Review

Healthy lifestyle management of pediatric obesity with a hybrid system of customized mobile technology: the PediaFit project

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Abstract

Pediatric obesity management strategies suffer from a high rate of dropout and persistence of weight excess, despite the use of new tools, such as the automated mobile technology (MT). We aimed to compare the efficacy of two personalized MT protocols with/without monthly in-presence recalls in terms of better adherence to follow-up, and improved anthropometric and lifestyle parameters.

MT contacts consisted in three not automated messages per week, inserted between three-monthly in-presence regular visits with (PediaFit 1.2) or without (PediaFit 1.1) monthly in-presence recalls. The sample included 103 children (mean age 10 years, range 6-14) recruited in the Pediatric Obesity Clinic between January 2017 and February 2019, randomized in Intervention group (IG) (n=24 PediaFit 1.1; n=30 PediaFit 1.2) and Control group (CG) (total n=49). Both IGs achieved significantly better results than the CGs for all considered parameters. Comparison of the two IGs at the 6th month showed that IG 1.2 had a statistically significant lower drop-out rate (10% *vs.* 62%), along with improved body mass index z-score, systolic blood pressure, sleep duration and physical activity.

The study suggests that the hybrid association of messaging through personalized/not automated MT plus monthly in-presence recalls may be considered for a favorable outcome of pediatric obesity programs.

Keywords: obesity; lifestyle; dropout; mobile technology; attrition; pediatric.

1.Introduction

Prevalence of global childhood obesity increased noticeably in the past four decades ("globesity"). Excessive accumulation of body fat is a complex and multifactorial condition influenced by genetic heritage, eating habits, physical activity, in conjunction with environmental, psychological and social factors [1-3]. Excess weight in childhood is likely to persist also in adult age and is associated with an increased risk of developing chronic diseases and a series of conditions/comorbidities that reduce the quality of life [4,5]. It is therefore necessary to develop effective interventions for adequate management [6]. However, these interventions are often compromised by a high rate of dropout (i.e. abandoning the intervention before reaching the set goals) which may affect up to 75% of subjects who start a medical weight management program [7].

Possible pre- and during/post-treatment dynamics underlying dropout include patient-related pre-treatment factors such as demographic, anthropometric, psychological, ethnic and socio-economic issues [8-11]. During treatment factors include exceeding costs of medical follow-up visits, distance of reference centers, poor public transportation, long waiting lists [12], dissatisfaction with short-term results [13], sense of neglect, low availability and suitability of the care system [10,11,14,15].

The current orientation for improving adherence to treatment focuses on motivation, problem-solving skills, and reduction of post-treatment influence [16] resorting to motivational therapies [17-19] web-based programs [20-22] school interventions [23-25] "exergaming" [26-28] parent engagement [29,30], and also automated mobile technology (MT) [31-34]. Results of automated MT are still controversial: in terms of adherence to follow-up some showed a lower tendency to dropout compared to controls [9,35,36] without, however, a significant improvement of anthropometric parameters in most of the cases [9,32]. Only few studies showed, actually, good results in terms of lifestyle and weight loss [37,38].

The purpose of our study is to evaluate the effectiveness of a personalized / non-automated mobile intervention with and without in-presence periodic recalls inserted between three-monthly visits, upon adherence to follow-up and improvement of anthropometric parameters and lifestyle.

2. Materials and Methods

2.1 Participants

Consecutive children aged 6-14 years old, affected by obesity [Body Mass Index (BMI) > 95th percentile for age and sex according to the CDC 2000 growth curves for 2-20 years old] [39] were recruited between January 2017 and February 2019 for this controlled clinical trial developed in the Pediatric Obesity Clinic of our University Hospital.
Patients had to be equipped with their own mobile phone or (if under 8 years) with their mother's.

2.2 Study design

The study consists of two compared phases: PediaFit 1.1 (January 2017 - January 2018) and PediaFit 1.2 (January 2018 - February 2019). Patients were randomly allocated to an Intervention (IG) or a Control group (CG) exclusively on the basis of the chronological order of their outpatient hospital booking.

