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Title - An Educational Intervention to Promote Healthy Lifestyles in Preschool Children: a cluster-RCT

Authors - Maurizio Iaia, MD[a], Melissa Pasini, RD[b], Antonella Burnazzi, RD[b], Patrizia Vitali, MSc[c], Elias Allara, MD[d,e], Massimo Farneti, MD[f].

Affiliations - [a]Primary Care Paediatrician and Community Paediatrician, Primary Care Department, Cesena, Forlì-Cesena, Italy; [b]Registered Dietitian, Dietetic and Nutrition Unit, Primary Care Department, Cesena, Forlì-Cesena, Italy; [c] Biostatistician, Epidemiology and Communication Unit, Public Health Department, Cesena, Forlì-Cesena, Italy; [d]PhD Student, Department of Public Health and Primary Care, University of Cambridge, Cambridge, UK; [e]Honorary Research Associate, Department of Translational Medicine, University of Eastern Piedmont Amedeo Avogadro, Novara, Italy; [f]Paediatrician, Director of Community Paediatrics Unit, Primary Care Department, Cesena, Forlì-Cesena, Italy

Corresponding Author - Maurizio Iaia, Unità Operativa Pediatria e Consultorio Familiare, Piazza Anna Magnani 146, I - 47522, Cesena, FC, Italy Tel.: +39 3476875959

E-mail: maurizio.iaia@auslromagna.it

Short title - A c-RCT on Preschool Children's Healthy Lifestyles

Acronyms / Abbreviations Used - AAP - American Academy of Paediatrics; BMI - Body Mass Index; CI - Confidence Interval; c-RCT - Cluster Randomized Controlled Trial; CHBS - Combined Health Behaviour Score; FV - Fruit and Vegetable; IOTF - International Obesity Task Force; ICC - Intra-cluster Correlation Coefficient ; ISS - Italian National Institute of Health; ITT - Intent to Treat; MI- Motivational interview; SHBS - Single Health Behaviour Score; SSB - Sugar-Sweetened Beverages; h/d - hours per day; d - day; RWG - Rapid Weight Gain;

Keywords - childcare centre, cluster randomized controlled trial, healthy lifestyles, motivational interviewing, obesity, preschool children, prevention, primary care

Funding - In September 2012, OROGEL S.p.A., a company based in via Dismano 2600, I-47522, Cesena, Forlì Cesena, Italy, granted €10,000 in support of our educational intervention. This sponsor played no role in designing and conducting our study; collecting, managing, analysing and interpreting its data; and preparing, reviewing and approving our paper.

Financial Disclosure - We, the authors, have no financial relationship relevant to this publication.

Conflict of Interest - The authors declare no conflict of interest.

Clinical Trial Registry Number - ACTRN12614000850673

Contributor's Statements

Maurizio Iaia - Dr Iaia promoted the idea for this study and its design and developed its score system for the evaluation of the intervention's effects on behaviours. He drafted the manuscript, coordinated the implementation of the intervention study and he is also the author of two versions of a manual guide "*5210 messaggi in codice per crescere in salute*" (one for medical staff and one for parents and teachers).

Melissa Pasini, Antonella Burnazzi - Drs Pasini and Burnazzi contributed to the study design and coordinated its implementation. They also measured children's weight and height at child care centres and they entered all the data into our database for statistical analysis.

Patrizia Vitali - Dr Vitali contributed to the statistical analysis model and carried out the statistical analysis of the results.

Elias Allara - Dr Allara contributed to our statistical analysis model and thoroughly reviewed our paper.

Massimo Farneti - Dr Farneti contributed to our study design and thoroughly reviewed our paper.

All the previously mentioned authors approved the final paper version as submitted and agreed to be held accountable for all its contents.

As a result, Dr M. Iaia has had full access to the data of the study and he is responsible for submitting this manuscript for publication.

ABSTRACT

Objective - Promoting 4 healthy behaviours among preschool children: ≥ 4 servings of fruit and vegetables/day, ≥ 2 h/day of active play, ≤ 1 hour/day of TV-watching and 0 sugar sweetened beverages/day.
Methods - We conducted a c-RCT on 425 three-year-old children at 16 childcare centres based in Cesena, Italy. We randomly allocated 8 childcare centres (199 children) to the intervention group and 8 childcare centres (226 children) to the control group. All the randomized childcare centres completed our study protocol. Parents recorded their children's target behaviours at home over 3 Saturdays, at baseline and at follow-up. Then trained nurses measured children's weight and height. We conducted a 6-month-long intervention trial in local health care centres where nurses and primary care paediatricians respectively conducted 2 subsequent motivational interviews with parents to encourage children's healthy behaviours at home. At the same time, teachers involved children in learning experiences about healthy behaviours. Our primary outcome is a children's combined health behaviour score (CHBS) at home. Our secondary outcomes measure the BMI z-score and the percentage of children that show a BMI trajectory crossing upward. After collecting CHBS and BMI data at baseline as well as at 1 and 2-year follow-ups, we performed an Intent-to-Treat (ITT) analysis.
Results - After 2 years from baseline, 48.4% of intervention group children showed a low-risk CHBS in comparison with 28.0% of control group children. A multilevel analysis showed that they were by far more likely to achieve low-risk scores (adjusted OR 3.41; 95% CI: 1.48-7.88; p 0.004). Our BMI outcomes showed no significant difference between groups.
Conclusions - A multidimensional educational intervention, which consists of motivational interviews with parents and teacher-led learning experiences for children, improved preschool children's CHBS in the long term without influencing the outcomes of BMI z-score and BMI increase.
Trial registration number: ACTRN12614000850673

An Educational Intervention to Promote Healthy Lifestyles in Preschool Children: a cluster-RCT

Maurizio Iaia, MD[a], Melissa Pasini, RD[b], Antonella Burnazzi, RD[b], Patrizia Vitali, MSc[c], Elias Allara, MD[d,e], Massimo Farneti, MD[f].
Affiliations - [a]Primary Care Paediatrician and Community Paediatrician, Primary Care Department in Cesena (FC), Italy; [b] Registered Dietitian, Dietetic and Nutrition Unit, Primary Care Department in Cesena (FC), Italy; [c] Biostatistician, Epidemiology and Communication Unit, Public Health Department in Cesena (FC), Italy; [d] Senior Registrar in Public Health, School of Public Health, University of Turin in Turin, Italy; [e] Research Associate, Department of Translational Medicine, University of Eastern Piedmont in Novara, Italy; [f] Paediatrician, director of Community Paediatrics Unit, Primary Care Department in Cesena (FC), Italy

