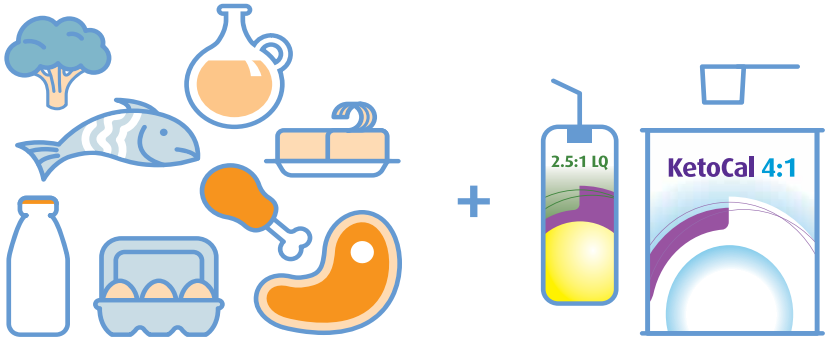
NUTRICIA
LIFE-TRANSFORMING NUTRITION | KETOGENICS

KETOCAL 2.5:1 LQ
CASE STUDIES

KetoCal 2.5:1 LQ is a Food for Special Medical Purposes for the dietary management of drug-resistant epilepsy and other conditions where the Ketogenic Diet is indicated, and must be used under medical supervision. This booklet is intended for Healthcare Professionals only.

CONTENTS

> “Go for it without expecting to be 100% seizure free. It will have a positive impact, changing seizures and energy levels and clarity of mind. All these factors that don’t always get recognised. There is so much more the Ketogenic Diet can offer”



INTRODUCTION

KetoCal 2.5:1 LQ is a nutritionally complete, ready to feed ketogenic formula containing approximately 20% energy as MCT. KetoCal 2.5:1 LQ is designed to meet the nutritional requirements of older children, adolescents and adults who require the Ketogenic Diet for the dietary management of drug-resistant epilepsy or other conditions for which the Ketogenic Diet is indicated. Presented herein is a series of 5 case studies following a clinical trial in which patients introduced KetoCal 2.5:1 LQ for a period of 4 weeks.

SUMMARY TABLE

Case Study	Author	Age / Gender	Diagnoses	History on Ketogenic Diet	Outcome of 4 week trial of KetoCal 2.5:1 LQ
1	**Tracy Cameron** Paediatric Dietitian Ketogenic Coordinator for the North of Scotland	14yrs / Male	Cerebral palsy with severe learning disability, drug-resistant epilepsy with polymorphic seizures, visual impairment and gastro-oesophageal reflux.	Ketogenic Diet from age 5 to 7 years. On request from parents, the Ketogenic Diet was reinstated (3:1 CKD) at age 12 and the family felt the diet has had positive benefits such as reduction in seizures and increased periods of alertness.	Reduced feed complexity whilst better meeting nutritional requirements. No GI tolerance issues. Parents reported seizures were shorter and less intense.
2	**Jude Munn** Specialist Dietitian The Barberry, Birmingham and Solihull Mental Health Foundation Trust	39yrs / Male	Drug-resistant juvenile myoclonic epilepsy.	Began Modified Ketogenic Diet at age 36, with 30g/day carbohydrate (later reduced to 20g/day). Diet led to a significant improvement in quality of life and clinical condition. Seizures reduced from ~6 per month to full remission of tonic clonic and <1 mycolonic jerks per month. This has been maintained for several years.	Found KetoCal 2.5:1 LQ to be very versatile, using it on breakfast cereal and as an alternative to milk and cream in coffee or as a snack when on the go. Enjoyed the taste and found it was satiating. Ketones improved and 100% seizure freedom was maintained during the 4 weeks.
3	**Nicole Mills** Paediatric Dietitian Cambridge University Hospitals NHS Foundation Trust	10yrs / Male	Juvenile Batten's disease and complex drug-resistant epilepsy.	From age 9, received a Classical Ketogenic Diet made up with KetoCal 4:1 LQ, Protifar and Liquigen. Achieved a significant seizure reduction despite a very mild ketosis, with the seizures reducing from 9-10 seizures daily to 5-6 seizures daily.	Small improvement in ketone levels and seizure frequencies. Parents noted a small seizure improvement (reduced recovery time and shorter in length) and reported that his sleep was less disturbed throughout the night. Feed preparation was easier and quicker as adding additional protein (Protifar) was no longer required.
4	**Nicole Mills** Paediatric Dietitian Cambridge University Hospitals NHS Foundation Trust	17yrs / Male	Quadriplegic cerebral palsy, microcephaly and drug-resistant epilepsy.	Started on Ketogenic Dietary Therapy at 12 years of age and achieved roughly a 50% reduction in seizure burden, though the diet did exacerbate his underlying constipation. Continued on the diet for the planned two years and weaned off the Ketogenic Diet age fourteen. After gradually weaning off the diet, seizures increased. The family and ketogenic team concluded Sam's quality of life was better when he was following a Ketogenic Diet despite the exacerbated constipation. At age 15 the Ketogenic Diet (Classical) was reinstated.	Switching to KetoCal 2.5:1 LQ led to a mild increase in ketosis and a subsequent, noticeable seizure reduction. There were no issues with tolerance reported and constipation appeared to be improved. Given the noticeable improvement in seizures and the early signs that KetoCal 2.5:1 LQ may ease the patient's constipation, the family opted to continue with KetoCal 2.5:1 LQ.
5	**Jude Munn** Specialist Dietitian The Barberry, Birmingham and Solihull Mental Health Foundation Trust	29yrs / Female	Drug-resistant epilepsy, Lennox-Gastaut syndrome, cerebral palsy and moderate learning disability.	Responded very well to the MKD and tolerated it with no gastrointestinal symptoms or other issues. Her seizure frequency reduced from 10-15 daily to just 2-3 seizures 3-4 days per week. Her wobbly legs were also much improved. This improvement was maintained for the 2 years since the MKD was introduced. She reported a much-improved quality of life and a marked cognitive improvement and alertness.	Successfully completed the 4 week trial of KetoCal 2.5:1 LQ, with no gastrointestinal adverse events or symptoms. While seizures did increase very slightly, this was suspected to be due to increased carbohydrate intake while on holiday. The increase was much less than would have normally been expected and she remained seizure free 3-4 days a week throughout the trial, suggesting that the MCT in KetoCal 2.5:1 LQ may have allowed for a little more flexibility in carbohydrate intake.