As illustrated in **Figure 1** and **Figure 2**, all 54 patients of the Intervention group (IG PediaFit 1.1, n = 24; PediaFit 1.2, n = 30) received from their own tutor assigned at the time of the first visit three personalized messages/week during the intervals between their three-monthly regular visits. In addition, the IG PediaFit 1.2 had monthly in-presence auxological-dietary recalls, aiming to give better personalized support and reinforce the purpose of weight and lifestyle management program.

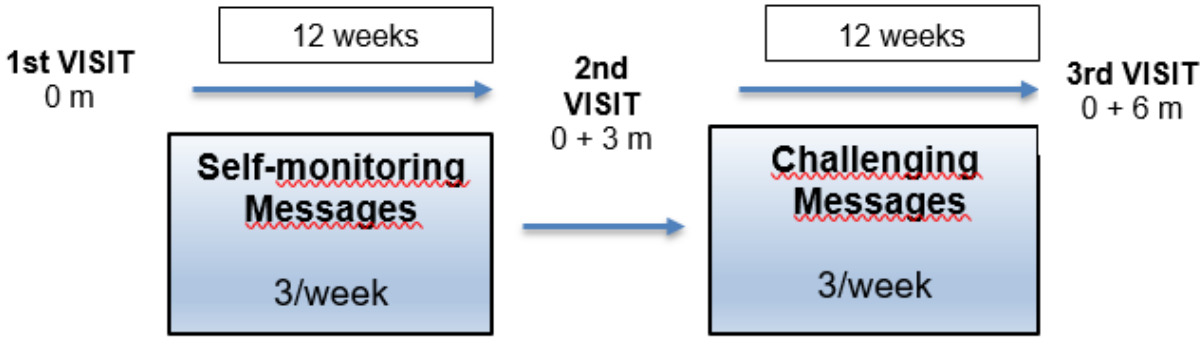

Figure 1. Intervention Group PediaFit 1.1 with 3 regular visits and 3 weekly messages (m = month)

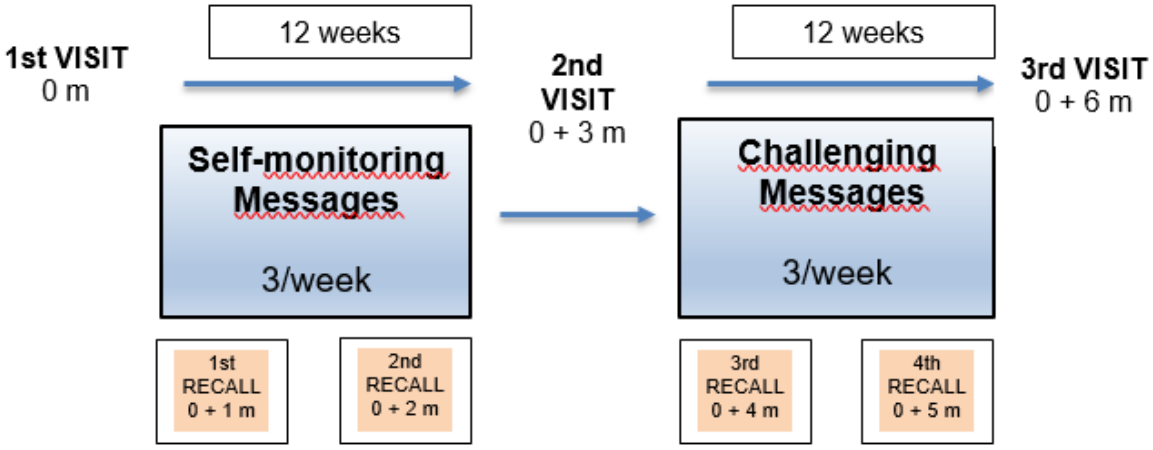

Figure 2. Intervention Group PediaFit 1.2 with 3 regular visits, 3 weekly messages, and 4 on site recalls (m = month)

Control groups (CG PediaFit 1.1, n = 25; CG PediaFit 1.2, n = 24; total n= 49) received standard treatment (healthy nutrition and physical activity plus the regular visits) without the MT aid.

Both groups received a first visit by a team consisting of a specialized pediatrician, a resident in pediatrics, a dietician and a medical student (IG tutor). During the first visit, patients were provided a poster drawn up along the lines of the "food traffic light", containing nutritional advice (**Appendix A**). After discussion of the poster, it was recommended to visit a dedicated Facebook page which is constantly updated (https://www.facebook.com/Pediafit/). The study was approved by the ethics committee of the hospital. Participants signed an informed consent parental agreement to participate in the program, be contacted and use the clinical data for research purposes.

