

A nutritional web-based approach in obesity and diabetes before and during the COVID-19 lockdown

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Federica Fraticelli¹ , Marta Di Nicola² and Ester Vitacolonna¹ 

Abstract

Introduction: Obesity and type 2 diabetes (T2D) are two closely related pandemic conditions. Novel technologies represent promising tools for their management, the use of which has been greatly encouraged during the COVID-19 pandemic. The aim of the present study is to compare a web-based nutritional intervention versus a traditional one, before and during the Italian ‘lockdown’ period due to the COVID-19 outbreak, in overweight and obese subjects affected by T2D or impaired glucose regulation (IGR).

Methods: For the study, 36 subjects were randomly allocated into two arms: a *traditional* arm, providing face-to-face individual and group-based intervention; and a *web* arm, deploying the in-presence traditional approach with intervention provided through web technologies. The outcomes were the data resulting from the comparison between the subjects’ anthropometric and clinical parameters as well as PREDIMED scores at baseline with those at 3 months (T3), 6 months (T6) and at lockdown.

Results: In the *web* arm we detected a progressive reduction in weight and body mass index (BMI) from baseline to T6 and a minimal increase of both parameters during the lockdown. Improvement of these parameters compared with baseline was observed in controls during the lockdown. The PREDIMED score improved at T6 compared with baseline in both arms. Significant variations were observed considering weight ($p < 0.001$), BMI ($p = 0.001$) and PREDIMED scores ($p = 0.023$) over time.

Discussion: The study showed the effectiveness and feasibility of a short-term nutritional web-based intervention in patients affected by T2D or IGR before and during the COVID 19 pandemic.

Clinical Trial registration number: NCT04386200, ClinicalTrials.gov.

Keywords

Web-based intervention, nutrition, type 2 diabetes, obesity, COVID-19, pandemic, telehealth

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Introduction

Obesity and type 2 diabetes (T2D) are two closely related pandemic conditions: most people with T2D are overweight or obese.¹ Evidence shows that obesity management, through strategies including lifestyle intervention, can slow the progression of impaired glucose regulation (IGR) to T2D and may enhance T2D treatment.² As is well known, a small weight loss in overweight or obese T2D subjects allows for glycaemic control improvement and a reduced need for glucose-lowering medications.²

Telemedicine is a tool that can support traditional clinical practice, and promote involvement and

¹Department of Medicine and Aging, School of Medicine and Health Sciences, “G. d’Annunzio” University of Chieti-Pescara, Italy

²Laboratory of Biostatistics, Department of Medical, Oral and Biotechnological Sciences, “G. d’Annunzio” University of Chieti-Pescara, Italy

Corresponding author:

Ester Vitacolonna, MD, Department of Medicine and Aging, School of Medicine and Health Sciences, “G. d’Annunzio” University, Via dei Vestini 66100 Chieti, Chieti-Pescara, Chieti, Italy.
Email: e.vitacolonna@unich.it

decision making and new methodologies to support educational interventions.^{3,4} Telehealth uses telecommunications and virtual technology to support and favour healthcare access (particularly for chronic diseases), as well as to reduce the crowding of facilities, thus resulting in cost-effectiveness.⁵ Mobile Health (mHealth), through mobile wireless technologies, is a resource that can improve access to health information and promote changes in health-related behaviours.⁶ The use of information technologies requires that both patients and healthcare providers are capable of accessing and utilizing the technology.

In recent years, there has been an increase in the number of technologies which can facilitate long-distance clinical care, education, and health administration, including live video teleconferencing, remote patient monitoring, the use of mobile health applications, texting and emailing.⁷ Although there is no doubt regarding the potential of these tools, especially in reducing physical co-presence, it must be emphasized that achieving behavioural changes is a very complex process.⁸ In this regard, a key challenge is to make essential information available to users, to help and involve the subjects in the decision-making process, and to develop and implement services that can be agreed and appreciated by the user.⁹ Information and communication technologies (ICT) can be a promising resource to promote and support an individual's active and meaningful participation in health management.⁹ Moreover, ICT could be used to foster healthy lifestyles and achieve well-being through an individual's empowerment, engagement and self-management.⁹

Patients' empowerment could be favoured by health education through a patient-centred approach or by promoting an active role for the patient; for example, by encouraging patients to look for online information or join group sessions with other patients.^{8,10} It has been observed that group-based lifestyle intervention versus standard care fostered modest weight loss at 6 and 12 months of treatment in adults with T2D.¹¹ Group dynamics and peer identification are likely to promote greater self-esteem, self-perception and well-being while reducing anxiety related to diabetes.¹²

In recent years, research has focused on mobile wireless technologies and wearable devices (mHealth) as promising and cost-effective tools for the promotion of health and behavioural changes among patients with chronic diseases. These are fostered by feedback, social support and easier interactions with healthcare providers, other patients, and family members.¹³

On 11 March 2020, the World Health Organization announced the outbreak of a Coronavirus Disease-2019 (COVID-19) pandemic;¹⁴ at the time, Italy was considered the epicentre of the disease in Europe.¹⁵ At that time, the Italian government announced a 'lockdown'

state. This restrictive measure consisted of the limitation of freedom of movement, activities and social interactions, although guaranteeing all essential services.¹⁵

