Differential outcome of the IDEFICS intervention in overweight versus non-overweight children

Did we achieve "primary" or "secondary" prevention?

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Short title: IDEFICS intervention outcome in children differs by weight status

Abstract

The aim of this study was to explore whether the IDEFICS intervention had a differential effect on children's weight trajectories depending on their baseline BMI status. Initially, 16,228 2-8 year olds were recruited to baseline examinations at survey centres in 8 European countries (Belgium, Cyprus, Estonia, Germany, Hungary, Italy, Spain and Sweden). In all countries, this survey was followed by a community-based intervention to promote healthy lifestyles. Subsequently, 11,041 (68%) of these children from intervention and control communities participated in 2-year follow-up examinations, constituting the full analytic sample here. Two sub-groups of children are considered in the present analysis: those who were overweight or obese (OWOB) prior to the intervention, and those who were not OWOB. Initial analysis combining both groups yielded evidence of interaction between OWOB status at baseline and the effect of the intervention (p=0.04). Therefore the present analysis investigated the intervention outcome after stratifying the sample into these two sub-groups.

Among children in all 8 countries who did not have prevalent overweight or obesity at baseline, there was no significant difference in risk of becoming OWOB in intervention versus control groups. However we observed a strong regional heterogeneity, which could be attributed to the presence of one distinctly outlying country, Belgium, where the intervention group had increased risk for becoming overweight.

In contrast, among the sample of children with prevalent OWOB at baseline, we observed a significantly greater probability of normalised weight status after 2 years. In other words, a protective effect against persistent OWOB was observed in children in intervention regions compared to controls, which corresponded to an adjusted odds ratio of 0.76 (0.58, 0.98).

This analysis thus provided evidence of a differential effect of the IDEFICS intervention, in which children with overweight may have benefited without having been specifically targeted. However, no overall primary preventive effect could be observed in children without initial overweight or obesity.

Background

The term primary prevention is often used in reference to the reduction of risk for incident disease among individuals who do not already have the disease, while secondary prevention refers to improvement of manifest disease at an early stage of its progression. In describing approaches for obesity prevention, it has become more common to refer to the alternative concepts of universal prevention (directed at the whole population), selective prevention (directed at high risk groups), and targeted prevention (directed at those with existing weight problems). These terminologies (1,2) are not mutually exclusive, and it is recognised that primary and secondary, as well as tertiary prevention are all part of universal prevention. In this paper we use the terms "primary" versus "secondary" prevention when referring to differential effects of population-oriented intervention on weight status, according whether participants were overweight at the baseline.

In responding to the epidemic of childhood obesity, the relative efficacies of universal as opposed to targeted and secondary prevention have been the topic of some debate. Since programmes to prevent obesity are likely to vary in impact according to characteristics of participants as well as type of intervention, it has been difficult to form a consensus on which approaches for childhood obesity prevention are most effective. In a recent systematic review, it was concluded that targeted, school-delivered, environmental, and empowerment interventions were effective in children, and importantly that interventions aiming to prevent, reduce or manage of obesity do not increase inequalities (3).

A key factor that may determine the effect of an intervention is whether participants have pre-existing weight problems. Numerous studies in high-risk children with overweight and obesity have reported efficacious treatment outcomes (4), whereas fewer primary preventive interventions directed at all children have shown significant benefits relative to controls (5). For this reason we decided to re-examine effects of the IDEFICS community based intervention on weight development, previously described by De Henauw et al. (6). In the present post-hoc analysis, we place special focus on children's weight status prior to exposure to an intervention carried out during the following academic year. The specific objective is to explore the possible differential effect in young children with and without prevalent overweight and obesity. An underlying question is whether population-based health promotion is an effective way to intervene in overweight children without singling them out or stigmatizing them. This information may help in the design future interventions to reduce the incidence, persistence and progression of overweight and obesity in children.

