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Very Low Energy Diets at the Canberra Obesity Management Service: A Comparison of Patient Participation and Clinical Outcomes Following a Change in Inter-Disciplinary Service Model

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Abstract

Aims: This study compared clinical outcomes and service efficiency for individual and group-based Very Low Energy Diets at Canberra Obesity Management Service in 2017 and 2018, respectively.

Methods: A retrospective review compared VLED commencement and completion rates, baseline demographics, anthropometric and metabolic changes, and medication use.

Results: A higher proportion of patients (but less males) completed VLED as part of the 2018 group-based model. Mean start weight and BMI were similar for both years. The 2018 group had greater baseline metabolic abnormalities. Co-morbid hypertension and dyslipidaemia were more common in the 2017 patients. Co-morbid T2DM, oral hypoglycaemic agents and/or insulin use was greater in the 2018 group. Greater mean reduction in weight, BMI and percentage body weight was observed in the 2017 patients. Changes in metabolic parameters were similar for both years. Compared to 2017, a higher proportion of the 2018 group reduced or ceased anti-hypertensive agents. Upon VLED completion, an equal number of patients from each year ceased insulin therapy.

Discussion: This study demonstrated that using the 2018 group-based service model was non-inferior to traditional VLED methods in improving metabolic profiles and reducing medication requirements. The greater anthropometric changes observed in 2017 were not statistically significant and likely due to a higher proportion of males undergoing VLED in 2017. Areas of future research include stratifying results according to gender, longer-term monitoring to determine the sustainability of clinical improvements, and comparing outcomes with other obesity services.

Keywords: Clinical outcomes; Hypertension; Medication; Obesity management; T2DM; VLED

Introduction

Obesity is a complex chronic health issue and a leading cause of morbidity and mortality [1]. Whilst obesity is recognised as a global public health problem, its prevalence is noticeably higher in settings that have transitioned away from traditional lifestyles to more obesogenic environments [2,3]. There is an array of evidence to support a multi-factorial basis for obesity, however, sub-optimal diets are recognised as a key factor in obesity and its associated co-morbidities [4]. Very Low Energy Diets (VLEDs) offer an evidence-based and medically sound method of achieving rapid weight reduction for people with a Body Mass Index (BMI) >30kg/m^2. According to the National Health and Medical Research Council (NHRMC) Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults, Adolescents and Children in Australia, VLEDs are a useful intervention to support weight

loss [5]. Historically, there has been caution regarding the use of VLEDs as a routine weight loss strategy, with some guidelines recommending use only when urgent weight loss is medically indicated. However, recent studies have highlighted the favourable risk profile, metabolic outcomes and sustained weight loss with VLEDs under appropriate medical supervision [5,6].

VLEDs consist of nutritionally complete meal replacements that facilitate weight loss by limiting overall energy and carbohydrate intake and inducing ketosis. VLEDs are particularly useful in patients who require rapid weight reduction prior to surgical procedures, in those whose mobility is compromised due to excess weight, and in those with Type 2 Diabetes Mellitus (T2DM) who wish to delay insulin therapy or reduce insulin requirements.[5] Although VLEDs have a strong evidence base for use in patients with obesity, there are known contra-indications and the NHMRC provides guidance on how this intervention should be delivered [5].

The Canberra Obesity Management Service (COMS) provides physician-led management of patients with severe obesity (BMI >40kg/m^2) and medical co-morbidities [7-9]. COMS offers case management, allied health support and a range of intensive interventions including a 12 week VLED, pharmacotherapy and bariatric surgery [10]. In 2018, COMS modified the way in which the VLED program was facilitated. The change in VLED provision was not based on a pre-existing service model but rather in response to increasing demand for intensive interventions and limited staffing resources. Whilst continuing to follow the NHMRC guidelines [5], COMS transitioned from individual appointments with a dietitian to a structured inter-disciplinary group approach with pre-planned medical reviews by a physician.