2.3 Messaging program

Messages were sent to the children, if age > 8 years (n = 29), or to a parent, usually the mother (n = 25). Both programs lasted 24 weeks and each was divided into two parts a) self-monitoring and b) challenges messages.

Self-monitoring messages (3 messages/week; **Appendix B**), sent by the tutor during the 12 weeks in the interval between the first and follow-up regular visit, focused on healthy behavior (topics regarded sugary drinks, fruit and vegetables consumption, breakfast, portions, screen-time, physical activity, hours of sleep) accompanied by empathetic and personalized advice and/or encouragement. The child's parent was required to submit body weight every weekend.

Challenge messages (3 messages/week; **Appendix C**), were sent during the 12 weeks in the interval between the second and the third follow-up regular visit, in order to reinforce the healthy behaviors learned. The messages were preceded by an empathetic and personalized phone call from his/her tutor as a reminder along with the request of a feedback.

PediaFit 1.2 (**Figure 2**) included, in addition, also free of charge *monthly recall visits*. Each patient in the PediaFit 1.2 IG underwent a total of 4 recall visits over six months (respectively at first, second, fourth and fifth month) during which the tutor and the dietician recorded on site auxological parameters, current food diary, news about dietary lifestyle, physical activity, and any critical issues.

2.4 Data collection

In both groups at the third and sixth month we calculated anthropometric parameters [body weight, height, waist circumference (CV), neck circumference (CC); BMI and BMI z-score]; Blood pressure; obesity related acanthosis nigricans (AN); laboratory (transaminases, gamma-glutamyl transferase, Uric acid, Glucose, Insulin, Homeostasis Model Assessment Index, total, low- and high-density lipoprotein cholesterol, Triglycerides) and instrumental (abdomen ultrasound to search for hepatic steatosis) investigations.

Lifestyle was investigated by requesting information about hours of sleep per night, minutes of physical activity per day/week, hours of sedentary lifestyle and screen-time per day, presence or absence of breakfast, number of meals per day, daily consumption of fruit and vegetable's portions and calculated consumption of sugary drinks (ml) over the course of a week.

2.5 Statistical data analysis

Continuous normally distributed parameters were reported as means ± standard deviation (SD). Dropout analysis was carried out by comparison of the adherence to the follow-up of the two groups at the third and sixth month with Exact Fisher Test. For the analysis of anthropometric results and healthy behavior a T-Student test was performed, comparing the outcomes of compliant patients at the third and sixth month (the dropout at the sixth month in the CG was very high making therefore the analysis unreliable). All analyzes were performed using the Statistical Package for the Social Sciences (SPSS, version 17.02). Statistical significance was defined as $p < 0.05$ (two-tailed).

3. Results

3.1 Characteristics of the sample

As shown in **Table 1**, the study included a sample of 103 patients [49 females (47%) and 54 males (52%)], aged between 6 and 14 years (Mean = 10 years), allocated into PediaFit 1.1 [49 participants, of which 25 females (57%) and 24 males (43%)], and PediaFit 1.2 [54 participants, of which 24 females (44%) and 30 males (66%)].

Table 1. Clinical parameters of the 103 patients allocated to Intervention and Control Groups of PediaFit 1.1 + PediaFit 1.2