During the lockdown period, most people had to change their exercise and nutritional habits, which impacted on their body weight.¹⁶ Obese individuals with and without diabetes should pursue lifestyle changes, while complying with the measures of social distancing and isolation of positive cases.¹⁷ In people with diabetes, changes in lifestyle habits, in addition to the restricted access to routine visits, might contribute to uncontrolled metabolic states or to worsening comorbidities.¹⁸ In this context, telemedicine can represent a useful tool for the management of diabetes, and other chronic diseases.^{18,19}

The COVID-19 pandemic has in fact greatly encouraged the delivery of telemedicine and telehealth, although their routine use by the health system would be required for high performance in an emergency state.²⁰ This circumstance offers the opportunity to verify their effectiveness in contexts of diabetes management never previously experienced.²¹

In this complex and constantly evolving scenario, the aim of the present study is to compare a web-based intervention versus a traditional nutritional one, with a focus on anthropometric and clinical parameters and adherence to a Mediterranean Diet (MedDiet), before and during the Italian 'lockdown' period, in overweight or obese people affected by T2D or IGR and involved in a nutritional and healthy lifestyle programme.

Methods

From February to September 2019, 50 overweight or obese individuals were recruited in a 12-month randomized control trial at the Diabetes, Nutrition and Metabolism Unit at the Hospital of University "Gabriele d'Annunzio" in Chieti, Italy. The study aimed at testing web-based strategies to promote adherence to a healthy lifestyle and medical nutritional therapy (MNT) over time.

Among these patients, 14 subjects withdrew from the study. The dropouts were due to work reasons that interfered with adherence to the study, non-compliance or failure to show up to scheduled appointments. In total, 36 individuals were randomly allocated either to a *web* arm ($n = 18$) or a *traditional* arm ($n = 18$) as reported in the participants' flow chart (Figure 1).

Study protocols were registered in the National Clinical Trials Registry (NCT04386200) and approved by the Ethics Committee of the Province di Chieti e Pescara (approval number 1913). In accordance with the Declaration of Helsinki, all participants gave their written informed consent prior to their inclusion in the study.

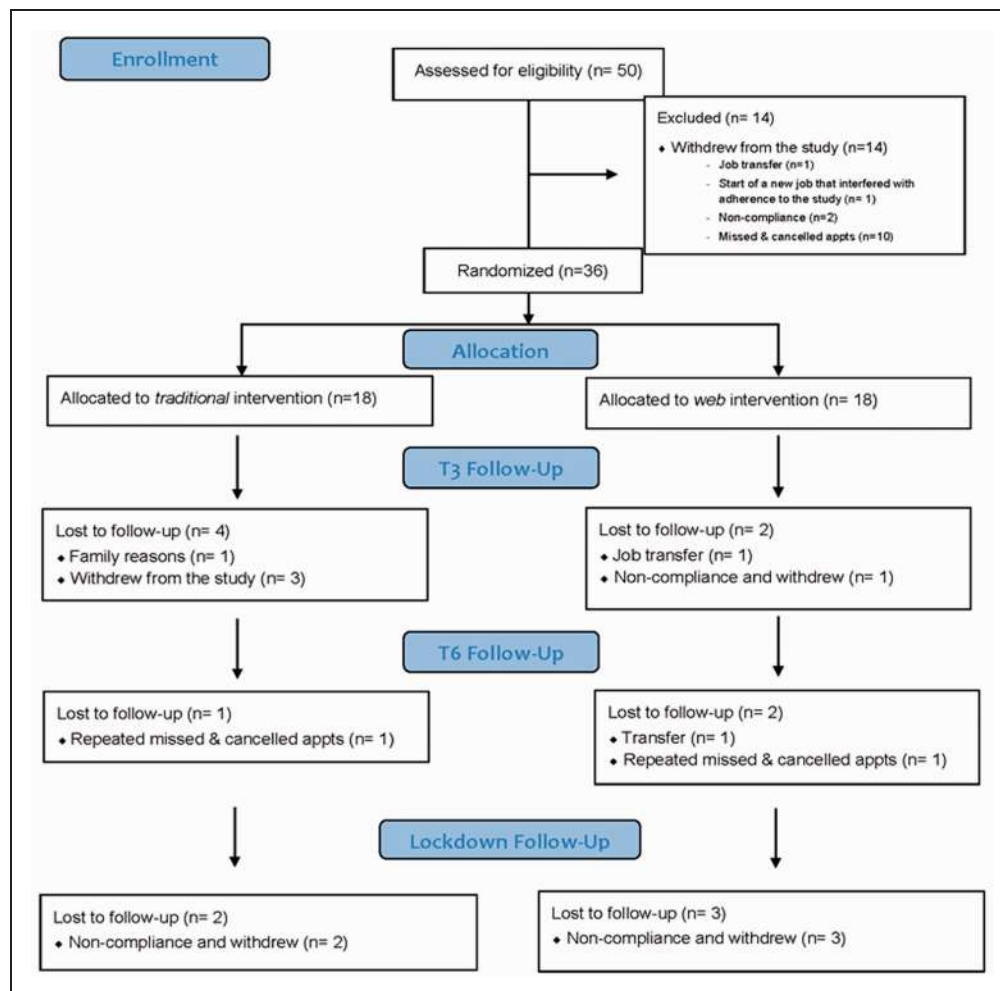


Figure 1. Participants' flow chart.