Correspondence - Dr M. Iaia, Primary Care Paediatrician and Community Paediatrician, Primary Care Department in Cesena, Forlì-Cesena, Italy; e-mail: maurizio.iaia@auslromagna.it

Obesity affects a growing number of children in early childhood. Obese preschool children tend to be obese during adolescence and adult age and are at high risk of comorbidities later in life[1-3]. It is also noteworthy that there is a strong association between adiposity rebound affecting children younger than 5 years of age with later onset of obesity and a higher risk of future occurrence of metabolic syndrome[4].

Early childhood is a critical time for preventing an obesity trajectory that is difficult to modify when children start elementary school. A Cochrane review[5] suggests that obesity prevention interventions may achieve the largest effect size in the first 5 years of life. For this reason, in 2011 an American Expert Committee of the Institute of Medicine (IOM) gave evidence-based recommendations for that age[2]. Children learn lifestyles during the first years of life from the adults who care for them. In their families, preschool children mainly develop eating and activity patterns from mimicking their parents' behaviours[2.]. Teachers also play a significant role because they provide models that can influence most children who spend many hours a day in childcare centres[6,7]. Health and education professionals providing guidance to parents of young children should be trained so as to promote healthy lifestyles.

Many modifiable lifestyle behaviours, such as low levels of physical activity, too much TV/videos, high intake of sugar-sweetened beverages (SSB) and, to a lesser extent, low fruit and vegetable (FV) intake, are associated with unhealthy weight gain in early and late childhood[8-12].

In 2011, in Cesena, Forlì-Cesena, Italy, we found that the prevalence of overweight and obese children (according to the cutoffs by international Obesity Task Force –IOTF[13]) was respectively 5.9% and 1.2% among two-year-old preschool children. Its value increased up to 11.7% and 5.1% among five-year-old preschool children. This trend highlights that the overweight prevalence doubled and the obesity prevalence increased by five times among older preschool children[14].

Furthermore, an Italian survey on eating and activity habits among a representative sample of school children living in Emilia Romagna, Italy[15] found that families' unhealthy lifestyles were also common among children in their later childhood.

On the basis of all the previous remarks, the local Primary Care Department in Cesena, Forlì-Cesena, Italy, put together our paediatric team that conceived a project aimed at implementing a community multi-level and multi-component obesity prevention intervention programme.

Our educational intervention tried to reach out to families and childcare centres and involved a large and representative population of 3-year-old children attending a childcare centre for 6-8 h/d.

To set 4 goals for healthy behaviours, we initially referred to the 5210 programme issued by the American Academy of Paediatrics (AAP) in 2007[11], which aims at preventing obesity among

children aged 2-18. According to its recommendations, children should eat ≥ 5 FV servings/d, spend no more than 2 h/d in front of a screen, do physical activity 1 h/d and take little or no SSB/d. Additionally many governments[16-18] issued new guidelines for early childhood obesity prevention. We accordingly adjusted the 5210 programme instructions to the young age of our intervention study participants.

Our study set out to promote the following healthy behaviours among 3-year-old preschool children: ≥ 4 FV servings/d, ≥ 2 h/d of active play, ≤ 1 h/d of TV-watching, and 0 SSB intake/d. Not only did we assess its effectiveness, but we also provided a breakdown of the costs of the educational intervention conducted by primary care paediatricians, paediatric nurses and childcare centre teachers.

Methods

Randomizing and Masking

In October 2012 we conducted our cluster randomized controlled trial (c-RCT) on 3-year-old children born in 2009 and attending the first session of public childcare centres (clusters) in Cesena, Forlì-Cesena, Italy. A person not involved in the study used a computer to create an allocation table to randomly allocate 8 clusters to the intervention group and 8 clusters to the control group.

Each cluster aimed to include at least 15 three-year-old children to be eligible for our trial.

Eligibility criteria for participants were: no chronic medical condition precluding them from study participation; being Italian or Italian-speaking foreign families.

We informed all childcare centre directors about our study procedures. They all agreed to take part in it without knowing the random allocation of their centres. We did not provide parents with any information about their children's allocation before we achieved their parental consent.

Our study evaluated a 6-month-long educational intervention for children at childcare centres and their parents in local primary care settings. We evaluated our outcomes after 1 and 2 years from baseline. Our analysis included all the participants initially recruited in compliance with the Intention-to-treat (ITT) method. We presented our research findings in compliance with CONSORT guidelines for c-RCT's[19].

The local Ethics Committee approved our study protocol.

Figure 1 shows the participant flow through the trial.

Measurements

We recorded children's measurements at baseline and follow-up.

Parents kept a diary (previously tested with a sample of parents in a pilot study[14]) to record their children's eating habits and activity behaviours at home on the last Saturday of October and the first 2 Saturdays of November when children were not at childcare centres (closed on Saturdays). We did not take measurements on Sundays because eating habits of Italian families are traditionally very different on Sundays and public holidays.

We retained the average results for each behaviour for the final analysis.

Besides the diaries we used a recall[14,20,21] to evaluate active play and TV-watching time.

Additionally, we asked if there was a TV in children's bedrooms.

At childcare centres trained nurses used a stadiometer and a digital scale to record children's height and weight (children should not wear shoes and heavy clothing). For this purpose the Italian National Institute of Health supplied high-precision instruments (SECA 872™ scale and SECA 214™ stadiometer). Height was measured to the nearest 1.0 mm and weight was measured to the nearest 0.1 kg. We calculated BMI units and age and sex-specific BMI categories according to the cut-offs issued by IOTF in 2012[13].

Parents' measurements at baseline included self-reported weight and height (used to calculate BMI), level of education and employment status.

Table 1 shows a summary of all baseline measurements.

After 2 years from follow-up we also used a standard Likert scale for parents and teachers to evaluate their degree of appreciation for our intervention study.