	INTERVENTION GROUP mean (SD)			CONTROL GROUP mean (SD)		
Variable[a]	**First visit n=54**	**3 months, n=40**	**6 months n=36**	**First visit n=49**	**3 months, n=13**	**6 months, n=5**
BMI (kg/m²)	29,2 (4,6)	27,0 (4,5)	25,6(4,2)	30,4 (6,1)	32,2 (6,6)	29,25(36)
BMI-zs	2,97 (0,5)	1,9 (0,4)	1,9 (0,4)	2,0 (0,8)	2,2 (0,6)	2,2 (0,3)
WC (cm)	85,1(10,2)	80,1 (9,5)	74,4(10,6)	86,3 (19,3)	90,9(13,3)	85,2 (4,0)
NC (cm)	33,1 (2,9)	31,0 (3,1)	29,9 (2,5)	33,5 (4,8)	33,6 (6,3)	35,4(3,3)
SBP (mmHg)	115,2(13,2)	112(15,8)	111,1(10,2)	112,2 (15,2)	112,7(9,8)	97 (5,4)
DBP (mmHg)	66,9 (12,2)	68,7(10,3)	68,6 (7,1)	65.7 (12,0)	67,7(12,3)	67,9 (10,3)
AN (grade)	1,5 (0,9)	0,9 (0,7)	0,7 (0,6)	1,33 (1,0)	1,75 (1,0)	1,2 (0,8)
F&V (portions/die)	1,2 (1,1)	2,11 (1,3)	2,68 (1,5)	1,5 (1,09)	1,8 (1,3)	1,6 (1,3)
SuD (ml/week)	894,3(514,)	196,4(302,9)	73,0(163,8)	1441,6(1424)	600(596,1)	428,5 (731,9)
Screen T (min/day)	199,4(110,)	143,4 (94,0)	98,2 (47,4)	245 (126,9)	176(152,9)	171,4 (94,4)
PA (min/week)	69,3 (125,7)	104,1(143,6)	162,3(128,2)	80 (100,8)	135,2(76,6)	148,5 (99,9)
Sleep (h/night)	8,2 (1,22)	8,5 (0,7)	8,8 (0,7)	7,8 (1,2)	8,3 (0,7)	8,7 (0,4)

[a] AN: Acanthosis Nigricans; BMI: body mass weight; BMI zs: z-score BMI; DBP: Diastolic Blood pressure; F&V: fruits and vegetable NC: Neck circumference; PA: physical activity; SBP: Systolic blood pressure; Screen T: screen time; Sleep: hours of sleep per night. SuD: Sugary drinks; WC: waist circumference

3.2 Participation to the messaging intervention

In PediaFit 1.1 and PediaFit 1.2 ***self-monitoring messaging*** received feed-back by 100% of the IG participants (n = 24 and n = 30, respectively), while ***messages with challenges*** received a feed-back by 67% (n = 16) and 96% (n = 29), respectively. The two messaging phases received a feedback from more than 50% of the expected messages in both IGs: 75% and 81% in the PediaFit1.1 and 83% and **80%** in the PediaFit 1.2 group.

3.3 Participation to Recalls (PediaFit 1.2)

Ninety-three percent of patients (n = 28) participated in both the first and second recall (dropout 7%, n = 2). At the regular follow-up visit (at 3 months), 93% of patients were examined (n = 28). Ninety-three percent patients (n = 28) returned also to the third recall and 90% returned to the fourth recall (n = 27). Overall 90% of patients (n = 27) took part in at least three of the four recalls in association with the regular follow-up visits.

3.4 ***Adherence to follow-up***

*3.4.1 PediaFit 1.1 (**Table 2**)*

Fifty percent of the IG (n = 12) and 24% of the CG (n = 6) returned to the regular follow-up visit at the third month (p = 0.079); while only 38% of the IG (n = 9) and 8% of the CG (n = 2) returned to follow-up visit at the sixth month (p = 0.018). Overall, 58% (n = 14) of the patients in the intervention group and 24% (n = 6) in the control group returned to at least one of the follow-up visits (p = 0.021).

Table 2. Adherence to follow-up of the 49 PediaFit 1.1 patients

Time	Compliant patients		Analysis
	IG 1.1	CG 1.1	P Value
First visit	24	25	
Regular Control at 3 Months	12 (50%)	6 (24%)	0,079
Regular Control at 6 Months	9 (37%)	2 (8%)	0,018
At least one check	14 (58%)	6 (24%)	0,021

IG= Intervention Group; CG = Control Group.

*3.4.2 PediaFit 1.2 (**Table 3**)*

Ninety-three percent (n = 28) of the IG and 29% (n = 7) of the CG returned to the follow-up visit at the third month (p = 0.000001). At the sixth month, 90% (n = 27) of the IG and 12% (n = 3) of the CG returned to the regular follow-up visit (p = 0.0000001). Overall, 93% (n = 28) of the IG and 33% (n = 8) of the CG returned to visit in at least one of the two follow-up regular visits scheduled at three or six months (p = 0.00025).