Inclusion and exclusion criteria

The inclusion criteria were overweight or obese (body mass index (BMI) ≥ 25 kg/m²) subjects (male or female), ≥ 18 years of age, affected by T2D or IGR (impaired fasting glucose (IFG) or impaired glucose tolerance (IGT)), with basic skills in the use of web-based technologies and Internet functions (e.g. the ability to browse the web, use email, download and/or upload multimedia files, access and consult a website), and with access to the Internet. These abilities had been communicated via an interview with medical staff. In accordance with current guidelines, the criteria for diagnosing T2D was a random plasma glucose ≥ 200 mg/dl, in a subject with classic symptoms of the disease (polyuria, polydipsia, weight loss). In the absence of classic symptoms, the diagnostic criteria, confirmed by at least two repeat testings, were fasting plasma glucose (FPG) ≥ 126 mg/dl (fasting defined as no caloric intake for at least 8 h) or 2-

hour plasma glucose ≥ 200 mg/dl during the 75 g oral glucose tolerance test (OGTT) or HbA1c ≥ 48 mmol/mol (6.5%) using a standardized and IFCC-aligned method.^{22,23} IGR (also known as "Dysglycemia") refers to 'a metabolic state between normal glucose homeostasis and diabetes'.^{24,25} IGR includes both IFG, characterized by FPG levels between 100 and 125 mg/dl, and/or IGT as 2-h plasma glucose during 75 g OGTT levels between 140 and 199 mg/dl or HbA1c 42–48 mmol/mol (IFCC aligned).^{22,23} The exclusion criteria were: subjects affected by type 1 diabetes, subjects affected by eating behaviour disorders, presence of conditions that could interfere with the development and completion of the project or failing adherence to the protocol.

Interventions and outcome assessment

At baseline, each subject underwent an individual interview focusing on MNT and healthy lifestyle with a

physician and a dietician from the diabetes team. Demographic characteristics, and clinical and anthropometric parameters were collected. Body weight and height, BMI, waist and hip circumferences (WC and HC, respectively), waist-to-hip ratio (WHR), capillary fasting blood glucose, venous HbA1c, and blood pressure were included.

In detail, participants' body weight and height were measured using mechanical scales with a stadiometer, while participants wore light clothing and no shoes; BMI was calculated by applying the formula kg/m^2 . WC and HC were registered using a flexible centimetre tape measure, and WHR was calculated using the formula WC/HC . Blood pressure was measured by the physician, and clinical biomarkers results were collected.

Moreover, adherence to the MedDiet was assessed using a validated 14-item questionnaire (PREDIMED) which generates a range of possible scores: no adherence (score ≤ 5), medium adherence ($6 \leq \text{score} \leq 9$), and maximum adherence (score ≥ 10).²⁶

Participants allocated in the *traditional* arm were actively involved in face-to-face individual and group-based intervention through a theoretical and practical course. Those allocated in the *web* arm integrated both the above-mentioned *traditional* approach with intervention provided through web technologies.

The first face-to-face individual intervention was a clinical check-up and the recording of the individual's clinical history. Also, during this first encounter, participants were instructed on how to keep a journal on dietary self-monitoring, based on the scientific literature.²⁷ The journal entries were discussed by the participant and the physician at the next meeting.

To ensure the active involvement of patients in the change process, educational group sessions intervention was considered essential to improve the lifestyle of obese and/or T2D subjects.¹⁰ For both arms, the group-based intervention was organized in sessions performed with small groups of up to 10 people in the presence of a trained facilitator, every 3 months. The programme, which included content on healthy nutrition and lifestyle and the promotion of physical activity, was conducted using a group session educational approach, in accordance with the best clinical practices described in the current scientific literature.^{12,28,29} In detail, each group session was structured in different stages: an opening stage with the reception of the participants and an introduction to the topic of the meeting; a second stage with a discussion and activities involving the participants, such as problem-solving exercises and real-life simulations; and a final stage in which instructions for the next meeting were shared and clarified.

In the group meetings of the *traditional* arm, participants were provided with useful information on healthy nutritional behaviour as well as learning

material and hand-outs with exercises, which were collected and discussed in the next meeting.

In the *web* arm, the same contents were made available only through a web-based platform used to create a classroom-like environment to enable interaction with healthcare providers and fellow patients. Personal credentials were provided to access the platform, where repeatable exercises with immediate feedback were also placed to assess patients' awareness. Furthermore, a one-to-one chat application was deployed whenever the web-based platform was not deemed user-friendly.