The new COMS model identifies potential VLED patients several weeks to months in advance with some joining at short notice if medically stable. The group attends a dietitian-led information session prior to individual medical, nursing and dietitian assessments. COMS physicians diagnose nutritional deficiencies, new co-morbidities and consider medication adjustments, whilst dietitians provide individualised VLED meal plans for each patient. Medical reviews are booked at 0, 6 and 12 weeks. Dietitian and nurse reviews occur at 0, 2, 6 and 12 weeks. To streamline the VLED process, all patients in the group had their individual follow-up appointments scheduled for the same days. The aim of this study is to determine whether the change in COMS VLED service provision led to improved clinical outcomes including weight and BMI reductions, improved metabolic profiles and medication requirements. This study also aims to compare 2017 and 2018 service model efficiency in terms of VLED commencement and completion rates.

Methods

A retrospective chart review was performed on all patients who commenced VLED in 2017 and 2018. Inclusion criteria comprised those who underwent a COMS facilitated VLED during the study period and in accordance with the Optifast Clinical Treatment Protocol.[11] Patients who initiated a VLED outside of COMS (under the guidance of an external health practitioner or without medical supervision) were excluded. Variables included: patient demographics (age, sex); baseline anthropometrics and metabolic profile (Blood Pressure [BP], weight, BMI, total cholesterol, triglycerides, glycated haemoglobin [HbA1c]); presence of co-morbidities (hypertension, dyslipidaemia and T2DM); VLED commencement, attrition and completion rates; clinical changes (weight, BMI, BP, total cholesterol, triglycerides, HbA1c); and changes to pharmacotherapy (dose adjustment and/or cessation).

Relevant data was sourced from medical, nursing and dietetic notes using a combination of paper and electronic files. Data was collected between October-December 2018 and de-identified prior to undergoing descriptive analyses. Independent (two-sample) T-tests and Fisher's exact tests were performed for statistical comparison of baseline characteristics and VLED completion rates. Changes in anthropometric data and metabolic parameters were calculated using Intention to Treat (ITT) analysis with Last Observation Carried Forward (LOCF) for those who did not complete the 12-week program. A low risk ethics application was submitted to the Canberra Health Services Research Ethics and Governance Office. The study was determined to be a Quality Improvement activity (2018/QAI/00214, 2018/ETH00531).

Results

Comparison of Attrition and VLED Completion Rates

Of the 64 patients identified, four did not meet inclusion criteria. A total of 60 patients commenced VLED under the guidance of COMS including 24 patients (40.0%) in 2017 and 36 patients (60.0%) in 2018. (Figure 1) outlines progression through the 12 week VLED including a comparison of attrition by year. 17 patients (70.8%) completed VLED in 2017 compared to 29 patients (81.0%) in 2018, however, this difference was not statistically significant (p=0.54).

