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Case Report

Translating Evidence into Practice: A Case Study of Extended Use of a Very Low Energy Diet for Treatment of Co-Morbid Obesity and Chronic Disease

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Abstract

We report the case of a 30-year-old male with significant obesity (body mass index 47 kg/m^2) with co-existing moderate obstructive sleep apnoea, hypertension, hypercholesteremia and hypogonadotropic hypogonadism, who was treated with a very-low-energy diet (VLED) and

lifestyle modification programme for 12 months. The patient lost weight throughout the entire treatment period (average weight loss was 2.1 kg/week, for a total of 42.7 kg), and showed marked improvement in co-morbidities and no adverse effects. This case demonstrates that prolonged (5-month) use of a VLED, under close medical supervision, is safe and effective in certain patients with obesity.

Keywords
Very low energy diet; case study; obesity; weight loss; obstructive sleep apnoea

1. Clinical Record

A 30-year-old male with severe obesity was recruited to a translational study within the Sleep Disorders Clinic in the Royal Prince Alfred Hospital (RPAH), Camperdown, Sydney, New South Wales, Australia. This translational pilot study was conducted between August 2019 and March 2021, to ascertain the feasibility and efficacy of offering a lifestyle programme as an adjunct to usual care in patients with obstructive sleep apnoea (OSA). Ethics was provided by Sydney Local Health District; *Weight loss for sleep disordered breathing: Translating Sleep, Lifestyle, Energy, Eating, Exercise Programme into practice*. Protocol No. X18-0506 and HREC/18/RPAH/727.

At baseline, the patient's weight was 147 kg and height was 1.77 m (body mass index [BMI] 47 kg/m^2). His waist circumference, measured at umbilicus, was 136 cm and neck circumference was 49 cm. His medical status and medications at baseline are outlined in Table 1.

Table 1 Medical status/history and medications at baseline.

Medical Condition	Treatment
Moderate OSA (AHI 17 events/hour)	Continuous positive airway pressure (CPAP) 17 cm H_2O
Hypertrophic cardiomyopathy	
Hypertension (130/90 mmHg)	Losartan – 25 mg/day in 1 dose
Hypercholesterolemia	Atorvastatin – 20 mg/day in 1 dose
Hypogonadotropic hypogonadism, secondary to obesity	Anastrozole – 1 mg/day in 1 dose
Vitamin D deficiency	Vitamin D, 7000 units/week (discontinued prior to trial start)

Initial fasting laboratory investigations revealed a mildly low plasma urea level of 2.7 mmol/L (reference range, 3.5-8.5 mmol/L), mildly elevated white cell count (WCC) of 10.1 × 10^9/L (reference range, 4.0-10.0 × 10^9/L), and mildly low packed cell volume (PCV) of 0.38 L/L (reference range, 0.40-0.50 L/L). Fasting insulin and glucose were within range however, his HOMA-IR score was 2.8 (reference range ≤2.0). All other values were within normal range and are shown in Appendix A. His blood pressure was measured at 130/90 mm/Hg during the baseline consultation. His normal cholesterol readings and blood pressure indicated hypertension and hypercholesterolemia were being well controlled by his medication regimen.

A full history was taken during the baseline consultation to identify any risks, barriers and facilitators to implementing a VLED and maintaining weight loss long term. A family history of cardiovascular disease (CVD) was noted. He reported that he had been an active child, who played sports, which ceased when he started University, at which point his weight increased to 104 kg as his lifestyle became increasingly sedentary. He moved to the United States of America (USA) at age 24 years and his weight steadily increased to 150 kg. He was diagnosed with moderate OSA, hypertrophic cardiomyopathy, hypercholesteremia and hypertension while in the USA. He reported that his rapid weight gain in the USA had multifactorial causes, including the cessation of smoking, increased work stress, increased alcohol consumption, decreased activity and large portion sizes.

His initial diet and social history showed a diet reliant on eating out and 'fast' food and drinking sessions, with up to 12 standard drinks consumed in a single session, between one and three times weekly. The in-depth diet history and food diary showed his diet was high in saturated fats and deficient in fibre and other micronutrients (especially calcium and B vitamins). His water consumption was low, and his lifestyle continued to be sedentary. He considered his excess energy intake and subsequent excess weight was likely due to his regular eating out and alcohol consumption. This would indicate a significant barrier to introducing a restrictive diet and maintaining a reduced weight, however he indicated that his readiness to change was high.

