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Impact of Targeted Intervention on Weight Reduction and Maintenance of Weight in Overweight / Obese Individual.

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ABSTARCT

The goal of therapy in overweight or obese patients is to prevent, treat, or reverse the complications of obesity which is reported with weight loss. We examined whether a targeted intensive lifestyle intervention for weight loss as compared to standard of care would lead to greater weight loss. In a centre for lifestyle diseases in a medical examination and boarding centre located at North India, we randomly assigned 800 overweight or obese patients to participate in targeted and frequently monitored intensive lifestyle intervention that promoted weight loss through decreased caloric intake and increased physical activity (intervention group) or to receive standard of care. The primary outcome was difference in weight reduction in the two group. After recruitment subjects were followed up every three months for one year. Weight loss was greater in the targeted intensive lifestyle intervention than in the control group through the duration of study [11.05 (95% CI 10.78-11.33)] kg over one year with significantly greater weight loss throughout the period of observation. Targeted intensive intervention led to greater reduction in HbA1c, blood pressure, physical activity and cardiovascular risk factors. A targeted intensive lifestyle intervention as compared to conventional measures leads to greater weight loss and associated clinical and metabolic improvement.

Keywords: Obesity, Overweight, Lifestyle Intervention

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INTRODUCTION

Overweight or obesity is associated with multiple morbidity and mortality [1]. If prevalence of obesity is not decreased the gain in life expectancy over last two centuries may be lost [2]. Obesity is now the most important cause for preventable disease and disability and has surpassed smoking [3]. The economic burden of treating obesity and obesity-related complications is enormous [5]. There are around 230 comorbidities and complications associated with obesity and weight loss leads to benefit in most of them [4].

A combination of diet (i.e. a reduction in caloric intake), exercise, and behavioural modification are a low-cost intervention for weight loss overweight or obese patients. In the Diabetes Prevention Program (DPP), intensive lifestyle modification with a goal of weight loss of 7 percent reduced the rate of progression from prediabetes to diabetes by 58% [6]. On similar lines in Look AHEAD (Action for Health in Diabetes), there was more weight loss and improved glycaemic control with an intensive lifestyle intervention which aimed at achieving and maintaining a loss of at least 7 percent of initial body weight [7]. Further weight loss leads to reduced use on antihypertensives, statin, reduction in urinary incontinence, sleep apnoea, fatty liver, depression and body image dissatisfaction. Reduction in cardiovascular events has however not been demonstrated with modest weight loss of less than 10%.

Very few studies have been done in overweight or obese patients without comorbidities. Further achieving weight loss of more than 10% and maintaining weight loss of even 5% over long term has been difficult with lifestyle measures alone [8]. It is known that it is possible to achieve greater weight loss and maintain the weight loss if there is frequent self-weighing, frequent and regular attendance at a weight loss program and participation in lifestyle intervention program [9, 10].

We at a centre for lifestyle diseases in a medical examination and boarding centre located at North India attempted to achieve a weight loss of ≥10% in our subjects with targeted intervention with frequent monitoring and compare it with standard of care in terms of magnitude of weight loss achieved and effect on complication and comorbidities thereon. We tried to see the effect in the patient who did not have complications also.

METHODS

Study Design

The Study was conducted at a centre for lifestyle diseases in a medical examination and boarding centre located at North India. Study was designed and conducted by authors. Analysis was carried out by and verified by authors. Free EMR software Healthplix was used for follow up and recall of the patient. The study was approved by institutional ethics committee. The study was not blinded but dietician and our physical training instructor were unaware of study group assignment. The authors vouch for the accuracy and completeness of the data and all analyses and for the fidelity of this report to the approved study protocol except the use of EMR. The study was sponsored by AFMRC. AFMRC had no role in study design, data analysis or reporting of results. "All guidelines as per declaration of Helsinki and good clinical practice guidelines were followed".