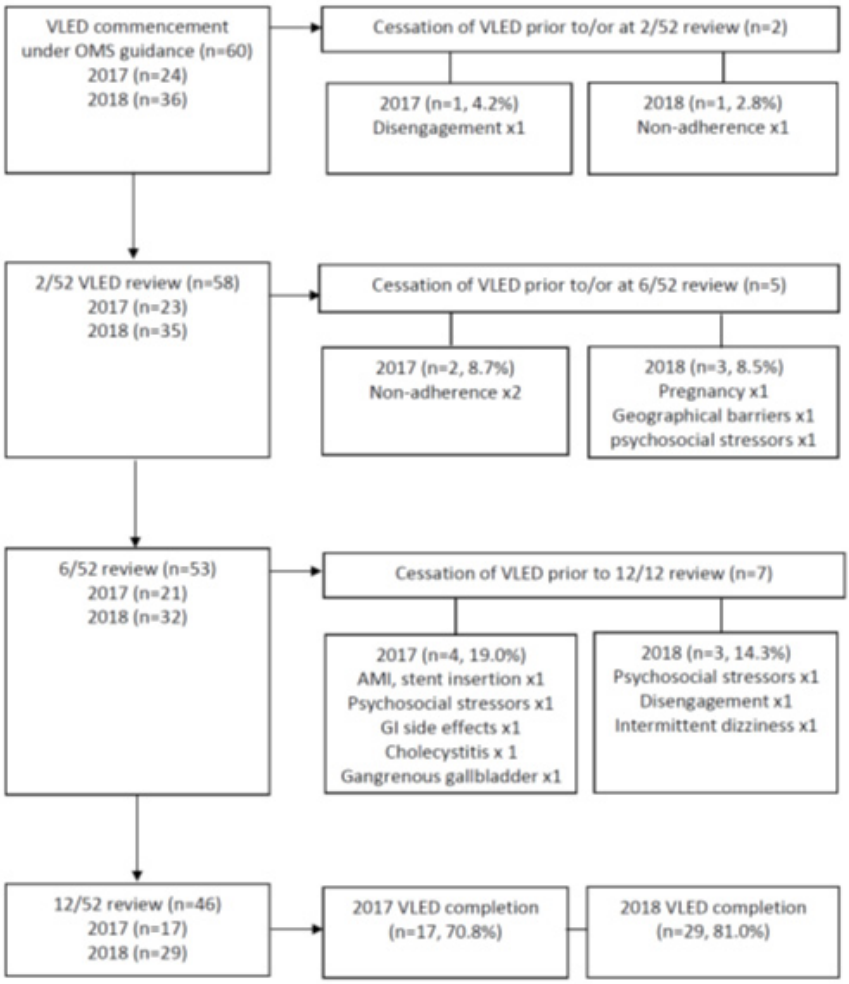

Figure 1: Flowchart outlining VLED commencement attrition and completion based on year.

Comparison of Baseline Characteristics

Patient demographics, baseline anthropometrics, BP, pre-existing co-morbidities and medications at commencement of the VLED are outlined in Table 1. Mean age was 47.3 years (±10.7, range 18-65 years) with the 2017 patients being on average one year older than the 2018 group. Males comprised 48.3% of all patients (n=29) with a greater proportion of males trialling VLED in 2017 (n=13, 54.2%) compared to 16 males (44.4%) in 2018 (Table 1).

	2017 (n=24)	2018 (n=36)	Total (n=60)	P value
Demographics Mean age, years (SD) Sex, male (%)	 47.8 (7.9) 13 (54.2)	 46.8 (13.4) 16 (44.4)	 47.3 (10.7) 29 (48.3)	 0.75 0.60
Anthropometrics Mean weight, kg (SD) Mean BMI, kg/m^2 (SD)	 146.9 (31.4) 50.1 (10.6)	 147.4 (38.0) 50.4 (7.4)	 147.2 (35.5) 50.2 (8.7)	 0.96 0.91

Metabolic profile Mean systolic BP, mmHg (SD) Mean diastolic BP, mmHg (SD) Mean total cholesterol, mmol/L (SD) Mean triglycerides, mmol/L (SD) Mean HbA1c, % (SD)	132.9 (15.9) 84.8 (13.5) 4.8 (1.2) 1.8 (0.9) 5.9 (0.7)	134.4 (14.9) 81.7 (7.1) 5.0 (1.0) 2.1 (1.3) 6.5 (1.8)	133.8 (15.1) 83.0 (10.1) 4.9 (1.0) 2.0 (1.2) 6.3 (1.5)	0.74 0.32 0.59 0.41 0.19
Co-morbidities Hypertension (%) Dyslipidaemia (%) T2DM (%)	15 (62.5) 7 (29.2) 6 (25.0)	22 (61.1) 10 (27.8) 11 (31.0)	37 (61.7) 17 (28.3) 17 (28.3)	1.00 0.91 0.78
Medication ≥1 anti-hypertensive agents (%) ≥1 lipid-lowering agents (%) ≥1 oral hypoglycaemic agents (%) Insulin (%)	15 (62.5) 6 (25.0) 4 (16.7) 2 (8.3)	19 (52.8) 9 (25.0) 10 (27.8) 4 (11.1)	35 (58.3) 15 (25.0) 14 (23.3) 6 (10.0)	0.60 1.00 0.37 0.54

Table 1: Patient baseline characteristics at commencement of VLED by year.