His stated goal weight was 90 kg and his 'ideal' body weight (body weight at a BMI of 25 kg/m^2) was calculated to be 78.3 kg. He indicated that he had always wanted to be able to rock climb, however his weight made this difficult as he could not lift his own body weight easily. He was prescribed a very low energy diet (VLED) with a protein intake of 1 g/kg of adjusted body weight as per the study protocol. Adjusted body weight was calculated as (Actual Body Weight - Ideal Body Weight × 0.25) + Ideal Body Weight. His prescription was 3 meal replacements using an acceptable meal replacement product (MRP) of his own choosing at his own cost. Protein was then calculated, considering the protein content of his chosen MRP, and supplemented using an acceptable powdered protein product, at his own cost, to make ≥95 g of protein intake per day. The RDI for protein in Australia is based on ideal weight and is set at 64 g/day (0.84 g/kg) for men between 19-70 years old and there is no guidance on adjusting this for an increased body weight due to an increased, less metabolically active fat mass [1]. Research suggests that higher protein can increase satiety and reduce hunger, therefore while his minimum was set at ≥95 gm/day, he was instructed to add an extra scoop of protein (30 gms) for the first month and as he desired thereafter [2, 3]. Both the MRP and protein powder came from a list of pre-selected, locally available products that had been compiled by the study dietitian (CH). He could choose any product from this list depending on his preferences for taste, availability, and cost. His regimen included two cups of non-starchy vegetables, one teaspoon of unsaturated oil (e.g. olive oil) and two litres of no calorie fluid per day. He was provided education around this protocol and acceptable meal replacement and powdered protein products, acceptable 'extras' (e.g. no sugar chewing gum), and possible side effects of this protocol (the most common one being constipation). This protocol is based on the Optifast® instructions for health professionals [4]. The original goal was to be on the VLED for eight weeks and slowly transition to a food-based weight maintenance diet by 12 weeks. However, in consultation with the lead physician (BY) and dietitian (CH) on the project and the patients' goals, it was decided to continue the VLED on a month-by-month basis, with increased contact with the study dietitian (CH) throughout. His weight loss trajectory over this time is shown in Figure 1. The intervention was delivered both in person and through telephone calls periodically due to the COVID-19 pandemic.

Figure 1 Patient weight loss over the 12 months on the very low energy diet program

His progress and pertinent notes during the treatment are provided in Table 2.

Table 2 Pertinent notes from all scheduled consultations with the dietitian during the 12 month period when the patient was on the very low energy diet (VLED).

Timepoint	Weight loss and dietitian notes
Baseline – Face-to-face (F2F)	Baseline data collected. Intervention explained. VLED start date set.
Week 1 Phone Call	**Weight loss**: 4.2 kg. **Patient report**: headaches and hunger at VLED start but decreasing over week
Week 2 Phone Call	**Weight loss:** 2 kg **Total**: 6.2 kg **Patient report**: one headache (likely related to insufficient fluid intake) **Deviations (**from VLED): one restaurant meal
Month 1 F2F	**Weight loss**: 4.5 kg **Total**: 10.7 kg **Patient report**: Travelled overseas for one week. Started swimming laps. **Deviations**: none reported **Protocol**: Resistance exercises introduced – handout and education provided.
Month 2 F2F	**Weight loss**: 9.3 kg **Total**: 22.2 kg **Patient report**: started high intensity interval training (HIIT) with personal trainer. Also reported his “head feels clear” and has been more “talkative and confident”. **Deviations**: large portion cheddar cheese VLED was continued at patients’ request and in consultation with lead physician.
Month 3	**Weight loss**: 8.3 kg **Total**: 30.5 kg

