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Observational Study

Effectiveness of RESET Care Program: A Real-World-Evidence on Managing Non-Alcoholic Fatty Liver Disease through Digital Health Interventions

RESET Care for NAFLD Management

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Abstract

BACKGROUND

Non-alcoholic fatty liver disease (NAFLD) management requires sustainable lifestyle modifications. This study aimed to evaluate the effectiveness of the RESET Care plan, a comprehensive program that is an integrated personalized diet, exercise, and cognitive behavior therapy, delivered *via* MyTatva's digital health application enabled through a body composition analyzer (BCA) and smartwatch.

AIM

This study evaluates the effectiveness of the comprehensive program delivered *via* MyTatva's digital health app enabled through IoT devices.

METHODS

This retrospective observational study analyzed deidentified data from 22 participants enrolled in the MyTatva RESET Care Program. Participants were divided into three groups: Group A, Diet Plan; Group B, Diet + Exercise Plan; and Group C, Diet +

Exercise + CBT Plan. Participants were provided with a BCA and smartwatch for continuous monitoring of anthropometric parameters. Statistical analysis, including one-way ANOVA and post-hoc Tukey's Honest Significant Difference ("HSD") test, was conducted to compare mean changes in anthropometric parameters across the groups.

RESULTS

All intervention groups showed significant improvement across all anthropometric parameters. Group C showed the most significant improvements, with mean weight reduction of 7% or more (6.99 ± 2.98 kg, $7.00\% \pm 3.39\%$; $P = 0.002$) from baseline, a benchmark associated with improved NAFLD conditions. Post-hoc analysis revealed that Group C had significantly greater improvements than Groups A and B. Weight reduction was observed in 85.7% of Group A participants, 77.8% of Group B participants, and 100% of Group C participants.

CONCLUSION

The comprehensive RESET Care plan achieved a 7% weight reduction in 12 weeks, demonstrating its effectiveness in managing NAFLD. These results support adopting digitally supported, patient-centric approaches for NAFLD treatment.

Key Words: Cognitive Behavioral Therapy (CBT); Digital health interventions; Diet and exercise regimens; Lifestyle modifications; Non-Alcoholic Fatty Liver Disease management

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Core Tip: This study evaluates the RESET Care Program, a comprehensive digital health intervention for managing Non-Alcoholic Fatty Liver Disease (NAFLD). By integrating personalized diet, exercise, and cognitive behavioral therapy (CBT) through a mobile app supported by IoT (Internet of Things) devices, the program offers continuous, tailored support for lifestyle modifications crucial to NAFLD management. Results demonstrate that participants receiving all three interventions (diet, exercise, CBT) achieved significant weight reduction and improved health outcomes. The RESET Care Program highlights the potential of digital tools in delivering accessible, scalable solutions for chronic disease management.

³ **INTRODUCTION**

Non-alcoholic fatty liver disease (NAFLD) has emerged as a global health burden, affecting approximately 1 in 4 individuals worldwide. NAFLD ranges from simple steatosis (fat accumulation) to non-alcoholic steatohepatitis (NASH), and its global prevalence in the general population is estimated between 6.3% and 33%, with NASH affecting 3-5%. Obesity is a major risk factor of NAFLD, with studies showing that the likelihood of developing NAFLD increases 5-fold at a body mass index (BMI) of 30–32.5 kg/m² and up to 14-fold at BMI of 37.5–40 kg/m² compared to a BMI of 20–22.5 kg/m².

Effective NAFLD management requires both dietary and physical activity modifications. Healthy weight loss with sustained muscle mass plays a pivotal role, with a reduction of 3%-5% decreasing hepatic steatosis, 5%-7% improving NASH conditions, and 10% or more needed to reverse hepatic fibrosis. Management also normalizes elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase), enhances insulin sensitivity, and thereby reduces cardiovascular risk by improving endothelial function and increasing cardiorespiratory fitness. However, diet or exercise alone is often not as effective as a combined approach. Integrating both balanced dietary changes and increased physical activity yields more sustainable improvements in NAFLD and overall metabolic health.

Traditional intervention methods usually involve in-person consultations, which often lack real-time and continuous patient monitoring. The recommendation of drastic changes in diet and exercise can also be overwhelming for patients, leading to low adherence rates. Many patients struggle to maintain these changes in the long-term due to a lack of continuous motivational support. In recent years, the health ecosystem has witnessed a significant shift toward digital health platforms, which complement pharmacological treatments in chronic disease management, and increase scalability. These platforms provide continuous monitoring and personalized support, helping to bridge the gap between health care setups and patients. Recent digital advances enable Internet of Things (“IoT”) devices to be integrated into such management plans to track health metrics, to address the limitations of traditional methods.