Study Patients

Subjects included in the study were in the age group of 25 to 50 years and met the following criteria: self-reported or detected during routine medical examination to have BMI between 25 to 34 kg/m^2, were expected to have a tenure of at least 1 year at same loaction, were willing for follow up every 3 months, and accepted to receive phone call for follow up purpose during this period. Patients with diabetes and hypertension were not excluded unless systolic BP was ≥160 mm of Hg, HbA1c ≥10% and triglyceride was ≥600 mg/dl. Subject were required to have the ability to complete a valid maximal exercise test, suggesting it was safe to exercise (This includes angina pectoris or significant ST segment depression at low levels of exercise, exercise induced ventricular arrhythmias, abnormal hemodynamic, such as flat or decreasing systolic blood pressure with increasing workload, and an abnormal response to exercise which would make it unsafe for the individual to participate) and easy accessibility to the centre where study was being carried out. Patients could be using any type of glucose-lowering medication, but not insulin. Patients with stable cardiovascular disease were included to increase the generalizability of the results.

Study Interventions

Subjects were randomly assigned to targeted intervention group or conventional care of obesity. Plan of care and follow up for the two group was built by the authors.

The targeted intervention was intended to achieve and maintaining weight loss of at least 10% by end of the year focusing on reduced caloric intake and increased physical activity. The program included both group and individual counselling sessions, occurring fortnightly during the period of the study. Specific intervention strategies included decreasing a calorie deficit of 500 kcal from a maintenance requirement of 22 kcal/kg. To implement a successful dietary intervention, a brief 24-hour dietary recall during fortnight review was done. Subjects were counselled on elimination of all caloric beverages and processed foods, portion control, self-monitoring and finally adopting a healthy, long-term approach to eating.

Goal for physical activity was at least 175 minutes/week of moderate intensity exercise such as brisk walking. This was achieved by gradually increasing the activity over 3 months. Scheduled group sessions educated and discussed methods for exercising safely and reducing barriers to exercise. Subjects were also introduced strength training which was supposed to comprise 25% of the weekly goal. Subjects were also discouraged from continuous inactivity or sitting of more than 60 minutes during wake hours. Subjects were encouraged to use trackers so that they take at least 10,000 steps each day.

Subjects were encouraged to self-monitor the food intake and physical activity and this constituted the most important behavioural therapy. Self-monitored logs were reviewed during the scheduled contact sessions. In each session weight was recorded and endorsed in the log book. Lectures were organised which emphasised on limiting times and places of eating, coping with negative thoughts, and relapse prevention.

Subjects on conventional therapy attended three group educational / social support sessions during the study period after the initial interaction. Content of the education and training was same as intervention arm.

Management of all comorbid conditions was as per existing guidelines in both the groups.

Study assessments

At 3 monthly visits, medical attendants who were unaware of study-group assignments measured weight, waist circumference, and blood pressure. Blood samples for HbA1c and lipid profile was collected in laboratory by the laboratory assistants who were unaware of study group assignments. Maximal-exercise tests at the start of study and submaximal-exercise tests at 3 months interval were performed in medical department by trained medical attendants who were unaware of study group assignments.

Study End Points

The primary end point was difference in weight loss in the two groups. The secondary end point was difference in change in waist circumference, lipid profile, HbA1c and physical activity in the two groups.

Statistical analysis

We determined that if the targeted intervention would lead to 10% more weight loss than conventional approach, with equal sample size in two groups and 80% chance of achieving statistical significance, 392 subjects would be required in each arm. We recruited 400 patients in each arm expecting some loss in follow up though there was no such loss.

We used the chi-square test and two-sample t-tests to compare the baseline characteristics in the two study groups. Change in weight, waist circumference, blood pressure, HbA1c, lipid profile and physical activity in the two groups was analysed using repeated measures in general linear model. Further Bonferroni post hoc test was done to compare the change in all quarters. All the statistical analysis was carried out using SPSS ver 28 for Mac and GraphPad Version 10.2.2 (341) Prism version for MacOS, GraphPad Software, Boston, Massachusetts USA, www.graphpad.com. Bray GA. The Battle of the Bulge: A History of Obesity Research, Dorrance, 2007.