Table 3. Adherence to follow-up of the 54 PediaFit 1.2 patients

Time	Compliant patients		Analysis
	IG 1.2	CG 1.2	P Value
First visit	30	24	
Control a 3 Months	28 (93%)	7 (29%)	0,000001
Control a 6 Months	27 (90%)	3 (12%)	0,0000001
At least one check	28 (93%)	8 (33%)	0,00025

IG= Intervention Group; CG = Control Group.

*3.4.3 PediaFit 1.1 vs PediaFit 1.2 (**Table 4**)*

In the comparison of the follow-up adherence between IG PediaFit 1.1 and IG PediaFit 1.2, the latter showed a statistically significant lower dropout rate (**Table 4**).

Table 4. Adherence to follow-up in the Intervention Group of PediaFit 1.2 vs PediaFit 1.1

	Drop out N (%)	P Value
IG PediaFit 1.2 (n=30)	3 (10%)	0,00009
IG PediaFit 1.1 (n= 24)	15 (62%)	

IG, Intervention Group

Considering the totality of patients (i.e. IG and CG of both phases of the project), 74% (n = 40) of the IG and 26% (n = 13) of the CG returned to the visit scheduled three months after the first (p = 0.00001).
At the regular follow-up visit 6 months after the first visit, returned 66% (n = 36) of the IG and 10% (n = 5) of the CG (p = 0.0000007).
Overall, 75% (n = 41) of the IG and 32% (n = 16) of the CG returned to visit at least one of the two regular follow-ups scheduled at three or six months (p = 0.00001) (**Table 5**).

Table 5. Adherence to follow-up of PediaFit 1.2 patients + PediaFit 1.1 (Total sample)

Time	Compliant patients		Analysis
	IG 1.1+ 1.2	CG 1.1 +1.2	P Value
First visit	54	49	
Regular follow-up visit 3 Months	40 (74%)	13 (26%)	0,000001
Regular follow-up visit 6 Months	36 (66%)	5 (10%)	0,0000007
At least one check	41(75%)	16 (32%)	0,00001

IG= Intervention Group; CG = Control Group.

*3.5 Clinical and anthropometric parameters (**Tables 6-8**)*

*3.5.1 PediaFit 1.1 (**Table 6**)*

The improvement of anthropometric parameters at three months in the IG compared to CG was statistically significant in particular for BMI (p = 0.026), BMI-zs (p = 0.018), percent reduction in cm of WC excess (p = 0, 02) and NC excess (p = 0.004). The others values, also improved but, however, they did not reach statistical significance. At the sixth month assessment, although the absolute values of parameters were still decreasing more in the IG *vs*. CG, the high drop-out rates did not allow a reliable statistic calculation.

Table 6. Changes of anthropometric parameters in patients of PediaFit 1.1

Variable[a]	3 MONTHS, mean (SD)			6 MONTHS, mean (SD)		
Group	IG	CG	P Value	IG	CG	P Value
BMI Kg/m²	-2,36 (1,29)	-0,94 (1,10)	0,026	-2,99 (2,96)	1 (0,42)	0,12
BMI zs	-0,28 (0,15)	-0,10 (0,11)	0,018	-0,33 (0,32)	0,06 (0,16)	0,14
Ex WC %	-36,11 (38,12)	3,20 (19,99)	0,02	-28,89 (43,65)	0 (0)	0,39
Ex NC %	-59,58 (42,20)	1,42 (25,80)	0,004	-54,031 (67,19)	21,25 (58,33)	0,199
SBP mmHg	-9,58 (9,87)	-5,00 (17,32)	0,453	-6,25 (14,33)	-5,00 (7,07)	0,911
DBP mmHg	-3,63 (7,10)	-1,25 (13,15)	0,92	-1,88 (10,67)	7,50 (10,61)	0,29
AN grade	-0,41 (0,51)	0,00 (0,63)	0,13	-0,75 (0,89)	0,00 (1,41)	0,36

[a] AN: Acanthosis Nigricans decrease; BMI: body mass index; BMI zs: z-score BMI; CG = Control Group; Ex WC: excess waist circumference by 95° percentile; Ex NC: Excess Neck circumference by 95° percentile; DBP: Diastolic Blood pressure; IG= Intervention Group; SBP: Systolic blood pressure.