Intervention

We carried out our intervention study from November 2012 to May 2013. To make it sustainable, we arranged it in existing local health care centres. Its components included:

a) 2 face-to-face motivational interviews (MI)[22] with parents (of approximately 20 min. each) - Paediatric nurses conducted the first MI. After 1-2 months, primary care paediatricians carried out the second MI to help families increasingly adopt healthy lifestyles. A preliminary analysis

of the children's diaries, which parents had given back before the first MI, helped us find out and address specific unhealthy behaviours. To accomplish this step, 9 nurses and 21 paediatricians received 2 different 20-hour-long trainings led by MI specialists. MI is a communication technique that enhances self-efficacy and helps families identify their own motivation for a change in their lifestyles[11,22].

b) Information tools - We created information tools specific for parents and teachers such as a leaflet for parents, a manual for parents and teachers[23], a poster highlighting 4 key behaviours to be displayed in waiting rooms of paediatric clinics and in childcare centre halls.

c) Learning experiences at childcare centres.

Teachers got a 10-hour-long training to promote more active play at childcare centres and inserted this subject into their annual educational timetables. Children and teachers also engaged in learning experiences (approx. 1 h/d) to achieve the following 3 behaviour goals:

• *Increasing FV intake* - to do this, children were supported by their teachers into adopting the following experiences: eating vegetables first at lunch, be repeatedly exposed to new FV, tending vegetable gardens, inventing and playing stories with FV characters and making creative experiences with FV. Moreover teachers repeatedly allocated “good FV-eaters” to different tables so as to raise the FV intake among “bad FV-eaters”;

• *Reducing time spent watching TV* - to do this, teachers launched a book-lending initiative among parents in order to stimulate interactive reading of specific books with their kids at home and reduce the time spent watching TV; and

• *Limiting SSB intake* - to do this, children drank water as the only beverage at special events, such as birthdays or parties, at childcare centres.

Peer imitation and teachers' good models provide children with a social learning setting that facilitates the development of healthy eating and activity patterns. This effect could also be magnified at home if both teachers and primary care paediatricians support parents in having healthy lifestyles.

Our intervention was supposed to be successfully completed after meeting all the following conditions: completing behaviour diaries at least on 2 out of 3 Saturdays; parents' participation in 2 MI sessions; at least one learning experience for each behaviour goal at childcare centres.

We offered to control children's parents routine health care advice during child health visits. At the same time control children were involved in the usual learning experiences at childcare centres.

Outcomes

Positive energy balance and unhealthy weight gain depend on the interaction between physical activity, sedentary lifestyle and eating habits.

On the basis of the best available evidence we firstly defined the best behaviour patterns that can restrict the development of unhealthy weight gain. We created an “ad hoc” score system to assess children's behavioural risks as either low, moderate, or high for each of the 4 target behaviours (see below) as well as for their combinations.

We considered ≥ 4 servings/d of FV as a realistic cut-off among preschool children (instead of ≥ 5 servings/d); we took into account that an average Italian FV serving is almost twice as much the amount generally recommended by many diet guidelines of other countries and WHO.

Evidence-based guidelines suggest that children aged 2 - 5 years should engage in ≥ 2 h/d of active play [2,6,16,17] and limit their TV-watching time to ≤ 1 h/d[18].

Then we set 0 servings of SSB per day as the gold standard. Preschool children that drink SSB regularly (versus infrequent/non-drinkers) show both cross-sectional[2] and prospective[10] correlations with higher BMI z-scores.

Our primary outcome is a children's combined health behaviour score (CHBS) at home. This marker is associated with all 4 targeted behaviours. To calculate it, we first assumed that the lowest behavioural risk of unhealthy weight gain involves ≥ 4 FV servings, ≥ 2 hours of active play, ≤ 1 hour of TV-watching, and 0 servings of SSB per day. Secondly, we set up the following risk score system for each behaviour: 0 healthiest behaviour, 1 moderately healthy behaviour and 2 least healthy behaviour. Thirdly, we summed up the scores of each behaviour to achieve the final value of CHBS (from 0 to 8). Fourthly, we sorted the final values out by 3 main levels of behavioural risk (0-2= low; 3-5 = medium; 6-8**=** high).

Every single health behaviour score (SHBS) that helped achieve the final CHBS was a secondary outcome. When we carried out the analysis of the behavioural outcomes, we used a simplified dichotomous criterion and we compared children that achieved low-risk scores with children that achieved medium / high-risk scores.

Then we measured the percentage of children with a TV in their bedrooms, as well.

Our secondary outcomes included anthropometrical parameters, such as:

- Change in BMI z-score: we used CDC 2000 Reference to convert BMI into an age- and sex-specific BMI z-score;

- Change in BMI units[24]; and

- Percentage of children showing a BMI increase ≥ 0.1 Kg/m² and ≥ 1 standard deviation (the latter value indicates a *rapid weight gain*-RWG[25]). A BMI increase during a growth span, in which BMI normally physiologically decreases, is useful to detect a risky weight gain in early childhood even before a child reaches overweight or obesity cut-offs.

Sample Size Calculation

We calculated sample size with a method that takes into account the intracluster correlation coefficient (ICC) of the dichotomized primary outcome, the average number of children per cluster, the outcome odds in both control and intervention groups and $Z_{a/2}$ and Z_b on the basis of a normal distribution[26-28].

We assumed an intracluster correlation coefficient (ρ= 0.012[14]), a minimum number of participants (at least 15 children) per cluster and an expected rate of 45% of intervention group children and 30% of control group children showing a low-risk CHBS (our primary outcome) with 80% power at an alpha level of 0.05 after 1 and 2 years from baseline. On the basis of those assumptions, we needed 8 clusters for both groups[14].

Statistical Methods

We performed descriptive statistical analyses to sum up the main characteristics of the study sample. To test differences in baseline distribution of outcomes and other predictors of interest, we used chi-square or t test, according to the type of variable, with the appropriate degrees of freedom.

To examine the hierarchical data structure (children's measurements, child, childcare centres), we applied a 3-level linear model, though preferring a 2-level model that used children as random effect because of a school random effect near to 0. We provided both multilevel models: a random intercept model and a random intercept and slope model. We chose the first model in order to apply a principle of parsimony. To compare both models, children's ICC was reported along with a likelihood ratio test.