Subjects and Methods

The IDEFICS cohort

Survey centres in 8 European countries (Belgium, Cyprus, Estonia, Germany, Hungary, Italy, Spain and Sweden) were represented in the IDEFICS cohort and intervention studies (7). Initially, 16,228 boys and girls were recruited to examinations, using standardised measurement techniques in all countries (8). Two age groups at the time of the baseline examinations are defined as follows: pre-schoolers (2-5 y) and schoolchildren (6-8 y). In all survey centres, recruitment was done at the community level, since the surveys were not designed to produce nationally representative samples.

Approval for this study was obtained from regional and/or local ethics committees or institutional review boards at all survey centres. Written informed consent was given by all parents or guardians, who were instructed that their children could participate but opt out of any parts of the study except for weight and height measurements, and that they could discontinue their participation in the study at any time.

The IDEFICS intervention

A controlled, non-randomised community-oriented intervention was initiated during the school year following the baseline anthropometric examination. The key messages of the intervention were adapted for all countries and included: increased consumption of fruits and vegetables, increased consumption of water, increased physical activity, less sedentary screen-time, increased sleep and more family time (6). Approximately half of the children in all survey countries belonged to intervention communities, whereas the remaining control communities were not exposed to the intervention. Two years after baseline, post-intervention examinations including anthropometric measurements were conducted in the majority of participating children. Results documenting the effect of the intervention on BMI (9), describing parental approval of the intervention (10), and examining longer-term differences between dietary habits of families in intervention versus control regions (11**)** are reported separately in this supplement. The present analysis explores whether there is a differential intervention outcome in children with and without prevalent overweight and obesity.

Statistical methods

The weight status of each child at baseline and follow-up examinations was calculated according to the age-specific classification system of Cole et al. (12). Analysis of the cross-product term for weight group by exposure to intervention was conducted to investigate possible modification of the intervention effect as a function of initial weight status. Based on the hypothesis (and subsequent evidence) of such an interaction, stratification by OWOB at baseline was considered necessary for all subsequent analyses

Differences between characteristics of children according to OWOB status at baseline were first examined using the chi-square test. In the main analyses, effects of exposure to the intervention are reported in terms of chi-square tests and odds ratios. For consistency, odds ratios in the primary and secondary prevention analyses were calculated in such a way that an inverse association would indicate protection against incident and persistent OWOB, respectively. Multivariable adjustment for age, sex, and country was accomplished by mixed logistic regression of weight status at follow-up on exposure to intervention plus covariates included as fixed effects. Random intercepts for schools within communities, and communities within survey centres were also included. In sensitivity analyses, we also tested random slopes models for the effect of intervention at the school level, but because this did not change the results, we are presenting the simpler random intercept model. Models were extended to include product terms between exposure to intervention and age group, sex, and survey country, respectively, in order to investigate whether the effect of intervention further differed between these subgroups. In the children whose parents reported their education levels according to ISCED (13), a 2-level version of this variable reflecting the highest educational level attained by either parent was also tested as a covariate and stratification factor. Finally, using random-effect meta-analysis, all country-specific estimates for intervention (obtained from the mixed logistic model including interaction between intervention and country) were combined into an overall estimate. The estimated I-squared statistic is given as a measure of heterogeneity between country-specific estimates. The pooled illustrations of effect size from the meta-analysis are comparable but may not be identical to overall estimates based on individual data in logistic models.

Statistical testing was conducted at a significance level of 5% without adjusting for multiplicity (2-sided tests). All analyses were performed using Stata v.13, and the METAN procedure was used for the meta-analysis plot (StataCorp LP, Texas, USA).

Results

Characteristics of participants, by OWOB sub-group

Of the full baseline cohort described above, 11,041 children from intervention and control communities participated in 2-year follow-up examinations and constituted the analytic sample for the present analysis. From this population, two sub-groups of children are considered separately in the main results. Children without prevalent overweight or obesity (non-OWOB) at baseline are defined here as the primary prevention sample, while those with prevalent overweight and obesity (OWOB) are referred to as the secondary prevention sample. As such, the primary prevention sample consisted of 8,995 children who were re-measured at the 2-year follow-up (69% of baseline participants). The secondary prevention sample consisted of 2,046 children who were re-measured at 2-year follow-up (64% of baseline participants).