F2F	**Patient report**: Feeling stressed due to moving house, continuing resistance training at home on his own, has started music lessons (which he discontinued years prior). **Deviations**: none reported VLED continued at patients' request and in consultation with lead physician. **Weight loss**: 8.7 kg **Total**: 39.2 kg
Month 4 Phone call (due to COVID restrictions)	**Patient report**: is self-quarantining at home, awaiting COVID-19 test results (has a cold). Slight hunger increase. Continuing resistance training at home. **Deviations**: Full meals (barbeque meats and vegetables) every evening for one week, while staying with family. MRPs for breakfast and lunch. Protein increased to 1 g/kg of actual body weight (108 g/day) to help reduce hunger and support resistance training. **Weight loss**: 3 kg **Total**: 42.2 kg
Month 5 F2F	**Patient report**: CPAP waking him up. Pressure reduced from 17 cm H_2O to 13 cm H_2O by sleep specialist. Primary care physician and endocrinologist have ceased all medications. Has started heavy weightlifting **Diet Prescription**: Cease VLED and commence transition. 2 × MRPs + 1 meal (1 portion protein, 1 portion carbohydrate + unlimited non-starchy vegetables) + 1 × fruit + 1 × dairy + 45 gm supplemental protein powder. ~ 1040 calories/day. **Weight loss**: 4.1 kg **Total**: 46.5 kg
Month 6 F2F	**Patient report**: Walking daily. Feels anxious about food, hunger is increasing. Still feels 'fat' and is surprised when he sees himself in mirror. Feels weight loss is stalling (explained that introducing carbohydrate will replenish glycogen stores ~3-4 kg) **Diet prescription**: 1 × MRP + 2 × meals + 2 × fruit **Weight loss**: -4.8 kg **Total**: 42.7 kg
Month 12 F2F	**Patient report**: has completed a 46 km overnight hike with backpack; 2 hr bouldering × 2/wk (can now lift own weight); biking riding × 3/wk; walking daily. Increased activity has increased hunger. **Deviations**: 'Unhealthy' snacks have resumed however is cooking most meals and growing and pickling own vegetables. **Diet prescription**: Patient wants to continue weight loss. VLED × 3/wk + 2500 cals/day × 4 days/wk (on bouldering and hiking days) + 1 × meal out/wk. Referred to GetHealthyNSW to help support weight maintenance

For the 12 month project period, the patient attended appointments with the study dietitian in person as per the protocol with deviation via phone consultations due to the COVID-19 pandemic. The patient continued an intensive regimen of VLED using a MRP of his own choosing three times a day for 5 months, and then began a transition phase (two MRPs plus one meal plus one piece of fruit per day). The VLED was ceased at 5 months due in part to the patient's request and to enable slow transition towards embedded dietary habits underpinning a permanent and sustainable

lifestyle change. At the 12 month time point, he was referred to Get Healthy NSW, which is a public health initiative allowing for 10 phone calls with a health professional over a six-month period [5].

The patient sustained continuous weight loss during the 12 month period with a slight gain prior to 12 months (Figure 1).

At the 12-month follow up, the patient had lost 29% of initial body weight and had reduced his weight from 147 kg at baseline to 105 kg (BMI 47 kg/m^2 to 33 kg/m^2). He had ceased all prescription medications on advice from his endocrinologist and primary care physician. The patient's CPAP pressure was reduced from 17 cm H_2O to 13 cm H_2O as per management by his sleep physician. His blood pressure was normotensive (120/80 mmHg) without medication. His HOMA IR score was reduced to 1.2 (reference range <2). His serum cholesterol was high (7.1 mmol/L (reference range <5.5 mmol/L)), without medication and he was advised to visit his primary care physician. The increased serum cholesterol is secondary to removing hypercholesteremia medications (Atorvastatin), in conjunction with the time it takes for cholesterol to respond to a change in diet [6]. It can take up to six months for hypercholesteremia to respond to a change in diets [6]. It is also possible that this patient has a familial hypercholesteremia and this should be monitored by his primary care physician [7, 8]. All other blood parameters were within the normal range. Of significant note, he increased physical activity from being sedentary to completing a 46 km overnight trek and had incorporated regular exercise into his weekly routine. He was also preparing most of his own meals instead of eating out and his alcohol consumption had reduced significantly. These lifestyle changes were by his own account, great achievements and he had become more confident as a result. The patient's reduction in CPAP prescription suggested improved OSA severity secondary to weight loss.

