Iran J Public Health, Vol. 54, No.9, Sep 2025, pp.1926-1937

Original Article

The Effects of Different Intervention Protocols on Anthropometric Measures, Lipid Profile, and Quality of Life: Insights from a Pandemic-Era Randomized Controlled Trial

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(Received 11 Apr 2025; accepted 16 Jul 2025)

Abstract

Background: To assess the effect of different treatment protocols on anthropometric measures, lipid profile, and weight-related quality of life amid the pandemic.

Methods: A single-blind randomized controlled trial was conducted at Hacettepe University's Family Medicine outpatient clinics in Ankara, Turkey, in 2022. Participants were stratified into three groups: intervention, control-1, and control-2. The intervention group received a calorie-restricted diet, exercise program, and follow-up calls every 15 days. Control-1 received the same plan with a single follow-up at week 4. Control-2 received general dietary and exercise advice and regular follow-up calls every 15 days. Outcomes were measured at baseline and 12 weeks, including quality of life assessed with the Turkish IWQOL-Lite scale.

Results: We 153 participants, with 51 individuals per group. At the 12th week, all groups exhibited significant improvements in weight, BMI, waist circumference, fat mass, and quality of life scores. The intervention group demonstrated improvements in physical function, self-esteem, work, and total quality of life score compared to baseline (P<0.001).

Conclusion: Developing and adhering to a personalized exercise and diet plan is crucial for maintaining a healthy lifestyle, even during a pandemic.

Keywords: Primary care; Lifestyle modification; Quality of life; Overweight; Obesity

Introduction

Preventing and managing obesity, a major health concern worldwide, has become increasingly crucial and challenging in primary healthcare settings during the Covid-19 pandemic (1,2). Quarantine and restrictions resulting from the Covid-19 pandemic may lead to irregular eating and decreased physical activity, and can also cause psychological issues such as depression, anxiety, and stress (3). In managing overweight and obesity, interventions such as dietary modification, increased

physical activity, behavioral therapy, medication, and surgery are recommended, requiring a multidisciplinary team (4-6). During the Covid-19 pandemic, these same strategies continued to be applied by multidisciplinary teams (4-6). Obesity has been linked to worse Covid-19 outcomes (1). Many studies recommend maintaining physical activity and a balanced diet during quarantine (7,8). Lifestyle changes focusing on calorie reduction and increased activity are essential for prevention and management of obesity (5-8).

Home-based activities like aerobic, strength, balance, flexibility exercises, as well as yoga, dance, and exergames, help reduce stress and anxiety during isolation (8,9). Adults are advised to do strength training twice weekly and aim for at least 150 minutes of moderate or 75 minutes of vigorous activity per week, tailored to individual fitness levels (8,9). These routines can be effectively tracked using sensors or mobile apps (8).

Elevated BMI (Body mass index) correlates with diminished quality of life, emphasizing the need for holistic well-being in the management plan (10).

Assessing the effects of customized treatment regimens, such as rigorous lifestyle adjustment and regular follow-up, on anthropometric measurements, lipid profiles, and weight-related quality of life during the Covid-19 epidemic was the aim of this study. The significance of multidisciplinary care, the function of family doctors as first-contact providers, and the utilization of telemedicine under pandemic-related restrictions were also highlighted in the study.

Methods

Study area, design, and sample size

The study was a single-blind randomized controlled trial. Participants were adults with overweight or obesity who applied to the Department of Family Medicine at Hacettepe University Faculty of Medicine between January 25 and October 31, 2022. Following informed consent, eligibility was assessed according to the criteria detailed in Supplementary Table 1 (Not published).

It is known that the three-months target weight loss rate of individuals with overweight and obese is 5% in guidelines (4,11). Based on this benchmark, the sample size calculation was performed using G*Power version 3.1. An a priori power analysis was conducted with a test family of t-tests, using the statistical test Means: Difference between two independent means (two groups). The analysis assumed a medium effect size of 0.57, a significance level (α) of 0.05, and a power (1–β) of 0.80. As a result, it was estimated that at least 49 participants would be required in each group.

