



THE FORUM
For Collaborative ResearchSM

Standard of Care: Lifestyle Management

Working Group Update

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Manuscript Update

- **Title:** Recommendations on Standardization of Diet and Exercise in Clinical Trials of NAFLD
- **Authors:** In progress based upon contributions
 - If interested in joining working group to support development, writing, and feedback of manuscript please email: oliver.glass@duke.edu and kgreen@forumresearch.org

Introduction

- Set the stage for the working group and the purpose and scope of the manuscript
- Lifestyle management with Diet and Exercise is fundamental to clinical care of NAFLD
- Need for standardization of diet and exercise in industry sponsored clinical trials

Proposed Content Sections

- **How Diet and Exercise Influence NAFLD**
 - Diet
 - Exercise
- **Issues Surrounding Diet and Exercise in Clinical Trials of NAFLD**
 - No mention of Diet and Exercise
 - Undefined Diet and Exercise
 - Diet Counseling and Specific Exercise Recommendations
- **Tools to Measure Diet and Exercise**
 - Examples
 - Potential Options
 - Summary
- **Challenges/Limitations for Industry**
 - Summary

Suggestions, Summary, and Future Directions

- **Proposed Tiered Approach to Diet and Exercise with Associated Data-Capture in Clinical Trials**
 - Levels 1-4 with increasing specificity
- **Summary**
 - Summary of available evidence, challenges, and tiered structure
- **Future Direction**
 - Implementation
 - Evolution of recommendations/guidance