CASE STUDY 1:

Tracy Cameron (Paediatric Dietitian)
Ketogenic Coordinator for the North of Scotland

BACKGROUND

Daniel* is a 14 year old boy with a history of seizures from a very young age. He also has a diagnosis of cerebral palsy with severe learning disability, drug-resistant epilepsy with polymorphic seizures, visual impairment and gastro-oesophageal reflux. Daniel is reliant on others for all aspects of his care. His epilepsy affects his ability to interact with others during the day, and increased seizures reduce his mood and alertness.

Daniel has drug-resistant epilepsy with multiple seizures, averaging 14 daily, which consist of myoclonic jerks, facial twitching and vocal events which occur in clusters. He is on multiple medications for his epilepsy including sodium valproate, topiramate and clonazepam. Daniel has also trialled vigabatrin and steroid treatment in the past without success. Additional medications include esomeprazole and domperidone for treatment of reflux (unrelated to the Ketogenic Diet), and half a sachet of movicol daily for the treatment of constipation, which can be a side effect of the Ketogenic Diet.

Daniel was managed with the Ketogenic Diet from 5 to 7 years but this was stopped as it was felt that the effect of the diet was limited. However, on request from Daniel's parents, the Ketogenic Diet was reinstated at age 12 and the family felt the diet has had positive benefits such as a reduction in seizures and increased periods of alertness. He was enterally fed from a few months old due to an unsafe swallow and is currently receiving the Ketogenic Diet via his gastrostomy.

DIETARY ASSESSMENT

On review, Daniel was tolerating his 3:1 Ketogenic Diet with a mild exacerbation of gastrointestinal symptoms including constipation, abdominal discomfort and flatulence. His prescribed nutritional intake was 1165kcal, 111.2g fat, 32.8g protein and 4.7g carbohydrate. This was provided by KetoCal 4:1 LQ (750ml/day) and Protifar (11g/day), with an additional 400ml of cooled boiled water added to maximise fluid intake. This regime was provided by a feeding pump as 3 x 200ml daytime bolus feeds and a 550ml continuous overnight feed fed at 55ml/hr.

His feed recipe had multiple ingredients and it was becoming increasingly difficult to meet his protein and mineral requirements from KetoCal 4:1 LQ alone (See Table 1).

There were no concerns regarding Daniel's growth. His weight was 44kg (25th centile) and his estimated height was 1.43m (2nd centile; estimated via segmental lengths). Daniel's ketone levels were measured using urine ketone strips which measure acetoacetate, and results were typically between 2 and 3 mmol/l.

*This is not the patients real name

REVIEW

Daniel commenced a trial of KetoCal 2.5:1 LQ with the goal of improving seizure control, ketone levels and nutritional status. He transitioned onto his full prescription of KetoCal 2.5:1 LQ over 3 days, to ensure tolerance of the medium chain triglycerides (MCT) which his previous feed did not contain. Too rapid an introduction of MCT can occasionally result in abdominal discomfort, vomiting or diarrhoea.

Daniel's overall Ketogenic Diet ratio was reduced to 2.5:1 with 25% fat as MCT, and the new regime of 800ml KetoCal 2.5:1 LQ provided 1224kcal, 114.4g fat (28.8g of which MCT), 36g protein and 7.9g carbohydrate. An additional 400ml of cool boiled water was also provided to meet fluid requirements. The change to KetoCal 2.5:1 LQ reduced the complexity of the feed recipe (as additional Protifar was no longer required) and improved the nutrition that Daniel was receiving. Table 1 illustrates the increase in protein and mineral provision.

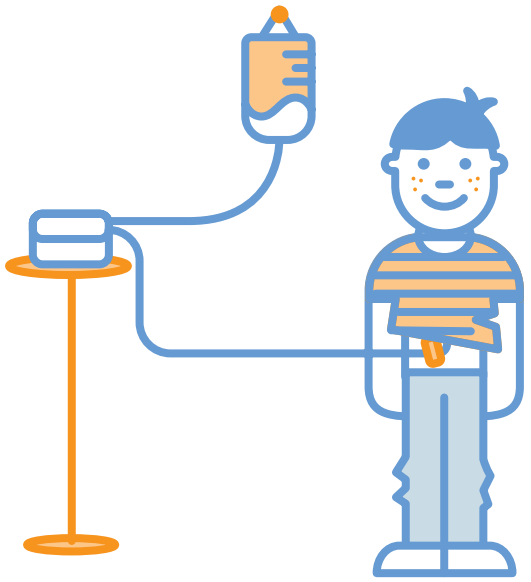
During the 4 week trial, ketone levels were routinely checked on a blood ketone monitor, which measured beta-hydroxybutyrate. Before commencing KetoCal 2.5:1 LQ Daniel's blood ketone concentrations typically measured between 0.6-2.7 mmol/l. At the end of the 4 week trial Daniel weighed 45.2kg and his height was 1.46m.