The study participants were stratified into three groups: intervention, control-1, and control-2. The study investigated the effect of the intervention and quality of life on the three groups in question.

The enrollment, exclusion, allocation, follow-up, and analysis of study participants across the three arms (intervention, control-1, and control-2) are outlined in the participant flowchart (Fig. 1).

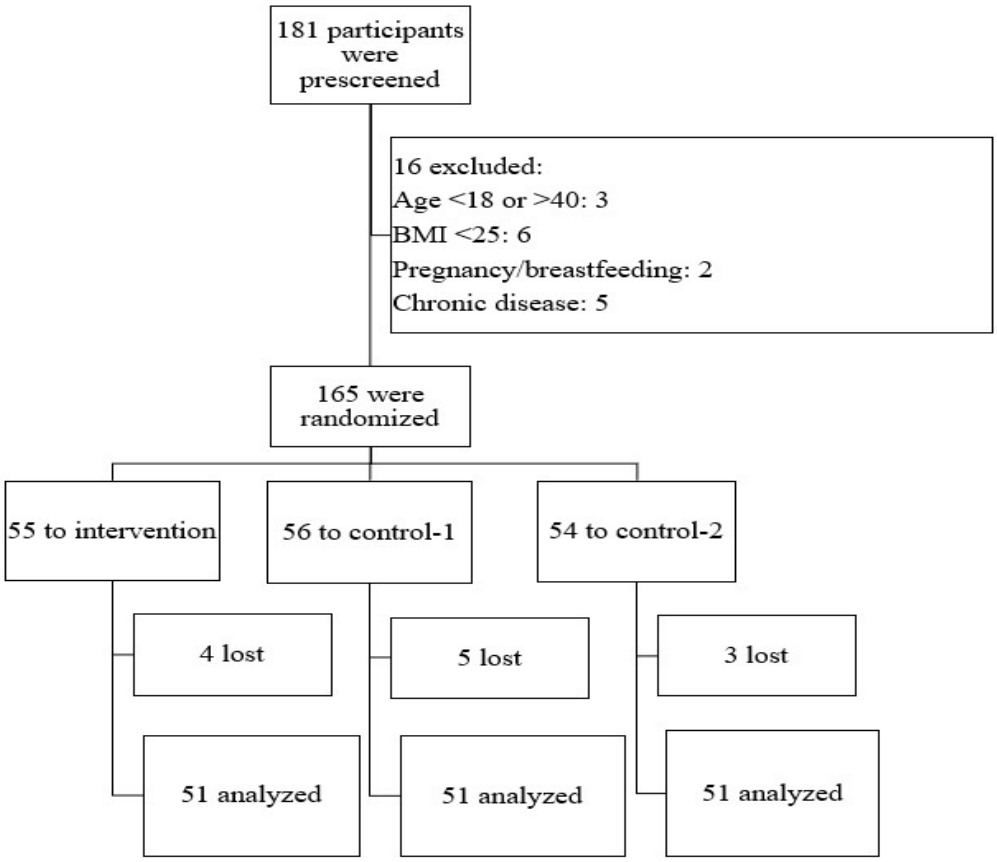

Fig. 1: Participant flowchart (This flowchart shows enrollment, exclusion, allocation, follow-up, and analysis for the intervention, control-1, and control-2 groups.)

Recruitment, intervention, and follow-up

The study was conducted over a total period of nine months, which encompassed participant recruitment, rolling enrollment, and data collection. Each participant was individually followed for a period of 12 weeks from the date of enrollment.
The frequency of follow-up was planned based on the literature, which states that behavioral interventions should be conducted on a monthly or weekly basis (4-6).

Intervention group

They were provided with a calorie-restricted meal plan and exercise program by a dietician or physiotherapist at their initial visit, and were then followed up by phone calls at weeks 2, 4, 6, 8 and 10 for 12 weeks.

Control-1 group

The participants received a calorie-restricted diet plan from a nutritionist and an exercise program from a physiotherapist during the initial medical interview; they were contacted at week four of a 12-week follow-up.