2. Discussion

The prevalence of overweight and obesity has reached epidemic proportions around the world, and a growing number of countries are affected, irrespective of their economic status [9, 10]. Obesity-associated co-morbidities and healthcare costs are ever increasing [10, 11]. Obesity is the risk factor for over 22 chronic conditions and diseases, including obstructive sleep apnoea. To treat obesity, meta-analyses indicate the most effective long-term non-surgical, non-pharmacological individual-level weight loss treatments are VLEDs [12, 13], which are defined as providing less than 3,350 kJ/800 kcal/day. VLEDs are typically achieved by total meal replacement diets, which involves replacing all meals and snacks with pre-packaged, nutritionally complete shakes or soups (to which water or milk is added), bars or other pre-packaged meal replacement products. They are commonly used in medically supervised weight reduction programmes for patients with BMI >30 kg/m^2 (or >27 kg/m^2 with obesity-related co-morbidities), or for whom rapid weight loss is necessary such as, prior to bariatric or knee replacement surgery [14, 15]. Treatment duration varies but is usually 8-16 weeks for weight loss or 2-4 weeks pre-surgery [15, 16]. To our knowledge, our report is the first to document personalised prescription via an outpatient service offered as an adjunct to usual care in a public hospital sleep disorders unit and the second to document the use of a VLED for 5 months [17].

People with obesity typically achieve a mean weight loss of 1.5-2.5 kg per week using a VLED [16]. This rate of weight loss has been reported to increase adherence and VLEDs are reported to be easy to follow [18]. Weight regain after these diets has shown to be no faster than after any other diet

[19, 20]. Furthermore, the greater initial weight loss after VLEDs compared to other diets has been shown to be predictive of long-term maintenance of a lower body weight [19, 21, 22]. Additionally, those who remain engaged with support after a VLED can retain clinically significant weight loss of greater than or equal to 5% of initial body weight in the long term (3 years) [23]. A meta-analysis of long-term weight maintenance, after either a VLED or a conventional food-based diet, showed weight loss at 4 to 5 years after commencing the intervention was 6.6% of initial body weight versus 2.1% respectively, demonstrating that greater long-term weight loss can be achieved with a VLED [22].

The 29% weight loss achieved by our patient at 12 months is similar to results reported for bariatric surgery. A recent systematic review of weight loss presented as a percentage of total weight loss (TWL) found, that the pooled mean loss for Roux-en-Y gastric bypass in 19 studies at one-year follow up was 31.9% [24]. Laparoscopic sleeve gastrectomy procedures from 13 studies had a pooled mean loss of 29.5% TWL at one year follow-up, this being most commonly performed surgery in Australia [24].

Whilst bariatric surgery is the most efficacious weight loss treatment in the short and long term, it is only cost effective for those with severe obesity and associated co-morbidities. It remains inaccessible for the proportion of the population in Australia who are most affected by severe obesity, with most surgeries being privately funded [25-27]. Obesity disproportionately affects lower socioeconomic individuals [26, 27], the majority of whom do not have private health insurance, however surgeries performed in the public health system only account for between 1.8% (NSW) and 13.5% (VIC) of all surgeries performed [25, 28]. According to the Bariatric Surgery Registry, this equates to around 757 public health procedures versus 12,962 private health procedures in the year 2019/20 [28]. According to 2013 figures (the latest published), there were approximately 404,594 Australians who were eligible for bariatric surgery and who did not have private health insurance in that year [29]. It is implausible that 757 bariatric procedures per year in this population (approximately 404,594) will suffice to stem the increasing rates of obesity in Australia. There is also strict inclusion criteria and a wait-list period of at least 12 months from referral date, to being admitted into a public hospital obesity service and surgery may be associated with an additional wait, if accessible at all.