There were no changes in gastrointestinal tolerance throughout the trial and anthropometry was appropriate. Ketone concentrations throughout the intervention period ranged from 0.9-2.1 mmol/l. Daniel did not achieve seizure freedom. However his average number of seizures per day reduced from 14 (whilst on his previous regimen) to 11 per day (whilst taking KetoCal 2.5:1 LQ). Daniel's parents also felt that his seizure clusters were shorter and less intense whilst taking KetoCal 2.5:1 LQ.

Table 1: Requirements for age, actual intake from previous and current regimen*

Nutrient	Requirements for age	Previous regimen 750ml KetoCal 4:1 LQ + 11g Protifar	New regimen 800ml KetoCal 2.5:1 LQ
Protein (g)	42.1 (min 39.2)	32.8	36
Sodium (mg)	1610	860	1040
Potassium (mg)	3128	1380	2200
Calcium (mg)	1000	878	1016

* Requirements for age based on healthy population RNIs.



DISCUSSION

Daniel continues on KetoCal 2.5:1 LQ and tolerates it very well. Due to an increase in weight, his recipe has been altered to maintain a minimum level of protein. His ratio is now 2:1 Ketogenic Diet with 30% MCT. This recipe includes several products, with KetoCal 2.5:1 LQ as a base and his family manage this well. The family feel that the Ketogenic Diet is now easier to manage, the study product is straightforward to use and that there has been no change to gastrointestinal tolerance which is an important consideration when altering feeds to include MCT.

Daniel will continue on the Ketogenic Diet for the foreseeable future. His recent yearly biochemistry, vitamin and minerals result indicate no cause for concern.

SUMMARY

It was a pleasure to see that Daniel tolerated the gradual move to a ketogenic, enteral feed containing MCT with no gastrointestinal changes. KetoCal 2.5:1 LQ is designed for older children (>8 years) and adolescents who are unable to meet their macro or micronutrient requirements from KetoCal 4:1 LQ or modular ketogenic feeds. As a ketogenic dietitian, with a caseload from infants to adolescents, having access to a product that will fulfil the nutritional needs of older children with larger protein requirements is a welcome addition to the portfolio.

CASE STUDY 2:

Jude Munn (Specialist Dietitian)
The Barberry, Birmingham & Solihull Mental Health Foundation Trust

BACKGROUND

Lee* is a 39 year old man with a drug-resistant Juvenile Myoclonic Epilepsy (JME). He experienced myoclonic jerks from the age of 14 years and his first convulsive seizure aged 15 years. Lee's father and cousin also have epilepsy. Since the JME diagnosis, Lee trialled many antiepileptic drugs (AEDs) including carbamazepine, lamotrigine, sodium valproate, levetiracetam, topiramate, zonisamide and primidone, however his JME proved resistant to AED treatment. Unfortunately, Lee also experienced a range of debilitating side effects from his AEDs including irritability, low mood, cognitive slowing, slurred speech and weight gain.

Prior to starting the Ketogenic Diet Lee was struggling to keep his job as he was having difficulties communicating with colleagues and clients. He felt his brain could not process information fast enough to follow a conversation and this also adversely affected his social life. Lee then found out that his company was going to be taken over and he would have to reapply for his job or even look for another. He felt unable to do interviews due to his condition and the side effects of the AEDs. His primidone was gradually withdrawn, and Vagus Nerve Stimulation (VNS) and the Modified Ketogenic Diet (MKD) were considered as non-AED management options. Lee opted for MKD as he felt it was less invasive.

USE OF THE KETOGENIC DIET

At age 36 Lee commenced the MKD for his drug-resistant JME. The MKD was initiated with a carbohydrate restriction of 30g/day and this was later reduced to <20g/day. AEDs were left unchanged as zonisamide, lamotrigine. The diet was phased in slowly and Lee found this helped him gradually learn to cook new ketogenic recipes, many of which he enjoyed creating himself. Around this time, Lee also embarked on a fitness regime and joined the gym. He discovered a new passion in yoga, running and cycling and found that having an extra ketogenic snack before exercising, such as a "fat bomb", helped ensure he had enough energy to perform.

Lee responded well to the MKD and tolerated it with no issues. His seizures quickly reduced from a baseline frequency of 6 per month, to complete remission of tonic clonic seizures and less than 1 myoclonic jerk per month (typically these occurred when he was sleep deprived). This improvement was subsequently maintained consistently for the 2 years since the MKD was introduced. Lee also reported much improved quality of life and marked cognitive improvement.

*This is not the patients real name

KETOCAL 2.5:1 LQ

Lee was invited to take part in a 4 week trial of KetoCal 2.5:1 LQ as it was felt the product would be helpful as it contains Medium Chain Triglycerides (MCT) (20% of total energy) and is suitable as a supplementary feed for adults on the MKD. MCT produces more ketones per gram than long chain triglycerides so can be useful to improve ketosis. One carton (200ml) of KetoCal 2.5:1 LQ was incorporated into his diet for the 4 weeks, and all other dietary recommendations remained the same, including a prescribed carbohydrate intake of <20g/day.

OUTCOME

Lee successfully completed the 4 week trial of KetoCal 2.5:1 LQ, consistently consuming his full prescription of 200ml KetoCal 2.5:1 LQ per day with no gastrointestinal adverse events or symptoms. He found KetoCal 2.5:1 LQ to be very versatile, using it on breakfast cereal, as an alternative to milk and cream in coffee, or as a snack when he was on the go. Lee reported that it was "very nice and tasty" and it made him "feel fuller for longer". He felt he could drink more of it.

