those for other weight loss regimens and have improved in recent years. Attrition rates can be used as a measure of how acceptable a weight loss plan is to the participant.

There have been few studies, however, on the acceptability of VLEDs in terms of improved quality of life. There has been one study looking at the experience of a VLED delivered in a group setting which showed that social support, participation in a research study and improvements in wellbeing contributed to weight reduction. Now, a new study, from researchers at Newcastle University, takes an in-depth look at participant experience of VLEDs.

Specifically, it examines perceived barriers to, and facilitators of, adherence and the various behaviour regulation strategies employed by a group of people with Type 2 diabetes taking part in a trial of a VLED for remission of the condition. The new findings are part of the Counterbalance study, which is a single-centre trial conducted in the UK with the aim of achieving normalisation of blood glucose levels (also known as diabetes remission), insulin secretion and action and reductions of liver and pancreatic fat through application of a VLED. This is the first qualitative study to look at the acceptability and experience of VLEDs in the context of diabetes remission. It complements the evidence on the efficacy of the VLED in diabetes remission that has emerged from the main Counterbalance study.

## Counterbalance

The Counterbalance study consisted on an eight-week VLED, followed by a two-week stepped return to a calorie-controlled diet. It involved 30 adults with Type 2 diabetes of duration 0.5 to 23 years. The diet allowed 800kcal per day, of which 600kcal was in the form of liquid formula soups and shakes. The rest of the calorie allowance was made up of vegetables, and participants were asked not to drink alcohol. In addition, all oral hypoglycaemic agents were stopped for the duration of the study.

The participants also attended the Magnetic Resonance Centre at weeks 1, 4 and 8 for biomedical measurements and interviews about their experience of the study. Weekly one-to-one support, to maximise adherence, was provided by email, phone and face-to-face contact. Changes in body mass, plasma ketones and food diaries were used to monitor adherence. Participants were also asked to record their fasting and post-meal blood glucose levels three times a week.

## Exploring experiences of the VLED

This new study is based on semi-structured interviews with participants, carried out before and after the eight-week VLED. Only those who achieved their weight loss goals – generally 2.8 per cent body weight loss at week 1 and 8 per cent at week 8 – were permitted to continue in the study. At the end of the VLED phase, the participants' weight had fallen from 98.0 ( $\pm 2.6$ )kg to 83.8 ( $\pm 2.4$ )kg. Furthermore, 12 of the 30 participants achieved remission of their Type 2 diabetes (fasting plasma glucose  $< 7$ mmol/l).



PHOTOS: THINKSTOCK

“What I found with the diet is that **the regimen suits me**. I like to know what I’m going to have to eat”

Woman, 35 years, diabetes duration 1.5 years

The interviews included open-ended questions about participants’ experience of the VLED. These were conducted face-to-face and audio-recorded, with field notes being taken before and after the interview. The interviewer was a health psychology PhD student, with a Masters in health psychology, supervised during the study by an experienced academic clinical psychologist. The interviews were anonymised and transcribed verbatim.

The analysis of the interview data aimed to:

- understand barriers and facilitators to completing a VLED within a clinical study
- understand how intervention procedures can be optimised to maximise acceptability of the VLED
- enable more individuals with Type 2 diabetes to succeed with dietary remission in the future.

A thematic approach to the data analysis was used, with coding of predefined theory-based themes, and inclusion of additional themes emerging from the data.

### Motivation and initial expectations

The main motives for taking part in Counterbalance were the prospect of diabetes remission and weight loss. Many participants had previously tried to lose weight and maintain the loss, with varying degrees of success. The prospect of large and rapid weight loss in Counterbalance was appealing. People wanted to dress better and feel more confident in their bodies. Improvements in long-term health and regaining control over their health were also a big draw. The wish to increase the length and quality of life with increasing age was another motivating factor. Many said how they wanted to

be healthy enough to take care of, and spend time with, family later in life.

**"The main thing that I’m after is trying to cut myself free from diabetes. That’s a very strong motivation, because I am not getting any younger..."**

Then there was the wish to get rid of the practicalities of managing diabetes, such as the need to take tablets and side effects associated with diabetes medication.

Participants thought about potential barriers before they began on the VLED. Some worried that stressful situations might lead to lapses. Availability of social support during the study was seen as important – participants could approve



or disapprove and study staff could offer information and encouragement, as well as feedback in terms of weight and blood glucose measurement.

### The VLED experience

Although some participants had worried that they would feel hungry on the diet, adhering to it turned out to be easier than anticipated.

**"I thought I would have been hungry from the moment I opened my eyes to the moment I closed my eyes but I wasn't"**

The most important factors affecting adherence were physical and social environments, emotional states and the possession of self-regulatory skills. For instance, sadness, loneliness and stress

tended to increase the desire to ‘give in’ to temptation. But awareness and weighing up of the pros and cons strengthened resolve. Impulse, triggered by the sight or smell of food, as well as a conscious decision to ‘break’ the diet led to deviations. It was when the participant was alone that such deviations were most likely to occur, underlining the importance of social pressure and support.

### Facilitators of adherence

The study revealed that the three main factors facilitating adherence to a VLED were: rapid results, social support and being involved in a research study. Weight loss led to being able to fit into smaller clothes and improvements in appearance and wellbeing, all of which provided extra motivation to continue. Receiving compliments was a very important form of social support.

Relatives and friends also helped adherence through:

- altering their own eating behaviour
- eating at different times from the participant
- refraining from offering food
- warning the participant before cooking, so they could avoid tempting sights and smells
- reminding participants of the ‘rules’.