*3.5.2 PediaFit 1.2 (**Table 7**)*

The improvement of anthropometric parameters at **three months** in the IG compared to CG, was significant in particular for reduction of BMI (p = 0.04), BMI zs (p = 0.04), SBP (p = 0.02) and DBP (p = 0.02) value, and degree of AN (p = 0.00). The percentage of reduction of WC excess (p = 0.33) and NC (p = 0.30), although improved, did not reach statistical significance. At **six months** the comparison

showed a persistence of significance especially for BMI (p = 0.003) and AN degree (p= 0,0003). The comparison, even in this case, is not totally reliable due to the high dropout of the CG with a wide standard deviation of observed values.

Table 7. Changes of anthropometric parameters in patients of **PediaFit 1.2**

Variable[a]	3 MONTHS, mean(SD)			6 MONTHS, mean (SD)		
	IG	CG	pValue	IG	CG	P Value
BMI Kg/m²	-2,2 (0,9)	-1,18 (1,6)	0,04	-4,6 (1,8)	+2,7 (2,8)	0,003
BMI zs	-1,29 (1,3)	-0,1 (0,2)	0,04	-1,8 (0,7)	-0,2 (0,3)	0,2
Ex WC %	-30,9 (23,83)	-20,83 (15,94)	0,33	-34,19 (27,07)	-5,00 (7,07)	0,15
Ex NC %	-38,41 (40,23)	-20,83 (18,00)	0,30	-57,18 (44,52)	-12,50 (17,67)	0,18
SBP mmHg	-14,03 (8,5)	-3,5 (13,7)	0,02	-24,64 (25,79)	-3,5 (2,12)	0,27
DBP mmHg	-11,59 (15,36)	+5,2 (6,4)	0,02	-2,37 (17,26)	-5,00 (0,0)	0,79
AN grade	-0,8 (0,5)	+0,3 (0,5)	0,00	-1,0 (0,6)	+1,0 (0,0)	0,0003

[a] AN: Acanthosis Nigricans decrease; BMI: body mass index; BMI zs: z-score BMI; CG = Control Group; Ex WC: excess waist circumference by 95° percentile; Ex NC: Excess Neck circumference by 95° percentile; DBP: Diastolic Blood pressure; IG= Intervention Group; SBP: Systolic blood pressure.

3.5.3 Comparison of PediaFit 1.1 vs PediaFit 1.2

At the three-month evaluation, patients in the IG PediaFit 1.2 showed a greater reduction of BMI-zs (p= 0,01), excess WC% (p= 0,000) and degree of AN (p=0.03) compared to patients of the IG PediaFit 1.1. The remaining anthropometric parameters also tended to improve more considerably in PediaFit 1.2 *vs.* PediaFit 1.1, but without reaching a statistically significant difference.
Except for BMI zs and blood pressure, at the sixth month too, the better performance of PediaFit 1.2 did not reach statistical significance, due to the wideness of the standard deviation in a too small sample (***Table 8***).

Table 8. Changes of anthropometric parameters of PediaFit 1.2 vs PediaFit 1.1 patients

Variable[a]	IG 3 MONTHS, mean (SD)			IG 6 MONTHS, mean (SD)		
	PediaFit 1.2	PediaFit 1.1	P Value	PediaFit 1.2	Pediafit1.1	P Value
BMI Kg/m²	-2,2 (0,9)	-2,36 (1,29)	0,6	-4,6 (1,8)	-2,99 (2,96)	0,17
BMI ZS	-1,29 (1,3)	-0,28 (0,15)	0,01	-1,8 (0,7)	-0,33 (0,3)	0,08
Ex WC%	-30,9 (23,83)	-36,11 (38,12)	0,000	-34,19 (27,07)	-28,89 (43,65)	0,70
Ex NC%	-38,41 (40,23)	-59,58 (42,20)	0,18	-57,18 (44,52)	-54,031(67,19)	0,89
SBP mmHg	-14,03 (8,5)	-9,58 (9,87)	0,16	-24,64 (25,7)	-6,25 (14,33)	0,07
DBP mmHg	-11,58 (15,0)	-3,63 (7,10)	0,11	-2,37 (17,26)	-1,88 (10,67)	0,64
AN grade	-0,8 (0,5)	-0,41 (0,51)	0,03	-1,0 (0,6)	-0.75(0,89)	0,4

[a] AN: Acanthosis Nigricans decrease; BMI: body mass index; BMI zs: z-score BMI; CG = Control Group; Ex WC: excess waist circumference by 95° percentile; Ex NC: Excess Neck circumference by 95° percentile; DBP: Diastolic Blood pressure; IG= Intervention Group; SBP: Systolic blood pressure.