Lee recorded his dietary intake using 3 day food diaries prior to and at the end of the 4 week trial. Despite a slight increase in carbohydrate intake (Table 2), Lee saw an increase in his average blood ketone concentrations whilst taking KetoCal 2.5:1 LQ, increasing from 0.8mmol/L to 1.2mmol/L. This may have been due to the MCT content of KetoCal 2.5:1 LQ. Lee also remained 100% seizure free during the 4 week trial.

During the 4 weeks that he was taking KetoCal 2.5:1 LQ, Lee completed Tough Mudder and The Wolf Run challenges. He had never done anything like this before and wanted to see if the diet would get him through it and if he was capable of it. Lee reports that he "absolutely smashed it!" and felt like he still had a "full tank" left so could still do more.

Table 2: Nutritional intake from Lee's baseline diet & diet during the KetoCal 2.5:1 LQ trial.

Nutrient	Baseline	4 week trial of KetoCal 2.5:1 LQ
Energy kcal / day	2836	2643
CHO g/day (% energy)	9.6 (1.4%)	27 (4%)
Fat g/day (% energy)	234 (74.4%)	221 (75%)
Protein g/day (% energy)	173 (24.4%)	136 (21%)
Ratio (Fat : CHO + Protein)	1.28 : 1	1.36 : 1

FOLLOW UP

Due to the introduction of the Modified Ketogenic Diet, Lee's happiness and QOL have significantly improved. He can communicate with people normally again, compete physically to a high standard and he has lost 13.5kg in the last 2 years (BMI now 23 kg/m²) in addition to gaining muscle mass. Most importantly, his seizures are now greatly reduced and he can live a normal lifestyle. Lee has become so interested in the MKD and Nutrition and Dietetics that he has applied and been accepted for a place to study Dietetics at University. Lee says "I'm so much more confident now, I'm like a different person…I even motivate others with epilepsy to better health these days too". Lee says he "just loves life right now".

Lee continues to use KetoCal 2.5:1 LQ every day and has it in his coffee at breakfast.

CONCLUSION

Overall, the Modified Ketogenic Diet led to a marked improvement both in Lee's clinical condition and his quality of life. KetoCal 2.5:1 LQ is versatile, easy to consume and a well-tolerated supplementary drink for the Modified Ketogenic Diet. It is nutrient dense and contains MCT oil and fibre to support adult patients in meeting their nutritional needs and promotes ketosis whilst on the MKD. For Lee, adding KetoCal 2.5:1 LQ into his diet was associated with a 50% increase in ketosis.

CASE STUDY 3:

Nicole Mills (Paediatric Dietitian)
Cambridge University Hospitals NHS Foundation Trust

BACKGROUND

Ben* is a 10 year old boy diagnosed with Juvenile Batten Disease at 4 years old. Juvenile Batten's is a rare genetic disorder of the nervous system, which is characterised by a progressive loss of motor and cognitive skills. Children often appear to be developing normally before the onset of symptoms and gradually lose motor function, swallow function and vision with many developing complex drug-resistant epilepsy. There is currently no cure for Batten's disease, therefore treatments aim to manage symptoms and reduce the rate of neurological decline.

Ben was diagnosed with epilepsy shortly before his 6th birthday, beginning with absence seizures and progressing to clusters of tonic seizures by age 7, which required several emergency admissions to the local paediatric intensive care unit. Due to significant weight loss and reduced swallow function Ben started nasogastric feeding, which was later converted to a gastrostomy.

The family had a short period of respite following the introduction of topiramate, which seemed to reduce Ben's frequency of seizures and recovery time. However, these improvements were short-lived with seizures increasing to 9-10 daily by age 9. Ben started to develop renal stones, which likely related to the increasing dosages of topiramate, therefore an alternative management strategy was considered.

KETOGENIC DIET

Ben was therefore referred to the Addenbrooke's tertiary neurology service at age 9 for consideration of Ketogenic Dietary Therapy for the management of drug-resistant epilepsy. As Ben received his full nutritional intake via his gastrostomy, he started on a classical 4:1 feed (KetoCal 4:1 LQ) with added protein to help meet his requirements (Protifar). To increase ketosis a Medium Chain Triglycerides (MCT) emulsion was later added (Liquigen).

At the end of the initial three month Ketogenic Diet trial period, Ben had achieved a significant seizure reduction despite a very mild ketosis, with seizures reducing from 9-10 seizures daily to 5-6 seizures daily. This improvement was maintained for the full year following Ketogenic Diet initiation. The Ketogenic Dietitians subsequently hoped to increase ketosis further with an aim to achieve seizure freedom; however were unable to do so without compromising protein intake. As Ben was growing and his protein requirement was increasing, it was becoming increasingly difficult to meet his protein needs whilst maintaining a very mild ketosis.