After 3 months (T3) and 6 months (T6) from baseline, BMI data, as well as WHR, capillary fasting blood glucose, venous HbA1c, blood pressure and PREDIMED scores were collected in both groups. In particular, at each face-to-face outpatient visit, the subjects' anthropometric and clinical parameters were detected and recorded as described for the baseline. The original protocol would have included the assessment of these parameters up to 12 months of treatment. Unfortunately, the outbreak of the COVID-19 pandemic caused mobility restrictions, which halted in-person group meetings and routine outpatient visits. In this new and unpredictable condition, it became necessary to identify new strategies to provide support to patients while reducing travel.

As for the *web* arm, multimedia content on healthy nutrition and active lifestyle to be adopted during the lockdown was shared using a web-based platform or a chat application; the same content was communicated by phone to subjects allocated to the *traditional* group. Subsequently, after about 40 days of lockdown, all patients involved in the project, regardless of the treatment group previously assigned, were engaged online using the PREDIMED questionnaire administered via the web.

Participants from both arms were therefore invited to record their weight and circumferences data at home and report them to their care providers using communication technologies. The participants had been previously instructed on how to collect reference points measurements using a flexible tape measure.

Due to the unexpected critical situation, the endpoint of this study became the comparison between the data of the two arms, and more specifically, the participants' anthropometric and clinical parameters as well as their PREDIMED scores, at baseline, T3, T6 and at lockdown.

Statistical analysis

This study was designed to show the effect of remote therapeutic reinforcement through web-based strategies compared with a traditional approach. The main outcome

was the difference in weight between the web arm and the traditional one. Assuming a difference of at least 3% with a standard deviation of 4.5% between two groups, 18 patients in each group were required for an 80% power and 5% significance.³⁰ Patients were randomly assigned to two groups (web or traditional) with 1:1 ratio.

Departures from normal distribution were evaluated for each variable using a Shapiro–Wilk’s test; as quantitative variables do not show a normal distribution they were reported as median and interquartile range (IQR). Categorical data were summarized as frequency and percentage. The primary and secondary quantitative outcomes such as BMI, WC, HC, WHR, fasting glucose, blood pressure and PREDIMED score were analysed using different linear mixed models. Linear mixed model is a powerful method for analysing data from longitudinal studies in which there are multiple measurements on each subject. This approach allows explicit modelling of the within-person and between-person variation in the outcome, while taking into account the correlation between repeated measurements on the same individual. Linear mixed model for repeated measurements was applied to regress baseline, T3, T6 and ‘lockdown’ measures on the fixed-effect factors assuming unstructured covariance matrix.

The false discovery rate correction (FDR) was used to control the family-wise type I error rate and an FDR adjusted *p*-value less than 0.05 was determined to be statistically significant. All the statistical analyses were performed using R software environment for statistical computing and graphics version 3.5.2.³¹

Results

The baseline characteristics of the 36 participants allocated to the *web* arm (*n* = 18, 9 males and 9 females) and the *traditional* arm (*n* = 18, 7 males and 11 females) have been summarized in Table 1.

The comparison of anthropometric and clinical parameters, plus PREDIMED scores at baseline with those at T3, T6 and at ‘lockdown’, for both groups, are presented in Table 2.

The *web* arm results showed a progressive weight loss and an improvement of BMI from baseline (weight = 102.5 IQR: 90.1–110.6 and BMI = 35.2 IQR: 30.1–39.8) to T6 (weight = 92.0 IQR: 83.5–105.0 and BMI = 33.4 IQR: 29.7–37.0). In this group, an increase in both parameters was observed between T6 and the lockdown period (weight = 93.0 IQR: 90.0–105.0 and BMI = 33.7 IQR: 30.0–37.3). In the *traditional* arm, however, weight and BMI values increased between baseline (weight = 95.5 IQR: 82.5–104.0 and BMI = 33.7 IQR: 29.4–37.1) and T6 (weight = 96.5 IQR: 78.8–100.5 and BMI = 34.1 IQR: 31.7–36.9), and decreased during lockdown (weight = 91.2 IQR: 72.8–95.8 and BMI = 32.1 IQR: 26.8–35.3). The comparison of these parameters between arms was not significant during the entire follow-up period; contrariwise, for both arms we observed a statistically significant variation when considering weight and BMI values over time (*p* < 0.001 and *p* = 0.001, respectively) (Table 2 and Figure 2). No statistically significant interaction was found between intervention arm and follow-up (*p* = 0.516 and 0.380, respectively).

Table 1. Baseline characteristics of the 36 subjects randomized to *web* group or *traditional* group.

Characteristic	Traditional group (n=18)	Web group (n=18)
Age (year) [†]	63.5 (53.0, 65.8)	56.5 (55.0, 63.0)
Weight (kg) [†]	95.5 (82.5, 104.0)	102.5 (90.1, 110.6)
BMI (kg/m ²) [†]	33.7 (29.4, 37.1)	35.2 (30.1, 39.8)
Waist circumference (cm) [†]	111.5 (102.2, 118.2)	112.5 (105.2, 119.9)
Hip circumference (cm) [†]	112.5 (105.5, 118.0)	119.8 (108.2, 126.8)
WHR [†]	1.0 (0.9, 1.0)	1.0 (0.9, 1.0)
Fasting Blood Glucose (mg/dl) [†]	118.0 (109.0, 127.0)	109.5 (97.5, 118.5)
HbA1c (%) [†]	6.5 (6.0, 7.4)	6.4 (5.9, 6.6)
HbA1c (mmol/mol) [†]	48 (42, 57)	46 (41, 49)
Systolic blood pressure (mmHg) [†]	145.0 (130.0, 150.0)	127.5 (115.0, 140.0)
Diastolic blood pressure (mmHg) [†]	80.0 (80.0, 88.8)	80.0 (75.0, 90.0)
Diagnosis [‡]		
T2D	14 (77.8%)	13 (72.2%)
IFG	4 (22.2%)	3 (16.7%)
IGT	0 (0.0%)	2 (11.1%)
PREDIMED (score) [†]	7.5 (7.0, 9.0)	8.0 (8.0, 9.5)