There was no significant difference between the mean starting weights of the 2017 patients (146.9kg SD 31.4) compared to the 2018 group (147.4kg SD 38.0). Mean BMI at commencement of the VLED program was also similar for the two cohorts (50.1kg/m^2 versus 50.4kg/m^2). All baseline metabolic parameters except for mean diastolic BP were higher in the 2018 group (Table 1). The prevalence of co-morbid hypertension and dyslipidaemia was 62.5% and 29.2% in the 2017 patients compared to 61.1% and 27.8% in the 2018 group. Similar numbers of patients were prescribed anti-hypertensive and lipid-lowering medications across both years. The 2018 group had a higher prevalence of co-morbid T2DM (31.0% versus 25.0%) and a greater proportion of patients who were prescribed one or more oral hypoglycaemic agents and/or insulin (Table 1).

Comparison of Anthropometric Changes

The 2017 patients experienced a greater mean weight reduction of 13.4kg (from 146.9kg to 133.4kg) compared to 11.9kg (from 147.4kg-135.5kg) in the 2018 group. The 2017 patients had a higher mean percentage change in body weight (-11.2% SD 6.6) compared to the 2018 group (-8.5% SD 5.9). Mean BMI change for the 2017 patients was -5.3kg/m^2 (from 50.1 kg/m^2 to 44.8 kg/m^2) compared to -3.1 kg/m^2 (from 50.4 kg/m^2 to 47.3 kg/m^2) for the 2018 group (Figure 2). Weight and BMI changes were not statistically significant (p=0.96, p=0.91).

Figure 2: Comparison of mean anthropometric changes using ITT analysis (by year).

Comparison of BP, Total Cholesterol, Triglycerides and HbA1c

The 2017 patients had a mean systolic BP reduction of 3.2 mmHg (from 132.9 mmHg to 129.7 mmHg) compared to 5.6mmHg observed in the 2018 group (from 134.4 mmHg to 128.9 mmHg). Reductions were also observed for mean diastolic BP for both years, with the 2017 patients having a greater reduction than the 2018 group (1.2 mmHg versus 0.7 mmHg, respectively). Mean total cholesterol levels demonstrated a downward trend for both years over the 12-week period. A greater mean reduction of 0.8 mmol/L (5.0 mmol/L to 4.2 mmol/L) was observed for the 2018 group compared to 0.6mmol/L (4.8 mmol/L to 4.2 mmol/L) for the 2017 patients. Mean Triglyceride levels for the 2018 group reduced by 0.6mmol/L (from 2.1 mmol/L to 1.5 mmol/L) compared to 0.4 mmol/L reduction (from 1.8 mmol/L to 1.4 mmol/L) for the 2017 patients (Figure 3). Mean HbA1c progressively decreased over the course of the VLED program at a similar rate for both years. The 2017 patients reduced their mean HbA1c from 6.0% to 5.6% and the 2018 group demonstrated a reduction from 6.5%to 6.1% (Figure 3).

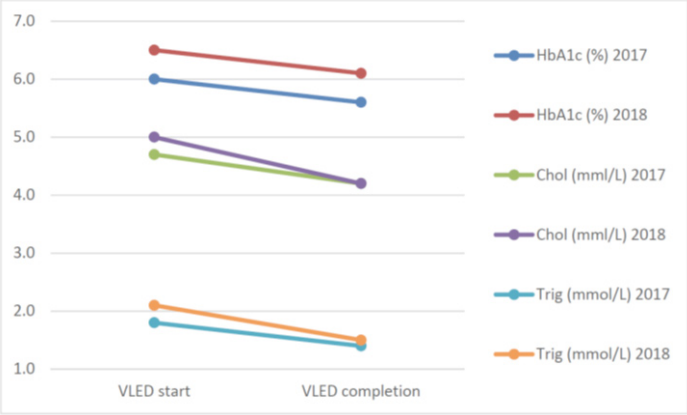

Figure 3: Mean total cholesterol, triglyceride and HbA1c levels based on ITT analysis (by year).