CHBS, a model for binary data, was adjusted for mothers' levels of education (low level: ≤ 8 years at school; mid/high level: > 8 years at school), children's gender and baseline BMI. A model for continuous data was fitted for BMI and BMI z-score, adjusted for mothers' levels of education and children's gender.

We carried out a sensitivity analysis and replaced any missing data in the intervention group with average values from CHBS, BMI, BMI z-scores in the control group for the same sex, age and the mothers' levels of education. Our results were the same.

We used STATA 12 to perform every analysis.

Results

Figure 1 shows the participant flow through the trial. We conducted our c-RCT on 425 three-year-old children at 16 childcare centres - out of 27 potentially eligible ones - that met our eligibility criteria and are based in Cesena, Forlì-Cesena, Italy. We randomly allocated 8 childcare centres (199 children) to the intervention group and 8 childcare centres (226 children) to the control group.

All the randomized childcare centres completed our study protocol.

5 children (3%) in the intervention group and 31 children (14%) in the control group were not involved in our trial because their parents did not allow them to take part into our c-RCT.

Table 1 shows no differences between the groups in the children's baseline characteristics. 48% were girls. Almost all the children were Italian.

There was a higher percentage of overweight and obese fathers (IOTF cut-offs) in the intervention group compared to the control group: 55% vs 36.4% overweight and 7.7% vs 4.1% obese ($\chi^2 = 7.34$; p 0.025).

A significantly higher percentage of children with a low-risk CHBS was found in the intervention clusters at 1 and 2-year follow-up (see Table 2): after 2 years from baseline 48.4% of children in the intervention group had a low-risk CHBS vs 28.0% of children in the usual care (p = 0.000). When we evaluated the effectiveness of our intervention study on the basis of mothers' level of education, we achieved significantly positive results only among those children whose mothers had a medium / high level of education (> 8 years) (see Figure 2 A, B). A higher percentage of intervention in comparison with usual care children showed a low-risk score for FV (≥ 4 s/d: 19.9% vs 9.5%; p=0.008) and sugar-sweetened beverage intake (0 glasses/d: 90.7 % vs 78.6%; p=0.002) at 2-year-follow-up. A low-risk score for active playtime was more frequent in intervention versus control children only at 1-year follow-up, without significant accidental physical injuries. As far as TV-watching time is concerned, there was no difference (see Table 2). The percentage of families without a TV in their children's bedrooms showed no differences at 1-year follow-up but it was significantly higher in the control group at 2-year follow-up.

Unadjusted odds ratio for low-risk CHBS showed a significant improvement in the intervention group compared to the control group at 2-year follow-up (see Table 3). Moreover, a multilevel analysis adjusted for potential confounders (mothers' levels of education, children's gender and baseline BMI) confirmed that low-risk CHBS is more likely in the intervention group than in the control group (adjusted OR 3.41; 95% C.I.: 1.48 - 7.88; p = 0.004) at 2-year follow-up (see Table 3). We also observed that those children, whose mothers have a medium / high level of education, are more likely to have a low-risk CHBS (OR = 2.56; p = 0.009). The ICC was 52% and the likelihood ratio test of the random intercept model compared to the linear regression model was significant (χ^2 = 95.7, p=0.000). The long-term effectiveness of the intervention did not vary significantly in random intercept and slope model. Our likelihood-ratio test was significant (χ^2 = 79.20, p=0.000). In both models we achieved similar results: the intervention group showed greater odds of low-risk CHBS than the control group at 2-year follow-up (adjusted OR 3.25; p=0.005) and among those children whose mothers have a medium / high level of education (OR=2.48; p=0.006).

As far as BMI z-score (see Figure 2 C) and BMI units (see Table 2) are concerned, we found no significant difference between groups at 1 and 2-year follow-ups, both in unadjusted and adjusted multilevel models (see Table 3) and in an analysis sorted out by the mother's level of education. The percentage of children in the intervention group who showed RWG (increase in BMI ≥ 1 SD) was smaller (not significant) than the one in the control group at 2-year follow-up (9.9 vs 14.1%). However, an identical percentage of children showed a BMI increase ≥ 0.1 kg/m² in both groups.

Table 4 shows only the cost breakdown associated with our intervention, should it be carried out again in the future. However, it does not show one-off costs, such as project planning, database management, statistical analysis, production of education materials.

Discussion

This is the first c-RCT that aims at assessing the effects of a combined educational intervention carried out by primary care paediatricians and childcare centre teachers on an unparalleled large population of 3 year-old children and their parents. On the basis of evidence, it successfully changed 4 energy-related behaviours in the medium and long term: FV intake, physical activity, TV watching time and SSB intake. After 2 years from baseline - 18 months after the intervention end – significant and beneficial changes in target behaviours and their CHBS took place among those intervention children whose mothers had a medium / high level of education. However no significant change in BMI outcomes occurred. Our study confirmed that it is difficult to successfully bring about anthropometric changes, as a systematic review of intervention studies for preventing obesity among preschool children[29] aged 3-6 years has recently reported. Nevertheless, we found that a lower, yet statistically insignificant, percentage of intervention group children showed RWG in comparison with usual care children.

We observed a lack of significant changes in behaviour among those children whose mothers had a low level of education (23% of mothers had ≤ 8 years of education). This result compels for the planning of educational programmes specifically designed for mothers with low levels of education.

Moreover, future investigation should use reliable indicators for preschool children's physical activity and FV intake to minimise any risk of bias, such as parents self-reporting their children's

behaviours, and to appropriately assess relationships between parents' / childcare teachers' specific activities and subjects and children's behaviour changes. For this reason, we suggest 2 validated methods for preschool children: accelerometers and Resonance Raman Spectroscopy (RRS) technology. On the one side accelerometers can detect low, medium, and high levels of physical activity as well as sedentary time[30]. On the other side, RRS is an inexpensive, non-invasive technique for measuring carotenoid status in the skin (hand palms) and it is used as valid biomarker of FV intake[31].