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RESULTS

Study Patients

A total of 1081 subjects were interviewed till 800 patients were recruited. They were randomly assigned to targeted intervention group or conventional treatment group. The baseline characteristics of the subjects in the two groups were similar (Table 1).

The average age of our subjects was 37.6 years, mean BMI was 27.8 kg/m^2, mean waist circumference was 96.3 cm, mean systolic blood pressure was 129.7 mm of Hg, mean diastolic BP was 85 mm of Hg, mean total cholesterol was 210.3 mg/dl, mean LDL cholesterol 130.2 mg/dl, mean triglyceride 200.6 mg/dl, mean HDL cholesterol 49.8 mg/dl and mean activity level was 9.1 METS. Subjects included 30.3% females, 14.1% were smokers, 10.3% had history of CAD, 20.4% had diabetes and 20.1% had hypertension. One year follow up was completed and there was no loss to follow up due to careful selection of subjects.

Table 1: Clinical parameters

Variable	Control group (n=400)	Intervention group (n=400)	P value
Sex (Female)	114(28.5%)	129 (32.3%)	0.28*
Age (years)	37.3(±7.4)	37.5(±7.5)	0.71#
Smoker	56 (14%)	57(14.2%)	1*
History of CAD	40(10%)	42(10.5%)	0.82*
Subjects with Diabetes	81(20.3%)	82(20.5%)	0.93*
Subjects with Hypertension	79(19.8%)	82(20.5%)	0.79*
Weight(kg)	85.5(±14.3)	85(±14.2)	0.80#
BMI(kg/m^2)	27.8(±0.6)	27.8(±1)	0.88#
Waist circumference (cms)	96.4(±4.8)	96.2(±4.8)	0.49#
HbA1c(%)	6.94(±0.43)	6.97(±0.46)	0.27#
Systolic BP (mm of Hg)	129.8(±5.8)	129.6(±5.6)	0.71#
Diastolic BP (mm of Hg)	85.0(±2.9)	85(±3)	0.78#
Total Cholesterol (mg/dl)	209.6(±17.3)	211(±17.1)	0.25#
LDL cholesterol (mg/dl)	130.3(±18.1)	130.1(±16.9)	0.87#
Triglyceride (mg/dl)	200 (±28)	201.3(±28.2)	0.51#
HDL (mg/dl)	50.1 (±6.0)	49.5(±6.2)	0.18#
SGOT	24.9 (±5.9)	24.6 (±5.6)	0.39#
SGPT	30.4(±9)	30.5(±8.8)	0.79#
Exercise capability (MET)	9 (±1)	9 (±1.3)	0.59#

Weight loss was significantly more in the intervention arm [15.1 (19.8 vs 4.7) kg, p < .000] as compared to control arm. Post hoc analysis revealed that this difference in weight loss was maximum between 9 to 12 months (4.4 kg) though this was significant throughout the duration of study [Fig 1].

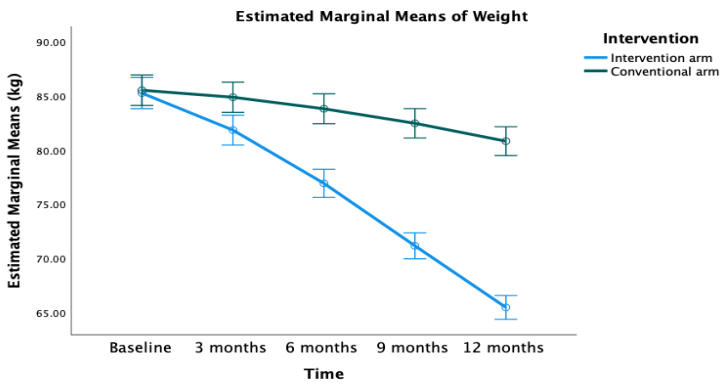

Figure 1

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Similarly, waist circumference decreased significantly more in the intervention group [1.2(1.8 vs 0.6 cm), p < .000)}]. The difference was most pronounced in the last quarter of the period of observation 0.5 cm, though it was significantly more in all quarters barring first quarter [Fig 2].

