# ELSEVIER

#### Contents lists available at ScienceDirect

#### Seizure

journal homepage: www.elsevier.com/locate/yseiz



## The modified ketogenic diet for adults with refractory epilepsy: An evaluation of a set up service



Kirsty J. Martin-McGill<sup>a,b,\*</sup>, Michael D. Jenkinson<sup>a,b</sup>, Catrin Tudur Smith<sup>c</sup>, Anthony G. Marson<sup>a,b</sup>

- <sup>a</sup> Institute of Translational Medicine, University of Liverpool, Liverpool, L69 3BX, UK
- <sup>b</sup> The Walton Centre NHS Foundation Trust, Liverpool, L9 7LJ, UK
- <sup>c</sup> Department of Biostatistics, University of Liverpool, Liverpool, L69 3BX, UK

#### ARTICLE INFO

Article history: Received 20 June 2017 Received in revised form 4 August 2017 Accepted 29 August 2017 Available online xxx

Keywords: Ketogenic Diet Adult Epilepsy

#### ABSTRACT

*Purpose*: The ketogenic diet (KD) has been proven to be effective in children with refractory epilepsy and is recommended by the National Institute of Health and Care Excellence (NICE). There is no randomised control trial (RCT) evidence for the clinical or cost effectiveness of KD in adults, for whom the KD is not currently recommended. We assessed the feasibility of the modified ketogenic diet (MKD) in adults with refractory epilepsy along with the willingness of patients to participate in a future RCT.

*Methods:* The service evaluation was undertaken in two parts; questionnaire and diet evaluation. *Results:* 102 patients completed a questionnaire, of which 51 patients were willing to try the MKD for 3 months to assess effect on seizures. Forty three patients were willing to participate in a clinical trial to investigate deliverability, efficacy and tolerability. Thirty seven of which would still be willing to participate if the trial were randomised. Of the 17 patients who commenced the diet, 9 completed the 12 week period, 7 of which stayed on the diet for the longer term. Constipation (n = 6) and loose stools (n = 3) were the only reported adverse effects.

Conclusion: Our results indicate that there is demand for a ketogenic diet service in adults. The MKD is well tolerated, feasible and financially viable to deliver to adults with epilepsy in the NHS. There is also interest in and willingness to participate in a UK based RCT that would ultimately inform decisions about commissioning appropriate services.

© 2017 Published by Elsevier Ltd on behalf of British Epilepsy Association.

#### 1. Introduction

The ketogenic diet (KD) has been proven to be effective in children with refractory epilepsy and is recommended as a treatment option by the National Institute of Health and Care Excellence (NICE) [1]. However, there is no randomised control trial (RCT) evidence for the clinical or cost effectiveness of KD in adults [2]. As a result, the KD is not routinely recommended as an

NHS treatment for adults with treatment refractory epilepsy in the UK, nor is it recommended in other EU countries.

The majority of new AFDs have been developed based on

The majority of new AEDs have been developed based on knowledge of neuron excitability and through mass screening of drugs in animal models. Whilst more than 20 new antiepileptic drugs (AEDs) have been developed over the past 30-40 years, there has been no substantial decrease in the proportion of patients with uncontrolled seizures. Given this failure, it is important to assess other treatment options such as the KD. However, designing and delivering a KD service, and assessing is clinical and cost effectiveness pose a number of challenges that need to be considered and addressed.

One challenge is access to a service that can provide the KD for both patients in a trial and as an NHS treatment. The arguments here can be somewhat circular, as at present few services are commissioned to provide the KD for adults. As a result there are few services in place to support a RCT, but commissioners will not commission further services without good evidence of cost effectiveness. We therefore need evidence about feasibility, service

E-mail addresses: Kirsty.martin@liverpool.ac.uk (K.J. Martin-McGill), Michael.jenkinson@liverpool.ac.uk (M.D. Jenkinson), cat1@liverpool.ac.uk (C. Tudur Smith), a.g.marson@liverpool.ac.uk (A.G. Marson).