Our study has strengths and weaknesses

Its strengths include:

1) The design of c-RCT provides a gold standard for studies to establish the relationship between cause and effect, and in particular between an intervention aimed at promoting health in a community and its outcomes at group level; 2) Its sample size is large; 3) It has a long-term follow-up. Most intervention studies assess behavioural outcomes in the short term so that it is very likely they show beneficial changes in children's lifestyles. Unlike those studies, our study revealed that children led healthy behaviours until at least 18 months from the intervention's end; 4) Our study launched an unprecedented education initiative: district nurses, primary care paediatricians and childcare centre teachers received a professional training course to improve their basic educational skills. They experienced a new way of co-working and formed a multilevel educational network in routine local health-promotion services; 5) Scientific research has recently revealed that multidimensional and multicomponent interventions are especially effective in early childhood [32]; 6) It can achieve great generalizability in developed countries because primary care paediatricians / general practitioners examine all preschool children and most of those children attend a childcare centre; and 7) All the parents and teachers expressed a medium / high degree of appreciation about our intervention.

Its weaknesses include:

1) Parents self-reported their children's behaviours. This indicator is not objective and can have a potential bias; 2) We could not validate our primary outcome of CHBS although it is based on an evidence-based approach to 4 energy balance-related behaviours[2,7-11]; 3) Nurses and

paediatricians had no or poor previous experience in MI. This could have limited the effectiveness of the intervention; and 4) We suffered a significant loss of data at follow up. Nevertheless, the ITT approach is likely to have successfully accounted for potential attrition bias.

Conclusions

Scientific research has shown that early childhood obesity prevention interventions (0-5 years) are associated with more effectiveness, and in particular when they combine home and school[5,32]. However, clear insights in basic behavioural and biological mechanisms of obesity development during the first years of life are still lacking and most obesity prevention programs have been focusing on school children. Our study was a multicomponent / multidimensional educational intervention that focused on preschool children and their parents. It was included in routines for local health care services and childcare centres, and it consisted of motivational interviews with parents and teacher-led learning experiences for children. On this basis we found that it improved preschool children's CHBS in the long term, but it achieved no significant improvement in BMI outcomes.

Acknowledgments

We are grateful to the following primary care paediatricians and paediatric nurses who work in Cesena, Forlì-Cesena, Italy, carried out MI's with parents and completed a crucial component of our intervention trial.

Paediatricians: Arturo Alberti, Antonio Belluzzi, Rita Casalboni, Giancarlo Cerasoli, Antonella De Pascale, Mila Degli Angeli, Paolo Faberi, Clara Faedi, Alessandra Foschi, Maurizio Iaia, Elide Lucchi, Marna Mambelli, Franco Mazzini, Marco Minghetti, Giuseppina Mingozzi, Loreta Piccolo, Barbara Poggioli, Antonella Stazzoni, Pierluigi Tonti, Miro Trebbi, Francesca Vaienti, Silvia Valentini.

Nurses: Tosca Alessandrini, Patrizia Amaduzzi, Monica Bertozzi, Flavia Bonavita, Roberta Bracci, Barbara Gori, Fiammetta Mazzotti, Roberta Ruffilli, Milva Silvani.

We thank the following colleagues for their effective cooperation that helped us conduct our study:

Gianpaolo Guelfi, psychiatrist who led the *Motivational Interviewing* training for primary care paediatricians; Francesca Castoldi and Emanuela Baldassarri, psychologists who led a similar training course for nurses;

Dr. Lorena Quaranta, Health Education Office Coordinator, who gave her support to planning information tools for parents and teachers;

Dr. Rita Scalambra, Uisp (Unione Italiana Sport per tutti - Italian Sports Union for Everyone), who led a training course about the *Promotion of Physical Activity among Preschool Children* for childcare centre teachers; and all the directors and teachers of the 16 randomized childcare centres.

We are also grateful to Leonardo Grilli, Associated Professor in Statistics, Department of Statistics, Information Technology, Applications “G.Parenti” University of Florence, for his helpful suggestions on designing the statistical analysis model.
Dr. Iaia is grateful to Giancarlo Biasini, Senior Professor of Paediatrics, for his constructive suggestions.

Conflict of Interest - The authors declare no conflict of interest.

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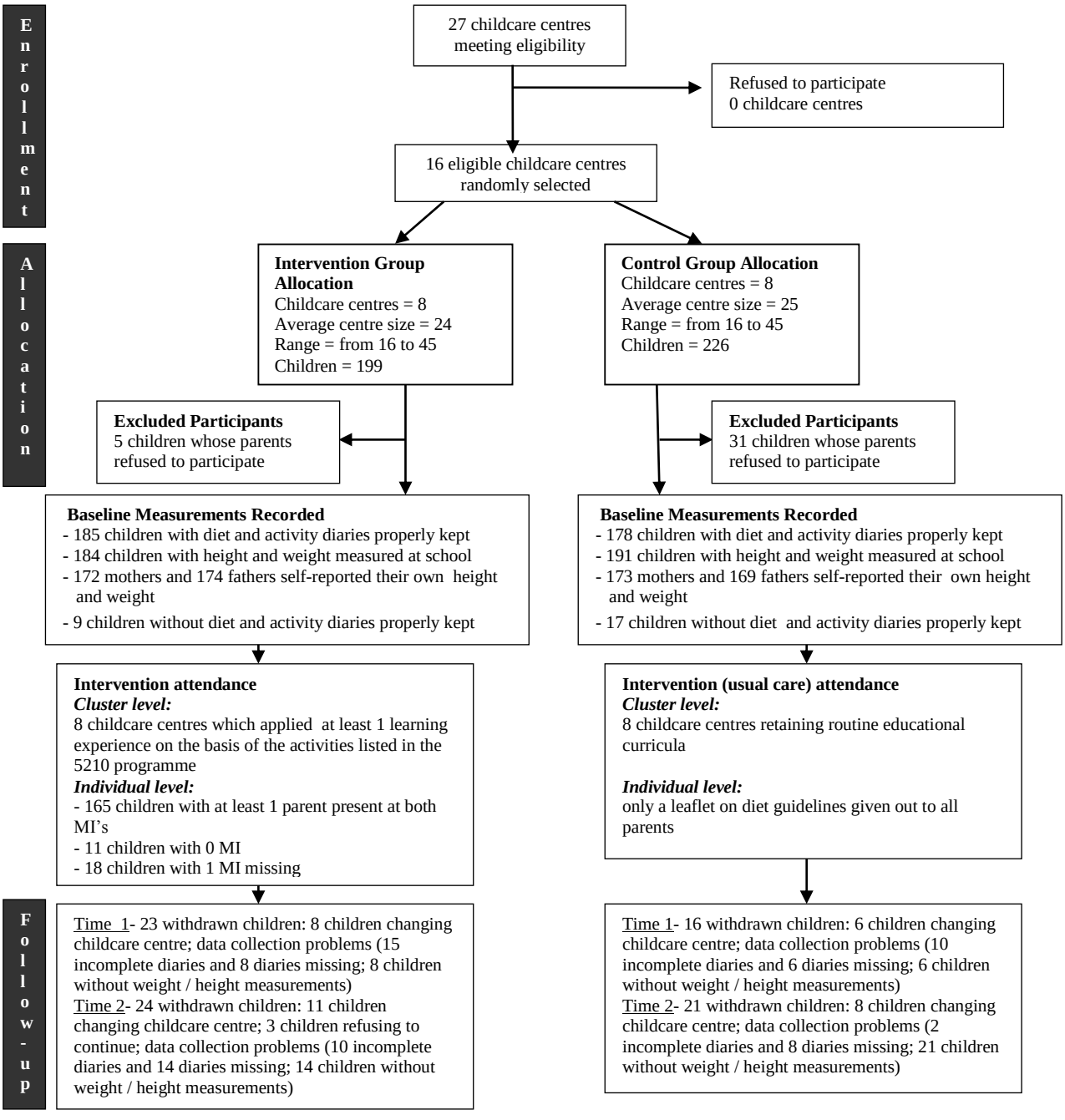
Captions

