SHORT RESEARCH ARTICLE

Development and Preliminary Validation of a Questionnaire on Parental Perception of The Ketogenic Diet

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ABSTRACT

Background: Epilepsy is a prevalent neurological disorder in children, often requiring specialized management strategies. The ketogenic diet (KD), a high-fat, low-carbohydrate therapy, has shown efficacy in reducing seizure frequency in drug-resistant epilepsy. However, adherence is challenging due to dietary restrictions, complexity, and side effects. Understanding parental perceptions is crucial to addressing barriers and improving adherence. This study aimed to develop and preliminarily validate a questionnaire assessing parental perceptions of the KD.

Methodology: Two questionnaires (pre- and post-intervention) were designed to evaluate ten domains, including parental understanding, effectiveness, dietary management, concerns, support, and financial impact. Content validity was assessed using the Content Validity Index (CVI) with expert evaluation based on Lawshe's method. Six experts, including dietitians and neurologists, reviewed item relevance and clarity. Internal consistency was analyzed using Cronbach's alpha.

Results: Content validity scores ranged from 0.83 to 1.0 (I-CVI) and 0.94 to 1.0 (S-CVI), indicating excellent validity. Some discrepancies in four domains were resolved through expert consensus. Internal consistency was confirmed with satisfactory Cronbach's alpha values.

Conclusion: The developed questionnaire demonstrated strong validity and reliability, making it a valuable tool for identifying adherence barriers. Further psychometric testing is required for comprehensive validation.

Keywords: Parental Perception, Ketogenic Diet, Seizures, Epilepsy

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INTRODUCTION

Epilepsy is one of the most prevalent neurological disorders among children, often requiring comprehensive management strategies to control seizures and improve quality of life. The ketogenic diet (KD), a high-fat, low-carbohydrate dietary therapy, demonstrated efficacy in reducing seizure frequency in drug-resistant epilepsy.[1,2] Despite its therapeutic potential, adherence to KD can pose significant challenges for families due to its restrictive nature, dietary complexity, and potential side effects.[3] Understanding parental perceptions of KD is essential to identify barriers to adherence and areas requiring additional support to enhance its acceptability and effectiveness.

To evaluate these perceptions, two comprehensive questionnaires were developed and administered pre- and post-intervention (Q1 and Q2). Each validated questionnaire consisted of ten domains covering key aspects of parental understanding, dietary management, and the impact of KD on the child and family. Content validity, a critical component of instrument development, was assessed using the content validity index (CVI), incorporating expert judgments based on Lawshe's method.[4] High I-CVI and S-CVI scores indicated robust validity, with minimal discrepancies noted in specific domains. To date, no validated instrument exists to assess parental perceptions of the ketogenic diet (KD) for children with epilepsy.

The primary objective of this study was to design and perform preliminary validation of questionnaire to assess questionnaire to evaluate parental perspectives on the KD both before and after dietary intervention. The goal was to establish a reliable tool to support the development of targeted strategies aimed at enhancing adherence and optimizing therapeutic outcomes.

METHODOLOGY

The questions in developed questionnaires were selected based on a multidisciplinary approach integrating neurology, dietetics, psychology, and health behavior research. The domains were structured to comprehensively assess parental perception of the ketogenic diet (KD) as a therapeutic intervention for childhood epilepsy.

Demographic information was collected to capture essential background data, including age, gender, epilepsy duration, current treatments, socioeconomic status, and parental education. These variables are crucial in understanding how different demographic and social factors influence attitudes toward the KD. There was total ten domains in the developed questionnaire they are parental understanding and awareness, perceived effectiveness, dietary management and compliance, concerns and side effects, support and resources, parental motivation and decision-making, impact on child's quality of life, long-term considerations, community and peer influence, and financial considerations.

Parental Understanding and Awareness: The inclusion of these questions aligns with health literacy and knowledge acquisition theories, assessing the extent to which caregivers comprehend the diet's mechanism and purpose.

Perceived Effectiveness: Drawing from the Health Belief Model (HBM), this section evaluates parental beliefs about the efficacy of KD in seizure management and whether they perceive its benefits to outweigh challenges.