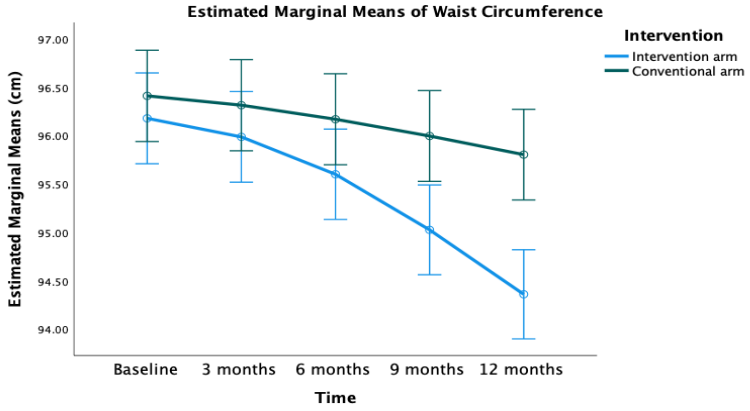

Figure 2

Even systolic BP decreased more significantly in the intervention group [6.4 (14.9 vs 8.5) mm of Hg, p < .000] than the conventional therapy group. The difference in decrease in SBP was most significant in the last quarter 2.1 mm of Hg, though it was significant in all quarters [Fig 3].

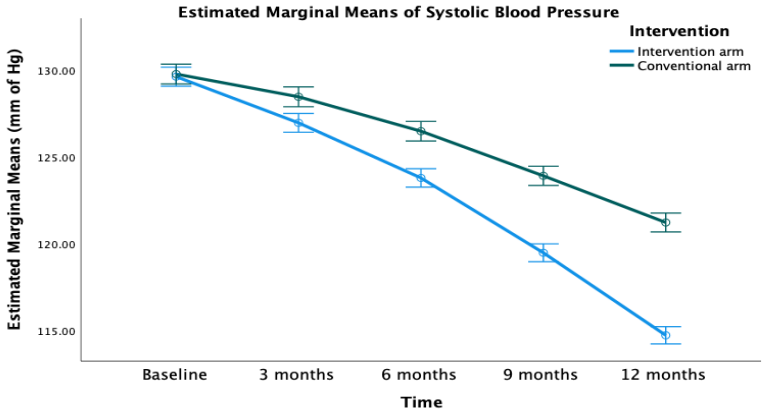

Figure 3

Decrease in diastolic blood pressure was significantly more [4.2 (9.7 vs 5.5) mm of Hg, p < .000] in the intervention arm. This difference between the two groups was most pronounced between 9 months and 12 months 1.4 mm of Hg, though it was significant at all time intervals [Fig 4].

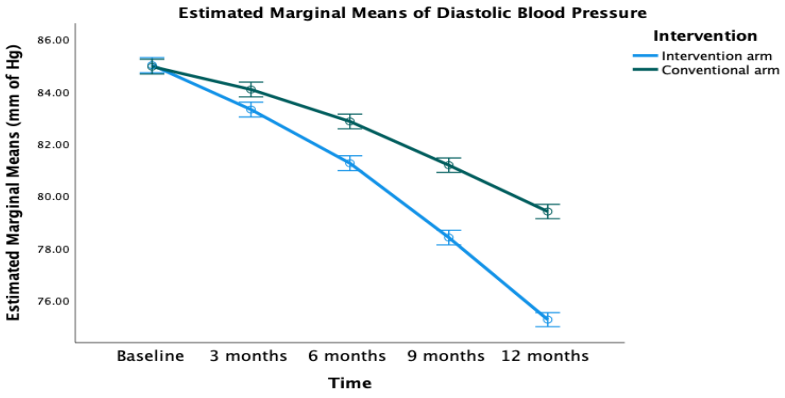

Figure 4

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Targeted intervention led to greater increase in physical activity [0.8 (1.4 vs 0.6) METS, p < .000] than conventional intervention. Difference in increase in physical activity between the two groups was maximum between 9 months and 12 months (0.36 METS), though it was significant at all time intervals [Fig 5].