In Table 1, we summarised initial characteristics of the primary, secondary and total analytic samples that were followed up after 2 years. The likelihood of having been exposed to the intervention did not differ as a function of weight status at baseline. However, sex, age, country and education differences were observed between the two groups with and without prevalent OWOB. As previously reported in the full baseline sample, the lowest prevalence of OWOB is observed in Belgium and Sweden, and the highest in Italy (8). Additional descriptive analyses (not shown) indicated that the proportion of families with higher parental educational attainment did not differ between intervention and control groups (58% and 59% respectively), a similarity that persisted after further sub-stratification by children's baseline weight status.

As described in Statistical Methods, the possibility of a differential effect of the intervention in these 2 study groups was explored by testing the interaction between exposure to intervention and initial weight status. Significant effect modification ($p = 0.04$) was observed, which necessitated stratification of the main analyses were according to OWOB at baseline.

(Table 1 here)

No preventive effect of intervention in children without overweight or obesity

There was no significant difference in risk of becoming overweight or obese among initially non-OWOB children in intervention versus control groups (p = 0.27), odds ratio (OR) = 1.08 (0.94, 1.25); the non-significant odds ratio here was in the unexpected direction of *more* risk of incident OWOB in the intervention group. These results are shown in the top portion of Table 2. Adjustment for possible confounding by age group, sex, and survey country further attenuated the estimate: OR = 1.03 (0.84, 1.28), p = 0.75.

However we observed a strong modification of the intervention effect by survey country (p=0.003 for interaction). This could be attributed to the presence of one distinctly outlying country, Belgium, where an unexpected excess risk of incident OWOB was observed in the intervention group (Table 2). In non-OWOB children in the Belgian intervention, the risk of becoming OWOB was over three times higher compared to the control community. In the subsample of Belgian children with information on parental education, inclusion of education and baseline BMI z-score respectively as covariates hardly changed the result: OR = 3.18, (1.65, 6.12) and 3.17 (1.57, 6.37). As a consequence of the observed heterogeneity, the combined estimate for the intervention effect shown in Figure 1 has a slightly larger confidence interval than the crude all-country estimate given in Table 2 that overlooked the interaction by survey country.

Because of this heterogeneity, further primary prevention results are presented in the 7-country sample. Specifically, in a re-analysis retaining all survey countries except Belgium, the pooled OR adjusted for age, sex and country was inverted to a protective direction (OR = 0.94 (0.80, 1.12)) and no interaction by country was observed (p = 0.5). In these remaining countries, no significant effect modification was observed for age group, sex, or education, and corresponding stratified analyses are shown in lower portion of Table 2.

Sensitivity analyses using a random slope model for the intervention effect on school level yielded similar results in the 7-country sample (not shown). In Belgium, there was considerable variation of the intervention effect between schools. However, this only partly explained the association between intervention and incident overweight (attenuated OR = 2.87 (1.50, 5.49), p = 0.001). Further adjustment for education or baseline BMI z-score did not attenuate the association observed in Belgium (not shown).

(Table 2 here)

Beneficial effect of intervention in children with overweight and obesity

Among the sample of children with prevalent OWOB at baseline, we observed a greater probability of normalised weight status after 2 years, i.e. a protective effect against persistent OWOB. This was statistically significant (p = 0.024) and is expressed in Table 3 as an odds ratio of 0.75 (95% CI: 0.58, 0.96). The results were independent of age, sex and country; adjusted odds ratios confirmed the beneficial intervention effect of OR = 0.76 (95% CI: 0.58, 0.98), p = 0.037.

Several additional analyses are not shown in Table 3. In the sample with data on parental education, associations were essentially unchanged after adjustment for education (OR = 0.77, (0.59, 1.01), p =

0.057). Independent of intervention status, education was protective for persistent OWOB (OR=0.68 (0.51, 0.92). The variation of intervention outcome on school and community levels was negligible.