*3.6 Lifestyle (**Tables 9-11**).*

3.6.1 PediaFit 1.1 vs CG

At **three months**, the improvement in lifestyle parameters in the IG *vs.* CG was significant in particular for the reduction in the consumption of sugary drinks (p = 0.002), and the increase in daily fruit and vegetable consumption (p = 0.04). The other analyzed parameters, although improved in the IG, did not reach statistical significance. At six months there was no statistical significance for any of the parameters analyzed, with high drop-out rates especially in the CG (drop-out rate = IG 25% and CG 66%).

Table 9. Changes of lifestyle's results in patients of PediaFit 1.1

Variable[a]	3 MONTHS, mean SD			6 MONTHS, mean SD		
	IG (n=12)	CG (n=6)	P Value	IG (n=9)	CG (n=2)	P Value
SuD (ml/week)	-673,5 (487,5)	-57 (419,75)	0,002	-860,0 (586)	0,0 (424,3)	0,17
ScreenT (min/die)	-45,0 (101,05)	6,67 (30,76)	0,38	-81,4 (95,9)	15 (63,6)	0,39
Sleep (h/night)	0,3 (0,5)	0,0 (0,0)	0,22	-0,58 (1,65)	0,0 (0,0)	0,65
F&V (portion/die)	1,25 (1,09)	0,2 (0,4)	0,040	2,03 (1,2)	0,33 (0,57)	0,19
PA (min/week)	0,76 (12,55)	20 (36,17)	0,09	11,2 (63,59)	15,0 (21,2)	0,59

[a] CG= Control Group; F&V: fruits and vegetables; IG= Intervention Group; PA: physical activity; ScreenT: screen time; SuD: Sugary drinks;

3.6.2 PediaFit 1.2 vs CG

At three months, the improvement in lifestyle parameters in the IG was statistically significant for all parameters assessed, except for the increase in sleep hours (but most children already had a standard of 8-9 hours of sleep). At **the sixth month** evaluation, statistical significance is maintained only for fruits and vegetables consumption (p=0,02) and screen-time (p=0,04). The other analyzed parameters, although improved in the IG, did not reach statistical significance, due to a high drop-out especially in CG (dropout's rate: IG 25% and 66% CG).

Table 10. Changes of lifestyle's results in patients of PediaFit 1.2

Variable[a]	3 MONTHS, mean (SD)			6 MONTHS, mean (SD)		
	IG (n=12)	CG (n=6)	P Value	IG (n=9)	CG (n=2)	P Value
SuD (ml/week)	-587,0 (367,8)	-35,7 (18,9)	0,02	-718,0 (504,2)	-683, 3 (500,2)	0,67
ScreenT (min/die)	-83,8 (93,0)	-8,5 (80,7)	0,02	-118,7 (100,2)	20,0 (124,9)	0,04
Sleep (h/night)	0,6 (0,9)	0,85 (1,1)	0,55	1,18 (1,5)	1,33 (1,52)	0,8
F&V (portion/die)	1,18 (1,6)	0,00 (0,5)	0,04	2,57 (1,1)	0,66 (1,15)	0,02
PA (min/week)	71,85 (118,0)	-30 (111,0)	0,03	112,2 (113,1)	133,3 (23,09)	0,7

[a] CG= Control Group; F&V: fruits and vegetables; IG= Intervention Group; PA: physical activity; ScreenT: screen time; SuD: Sugary drinks;

*3.6.3 Comparison of PediaFit 1.1 and PediaFit 1.2 (**Table 11**)*

Lifestyle changes in the IG PediaFit 1.2 and IG PediaFit1.1 showed a statistically significant improvement of Physical Activity (p = 0.03 at three months and p = 0.01 at six months) and hours of sleep per night (p = 0.02 at three months and p = 0.02 at six months). Also the other analyzed parameters improved but did not reach statistical significance.