Pharmacotherapy for weight loss has only modest benefits and there are four medications approved for the treatment of obesity in Australia: orlistat; phentermine; liraglutide; and bupropion/naltrexone. Reviews show that weight loss of 2-6% can be achieved at one year [30]. These medications are only approved for short term use (three months) and are prohibitively expensive for most, with injectable liraglutide costing around $400/month and naltrexone/bupropion costing around $260/20 days supply. In contrast, VLEDs (which replace all food) are cheaper than normal groceries, based on average per capita food expenditure in Australia and cost less to administer than conventional food diets, in terms of dietetic support [2]. A VLED programme's average cost per week is $60.00, depending on the MRP chosen [2]. In Australia, Suncorp's latest 'Cost of food report' estimated the average Australian spends around $300.00 on food each week, of which $153.00 is groceries and the remainder being take-away meals, eating out, coffees and alcohol [31]. Apart from buying the equivalent of two cups of vegetables per day, our participant could forgo all other food expenditures.

Accessing dietetic care in the community for people with chronic disease, secondary to obesity is facilitated via the Australian government Medical Benefits Scheme (MBS). Chronic disease

management (CDM) items provide people with chronic disease up to five, 20-minute consultations over the course of a year (Appendix B). These allied health consults are often shared between numerous allied health practitioners. However, evidence-based practice (EBP) stipulates obesity and chronic illness require long-term ongoing care. The current MBS for CDM (≤5 × 20 minute consults in a 12 month period), acts as a barrier to VLED use and other evidence-based practices (EBP) for obesity treatment. These constraints are recognised by the Allied Health Professionals Australia who contends that the; "Current fees [for the Medicare rebate] remain well below the true cost of providing adequate patient care and are limiting access for many of those with the greatest need." [32]. Most often, allied health professionals charge a gap fee (a fee over and above the current Medicare Rebate) in order to be adequately remunerated for the time that dealing with complex health problems requires. Consequently, if a person with chronic disease secondary to obesity needs long term, ongoing care in line with EBPs, they are faced with an overburdened pathway towards bariatric surgery, with concomitant waiting times and rigid criteria for attendance, medication or funding this help themselves. This case study from a translational trial gives an example of how targeted funding and strategic placement of chronic disease healthcare models may result in significant change. VLEDs and EBP, offered as an adjunct to an existing clinical care model in public health, can reach those people who are presently not well served by the current CDM model. The recent MBS CDM review noted these barriers in their report, however, to date no changes have been made to this system.

Weight maintenance will present the patient's next challenge, however his lifestyle and living conditions changed significantly over the year and may help sustain his progress. The post weight loss period is particularly sensitive to relapse and referring this patient to a free health coaching phone service "Get Healthy NSW" will potentially assist his weight loss maintenance and achieve his goal weight of 90kg [5]. By utilising this referral pathway, this patient was able to access long term, individualised care that will help him maintain his weight.

Our report shows that, under medical supervision, a full VLED may be used safely and effectively for a period of five months and result in significant changes in health and lifestyle. By providing this service as an adjunct to existing care, this programme can provide the extended healthcare that is in line with current best practice and EBP for long-term chronic illnesses associated with obesity.

Abbreviations

CPAP	Continuous Positive Airway Pressure
VLED	Very Low Energy Diet
OSA	Obstructive Sleep Apnoea
AHI	Apnoea-Hypopnoea Index
RPAH	Royal Prince Alfred Hospital

