



Evaluation of a simplified modified Atkins diet for use by parents with low levels of literacy in children with refractory epilepsy: A randomized controlled trial



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ABSTRACT

Purpose: This study was planned to develop and evaluate a simple, easy-to-understand variation of the modified Atkins diet, for use by parents with low levels of literacy in children with refractory epilepsy.

Methods: This study was conducted in two phases. In the first phase, a simplified version of the modified Atkins diet was developed. In the second phase this was evaluated in children aged 2–14 years who had daily seizures despite the appropriate use of at least two anticonvulsant drugs, in an open-label randomized-controlled-trial. Children were randomized to receive either the simplified modified Atkins diet or no dietary intervention for a period of 3 months with the ongoing anticonvulsant medications being continued unchanged in both the groups. Reduction in seizure frequency was the primary outcome-measure. Data was analyzed using intention to treat approach. Adverse effects were also studied. (Clinical trial identifier NCT0189989).

Results: Forty-one children were randomly assigned to the diet-group, and 40 were assigned to the control-group. Two patients discontinued the diet during the study period. The proportion of children with >50% seizure reduction was significantly higher in the diet group as compared to the control group (56.1% vs 7.5%, $p < 0.0001$). The proportion of children with 90% seizure reduction was also higher in the diet group (19.5% vs 2%, $p = 0.09$). Six children in the diet group were seizure free at 3 months compared with two in the control group ($p = 0.26$). At 3 months, 6 children had constipation and 5 had weight loss.

Conclusion: A simplified version of the modified Atkins diet was developed for use by parents with low levels literacy. This diet was found to be feasible, efficacious and well tolerated in children with refractory epilepsy.

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1. Introduction

The ketogenic diet is a well established therapeutic option for children with refractory nonsurgical epilepsy. However, it has the drawbacks of calorie restriction, requirement for hospitalization for initiation and strict weighing of foods. The modified Atkins diet,

which is a less restrictive option, may be started on an outpatient basis without fasting and with no calorie or protein restriction. The modified Atkins diet has been demonstrated to be effective in children with epilepsy in multiple uncontrolled studies (Kossoff et al., 2003, 2006; Kang et al., 2007) and in a recent randomized controlled trial from India (Sharma et al., 2013). In the previously mentioned randomized study, the modified Atkins diet was explained to the parents by means of recipes with pre-calculated carbohydrate content which required some weighing of foods (Sharma et al., 2013).

Both the ketogenic and the modified Atkins diet require the parents to be educated and motivated. Parents need to understand complex instructions about diet preparation and measuring

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ketones in urine. Hence children of parents with low levels of literacy and poor socioeconomic status have not been able to benefit from these therapies. Also, the paucity of trained dieticians and limited availability of labeled foods in resource-constraint settings have made these dietary therapies even more inaccessible. Hence this study was planned to develop and evaluate a simple, easy-to-understand variation of the modified Atkins diet, for use by parents with low levels of literacy in children with refractory epilepsy.

2. Methods

This study was conducted in a pediatric tertiary care teaching hospital in north India from September 2012 to November 2015. This is a government run hospital which caters to the low and middle socio-economic strata patients from New Delhi and the neighboring states. This study was funded by the Indian Council of Medical Research extramural projects grant. Approval from the institutional ethics committee was obtained. A written informed consent was obtained from the parents. The study was registered at Clinicaltrials.gov (Clinical trial identifier NCT0189989). This study was conducted in two phases. In the first phase, a simplified version of the modified Atkins diet was developed. In the second phase this simplified modified Atkins diet was evaluated in children with refractory epilepsy in a randomized controlled trial.

2.1. Phase I

The simplified modified Atkins diet was planned as carbohydrates intake restricted to 10 g/day. Fats were actively encouraged. Carbohydrate-free protein foods were given unrestricted. Calcium and multivitamin supplementation were provided in addition. In the previously used version of modified Atkins diet from India, parents had to understand the carbohydrate values of various food items and weigh foods to order to provide the restricted carbohydrate amounts.