*This is not the patients real name

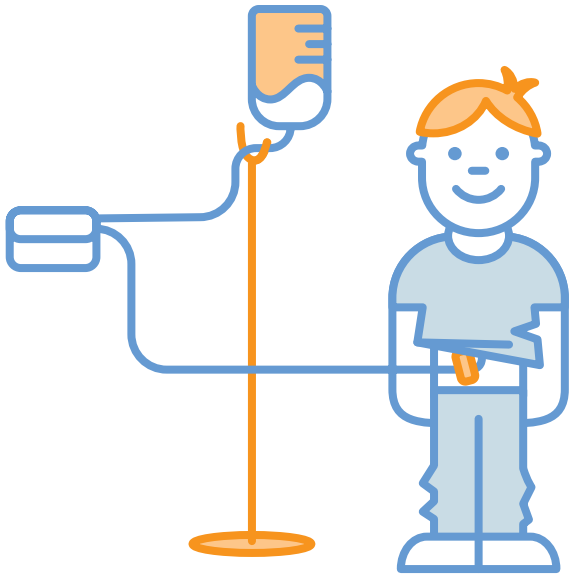
KETOCAL 2.5:1 LQ

Ben was put forward for a 4 week trial of KetoCal 2.5:1 LQ as his seizures were improved by the Ketogenic Diet, but we had been unable to gain a stronger ketosis using existing products whilst continuing to meet his protein requirement (within an appropriate energy provision). As KetoCal 2.5:1 LQ provides 20% of energy from MCT and has more protein than the KetoCal 4:1 LQ within the same calorie provision, it was hoped this may increase ketosis and subsequently achieve greater seizure control.

The parental motivation for switching to KetoCal 2.5:1 LQ was firstly to see whether ketosis and subsequent seizure control could be improved, but also to make the feed preparation less complex. Their previous feed recipe included precise amounts of KetoCal 4:1 LQ, Liquigen and Protifar. The introduction of the protein-rich KetoCal 2.5:1 LQ would allow them to omit the Protifar from the feeds whilst continuing to meet his protein requirement. Table 3 illustrates Ben's feed regimes and clinical status at baseline and upon the introduction of KetoCal 2.5:1 LQ for 4 weeks.

Table 3: Dietetic prescription and clinical status at baseline and during trial of KetoCal 2.5:1 LQ.

	Baseline Ketogenic Diet	4 week trial of KetoCal 2.5:1 LQ
Feed recipe (per feed)	250ml KetoCal 4:1 LQ + 2.5g Protifar + 12ml Liquigen. (200ml fed)	200ml KetoCal 2.5:1 LQ + 40ml Liquigen. (200ml fed)
Feeding regimen	3 x 200ml pumped bolus feeds per day.	3 x 200ml pumped bolus feeds per day.
Nutritional provision	**Energy:** 1020 kcal, **Carbohydrate:** 3.6g **Protein:** 25.0g **Fat:** 99.4g (of which 13.9g MCT)	**Energy:** 1034 kcal, **Carbohydrate:** 6.2g **Protein:** 25.4g **Fat:** 99.6g (of which 37.6g MCT)
Urine Ketones	**Morning:** 0-0.5mmol/L (0 to +/-) **Evening:** 0.5-1.5mmol/L (+/- to +)	**Morning:** 0.5-1.5mmol/l (+/-to +) **Evening:** 1.5mmol/l (+)
Seizure frequency	5- 6 seizures per day	4 – 5 seizures daily, shorter in duration
Weight	Tracking 50th centile	Continuing to track 50th centile
Tolerance	No issues	No issues



OUTCOME

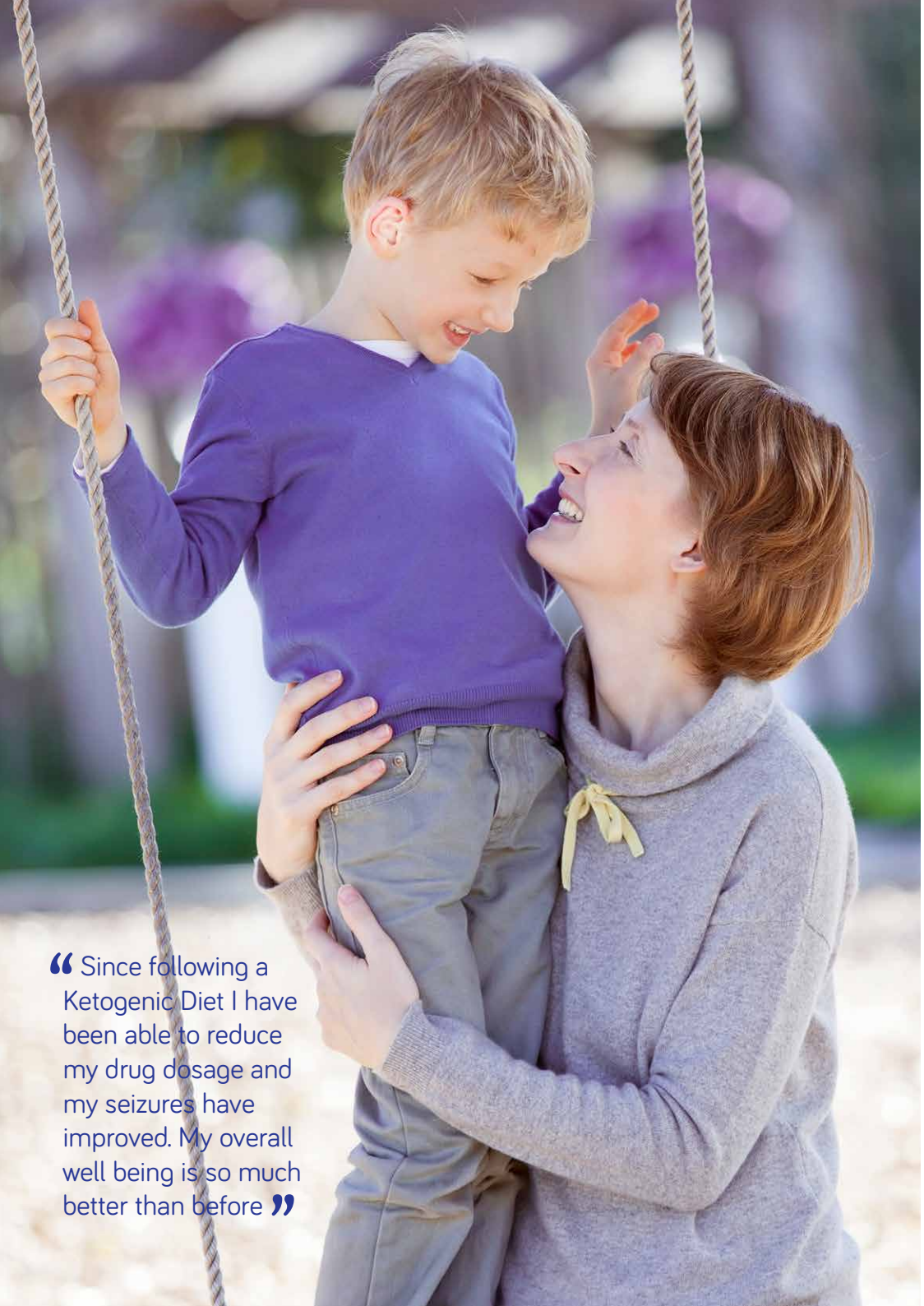
Alongside a small improvement in ketone levels and seizure frequency, Ben's parents noted a small seizure intensity improvement (reduced recovery time and shorter in length) and reported that his sleep was less disturbed throughout the night. There were no negative effects of switching to KetoCal 2.5:1 LQ and the family felt that feed preparation was easier and quicker without the Protifar.