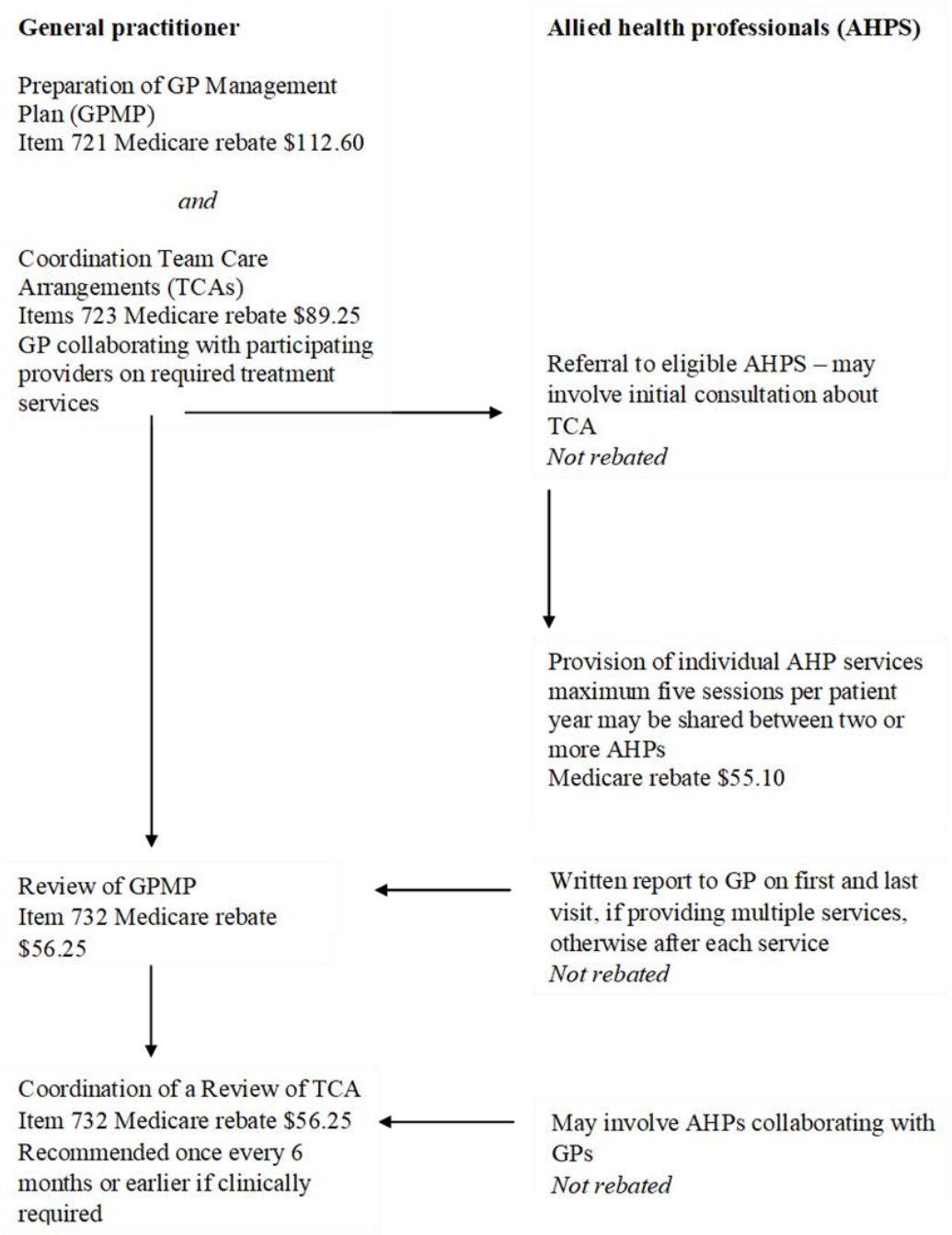
Appendix

Appendix A Pathology results at baseline, 6 months and 12 months.

Fasting Status Pathology Measure	**Baseline**	**6 months**	**12 months** (post cessation of all medication)	**Ref. Range**