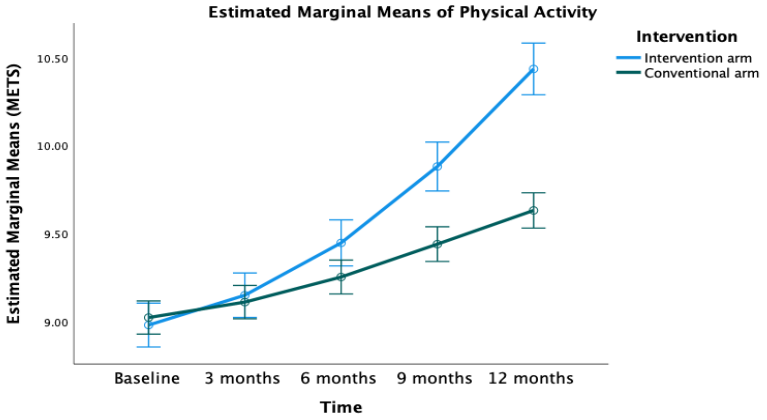

Figure 5

Total cholesterol decreased significantly more [6.9 (23.3 vs 16.4) mg/dl, p < .000] in the intervention arm as compared to control arm. Further this difference in decrease in total cholesterol between the two groups was maximum in first 3 months (2.14 mg/dl), though it was significant at all time intervals [Fig 6].

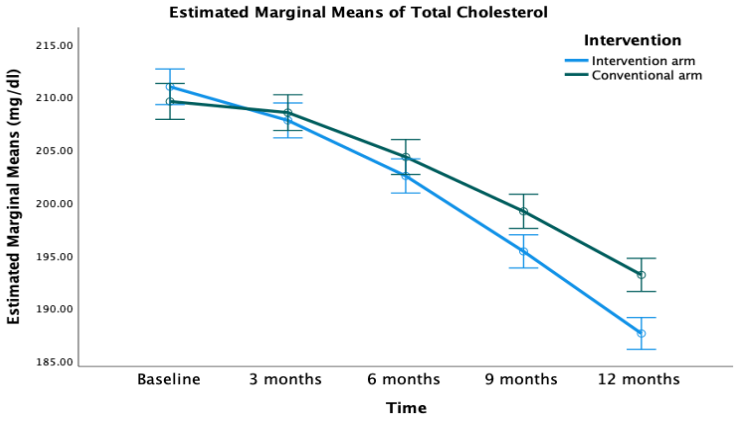

Figure 6

LDL cholesterol decreased significantly more in the intervention arm [1.8 (8.3 vs 6.5) mg/dl, p < .001] as compared to control arm. Post hoc analysis revealed that this difference in fall was maximum in last 3 months (0.60 mg/dl) though this was significant throughout the duration of study [Fig 7].