SUMMARY

Switching to KetoCal 2.5:1 LQ allowed Ben's protein requirement to be met without requiring an additional protein supplement; this made the feed preparation easier for the family.

As the product contains 20% of energy as MCT fat, the MCT content of the diet increased within the same energy allowance. Subsequently, ketone levels improved slightly, as did seizure control.

Given the improvement to seizure control, reduction in feed complexity and preparation time and given that there were no negative effects to switching the feed, Ben's parents chose to continue with the KetoCal 2.5:1 LQ at the end of the study period.



CASE STUDY 4:

Nicole Mills (Paediatric Dietitian)
Cambridge University Hospitals NHS Foundation Trust

BACKGROUND

Sam* is a 17 year old boy with Quadriplegic Cerebral Palsy and microcephaly. At 6 weeks old he suffered a brain haemorrhage and was later diagnosed with epilepsy at around 5 months old. He has severe global developmental delay and from a young age Sam has been fully reliant on enteral feeding as his swallow was regularly assessed as being unsafe.

Over the years Sam had been tried on numerous anti-epileptic medications and dosage adjustments aiming to control his epilepsy, each achieving seizure control for a maximum of a couple of months. Some of the medications also appeared to make Sam hyperactive, although no other side effects were reported. As his epilepsy progressed, seizure types would change and he became gradually more drug-resistant. Before the initiation of the Ketogenic Diet, Sam typically had around 10 daily seizures: tremors, stiff legs, lip smacking and shivers, alongside approximately 30-40+ absences daily.

KETOGENIC DIET

Sam was started on Ketogenic Dietary Therapy at 12 years of age and achieved a 50% reduction in seizure burden and a complete cessation of tonic clonic seizures. Although the Ketogenic Diet was effective at controlling his seizures, it exacerbated his constipation. He had required several hospital admissions with pseudoobstructions and had a complex daily laxative regimen. Sam continued on the diet for the recommended 2 year therapy duration and weaned off the Ketogenic Diet age 14.

Although his constipation improved, unfortunately after gradually weaning off the diet, his seizures increased over a period of 6 months and did not appear to be settling. This included around 5 tonic clonic seizures per day alongside multiple absences. The family and ketogenic team concluded Sam's quality of life was better when he was following a Ketogenic Diet, and accepted the risk that his constipation would likely become more problematic.

At age 15, Sam returned to the Ketogenic Diet. As he received his full nutritional intake via gastrostomy, he was re-started on a classical 4:1 feed (KetoCal 4:1 LQ) with added protein to help meet his requirements (Protifar) and an added Medium Chain Triglyceride (MCT) emulsion (Liquigen) to enhance ketosis.

*This is not the patients real name

KETOCAL 2.5:1 LQ

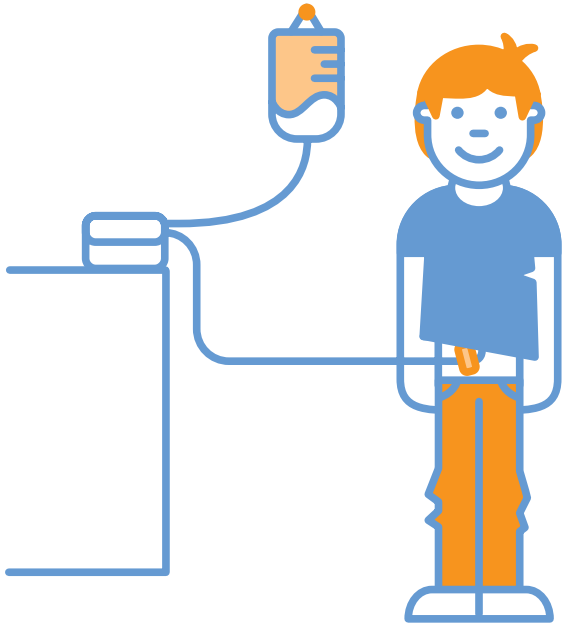
Before KetoCal 2.5:1 LQ was introduced, Sam was on a combination of four anti-epileptic medications together with the Ketogenic Diet and his seizures have reduced to an average of 2 daily (mostly lip smacking). Sam was put forward for a 4 week trial of KetoCal 2.5:1 LQ as his seizures were improved by the Ketogenic Diet with a very mild ketosis and the family had been adding Protifar to feeds to meet his protein requirement.

