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ORIGINAL RESEARCH

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Impact of the motivational interviewing for childhood obesity treatment: The Obemat2.0 randomized clinical trial

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Summary

Background and Objective: The aim was assessing a short training for healthcare providers on patient-focused counselling to treat childhood obesity in primary care, along with dietitian-led workshops and educational materials.

Methods: Randomized clustered trial conducted with paediatrician-nurse pairs (Basic Care Units [BCU]) in primary care centres from Tarragona (Spain). BCUs were randomized to intervention (MI) (motivational interview, dietitian-led education, and educational materials) or control group (SC, standard care). Participants were 8–14-year-old children with obesity, undergoing 1–11 monthly treatment visits during 1 year at primary care centres. The primary outcome was BMI *z*-score reduction.

The trial was registered at clinicaltrials.gov as NCT03749200.

Results: The study included 44 clusters (23 MI). Out of 303 allocated children, 201 ($n = 106$ MI) completed baseline, final visits, and at least one treatment visit and were included in the analysis. BMI *z*-score reduction was −0.27 (±0.31) in SC, versus −0.36 (±0.35) in MI ($p = 0.036$).

Mixed models with centres as random effects showed greater reductions in BMI in MI than SC; differences were $B = -0.11$ (95% CI: −0.20, −0.01, $p = 0.025$) for BMI *z*-score, and $B = -2.06$ (95% CI: −3.89, −0.23, $p = 0.028$) for BMI %. No severe adverse events related to the study were notified.

Conclusion: Training primary care professionals on motivational interviewing supported by dietitians and educational materials, enhanced the efficacy of childhood obesity therapy.

KEYWORDS

adolescents, childhood obesity, children, clinical trial, motivational interview, paediatric obesity, primary care

1 | INTRODUCTION

Obesity has emerged as a critical etiological factor contributing to the rise of non-communicable diseases (NCDs), which stand as the leading cause of mortality worldwide.[1] Research demonstrates a significant connection between childhood and adulthood obesity, with a substantial proportion of adults with obesity having been diagnosed with obesity during childhood.[2] Furthermore, the consequences of childhood obesity extend beyond the paediatric age, as individuals are more likely to experience cardiometabolic alterations in adulthood.[3]

Given the high prevalence of childhood obesity, it is crucial to offer prevention and treatment programmes through appropriate settings that can reach the widest target population. In this context, primary care serves as the first line of contact, playing a pivotal role.

The efficacy of treatment intervention strategies has been addressed by numerous studies and reviews. It is well known that improving diet and increasing physical activity leads to a reduction of body mass index (BMI) in children.[4–6] Multicomponent interventions addressing these lifestyle factors are recognized as the most effective in children.[7] However, inducing lifestyle behavioural changes poses challenging. In children, the efficacy of treatment interventions might be comprised for several reasons, such as parental misperception of the child's actual weight status, or a lack of motivation I both parents and children to make changes.[8,9] Paediatricians have reported primary barriers to the success of childhood obesity treatment, including a lack of family motivation, and their own insufficient knowledge to effectively promote positive patients' behaviour changes.[10] Although the necessary changes to reduce BMI are well known, the success of the treatment depends on families actively adopting these behavioural modifications. Thus, motivational approaches for obesity treatment have gained increased attention in recent years.[11,12] Motivational interview is a method of communication; it is a patient-focused assistance, where the aim should be to cause a sustained change in behaviour.[13] In the process of behaviour changes, patients feel ambivalences. Ambivalences are simultaneous and opposing feelings in relation to a change in behaviour (e.g., wanting to modify a behaviour while remaining reluctant to do so). As part of motivational interviewing, the therapist focus on patient's aims and feelings and helps the patient to resolve ambivalences.[13] The use of a patient-focused counselling strategy seems effective to maintain behaviour changes over time in adults.[11] In a longitudinal intervention study conducted in a specialized clinical setting, which assessed the effectiveness of motivational interviewing in decreasing BMI *z*-score in 110 children with obesity, a mean reduction of 0.5 SD was achieved in the subset of children ($n = 86$, 78.2%) who successfully completed the intervention.[14] A recent systematic review[15] identified only two randomized clinical trials evaluating the effectiveness of motivational/patient-focused interviews in childhood obesity treatment programmes within primary care settings. These trials consisted of a pilot study involving 60 children aged 4–8 with overweight or obesity, and a well-conducted clinical trial with 645 children aged 2–8 with overweight. The review, drawing from these two studies, indicated a potentially more pronounced effect of patient-focused interviews in the treatment of childhood obesity, particularly in very young children.

We hypothesized that providing training and tools to primary healthcare professionals for implementing a motivational programme would enhance the efficacy of standard strategies performed in primary care centres for children leaving with obesity. To assess the effectiveness of professionals in treating childhood obesity, a cluster design would be essential. Since trained professionals would not be able to act differently when treating children in control or intervention groups, the professionals in each treatment group should be distinct.

Our aim was to assess, at participants' level, the efficacy of a short training to paediatricians and nurses in conducting motivational interviewing for the multicomponent treatment of childhood obesity. This was supported by dietitian-led education and printed educational materials, and it was compared to regular multicomponent treatment in primary care.

2 | METHODS

2.1 | Research question

- Population: children with obesity from 8 to 14 years of age.
- Intervention: multicomponent intervention (diet and physical activity recommendations) provided by paediatricians and paediatric nurses who received a short training on motivational interviewing and were supported by dieticians-led workshops and educational materials.
- Control: standard primary care, which was multicomponent intervention (diet and physical activity recommendations) provided by paediatricians and paediatric nurses.
- Outcomes: primary outcome was BMI *z*-score reduction, and secondary outcomes were BMI percentage (%), BMI (kg/m^2), waist circumference and waist-to-height reduction at individual participant's level.
- More detailed information, as well as other assessed secondary outcomes is provided along the methods section.