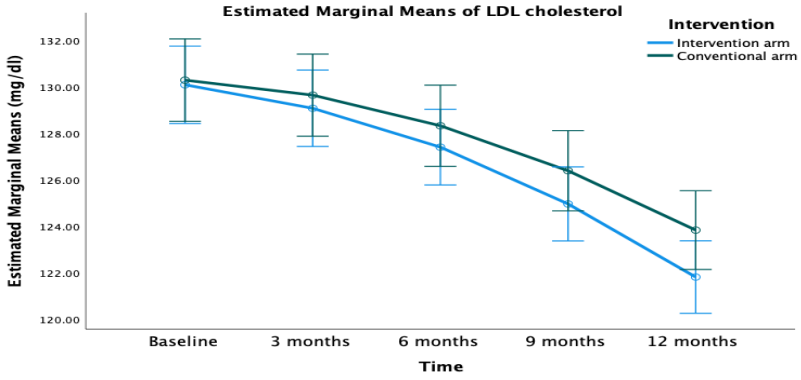

Figure 7

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Triglyceride decreased significantly more in the intervention arm [16.9 (43.5 vs 26.6) mg/dl, p < .000] as compared to control arm. Post hoc analysis revealed that this difference in fall was maximum in the last 3 months (6.4 mg/dl) though this was significant throughout the duration of study [Fig 8].

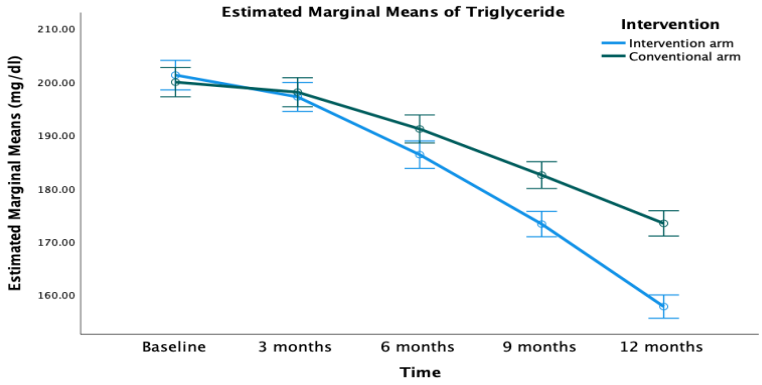

Figure 8

HDL cholesterol increased significantly more in the intervention arm [4.2 (7.4 vs 3.2) mg/dl, p < .000] as compared to control arm. Post hoc analysis revealed that this difference in increase was maximum in the last 3 months (1.53 mg/dl) though this was significant throughout the duration of study [Fig 9].

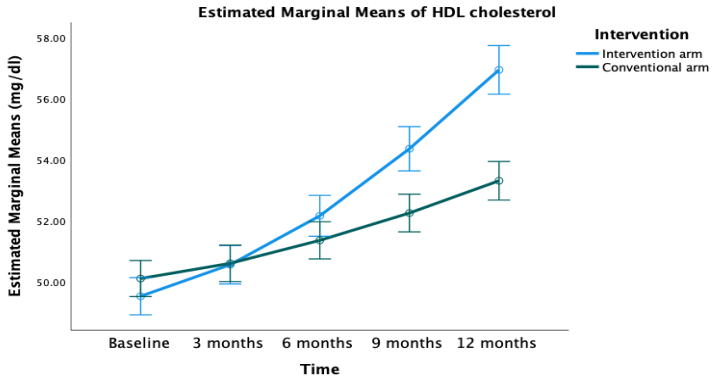

Figure 9

HBA1c decreased significantly more in the intervention arm [0.6 (0.7 vs 0.1) mg/dl, p < .000] as compared to control arm. Post hoc analysis revealed that this difference in fall was maximum in the last 3 months (0.2%) though this was significant throughout the duration of study [Fig 10].