BMI: Body Mass Index; WHR: waist-to-hip ratio; T2D: Type 2 Diabetes; IFG: Impaired Fasting Glucose; IGT: Impaired Glucose Tolerance; PREDIMED: PREvención con Dieta MEDiterránea.

[†]Data are presented as median and interquartile range (IQR).

[‡]Data are presented as frequency and percentage (%).

Table 2. Median and interquartile range (IQR) of evaluated parameters at different control of follow-up; p-values derived from linear mixed model between arms.

Variable	Baseline				Lockdown period				p-value		
	T3		T6		Web arm		Traditional arm			Time*	Group**
Weight (kg)	95.5 (82.5, 104.0)	102.5 (90.1, 110.6)	94.5 (76.8, 97.4)	97.0 (85.1, 106.6)	96.5 (78.8, 100.5)	92.0 (83.5, 105.0)	91.2 (72.8, 95.8)	93.0 (90.0, 105.0)	<0.001	0.075	0.516
BMI (kg/m ²)	33.7 (29.4, 37.1)	35.2 (30.1, 39.8)	34.2 (29.0, 36.6)	34.7 (28.7, 37.9)	34.1 (31.7, 36.9)	33.4 (29.7, 37.0)	32.1 (26.8, 35.3)	33.7 (30.0, 37.3)	0.001	0.338	0.380
Waist circumference (cm)	111.5 (102.2, 118.2)	112.5 (105.2, 119.9)	111.5 (100.2, 115.8)	107.0 (97.0, 115.5)	108.0 (102.0, 116.5)	106.0 (98.5, 109.4)	112.0 (95.2, 119.8)	110.5 (104.0, 115.5)	0.171	0.633	0.761
Hip circumference (cm)	112.5 (105.5, 118.0)	119.8 (108.2, 126.8)	113.8 (106.0, 118.2)	116.5 (108.8, 123.0)	115.0 (106.5, 120.5)	114.0 (109.2, 123.8)	112.0 (102.0, 113.0)	112.0 (109.5, 114.5)	0.129	0.475	0.273
WHR	1.0 (0.9, 1.0)	1.0 (0.9, 1.0)	1.0 (0.9, 1.0)	0.9 (0.8, 1.0)	1.1 (1.0, 1.1)	1.1 (1.0, 1.2)	1.1 (1.0, 1.1)	0.9 (0.9, 0.9)	0.044	0.295	0.097
Systolic blood pressure (mmHg)	145.0 (130.0, 150.0)	127.5 (115.0, 140.0)	130.0 (117.5, 142.5)	120.0 (112.5, 130.0)	140.0 (127.5, 142.5)	130.0 (115.0, 130.0)	132.0 (125.0, 139.2)	127.5 (121.2, 131.2)	0.962	0.054	0.913
Diastolic blood pressure (mmHg)	80.0 (80.0, 88.8)	80.0 (75.0, 90.0)	75.0 (72.5, 85.0)	80.0 (77.5, 85.0)	80.0 (77.5, 80.0)	80.0 (70.0, 85.0)	79.5 (76.8, 80.0)	85.0 (82.5, 85.5)	0.110	0.929	0.078
Fasting Blood Glucose (mg/dl)	111.0 (102.0, 149.5)	119.0 (114.0, 125.0)	105.0 (94.0, 121.0)	109.0 (103.5, 128.0)	103.5 (97.0, 107.0)	105.0 (104.0, 113.5)	109.0 (104.0, 119.0)	134.0 (119.8, 146.5)	0.839	0.652	0.294
PREDIMED	8.0 (7.0, 8.8)	8.0 (7.0, 9.0)	8.0 (6.0, 10.0)	8.0 (7.0, 10.0)	9.0 (8.5, 10.0)	10.0 (9.0, 11.0)	7.5 (7.0, 9.0)	8.0 (8.0, 9.5)	0.023	0.877	0.941

BMI: Body Mass Index; WHR: waist-to-hip ratio; PREDIMED: PREvención con Dieta MEDiterránea.

Bolded p-values are significant after FDR correction.

*Effect of time, for each variable; the differences have been tested between the means of the two arms at different follow-up control.

**Effect of group for each variable; the differences have been tested between the means of web arm in four times (baseline, T3, T6 and lockdown) and the means of the traditional arm at the same four times.