Control-2 group

The family doctors emphasized the significance of weight loss while the participants received no program. In accordance with "The 2019 Obesity Diagnosis and Treatment Guide by the Turkish Endocrine and Metabolism Association", dietary and physical activity recommendations were provided (4). Over the course of 12 weeks, phone calls were made at weeks 2, 4, 6, 8, and 10.
In the single-blind trial, patients were assigned to groups based on the order of admission. Partici-

pants were randomly assigned to one of three groups (intervention, control-1, control-2) using block randomization with fixed blocks of six to ensure equal group distribution. A total of 25 blocks were used, with two participants per group in each block. Allocation sequences were pre-generated and applied consecutively as participants were enrolled (see Supplementary Materials for details).

Data collection and outcome measurement

While researchers were aware of the intervention methods, participants were blinded to their group assignments and the specific methods they would receive. Participants were randomly selected from Family Medicine Clinic patients, were independent and diverse, and were interviewed individually. There were no personal relationships among participants.

Assessment of Individual Factors: A 24-item structured questionnaire was developed based on a literature review and expert input from family medicine, nutrition, and physiotherapy. Turkish version of "The Impact of Weight on Quality of Life-Lite Version (IWQOL-Lite)" scale was used in the design of the questionnaire that was specifically designed for this study (14,15). For more information on the questionnaire and scale, see the supplementary data.

Anthropometric Measures: Height and waist circumference were measured using a standard tape, while body weight, BMI, fat mass, and lean mass were assessed with a body composition analyzer, which also calculated BMI. "Anthropometric measurements" refers to both tape and analyzer-based parameters. Overweight and obesity were classified according to WHO criteria (12,13).

Lipid profile: Triglyceride, Total Cholesterol, LDL-Cholesterol and HDL-Cholesterol levels were measured.

Telemedicine applications: During non-video telephone interviews, participants' adherence to diet and exercise programs was assessed and motivational support was provided by the family physician. Barriers to adherence were discussed, and solutions were suggested. Adherence was self-rated on a 10-point Likert scale at each call with 1 indicating very poor adherence and 10 indicating very good adherence. All interviews were conducted via telemedicine to minimize the risk of transmission.

Intervention methods are mentioned in details at Supplementary Fig. 1. The intervention protocol for exercise and diet programs is available in the Supplementary Table 2 (Not published).

Data management and analysis

Descriptive statistics were presented as mean ± standard deviation, median (IQR) for continuous variables, and frequency (%) for categorical variables. Normality was assessed using the Shapiro-Wilk test, and variance homogeneity with Levene's test. Chi-square test was used to examine the associations between categorical variables; however, for variables with small expected cell counts (e.g., "Profession" and "Alcohol use"), Fisher's exact test was applied instead. Non-normally distributed two-group comparisons were analyzed with the Mann-Whitney U test, and three-group comparisons with the Kruskal-Wallis H test. Wilcoxon signed-rank test was used for repeated binary measures in dependent groups. To evaluate the independent effects of demographic and socioeconomic variables on body mass index (BMI), a multiple linear regression analysis was conducted. The model included age, gender, group assignment, and monthly income as predictors, with BMI (BMI_control) as the dependent variable. A P-value <0.05 was considered statistically significant. Analyses were performed using IBM SPSS Statistics for Windows, Version 23.0 (IBM Corp., Armonk, NY).

Ethical Considerations

Ethical approval was obtained from the Hacettepe University Clinical Research Ethics Committee (Ref: 2021/30-06; KA-21069), the Turkish Medicines and Medical Devices Agency (No: E-66175679-514.11.01-657910), and the Turkish Ministry of Health COVID-19 Scientific Research Evaluation Commission.

Results

The study comprised 51 participants from each group. The study population consisted of 69.9% female participants with a mean age of 28.45 (SD ± 7.48) years. Detailed comparison of participants' characteristics was at Table 1.