Dietary Management and Compliance: Based on behavioral and nutritional sciences, these questions explore practical challenges related to meal preparation, adherence, and disruption to family routines.

Concerns and Side Effects: Rooted in risk perception theory, this domain examines parental fears regarding potential adverse effects, long-term safety, and overall health implications.

Support and Resources: Grounded in social support theory, these questions assess parental confidence in healthcare guidance, resource availability, and overall support networks.

Parental Motivation and Decision-Making: This section reflects aspects of self-efficacy and decision-making models, analyzing parents' confidence in their choices and their approach to treatment decisions.

Impact on Child's Quality of Life: Informed by quality-of-life assessment frameworks, these questions explore perceived changes in energy levels, social interactions, and overall well-being.

Long-Term Considerations: Incorporating aspects of sustainability research, this section gauges concerns about maintaining the KD over extended periods and potential exploration of alternative treatments.

Community and Peer Influence: Based on social influence theories, this domain assesses the role of peer feedback, parental isolation, cultural beliefs, and support groups in shaping perceptions.

Financial Considerations: Economic burden is a significant determinant in treatment adherence; therefore, these questions analyze financial feasibility, insurance coverage, and the impact on household expenses. By organizing the questionnaire into these domains, it systematically captures factors influencing parental perception, ensuring a holistic understanding that can guide interventions and support systems for families managing epilepsy through dietary therapy.

The custom-designed pre- and post-intervention questionnaires were evaluated for reliability and validity. For content validation, Lawshe's method was

applied using a selected panel of six experts including dieticians, neurologists, and academician.[5] Each item of the questionnaire was evaluated on a four-point scale into not-relevant, somewhat relevant, quite relevant, and highly relevant depending upon its relevance to the measured domain. Two forms of content validity index (CVI) were estimated in terms of relevance and clarity, one for each item (I-CVI) and another for scale (S-CVI).[6] Further, reliability was tested employing the internal consistency of the questionnaire using Cronbach's alpha.[7] The developed tool is a proprietary instrument developed and copyrighted by the author(s). Any reproduction, adaptation, or use of this tool beyond the scope of this study requires explicit written permission from the author(s).

Approval of Institutional Ethical Review Board: The study was approved by the Institutional Ethical Committee of Sri Ramachandra Institute of Higher Education and Research, Porur, Chennai. **(REF NO: IEC/24MAR/185/09).**

Results

To evaluate the perception of parents on ketogenic diets for children with drug resistant epilepsy, two questionnaires were developed and administrated, Q1 (pre-intervention) and Q2 (post-intervention). Each of the questionnaires comprised of a total of 10 domains: 1) parental understanding and awareness, 2) perceived effectiveness, 3) dietary management and compliance, 4) concerns and side effects, 5) support and resources, 6) parental motivation and decision-making, 7) impact on child's quality of life, 8) long-term considerations, 9) community and peer influence, and 10) financial considerations, with three items each except Domain 9, which had four items.

Both questionnaires were preliminary validated using the content validity index (CVI) based on the judgment of experts (using Lawshe's method) to determine the relevance and clarity of the questions presented. Domains 3, 5, 7, and 8 in Q1 and Q2 had only one item each that one of the six experts found was not very relevant. Hence, these stood out to be the only items that were not universally agreed upon by the experts. Besides, the results of preliminary validation showed that in both Q1 and Q2, the I-CVI for each item under the discrete domains was in the range of 0.83 to 1[Figure 1], while the S-CVI ranged from 0.94 to 1 in the pre-intervention and post-intervention scales. Any value above 0.8 for I-CVI and 0.9 or above for S-CVI for each domain is considered acceptable as per Polit et al. (2007).[8] These findings indicate excellent content validity in the items as well as the scale for both the Pre and Post intervention questionnaires in terms of relevance and clarity.