***Probability that the effect of time is greater in one distinct arm (interaction time*arm).

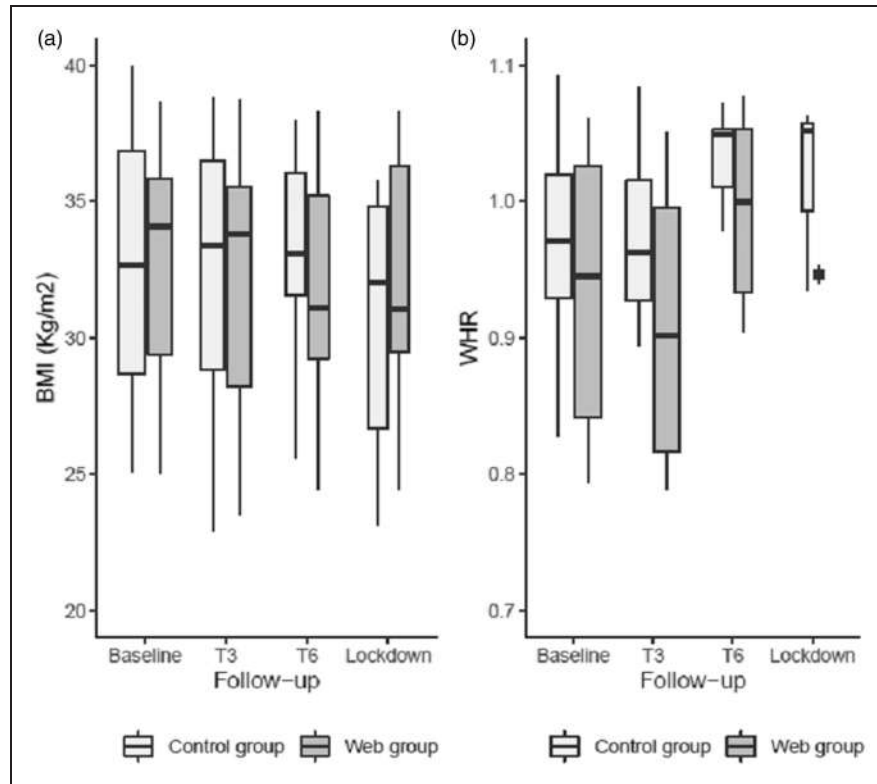


Figure 2. The within- and between-patient variation of Body Mass Index (BMI) (Panel a) and waist-to-hip ratio (WHR) (Panel b) over time (at baseline, after 3 months (T3), after 6 months (T6), at lockdown).

In the *web* arm, the median WHR decreased between baseline and T3, and between T6 and the lockdown period. In the *traditional* arm, an increase at T6 and a subsequent stabilization of parameter was shown (Table 2 and Figure 2). The model shows, however, that the variation during the follow-up of WHR is not significant for either arm (Table 2).

No other significant differences were detected for the waist and hip circumference, blood pressure, and fasting blood glucose values.

Finally, variation of PREDIMED scores was significant during the entire follow-up period ($p=0.023$); this effect is the same in both arms (interaction effect $p=0.941$) (Table 2 and Figure 3).

In detail, the PREDIMED questionnaire registered an improved median score at T6 compared with baseline in both arms (*web* 2.5 IQR: 0.2–3.2 vs. *traditional* 1.0 IQR: 0.2–2.5). Interestingly, in the *web* arm, the median score of PREDIMED increased from medium (8.0 IQR: 7.0–9.0) to maximum adherence at T6 (10.0 IQR: 9.0–11.0). In the *traditional* arm PREDIMED improved from baseline to T6, while remaining in the range of medium adherence (8.0 IQR: 7.0–8.8 vs. 9.0 IQR: 8.5–10.0, respectively). These results, however,

were not maintained during lockdown in either group (*web* 8.0 IQR: 8.0–9.5 vs. *traditional* 7.5 IQR: 7.0–9.0).

Discussion

The incidence of diabetes and obesity is growing rapidly worldwide, and this is due to unhealthy lifestyles and nutritional habits as well as a genetic vulnerability.³² Hence there is a need to promote lifestyle interventions that may favour obesity management and weight loss in overweight or obese T2D people.²

Novel technologies represent promising tools for diabetes management.⁴ Telemedicine intervention has proven effective in improving BMI in overweight and obese people and in patients with chronic diseases, including diabetes, especially for treatments over 6 months.³³ Moreover, a recent review reported an improvement in clinical outcomes in patients with diabetes (especially in recently diagnosed diabetic subjects, age < 55 years, high baseline HbA1c) assisted by telemedicine interventions.³⁴ However, research highlighted the need take into account some aspects required by this approach, such as the need for a patient's adequate technological/digital literacy, the empowerment