Abbreviations: AEDs, antiepileptic drugs; BMI, body mass index; HDL, high density lipoprotein; KD, ketogenic diet; LDL, low density lipoprotein; MCT, medium chain triglyceride; MKD, modified ketogenic diet; NHS, National Health Service; RCT, randomised control trial; TG, triglyceride; WCFT, Walton Centre NHS Foundation Trust.

<sup>\*</sup> Corresponding author at: Dietetics Office, The Walton Centre NHS Foundation Trust, Liverpool, L9 7LJ, UK.

throughput and costs to design the most efficient means of delivering the KD to adults with refractory epilepsy in the NHS.

A second challenge is to choose the most appropriate type of KD to provide. There are various types of KD, including the classical KD (4:1 ratio of fat to carbohydrate and protein,  $\sim 90\%$  fat), the medium chain triglyceride (MCT) KD ( $\sim 75\%$  fat), the modified ketogenic diet (MKD,  $\sim 80\%$  fat) and the modified Atkins diet (MAD,  $\sim 65\%$  fat). There is a trend within RCT evidence for KDs with a higher fat and lower carbohydrate content to have greater antiepileptic efficacy [2]. However, these KDs are also associated with a greater number of side effects.

The MKD is the least restrictive KD and induces ketosis through encouraging a high fat and low carbohydrate intake, but without the requirement to limit protein, fluid or energy intakes, in contrast to other KDs. There is no need for a fasting start or hospitalisation to commence the diet [3], promoting ease of use and reducing costs. As with all KDs the MKD has some side effects, however these are predominantly gastrointestinal related (constipation, diarrhoea and reflux), along with raised lipid profiles and weight loss. In an adult population this weight loss may be a desirable outcome in those overweight and obese individuals [4]. On balance the MKD is the intervention that is most likely to be tolerated by adults with refractory epilepsy and the diet we have chosen to assess.

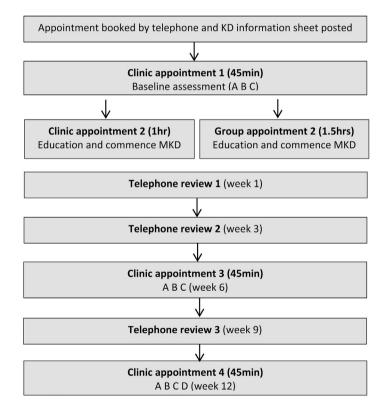
This study has two parts. Firstly, we assessed patients' views about access to a KD service and their willingness to participate in

an RCT. Secondly we assessed the feasibility of delivering a KD service in a unit with no prior service.

#### 2. Materials and methods

Questionnaire development was undertaken by a multidisciplinary team, including a Neurologist, Neurosurgeon, Biostatistician and Dietitian at the University of Liverpool and The Walton Centre NHS Foundation Trust (WCFT). Data collected included demographics, attitudes towards the use of the MKD in refractory epilepsy, willingness to try the diet and willingness to participate in a RCT. The questionnaire contained background information regarding the MKD to assist patients in making an informed decision. The questionnaire was circulated to patients attending WCFT Mersey region, epilepsy clinics.

Patients attending these clinics were offered the opportunity to try the MKD for a 3 month period. Ketogenic service inclusion criteria included age  $\geq \! 18$  years, patient at WCFT, prior use of at least 2 anticonvulsant medications, at least 2 seizures per month. Exclusion criteria included having prior use of a KD, kidney dysfunction (chronic kidney disease, renal stones, cancer, low phosphate/potassium/salt diets), liver dysfunction (alcoholic liver disease, non-alcoholic liver disease, cancer, hepatitis, haemochromatosis, primary biliary cirrhosis), gall bladder dysfunction (gall stones, cholecystectomy in past 12 months, cancer), metabolic disorder (carnitine deficiencies,  $\beta$  oxidation defects [medium-



Key	
Α	Anthropometry (weight, height, BMI, MAC, TSF, MAMC, FM)
В	Biochemistry (renal, bone, LFT, fasting lipid, fasting glucose, carnitine [only on initial screen])
С	Collect food and ketone diaries
D	Service evaluation questionnaire

Fig. 1. Schematic of service design.

#### Download English Version:

### https://daneshyari.com/en/article/4935247

Download Persian Version:

https://daneshyari.com/article/4935247

<u>Daneshyari.com</u>