Figure 1 - Participant flow through the trial

Figure 2 - Children with a low-risk CHBS sorted out by their mother's levels of education and mean BMI z-score (males and females together): A) No intervention effect is noticeable if their mothers have a low level of education. B) The intervention effect is significant at 2-year follow-up if their mothers have a medium or high level of education. C) There is no significant difference in BMI z-scores between the groups at 1 and 2-year follow-ups.



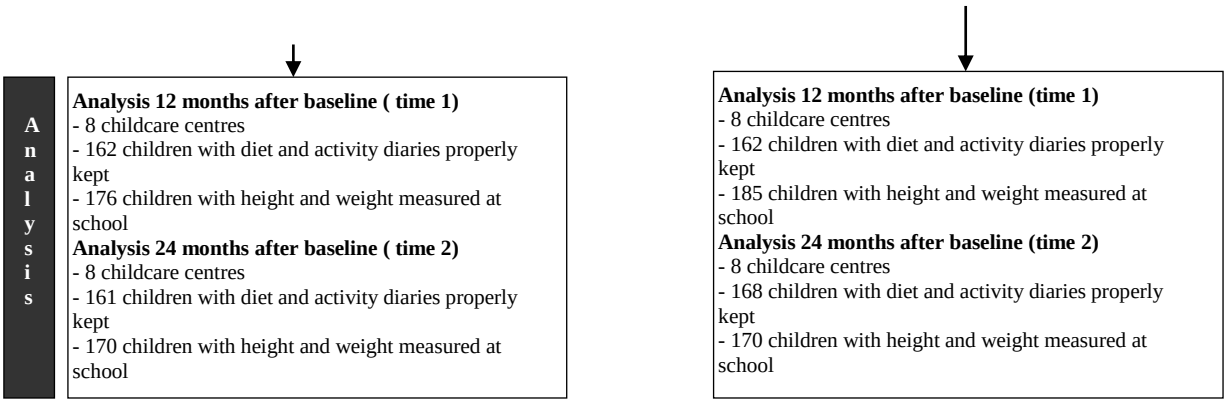
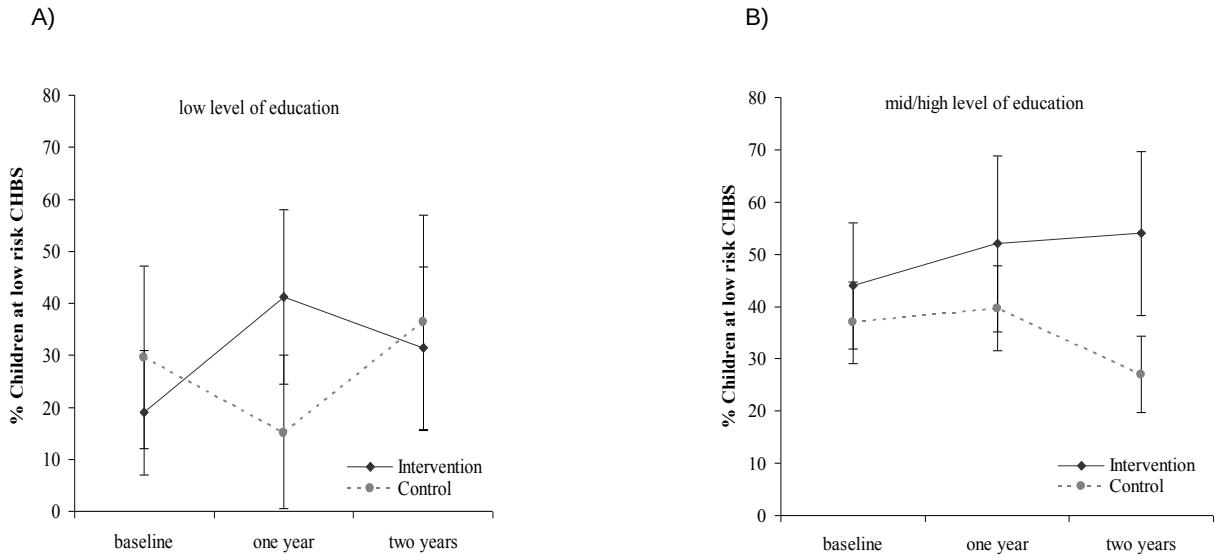