Comparison of Changes to Pharmacotherapy

Of the 35 patients (58.3%) who commenced VLED whilst prescribed one or more anti-hypertensive medications, 19 (54.3%) were from the 2018 group. Over the 12-week period, five of the 35 patients (14.3%) including four patients from the 2018 group ceased all anti-hypertensive therapy. A further eight patients (22.9%), including another four who commenced the VLED program in 2018, had their anti-hypertensive doses and/or the number of anti-hypertensive agents reduced (Figure 4).

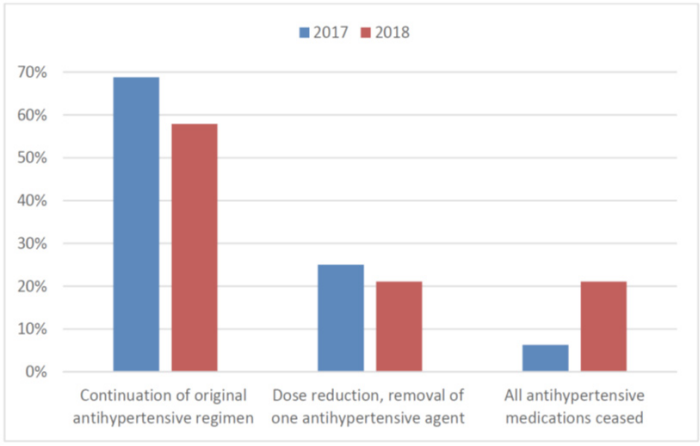

Figure 4: Status of anti-hypertensive medications during course of VLED (by year).

A total of 15 patients (25.0%) were prescribed lipid-lowering agents or fenofibrates at the time of commencing VLED, nine (60.0%) of whom were from the 2018 group. Despite a reduction in mean total cholesterol and triglyceride levels over the 12 week VLED period, only one patient from 2018 adjusted their lipid-lowering regimen (one of two agents was ceased at the 12-week review).

14 patients (23.3%) were already established on oral hypoglycaemic agents prior to commencing VLED including 10 patients (71.4%) from the 2018 group. All three of the 2018 patients who were prescribed sulphonyl urea or a sodium-glucose co-transporter 2 inhibitor (SGLT-2) had these medications ceased prior to VLED commencement. Over the course of 12 weeks, a further three patients (one from 2017 and two from 2018) underwent a reduction in the dose and/or cessation of one component of a combination agent. Two additional patients (one from 2017 and one from 2018) were commenced on an oral hypoglycaemic agent following a step-wise cessation of insulin over the course of VLED.

Of the six patients (10.0%) prescribed insulin to manage their T2DM, four (66.7%) were from 2018. All six patients underwent a dose reduction at commencement of VLED with five patients (four from 2018) undergoing further titration over the course of 12 weeks. One patient from 2017 who experienced medical complications between weeks 6 and 12 was recommenced on their original insulin regimen following early VLED cessation. Insulin therapy was completely ceased in two patients (one from 2017 and one 2018) following completion of VLED.

Discussion

This paper compares clinical outcomes and service efficiency based on two different VLED service models in a publicly funded specialist obesity service. We chose to conservatively present our data using ITT analysis rather than using Per Protocol (PP) analysis. Whilst the latter method would have theoretically yielded more favourable results, it would not have accurately reflected the 'real world' nature of our service or patient experience.

VLED Commencement, Attrition and Completion Rates

The 2018 group process resulted in a greater number of patients commencing VLED and a lower attrition rate compared to 2017. Reasons for attrition in both years were consistent with those documented for general non-engagement with obesity services [12], however, in contrast to another Australian study that reported particular co-morbidities as positive predictors of attendance [13], our study revealed that prioritising other medical conditions was a barrier to completing VLED.

