

Long-Term Effects of a Novel Continuous Remote Care Intervention Including Nutritional Ketosis for the Management of Type 2 Diabetes: A 2-Year Non-randomized Clinical Trial

Shaminie J. Athinakaran¹, Rebecca N. Adams¹, Sarah J. Hallberg^{1,2}, Amy L. McKenzie¹, Nasir H. Bhanpuri¹, Wayne W. Campbell³, Jeff S. Volek^{1,4}, Stephen D. Phinney¹ and James P. McCarter^{5}*

Reflection by Prateek Naharia | nahariap@bu.edu | MSBA, Boston University.
Dt. 5th December 2023

Problem Being Addressed:

The study addresses the pressing issue of effective long-term management of type 2 diabetes, a chronic condition with significant global prevalence and associated healthcare burden. Traditional approaches to diabetes management often fall short in achieving sustained glycemic control and addressing associated comorbidities, highlighting the need for innovative interventions. Type 2 diabetes is a complex and multifactorial disease characterized by insulin resistance and relative insulin deficiency, leading to hyperglycemia and associated complications such as cardiovascular disease, kidney disease, and neuropathy. The burden of type 2 diabetes is substantial, with an estimated 425 million adults affected globally, and this number is projected to rise to 629 million by 2045. Given the chronic nature of the disease and its associated complications, there is a critical need for interventions that can provide sustained improvements in glycemic control, body composition, and overall metabolic health.

Contribution Made:

The study contributes by evaluating the effects of a novel continuous remote care intervention on various clinical, anthropometric, and laboratory measures over a 2-year period. It also assesses the impact on body composition using dual-energy X-ray absorptiometry (DXA) and examines changes in bone density, fat, and lean mass. The continuous remote care intervention, which includes instruction in nutritional ketosis, aims to provide comprehensive support for individuals with type 2 diabetes, addressing not only glycemic control but also associated comorbidities and overall metabolic health. The study's comprehensive assessment of outcomes, including primary and secondary measures, provides a holistic view of the intervention's impact on various aspects of diabetes management, making it a valuable addition to the existing literature.

Evaluation Used or the Argument Made:

The study employs linear mixed-effects models (LMMs) and generalized estimating equations to assess within-group changes and between-group differences in study outcomes, controlling for relevant covariates. The use of multiple imputation to replace missing values facilitates an intent-to-treat analysis, enhancing the robustness of the findings. The statistical methods used in the study allow for the rigorous evaluation of the intervention's effects over time, providing valuable insights into the sustained impact of the continuous remote care intervention on glycemic control, body composition, and metabolic health. By

utilizing advanced statistical techniques, the study strengthens the credibility of its findings and contributes to the methodological advancement of research in diabetes management.

Opinion on Whether It's a Meaningful Contribution:

The study's findings provide valuable insights into the potential of continuous remote care interventions in achieving sustained improvements in glycemic control, body composition, and metabolic health in individuals with type 2 diabetes. The comprehensive evaluation and use of advanced statistical methods strengthen the credibility of the results, making it a meaningful contribution to the field of diabetes management. The study's focus on long-term outcomes is particularly valuable, as sustained improvements in diabetes management are essential for reducing the risk of complications and improving overall quality of life for individuals with type 2 diabetes. The findings underscore the potential of continuous remote care interventions to address the multifaceted nature of type 2 diabetes and its associated comorbidities, highlighting the importance of holistic approaches to diabetes management.

Limitation about the Paper:

One limitation of the study is the potential for selection bias due to its non-randomized design. While the study attempts to address this limitation through the use of statistical methods to control for relevant covariates, the possibility of unmeasured confounders influencing the results cannot be entirely ruled out. Additionally, the study acknowledges challenges related to obtaining full body scans in obese patients, which may have impacted the assessment of body composition. Furthermore, while the study reports on adverse events encountered, the specific nature and frequency of these events are not extensively discussed. A more detailed exploration of adverse events and their potential impact on the intervention's safety profile would have provided a more comprehensive understanding of the intervention's tolerability and safety.

Conclusion:

In conclusion, the study provides compelling evidence supporting the potential benefits of continuous remote care interventions in achieving sustained improvements in type 2 diabetes management. Despite certain limitations, the rigorous evaluation and comprehensive assessment of outcomes make this study a valuable addition to the existing literature on diabetes management. The findings underscore the importance of further research in this area and the potential for innovative remote care interventions to positively impact long-term health outcomes in individuals with type 2 diabetes. The study's focus on sustained improvements in glycemic control, body composition, and metabolic health highlights the potential of continuous remote care interventions to address the multifaceted nature of type 2 diabetes and its associated comorbidities, emphasizing the need for holistic and personalized approaches to diabetes management.