2.2 | Design, setting and time frame

This research was a randomized clustered clinical trial designed for the treating children with obesity. It encompassed two study arms (as outlined below) and was conducted in the Tarragona province (Spain). The eligibility criteria for clusters in primary care centres included the presence of basic care units (BCUs), comprising pairs of a paediatrician and paediatric nurse responsible for delivering care to a designated subset of the population within the area. Prior to the clinical trial, paediatricians and paediatric nurses were already paired in BCUs, each BCU with a pre-assigned subset of the population. This organization of public primary care in the country was standard practice.

In March 2016, the study coordinator engaged paediatricians and paediatric nurses (referred to as healthcare providers or HCPs hereafter) in primary care centres through face-to-face meetings. Once they agreed to participate in the study, each basic care unit (BCU) was randomly assigned to either the control or the Obemat2.0 intervention group.[16] To note, each primary care centre was regarded as a cluster, and BCUs served as the units for randomization. Randomization was carried out at the cluster level in a 1:1 ratio by a blinded project manager using the EPIDAT 3.0 Statistical Program, without restrictions nor stratification. Notably, as each BCU was responsible for a specific subset of the population in the area, randomization was exclusively performed only at the BCU level, and children themselves were not subject to randomization. HCPs underwent training provided by specialized paediatricians and dietitians from reference hospitals in the area (namely Hospital Universitari de Tarragona Joan 23 and Hospital Universitari Sant Joan Salut Reus, Spain). The recruitment of children with obesity was conducted by HCPs at primary care centres among the population under their regular care. Recruitment of participants began in June 2016 and concluded in March 2018. In the study, paediatric nurses primarily executed the intervention, while paediatricians at primary care centres were responsible for conducting clinical evaluations and, when necessary, also participated in the intervention process.

The baseline and final assessments of participants were conducted at the reference hospitals by the same research team using standard equipment. The treatment for children with obesity took place in the primary care centres within the area from June 2016 to June 2019.

The trial was registered at clinicaltrials.gov under the identifier NCT03749200, and the trial's protocol was published beforehand.[17] The Consort checklist information for reporting cluster randomised trials is provided in Tables S1 and S2.

2.3 | Study population

All children aged 8 to less than 14 years, diagnosed with obesity, and attending to regular health checks at primary care centres were invited to participate in the study. The screening criteria included having a BMI greater than the 97th percentile, based on the Hernandez references from 1988,[18] as specified by the Guidelines for Clinical Practice on the Prevention and Treatment of Childhood and Adolescent Obesity of the Spanish Health System.[19] Exclusion criteria comprised children with eating disorders, families unable to attend scheduled visits, concurrent involvement in another clinical trial, the presence of endocrine disorders (such as growth hormone disorder, hypothyroidism, Cushing's disease, precocious puberty, or others), and a lack of proficiency in local languages.

We determined the sample size for each group by considering the number of individuals required for a simple random design and then multiplied it by the design effect. Assuming a standard deviation of 0.75 and a 30% lost to follow-up, a total of 98 children with obesity were required in each group to detect a BMI *z*-score difference ≥0.36. This difference was determined based on an alpha risk of 0.05 and a beta risk of 0.2 in a bilateral contrast, which was achieved in a previous study with a 1-year multicomponent intervention.[20] Calculations were conducted using GRANMO v7.12 software.[21] As the design effect in cluster randomized trials corresponded to 1.7, the final calculated sample size was 167 participants in each group ($n = 334$ overall).

2.4 | Interventions

The interventions were performed and evaluated at participants' level. Given the nature of the intervention, neither participants nor researchers could be blinded. All participants underwent assessments at baseline and post-treatment (12 months (+3) later), involving the number of monthly interviews with patients and families (up to 11 interviews) and the completion of questionnaires.

2.4.1 | Control intervention

HCPs assigned to the control group were instructed to administer standard care, thereby conducting a routine multicomponent intensive intervention at primary care, adhering to the Guidelines for Clinical Practice on the Prevention and Treatment of Childhood and Adolescent Obesity of the Spanish Health System.[19] During the visits, families received guidance on various lifestyle modifications, which encompassed reducing sedentary activities, increasing physical activity, and improving dietary habits. The dietary advice involved dividing daily food intake into five meals, moderately reducing energy intake by eliminating energy-dense and unnecessary foods. Additionally, families were counselled to limit eating between meals and decrease portion sizes when necessary.

Furthermore, the suggested dietary modifications included consuming four to five portions of fruits and vegetables daily, increasing the consumption of whole grain cereal products, and refraining from sugared beverages, cakes, pastries, junk food, fried food products, energy-dense dairy desserts, and oil-based sauces.

2.4.2 | Obemat2.0 intervention

The dietary and physical activity recommendations provided in this intervention group were grounded on the same principles as those in the control group. However, HCPs in this group underwent 12-h training session led by a physician and two dietitians. The training encompassed specific educational content for each visit (dietitian), tips for conducting patient-centred interviews (provided by an endocrinologist with expertise and experience in motivational interviewing) (delivered by an endocrinologist with expertise and experience in motivational interviewing[14]) and defining attainable objectives during each visit (dietitian). Moreover, all these elements were reinforced with the aid of educational materials. The educational materials to be used by the HCPs during the intervention, designed by dietitians, were published elsewhere[22] and can be accessed at http://llibres.urv.cat/index.php/purv/catalog/book/447. In summary, the educational materials facilitated a standardized intervention by HCPs organized in four steps:

1. Assessment of objectives accomplishment: This involved reviewing specific improvements in diet, physical activity, and assessing anthropometry discussed during the previous visit.
2. Advice on a specific topic: The HCPs provided education on various topics related to diet and physical activity from a general perspective.
3. Proposing a task related to the visit's topic to be performed at home: For instance, the HCPs might suggest creating a list of healthy breakfast options that the child enjoys.
4. Setting new achievable objectives for the next visit: HCPs asked the family to define new attainable goals for the child's progress in the upcoming visit. For example, if an educational topic or a concern raised by the family related to the consumption of vegetables, the child and family were asked about possible improvements and objectives they would like to set regarding their diet.