The MyTatva digital health application offers the Reducing liver inflammation through Exercise Sleep and Eating Transformation (RESET) plan, a novel comprehensive approach for NAFLD management by integrating personalized support from nutrition, physiotherapy, and cognitive behavioral therapy (CBT) coaches. We aimed to evaluate the effectiveness of the RESET plan by analyzing the reduction in anthropometric parameters across three different digital intervention groups.

MATERIALS AND METHODS

Research objective

The primary objective of this study was to compare the effectiveness of the RESET Care Program’s three intervention arms: Diet Plan; Diet + Exercise Plan; and Diet + Exercise + CBT Plan.

Study design and participants

This retrospective observational study utilized deidentified data from 22 patients, automatically retrieved through MyTatva’s app. Initially, physicians recommended MyTatva’s RESET Care Plan to 32 patients, of which 27 consented to participate.

However, 4 patients did not meet the eligibility criteria, leaving 22 participants for the analysis.

The RESET Care Program is a 12-week digital health intervention aimed at managing NAFLD, focusing on diet, exercise, and CBT. The program integrates IoT devices such as a BCA machine and a smartwatch, which allow for the regular monitoring of each participant's anthropometric parameters.

Participants included adults aged 18-65 years with a body mass index (BMI) between 25 kg/m² and 40 kg/m², willing to use digital health technology (smartphone, BCA machine, and smartwatch), and able to provide informed consent during onboarding with the application. Participants needed to have stable internet access and basic technological knowledge. Participants with any secondary causes of hepatic steatosis (*e.g.*, significant alcohol consumption, viral hepatitis), advanced liver disease (*e.g.*, cirrhosis), or other significant liver conditions, as well as those participating in another weight loss program or clinical trial, pregnant or lactating individuals, or those with severe psychiatric conditions that could interfere with participation were excluded from the study.

In this retrospective analysis, participants were categorized into three groups of the RESET Care Program offered through the digital health app. Group A consisted of participants who used the application for personalized dietary guidance. Group B participants received both the personalized diet plans and the structured exercise routines. Group C comprised participants who received the comprehensive RESET Care Program, including dietary plans, structured exercise routines, and CBT modules. This categorization enabled the evaluation of the effectiveness of varying levels of digital health intervention in improving health outcomes, allowing for a real-world assessment of the program's impact.

Digital health program

Upon onboarding, the detailed baseline assessment included demographic information, ethnicity, medical history, family history, and current work status. Each intervention

arm is designed to progressively enhance support and effectiveness, considering the unique needs of the participant (Figure 1).

Group A participants receive a personalized diet plan based on a unique Individual Dietary Intervention Strategy (also known as IDIS) plan focusing on gradual and sustainable changes to their eating patterns. Participants in the Diet Plan option of the RESET Care Program received an introductory call from a dedicated diet coach to assess baseline parameters such as demographics, cultural dietary habits, lifestyle, preferences, and local food availability. This initial assessment ensured that dietary recommendations were practical and tailored to each participant's routine. A personalized diet chart was developed, focusing on subtle, sustainable changes to support healthier eating habits. Participant adherence was monitored at 15-day intervals through the application and follow-up calls, allowing the diet coach to track compliance and adjust as needed. For participants showing positive health improvements, the plan was advanced to include additional lifestyle changes, like reducing dining out and optimizing meal timing. For those facing challenges, initial efforts emphasized building foundational healthy habits before gradually incorporating more comprehensive dietary modifications.

Group B combined a personalized dietary plan with an exercise plan *via* the FITT approach tailored to individual physical activity levels and lifestyle requirements. This plan emphasizes incremental adjustments in both diet and exercise, supported by a 15-day follow-up by coaches. The personalized exercise plan in the RESET Care Program was developed based on participant baseline physical activity levels, job demands, and any physical limitations. For those with sedentary jobs, the plan included strategies like walking breaks, stretching exercises, and desk workouts. For participants who traveled frequently, adaptable routines suitable for various environments were provided. The plan focused on gradually increasing both the intensity and duration of activities to build endurance and strength progressively. Participant adherence and progress were monitored at 15-day intervals through the application and follow-up calls, allowing for timely adjustments to optimize their outcomes. As participants built endurance and

demonstrated adherence, the plan was modified to include more vigorous exercises tailored to their growing fitness levels.

Group C integrated CBT with diet and exercise interventions. This comprehensive approach addresses psychological barriers to lifestyle changes, providing continuous support through regular CBT sessions. These sessions help participants develop coping strategies for stress, dysregulated eating behavior, and sedentary lifestyle, enhancing long-term adherence to these interventions.

After the 90-day intervention period, participants underwent a final assessment to evaluate changes in their anthropometric parameters.