It was particularly helpful to get support from a friend or relative who had successfully gone through a weight loss programme. So was creating a support system with others who were losing weight at the same time. Another element was the feeling of being privileged by being in the study, for it involved only a small number of people. Not wanting to let the researchers down, appreciating the time and effort involved on their part and wanting to contribute to diabetes research were all powerful drivers of adherence.

**"I do recognise...that this is a medical study so I’m one of a handful of people that are lucky to actually be on it..."**

### Behaviour regulation

The researchers learned about the behaviour regulation strategies employed to facilitate their adherence to the diet. These centred around planning, avoiding and distraction. Some of these strategies are listed in the following table.



Theme	Strategy
Food removal	Throwing away/giving away/eating up leftovers before starting the VLED
Avoidance of...	Television, to avoid food ads or snacking Social events with abundance of food
Planning	Having healthy nibbles (carrots, pieces of apple) to hand Carrying a bottle of water
Hunger management	Drinking the VLED shakes hot or very cold to improve palatability Going to bed earlier Getting active/distracting oneself from food with gardening or hobbies Reminding oneself of one's success
Social	Telling others about one's weight loss attempts to gain support and understanding Getting a weight loss 'buddy' to share experience and tips with

### Strategies facilitating adherence to a VLED

## Changes in physical and psychological wellbeing

Weight loss, improvements in blood glucose and physical fitness, compliments from others and a sense of confidence, control and achievement all contributed to participants' overall improvement wellbeing and happiness.

**"I feel better inside, not just looking better on the outside...I just feel I don't feel ill, and that's how I felt before"**

While they had expected to feel grumpy or irritable while on the VLED, participants reported that their mood actually remained stable.

Participants also became more sensitive to the feeling of hunger and learned how their bodies responded to food, and food restriction, and how they behaved when tempted. All of this helped them to a better understanding of their relationship with food. While energy levels dropped, initially, because of the calorie restriction, they increased gradually over the eight-week trial.

Fitness levels improved too, with the ability to do activities for longer than previously and at a greater level of intensity. The participants found they could also function better in daily life – with more walking, climbing stairs, working in the garden and playing with grandchildren.

## Acceptability of the VLED

The meal replacement soups and shakes are easy to prepare. Minimal input is required into shopping, preparing or making decisions about food. This simplicity really appealed to participants.

**"Well, anyone could follow it because there's not a lot of food and not a lot to do with it"**

The first couple of days on the new regimen were the most challenging, but the initial two to three weeks turned out to be easier than expected when it came to feeling hungry and getting used to the VLED. At the midway point, participants did report getting bored with the lack of variability and solid food that the diet entailed. Most people overcame this feeling by putting the eight-week time period into perspective, and focusing on the potential long-term health gains.

## Discussion

In conclusion, the VLED for diabetes remission was both acceptable and easier to adhere to than participants had feared. Barriers to adherence mentioned included hunger, emotional distress and environmental triggers, but these proved minimally disruptive in reality. Rapid outcomes, social support, and being involved in a study aided adherence.

Various behaviour strategies, as listed above, were used to deal with barriers to adherence. The taste and structure of the VLED, with its soups, shakes and vegetables, was generally well accepted, though participants made suggestions for introducing greater variety. They also wanted to more opportunities to meet other participants for support.

The main motivators for taking part in the Counterbalance study were the prospect of diabetes remission and weight loss. However, issues relating to overall health, family, quality of life and improved appearance were important too. Previous research has underlined the importance of improved body image and health in successful weight loss.

The National Weight Control Registry in the USA states that 83 per cent of its members experience a specific trigger for their weight loss, which could be medical reasons, reaching a highest-ever weight or seeing their reflection in a mirror. In this study, participants were motivated by the shock of a Type 2 diabetes diagnosis, fear of the consequences of the condition or trying to conceive a baby. Social support was seen as very important and was able to override environmental and emotional triggers that might have led to a lapse. Thus, this aspect should be emphasised in future diabetes remission trials.

Lapses were few. Previous work has shown that subjective feelings of appetite are significantly reduced among people without diabetes on a VLED because of the induction of ketones, and associated changes in appetite hormones. This might explain the low number of lapses and reported lack of hunger noted in the present study.

**“It was fairly hard to start with but it got easier as the weeks went on and then when I started getting a bit fitter ... I could walk further and stand up and sit down and dig the garden. It's great now. I feel great.”**

Man, 44 years, diabetes duration 2.5 years

“My cholesterol has come down from around 7 to 3.3 so my nurse has taken me off my statins. She said my blood sugar is now that of a normal person, not a diabetic. In six months, I’ve lost **3 stone 2 pounds**. My nurse was over the moon!”

Woman 47 years, diabetes duration 2.5 years

PHOTOS: THINKSTOCK

A further factor in the success rates in this study was that half of the participants reported having a ‘buddy’ either inside or outside the trial, who could provide them with individualised

social support. Other studies have shown that social support has significant benefit in diabetes control and weight loss. Finally, regular monitoring and feedback from study staff were also powerful facilitators for success on the VLED. Other research has shown that individuals who weigh themselves lose more weight, and consume fewer calories, than those who do not monitor their weight.

In conclusion, the current study shows encouragingly high levels of adherence to a VLED and provides valuable insights into how the participants achieved their success. It should be kept in mind, however, that less favourable outcomes might occur in a primary care setting, with fewer

resources and less motivated individuals. However, the findings of the current study dispel concerns about the acceptability of VLEDs under clinical supervision and highlight opportunities to further optimise support during dietary diabetes remission.

**This is a digested version of Rehackova L, Araujo-Soares V, Adamson AJ et al (2017). Acceptability of a very-low-energy diet in Type 2 diabetes: patient experience and behaviour regulation *Diabetic Medicine* 34 (11); 1554–1567. To download this paper, go to <http://onlinelibrary.wiley.com/doi/10.1111/dme.13426>**



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