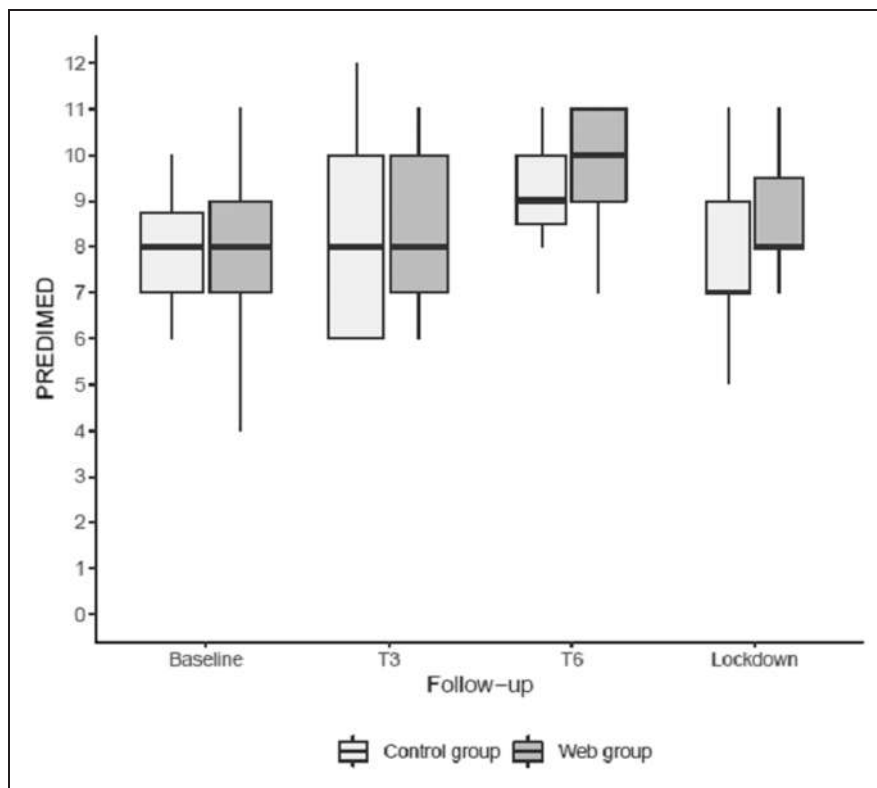


Figure 3. The within- and between-patient variation of PREDIMED scores over time (at baseline, after 3 months (T3), after 6 months (T6), at lockdown).

process triggered by health education, and the behavioural changes supported by easier interactions with care providers, other patients, and family members.^{8,13}

The pandemic outbreak of COVID-19 has made it necessary, in many countries including Italy, to introduce government policies aimed at social distancing and limiting activities and freedom of movement. It follows that the lockdown period may have impacted negatively on both lifestyle and psychological well-being.^{35,36}

In this scenario, the use of web and new communication technologies has become essential to overcome distance and physical co-presence in most aspects of life, including health.¹⁸ The current pandemic has accelerated, in fact, the regular use of telemedicine in clinical practice, without forgetting that routine use by the health system would be desirable.²⁰ Patients affected by conditions such as obesity and diabetes mellitus are at high risk for serious infections and sequelae. Providing them with strategies to foster a healthy lifestyle can be critical.³⁷ To that aim, the Regional Government of Abruzzo approved a document on the implementation of telemedicine in diabetes management during the COVID-19 pandemic.³⁸

In light of these scientific elements, the present study aims to verify the effects of a traditional nutritional

intervention versus a web-based one, with a focus on anthropometric and clinical parameters and adherence to the MedDiet, in overweight or obese individuals affected by T2D or IGR before and during the Italian lockdown period in 2020. All participants had already been involved in a nutritional and healthy lifestyle programme before the lockdown.

A free-of-charge web platform was used to integrate face-to-face learning with an online environment. The study was facilitated by our previous research on a possible combination of new technologies with behavioural change theories (i.e. transtheoretical model of change, social cognitive theory, self-determination theory).³⁹⁻⁴¹ Our research showed how the process of change of a single participant, as part of a community, can be favoured by the dynamics of mutual group support and by the reinforcement, even at a distance, of care providers.

Results detected that participants allocated to the *web* arm achieved a progressive weight loss and an improvement of median BMI until T6 and a minimal increase of weight and BMI between T6 and lockdown. Similarly, a clear improvement of median weight and BMI values compared with baseline was observed during lockdown in the control group, where a traditional approach would have been used.

These data regarding the intervention adopted during the lockdown are even more interesting in light of the results of a recent survey which reported 48.6% perceived weight gain but only 13.9% perceived weight reduction in the Italian population during the COVID-19 pandemic.⁴² Another Italian study detected a 1.51 kg self-reported weight gain and a 0.58 kg/m² BMI increase in a sample of outpatients with obesity, after the first month of lockdown.⁴³ Our results observed a significant variation when considering weight and BMI values over time for both arms.

These data are consistent with a recent study that showed a significant weight loss at 6 and 12 months of intervention in patients with T2D involved in a digital lifestyle change programme.⁴⁴ Its authors concluded that a digital approach could provide a strategy to help people access nutritional advice and weight management support.⁴⁴ In our study, the improvement of BMI detected in the *traditional* arm during lockdown is in accordance with a recent study in patients with T2D, which combined tele-monitoring with individual phone coaching for structured lifestyle intervention.⁴⁵ Results showed, after 3 months, a significant BMI improvement in tele-assisted participants compared with usual care ones, thus confirming the promising potential of this approach in support of patients with T2D.⁴⁵

BMI is the obesity index that, more than others, is related to the estimated risks for coronary heart disease and stroke in the T2D population based on specific cardiovascular risk calculators, such as the Framingham Risk Score, the UKPDS version 2.0 and the ADVANCE risk engines.⁴⁶ Interestingly, we observed an improvement in BMI or a stabilization of the parameters when participants were engaged with web-based intervention, thus confirming the potential of this approach.