Data collection and statistical analysis

To facilitate comprehensive data collection, patients were provided with a BCA machine. This device enabled auto-fetching of patients' BCA measurements regularly, ensuring continuous real-time monitoring of their data. The collected data were organized in a Microsoft Excel spreadsheet. Analysis was conducted using Statistical Package for the Social Sciences (SPSS) Ver. 25.0 (IBM Corp., Armonk, NY, United States). Quantitative data were expressed as means and standard deviations. Statistical analysis was performed to establish significance at a P value < 0.05 , adhering to a 5% significance level. A one-way ANOVA was performed to compare mean changes in anthropometric parameters among the three intervention groups. Post-hoc comparisons using Tukey's Honest Significant Difference (HSD) test were conducted to further investigate significant differences between groups.

Ethical considerations

The study received approval from the ACEAS-Independent Ethics Committee, with Protocol Number MTNAFLD120324. The study was conducted in accordance with the Declaration of Helsinki and its subsequent revisions.

RESULTS

Patient demographic and baseline parameters

The study cohort consisted of 22 participants, with a distribution of 31.8%² in Group A, 40.9% in Group B, and 27.3% in Group C. The mean age of participants was 45.59 ± 11.02 years, with the majority being obese (72.7%). The cohort included 63.6% males and was predominantly from South India (40.9%). Employment status varied, with 54.6% employed and residing within metropolitan areas. Detailed demographic and baseline parameters are provided in Table 1.

Change in eating and exercise patterns

The overall cohort consisted of 31.8% vegetarians ($n = 7$) and 68.2% non-vegetarians ($n = 15$). Among the intervention groups, changes in participant dietary habits were evaluated by tracking the reduction in consumption of energy-dense, nutrient-poor (EDNP) foods and the increase in nutrient-rich foods (NRFs) over the course of the study. Participants also increased their consumption of fruits, vegetables, millet, eggs, chicken/fish, and pulses, as well as healthy fats like nuts and seeds (Table 2). Participants in all groups demonstrated a reduction in the consumption of refined and fried foods, sweets, high-salt snacks, meals from restaurants, and red meat (Table 3). At baseline, all groups had very low physical activity frequency; however, by the end of the study, there was a noticeable increase in physical activity across all groups, with Group C showing slightly better improvement.

Change in anthropometric parameters

Changes in anthropometric parameters were assessed across all three intervention groups over a 90-day period. Participants in Group C showed the most significant improvements, with a mean weight reduction of 6.99 kg, BMI reduction of 2.18 kg/m², subcutaneous fat reduction of 1.26%, and visceral fat reduction of 2.16%. These findings indicate that the comprehensive intervention in Group C⁴ was the only intervention group that achieved a mean weight reduction of 7% from baseline with 33.33% of participants having achieved a body weight reduction of ≥ 7%. The detailed changes for

each anthropometric parameter captured through the BCA machine are presented in Table 4, while the percentage reductions are illustrated in Figure 2.

Statistical findings

A one-way ANOVA was performed to compare the mean changes in anthropometric parameters among the three intervention groups. The results of the ANOVA indicated significant differences among the groups for all parameters: Weight ($P = 0.00050$); BMI ($P = 0.00003$); subcutaneous fat ($P = 0.00198$); and visceral fat ($P = 0.00015$). Detailed ANOVA results are provided in Table 5. To further investigate which groups differed significantly from each other, post-hoc comparisons using Tukey's HSD test were conducted. Tukey's HSD revealed that Group C had significantly greater improvements in all anthropometric parameters compared to both Group A and Group B.

DISCUSSION

Participants in the comprehensive RESET Care Program (Group C) showed superior weight reduction and improvements in anthropometric parameters compared to Group A and Group B. The program's effectiveness highlights the enhanced benefits of combining diet, exercise, and CBT for better NAFLD outcomes. Additionally, Group C had a slightly younger average age and a higher percentage of employed participants, which suggests that younger, employed individuals might be more motivated to integrate lifestyle changes effectively.

Diet plays a crucial role in the management of NAFLD, as excessive intake of EDNP foods can lead to fat accumulation in the liver through increased *de novo* lipogenesis, exacerbating hepatic steatosis, inflammation, and insulin resistance. In contrast, NRFs, high in essential nutrients, fiber, healthy fats and antioxidants, help reduce hepatic fat accumulation, improve liver function, enhance insulin sensitivity, and combat inflammation. The review findings by Chai *et al* (2023) and Perumpail *et al* (2017) support the significant roles of diet and exercise in managing NAFLD. Both reviews highlight that low-carbohydrate diets are more effective than low-fat diets in improving

hepatic fat content, reducing BMI and triglycerides, and enhancing metabolic indicators. The Mediterranean and Paleo diets emerged as promising regimens for NAFLD patients, leading to improved BMI and liver function. In the present study, the RESET program's dietary component provided personalized, structured nutritional guidance, which supported participants in adopting healthier eating habits. These changes were particularly notable in the reduction of EDNP foods and the increased consumption of NRFs. Additionally, the 25% reduction in red meat consumption among the non-vegetarian participants is significant, as high red meat intake is associated with an increased risk of NAFLD.