As shown in Table 3, there was no evidence of any modification of this "secondary" preventive effect by country (p = 0.9), age group (p = 0.4), sex (p = 0.4), or education (p = 0.8). However, stratified results are presented, to explore if there was a stronger or weaker effect in any subgroup. A beneficial effect of the intervention in initially OWOB children could be observed in girls (OR = 0.69; 95% CI: 0.48, 0.97) but not in boys (OR = 0.86; 95% CI: 0.58, 1.28). Similarly the secondary prevention effect appeared to be stronger within the older age group (6-8 years, OR = 0.68 (95% CI: 0.48, 0.97)) than in the younger age group (2-5 years, OR = 0.86 (95% CI: 0.58, 1.26)). Finally, after stratifying by parental education, the risks were of similar magnitude in both groups although not significant in either.

(Table 3 here)

The purpose of Figure 1 is to illustrate country-specific primary and secondary preventive effects of the intervention respectively, in children without (above) and with (below) OWOB at baseline. The overall intervention effects obtained by meta-analysis hardly differed from the corresponding main results given in Tables 2 and 3 and confirmed the secondary preventive impact of the intervention. For the subgroup without OWOB, the survey centre in Belgium shows a dramatically outlying estimate which accounted for much of the between-country heterogeneity.

(Figure 1 here)

Conclusion

The IDEFICS health promoting intervention resulted in a statistically significant beneficial outcome in initially overweight and obese children, that is, a treatment-like effect was demonstrated among these higher-risk children in the 8-country sample. This overall effect was not dependent on age, sex, or survey country, and only marginally attenuated by parental education. Within age and sex groups, protective effects tended to be stronger in children who were of school age at baseline, and in girls.

In contrast to the effect described above in OWOB children, there was no overall preventive effect of the intervention in children without overweight or obesity at baseline, which is in line with current knowledge on magnitude of primary preventive effects. In contrast, the significant heterogeneity across the intervention countries was unexpected, and could be attributed to intervention and control communities in the Flanders region of Belgium, where only 16 (3%) of the normal weight controls became overweight at follow-up, compared to 52/595 (9%) in the intervention group.

This regional response to the intervention in Belgium versus other countries might reflect different characteristics of children in intervention versus control areas, e.g. health and socioeconomic characteristics as well as competing participation in other studies may have influenced this result. We can only speculate on mechanisms by which the intervention in non-OWOB children in Belgium produced the observed impact on weight trajectories. For instance, use of the dichotomous weight outcome indicator results in loss of information on longitudinal changes. Notably, baseline BMI z-scores in the non-OWOB Belgian sample were higher in the intervention sample than in controls.

Because the intervention group started closer to the OWOB cut-point, their increases might have been more likely to result in development of overweight. However, we observed that this association was not attenuated by further adjustment for baseline BMI z-score. Alternatively, it is possible that an unintended negative effect of the intervention among children or families without weight concerns may have occurred by the end of the intervention period. This finding could be an example of information dissemination paradox (14) or "boomerang" effect (15), reactive response in which people might reject or doubt the relevance of information received. Other potential explanations for the outcome, based on parental views on the intervention process (10), and on data collected in the extended 6-year follow-up of these families (11) will be considered in future country-specific analyses.

In addition to this heterogeneity of intervention outcome among non-OWOB children in Belgium, several general limitations have been considered. Importantly, 32% of the full baseline sample was lost to post-intervention follow-up. As reported in an accompanying piece (9) these drop-outs were somewhat more likely than participants to be overweight at the baseline (18.5 vs 22%), implying that this was a more self-selected group. Secondly, the number of prevalent and incident cases of obesity per se, as opposed to overweight including obesity, was too limited for an adequately powered analysis of this more extreme weight class. Therefore the present analysis is based on the widely-used combination of overweight and obesity (12), employing simple prospective models for both incidence and remission in which prevalent conditions are excluded and incident conditions are ascertained. It is also important to point out that the original study design did not envision subgroup effects, and it is thus acknowledged that analyses that have been stratified by baseline OWOB, country, and other potential modifiers have low statistical power. Finally, we recognize that a limited number of potentially relevant covariates were included in the models. For instance, although results were stable after adjusting for parental education, other high-risk characteristics such as family income and parental weight status might have been worth consideration in the secondary prevention model.