To simplify the administration of this diet, the following modifications were made – the weighing of individual food items with gram scales was replaced with the measuring of individual food items with standardised measuring equipment (such as metric tablespoons – Fig. 1) and recipe design by means of totalling carbohydrate content of individual food items was replaced with recipe design by means of totalling standardised measurements according to a provided pictorial representation and exchange lists (Figs. 1 and 2). In addition, recipes provided either no carbohydrate or 2.5 g carbohydrate for simplicity and the recipes contained easily available, commonly used Indian foods. These recipes were standardised beforehand using the kitchen measures (the metric tablespoons) so that no weighing was required.

A Parent guideline booklet was developed in simple to read Hindi format along with pictorial representations so that even parents with low levels of literacy could understand the instructions. The parents were taught how to note down and maintain record of daily seizures in the seizure diary by using simple bars and color codes to document urine ketones.

2.2. Phase II

The simplified modified Atkins diet was evaluated in children with refractory epilepsy in an open-label randomized controlled trial. The study design was similar to the randomized controlled trial on the ketogenic diet by Neal et al. and the previous randomized controlled trial on the modified Atkins diet (Sharma et al., 2013; Neal et al., 2008).

2.2.1. Patient selection

Children aged 2–14 years who had daily seizures (or more than seven seizures per week) despite the appropriate use of at least two anticonvulsant drugs and were dietary-therapy-naïve were enrolled. Children with known or suspected inborn errors of metabolism, systemic illness, surgically remediable causes of epilepsy, or motivational issues in the family that would preclude compliance were excluded.

2.2.2. Procedure

Each child underwent detailed a clinical evaluation. The seizure type, frequency, age at onset, perinatal details, family history, developmental status, and treatment history were noted. Results of investigations such as neuroimaging and EEG were also documented. Eligible children were randomized into two groups: the intervention and the control arm. Variable block size randomization (2, 4, or 6) was done using computer generated randomization sequence. The allocation concealment was done using opaque sealed envelopes. There was no blinding.

Both groups underwent a baseline 4-week observation period, during which parents were asked to maintain a daily seizure diary noting the seizure type, duration, and frequency. In the intervention arm, the children were administered simplified modified Atkins diet after this 4-week baseline period. The control group received their routine diet. During the 3-months trial period, the ongoing anticonvulsant medication remained unchanged in both the groups, unless the change in the anticonvulsant regimen was medically indicated.

Children were followed up as outpatients at 15 days, 1, 2 and 3 months. A 3-day dietary intake chart was reviewed at each visit in the diet group to check and reinforce compliance. Parents were asked regarding any difficulties they faced with understanding the instructions and preparation of the diet. Tolerability of the diet and any adverse events was evaluated by means of parental interview at each visit. Parents were questioned for the following symptoms – vomiting, lethargy, poor appetite, refusal to feed and constipation in particular. Any other parental concerns were also noted.

Urinary ketones were checked using urine dipstick at each hospital visit. Two ml fasting venous blood sample was drawn for liver and renal function tests, and fasting lipid profile at baseline and at the end of 3 months study period. Parents of children on the diet group were asked to rate the effects of the simplified modified Atkins diet on the following non-seizure domains at 3 months after starting the diet: alertness, activity level, speech/communication, comprehension/understanding, sleeping, motor skills, social interaction and behavior. The questions were open ended and parents were subjectively asked to rate the characteristics on a Likert scale ranging from much worse (1), somewhat worse (2), same (3), somewhat better (4), or much better (5).

2.3. Outcome measures

The primary outcome measure was the proportion of patients who achieved >50% seizure reduction (Seizure frequency measured as average seizure per week in the preceding 4 week period) from the baseline in the simplified modified Atkins diet plus AED therapy group at 3 months in comparison to the AED alone group. The secondary outcome measures included the proportion of patients who achieve seizure freedom in both the groups and tolerability and the adverse effects of the simplified modified Atkins diet as per parental reports. We also compared the changes in biochemical parameters at 3 months when compared to the baseline in both the groups. The effect of the diet on the non-seizure domains was also noted as per parental reports.

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