It was hoped that switching to KetoCal 2.5:1 LQ would meet his protein requirement without an additional supplement and make feed preparation less complex.

Given the greater proportion of MCT fat within KetoCal 2.5:1 LQ, we also hoped Sam's constipation would be improved (high MCT doses have a recognised laxative effect for some people).

Table 4: Dietetic prescription and clinical status at baseline and during trial of KetoCal 2.5:1 LQ.

	Baseline Ketogenic Diet	4 week trial of KetoCal 2.5:1 LQ
Feed recipe (per feed)	**Morning:** 385ml KetoCal 4:1 LQ + 10g Protifar + 60ml Liquigen + 5g Optifibre **Afternoon:** 200ml KetoCal 4:1 LQ + 2.5g Protifar + 20ml Liquigen **Evening:** 385ml KetoCal 4:1 LQ + 10g Protifar + 60ml Liquigen	**Morning:** 350ml KetoCal 2.5:1 LQ + 5g Protifar + 60ml Liquigen **Afternoon:** 200ml KetoCal 2.5:1 LQ + 2.5g Protifar + 40ml Liquigen **Evening:** 350ml KetoCal 2.5:1 LQ + 2.5g Protifar + 60ml Liquigen
Nutritional provision	**Energy:** 2168 kcal, **Carbohydrate:** 6.2g **Protein:** 49.6g **Fat:** 213.9g (of which 70g MCT) **Fibre:** 15.2g	**Energy:** 2134 kcal, **Carbohydrate:** 10g **Protein:** 49.2g **Fat:** 208.9g (of which 112.6g MCT) **Fibre:** 9.9g
Blood Ketones	**Morning:** 0.3-0.4mmol/L **Evening:** 1.4-1.6mmol/L	**Morning:** 0.4-0.6mmol/L **Evening:** 1.4-1.6mmol/L
Seizure frequency	Average 2 daily	Average 1 daily
Weight	50th-75th centile	Continuing to track 50th-75th centile
Tolerance	Severe constipation; bowels opening O.D with occasional Sodium Picosulphate required	Bowels opening O.D-B.D, did not require Sodium Picosulphate during the trial



OUTCOME

The morning ketone levels increased by a small amount when taking the KetoCal 2.5:1 LQ, and the average number of daily seizures reduced from 2 to 1 per day. Alongside a noticeable seizure improvement, throughout the KetoCal 2.5:1 LQ trial Sam did not require sodium picosulphate (for severe constipation); up to this point it was unusual for Sam to manage 4 weeks without it.

Considering Sam's weight and age, his protein requirement was too high to be met by KetoCal 2.5:1 LQ, therefore the amount of Protifar could be reduced, but not withdrawn. Therefore the complexity of the feed preparation did not change for the family.

SUMMARY:

Switching to KetoCal 2.5:1 LQ led to a mild increase in ketosis and a subsequent, noticeable seizure reduction. There were no issues with tolerance reported, and no noticeable negative implications to switching to KetoCal 2.5:1. LQ. Given the noticeable improvement to seizures and the early signs that KetoCal 2.5:1 LQ may be helping his constipation, Sam's family opted to continue with KetoCal 2.5:1 LQ after the study period.

CASE STUDY 5:

Jude Munn (Specialist Dietitian)
The Barberry, Birmingham & Solihull Mental Health Foundation Trust

BACKGROUND

Emily* is a 30 year old woman with drug-resistant epilepsy with a working diagnosis of Lennox-Gastaut syndrome, cerebral palsy and moderate learning disability. Emily was diagnosed with epilepsy at the age of 2, she had been seizure free prior to this. Her seizure frequency was 10-15 myoclonic jerks per day and in adolescence Emily found her seizures increased during menstruation. Emily's antiepileptic drugs (AEDs) included levetiracetam, sodium valproate and, during menstruation, clobazam, but her epilepsy proved resistant to AED treatment. Vagus Nerve Stimulation or surgery were not considered an option for Emily.

At age 28, Emily's mum and epilepsy Specialist Nurse attended an appointment to discuss the Modified Ketogenic Diet (MKD) to help manage her epilepsy. Emily was initially hesitant about the thought of the diet but her Mum and nurse were keen to do a 3-month trial and encouraged Emily to give it a go. Prior to starting the Ketogenic Diet Emily was unable to hold a cup or eat meals without spilling; she had wobbly legs, episodes where her knees gave way and she would drag her legs. This typically lasted about 20 minutes and she would need support to walk.

*This is not the patients real name

USE OF THE KETOGENIC DIET

The Modified Ketogenic Diet was initiated with an initial carbohydrate restriction of 30g/day. AEDs were left unchanged and the diet was phased in slowly, replacing one daily meal each week with a ketogenic alternative, over the course of a month, until her diet consisted of 5-10g carbohydrate per main meal (breakfast, lunch, dinner) and 2-3g of carbohydrate from snacks. Liberal use of fats was advised (e.g. butter, oils, double cream) alongside normal protein portions. A month after starting the MKD, Emily attended a cookery session where she had the opportunity to meet a few other patients either already on or about to start the Ketogenic Diet. She found this very useful.