The reasons for attrition in the 2017 patients had a stronger medical focus, with two patients experiencing serious gallbladder complications (a known VLED risk) [11,14]. It is possible that enhanced medical monitoring (including regular liver function tests to check for potential gallbladder sequelae) as part of the 2018 service model resulted in a reduction in medical risks.

Whilst the higher commencement and completion rates for the 2018 group were not statistically significant, it is consistent with evidence that VLED adherence is increased within a supportive and accountable group framework [15]. A comparison of data from future years will indicate if a there is a sustained or increased trend in completion rates associated with the new group service model.

Baseline Characteristics

Until recently, the Optifast Clinical Treatment Protocol did not recommend VLED in patients aged over 65 years except when rapid weight loss may be lifesaving [16]. The most recent protocol has revised this statement, noting that although VLED is generally not advised in this age group, there may be a role if completed under medical guidance [11]. Findings from a 2017 randomised trial also note that VLED may useful in the treatment of obesity and improving nutritional status in older patients [17]. Given this emerging evidence and based on our favourable outcomes using VLED in patients aged up to 65 years, COMS may consider facilitating specific VLED programs for older patients in the future.

A higher proportion of males underwent VLED in 2017. Although the ratio of males to females between years was not statistically significant, there is evidence to indicate that gender differences impact on the amount of weight loss achieved in patients with obesity [18]. This could explain the greater average weight loss achieved in 2017 compared to 2018. Further analysis of the new service model over time and stratifying results by gender would provide better insights into potential gender differences when undergoing a COMS VLED program.

There was no statistically significant difference in the number of pre-existing co-morbidities between years, however, most baseline metabolic parameters were worse for the 2018 group. Further, a higher proportion of the 2018 group were prescribed oral hypoglycaemic agents and insulin prior to commencing VLED. The greater medical complexity of the 2018 group may reflect the change in service model including early identification and prioritisation of patients who were considered medically at-risk. Whilst the new VLED process can lead to improved health outcomes, it does require pre-planning, more intensive medical monitoring and follow-up, which could prove difficult to coordinate outside of a specialist inter-disciplinary setting like COMS.

Anthropometric Changes

A greater mean weight reduction was observed in the 2017 patients, however, the weight loss achieved by both cohorts was within the expected range outlined in the Optifast Clinical Treatment Protocol [10]. This is a positive achievement given that the 2018 group had a higher proportion of patients with T2DM and metabolic resistance to weight loss.

Clinically significant weight loss (≥5% reduction in baseline weight) is known to improve health outcomes and metabolic profiles [5,19,20] and was achieved by both VLED cohorts. Whilst there is ambiguity regarding when BMI reduction is considered clinically significant, there is evidence to demonstrate that small reductions can substantially reduce the burden of chronic disease at a population level [21].

There are some high quality Australian and UK VLED studies, however, they report on one, two and/or three year outcomes rather than discussing clinical care model changes over the 12 week course of VLED [6,13,14,17]. As such, it is difficult to compare our results due to differences in study design and the 'real world' nature of our study in contrast to the formal trial conditions of these other studies. Further research should focus on assessing long term weight trajectories and metabolic profiles of COMS patients undergoing VLED to enable better comparisons to the literature.

BP, Total Cholesterol, Triglycerides and HbA1c

Correlations between weight loss and BP reduction are complex and not necessarily predictable [21,22]. The results from our study are consistent with this concept, with the 2017 patients achieving a greater mean weight loss yet the 2018 group demonstrating a greater mean reduction in systolic BP. It is difficult to attribute these findings to a single cause although it is important

to note that the 2018 group had a higher mean baseline systolic BP and a greater proportion who ceased anti-hypertensive agents.

Despite the 2018 group having a higher mean baseline total cholesterol level, both years recorded the same level on completion of VLED. The 2018 group also demonstrated a greater range reduction in triglycerides compared to the 2017 patients. There is evidence to suggest that weight loss leads to improved cholesterol profiles, although the linearity of this relationship has not been unequivocally established [7]. The findings from our study highlight the complexities of this link, with a greater reduction of total cholesterol and triglycerides levels observed in those who achieved less overall weight loss.