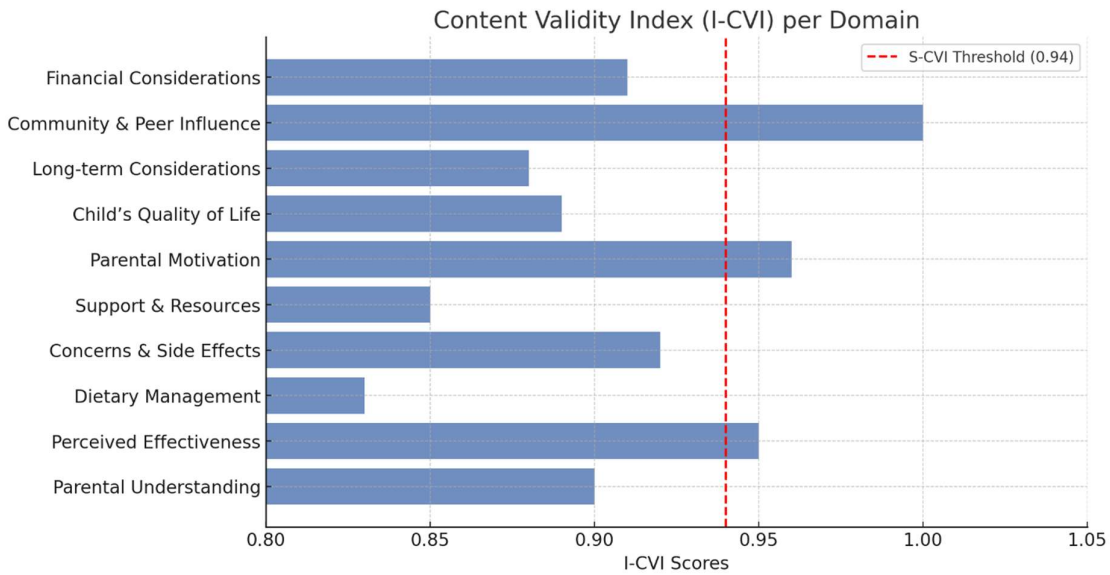

Figure 1: Content Validity Index (I-CVI) per Domain

*This horizontal bar chart displays the I-CVI scores for each domain in the questionnaires, with a red dashed line indicating the overall S-CVI threshold (0.94). It visually highlights the strong content validity across domains, with all values above the acceptable limit of 0.8.

Discussion

The study successfully developed and established content validity and internal consistency as an initial validation step of the two questionnaires (Q1 and Q2) to assess parental perceptions of the ketogenic diet (KD) for children with epilepsy. Both tools demonstrated excellent content validity, as evidenced by I-CVI scores between 0.83 and 1 and S-CVI scores exceeding 0.94, aligning with established thresholds for acceptability.[8] While minor discrepancies in relevance were noted in four domains, the high overall agreement among experts highlights the robustness of the instrument. Reliable tools like

these are essential for identifying parental challenges with KD adherence and can inform targeted interventions to optimize dietary management and therapeutic outcomes.[1,6]

Strength of the Study

One major strength of this preliminary validation process, ensuring high content validity and reliability, as evidenced by strong I-CVI and S-CVI scores. The inclusion of diverse domains covering key aspects of parental perception allows for a holistic assessment, providing valuable insights into adherence challenges and areas requiring support.

Limitations

As a part of exploratory phase only content validity and internal consistency of the questionnaire were tested. The study's reliance on expert judgment for content validation may introduce subjective bias, and the relatively small expert panel (six members) may not fully capture broader perspectives. Additionally, while the questionnaire was validated for content and internal consistency, further psychometric testing, such as construct validity, factor analysis and test-retest reliability, would strengthen its robustness.

Conclusion

This study introduces a novel tool to assess parental perceptions of the ketogenic diet for children with epilepsy, addressing a critical gap in clinical practice. With excellent content validity and reliability, the questionnaires facilitate targeted interventions to improve adherence and optimize outcomes, enhancing the diet's therapeutic potential and family-centered care. Thus, further psychometric testing (construct validity, test-retest reliability, criterion validity, etc.) is required for comprehensive validation.

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Availability of Data: The questionnaires developed in this study are copyrighted (Copyright Registration No: 33548/2024-CO/L). Any unauthorized use, reproduction, or distribution is prohibited. Relevant data and questionnaires available upon request to the corresponding author if they approve.

No use of generative AI tools: This article was prepared without the use of generative AI tools for content creation, analysis, or data generation. All findings and interpretations are based solely on the authors' independent work and expertise.

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