Table 1: Comparison of participant characteristics

Variables	Intervention		Control-1		Control-2		
	n	%	n	%	n	%	*P*
Gender*							0.69
Male	13	25.5	17	33.3	16	31.4	
Female	38	74.5	34	66.7	35	68.6	
Profession*							0.27
Housewife	15	29.4	4	7.8	8	29.6	
Worker	4	7.8	6	11.8	7	41.2	
Civil servant	6	11.8	12	23.5	7	28	
Student	19	37.3	21	41.2	22	35.5	
Health employee	5	9.8	7	13.7	4	25	
Other	2	33.3	1	2	3	50	
Education*							0.63
Primary	3	5.9	2	3.9	1	2	
Middle	6	11.8	2	3.9	2	3.9	
High	26	51	28	54.9	27	52.9	
University	13	25.5	15	29.4	19	37.3	
Master/PhD	3	5.9	4	7.8	2	3.9	
Marital status*							0.27
Married	24	47.1	24	47.1	17	33.3	
Single	27	52.9	27	52.9	34	66.7	
Employment*							0.07
Employed	14	27.5	25	49	18	35.3	
Unemployed	37	72.5	26	51	33	64.7	
Smoking*							0.82
Current	11	21.6	16	31.4	12	23.5	
Never	33	64.7	29	56.9	33	64.7	
Ex-smoker	7	13.7	6	11.8	6	11.8	
Alcohol*							0.52
No	38	74.5	32	62.7	34	66.7	
Special occasions	11	21.6	15	29.4	13	25.5	
Daily	1	2	0	0	0	0	
Only with meals out	1	2	4	7.8	4	7.8	
BMI*							0.01
Overweight	13	25.5	23	45.1	27	52.9	
Obese	38	74.5	28	54.9	24	47.1	
Physical activity before Covid-19 *							0.79
Yes							
No	12	23.5	13	25.5	15	29.4	
	39	76.5	38	74.5	36	70.6	
	Mean	SD	Mean	SD	Mean	SD	*P*
Age **	28.98	7.24	29	8	27.37	7.20	0.42
Amount of cigarettes **	9.09	6.36	13	7.52	10.50	10.88	0.28

n: Number; %: Percent; SD: Standard Deviation
*Chi-Square Test, **Kruskal Wallis Test

Of the participants, 58.8% were deemed obese with statistically significant variances found amongst the groups concerning BMI ($P = 0.01$). The total raw scores of all groups in the 12th week surpassed the baseline score (intervention ($P<0.001$), control-1 ($P<0.001$), and control-2 ($P=0.002$)). The raw scores of the groups in IWQOL-Lite at baseline and 12th week are compared in Table 2.

At the 12th week, respectively the intervention, control-1 and control-2 groups exhibited lower weight ($P<0.001$; $P<0.001$; $P=0.002$), waist circumference ($P=0.001$; $P=0.003$; $P=0.004$), BMI ($P<0.001$; $P<0.001$; $P=0.003$) values than the baseline (Table 2). Compared to 19.6% of the control groups, 33.3% of the intervention group lost at least 5% of their body weight by week 12. In all, 24.2% lost the desired amount of weight.