It is worth mentioning that the brief training provided to therapists did not guarantee proficiency in motivational communication techniques. Therefore, the educational materials were designed including a section where families were encouraged to stablish their own goals at each visit. This approach aimed to assist therapists in maintaining a 'motivational interview mode'.

Furthermore, during the first 4–6 months, children in the intervention group had the opportunity to engage in workshops where dietitians and a paediatrician offered education activities on three different topics: increasing physical activity by using an eHealth monitor (Fitbit®), led by a paediatrician; enhancing food choices by reading labels and reducing portions, led by a dietitian; adopting healthy cooking methods, led by a dietitian.

Additional details about the content of the interventions where previously published.[17]

2.5 | Outcomes and measures

The primary outcome was the change in BMI *z*-score (before and after the intervention) at the individual participant level. Additionally, several secondary outcomes were evaluated, including reductions in BMI percentage (%), BMI (kg/m^2), waist circumference (cm), waist-to-height ratio, body composition measures, blood pressure, and biochemical parameters.

2.5.1 | Anthropometry

Weight (kg) and height (m) were measured with a SECA769 scale (precision 50 g) and SECA 216 Stadiometer (precision 1 mm), respectively. Waist circumference (cm) was measured using a non-extensible Holtain tape (precision 1 mm) at the mid-point between the last rib margin and the iliac crest. We calculated waist-to-height ratio, BMI as $\text{BMI}\left(\text{kg}/\text{m}^2\right) = \frac{\text{weight (kg)}}{\text{height}^2\text{ (m)}}$, and BMI *z*-scores for age and sex according to the World Health Organization (WHO) references[23] using the WHO programmes.[24]

2.5.2 | Body composition

Fat mass (kg) and fat free mass (kg) were assessed by measuring body volume (L) using Air Displacement Plethysmography in a Bod Pod® (COSMED, Life Measurements, Inc, Concord, CA). The participant wore swimsuits and swim caps during the measurements, and each measurement was performed in duplicate to ensure accuracy. Body density [kg/L] was then calculated as $\text{Body density}\left(\frac{\text{kg}}{\text{L}}\right) = \frac{\text{Body weight(kg)}}{\text{Body volume (L)}}$. Fat mass (%) was calculated using the Siri equation as previously described[25]:

$$\text{Fat mass}\,(\%) = \frac{C1}{\text{Body density} - C2 \times 100}.$$

Rather than using the $C1$ and $C2$ as constant values, $C1$ and $C2$ were calculated as[26]:

$$C1 = \frac{D_{FFM} \times D_{FM}}{D_{FFM} - D_{FM}}, C2 = \frac{D_{FM}}{D_{FFM} - D_{FM}}$$

being D_{FFM} the density of the fat free mass, and D_{FM} the density of the fat mass, assuming a constant density of the Fat mass = 0.9007 kg/L, and estimating the density of the fat free mass as follows[27]

$$D_{FFM}\left(\frac{kg}{L}\right) = 1.0791 + (0.0009 \times Age) + (0.0021 \times Sex) - (0.0014 \times BMI)$$

with age in years, sex 1 for boys and 2 for girls, BMI as *z*-score, as previously validated against the 4 components model in children with obesity.[28] Fat mass (kg), fat free mass (Kg), fat mass index (FMI) (kg/m^2), fat free mass index (FMI) (kg/m^2) were then calculated.

2.5.3 | Medical examination

Paediatricians or nurses explored the Tanner maturation stage[29,30] and examined the presence and placement of Acanthosis Nigricans at visits 1 and 11. For measuring systolic (SBP) and diastolic blood pressure (DBP) (mmHg), study personnel used a Dinamap Pro 100 device on child's the left arm during baseline and final visits. The measurements were taken in duplicate, with at least a 5-min interval between measures. The child was seated with the arm laying comfortably during the process.

The mean of the two measures was calculated. Blood pressure percentiles per age, sex and height-for-age were determined based on the references provided by the American Academy of Paediatrics from 2017 were calculated.[31]

2.5.4 | Biochemical analyses

At baseline and after the intervention, a fasted blood sample was drawn and glucose (mg/dL), total cholesterol (mg/dL), high-density lipoproteins cholesterol (HDL) (mg/dL), low-density lipoproteins cholesterol (LDL) and Triglycerides (mg/dL), were quantified using routine clinical diagnostic enzymatic methods, and insulin (μIU/mL) was quantified by immunoradiometric assays. The homeostasis model assessment for insulin resistance index (HOMA-IR) as a proxy for insulin resistance.[32]

2.5.5 | Complementary information

At baseline, a sociodemographic questionnaire was administered, which included questions about parents' education attainment based on UNESCO standards.[33] The education levels were recoded into three categories: low, medium and high.

Parental occupation was determined using the National Classification of Occupations from the National Statistics Institute from 2011, and subsequently recoded into three categories: low, medium and high.[34]

Marital status and household income were also collected. Household income was divided into three groups: group 1—≤3000€, group 2—3000€ to ≤5000€ and group 3—>5000€.

Parents' weight (in kilogrammes) and height (in metres) were measured, and their BMI was calculated accordingly.

To evaluate adherence to the therapy, the attendance to visits was recorded, ensuring that the participants' engagement with the intervention was closely monitored.

2.5.6 | Adverse events

Due to the nature of the study, the likelihood of encountering health hazards (e.g., requiring hospitalization or psychological complications) was low. Potential adverse events could be the development of eating disorders, anxiety and emotional discomfort related to the treatment. The team collected any adverse event if reported by the primary healthcare providers.

2.5.7 | Usability of the educational materials

HCPs in the motivational intervention group provided feedback about the usability of the educational materials. They were asked to complete a questionnaire that gauged their perception of the materials' usability for implementing the intervention in their usual practice.