There is a general consensus as well as some published evidence that obesity management strategies should be population-based to support structural changes in the community, as opposed to individualised interventions to change behaviours (16). With specific regard to children, one rationale for this viewpoint is that targeting high-risk children at school for weight normalisation at an early age could potentially be stigmatising and harmful to mental well-being. However, it has been pointed out that some population-based non-targeted health interventions may have the unintended effect of increasing inequalities in health between lower- and higher-income groups (14, 17). In the case of childhood obesity, disappointingly small effects of many previous interventions may in part be a consequence of not placing enough focus on outreach to high-risk areas - often characterised by high rates of obesity, low participation rates, and poor socioeconomic conditions. Targeted obesity interventions in high-risk communities with a high prevalence of obesity may offer the means to avoid exacerbation of socioeconomic disparities following healthy lifestyle interventions.

The present results imply that children with prevalent overweight may constitute one such group who stand to derive a benefit from health-promoting interventions, whether or not they are directed at all children in the community. Extending such activities to the whole population might offer other health benefits in normal-weight children, but it is necessary to continue vigilant monitoring of any potential harmful effects of both primary and secondary prevention efforts. Further investigations could also address the cost-effectiveness of universal prevention in populations including children with pre-existing weight problems, compared to clinical approaches.

In conclusion, the IDEFICS intervention did not succeed in preventing incident overweight in children who were not overweight at baseline, but may have achieved “secondary” prevention in children with overweight or obesity. Both of these are important components of population-based prevention paradigms.

Table 1: Number of subjects and descriptive characteristics in sub-groups that were stratified according to presence or absence of OWOB (overweight including obesity[§]) and in total analytic sample.

	Overweight status[§] at baseline		
	% Non-OWOB ¤	% Prevalent OWOB ¤¤	Total (100%)
Exposure			
• Intervention	4638 (81%)	1089 (19%)	5727
• Control	4357 (82%)	957 (18%)	5314
Sex* **			
• Male	4638 (83%)	959 (17%)	5597
• Female	4357 (80%)	1087 (20%)	5444
Age group* **			
• Pre-school	4306 (87%)	646 (13%)	4952
• School	4689 (77%)	1400 (23%)	6089
Country* **			
• Belgium	1164 (93%)	88 (7%)	1252
• Cyprus	1343 (77%)	403 (23%)	1746
• Estonia	1145 (86%)	189 (14%)	1334
• Germany	1030 (86%)	166 (14%)	1196
• Hungary	1079 (87%)	167 (13%)	1246
• Italy	901 (58%)	647 (42%)	1548
• Spain	979 (81%)	229 (19%)	1208
• Sweden	1354 (90%)	157 (10%)	1511
Total	8995 (81%)	2046 (19%)	11041
Education* **			
• Low	3386 (76%)	1044 (24%)	4430
• High	5322 (85%)	910 (15%)	6232
Total	8708 (82%)	1954 (18%)	10662

§ Weight status at baseline (non-OWOB and OWOB) is categorised according to Cole et al. 2000

¤ non-OWOB also referred to as “primary” prevention group

¤¤ prevalent OWOB also referred to as “secondary” prevention group

*** p<0.001, for comparison between non-OWOB and OWOB groups: significantly more girls, schoolchildren, and children of less educated parents were OWOB at baseline. Prevalence also varied significantly across 8 countries but did not differ by exposure to intervention (top).

Table 2: "Primary" preventive effect of intervention in sample of children without OWOB (overweight or obesity) at baseline, and stratified by sex, age group, and parental education.