Table 2: Comparison of Baseline and 12th Week IWQOL-Lite and Anthropometrics

Variable		Baseline		12th week		
IWQOL-Lite	Groups	Median	IQR	Median	IQR	*P*
Physical function	Intervention	68.18	43.18	79.54	27.27	<0.001
	Control-1	68.18	43.18	77.27	27.27	<0.001
	Control-2	70.45	38.64	84.09	36.36	0.05
Self-esteem	Intervention	50	57.14	75	42.86	<0.001
	Control-1	57.14	39.29	82.14	39.29	<0.001
	Control-2	50	64.29	60.71	60.71	0.001
Sexual life	Intervention	75	62.50	87.50	37.50	0.001
	Control-1	87.50	43.75	93.75	25	0.02
	Control-2	81.25	37.50	93.75	43.75	0.08
Public distress	Intervention	90	25	90	20	0.20
	Control-1	85	40	95	20	0.005
	Control-2	85	25	90	25	0.24
Work	Intervention	75	50	87.50	25	<0.001
	Control-1	87.50	25	87.50	25	0.64
	Control-2	87.50	50	87.50	37.50	0.09
Total	Intervention	63.79	26.72	81.90	26.72	<0.001
	Control-1	73.28	26.72	82.76	25.86	<0.001
	Control-2	69.83	31.03	81.03	40.52	0.002
Anthropometric measurements	Groups	Median	IQR	Median	IQR	*P*
Weight (kg)	Intervention	89.50	27.90	88	23.40	<0.001
	Control-1	84.50	24.10	79.90	21.30	<0.001
	Control-2	85.10	18.20	84	21.90	0.002
Waist circumference (cm)	Intervention	106	15	102	14	0.001
	Control-1	101.50	17	100	17	0.003
	Control-2	101	12	100	16	0.004
BMI (kg/m^2)	Intervention	31.50	5.20	30.60	5.80	<0.001
	Control-1	30.50	5.20	29.50	5.50	<0.001
	Control-2	29.70	4.40	29.20	5.20	0.003
Fat (%)	Intervention	38.50	12.10	35.70	11.70	<0.001
	Control-1	35	9.30	35.40	11	0.09
	Control-2	34.40	12.30	33.20	12.60	<0.001
Fat mass (kg)	Intervention	33.50	16.50	31.10	14.60	<0.001
	Control-1	28.70	13.50	28.80	10.90	0.02
	Control-2	26.80	12.20	25.20	10.20	<0.001

IQR: Interquartile Range
Wilcoxon Signed Rank Test

Comparing baseline and 12th week IWQOL-Lite scale scores, the intervention group displayed the most significant differences in physical functions (P<0.001), self-esteem (P=0.02), work (P=0.01), and total score (P=0.003). Control 2 exhibited the smallest differences in all aspects, with statistical significance.

Statistically significant differences were noted in the work subgroup for intervention and control-1 groups (P=0.004). For intervention and control-2 groups, significant differences were observed in physical functions (P<0.001), self-esteem (P=0.003), work (P=0.05), and total score (P=0.001). In control-1 and control-2 groups, physical functions (P=0.02) and total score (P=0.03) showed significant differences (Table 3).

Table 3: Intergroup Comparison of IWQOL-Lite Score Changes

Variable	Groups	Median	IQR	*P*
Physical function	Intervention Control-1	13.63 9.09	20.45 18.18	0.13*
	Intervention Control-2	13.63 2.27	20.45 15.91	<0.001*
	Control-1 Control-2	9.09 2.27	18.18 15.91	0.02*
	Intervention Control-1 Control-2	13.63 9.09 2.27	20.45 18.18 15.91	<0.001**
Self-esteem	Intervention Control-1	17.86 10.71	28.57 32.14	0.21*
	Intervention Control-2	17.86 3.57	28.57 17.86	0.003*
	Control-1 Control-2	10.71 3.57	32.14 17.86	0.19*
	Intervention Control-1 Control-2	17.86 10.71 3.57	28.57 32.14 17.86	0.02**
Sexual life	Intervention Control-1	12.50 0	25 12.50	0.14*
	Intervention Control-2	12.50 0	25 12.50	0.05*
	Control-1 Control-2	0 0	12.50 12.50	0.73*
	Intervention Control-1 Control-2	12.50 0 0	25 12.50 12.50	0.13**
Public distress	Intervention Control-1	0 5	20 50	0.19*
	Intervention Control-2	0 5	20 30	0.87*
	Control-1 Control-2	5 5	50 30	0.31*
	Intervention Control-1	0 5	20 50	0.39**

Table 3: Continued…

	Control-2	5	30	
Work	Intervention Control-1	12.50 0	25 25	0.004*
	Intervention Control-2	12.50 0	25 12.50	0.05*+
	Control-1 Control-2	0 0	25 12.50	0.35*
	Intervention Control-1 Control-2	12.50 0 0	25 25 12.50	0.01**
Total	Intervention Control-1	14.65 11.21	22.41 16.38	0.24*
	Intervention Control-2	14.65 6.03	22.41 14.66	0.001*
	Control-1 Control-2	11.21 6.03	16.38 14.66	0.03*
	Intervention Control-1 Control-2	14.65 11.21 6.03	22.41 16.38 14.66	0.003**
IQR: Interquartile Range *Mann-Whitney U Test, **Kruskal Wallis-H Test, +Borderline Significant				

Baseline and 12th week anthropometric measurement differences revealed significant distinctions. In the intervention and control-1 groups, fat ratio (P=0.03) and fat mass (P=0.02) showed significant differences. For the intervention and control-2 groups, weight (P=0.03) and fat mass (P=0.04) differences were statistically significant. The intervention group displayed a significantly higher percentage decrease in body weight compared to control-2 (P=0.05) (Table 4).