The questionnaire focused on several key aspects:

1. Facilitation of the education task: HCPs were asked to rate how much the materials assisted them in delivering the educational content to their patients and families.
2. Family's understanding: HCPs were prompted to express their views on whether the materials contributed to better comprehension by the families of the intervention's objectives and recommendations.
3. Recommendation to other HCPs: Participant HCPs were asked if they would recommend the use of these educational materials to other healthcare professionals for similar interventions.
4. Intention to continue use: HCPs were also inquired about their likelihood of continuing to use the educational materials in their future practice.

Responses to these questions were collected using a Likert scale, where participants could choose from options such as 'don't know', 'no', 'sometimes', 'frequently', and 'always'. This approach facilitated a quantifiable assessment of the materials' usability and the level of confidence the HCPs had in using them effectively. The feedback provided

by the HCPs would assist in evaluating the practicality and acceptance of the educational materials in the context of their clinical practice.

2.6 | Statistics

Statistical analyses are presented for intention-to-treat, including participants who performed the baseline, and final visits, and at least 1 treatment visit in between. Descriptive statistics are shown as mean ± standard deviation or median and interquartile range as appropriate. Normality was assessed by visualization of graphical distribution and confirmed by Kolmogorov–Smirnov test. Differences between intervention groups at baseline were assessed with either a Student *T*-test or a Mann Whitney *U*-test. Differences in distribution of categorical variables at baseline and, differences in dropout rates between groups were tested with Chi-squared tests or Exact Fisher tests. To quantify changes between baseline and after the intervention in the primary and secondary outcomes, we calculated the difference between the final and the baseline visit, and groups were compared using Student *T*-tests or a Mann Whitney *U*-tests. The effect of the intervention on the primary outcome (BMI *z*-score) and secondary outcomes (BMI percentage (%), BMI (kg/m^2), waist circumference (cm), waist-to-height ratio, fat mass index (kg/m^2), fat free mass index (kg/m^2), fat mass percentage (%), SBP (percentile), HOMA-IR, triglycerides (mg/dL), and HDL (mg/dL)) was analysed by means of mixed models, accounting for the cluster design, where 'centre' (cluster) was included as random effect. Models were adjusted for sex and age at enrolment as potential confounding. Prior to fitting the model, we performed multiple imputations using random forest, using the mice package for R.[35]

Statistical analyses were performed with IBM SPSS 28.0 (Inc., Arkmonk, Illinois, USA) and Rstudio v1.4.1717 (Integrated Development for R. RStudio, PBC, Boston, MA 202). Significance was accepted at the level $p < 0.05$.

2.7 | Ethics

The study followed the rules of the Declaration of Helsinki[36] and was approved by the ethics committees of all study centres: CEIC Hospital Universitari de Tarragona Joan 23 (CP.OBEMAT2.0-C.I.01p/2016), CEIC Hospital Universitari Sant Joan (code 16-01-28/1ass2), CEIC IDIAP Jordi Gol (code PI14/116). Parents or guardians signed informed consent prior to study enrolment. Children ≥12 years signed informed assent to participate in the study.

3 | RESULTS

Forty-five BCUs were approached to participate in the study. One BCU (a paediatrician and a paediatric nurse) rejected to participate in the study. Eighty-two paediatricians and nurses from 15 centres (clusters), distributed in 44 BCUs (21 in the control group and 23 in the intervention group) took part in the study as HCPs. All of them received the assigned training. Figure 1 depicts the flow chart of children's participation in the study. In total, 201 children underwent both baseline and final assessments and received at least one intervention visit, and consequently included in final analyses.

There were no differences between groups in number of eligible children, nor in reasons for exclusion at the eligibility assessment. Twenty-five (8.3%) of those participants who attended to the baseline assessment visit, never attended to any treatment visit (8.0% in the control and 8.4% in the intervention group). Twenty-four patients (7.9%) attended to the first treatment visit, but not to the second one (8.8% control, 9.6% intervention). There were no statistically significant differences between groups in number, nor reasons to withdraw the treatment. Overall, 66% of allocated children were analysed (63% and 70% in intervention and control group, respectively). Table 1 shows the characteristics of the study sample at baseline. There was a lower proportion of girls in the control compared to the intervention group ($p = 0.043$). There were no baseline differences between groups in parents' education, occupation, family income, nor parents' marital status. Mother's BMI was higher in the control than in the intervention group (Table 2).

3.1 | Main outcome measure

The mean BMI *z*-score reduction was −0.27 (±0.31) in the control group, versus −0.36 (±0.35) in the motivational intervention group ($p = 0.036$) (Figure 2). Results from mixed models, accounting for potential confounding (sex and age at enrolment) and considering a random effect by centre (cluster), yielded similar findings. Difference in BMI *z*-score reduction between groups was $B = -0.11$ (95% CI: −0.20, −0.01, $p = 0.025$) (Table 3). Conclusions between imputed and non-imputed data in mixed models did not differ.