Figure 1 - Participant flow through the trial



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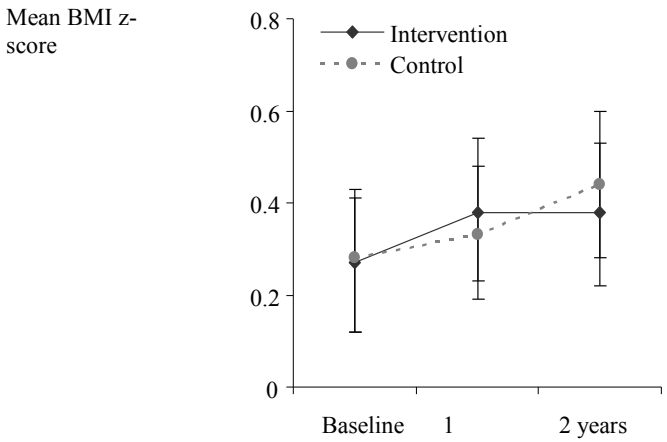

Figure 2 - Children with a low-risk CHBS sorted out by their mother's levels of education and mean BMI z-score (males and females together): A) No intervention effect is noticeable if their mothers have a low level of education. B) The intervention effect is significant at 2-year follow-up if their mothers have a medium or high level of education. C) There is no significant difference in BMI z-scores between the groups at 1 and 2-year follow-ups.

Table 1 – Children and parents baseline characteristics for overall and by intervention assignment

	Amount (%)				
	Intervention	Control	Total		
	(n = 194)	(n = 195)	(n = 389)	χ^2/ t test	*p-value*
Children's Characteristics					
Mean Age (SE)	3.39 (0.02)	3.43 (0.01)	3.41 (0.09)	t = 1.22	*0.22*
Sex					
F	98 *(50.5%)*	89 *(45.6%)*	187 (48%)	χ^2 = 0.926	*0.336*
M	96 (*49.5%)*	106 *(54.4%)*	202 (52%)		
Race / Ethnicity					
Italian	175 *(90.7%)*	178 *(91.8%)*	353 (91.2%)	χ^2= 0.141	*0.708*
Foreign	18 *(9.3%)*	16 *(8.2%)*	34 (8.8%)		
Mean BMI (SE)	16.2 (0.10)	16.2 (0.10)	16.2 (0.07)	t = 0.33	*0.74*
Mean BMI z-score (SE)	0.27 (0.07)	0.28 (0.08)	0.28 (0.03)	t = 0.09	*0.92*
BMI category (cut-offs IOTF 2012)					
Normal	156 *(84.7%)*	162 *(84.8%)*	318 (84.8%)	χ^2 = 1.07	*0.59*
Overweight	25 *(13.6%)*	23 *(12.0%)*	48 (12.8%)		
Obese	3 *(1.6%)*	6 *(3.1%)*	9 (2.4%)		
Children's healthy behaviours:					
FV intake s/d	2.4 (0.9)	2.3 (0.9)	2.4 (0.7)	t = -0.288	*0.773*
Active playtime min/d	134.7 (5.6)	133.3 (5.8)	134 (4.0)	t = -0.16	*0.866*
TV-watching min/d	97.8 (4.3)	104.5 (4.6)	101.1 (3.2)	t = 1.069	*0.286*
SSB intake s/d	0.38 (0.04)	0.35 (0.04)	0.36 (0.03)	t = -0.51	*0.608*
TV in children's bedrooms					
No	149 (83.7%)	150 (89.8%)	299 (86.7)	χ^2 = 2.79	*0.095*
Yes	29 (16.3%)	17 (10.2%)	46 (13.3)		
Parents' Characteristics					
Mothers					
Mean BMI (SE)	22.4 (0.28)	22.80 (0.32)	22.6 (0.21)	t = 1.18	*0.23*
BMI category					
Normal (BMI < 25 kg/m²)	139 (80.4%)	127 (73.8%)	266 (77.7%)	χ^2 = 5.51	*0.111*
Overweight (BMI 25-29.9 kg/m²)	26 (15.1%)	36 (20.9%)	62 (18.0%)		
Obese (BMI ≥ 30 kg/m²)	8 (4.6%)	9 (5.2%)	17 (4.9%)		
Level of education					
None	5 (2.6%)	0 (0%)	5 (1.3%)	χ^2 = 7.493	*0.112*
Primary school	1 (0.5%)	2 (1.1%)	3 (0.8%)		
Secondary school	39 (20.2%)	28 (15.0%)	67 (17.6%)		
High school	96 (49.8%)	98 (52.4%)	194 (51.1%)		
Graduation	52 (26.9%)	59 (31.5%)	111 (29.2%)		
Employment status					
Working full-time	87 (47.8%)	73 (42.0%)	160 (44.9%)	χ^2 = 5.063	*0.08*
Working part-time	48 (26.4%)	65 (37.3%)	113 (31.7%)		
Unemployed	47 (25.8%)	36 (20.7%)	83 (23.3%)		
Fathers					
Mean BMI (SE)	26.0 (0.23)	25.2 (0.22)	25.6 (0.16)	t = -2.44	*0.01*
BMI category					
Normal (BMI < 25 kg/m²)	63 (37.3%)	85 (43.6%)	148 (44.4%)	χ^2 = 7.34	*0.025*
Overweight (BMI 25-29.9 kg/m²)	93 (55.0%)	71 (36.4%)	164 (49.3%)		
Obese (BMI ≥ 30 kg/m²)	13 (7.7%)	8 (4.1%)	21 (6.3%)		
Level of education					
None	5 (2.8%)	0 (0%)	5 (1.4%)	χ^2 = 9.018	*0.061*
Primary school	0 (0.0%)	3 (1.8%)	3 (0.9%)		
Secondary school	57 (31.7%)	58 (34.5%)	115 (33.1%)		
High school	83 (46.1%)	69 (41.1%)	152 (43.7%)		
Graduation	35 (19.4%)	38 (22.6%)	73 (21.0%)		
Employment status					
Working full-time	170 (93.4%)	154 (90.6%)	324 (92.1%)	χ^2= 2.784	*0.249*
Working part-time	6 (3.3%)	12 (7.1%)	18 (5.1%)		
Unemployed	6 (3.3%)	4 (2.3%)	10 (2.8%)		