Table 4: Intergroup Comparison of Changes in Anthropometric Measurements

Variable	Groups	Median	IQR	*P*
Weight (kg)	Intervention Control-1	3.10 1.30	6 3.20	0.109*
	Intervention Control-2	3.10 1.20	6 4	0.032*
	Control-1 Control-2	1.30 1.20	3.20 4	0.604*
	Intervention Control-1 Control-2	3.10 1.30 1.20	6 3.20 4	0.083**
Weight (%)	Intervention Control-1	3.40 1.72	6.80 3.81	0.149*
	Intervention Control-2	3.40 1.54	6.80 4.67	0.049*
	Control-1 Control-2	1.72 1.54	3.81 4.67	0.606*
	Intervention Control-1 Control-2	3.40 1.72 1.54	6.80 3.81 4.67	0.125**

Table 4: Continued…

Waist circum-ference (cm)	Intervention Control-1	1 0	4 5	0.449*
	Intervention Control-2	1 0	4 2	0.388*
	Control-1 Control-2	0 0	5 2	0.851*
	Intervention Control-1 Control-2	1 0 0	4 5 2	0.635**
BMI (kg/m²)	Intervention Control-1	1.10 0.50	2.20 1.20	0.136*
	Intervention Control-2	1.10 0.40	2.20 1.50	0.052*
	Control-1 Control-2	0.50 0.40	1.20 1.50	0.675*
	Intervention Control-1 Control-2	1.10 0.50 0.40	2.20 1.20 1.50	0.127**
Fat (%)	Intervention Control-1	1.70 0.30	3.90 3.50	0.033*
	Intervention Control-2	1.70 0.50	3.90 2.90	0.214*
	Control-1 Control-2	0.30 0.50	3.50 2.90	0.220*
	Intervention Control-1 Control-2	1.70 0.30 0.50	3.90 3.50 2.90	0.080**
Fat mass (kg)	Intervention Control-1	2.70 0.70	5.70 4.20	0.019*
	Intervention Control-2	2.70 0.90	5.70 3.10	0.044*
	Control-1 Control-2	0.70 0.90	4.20 3.10	0.395*
	Intervention Control-1 Control-2	2.70 0.70 0.90	5.70 4.20 3.10	0.033**
Fat free mass (kg)	Intervention Control-1	0.40 0.80	2.40 2.80	0.581*
	Intervention Control-2	0.40 0	2.40 2	0.252*
	Control-1 Control-2	0.80 0	2.80 2	0.125*
	Intervention Control-1 Control-2	0.40 0.80 0	2.40 2.80 2	0.056**

IQR: Interquartile Range
*Mann-Whitney U Test. **Kruskal Wallis-H Test

At week 12, triglyceride levels increased significantly in the control-2 group (P=0.01), while total cholesterol showed a borderline significant decrease (P=0.05). No significant changes were observed in LDL and HDL cholesterol levels across groups (Supplementary Table S3).
According to the multiple linear regression analysis (Supplementary Table S4), age, gender, group, and monthly income level were not statistically significant predictors of BMI ($P > 0.05$).