3.2 | Secondary outcome measures

Mean BMI reduction was +0.25 kg/m^2 (±1.56) and +1.00% (±6.04) versus −0.31 kg/m^2 (±1.80) and −1.16% (±6.85%) (in control and intervention group, respectively, $p = 0.010$ for BMI kg/m^2 and $p = 0.019$ for BMI %) (Figure 2). The mean waist circumference change was +1.51 cm (±4.66), and the waist-to-height ratio was −0.01 (±0.03) in children in the control group, compared to −0.20 cm (±5.42), and −0.02 (±0.03) in children in the motivational intervention group ($p = 0.016$, and $p = 0.005$, respectively) (Figure 3). Results from mixed models, accounting for potential confounding (sex and age at enrolment) and incorporating random effects by centre (cluster), yielded similar findings. Difference in BMI % reduction between groups was $B = -2.06$ (95% CI: −3.89, −0.23, $p = 0.028$), and the difference in BMI (kg/m^2) reduction was $B = -0.54$ (95% CI: −1.02, −0.06, $p = 0.028$). Statistically significant differences in waist

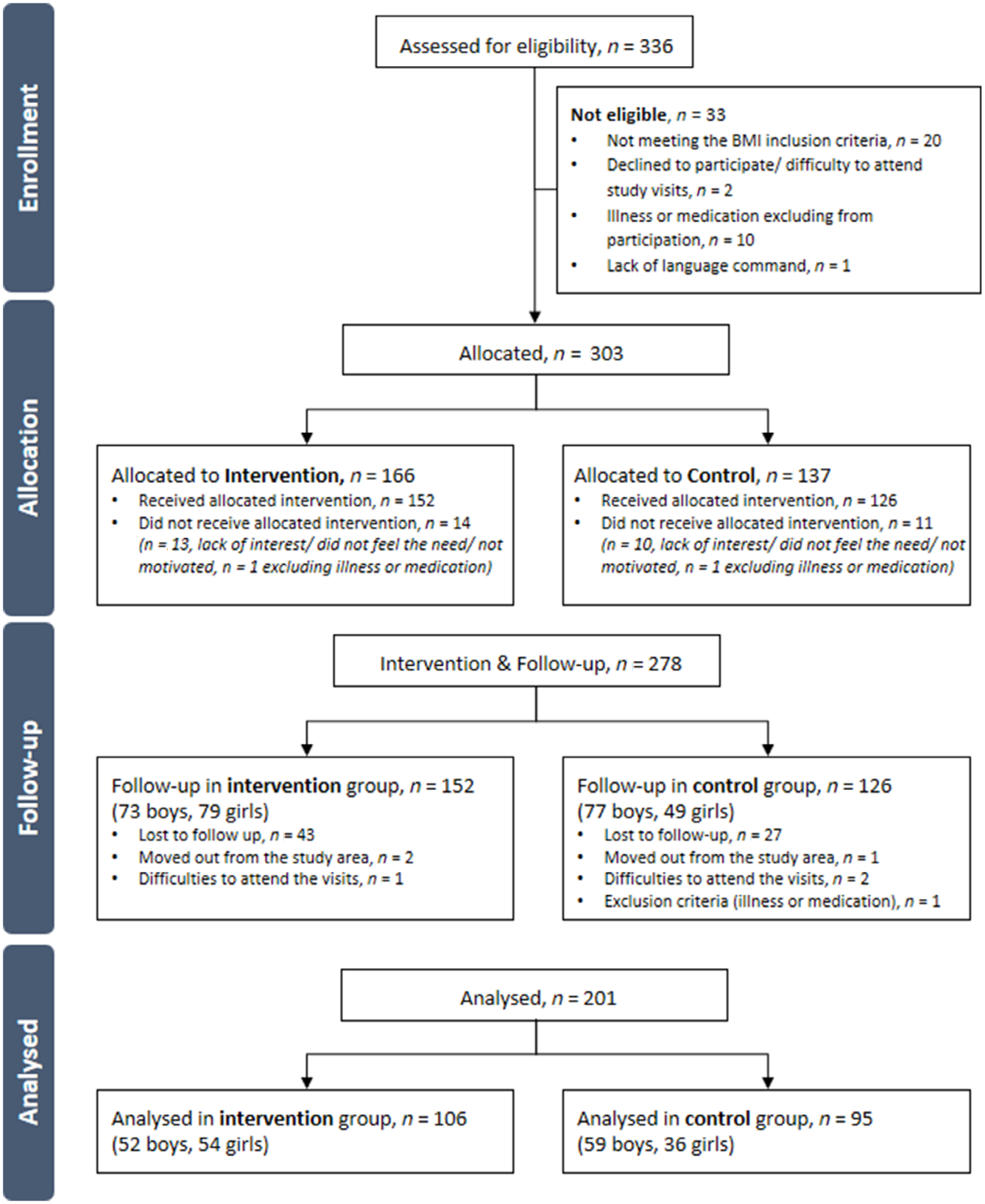

FIGURE 1 Flow chart of participants.

(cm) and WHtR between intervention groups were observed as well (Table 3). There were no significant differences in reductions for any of the other secondary outcome variables (body composition, HOMA-IR nor lipids profile), neither non-adjusted nor adjusted analyses (data not shown). Conclusions between imputed and non-imputed data did not differ.

TABLE 1 Description of baseline characteristics of the study sample included in the final analyses.

	Control	Intervention
Sample size, *n*	95	106
Boys, *n* (%)	59 (62.1%)	52 (49.1%)*
Girls, *n* (%)	36 (37.9%)	54 (50.9%)*
	Mean (SD)	**Mean (SD)**
Age, baseline (months)	127 (19)	130 (18)
Weight (kg)	56.9 (12.1)	57.1 (12.0)
Height (m)	1.48 (0.10)	1.48 (0.11)
Waist circumference (cm)	84.4 (7.1)	84.4 (7.7)
Waist-to-height ratio	0.57 (0.036)	0.57 (0.037)
Body mass index (kg/m^2)	25.70 (2.54)	25.75 (2.73)
Height (*z* score)	0.95 (1.00)	0.78 (1.06)
Body mass index (*z* score)	2.66 (0.47)	2.55 (0.41)
Body composition		
Fat mass index (kg/m^2)	10.4 (1.9)	10.4 (2.1)
Fat free mass index (kg/m^2)	15.3 (1.7)	15.3 (1.8)
Fat mass (%)	40.3 (5.2)	40.2 (5.4)
Systolic blood pressure (mmHg)	109 (7)	108 (10)
Diastolic blood pressure (mmHg)	63 (8)	62 (8)
Systolic blood pressure (percentile)	66.2 (25.1)	63.7 (24.7)
Diastolic blood pressure (percentile)	50.0 (21.6)	48.1 (23.0)
Serum biochemical analyses		
Glucose (mg/dL)	83.9 (5.4)	82.7 (5.8)
Insulin (IU/mL)	12.3 (6.1)	13.5 (6.6)
HOMA-IR	2.57 (1.26)	2.78 (1.41)
HDL—cholesterol (mg/dL)	54.1 (12.9)	52.2 (12.2)
LDL—cholesterol (mg/dL)	92.3 (25.9)	98.8 (26.0)
Triglycerides (mg/dL)	80.2 (38.5)	85.0 (36.7)
Medical examination	***n* (%)**	***n* (%)**
Acanthosis nigricans	10 (11.9)	23 (22.5)*
Tanner stage		
1	45 (50.0)	38 (36.5)
2	19 (21.1)	39 (37.5)
3	12.2 (9.0)	10 (9.6)
4	9 (10.0)	10 (9.6)
5	6 (6.7)	7 (6.7)