Sample		Exposure to Intervention		OR (95% CI) for OWOB at follow-up and intervention	
All	**OWOB** status at follow-up	Intervention (n = 4638)	Control (n = 4357)	unadjusted	adjusted
	No	4206 (91%)	3980 (91%)	1.08 (0.94, 1.25)	1.03 (0.84, 1.28) §
	Yes	432 (9%)	377 (9%)	*p = 0.27*	*p = 0.75*
Analyses of Belgium and other 7 countries					
Belgium vs. 7 countries, p-value for interaction ‡ = 0.003					
Belgium	No	543 (91%)	553 (97%)	3.31 (1.87, 5.87)	3.30 (1.70, 6.40) §§
	Yes	52 (9%)	16 (3%)	*p <.0001*	*p <.0001*
7 countries	No	3663 (91%)	3427 (90%)	0.98 (0.85, 1.15)	0.94 (0.80, 1.12) §
	Yes	380 (9%)	361 (10%)	*p = 0.8*	*p = 0.5*
Analyses in 7 countries, stratified by age, sex, education					
Sex of the child, *p-value for interaction ‡ = 0.6*					
Boys	No	1873 (90%)	1778 (90%)	1.03 (0.84, 1.27)	0.99 (0.79, 1.23)§§§
	Yes	210 (10%)	193 (10%)	*p = 0.8*	*p = 0.9*
Girls	No	1790 (91%)	1649 (91%)	0.93 (0.75, 1.17)	0.90 (0.71, 1.14) §§§
	Yes	170 (9%)	168 (9%)	*p = 0.5*	*p = 0.4*
Age group, *p-value for interaction ‡ = 0.3*					
Pre-school	No	1693 (91%)	1651 (90%)	0.91 (0.73, 1.14)	0.87 (0.68, 1.11) §§§§
	Yes	163 (9%)	175 (10%)	*p = 0.4*	*p = 0.25*
School age	No	1970 (90%)	1776 (91%)	1.05 (0.86, 1.29)	1.01 (0.81, 1.27) §§§§
	Yes	217 (10%)	186 (9%)	*p = 0.6*	*p = 0.9*
Parental education†, *p-value for interaction ‡ = 0.2*					
Low	No	1381 (88%)	1276 (87%)	0.99 (0.80, 1.22)	0.84 (0.66, 1.06) §
	Yes	185 (12%)	189 (13%)	*p = 0.4*	*p = 0.15*
High	No	2141 (92%)	2046 (93%)	1.04 (0.84, 1.30)	1.02 (0.81, 1.28) §
	Yes	179 (8%)	164 (7%)	*p = 0.7*	*p = 0.9*

§ adjusted for age, sex, country, community (random effect) and school (random effect)

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† reduced number of observations (n = 7561) due to missing values for education

‡ p-value for product term of stratum variable × intervention status in the adjusted model

Table 3: "Secondary" preventive effect of intervention in OWOB (treatment), in the sample of children with OWOB (overweight or obesity) at baseline, and stratified by sex, age group, and parental education.

Sample		**Exposure to Intervention**		**OR (95% CI) for OWOB at follow-up and intervention**	
All	**OWOB** at follow-up	Intervention (n = 1089)	Control (n = 957)	unadjusted	adjusted
	No	171 (16%)	117 (12%)	0.75 (0.58, 0.96)	0.76 (0.58, 0.98) §
	Yes	918 (84%)	840 (88%)	*p = 0.024*	*p = 0.037*
Stratified analyses					
Sex of the child, *p-value for interaction ‡ = 0.40*					
Boys	No	73 (14%)	51 (12%)	0.80 (0.55, 1.18)	0.86 (0.58, 1.28)§§
	Yes	447 (86%)	388 (88%)	*p = 0.27*	*p = 0.45*
Girls	No	98 (17%)	66 (13%)	0.70 (0.50, 0.98)	0.69 (0.48, 0.97) §§
	Yes	471 (83%)	452 (87%)	*p = 0.04*	*p = 0.035*
Age group, *p-value for interaction ‡ = 0.41*					
Pre-school	No	80 (24%)	60 (20%)	0.79 (0.54, 1.16)	0.86 (0.58, 1.26) §§§
	Yes	260 (76%)	246 (80%)	*p = 0.22*	*p = 0.43*
School age	No	91 (12%)	57 (9%)	0.69 (0.49, 0.98)	0.68 (0.48, 0.97) §§§
	Yes	658 (88%)	594 (91%)	*p = 0.040*	*p = 0.036*
Parental education†, *p-value for interaction ‡ = 0.75*					
Low	No	67 (12%)	46 (9%)	0.74 (0.50, 1.10)	0.74 (0.49, 1.10) §
	Yes	482 (88%)	449 (91%)	*p = 0.13*	*p = 0.13*
High	No	96 (19%)	64 (15%)	0.76 (0.54, 1.07)	0.80 (0.56, 1.14) §
	Yes	399 (81%)	351 (85%)	*p = 0.12*	*p = 0.23*