Regular physical activity, such as 40–45-minute sessions three times a week, enhances metabolic health and reduces liver fat content. Combining dietary modifications to compliment structured physical activity resulted in the most significant improvements in hepatic fat content, BMI, and other metabolic parameters. Chai *et al* (2023) reported that participants in the diet-only group experienced an average BMI reduction of 1.5 kg/m² over 6 months. The diet combined with exercise group showed an even greater BMI decrease of 2.0 kg/m², highlighting the enhanced effectiveness of combining diet and exercise for comprehensive NAFLD management. Similarly, in the present study, we observed that the Group B participants reported more significant reductions in weight and BMI compared to Group A.

In the study by Vincent *et al* (2018), a 52-week lifestyle intervention involving diet and regular exercise group achieved a mean weight reduction of 5.6 kg and a BMI reduction of 1.5 kg/m², with 67% of non-obese and 61% of obese patients experiencing remission of NAFLD. Montemayor *et al* (2022) reported that a combination of a customized hypocaloric diet and enhanced physical activity showed significant reductions in intrahepatic fat, BMI, and liver stiffness. Specifically, the mean weight reduction was 6.8 kg and BMI reduction was 2.6 kg/m² in the Mediterranean diet-physical activity group. Comparatively, in the present study, the reduction in BMI was 1 kg/m², achieved in 12 weeks.

All intervention groups were effective in managing NAFLD; however, Group C showed a weight reduction of 7% (6.99 ± 2.98 kg) and a BMI reduction of 6.76% (2.18 ± 0.99 kg/m²). The enhanced effectiveness of the overall plan can be attributed to the combined benefits of diet and physical exercise, along with the psychological support provided by the CBT coach, which addresses behavioral barriers to adherence and promotes lasting lifestyle changes. Similarly, the study conducted by Moscatiello *et al* (2011) demonstrates that participants who received CBT sessions experienced a significant weight loss of 5.6% over 2 years, compared to only 1.4% in the diet-only group. The study conducted by Montesi *et al* (2014) demonstrated the effectiveness of CBT in the management of NAFLD with a significant reduction in BMI (-2.04 ± 1.42 kg/m²) in the CBT + exercise group compared to those who received CBT support only (-1.09 ± 1.68 kg/m²).

When combined with diet and exercise, CBT provides a comprehensive approach, resulting in significant weight and BMI reductions, and promoting long-term, sustainable improvements in anthropometric parameters. Our study's intra-group analysis further supports this, showing significant reductions in anthropometric parameters across all intervention groups over the 12-week duration, with the highest reductions observed in Group C. The digitally delivered RESET Care Program offers a personalized approach based on root-cause analysis, tailoring interventions to individual needs and integrating CBT to ensure sustained lifestyle changes.

One of the main challenges in implementing the digital health intervention was ensuring participants' consistent engagement with the application and monitoring tools, especially for those less familiar with technology. To address this, participants received thorough onboarding, including guidance on using the application, BCA, and smartwatch. Regular follow-up calls from health coaches helped maintain engagement, provide technical support, and encourage adherence to the program. For those who struggled with lifestyle changes, coaches emphasized gradual habit-building to foster long-term commitment to the intervention. The RESET Care Program offers potential economic benefits by reducing the need for frequent in-person visits, lowering travel

costs, and saving time for participants. While initial setup costs for digital tools and training are necessary, the program's scalability and potential to improve long-term health outcomes, particularly by preventing NAFLD complications, suggest that it may offer significant cost savings in managing chronic liver conditions. The small sample size restricts the generalizability of the findings and highlights the need for larger, long-term studies to assess the program's effectiveness on a broader scale. Additionally, the reliance on self-reported dietary data may introduce reporting biases, and the study lacks insights into the individual contributions of each component, such as exercise-only or CBT-only interventions. Long-term follow-up is necessary to confirm the sustainability of the results.

CONCLUSION

The RESET Care Program is effective in NAFLD management, through promoting healthy weight loss and significant improvements in other anthropometric parameters. This addresses a critical need for a scalable, multifaceted approach to NAFLD management, by providing personalized, real-time monitoring through tailored interventions. This program could serve as a valuable tool for clinicians in remotely monitoring patients with chronic conditions like NAFLD, enhancing overall management and care.

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