*p-value <0.05 for differences compared to control.

Adverse events related to the study were not notified by primary healthcare providers.

3.3 | Usability of the educational materials

Twenty-nine HCPs completed the questionnaire on usability of educational materials. HCPs found that materials facilitated the intervention, both from the patients and the HCPs' perspective, would recommend other professionals to use it, and had the intention to continue using it after the end of the trial (Figure 4).

TABLE 2 Family characteristics.

	Control	Intervention
Mother's BMI (kg/m^2), mean (SD)	29.6 (5.2)	27.4 (5.4)*
Father's BMI (kg/m^2), mean (SD)	28.9 (4.1)	28.9 (4.2)
Mother's education attainment level		
Low, *n* (%)	17 (18.9%)	29 (29.0%)
Medium, *n* (%)	58 (64.4%)	56 (56.0%)
High, *n* (%)	15 (16.7%)	15 (15.0%)
Father's education attainment level		
Low, *n* (%)	34 (39.1%)	36 (37.9%)
Medium, *n* (%)	43 (49.4%)	41 (43.2%)
High, *n* (%)	10 (11.5%)	18 (18.9%)
Mother's occupation		
Low, *n* (%)	33 (36.3%)	33 (33.0%)
Medium, *n* (%)	49 (53.8%)	56 (56.0%)
High, *n* (%)	9 (9.9%)	11 (11.0%)
Father's occupation		
Low, *n* (%)	24 (27.6%)	28 (29.5%)
Medium, *n* (%)	57 (65.5%)	60 (63.2%)
High, *n* (%)	6 (6.0%)	7 (7.4%)
Household income		
Group 1, *n* (%)	15 (18.5%)	18 (19.4%)
Group 2, *n* (%)	59 (72.8%)	68 (73.1%)
Group 3, *n* (%)	7 (8.6%)	7 (7.5%)
Mother's origin		
Spain, *n* (%)	68 (74.7%)	80 (79.2%)
Foreign country, *n* (%)	23 (25.3%)	21 (20.8%)
Father's origin		
Spain, *n* (%)	69 (75.8%)	79 (78.2%)
Foreign country, *n* (%)	22 (24.2%)	22 (21.8%)
Family structure		
Married/living together, *n* (%)	68 (74.7%)	72 (71.3%)
Parents separated/divorced, *n* (%)	23 (25.3%)	29 (28.7%)

Note: Education attainment level, low: none, primary or high school; medium: secondary studies or professional training; high: University studies, Master, PhD. Household income. Parents' occupation, low: elementary, operators, elemental services; medium: technicians, administrative; high: managers, highly qualified tasks; scientific.
*p-value <0.001 for differences compared to control.

4 | DISCUSSION

4.1 | Efficacy of motivational interview for treating childhood obesity

The findings of this study underscore the effectiveness of brief motivational interview training for paediatricians and paediatric nurses in

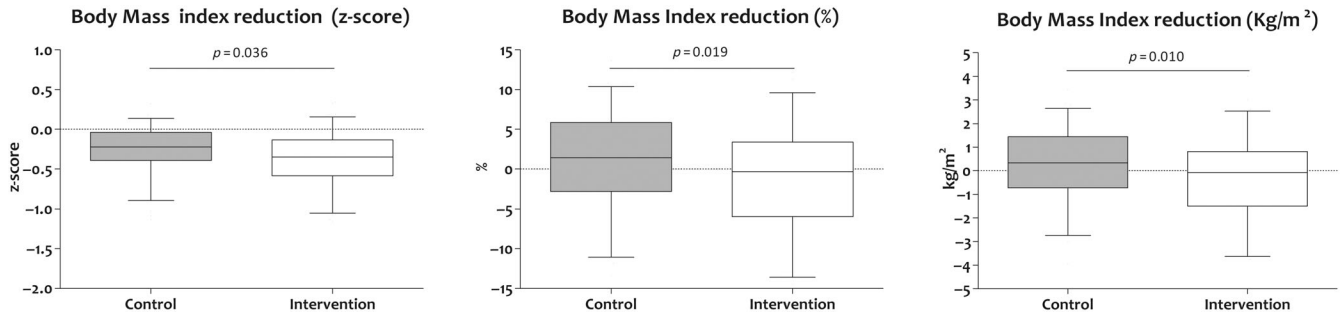

FIGURE 2 Change in body mass index according to the intervention.

primary care, supplemented by support from dietitians and educational materials. The results revealed that participants who underwent motivational interview training, achieved significantly greater reductions in BMI *z*-score, BMI %, waist circumference, and waist-to-height ratio compared to the non-trained control group.