Table 11. Changes of lifestyle parameters PediaFit 1.2 vs PediaFit 1.1

Variable[a]	3 MONTHS, mean SD			6 MONTHS, mean SD		
	IG PediaFit 1.2	IG PediaFit 1.1	P Value	IG PediaFit 1.2	IG PediaFit 1.1	P Value
SD (ml/week)	-587,0 (367,8)	-673,5 (487,5)	0,6	-860,0 (586)	-718,0 (504,2)	0.5
ScreenT (min/day)	-83,8 (93,0)	-45,0 (101,05)	0,22	-118,7 (100,2)	-81,4 (95,9)	0,3
Sleep (h/night)	0,6 (0,9)	0,3 (0,5)	0,02	1,18 (1,5)	-0,58 (1,65)	0,02
F&V (portion/die)	1,18 (1,6)	1,25 (1,09)	0,5	2,57 (1,1)	2,03 (1,2)	0,5
PA (min/week)	71,85 (118,0)	0,76 (12,55)	0,03	112,2 (113,1)	11,2 (63,59)	0,01

[a] CG= Control Group; F&V: fruits and vegetables; IG= Intervention Group; PA: physical activity; ScreenT: screen time; SD: Sugary drinks;

4. Discussion

Communication technologies are an important part of adolescent life, and their use to encourage positive lifestyle changes is an attracting issue [41] also through promoting healthy information and facilitating empathic communication between patient and doctor [41].

Similarly to other automated programs for improving obesity management with MT [9,35], participants in our two personalized approach series achieved a low dropout rate. This result was particularly relevant in PediaFit 1.2, characterized by a follow-up adherence rate of 90%. Noticeably, and contrary to other previous studies, [9,35] our non-automated approach resulted encouraging not only in terms of **adherence** but also of **anthropometric and lifestyle variations**. Only two more recent trials had comparable good results [34, 37].

With regard to lifestyle changes, both interventions displayed improvements compared to the control groups with a statistically significant reduction of sugary drinks, and a higher consumption of fruit and vegetables (PediaFit 1.1). In PediaFit 1.2 at 3 months all parameters were significantly improved compared to the control groups. This figure was not confirmed at 6 months, because they remained significant only for the screen-time and the consumption of fruit and vegetables. Comparing the data of the two intervention groups, PediaFit 1.2 *vs.* PediaFit 1.1. also showed an improvement in blood pressure and hours of sleep per night.

Summing up, monthly recalls inserted between regular follow-up visits (i.e. PediaFit 1.2) in addition to attaining a high improvement of the anthropometric and lifestyle parameters vs controls also obtained a striking reduction of the dropout rate.

A number of factors are likely accountable for the encouraging results obtained. We believe that the hybrid technology was appropriate to the nature and purpose of the intervention. The study protocol resorting messages tailored to the patients by a tutor known by family and children met at their first visit, rather than by an automatic server, likely facilitates the patient-doctor alliance.
The monthly recalls inserted between three-monthly in person visits and messages, also allowed patients and their family to feel better supported. The free-of charge nature might have been a further trigger. All together, these factors might have had possible additive effects. Finally, the positive results of our study were favored by the presence of a multidisciplinary team adequately trained on the

management of obesity and its comorbidities, which may point toward the importance of an adequate medical training on the obesity management.

Our study has, however, also a number of limitations which may have impacted or influenced the interpretation of the findings from our research, leaving some unanswered questions that our study did not address. Firstly, the small size of the sample might have not been representative of the target population and not allowed an adequate statistical evaluation. On the other hand, the costs and/or time required by a dedicated tutor *vs.* an automated approach might not be easily afforded for a larger sample. Secondly, lifestyle changes were based on self- reported evidences. Thirdly, the short follow-up might not have allowed to catch the process of lifestyle changes which, as seen in adults, may require consolidation over the years [42, 43]. Last but not least, patient's compliance may have been positively or negatively influenced by the assigned tutor's empathy.

5. Conclusions

The results suggest that the implementation of a hybrid mobile technology with monthly messaging and in presence free-of charge recalls may be considered for weight management of children and teens with obesity or overweight. Future studies are needed to confirm these results by carrying out a trial with a larger sample and longer-term follow-up and to verify whether such an approach could conceivably have cost/benefit efficacy also in terms of costs related to obesity comorbidities.

6. Patents: none

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