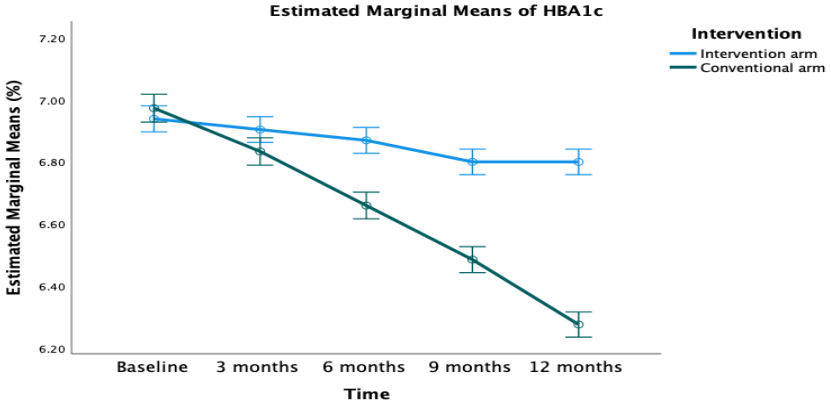

Figure 10

DISCUSSION

The study conducted by the centre for lifestyle diseases in a medical examination and boarding centre located at North India presents an intensive targeted lifestyle intervention aimed at achieving significant weight loss among military personnel, compared to a conventional care approach. This research is particularly relevant in the context of increasing obesity rates globally and the unique challenges posed by lifestyle diseases in military populations.

The methodology of our study is closely aligned with that of landmark studies such as the Diabetes Prevention Program (DPP) [10] and the Look AHEAD trial [6], which both employed lifestyle interventions to achieve weight loss and manage comorbid conditions in civilian populations. However, unlike these studies, which primarily focused on broad civilian populations, the current study targeted a specific, relatively homogeneous personnel group who are employed or relatives of the individual employed in a particular organisation, facilitating highly controlled interventions and potentially enhancing compliance due to the structured regulated environment.

The use of a non-blinded design with the dietician and physical trainer unaware of group assignments mirrors elements of the Look AHEAD trial, which utilized a similar strategy to prevent bias in lifestyle advice. However, this study uniquely incorporates the Healthplix EMR for monitoring, which represents an innovative approach to leveraging technology for enhanced follow-up and data accuracy in a research setting.

The reported weight loss (15.1 kg on average in the intervention group) significantly exceeds that observed in the DPP and Look AHEAD trials, where average reductions were generally less than 10 kg. This substantial difference may be attributed to the targeted intervention's design, which possibly included more rigorous physical training components and dietary monitoring, reflective of military discipline and regularity.

Conducting this study in an Indian military context adds novel insights into the applicability of intensive lifestyle interventions in different cultural and operational settings. India faces unique public health challenges with rising obesity and diabetes rates amidst a backdrop of diverse dietary habits and varying access to healthcare facilities [11]. The adaptation of intervention strategies to fit the Indian dietary preferences and lifestyle, coupled with implementation within the disciplined framework of the military, likely contributed to the high adherence and effectiveness observed.

The improvements in metabolic parameters such as lipid profiles, blood pressure, and HbA1c in the intervention group were profound and align with outcomes from other intensive intervention studies like those in the STENO-2 Study [12], where multifactorial intervention significantly reduced the risk of cardiovascular and microvascular events by improving similar metabolic parameters. Our study's findings on HDL cholesterol and triglyceride improvements are particularly notable, exceeding typical results seen in civilian studies, potentially reflecting the added benefit of a structured physical regimen and follow up that is more feasible in a military setting.

While the study's results are promising, several limitations must be acknowledged. The non-blinded design, although partially mitigated by the unawareness of the intervention group among key personnel, could still introduce biases in reporting and adherence encouragement. The exclusion criteria, particularly the omission of insulin-using diabetic patients, limit the generalizability of the findings to all diabetic populations, a significant concern given the high prevalence of diabetes in India.

Furthermore, the study's intensive nature, requiring frequent monitoring and hands-on intervention, may not be practical or cost-effective on a larger scale or in less controlled environments. This raises questions about the feasibility of replicating such a program across the broader organisation or civilian sectors without significant resource allocation and structural adjustments.

CONCLUSION

In summary, the study conducted by the centre for lifestyle diseases in a medical examination and boarding centre located at North India represents a significant contribution to the literature on targeted weight loss interventions. Its success in achieving substantial weight loss and improvements in comorbid

conditions offers a compelling case for the adoption of similar strategies in other military and potentially civilian populations. However, future research should aim to address the scalability of such interventions, explore broader applicability, including more diverse patient populations, and consider the long-term sustainability of the health benefits observed.

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