The available evidence on the efficacy of motivational interviewing for treating childhood obesity is relatively limited. A systematic review published in 2020, identified only seven studies that explored the use of motivational interviewing in the prevention or treatment of childhood obesity.[37] These studies included children from 9 months to 10 years. The review found that the mean differences in BMI of families interviewed who received a motivational approach compared to control groups ranged from −0.04 kg/m^2 to −0.93 kg/m^2, or 2.0–3.1 BMI percentiles, or 0.12 *z*-score. Notably, it is essential to interpret these findings in the context of the age group studied, which included very young children. In this particular age range, motivational interventions primarily targeted the parents with a focus on prevention rather than direct treatment of childhood obesity.

Systematic review and metanalysis of multicomponent interventions for obesity treatment revealed a mean BMI *z*-score reduction compared to usual care or no intervention of −0.06 (−0.10, −0.02) in children[6] and −0.13 (−0.21 to −0.05) in adolescents (12–17 years).[4] The effect of the intervention in our study was similar to or higher than previous studies.

The 'Brief Motivational Interviewing to Reduce BMI' study compared two motivational interventions of varying intensity with a usual care group, in 2–8 years children with overweight (without obesity).[38] The study found that children in groups with additional visits under dietitians care and using motivational interview had greater BMI decrease than controls.[38] Similarly, in a clinical trial involving young children (4–7 years) using motivational interviews with paediatricians compared to receiving a leaflet, a comparable BMI reduction of 0.3 kg/m^2 was observed.[39]

When evaluating the effectiveness of an intervention, it is crucial to consider the comparability of the efforts exerted in the intervention group compared to the control group (usual care or no care). In several of the aforementioned trials, although the intervention proved effective compared to usual or no care, the dedicated efforts were not comparable. This factor may compromise the genuine efficacy of the new programme compared to previous ones, necessitating a more in-depth analysis on cost-effectiveness for widespread implementation. Our study stands out as the first to compare intervention groups that were under programmes of similar intensity. Consequently, we presume that the observed findings resulted from the motivational interview training and the support with educational materials, rather than any disparities in the dedication to intensify the intervention.

All in all, the intervention reported in this manuscript, along with those reported before, demonstrated limited success in terms of BMI change. However, it is essential to acknowledge the potential success of the intervention in preventing further BMI increase that might have occurred without treatment; therefore, the actual reduction achieved through the intervention could be greater than what was observed in the study.

4.2 | Barriers and solutions to implement childhood obesity interventions

When designing and implementing a childhood obesity treatment programme, a crucial consideration is the setting in which it takes place. In numerous countries, the most widely adopted healthcare monitoring system is primary care, which offers excellent accessibility to reach the maximum target population. A previous meta-analysis,[40] where brief interventions in primary care were analysed, the reported mean BMI *z*-score reduction was weak, at the level of −0.04 (−0.08, −0.01) SD. Paediatric primary care health providers have reported that training on patient-centred counselling improved their self-perception of self-efficacy.[41] Furthermore, paediatricians identified the perception of lacking sufficient time for counselling, limited access to support from dietitians and the non-availability of educational materials to assist families as the main barriers for treatment success.[41] Additionally, previous studies have demonstrated that involving dietitians trained in motivational interviewing can enhance the efficacy of interventions to treat childhood obesity in primary care.[38] Thus, using specialized paediatricians and dietitians to train primary healthcare professionals, equipping them with additional skills in motivational interviewing to treat childhood obesity, along with the provision of educational materials, has the potential to enhance the efficacy of interventions offered in this setting.

TABLE 3 Mixed models analyses on the effect of the intervention on anthropometrics reduction differences between groups.

Predictors	BMI (z-score) Estimate (95% CI)	*p*-value	BMI (kg/m²) Estimate (95% CI)	*p*-value	BMI (%) Estimate (95% CI)	*p*-value	Waist (cm) Estimate (95% CI)	*p*-value	Waist-to-height ratio Estimate (95% CI)	*p*-value
(Intercept)	−0.28 (−0.63, −0.07)	0.117	1.99 (0.20, 3.78)	0.029	7.77 (0.93, 14.62)	0.026	9.26 (3.94, 14.58)	0.001	0.01 (−0.02, 0.04)	0.583
Group	−0.11 (−0.20, −0.01)	**0.025**	−0.54 (−1.02, −0.06)	**0.028**	−2.06 (−3.89, −0.23)	**0.028**	−1.51 (−2.94, −0.08)	**0.039**	−0.01 (−0.02, −0.00)	**0.015**
Age (months)	0.00 (−0.00, 0.00)	0.599	−0.01 (−0.03, −0.00)	**0.032**	−0.05 (−0.10, −0.00)	**0.032**	−0.05 (−0.09, −0.02)	**0.005**	−0.00 (−0.00, 0.00)	0.185
Sex (girl)	0.07 (−0.02, 0.17)	0.120	−0.02 (−1.84, 1.80)	0.984	−0.02 (−1.84, 1.80)	0.984	−0.68 (−2.10, 0.74)	0.349	−0.00 (−0.01, 0.01)	0.933
Random effects for centre, *n* = 201 observations										
σ2	0.11		2.80		41.11		24.56		0.00	
τ_{00}	0.00		0.03		0.43		0.45		0.00	
ICC	0.02		0.01		0.01		0.02		0.02	
N centres	15		15		15		15		15	
Marginal R2/conditional R2	0.036/0.059		0.049/0.059		0.050/0.059		0.068/0.084		0.041/0.059	

Note: *E*: Estimate, *p*: *p*-value, age at enrolment. Significant effect estimates (*p*-value <0.05) on anthropometrical changes by the intervention are marked in bold numbers.

4.3 | Applicability and feasibility of Obemat2.0

In terms of applicability and feasibility of the programme, our study estimated a visit duration of 20 min, which was similar to other studies[42,43] and appears feasible for primary care centres. Although this study did not directly compare the duration of visits between the MI and control groups, a prior study noted that physicians employing techniques inconsistent with MI (such as giving advice without permission, etc.) tended to have longer visit encounters.[44] The positive perceptions of the HCPs regarding the usability of educational materials further reinforce the notion that this programme would be beneficial for the primary care practice. The fact that only a brief training in motivational interviewing, supported by educational materials, resulted in improved BMI *z*-score reduction, indicates that investing in training professionals on these skills could be cost-effective. Recently, Woolford et al.[45] reported a cost saving of $3159 per BMI percentile decrease per participant over 2 years by training paediatricians, nurse practitioners, and registered dietitians.