Sodium	143 mmol/L	143 mmol/L	139 mmol/L	(135-145)
Potassium	4.4 mmol/L	4.6 mmol/L	4.2 mmol/L	(3.5-5.2)
Chloride	103 mmol/L	104 mmol/L	101 mmol/L	(95-110)
Bicarbonate	29 mmol/L	32 mmol/L	27 mmol/L	(22-32)
Urea	L 2.7 mmol/L	4.1 mmol/L	3.8 mmol/L	(3.5-8.0)
Creatinine	68 µmol/L	71 mmol/L	70 mmol/L	(60-110)
Estimated GFR	>90 mL/min/1.73m²	>90 mL/min/1.73m²	>90 mL/min/1.73m²	(≥60)
Glucose Fasting	4.8 mmol/L	5.2 mmol/L	5.0 mmol/L	(3.5-5.4)
Bilirubin Total	3 µmol/L	7 µmol/L	10 µmol/L	(≤20)
Albumin	39 g/L	37 g/L	38 g/L	(33-48)
Protein	73 g/L	72 g/L	72 g/L	(60-80)
ALP	90 U/L	73 U/L	80 U/L	(30-110)
Gamma GT	36 U/L	23 U/L	22 U/L	(5-50)
ALT	24 U/L	19 U/L	18 U/L	(10-50)
AST	16 U/L	18 U/L	19 U/L	(10-35)
WCC	H 10.1 × 10^9/L	7.4 × 10^9/L	7.7 × 10^9/L	(4-10)
HB	136 g/L	136 g/L	137 g/L	(130-170)
PLT	263 × 10^9/L	258 × 10^9/L	247 × 10^9/L	(150-400)
PCV	L 0.38 L/L	0.4 L/L	L 0.39 L/L	(0.4-0.5)
MCV	84.2 fL	85.6 fL	85.9 fL	(80-100)
RCC	4.57 × 10^{12}/L	4.66 × 10^{12}/L	4.55 × 10^{12}/L	(4.5-5.5)
MCH	28.4 pg	29.1 pg	30.2 pg	(27-32)
MCHC	338 g/L	341 g/L	352 g/L	(315-355)
RDW	12.0%	12.6%	L 11.3%	(11.6-14.0)
Neutrophils	6.7 × 10^9/L	4.7 × 10^9/L	4.3 × 10^9/L	(2.0-7.0)
Lymphocytes	2.6 × 10^9/L	2.0 × 10^9/L	2.5 × 10^9/L	(1.0-3.0)
Monocytes	0.7 × 10^9/L	0.5 × 10^9/L	0.6 × 10^9/L	(0.2-1.0)
Eosinophils	0.1 × 10^9/L	0.1 × 10^9/L	0.3 × 10^9/L	(0.0-0.5)
Basophils	0.0 × 10^9/L	0.0 × 10^9/L	0.0 × 10^9/L	(0.0-0.1)
Normoblast	0.00 × 10^9/L	0.00 × 10^9/L	0.00 × 10^9/L	
Blood Film	No film review			
TSH	1.960 mIU/L	1.560 mIU/L	2.190 mIU/L	(0.27-4.20)
Free T4	15.4 pmol/L	15.2 pmol/L	15.1 pmol/L	(12.0-25.0)
Free T3	5.4 pmol/L	4.6 pmol/L	4.5 pmol/L	(2.5-0.6)
Insulin Level	91 pmol/L	79 pmol/L	37 pmol/L	(10-96)
Homa IR	H 2.8	H 2.6	1.2	(≤2.0)
Cholesterol	3.9 mmol/L	H 6.2 mol/L	H 7.1 mol/L	(≤5.5)
Triglycerides	1.7 mmol/L	0.7 mmol/L	H 2.1 mmol/L	(≤2.0)
HDL Cholesterol	1.11 mmol/L	1.5 mmol/L	1.63 mmol/L	(≥1.00-)
LDL Cholesterol	2.0 mmol/L	H 4.4 mmol/L	H 4.5 mmol/L	(≤3.0)

Non-HDL Cholesterol	2.8 mmol/L	H 4.7 mmol/L	H 5.5 mmol/L	(≤4.0)
Total Chol: HDL Chol Ratio	3.5 mmol/L	4.1 mmol/L	4.4 mmol/L	



Appendix B Referral pathway for allied health professionals.

Adapted from: Foster et al., 2008, Medical Journal of Australia, 188(1), DOI:10.5694/j.1326-5377.

Author Contributions

EC conceived the study, procured the funding and was lead investigator. BY was the attending physician during the programme and a lead investigator. CH was the study dietitian and study co-

ordinator during the programme. CH collected the data and wrote the case study. EC, BY, RVS and AS contributed to the manuscript with advice and editing.

Competing Interests

RVS reported serving on the Nestlé Health Science Optifast VLCD advisory board. AS reported owning 50% of the shares in Zuman International, which receives royalties for books she has written and payments for presentations at industry conferences; receiving presentation fees and travel reimbursements from Eli Lilly and Co, the Pharmacy Guild of Australia, Novo Nordisk, the Dietitians Association of Australia, Shoalhaven Family Medical Centres, the Pharmaceutical Society of Australia, and Metagenics; and serving on the Nestlé Health Science Optifast VLCD advisory board from 2016 to 2018. No other disclosures were reported.

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