§ adjusted for age, sex, country, community (random effect) and school (random effect)

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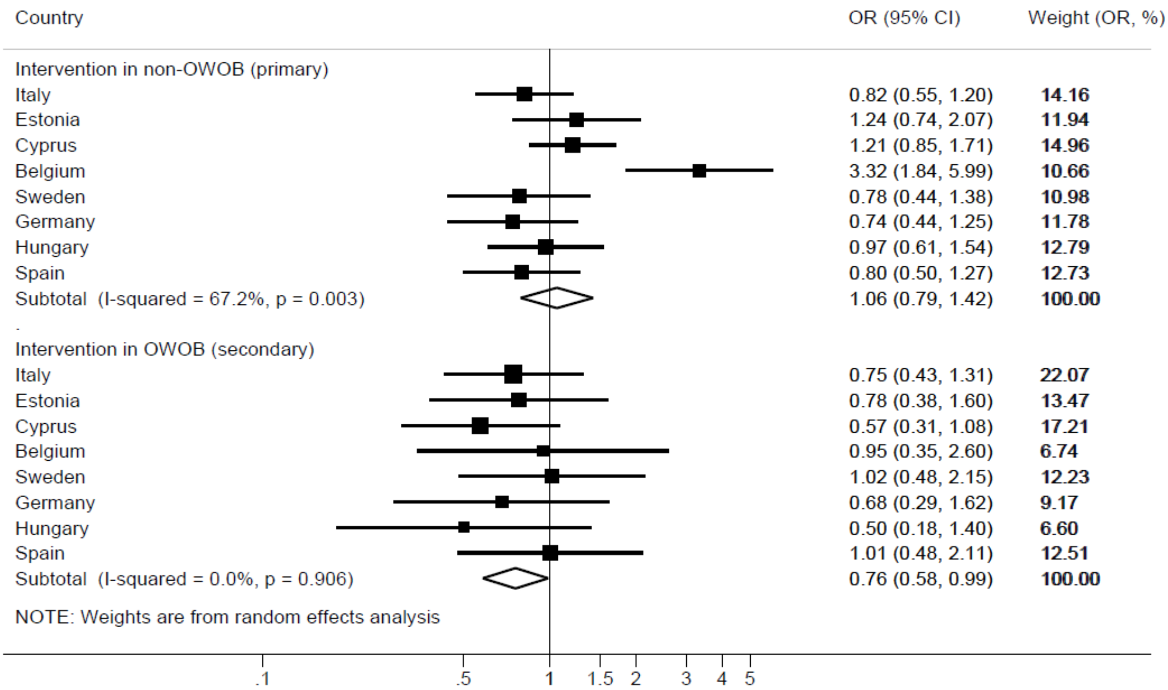
† reduced number of observations (n = 1954) due to missing values for education

‡ p-value for product term of stratum variable × intervention status in the adjusted model

Figure 1: Country-specific and combined estimates of intervention effect in study groups stratified according to absence (above) or presence (below) of OWOB at baseline. Meta-analysis of for intervention effect (OR) on overweight at follow-up, combined from country-specific estimates obtained by mixed logistic regression.



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Acknowledgements:

This study was conducted as part of the IDEFICS study (http://www.idefics.eu). We gratefully acknowledge the financial support of the European Community within the Sixth RTD Framework Programme Contract no. 016181 (FOOD) and the grant support from EU for the IDEFICS study. We are grateful for the support provided by school boards, headmasters and communities. We thank the IDEFICS children and their parents for participating in this extensive examination.

The authors are also grateful to the Federal Centre for Health Education that financially supported the production of this supplement.

The authors would also like to thank the Swedish Research Councils FORTE, FORMAS, and VR, for supplementary support of local research efforts at the University of Gothenburg.