The short training on motivational interview to primary care professionals, along with the provision of educational materials, did not increase patient adherence to the therapy. Nevertheless, the higher recruitment by trained healthcare professionals could be interpreted as an indicator of their greater self-confidence in treating childhood obesity, which potentially facilitates success.[10,41]

4.4 | Limitations, strengths and transferability

The main limitation of the study is the high attrition rates. However, it is important to note that the observed rates align with those commonly observed in weight management programmes for children with obesity,[46,47] especially in primary care settings. To address this limitation, intention-to-treat analyses were conducted, which indicated that despite the small differences in BMI *z*-score reduction between groups, the implementation of the motivational intervention in primary care could yield significantly more effective results. Due to a high attrition rate, we cannot rule out the possibility of unreported emotional adverse events occurring in these children and adolescents. However, it is noteworthy that serious adverse events, such as eating disorders, were not reported.

On the other hand, the fact that paediatricians and nurses underwent brief training in motivational interviewing did not guarantee that interviews and/or communication were consistently motivational. Given the brevity of the training, it is quite likely that the communication skills were not highly improved over an extensive period in all the therapists. Furthermore, some therapists in the control group could have greater motivational interviewing skills than therapists receiving the brief training. Consequently, the authors speculate that providing more intensive or recurrent training on motivational interviewing could potentially enhance the efficacy of healthcare professionals.

Strengths from our study include the design employing similar intensity in both groups, a broader age range compared to previous

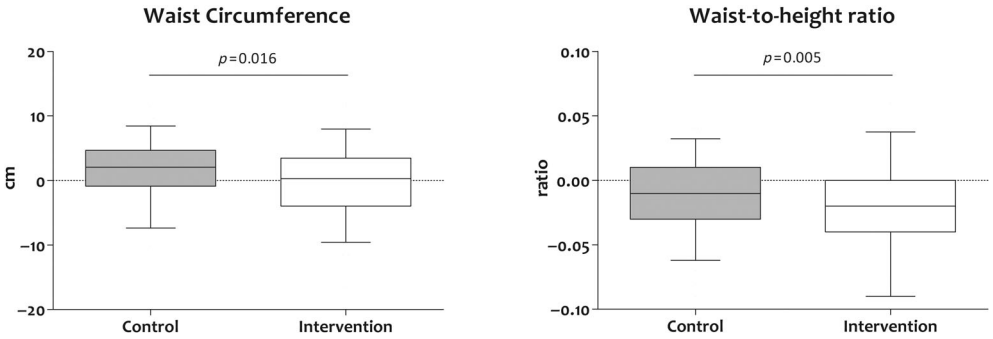

FIGURE 3 Change in waist circumference and waist-to-height ratio according to the intervention.

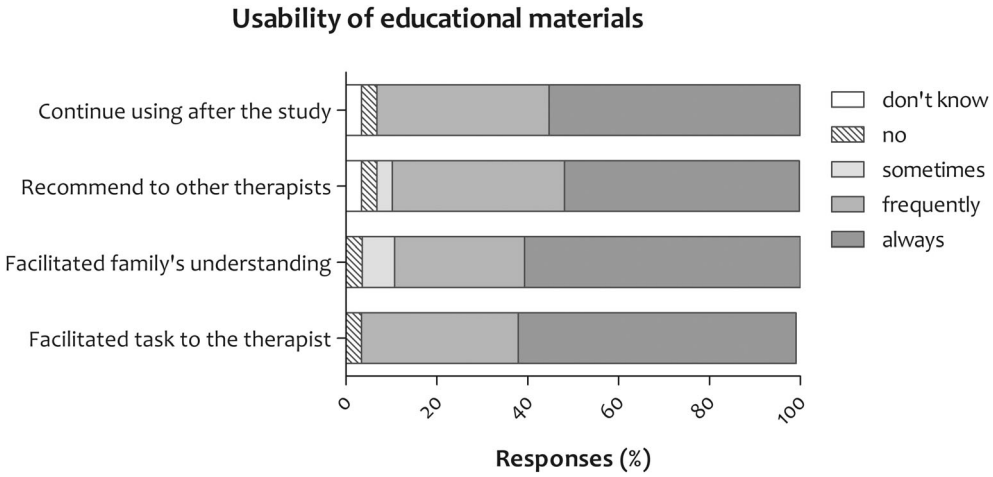

FIGURE 4 Therapists' experience with the usability of educational materials provided in Obemat2.0.

studies, and positive feedback regarding the programme's applicability. The authors presume that the results of this study may be applicable to other populations in similar settings, such as primary care centres conducting childhood obesity treatment programmes. The generalizability of the results to the wider population should be explored through implementation studies on a larger scale. In the meantime, for transferability of the present study's findings to the population, the authors published the educational materials.[22]

4.5 | Conclusion

In conclusion, providing training to healthcare professionals in patient-centred approaches to treat childhood obesity, utilizing the Obemat2.0 program and educational materials in a primary care setting, along with the support of dietitians, has the potential to enhance the efficacy of the multicomponent childhood obesity treatment.

AUTHOR CONTRIBUTIONS

VL, AF, NF, RC, JE and JB obtained funding and resources; VL and AF designed the study methodology; JM, DG, NG, PH, MG, MZ, CA, AS, MM, AA, EB, AB, SP, GM, SG, CT and MA performed data collection; VL, JM and MA performed data curation and analyses; VL drafted the manuscript; all the authors contributed to the manuscript and approved the final version.

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CONFLICT OF INTEREST STATEMENT

No conflict of interest was declared.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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