Discussion

This study found that intensive lifestyle intervention in primary care significantly improved quality of life among overweight and obese patients, beyond standard diet and physical activity recommendations.
The literature primarily addresses intensive lifestyle interventions for individuals with overweight and obesity, yet research in primary care settings during the pandemic remains limited (16-18). In contrast, our study uniquely assesses three groups, involving a physician, dietitian, and physiotherapist. This expands the scope of professional engagement for a comprehensive approach to managing weight issues in primary healthcare settings.
In contrast to Pearl et al.'s findings, this study revealed a notable increase in the total raw scale score in the intervention group (19). The intensive lifestyle intervention significantly enhanced physical function, self-confidence, sexual life, and work subgroups (19). Personalized guidance and frequent follow-ups contributed to a more substantial increase in the intervention group's total raw scale score compared to other groups.
In the study by Eriksson et al, the three-month data of a randomized controlled trial of a 3-year lifestyle intervention in primary care and the three-month data of this study showed that the groups with intensive lifestyle interventions had a greater reduction in waist circumference compared to the recommendation group (20). However, this study findings showed a reduction in weight and BMI measurements among all three groups.
Mistik et al. compared the frequency of follow-up interviews over 12 weeks (18). While there was no significant statistical variation in BMI reduction, the greatest reduction was observed in the weekly group (18). The exercise and diet regimen, arranged by professionals, is believed to have contributed to the decrease in BMI observed in both the intervention and control-1 groups. Similarly, the frequent follow-up is likely responsible for the significant decrease observed in the control-2 group.
Anderson et al.'s study found decreases in body weight, waist circumference, and BMI, like this study's intervention group (21). The current study's weight loss met the goal, but the ≥5% target within 12 weeks wasn't reached. Anderson et al.'s intervention group had a higher proportion of participants who achieved ≥5% weight loss, possibly due to differences in follow-up personnel; this study used a family physician.
Kempf et al.'s 12-week trial incorporating telemedical coaching demonstrated greater body weight and BMI reduction in the intervention group, like our findings (22). While the impact of regular telephone follow-up was not statistically significant in our study, overall changes were notable after three months.
A 12-month randomized controlled trial of a 3-year lifestyle intervention by Eriksson et al. showed no significant lipid profile differences between groups (20,21). A retrospective analysis revealed that ≥5% weight loss led to significant changes in HDL and triglyceride levels but not in total and LDL cholesterol levels (23).
A 12-week randomized controlled trial found that weekly telemedical coaching reduced the lipid profile of the intervention group (22). The coaches' weekly monitoring of body weight and average number of steps may have contributed to the success of this study in changing lipid profiles.
Multivariate models are essential for controlling potential confounding factors that may distort the true relationships between variables. In the

present study, the examined predictors were not significantly associated with BMI, indicating that the unadjusted effects may have been misleading. The model's limited explanatory power suggests that BMI is influenced by factors not included in the analysis. Incorporating variables like physical activity, diet, and metabolism could enhance the accuracy and clinical relevance of future models. This approach could provide a more comprehensive understanding of BMI dynamics within the studied population.

A major strength of this study is its inclusion of both overweight and obese individuals during the Covid-19 pandemic—a context rarely addressed in previous trials. The use of two control groups allowed for a more comprehensive intervention comparison. Standardization was ensured by having all assessments performed by a single researcher, and the predetermined sample size was achieved through power analysis. Ethical standards were maintained by providing interventions to all groups, minimizing bias and preserving study integrity. Conducting future studies with multidisciplinary teams in primary healthcare services could offer valuable insights into treating patients with overweight and obese collaboratively.

The three-month follow-up period may be inadequate for a comprehensive evaluation of the long-term effects of lifestyle interventions. However, this duration is clinically significant, as achieving a weight loss of more than 5% within a three-month period is considered a successful outcome in the management of obesity (4,11). Challenges in reaching participants during telephone follow-ups led to exclusions, potentially influencing the study's completeness.

Conclusion

Quality of life and anthropometric measures exhibited significant alterations three months following randomization across all groups. The findings suggest that frequent follow-up with an individualized diet and exercise programmed is a more efficacious approach in enhancing quality of life.

In the management of obese and overweight patients, the family physicians have a key role to plays part of the multidisciplinary team. Family physicians can improve the quality of life and anthropometric measurements by following these patients frequently in daily practice.

Journalism Ethics considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

Acknowledgements

The research is funded by the Scientific Research Projects Coordination Unit under project number 19916.

Clinical Trials Registration Number

NCT06321809, Date: 2024-03-04, retrospectively registered

Conflict of Interest

The authors declare that they have no competing interests.

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