Regarding the median WHR, we detected a fluctuating trend with a decrease between baseline and T3, an increase between T3 and T6, and a subsequent improvement between T6 and the lockdown period, in the *web* arm. Contrariwise, an increase at T6 and a subsequent stabilization of the median WHR was found in the *traditional* arm. Although they are not statistically significant, the positive WHR results of our study seem promising. A recent work has, in fact, demonstrated that overall (BMI) and central (WHR) obesity can represent risk factors for COVID-19 hospitalization.⁴⁷

Finally, another interesting result concerned the PREDIMED questionnaire. We detected an improvement of scores at T6 versus baseline in both arms; in particular, the *web* group score rose from a medium to a maximum range of adherence to the MedDiet at T6. During the lockdown period we found a slight

worsening of previous scores, albeit more evidently in the *web* arm. Both groups reached medium adherence scores; the median value was, however, better in the *web* group participants than in controls. Despite showing a slight deterioration during lockdown, these results are in accordance with the above-mentioned Italian survey which observed that about 60% of the Italian population ranked in the medium adherence score to the MedDiet (7 IQR: 6–9) during the COVID-19 pandemic.⁴² It is also worth noticing that the survey found a lower score in Central Italy, where our research was conducted, compared with Northern and Southern Italy and the Islands, as well as an inverse correlation between PREDIMED score and BMI. Overweight and obese individuals had, in fact, a lower level of adherence to the MedDiet in comparison to those with normal weight.⁴² In light of these findings and the emergency scenario described, we hypothesize that the provided web-based intervention enabled participants to keep in touch and stay engaged, thus contributing to avoiding radical and unhealthy lifestyle changes during the lockdown. Self-care and therapeutic compliance could be improved by an individual's perception of having a healthcare team always available via telemedicine.⁸

Furthermore, this study showed that internal and external obstacles intervened during the procedure, resulting in non-compliance and withdrawal of some participants from both arms. The lack of motivation or of willpower, busyness, as well as social and family environment and logistic problems were described as possible crucial internal and external hurdles to lifestyle change.^{48,49} Both internal factors, such as the user's behaviour and motivation, and external ones, including lack of organizational support and home obstructions, can hinder the realization of healthcare e-consultation services.⁵⁰

The present study has some limitations, the first being the number of dropouts that occurred during the study. We believe that some of the obstacles encountered by patients, such as difficulty in accessing face-to-face intervention, might be overcome by an entirely web-based approach. Other limitations are the possible inaccuracy of self-measurement of participants' circumferences during lockdown and the lack of data for some factors such as the patients' socioeconomic status, social support, and adherence to medical therapy, which impacted on our results.

The unexpected deviation from the original protocol due to the pandemic outbreak might also be considered as a limitation; we believe, however, that it represented a strength and an opportunity. In fact, it allowed for the promotion of technological tools for the remote management of subjects with diabetes. Furthermore, the tools and the multimedia material devised for

the project are free and re-usable, with a proven sustainability for the healthcare system; also, the methodological approach adopted offers potential implementation in other types of clinical practice. Finally, by imputing trajectories for the anthropometric variables to assess the effect of missing data on the stability of the results, we observed similar results in the median values compared with those considered for the main analysis.

In conclusion, the study showed the effectiveness and feasibility of a short-term nutritional web-based intervention in patients affected by T2D or IGR before and during the COVID-19 pandemic. The lockdown was an emergency scenario which impacted on the socioeconomic, professional, behavioural, and psychological state of the participants; it also had implications in various aspects of their lives, including lifestyle, nutritional habits, and anthropometric parameters. In this context, found that the provided web-based intervention allowed us to keep in touch with participants and helped them maintain some of the positive results they had previously obtained, which might have otherwise been lost. Although the results of the present study are encouraging, more extensive research with larger sample sizes needs to be conducted to further explore the effectiveness of a nutritional web-based intervention, so as to optimize the provision of outpatient visits.

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Author contributions

The study was designed by EV and FF. EV contributed to the recruitment of patients, clinical evaluation and data acquisition. FF performed the nutritional intervention and contributed to data acquisition and interpretation. EV and FF enrolled participants, MDN assigned participants to different arms. The manuscript was drafted by EV and FF. MDN was the biostatistician that performed and supervised the statistical analyses and helped in the drafting and editing of the article. All authors were involved in critical revision and approved the final version of the manuscript before submission. EV and MDN are the guarantors of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Declaration of conflicting interests



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ORCID iDs

Federica Fraticelli  <https://orcid.org/0000-0002-8169-1864>
Ester Vitacolonna  <https://orcid.org/0000-0003-1756-661X>

Supplemental material

Supplemental material for this article is available online.

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