Table 2 - Amount and percentage of children with a low risk of CHBS and SHBS, TV in bedroom, mean values (95% C.I.), BMI score and BMI z-score (at baseline and follow-up)

	Baseline			1 year			2 years		
	Intervention N (%)	**Control N (%)**	**P value §**	**Intervention N (%)**	**Control N (%)**	**P value §**	**Intervention N (%)**	**Control N (%)**	**P value §**
PRIMARY OUTCOME									
CHBS (low risk = 0-2)	70 (37.8%)	63 (35.4%)	*0.629*	80 (49.4%)	59 (36.4%)	*0.018*	78 (48.4%)	47 (28.0%)	*0.000*
SECONDARY OUTCOME									
SHBS (low risk = 0)									
• FV intake/d ≥ 4 servings/d	25 (13.5%)	18 (10.1%)	*0.316*	27 (16. 7%)	23 (14.1%)	*0.538*	32 (19.9%)	16 (9.5%)	*0.008*
• Active playtime/d ≥ 120 min/d	102 (55.1%)	92 (51.7%)	*0.510*	132 (81.5%)	108 (66.7%)	*0.002*	121 (74.7%)	124 (73.8%)	*0.855*
•TV-watching/d ≤ 60 min/d	58 (31.4%)	56 (31.5%)	*0.982*	37 (22.8%)	26 (16.5%)	*0.123*	34 (21.0%)	23 (13.7%)	*0.080*
• SSB intake/d - Glasses/d	157 (85.9%)	149 (84.7%)	*0.762*	148 (91.4%)	132 (81.5%)	*0.009*	147 (90.7%)	132 (78.6%)	*0.002*
TV in bedroom	29 (16.3%)	17 (10.1%)	*0.095*	23 (15.1%)	19 (13.1%)	*0.616*	28 (18.1%)	13 (8.8%)	*0.019*
	Mean Value (95% CI)	**Mean Value (95% CI)**		**Mean Value (95% CI)**	**Mean Value (95% CI)**		**Mean Value (95% CI)**	**Mean Value (95% CI)**	
BMI score	16.2 (15.9-16.4)	16.2 (16.0-16.4)	*0.739*	16.1 (15.9-16.3)	16.0 (15.8-16.2)	*0.631*	16.1 (15.8-16.4)	16.3 (16.0-16.6)	*0.399*
BMI z-score	0.27 (0.13-0.42)	0.28 (0.13-0.44)	*0.929*	0.38 (0.22-0.53)	0.33 (0.18-0.47)	*0.671*	0.38 (0.23-0.54)	0.44 (0.27-0.60)	*0.644*

§ c square test

Table 3 - Unadjusted and adjusted odd ratios (95% C.I.) for low-risk CHBS and beta coefficient (95% C.I.) for “BMI and BMI z-score” in the intervention group compared to the control group at 1 and 2-year follow-ups

	1 year				**2 years**			
	OR unadjusted (95% CI)	***p* value**	**OR adjusted* (95% CI)**	***p* value**	**OR unadjusted (95% CI)**	***p* value**	**OR adjusted* (95% CI)**	***p* value**
PRIMARY OUTCOME								
CHBS (low risk = 0-2)	1.96 (0.88-4.36)	*0.101*	2.09 (0.92-4.77)	*0.078*	3.43 (1.52-7.77)	0.003	3.41 (1.48-7.88)	*0.004*

* OR adjusted for the following potential confounders: gender, mother's levels of education, children's BMI

	b **unadjusted (95% CI)**	***p* value**	**b adjusted ** (95% CI)**	***p* value**	b **unadjusted (95% CI)**	***p* value**	**b adjusted ** (95% CI)**	***p* value**
BMI Outcomes								
BMI score	0.12 (-0.09 - 0.32)	*0.261*	0.10 (-0.10 - 0.31)	*0.332*	0.06 (-0.27 - 0.15)	0.569	-0.07 (-0.30 - 0.14)	*0.537*
BMI z-score	0.07 (-0.05 - 0.19)	*0.277*	0.06 (-0.06 - 0.19)	*0.334*	0.011 (-0.11 - 0.14)	0.868	0.006 (-0.12 - 0.14)	*0.926*

** b adjusted for the following potential confounders: gender, mother's levels of education, children's BMI

Table 4 - Breakdown of costs associated with the intervention (intervention group: 8 childcare centres and 199 children) *

Item	**Unit Price** h/€ (price in € in 2012)
Training	
- 1 psychiatrist leading a total 20-hour-long training program (4 sessions) on MI for paediatricians	3,500 €
- 2 psychologists leading a 20-hour-long training program (4 sessions) on MI for paediatric nurses	1,500 €
- 2 experts in early childhood physical activity who led a 10-hour-long training program (3 sessions) for childcare centre teachers	500.00 €
Time for carrying out the intervention study	
Time devoted by 22 paediatricians:	
- to receive a 20-hour-long training on MI	440 hours
- to conduct 180 face-to-face interviews with parents (of approx. 20 min. each)	60 hours
Time devoted by 9 nurses:	
- to receive a 20-hour-long training on MI	180 hours
- to conduct 180 face-to-face interviews with parents (of approx. 20 min. each)	60 hours
Time devoted by 3 health professionals (research team) to hold 3 meetings (of approx. 2 hours each) with teachers to encourage education initiatives at childcare centres	18 hours
Time devoted by 21 teachers at 8 childcare centres	
- To receive the overall 10-hour-long training on early childhood physical activity	210 hours
- To participate in the overall 6-hour-long meetings held by research team professionals	126 hours
Cost of materials	
Printed education materials (30 posters, 200 leaflets for parents, 220 manuals for parents and teachers)	4,000 €

* Additional costs for the intervention study: time for preliminary consultation with participants; phone bills for appointments with parents at paediatricians' offices; costs and expenses covered by health care providers for study-related examinations; costs and expenses covered by parents (i.e. time and travelling expenses to undergo the study examinations); and time devoted by teachers to arrange learning experiences at childcare centres (included in the year education plan without additional workload for teachers)