Emily responded very well to the MKD and tolerated it with no gastrointestinal symptoms or other issues. Her seizure frequency reduced to from 10-15 daily to just 2-3 seizures every 3-4 days. Her wobbly legs were also much improved. This improvement was maintained for the 2 years since the MKD was introduced. Emily reported a much-improved quality of life and a marked cognitive improvement and alertness.

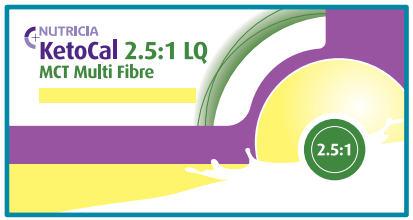
Emily lost weight gradually as she found her appetite was reduced since commencing the diet. She lost 4.5kg in the first 9 months on the diet, bringing her weight to 60.3kg and her BMI to 22 kg/m². KetoCal 4:1 LQ was therefore prescribed to increase energy intake by 300kcal and fat intake by 29.6g

to assist with weight maintenance and with the hope that the additional fat may improve ketosis.

Overall Emily had good compliance to the diet, occasionally consuming a higher than recommended carbohydrate intake at parties or when on holiday, but this quickly resulted in an increase in her seizures therefore Emily usually went back to <30g per day carbohydrate.

KETOCAL 2.5:1 LQ:

Emily was invited to take part in a 4 week trial of KetoCal 2.5:1 LQ as it was felt the product would be helpful as it contains MCT fat (20% of total energy) and could replace the KetoCal 4:1 LQ Emily was having at the time. It is more suitable nutritionally for adults as a supplementary feed on the MKD. MCT produces more ketones per gram than long chain triglycerides so can be useful to improve ketosis. Emily chose to have two carton's (400ml) of KetoCal 2.5:1 LQ and they were incorporated into her diet for the 4 weeks, all other dietary recommendations remained the Emilye, including a prescribed carbohydrate intake of <30g/day.



OUTCOME

Emily successfully completed the 4 week trial of KetoCal 2.5:1 LQ, with no gastrointestinal adverse events or symptoms. Emily had the full prescription of 2 carton's (400ml) throughout the trial, with the exception of 5 days when Emily was on holiday and found it too hot to have the full prescription (she had 200-300ml on these days) and when she was out and missed the usual time when she would normally consume the second carton. Emily found KetoCal 2.5:1 LQ to be very useful; she had it as an alternative to milk or milkshakes and as a snack when she was out and about at college and clubs.

Emily recorded her dietary intake using 3 day food diaries prior to and at the end of the 4 week trial. Emily did have an increased carbohydrate intake while taking KetoCal 2.5:1 LQ (largely due to going on holiday) but the overall Ketogenic Diet ratio increased from 1:1 to 1.3:1 (Table 5). Her average blood ketone concentrations did not change; remaining at approximately 0.3mmol/L.

Seizure frequency increased very slightly during the trial from an average of 2-3 seizures 3-4 days a week, to 4-5 seizures 3-4 days a week, but it was felt this was largely due to an increase in carbohydrate intake whilst Emily was on holiday. Despite an average increase in carbohydrate intake of 9g/day, Emily's seizure frequency did not increase as dramatically as would normally have been expected based on previous occasions where she had increased carbohydrate intake. Emily still remained seizure free 3-4 days a week throughout the trial, suggesting that KetoCal 2.5:1 LQ may

have allowed for a little more flexibility in carbohydrate intake, likely due to the additional MCT intake from the product (14.4g.day). As she remained seizure free 3-4 days a week, this was still a marked improvement from 15 seizures every day which Emily had prior to commencing the MKD diet.

Emily put on 0.8kg whilst on the trial which was thought to be due to a reduction in activity whilst on holiday.

FOLLOW UP

Due to the introduction of the Modified Ketogenic Diet, Emily has seen a dramatic improvement in her epilepsy, and her QOL have significantly improved. She is able to hold her drinks without spilling, her wobbly legs are much improved, and she is notably more alert.

Emily liked the study drink so much that she continues 1-2 cartons (200-400ml) of KetoCal 2.5:1 LQ every day as a drink or snack.

CONCLUSION

The Modified Ketogenic Diet led to a marked improvement both in Emily's epilepsy and her quality of life. KetoCal 2.5:1 LQ is versatile, easy to consume and well-tolerated as a supplementary drink for the Modified Ketogenic Diet. It is nutrient dense, contains MCT oil and fibre to support adult patients in meeting their nutritional needs and may help promote ketosis whilst on the MKD, allowing more flexibility with respect to an increased carbohydrate intake.

Table 5: Nutritional intake from Emily's baseline diet & diet during the 4 week KetoCal 2.5:1 LQ trial.

Nutrient	Baseline	4 week KetoCal 2.5:1 LQ Trial
Energy (kcal)/day	1480	1452
Carbohydrate g/day (% energy)	14g (4%)	23g (6%)
Fat g/day (% energy)	112g (68%)	121g (75%)
Protein g/day (% energy)	102g (28%)	67g (19%)
Ratio (Fat : CHO+Protein)	1 : 1	1.3 : 1

HELPING MAKE THE KETOGENIC DIET **EASIER**

- **CONTINUED INVESTMENT IN RESEARCH**
- **RECIPE BOOKS**
- **COOKERY EDUCATION**
- **KETOGENIC RANGE**
  proven to help aid adherence to a ketogenic diet
- **WEB INFORMATION AND FILMS**
  about ketogenic diet, see adresses for each country

All the products shown are Foods for Special Medical Purposes and must be used under medical supervision.

This information is intended for Healthcare Professionals only.

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