The 2018 service model lead to improved HbA1c levels in a greater proportion of patients with T2DM. A recent UK study of VLED outcomes in T2DM patients recorded rates of remission based on a reduction of HbA1c post-cessation of all anti-diabetic medication through to 12 months [14]. Whilst direct comparison is limited due to our study comprising patients both with and without T2DM, this highlights the opportunity for COMS to prospectively collect data on those with T2DM and to monitor remission over longer periods following VLED completion.

Changes to Pharmacotherapy

A greater proportion of the 2018 group were observed to cease all anti-hypertensive medication upon completion of VLED. In contrast to the UK trial where all anti-hypertensive medications were ceased at commencement of the program [14], COMS patients had their BP monitored closely and medications adjusted during the VLED process. No adverse events were associated with this approach and indeed, given some of the higher metabolic risk profiles of COMS patients compared to the UK study [14], the cautious approach of monitoring prior to reduction or cessation is justified.

The proportion of patients from the 2018 group who continued on lipid-lowering and/or fenofibrate agents was similar to that observed in a UK trial [14]. It would seem that the risk-benefit profile of continuing these medications in patients with severe obesity is more favourable than ceasing. Further, it is more difficult to determine the early clinical sequelae of continuing these medications compared to anti-hypertensive or oral hypoglycaemic agents, where BP and blood glucose are easily measured and patients can self-report symptoms of hypotension or hypoglycaemia.

It is difficult to draw comparisons with the UK VLED trial for patients with T2DM as their trial protocol specified cessation of all oral hypoglycaemic agents upon commencement of VLED [14]. It is, however, worth noting that COMS patients who were prescribed a sulphonylurea or SGLT-2 had this medication ceased prior to commencing VLED, and those prescribed other hypoglycaemic agents underwent a stepped reduction when clinically indicated. Although we cannot compare the final rates of COMS patients on oral hypoglycaemic agents to other studies due to different follow-up time points, it is worth noting that the two additional patients who commenced oral hypoglycaemic agents following cessation of insulin therapy represents a clinical improvement rather than a deterioration in blood glucose profile.

A greater proportion of the 2018 group underwent titration of their insulin dosing over the 12 weeks, however, an equal number of patients from each year were ceased insulin therapy at VLED completion. This highlights the benefits of VLED on blood glucose profile regardless of the COMS service model used. It was not possible to compare these results to the UK VLED trial of patients with T2DM as that particular trial excluded the insulin-dependent patients [14], however, given the medical and psychosocial benefits of reducing or ceasing insulin, this is a COMS outcome of interest that warrants further investigation over time.

Conclusion

COMS has successfully implemented a change in VLED service provision to focus on an inter-disciplinary group approach. The 2018 service model facilitated an increase in patient throughput by 50% without needing to increase COMS staffing. The 2018 model resulted in a higher proportion of patients with T2DM commencing and completing VLED compared to 2017, and a more structured approach to metabolic monitoring and medication management. Further, despite the higher risk profile of the 2018 group, there was no increase in adverse clinical outcomes. Although there was no statistically significant difference in weight change between groups, the clinical significance for the 2018 group is particularly relevant and supports the use of group-based VLED in the future.

Whilst this study has limitations including small sample size and short duration of follow-up, it provides a basis upon which COMS can further refine its service model and improve patient outcomes. Future research should include stratifying results according to gender, longer-term monitoring to determine sustainability of clinical improvements, and comparison with other services. COMS intends on providing periodic support post-VLED to help combat weight regain, to consider augmentation with weight loss pharmacotherapy, and/or to further adjust medications that may have been altered during the VLED process. Collecting patient feedback regarding the group-based approach would also be useful to gauge patient experiences and to further optimise the COMS VLED program.

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Authorship Declaration

CH was responsible for proposing a comparison of individual and group-based VLED service models. LB, CHM, KL and HS were responsible for collating the data. LB performed the descriptive analyses and sought further statistical support. LB was responsible for writing the manuscript with additional and editing contributions from all co-authors.

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